

EXHIBIT A

DOCKET NO.: CV-14-6025333-S : **COMPLEX DOCKET**

ROBIN SHERWOOD and
GREG HOELSCHER : **J.D. OF WATERBURY**

V. : **AT WATERBURY**

STAMFORD HEALTH SYSTEM, INC.
D/B/A STAMFORD HOSPITAL : **June 1, 2015**

DEFENDANT STAMFORD HOSPITAL'S
ANSWER AND SPECIAL DEFENSES TO COMPLAINT

The defendant, Stamford Health System, Inc., d/b/a Stamford Hospital (hereinafter “Stamford Hospital”), hereby responds to the plaintiff’s Complaint dated August 13, 2014 as follows:

FIRST COUNT:

1. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 and, therefore, leaves plaintiff to her proof.
2. The defendant admits that, Stamford Health System, Inc., d/b/a Stamford Hospital is a hospital located at 30 Shelburne Road, Stamford, Connecticut 06902. The remaining allegations of Paragraph 2 are denied.
3. Denied.
4. Denied.

II. BACKGROUND OF PELVIC MESH PRODUCTS SOLD, DISTRIBUTED AND/OR MANUFACTURED BY THE DEFENDANT STAMFORD HOSPITAL

A. Johnson & Johnson

5. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 5 and, therefore, leaves plaintiff to her proof.

6. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 6 and, therefore, leaves plaintiff to her proof.

7. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 7 and, therefore, leaves plaintiff to her proof.

8. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 8 and, therefore, leaves plaintiff to her proof. The defendant notes that the paragraph is nonsensical because none of these entities are defendants in this case even though they have been labeled as defendants.

9. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 9 and, therefore, leaves plaintiff to her proof.

10. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 10 and, therefore, leaves plaintiff to her proof.

11. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 and, therefore, leaves plaintiff to her proof.

12. The defendant denies that Johnson & Johnson/Ethicon marketed Prolift without clearance or approval from the FDA. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the balance of the allegations set forth in paragraph 12 and, therefore, leaves plaintiff to her proof.

13. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 and, therefore, leaves plaintiff to her proof.

14. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 and, therefore, leaves plaintiff to her proof.

15. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 15 and, therefore, leaves plaintiff to her proof.

16. The defendant denies the allegations set forth in paragraph 16.

17. The defendant denies the allegations in paragraph 17.

18. Paragraph 18 labels certain terms and collectively defines them so no response is required. To the extent a response is required, the defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 and, therefore, leaves plaintiff to her proof.

B. AMS

19. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 19 and, therefore, leaves plaintiff to her proof.

20. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 20 and, therefore, leaves plaintiff to her proof.

21. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 21 and, therefore, leaves plaintiff to her proof.

C. STAMFORD HOSPITAL

22. The defendant denies the allegations in paragraph 22 and avers that under Connecticut Product Liability Act, including the section plaintiff cites in paragraph 22, Stamford Hospital cannot be a “Product Seller” for a medical device that is implanted during a patient’s surgery in one of its operating rooms.

23. Denied.

24. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 and, therefore, leaves plaintiff to her proof.

25. Denied.

26. Denied. Stanford Hospital avers that plaintiff has mischaracterized FDA regulations.

27. Denied.

28. Denied.

29. Denied

III. FACTUAL BACKGROUND

30. Denied.

31. Denied.

32. Denied.

33. The defendant denies the allegations in paragraph 33. With respect to the allegations regarding a “study” in paragraph 33, the defendant lacks knowledge or information sufficient to form a belief as to the truth of these allegations and, therefore, leaves plaintiff to her proof.

34. Denied.

35. Denied.

36. Denied except that Stamford Hospital admits that the FDA issued notices regarding this type of product in 2008 and 2010, which speak for themselves.

37. The defendant admits that on October 20, 2008, the Food and Drug Administration (“FDA”) issued a Public Health Notification, which speaks for itself. With

regard to the remainder of Paragraph 37, defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, leaves plaintiff to her proof.

38. Denied.

39. Denied.

40. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 40 and, therefore, leaves plaintiff to her proof.

41. With regard to the allegations in Paragraph 41, the defendant lacks knowledge or information sufficient to form a belief as to the truth of these allegations, namely whether on a worldwide bases the “Defendant’s Pelvic Mesh Products,” most of which were not even used in Ms. Sherwood’s surgery, “were at all times utilized and implanted in a manner foreseeable to the Defendant” and the defendant, therefore, leaves plaintiff to her proof.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. The defendant denies that any act or omission on its part caused any injuries to plaintiff. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 48 and, therefore, leaves plaintiff to her proof.

49. The defendant denies that any act or omission on its part caused any injuries to plaintiff. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 49 and, therefore, leaves plaintiff to her proof.

50. The defendant denies that any act or omission on its part caused any injuries to plaintiff. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 50 and, therefore, leaves plaintiff to her proof.

51. The defendant denies that any act or omission on its part caused any injuries to plaintiff. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 51 and, therefore, leaves plaintiff to her proof.

52. The defendant denies that any act or omission on its part caused any injuries to plaintiff. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 52 and, therefore, leaves plaintiff to her proof.

53. Denied.

54. Denied.

55. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 55 and, therefore, leaves plaintiff to her proof.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. The defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 60 and, therefore, leaves plaintiff to her proof.

61-81. The allegations contained in Paragraphs 61-81 are denied.

FIRST SPECIAL DEFENSE

1. Plaintiff's claims against Stamford Hospital are barred by the applicable statute of limitations as the surgery allegedly occurred in 2006 and this action was commenced at the end of 2014.
2. Plaintiff's claims are barred by the doctrine of laches.
3. Plaintiff's claims are barred because she has engaged in impermissible claim splitting by maintaining actions for the same relief in two different lawsuits.
4. Plaintiff's claims are barred by the doctrine of waiver in that she already commenced an action against the product manufacturer and elected not to pursue Stamford Hospital in that action.

**THE DEFENDANT,
STAMFORD HEALTH SYSTEMS, INC.,
D/B/A STAMFORD HOSPITAL**

/s/ Simon I. Allentuch
SIMON I. ALLENTUCH
NEUBERT, PEPE & MONTEITH, P.C.
195 Church Street, 13th Floor
New Haven, CT 06510
Tel. (203) 821-2000
Juris No. 407996

CERTIFICATION

THIS IS TO CERTIFY THAT a copy of the foregoing was emailed this 1st day of June,
2015, to the following counsel:

Brenden P. Leydon, Esq.
Jackie Fusco, Esq.
Tooher, Woel & Leydon, LLC
80 Fourth Street
Stamford, CT 06905

/s/ Simon I. Allentuch
SIMON I. ALLENTUCH
NEUBERT, PEPE & MONTEITH, P.C.

EXHIBIT B

<p style="text-align: center;">A P P E A R A N C E S</p> <p>Page 2</p> <p>FOR THE PLAINTIFFS:</p> <p>TOOHER, WOCL & LEYDON, LLC 80 Fourth Street Stamford, Connecticut 06905</p> <p>BY: BRENDEN P. LEYDON, ESQUIRE -and- JACQUELINE E. FUSCO, ESQUIRE</p> <p>FOR THE DEFENDANT, JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY, GYNECARE A DIVISION OF ETHICON, INC.: SHIPMAN & GOODWIN, LLP One Constitution Plaza Hartford, Connecticut 06103-1919</p> <p>BY: ROBERT R. SIMPSON, ESQUIRE -and- MICHELLE L. QUERIJERO, ESQUIRE -and- TUCKER ELLIS, LLP 950 Main Avenue, Suite 1100 Cleveland, Ohio 44113-7213</p> <p>BY: RITA A. MAIMBOURG, ESQUIRE</p> <p>FOR THE DEFENDANT, STAMFORD HEALTH SYSTEM INC. D/B/A STAMFORD HOSPITAL: NEUBERT, PEPE & MONTEITH, PC 195 Church Street, 13th Floor New Haven, Connecticut 06510</p> <p>BY: SIMON ALLENTUCH, ESQUIRE</p>	<p style="text-align: center;">S T I P U L A T I O N S</p> <p>Page 4</p> <p>IT IS HEREBY STIPULATED AND AGREED by and between counsel for the parties that the proof of the official authority of the Notary Public before whom this deposition is taken is waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that the reading and signing of the deposition is not waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that notice of the time and place of the taking of the deposition is waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that all objections, except as to the form of the question, are reserved until the time of trial.</p> <p style="text-align: center;">* * *</p>
<p style="text-align: center;">A P P E A R A N C E S (Cont.d)</p> <p>Page 3</p> <p>FOR THE DEFENDANT, AMERICAN MEDICAL SYSTEMS, INC.:</p> <p>HALLORAN & SAGE 315 Post Road West Westport, Connecticut 06880</p> <p>BY: THOMAS P. O'DEA, JR., ESQUIRE -and- REED SMITH, LLP Three Logan Square 1717 Arch Street, Suite 3100 Philadelphia, Pennsylvania 19103</p> <p>BY: LOUIS W. SCHACK, ESQUIRE</p> <p>FOR THE DEFENDANTS, BRIAN J. HINES, MD AND UROGYNECOLOGY & PELVIC SURGERY, LLC: HEIDELL, PITTONI, MURPHY & BACH, LLP 855 Main Street, Suite 1100 Bridgeport, Connecticut 06604</p> <p>BY: HEIDI M. CILANO, ESQUIRE</p>	<p>Page 5</p> <p>1 (Plaintiff's Exhibits 1 and 2 2 marked for identification.) 3 MR. CILANO: We're going to reserve 4 reading a signing too. 5 THE COURT REPORTER: Usual stipulations, 6 with read and sign? 7 MS. CILANO: Yes, please. 8 B R I A N J. H I N E S, M. D., 9 1351 Washington Boulevard, Stamford, Connecticut, 10 called as a witness, after having been duly sworn, was 11 examined and testified as follows: 12 DIRECT EXAMINATION 13 BY MR. LEYDON: 14 Q Good morning, doctor. My name is Brenden 15 Leydon. I represent the plaintiffs in this matter, 16 Mr. and Mrs. Farrell. 17 Have you ever been deposed before? 18 A I have. 19 Q And your attorney's probably instructed 20 you of this, but the way it works is, the court 21 reporter is here taking us down. She can only take 22 down one person at a time. So, please, allow me to 23 finish my question, and I will, likewise, allow you 24 to finish your answer. If for some reason I cut you 25 off in your answer, you haven't finished, please let</p>

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1 that the government was sort of slow to get onboard.
2 I think that -- I don't remember when it was, what
3 month it was, but I remember feeling, you know what,
4 not only have I known these things, but I've
5 actually been -- my practice has evolved, and I've
6 been counselling patients based on these things
7 before the FDA released their -- their statements.
8 Q Did it concern you that the FDA was
9 looking into this product as something that had
10 problems?
11 MR. SCHACK: Object to the form.
12 MS. CILANO: Object to the form as well.
13 THE WITNESS: I was concerned about
14 certain issues with the use of vaginal mesh,
15 not based upon what the FDA said, but based
16 upon my experiences.
17 BY MR. LEYDON:
18 Q What experiences were those?
19 A An experience like what occurred with
20 Ms. Farrell, experiences of -- of seeing mesh
21 exposure, mesh erosion.
22 Q Did you ever have any suspicion that the
23 mesh itself might be a defective product?
24 MS. MAIMBOURG: Objection as to form.
25 MS. CILANO: Object to the form.

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1 MR. SCHACK: The same objection.
2 THE WITNESS: No.
3 BY MR. LEYDON:
4 Q And, sitting here right now, do you have
5 any suspicion that the mesh might be a defective
6 product?
7 MR. SCHACK: Objection.
8 MS. CILANO: Object to the form.
9 THE WITNESS: No.
10 BY MR. LEYDON:
11 Q Given those answers, you, obviously,
12 never communicated to Mary Beth Farrell that there
13 might be a defect in the mesh, correct?
14 A Communicate that there might have been a
15 defect?
16 Q Correct.
17 A No.
18 Q Would it be fair to say, from your
19 perspective, Mary Beth Farrell was never presented
20 any information to cause her to believe that this
21 mesh product was defective?
22 MS. CILANO: By whom?
23 BY MR. LEYDON:
24 Q By any knowledge you have -- do you have
25 any knowledge of when Mary Beth Farrell was

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1 presented information that should have caused her to
2 believe that this mesh was defective?
3 MR. ALLENTUCH: Objection.
4 THE WITNESS: I don't believe that the
5 mesh that was implanted in Mary Beth Farrell
6 was defective.
7 BY MR. LEYDON:
8 Q So then you certainly would not contend
9 that Mary Beth Farrell should have known at any
10 point in time that the mesh was defective, correct?
11 MS. CILANO: Object to the form.
12 MR. ALLENTUCH: Objection.
13 THE WITNESS: I think I've said that I
14 don't believe that the mesh that was implanted
15 in Mary Beth Farrell was defective.
16 BY MR. LEYDON:
17 Q As a result of that, and your prior
18 testimony, therefore, you certainly could not
19 contend that Mary Beth Farrell should have known
20 that the mesh was defective, correct?
21 MR. ALLENTUCH: Objection.
22 MS. CILANO: Object to the form.
23 THE WITNESS: Correct.
24 BY MR. LEYDON:
25 Q Do you have any recollection of the

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1 informed consent discussion that you had with Mary
2 Beth Farrell?
3 A I don't have a specific recollection of
4 the -- of the meeting that I had with her.
5 MR. LEYDON: You can mark that as -- what
6 are we up to -- five.
7 (Plaintiff's Exhibit 5 marked
8 for identification.)
9 BY MR. LEYDON:
10 Q (Handing.) Doctor, showing you what's
11 marked as Plaintiff's Exhibit 5, have you seen that
12 before?
13 A Yes.
14 Q And what is that?
15 A This was a page copied off of our -- what
16 used to be our website.
17 Q And have you changed that at all?
18 A The practice doesn't exist any longer, so
19 the website is -- no longer exists. It shouldn't
20 anyway. I don't think it does.
21 Q But this is a fair and accurate
22 representation of what was on your website
23 previously?
24 A Yes.
25 MR. LEYDON: Mark that next.

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1 mesh placed at the time of this procedure? And I
2 think that it's basically trying to weigh the risk
3 of recurrence of prolapse in a young woman who, you
4 know, has young children and leads an active life,
5 when the repair would be done with her autologous
6 tissue verse a risk of five or 10 percent of vaginal
7 mesh exposure, which in my experience, at that time,
8 often was asymptomatic, and, if symptomatic, could
9 be dealt with fairly successfully. And the risk at
10 that time, as it was understood, of a repair of a
11 cystocele done with somebody's own tissue -- the
12 risk of that recurring over the first two or three
13 years was somewhere in the ballpark of 40 percent.
14 That would be a -- an approximate of
15 the type of conversation that I would have had with
16 Ms. Farrell.
17 Q Okay. But you don't have any particular
18 recollection of the discussion you had with her; is
19 that correct?
20 A No.
21 Q And in terms of your discussion with
22 patients and informed consent, is it any different
23 now than it was at the time you were talking with
24 Ms. Farrell?
25 MS. CILANO: For this particular surgery?

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1 MR. LEYDON: Yes.
2 THE WITNESS: Well, I don't do this
3 surgery now.
4 BY MR. LEYDON:
5 Q What do you mean when you say you don't do
6 this surgery now?
7 MS. CILANO: He doesn't do this surgery
8 now.
9 MR. LEYDON: I think he can explain.
10 MS. CILANO: Objection. He's answered it.
11 You can answer again that you don't do
12 this surgery now.
13 MR. LEYDON: Or however you want to answer
14 it.
15 THE WITNESS: So no -- first of all, the
16 product that we used in Ms. Farrell doesn't
17 exist on the market any longer, so we don't do
18 that. And subsequent to Ms. Farrell's surgery,
19 and, you know, the experience over, you know,
20 months, years after that, I changed my practice
21 how and in what patients I would use
22 transvaginal mesh.
23 BY MR. LEYDON:
24 Q How so?
25 A I became aware that the -- that the mesh

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1 exposure that had sort of garnered all of the -- you
2 know, all the attention as the -- the main
3 complication, if you will, associated with the use
4 of vaginal mesh, that that really wasn't the
5 complication that -- that I was aware of and
6 concerned about. It was contraction and tightening
7 of vaginal mesh, which happened to Ms. Farrell, that
8 changed how I would -- how I would place vaginal
9 mesh, the age of the patient that I would place
10 vaginal mesh, and -- and whether or not I would
11 place vaginal mesh in opposite compartments in the
12 vagina, as was done for Ms. Farrell.
13 Q So if Ms. Farrell was to come to you
14 today, is it fair to say you would not have done
15 this procedure the way you did it?
16 A That's correct.
17 Q Is that in part because of what happened
18 to Ms. Farrell?
19 A My hesitancy is -- are you asking the
20 question specifically about Mary Beth Farrell as an
21 individual, if she were to come in today, or a
22 generic person?
23 Q No. My first question was if someone like
24 her came in today.
25 A Yeah.

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1 Q I believe your answer was you would not
2 have done the same procedure you did with her.
3 A That's correct.
4 Q And my follow-up question was: Is the
5 reason for that, at least in part, because of your
6 personal experience in what happened to Ms. Farrell?
7 A That's correct.
8 Q And is that also because of further
9 information that's come out about problems with this
10 type of mesh and its use in that way?
11 MR. SCHACK: Objection to form.
12 THE WITNESS: No.
13 BY MR. LEYDON:
14 Q What are the other reasons for it, or is
15 it solely because of what happened to Ms. Farrell?
16 A Ms. Farrell was the first of two or three
17 patients that I had operated on that, unfortunately,
18 had this problem with contracted mesh and pain.
19 I'm -- I'm in business to try and help women. I can
20 deal with certain types of risk associated with
21 surgery. Surgery has risk. After -- after
22 witnessing just in my own practice what could
23 happen, though rarely, but what could happen to a
24 patient like Ms. Farrell, I changed how I was using
25 vaginal mesh.

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1 Q And how did you change it?
2 A So understand -- my understanding of the
3 type of problem that Ms. Farrell experienced as it
4 related to a -- to a contraction of a vaginal mesh
5 made me very reluctant to use mesh in -- in our
6 younger group of patients. I almost entirely
7 stopped using mesh on both the anterior and
8 posterior vaginal walls. When you use a mesh for a
9 prolapse repair, the efficacy in terms of
10 anatomically correcting the prolapse is outstanding.
11 The vagina, if examined, looks straight. What we
12 subsequently began to understand was that the vagina
13 doesn't need to be rigid and straight, and that by
14 adopting a different way of using mesh, by perhaps
15 using it on one wall and allowing for the elasticity
16 of the other wall and the apex to remain, may be a
17 way to diminish the risk of this type of problem,
18 but continue to enjoy the -- the added efficacy of
19 mesh used vaginally.
20 Q And so if a manufacturer had advised you
21 of that risk, because it was something they knew or
22 should have, prior to Ms. Farrell, is it fair to say
23 you would have not done the procedure at Ms. Farrell
24 at that time?
25 MS. MAIMBOURG: Objection.

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1 MR. SCHACK: Objection.
2 THE WITNESS: Not necessarily.
3 BY MR. LEYDON:
4 Q Why is that?
5 A I'm not sure I understand what you're
6 saying the manufacturer would have said to me.
7 Q That this very risk we're discussing,
8 which is the reason you would not use this type of
9 procedure on Ms. Farrell, was a known and
10 significant risk, if the manufacturer had advised
11 you of that prior to that, so, rather than first
12 experiencing with Ms. Farrell, you had outside
13 information that this could happen, wouldn't that
14 have changed your practice prior to that?
15 MR. SCHACK: Objection.
16 MS. MAIMBOURG: Objection as to form.
17 THE WITNESS: Yeah. I think you have to
18 be careful, you know, taking any one source
19 and -- and changing your practice, changing
20 your life based upon any one piece of
21 information. Clearly, if I had gotten that
22 type of information that was really
23 specifically referring to what happened to
24 Ms. Farrell, I would have had to examine that
25 carefully.

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1 MR. CILANO: Is this a good time for a
2 restroom break?
3 MR. LEYDON: Sure.
4 (Recess: 11:24 a.m. until 11:31
5 a.m.)
6 BY MR. LEYDON:
7 Q Doctor, one of the alternatives you
8 described to using the mesh would be a surgery using
9 the patient's own tissue. I believe you described
10 autologous tissue. Is that correct?
11 A Correct.
12 Q Is that a procedure you also do?
13 A Yes.
14 Q Prior to your operating on Ms. Farrell was
15 there any type of controversy in the medical
16 community about the efficacy and safety of
17 transvaginal mesh?
18 MR. SCHACK: Objection.
19 MS. MAIMBOURG: Objection as to the form.
20 MR. ALLENTUCH: Objection.
21 MS. CILANO: I'll object to the form as
22 well.
23 THE WITNESS: I can't remember that many
24 years ago what conversation was happening or
25 when.

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1 BY MR. LEYDON:
2 Q Are there any periodicals that you
3 regularly subscribe to in terms of your business or
4 professional practice?
5 A Yes.
6 Q And what are those?
7 A I look at what are called the "Green
8 Journal" and the "Gray Journal," which are
9 obstetrics and gynecology, and the "Journal of
10 Obstetrics and Gynecology." I also look at -- the
11 name has changed a couple of times, but it's the
12 "Journal of the Urogynecologic Association," and
13 that specific title of the journal has changed over
14 the years. I don't know what it was called then.
15 Q "American Journal of Obstetrics and
16 Gynecology," are you familiar with that?
17 A I think I mentioned that one, didn't I?
18 Q That was one of the ones that was
19 mentioned. Okay.
20 And then are you familiar with the
21 "International Urogynecologic Journal"?
22 A That was the third one I was referring to.
23 Q Okay.
24 MR. LEYDON: Mark that.
25 (Plaintiff's Exhibit 7 marked

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1 was on the shelf. I wouldn't know that.
 2 MR. LEYDON: I'm just about winding up,
 3 actually. I just want to check my notes. And
 4 if we could take a five-minute break --
 5 THE WITNESS: Sure.
 6 (Recess: 12:13 p.m. until 12:40
 7 p.m.)
 8 MR. LEYDON: I have no further questions.
 9 MR. SIMPSON: What time is it? It's
 10 almost time for lunch.
 11 Can I chat with you for a second?
 12 MR. LEYDON: Sure.
 13 (Brief interruption in the
 14 proceedings.)
 15 MR. SIMPSON: During the break I talked to
 16 Attorney Leydon. And, given the fact that he
 17 is willing to -- he is done with his
 18 questioning, and there is a pending motion for
 19 summary judgment with Dr. Hines, at this point,
 20 for Johnson & Johnson and Ethicon, we're going
 21 to suspend the deposition, and have the
 22 opportunity, if needed, to call Dr. Hines at a
 23 later date, but that we're not going to -- so
 24 we're going to leave the deposition open for a
 25 period of time.

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1 I think Attorney Cilano wanted to say
 2 something on the record.
 3 MS. CILANO: Right. It's my understanding
 4 that the plaintiffs have completed their
 5 questioning of Dr. Hines. Correct?
 6 MR. LEYDON: That is correct.
 7 MS. CILANO: Okay. And you're prepared to
 8 go forward now on the motion for summary
 9 judgment?
 10 MR. LEYDON: Yes.
 11 MS. CILANO: Okay. All right. That's
 12 fine.
 13 MS. MAIMBOURG: Does anybody else want to
 14 make a statement?
 15 MR. SCHACK: I would just join in counsel
 16 for Ethicon with their statement for the
 17 suspension of the deposition.
 18 MS. CILANO: Okay. We're all the set.
 19 (Time noted: 12:51 p.m.)
 20 * * *
 21
 22
 23
 24
 25

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1
 2
 3 I, BRIAN J. HINES, M.D., have read the
 4 foregoing pages, and find the answers to the questions
 5 therein contained to be true and correct, with the exception
 6 of changes, if any, as may be noted on the Correction Page.
 7
 8
 9
 10 Dated _____ BRIAN J. HINES, M.D.
 11
 12 Subscribed and sworn to before me this ____ day
 13 of _____, 2014.
 14
 15
 16
 17
 18
 19 _____
 20 Notary Public
 21 My Commission Expires:
 22
 23
 24
 25

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1 STATE OF CONNECTICUT)
 2) SS: DANBURY
 3 COUNTY OF FAIRFIELD)
 4 I, Deborah R. Pomponio, a Registered Merit Reporter
 5 and Notary Public within and for the State of Connecticut,
 6 do hereby certify that the within deposition of BRIAN J.
 7 HINES, M.D. was held before me on the 25th day of March,
 8 2014.
 9 I further certify that the witness was first sworn by
 10 me to tell the truth, the whole truth and nothing but the
 11 truth, and was examined by counsel, and his testimony was
 12 recorded stenographically by me, it was reduced to
 13 typewriting under my supervision, and I hereby submit that
 14 the within contents of said deposition are true and accurate
 15 to the best of my ability.
 16 I further certify that I am not a relative of nor an
 17 attorney for any of the parties connected with the aforesaid
 18 examination, nor otherwise interested in the testimony of
 19 the witness.
 20 Dated at Danbury, Connecticut, the 27th day of March,
 21 2014.
 22
 23 _____
 24 Deborah R. Pomponio, RMR
 25 Notary Public
 CT License No. 79
 (My Commission expires January 31, 2015.)

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I N D E X

1 WITNESS: DIRECT CROSS REDIRECT RECROSS

2 BRIAN J. HINES, M.D.

3 by Mr. Leydon: 5

4 EXHIBITS: (for identification) PAGE

5 PLAINTIFF'S EXHIBITS:

6 1 Notice of Deposition, 1/7/14, with.....5

7 1 Attached Schedule A.....5

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INSTRUCTION SHEET

1 DATE SENT: 3/27/14

2 DATE OF DEPOSITION: 3/25/14

3 RE: FARRELL V JOHNSON & JOHNSON, ET AL

4 TO: BRIAN J. HINES, M.D.

5 HEIDELL, PITTONI, MURPHY & BACH, LLP

6 855 Main Street, Suite 1100

7 Bridgeport, Connecticut 06604

8 BY: HEIDI M. CILANO, ESQUIRE

9 Enclosed please find a copy of the transcript of your

10 deposition. Please read and sign the Jurat Page before any

11 Notary Public.

12 Enclosed is an Errata Sheet. If you deem it necessary

13 to make any corrections, please do so on this page, and then

14 sign the Errata Sheet before any Notary Public. If there

15 are no corrections, please write "No Corrections" and sign

16 your name.

17 Finally, please send a copy of the Errata Sheet to all

18 counsel listed on the appearance page.

19 RETURN ORIGINAL SIGNED AND NOTARIZED JURAT PAGE AND

20 ERRATA SHEET FOR PROPER FILING WITHIN THIRTY (30) DAYS TO:

21 TOOHER, WOCL & LEYDON, LLC

22 80 Fourth Street

23 Stamford, Connecticut 06905

24 BY: BRENDEN P. LEYDON, ESQUIRE

25

Page 85

ERRATA SHEET

1 Case Name: FARRELL V JOHNSON & JOHNSON, ET AL

2 Deponent's Name: BRIAN J. HINES, M.D.

3 Date of Deposition: 3/25/14

4 PAGE LINE FROM TO

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10 _____

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20 _____

21 Date Deponent's Signature

22 Subscribed and sworn to before me this ___ day of _____.

23 _____

24 Notary Public

25 My commission expires: _____

EXHIBIT C

D. N. UWY-CV14-6025333-S : SUPERIOR COURT/CLD
ROBIN SHERWOOD, ET AL : J.D. OF WATERBURY
V. : AT WATERBURY
STAMFORD HOSPITAL : OCTOBER 31, 2016

AFFIDAVIT OF ROBIN SHERWOOD

Personally appeared, Robin Sherwood, who made oath to the following:

1. I am over the age of 18 and understand the obligations of an oath;
2. The matters attested to herein are of my own personal knowledge and belief;
3. In April of 2006 Dr. Hines convinced me to undergo a surgical procedure to implant various mesh products into me;
4. Dr. Hines was the Director of Urogynecology at Stamford Hospital, a teaching hospital, and he recommended the implant surgery be performed there;
5. I relied upon the integrity of Stamford Hospital, and Dr. Hines affiliation with them, in proceeding to go forward with the surgery.
6. Dr. Hines never told me about the experimental nature of the Prolift;
7. Despite his knowledge about complications related to the Prolift mesh at no time did Dr. Hines suggest that my problems were related to a defect in the mesh itself.
8. I did not know at the time I agreed to have the surgery at Stamford Hospital that doctors affiliated with Stamford Hospital were conducting studies on the Prolift as well as seeking compensation to

promote it.

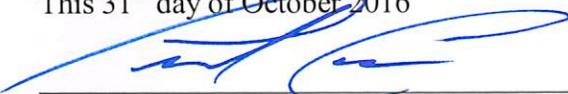
9. I did not know at the time I agreed to have the Prolift implant that Stamford Hospital had approved its purchase from J&J/Ethicon and its resale to me without proper clearance from the FDA and supporting long term studies regarding the long term complications associated with it.
10. Had I known about the experimental nature of the Prolift I would not have had it implanted in me.
11. If I had been properly informed regarding these matters I would not have gone through with the mesh implants.
12. At the time I filed my lawsuit against Johnson & Johnson in the MDL in April of 2013 I did not know that Stamford Hospital's conduct caused my injuries.
13. At the time I filed my lawsuit against Johnson & Johnson in the MDL in April of 2013 I did not know that Stamford Hospital's conduct had caused injuries and that I had suffered actionable harm.
14. I did not know until some point after my surgery in June of 2014 that Stamford Hospital's conduct caused my injuries.
15. At no point during or after my treatment with Dr. Hines and Stamford Hospital did either, or anyone on their behalf, provide me with information relating to issues with this product.
16. At no point did Stamford Hospital inform me that there were no long term studies about the safety and efficacy of the Prolift when it was approved for use at Stamford Hospital.
17. At no point did Stamford Hospital inform me that it had conducted a study on vaginal paravaginal pelvic organ prolapse repairs using polypropylene mesh and concluded that the mesh caused dyspareunia in 27% of the women.
18. At no point did Stamford Hospital inform me that it conducted a study in 2008 and concluded that there was a lack of risk benefit

information regarding the Prolift such that proper informed consent could not be obtained.

19. At no point did Stamford Hospital inform me that it had received a Public Health Notification in 2008 that warned of numerous complications associated with transvaginal placement of mesh like the Prolift.
20. At no point did Stamford Hospital inform me that Dr. Hines concluded in 2009 that the Prolift product was unsafe.
21. At no point did Stamford Hospital inform me that the FDA warned in 2011 that complications from the pelvic organ prolapse products like the Prolift implanted into me produced serious complications that were not rare and that mesh used in transvaginal POP repair introduced risks not present in traditional non-mesh surgery for POP repair.
22. At no point did Stamford Hospital inform me that in 2012 J&J pulled the dangerous Prolift products from the market.
23. Although I was having issues after the implant surgery I did not know that the issues were caused by 1) a defect in the product; 2) by Stamford Hospital's conduct; or 3) that they constituted actionable harm by Stamford Hospital.


Robin Sherwood

Subscribed and sworn to before me
This 31th day of October 2016



Notary Public / ~~Commissioner of the Superior Court~~
My Commission Expires:

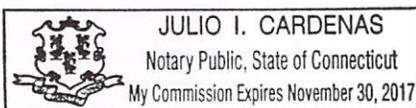


EXHIBIT D

Food Frequency Questionnaire focuses on folate-rich foods consumed by urban, reproductive-aged Latina women. It correlates well with the "gold standard" Willett Food Frequency Questionnaire; however, the short Food Frequency Questionnaire seems to be more sensitive. A short Food Frequency Questionnaire focusing on folate-rich foods is easier for patients to complete and may provide a better estimate of their folate intake.

An Evaluation of Lamotrigine on Mood in Women With Epilepsy and Comorbid Depressive Symptoms

James M. Miller, PharmD

GlaxoSmithKline, Research Triangle Park, NC

Anne E. Hammer, BS, Robert P. Kustra, PharmD, and Jouko I. Isojarvi, MD

OBJECTIVE: This analysis evaluated the effects of the anti-epileptic drug lamotrigine on mood in a subset of women with epilepsy and comorbid depressive symptoms from a larger study.

METHODS: In this multicenter open-label study, lamotrigine was added onto a stable antiepileptic drug regimen in the adjunctive phase and became a single agent in the monotherapy phase. Patients were eligible if they had epilepsy, exhibited at least minimal depressive symptoms (Center for Epidemiological Studies Depression Scale 12 or greater) but excluded if they had major depression determined by a Mini International Neuropsychiatric Interview. Patients were evaluated using the Beck Depression Inventory-II, Center for Epidemiological Studies Depression Scale, and Profile of Mood States at baseline, end of adjunctive phase (week 19) and end of monotherapy phase (week 36).

RESULTS: A total of 102 women (mean age 38.6 years) were evaluated of a total population of 159. Sixty-six patients completed the adjunctive phase, and 46 completed the monotherapy phase. Mild or moderate depression was present at baseline, which improved to mild or minimal after lamotrigine therapy. Mean baseline, end of adjunctive, and monotherapy scores for the Beck Depression Inventory-II were: 18.3, 12.5, and 8.1, respectively; for the Center for Epidemiological Studies Depression Scale, 25.7, 16.3, and 12.3, respectively; and for total Profile of Mood States were 57.7, 39.1, and 24.1, respectively. All change scores from baseline were highly significant at $P < .001$. The most common adverse events were headache, dizziness, nausea, insomnia, and back pain. These results were consistent with those of the entire study population.

CONCLUSION: The addition of lamotrigine to antiepileptic drug therapy demonstrated antidepressant activity in this subgroup of women with epilepsy.

UROGYNECOLOGY

Wound Infections in Patients With Interstim Sacral Nerve Stimulators

Ron Dinsmore Jr, MD

Stamford Hospital, Stamford, CT

Blair Washington, MD, and Brian Hines, MD

OBJECTIVE: To identify risk factors for the development of wound infections in patients with an Interstim sacral nerve stimulator and to describe the management of these infections.

METHODS: The charts of 53 patients who underwent Interstim implantation were reviewed. Regression analysis was performed and odds ratios were calculated to identify variables that were associated with the development of wound infection.

RESULTS: Wound infections developed in 9.4% (5/53) of patients. The interval between implantation and the development of symptoms was 2–44 weeks, with a median of 6 weeks. All patients were initially managed conservatively with antibiotics for 3–5 weeks, and then all patients had the implant removed. Wound cultures were obtained. All 5 patients underwent reimplantation of the implant on the contralateral side. Body mass index more than 35 was significantly associated with the development of a wound infection, odds ratio 2.7, 95% confidence interval 1.1–4.3.

CONCLUSION: Patients with a body mass index more than 35 are at increased risk for wound infection after Interstim implantation. Wound infections may present remote from the initial surgery. Most infections require removal of the neurostimulator.

Vaginal Paravaginal Repair With a Polypropylene Mesh Graft

Blair B. Washington, MD

Stamford Hospital, Stamford, CT

Ronald S. Dinsmore Jr, MD, and Brian Hines, MD

OBJECTIVE: The objective of this study was to describe outcomes of a technique of vaginal paravaginal repair using a polypropylene mesh graft in patients with recurrent stage III/IV anterior vaginal wall prolapse.

METHODS: This was an observational study. Twenty-four women underwent a vaginal paravaginal repair using a polypropylene graft. The same surgeon performed all of the repairs. Pelvic organ prolapse was staged according to the pelvic organ prolapse quantification system. Outcomes measured included recurrence of prolapse, changes in functional status, and surgical complications. Risk factors for recurrent anterior wall prolapse were evaluated.

RESULTS: The mean age was 71.2 years, and all patients had previously undergone a standard anterior colporrhaphy and now had either stage III or IV prolapse. Patients were evaluated at 6-month intervals, and the median length of

follow-up was 18 months. Postoperatively, 4 women had asymptomatic stage II anterior wall prolapse, for a failure rate of 18%. No risk factors for recurrent anterior wall prolapse were identified. Pelvic pressure resolved in 20 of 23, urinary frequency resolved in 17 of 23, and urgency resolved in 18 of 23 ($P < .05$, 2-tailed Fisher exact test). Eleven women were sexually active preoperatively, and 3 reported postoperative dyspareunia. Complications included 2 erosions of the mesh into the vagina.

CONCLUSION: Vaginal paravaginal repair with a polypropylene mesh graft is associated with very good anatomic cure rate, significant improvements in functional status, and a low rate of complications.

Predicting Voiding Dysfunction After Incontinence Surgery

Terry S. Dunn, MD

Denver Health Medical Center, Denver, CO

Leslie C. Hurt, MD, and B. J. Hessler

OBJECTIVE: To determine whether age, body mass index (BMI) or ethnicity affected length of catheterization after incontinence surgery or affected postoperative complications.

METHODS: This was a retrospective study of 134 women who underwent incontinence procedures between January 2003 and April 2005. All patients who underwent incontinence surgery and had complete medical records available for review were included. Type of surgery, age, ethnicity, BMI, days of postoperative catheterization, and complications were analyzed. Statistical analysis was performed with a variance type of modeling performed in a stepwise fashion. A subanalysis was also performed using logistic regression on patients who had postoperative complications.

RESULTS: A total of 134 patients were reviewed. There was no association between age ($P = .271$), ethnicity ($P = 9.70$), or BMI and length of catheterization. There was a slight association between surgery types and days of catheterization ($P = .05$); however, this became nonsignificant when controlling for age. The postoperative complications included 7% with a urinary tract infection, 13% with urinary retention, .8% wound separation, 3% cuff abscess, and 2% with takedown of the incontinence procedure. Logistic regression revealed no correlation between age, ethnicity, or BMI and complications. There was an association between complications and more extensive surgery.

CONCLUSION: There was no correlation between age, BMI, or ethnicity and length of catheterization and complications. There was an association between type of surgery (additional procedures) and complications.

Urethral Diverticulum, Vesicovaginal, and Rectovaginal Fistula Repairs Using a Xenograft

Neena Agarwala, MSc, MD

University of Nebraska Medical Center, Omaha, NE

Amber Cohn, MD

BACKGROUND: Urogenital and rectovaginal fistulae are significant, although uncommon, complications of gynecologic surgery, and fistula repair can be a challenging surgery for even the most experienced gynecologist. An interposition xenograft (acellular bovine collagen matrix), derived from bovine pericardium, has been used to accomplish successful repairs.

CASE: The first patient developed a vesicovaginal fistula after an abdominal hysterectomy, and a successful laparoscopic repair was accomplished using an interposition xenograft. The second patient presented with a vesicovaginal fistula after a transvaginal tape procedure, the third patient presented with a urethral diverticulum resulting in a urethrovaginal fistula, and both had a successful transvaginal repair with an interposition xenograft. The fourth patient presented with a rectovaginal fistula as well as vaginal vault prolapse and a long history of a pessary use, and the fifth patient developed a rectovaginal fistula 17 years after a forceps delivery. After 2 previous unsuccessful repairs, a successful transvaginal repair was accomplished in both using an interposition xenograft.

CONCLUSION: Using an interposition xenograft may be a successful option in urogenital and rectovaginal fistula repair.

A Randomized Comparison of GYNECARE TVT and Boston Scientific Lynx Suprapubis Mid-Urethral Sling

Neena Agarwala, MSc, MD

University of Nebraska Medical Center, Omaha, NE

Jennifer Griffin, MD

OBJECTIVE: A randomized prospective comparison of 2 synthetic slings was undertaken to evaluate efficacy, complication rates, and training of residents.

METHODS: Eighty-three women with stress urinary incontinence were consecutively assigned to GYNECARE TVT tension-free vaginal tape or Lynx Suprapubis Mid-Urethral Sling between January 2004 and August 2005. Intraoperative complications, ease of trocar placement, postoperative voiding difficulties, subjective and objective cure rates, and postoperative interventions were assessed.

RESULTS: Both groups were similar in mean age, parity, weight, preoperative post-void residual, cystometric capacity, flow rate, and urethral closure pressures. Postmenopausal status and previous surgery rate was also compara-

Supplement to

OBSTETRICS & GYNECOLOGY

Volume 107, Number 4 (Supplement), April 2006

Abstracts of Papers and Posters
to be Presented at the
ACOG 54th Annual Clinical Meeting

May 6–10, 2006
Washington, DC

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EXHIBIT E

FDA held regulatory meetings via telephone with the following device user facilities to address significant deviations from the Medical Device Reporting Regulation (21 CFR Part 803) for which we determined the facility had not provided an adequate response.

User Facility	Inspection Completed	Form FDA 483 Observations ^{1,2}	Form FDA 483
Advocate Lutheran General Hospital Park Ridge, IL	01/11/2016	<ol style="list-style-type: none"> The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to death of a patient of the facility. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer with 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. An MDR adverse event report was submitted on a form other than FDA Form 3500A (MEDWATCH form) or an approved electronic equivalent. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. The user facility report submitted on FDA Form 3500A did not include all information reasonably known. The written MDR procedure does not include documentation and recordkeeping requirements for all Medical Device Reports and information submitted to FDA and device manufacturers. Written MDR procedures have not been developed. 	[link]

¹ Form FDA 483, Inspectional Observations lists observations made by the FDA representative(s) during the inspection of a facility. They are inspectional observations and do not represent a final Agency determination regarding the facility's compliance.

² MedSun hospitals are asked to submit all mandatory and voluntary reports to FDA through the MedSun reporting system. FDA sends a copy of reports received through MedSun to the appropriate device manufacturer on behalf of the hospital, which fulfills any applicable requirement for hospitals to submit medical device reports for those events to the manufacturers.

User Facility	Inspection Completed	Form FDA 483 Observations ^{1,2}	Form FDA 483
Cedars-Sinai Medical Center Los Angeles, CA	12/07/2015	<ol style="list-style-type: none"> 1. Written MDR procedures have not been developed. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient in the facility. 	[link]
Huntington Memorial Hospital Pasadena, CA	12/11/2015	<ol style="list-style-type: none"> 1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. Written MDR procedures have not been implemented. 	[link]
Indiana University Hospital Indianapolis, IN	02/03/2016	<ol style="list-style-type: none"> 1. The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication and evaluation of events that may be subject to medical device reporting requirements. 2. MDR event files have not been established and maintained. 	[link]
New York Presbyterian Hospital New York, NY	12/10/2015	<ol style="list-style-type: none"> 1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. Written MDR procedures have not been developed, maintained, and implemented. 	[link]

User Facility	Inspection Completed	Form FDA 483 Observations ^{1,2}	Form FDA 483
Reading Hospital and Medical Center West Reading, PA	12/16/2015	<ol style="list-style-type: none"> 1. The user facility did not submit FDA Form 3500A or electronic equivalent to within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. The written MDR procedure does not include an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting. 4. The written MDR procedure does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable. 5. MDR event files have not been established and maintained. 	[link]
Rochester General Hospital Rochester, NY	12/09/2015	<ol style="list-style-type: none"> 1. Written MDR procedures have not been implemented. 	[link]
University of Rochester Medical Center Rochester, NY	01/29/2016	<ol style="list-style-type: none"> 1. The written MDR procedure does not include documentation and recordkeeping requirements for systems that ensure access to information that facilitates timely follow-up and inspection by FDA. 	[link]

For the following inspected device user facilities, FDA determined there were no significant deviations from the Medical Device Reporting Regulation (21 CFR Part 803) or that the response the facility provided was adequate.

User Facility	Inspection Completed	Form FDA 483 Observations ^{3,4}	Form FDA 483
Allegheny General Hospital Pittsburgh, PA	12/17/2015	<ol style="list-style-type: none"> 1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. Written MDR procedures have not been implemented. 4. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. 5. The user facility report submitted on FDA form 3500A did not include all information reasonably known. 6. The written MDR procedure does not include an internal system which provides for timely transmission of complete medical device reports to FDA and manufacturers. 	[link]

³ Form FDA 483, Inspectional Observations lists observations made by the FDA representative(s) during the inspection of a facility. They are inspectional observations and do not represent a final Agency determination regarding the facility's compliance.

⁴ MedSun hospitals are asked to submit all mandatory and voluntary reports to FDA through the MedSun reporting system. FDA sends a copy of reports received through MedSun to the appropriate device manufacturer on behalf of the hospital, which fulfills any applicable requirement for hospitals to submit medical device reports for those events to the manufacturers.

User Facility	Inspection Completed	Form FDA 483 Observations ^{3,4}	Form FDA 483
Brigham and Women's Hospital Boston, MA	12/10/2015	<ol style="list-style-type: none"> 1. The user facility did not submit FDA Form 3500A or electronic equivalent to within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. Written MDR procedures have not been developed and maintained and implemented. 4. MDR event files have not been established and maintained. 	[link]
Carolinas Medical Center Charlotte, NC	12/11/2015	No 483 Issued	N/A
Dartmouth-Hitchcock Medical Center Lebanon, NH	12/17/2015	<ol style="list-style-type: none"> 1. Written MDR procedures have not been developed and maintained and implemented. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. MDR event files have not been established and maintained. 	[link]
Froedtert Hospital Milwaukee, WI	12/16/2015	No 483 Issued	N/A

User Facility	Inspection Completed	Form FDA 483 Observations ^{3,4}	Form FDA 483
General Hospital Corporation Boston, MA	12/18/2015	<ol style="list-style-type: none"> 1. Written MDR procedures have not been developed and maintained and implemented. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 3. The user facility did not submit FDA Form 3500A or electronic equivalent to the FDA, because the device manufacturer was unknown, within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 4. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. 	[link]
UCLA Ronald Reagan Medical Center Los Angeles, CA	12/18/2015	<ol style="list-style-type: none"> 1. The user facility failed to provide all information concerning individual adverse event reports that is reasonably known to them, including information found in documents in possession of the user facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 	[link]
UMass Memorial Medical Center Worcester, MA	12/11/2015	<ol style="list-style-type: none"> 1. The written MDR Procedure does not include an internal system which provides for the timely and effective identification and communication and evaluation of events that may be subject to medical device reporting requirements. 2. MDR event files have not been established and maintained. 3. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 	[link]

User Facility	Inspection Completed	Form FDA 483 Observations ^{3,4}	Form FDA 483
Virginia Mason Medical Center Seattle, WA	04/15/2016	<ol style="list-style-type: none"> 1. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. An authorized FDA employee was not permitted to copy MDR required records during reasonable times. 4. Written MDR procedures have not been implemented. 	[link]

EXHIBIT F

<p style="text-align: center;">A P P E A R A N C E S</p> <p>Page 2</p> <p>FOR THE PLAINTIFFS:</p> <p>TOOHER, WOCL & LEYDON, LLC 80 Fourth Street Stamford, Connecticut 06905</p> <p>BY: BRENDEN P. LEYDON, ESQUIRE</p> <p>FOR THE DEFENDANTS, JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY, GYNECARE A DIVISION OF ETHICON, INC.: SHIPMAN & GOODWIN, LLP One Constitution Plaza Hartford, Connecticut 06103-1919</p> <p>BY: CHRISTOPHER DRURY, ESQUIRE</p> <p>FOR THE DEFENDANTS, STAMFORD HEALTH SYSTEM, INC. D/B/A STAMFORD HOSPITAL; UROGYNECOLOGY & PELVIC SURGERY, LLC: NEUBERT, PEPE & MONTEITH, PC 195 Church Street, 13th Floor New Haven, Connecticut 06510</p> <p>BY: SIMON I. ALLENTUCH, ESQUIRE</p> <p>FOR THE DEFENDANT, AMERICAN MEDICAL SYSTEMS, INC.: DISERIO, MARTIN, O'CONNOR & CASTIGLIONI, LLP One Atlantic Street Stamford, Connecticut 06901 -not present-</p>	<p style="text-align: center;">S T I P U L A T I O N S</p> <p>Page 4</p> <p>IT IS HEREBY STIPULATED AND AGREED by and between counsel for the parties that the proof of the official authority of the Notary Public before whom this deposition is taken is waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that the reading and signing of the deposition is not waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that notice of the time and place of the taking of the deposition is waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that all objections, except as to the form of the question, are reserved until the time of trial.</p> <p style="text-align: center;">* * *</p>
<p style="text-align: center;">A P P E A R A N C E S (Cont.d)</p> <p>Page 3</p> <p>FOR THE DEFENDANT, BRIAN J. HINES, MD:</p> <p>SACHNER & O'CONNOR, LLC</p> <p>THE CROSSROADS WEST</p> <p>765 Straits Turnpike</p>	<p>Page 5</p> <p>1 (Plaintiff's Exhibit 1 marked 2 for identification.) 3 THE COURT REPORTER: Usual stipulations, 4 with read and sign? 5 MR. ALLENTUCH: Yes. 6 MR. LEYDON: That's fine. 7 K A T H L E E N S I L A R D, 8 6 Intrieri Lane, Greenwich, Connecticut 06830, 9 called as a witness, after having been duly sworn, was 10 examined and testified as follows: 11 DIRECT EXAMINATION 12 BY MR. LEYDON: 13 Q Good morning, Ms. Silard. My name is 14 Brenden Leydon. I represent the plaintiffs in this 15 action. 16 Have you ever had your deposition 17 taken before? 18 A Yes. 19 Q Approximately how many times? 20 A Half a dozen. 21 Q So you're probably well aware of this, 22 but, just so the record is clear, I am going to set 23 forth the ground rules. As you know, I'll be asking 24 questions that you will then answer. Please let me 25 finish my question before you answer, even if you</p>

Page 10

1 you had information about these various topics on
2 behalf of Stamford Hospital. Are you familiar
3 with -- let me -- have you seen this deposition
4 before?
5 A Yes.
6 Q Okay. And when was the first time you saw
7 it?
8 A Well, counsel provided it to me. I'm not
9 sure of the date, but recently.
10 Q Well, we originally -- your deposition was
11 noticed for early September. So it probably would
12 have been sometime prior to that for the designation
13 of topics; correct?
14 A Could be, yeah.
15 Q And what knowledge do you have regarding
16 the operating margin as generated by the sale and
17 implementation of pelvic mesh products at Stamford
18 Hospital?
19 A I don't have knowledge of specific
20 operating margins related to knowledge a specific
21 procedure at the hospital. We're a \$500 million
22 corporation. So I don't monitor the specific profit
23 margin from the specific procedure.
24 Q Okay. Is there any particular knowledge
25 you have with regards to pelvic mesh and the

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1 operating margin?
2 A No. I do not know the operating margin
3 for a specific procedure such as the pelvic mesh.
4 Q The next topic is surgical mesh products
5 and pelvic mesh products approval process from 2002
6 to the present. Do you have any knowledge on that
7 topic?
8 A Generally speaking, when a product -- I do
9 not have specific knowledge about this product.
10 But, generally speaking, when a product would be
11 brought into the hospital, a physician would make a
12 recommendation for the purchase of a product
13 relative to a procedure, and that would be brought
14 to materials management, and then they would -- they
15 would purchase the product for the physician to be
16 used in a procedure.
17 Q Okay. And are there committees that are
18 involved in that type of decision?
19 A There are established committees now. At
20 the time it was very ad hoc.
21 MR. ALLENTUCH: Brenden, let me just ask
22 you, because we have two cases, different
23 products -- I know this is noticed in LeMay,
24 but there's been some discussion and briefing
25 about Farrell. Are you asking her or is the

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1 topic here the Prolift? Because that's -- or
2 is it --
3 MR. LEYDON: I mean, it's -- I think
4 Prolift and Plus M are going to be my focus.
5 But certainly the Prolift is a topic that I'm
6 asking about.
7 MR. ALLENTUCH: Okay. All right.
8 Do you understand what he's saying, that
9 he's talking about two different -- two
10 different products, one in LeMay, which is the
11 Prolift Plus M --
12 THE WITNESS: Right.
13 MR. ALLENTUCH: -- versus the Farrell
14 case, which is the Prolift? Just so you know
15 he's talking about different products.
16 THE WITNESS: Okay. Well, that's why I
17 said generally --
18 MR. LEYDON: Yeah, that's fine.
19 THE WITNESS: -- how products get
20 approved. I wasn't speaking specifically about
21 one product. I would not have that knowledge.
22 MR. LEYDON: Understood. And I will get
23 more specific later. I was looking for a
24 general overview.
25 MR. ALLENTUCH: Okay. Thank you.

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1 MR. LEYDON: And it is understood the
2 questions may relate to the Farrell case. And
3 I'm not looking to, you know, duplicate
4 efforts, which is why we're doing this.
5 MR. ALLENTUCH: Sure.
6 BY MR. LEYDON:
7 Q And you said presently there are various
8 committees that have specific product categories
9 they would likely be approved by; is that correct?
10 A Value analysis teams, yes.
11 Q Okay. And do you know how long that
12 process has been in place with the specific VAT
13 teams?
14 A It got reinvigorated sometime between 2009
15 and 2010. And it sort of evolved over that period
16 of time, where, you know, I think now it's much more
17 formal.
18 Q Okay. And prior to 2009 there still was
19 something called a "VAT committee" or some committee
20 of that nature?
21 A Periodically there were meetings with
22 regard to products and purchase of services. It's
23 not just products, services.
24 Q Okay. The Prolift product which was
25 implanted into Mary Beth Farrell, do you have any

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1 knowledge as to how that product came to be at
2 Stamford Hospital?
3 A I do not.
4 Q Do you know who might have any knowledge
5 as to how that product came to be approved at
6 Stamford Hospital?
7 A I would not know at the time who or how it
8 was approved. As I mentioned, generally speaking,
9 the physician would speak with materials management
10 or the operating room staff and let them know that
11 they were interested in bringing a product in for a
12 particular patient or procedure, and it would be
13 procured through that process.
14 Q And were there any forms during that time
15 period for when an item such as the Prolift were
16 approved by Stamford Hospital?
17 A There might have been. I'm not sure.
18 They might have -- the physician might have
19 completed a form to request the product.
20 Q And do you know what has been done to try
21 to attempt to get any such forms or documents
22 regarding a Prolift?
23 MR. ALLENTUCH: Objection to form.
24 THE WITNESS: I am not understanding the
25 question. Has there been anything done to get

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1 a form?
2 BY MR. LEYDON:
3 Q Yeah. Has there been any inquiry or
4 process to attempt to find what forms are out there
5 that relate to how the Prolift got approved at
6 Stamford Hospital?
7 A I have not been involved in securing
8 forms.
9 Q Do you have any knowledge as to anyone
10 that might have been or what process was involved?
11 A I am not aware of that.
12 Q The Prolift Plus M that was implanted in
13 Ms. LeMay, do you know how that product came to be
14 approved at Stamford Hospital?
15 A I, again, was not familiar or am not
16 familiar with the specifics around that product.
17 But, generally speaking, if a product is to be
18 requested by a physician, it would go to the
19 operating room or to materials management and
20 request the product for a particular patient or for
21 a procedure.
22 Q And were there other people involved in
23 that process, say the department head or other
24 people at Stamford Hospital?
25 A Well, the operating room and materials

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1 management has a couple hundred people working in
2 it. So there could have been many people involved
3 in it.
4 Q Materials management are people involved
5 in sort of stocking the shelves; correct?
6 A They have various roles. It could be from
7 negotiating a price, or it could be from developing
8 a contract and then purchasing it and then
9 delivering it.
10 Q So, in addition to the people in materials
11 management, at the time of the Plus M that was
12 implanted in Ms. LeMay, wasn't there clearly
13 established at that point a process where the
14 department head at least and other people on a VAT
15 committee approved those products?
16 MR. ALLENTUCH: Objection to form.
17 It might be helpful -- I mean, it's up to
18 you -- to tell her when the Prolift Plus M
19 was -- was marketed, or when it came into
20 existence. You're asking her about a specific
21 product that she says she doesn't know about.
22 So if you give her a time period you're going
23 to get a real answer versus without a time
24 period.
25

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1 BY MR. LEYDON:
2 Q Okay. Do you have any knowledge yourself
3 as to when the Prolift Plus M came to Stamford
4 Hospital?
5 A I was not personally involved in that.
6 From reading some documents, I -- I have an idea
7 when it was -- when Dr. Hines requested the product.
8 Q And the documents seem to suggest in 2009.
9 Does that refresh your recollection?
10 A Yes. Around then, yes. I don't have a
11 specific date.
12 Q So, during that timeframe, isn't it
13 correct that there was a more established process, a
14 Dr. Bruck, who was the department head, had to sign
15 off on those, and there was a committee that did so?
16 A At that point in time we don't have
17 evidence of continued VAT analysis. It was ad hoc
18 still. It was just getting started up and
19 reinvigorated.
20 Q There were forms at that time though, were
21 there not?
22 A Generally speaking. I have not seen
23 the -- the process for that -- the completion of
24 forms, but I would imagine there was.
25 Q But the specific form relating to the

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1 the present tense. Did that policy exist going back
 2 to, say, 2005 at least?
 3 A Yes.
 4 Q Thank you.
 5 MR. LEYDON: I have no further questions.
 6 MS. KELSON: No questions.
 7 MR. DRURY: No questions.
 8 MR. ALLENTUCH: Thanks.
 9 (Time noted: 11:25 a.m.)
 10 * * *
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1
 2
 3 I, KATHLEEN SILARD, have read the foregoing
 4 pages, and find the answers to the questions therein
 5 contained to be true and correct, with the exception of
 6 changes, if any, as may be noted on the Correction Page.
 7
 8
 9
 10 _____
 11 Dated KATHLEEN SILARD
 12 Subscribed and sworn to before me this ___ day
 13 of _____, 2015.
 14
 15
 16
 17
 18
 19 _____
 20 Notary Public
 21 My Commission Expires:
 22
 23
 24
 25

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1 STATE OF CONNECTICUT)
 2) SS: DANBURY
 3 COUNTY OF FAIRFIELD)
 4 I, Deborah R. Pomponio, a Registered Merit Reporter
 5 and Notary Public within and for the State of Connecticut,
 6 do hereby certify that the within deposition of KATHLEEN
 7 SILARD was held before me on the 27th day of October, 2015.
 8 I further certify that the witness was first sworn by
 9 me to tell the truth, the whole truth and nothing but the
 10 truth, and was examined by counsel, and his testimony was
 11 recorded stenographically by me, it was reduced to
 12 typewriting under my supervision, and I hereby submit that
 13 the within contents of said deposition are true and accurate
 14 to the best of my ability.
 15 I further certify that I am not a relative of nor an
 16 attorney for any of the parties connected with the aforesaid
 17 examination, nor otherwise interested in the testimony of
 18 the witness.
 19 Dated at Danbury, Connecticut, the 27th day of
 20 October, 2015.
 21
 22 _____
 23 Deborah R. Pomponio, RMR
 24 Notary Public
 25 CT License No. 79
 (My Commission expires January 31, 2020.)

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I N D E X

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2	KATHLEEN SILARD				
3	by Mr. Leydon:	5		49	
4	by Mr. Allentuch:		45		
5					
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7	EXHIBITS: (for identification)				PAGE
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EXHIBIT G

ACOG PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR
OBSTETRICIAN–GYNECOLOGISTS
NUMBER 79, FEBRUARY 2007

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Gynecology with the assistance of Scott W. Smilen, MD, and Anne M. Weber, MD, MS. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.



Pelvic Organ Prolapse

With the advancing age of the U.S. population, obstetrician–gynecologists are likely to encounter women with pelvic organ prolapse with greater frequency. The lifetime risk (to age 80 years) for undergoing surgery for prolapse or urinary incontinence has been estimated at 11% (1). Approximately 200,000 inpatient procedures for prolapse are performed annually in the United States (2). The most common indication for hysterectomy in women aged 55 years and older in the United States is prolapse (3). The purpose of this document is to review current treatment options.

Background

Pelvic organ prolapse occurs with descent of one or more pelvic structures: the uterine cervix or vaginal apex, anterior vagina (usually with bladder, cystocele), posterior vagina (usually with rectum, rectocele), or peritoneum of the cul-de-sac (usually with small intestine, enterocele). However, a specific definition of what constitutes clinically significant prolapse remains elusive. Although almost half of parous women can be identified as having prolapse by physical examination criteria, most are not clinically affected (4); the finding of prolapse on physical examination is not well correlated with specific pelvic symptoms.

Possible risk factors for pelvic organ prolapse include genetic predisposition, parity (particularly vaginal birth [5]), menopause, advancing age, prior pelvic surgery, connective tissue disorders, and factors associated with elevated intraabdominal pressure (eg, obesity, chronic constipation with excessive straining) (6, 7). Whether hysterectomy for conditions other than prolapse is a risk factor for subsequent prolapse is still controversial. Until recently, advocates of supracervical (or subtotal) hysterectomy claimed that preservation of the cervix (and, more important, the upper vagina and its pelvic attachments through the cardinal–uterosacral ligament complex) would prevent the development of subsequent prolapse. However, evidence from randomized trials comparing supracervical hysterectomy with total hysterectomy has shown no

difference in vaginal support with short-term follow-up after hysterectomy, regardless of cervical preservation or removal (8, 9).

Evaluation

Each woman's condition should be thoroughly evaluated to ascertain the nature and severity of her symptoms along with the extent of prolapse. Many patients with prolapse are asymptomatic and seek only reassurance or a better understanding of their condition. Women with asymptomatic or mildly symptomatic prolapse can be counseled that treatment is appropriate only when symptoms warrant it. It cannot be assumed that nonspecific symptoms, such as pelvic pressure or back pain, will be alleviated with prolapse treatment. The most specific symptom of prolapse is when the woman can see or feel a bulge of tissue that protrudes to or past the vaginal opening. Because prolapse is a dynamic condition responsive to the effects of gravity when women are in an erect position, some women may experience little or no bulging early in the day with progressively more protrusion as the day goes on, especially after long periods of physical exertion, such as lifting or standing.

Patients with prolapse, perhaps particularly anterior vaginal prolapse, may experience difficulty voiding or incomplete bladder emptying; however, symptoms of urinary urgency or frequency or urge incontinence are not related to prolapse severity. Women with advanced prolapse may recall symptoms of stress incontinence in the past that gradually improved and even resolved as the prolapse became worse. Some women with severe prolapse discover they can void more completely when the prolapse is reduced. Similarly, some women with posterior vaginal prolapse use manual pressure applied to the perineum or posterior vagina to assist defecation. Because many women will not volunteer such information, it is critically important that clinicians ask specific questions to assess voiding and defecating.

The maximum degree of descent may be observed on physical examination with the patient supine in heel stirrups, performing a Valsalva maneuver. If the patient suggests that her prolapse is not being seen at its worst extent, she can be asked to strain while in the standing position. Efficiency of bladder emptying should be evaluated by measuring the patient's voided volume when she has a comfortably full bladder, followed by assessment of postvoid residual urine volume by catheterization or bladder ultrasonography. Valsalva and cough stress testing can be performed with the prolapse reduced to determine if a subjectively stress-continent patient has occult (or potential) stress incontinence; however, cur-

rently, there is no consensus on how to best reduce prolapse for stress testing nor on how to use information from stress testing with and without prolapse reduction in making recommendations for care.

Several systems have been developed to classify pelvic organ prolapse. The Baden-Walker system (or some modification) is in widespread clinical use (see box, "Baden-Walker System for the Evaluation of Pelvic Organ Prolapse on Physical Examination"); the Pelvic Organ Prolapse Quantification (POP-Q) system (10) was introduced for use in clinical practice and research. Some have argued that the nine points of the POP-Q system may be more detailed than necessary for clinical practice, and the full POP-Q system may be better suited for clinical research purposes. The Baden-Walker system is probably adequate for clinical practice as long as descent or protrusion affecting all pelvic compartments (anterior, apical, and posterior) is assessed. It often is useful to include an estimation or measurement of the extent of protrusion relative to the hymen, as in the POP-Q system, to better assess change over time (see box, "Stages of Pelvic Organ Prolapse").

Clinical Considerations and Recommendations

► *Are effective nonsurgical treatments available for women with pelvic organ prolapse?*

The option of nonsurgical management should be discussed with all women with prolapse. Although pessary use is the only specific nonsurgical treatment, pelvic floor muscle rehabilitation and symptom-directed therapy may be offered, despite the lack of data supporting their use to prevent prolapse progression (11, 12).

Baden-Walker System for the Evaluation of Pelvic Organ Prolapse on Physical Examination

Grade posterior urethral descent, lowest part other sites

Grade 0: Normal position for each respective site

Grade 1: Descent halfway to the hymen

Grade 2: Descent to the hymen

Grade 3: Descent halfway past the hymen

Grade 4: Maximum possible descent for each site

Baden WF, Walker T. Fundamentals, symptoms and classification. In: Baden WF, Walker T, editors. Surgical repair of vaginal defects. Philadelphia (PA): J.B. Lippincott; 1992. p. 14.

Symptom-directed therapy with observation of prolapse (watchful waiting) can be recommended for women with low-stage prolapse (ie, stage I and stage II, especially when descent is still above the hymen) and nonspecific symptoms. The POP-Q stages of pelvic organ prolapse are shown in the box. Women with prolapse who are asymptomatic or mildly symptomatic can be observed at regular intervals, which can be conveniently combined with annual well-woman care unless new bothersome symptoms develop between visits. Although estrogen receptors are plentiful throughout the pelvis, their role in pelvic support is not fully understood, and there is no evidence currently to support the pharmacologic use of estrogen to prevent or treat prolapse.

Stages of Pelvic Organ Prolapse

Stages are based on the maximal extent of prolapse relative to the hymen, in one or more compartments.

Stage 0: No prolapse; anterior and posterior points are all -3 cm, and C (cervix) or D (posterior fornix) is between $-TVL$ (total vaginal length) and $-(TVL - 2)$ cm.

Stage I: The criteria for stage 0 are not met, and the most distal prolapse is more than 1 cm above the level of the hymen (less than -1 cm).

Stage II: The most distal prolapse is between 1 cm above and 1 cm below the hymen (at least one point is -1 , 0, or $+1$).

Stage III: The most distal prolapse is more than 1 cm below the hymen but no further than 2 cm less than TVL.

Stage IV: Represents complete procidentia or vault eversion; the most distal prolapse protrudes to at least $(TVL - 2)$ cm.

Pelvic Organ Prolapse Quantification System

Six vaginal sites used in staging prolapse:

Points Aa and Ba anteriorly

Points Ap and Bp posteriorly

Point C for the cervix or vaginal apex

Point D for the posterior fornix (not measured after hysterectomy)

Three additional measurements:

GH – genital hiatus

PB – perineal body

TVL – total vaginal length

Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10–7.

Pessaries

Traditional indications for pessary treatment include pregnancy and specific medical contraindications to surgery in elderly and debilitated patients; however, pessaries also can be used in all circumstances when women prefer a nonsurgical alternative. Pessaries can be fitted in most women with prolapse, regardless of prolapse stage or site of predominant prolapse, and are used by 75% of urogynecologists as first-line therapy for prolapse (13). Pessary devices are available in various shapes and sizes, and can be categorized as supportive (such as a ring pessary) or space-occupying (such as a donut pessary). Pessaries commonly used for prolapse include ring pessaries (with and without support) and Gellhorn, donut, and cube pessaries.

In most patients (range, 50–73%), an appropriately sized pessary can be fitted successfully in one or two office visits; however, a lower percentage (range, 41–67%) maintain pessary use after fitting (14–19). Although some clinicians use pessaries less frequently for advanced prolapse, recent studies have not found an association between prolapse stage and the outcome of a pessary trial (16, 19). Other factors related to successful pessary fitting or continued pessary use are not consistent across studies (Tables 1 and 2). However, the type of pessary that can be fitted is probably related to the severity of prolapse. In one study protocol, ring pessaries were inserted first, followed by Gellhorn pessaries if the rings did not stay in place. Ring pessaries were used more successfully with stage II (100%) and stage III (71%) prolapse, and stage IV prolapse more frequently required Gellhorn pessaries (64%) (16). For women who can be fitted and whose pelvic organ support can be maintained with a pessary, treatment has a high likelihood of benefit. In one study, 2 months after successful fitting, 92% of patients were satisfied with pessary management, nearly all prolapse symptoms had resolved, and 50% of urinary problems were reduced (17). Neither stage of prolapse (19) nor sexual activity (18) contraindicates pessary use. Clinicians should discuss the option of pessary use with all women who have prolapse that warrants treatment based on symptoms. In particular, pessary use should be considered before surgical intervention in women with symptomatic prolapse.

Symptom-Directed Therapy

Therapy may include weight loss and exercise, in addition to therapy targeted at specific symptoms. Although weight loss and exercises (either aerobic exercise or pelvic floor muscle exercises) have not been proved beneficial specifically for prolapse treatment or prevention, such recommendations are appropriate as general health

Table 1. Factors Affecting Pessary Fitting for Pelvic Organ Prolapse

Author Percent of Study Population With Successful Pessary Fit	Factors Associated With Successful Pessary Fitting	Factors Not Associated With Successful Pessary Fitting
Clemons et al, 2004*: 73 of 100 women (73%)	Longer vaginal length (more than 7 cm) Narrower vaginal introitus (less than four finger-breadths)	Age Parity Estrogen use Sexually active Previous hysterectomy Previous prolapse surgery Pelvic organ prolapse stage Predominant prolapse compartment Genital hiatus size
Mutone et al, 2005†: 288 of 407 women (71%)	(not stated)	(not stated)

*Clemons JL, Aguilar VC, Tillinghast TA, Jackson ND, Myers DL. Risk factors associated with an unsuccessful pessary fitting trial in women with pelvic organ prolapse. *Am J Obstet Gynecol* 2004;190:345–50.

†Mutone MF, Terry C, Hale D, Benson JT. Factors which influence the short-term success of pessary management of pelvic organ prolapse. *Am J Obstet Gynecol* 2005;193:89–94.

Table 2. Factors Affecting Continued Pessary Use for Pelvic Organ Prolapse

Author Percent of Study Population With Continued Pessary Use	Factors Associated With Continued Pessary Use	Factors Not Associated With Continued Pessary Use
Brincat et al, 2004*: 82 of 136 women (60%)	Sexually active (vs not sexually active) Pessary use for prolapse (vs for stress incontinence)	Age Parity Menopausal status Surgical history
Mutone et al, 2005†: 168 of 407 women (41%)	No previous hysterectomy No previous surgery for prolapse Normal weight (vs obesity)	Age Levator ani strength Pelvic organ prolapse stage Predominant prolapse compartment Genital hiatus size Perineal body length Total vaginal length

*Brincat C, Kenton K, Fitzgerald MP, Brubaker L. Sexual activity predicts continued pessary use. *Am J Obstet Gynecol* 2004;191:198–200.

†Mutone MF, Terry C, Hale D, Benson JT. Factors which influence the short-term success of pessary management of pelvic organ prolapse. *Am J Obstet Gynecol* 2005;193:89–94.

guidelines. In addition, symptoms related to altered voiding or defecatory habits should be addressed. For example, patients with defecatory problems, such as incomplete emptying and straining, often benefit from behavior training (such as establishing a scheduled time to facilitate regular bowel habits), dietary modification (such as increased dietary fiber or fiber supplements as needed), and splinting or laxative or enema use to permit evacuation without straining. Women with urinary incontinence as their primary symptom can be treated with behavior modification (timed voiding), fluid intake alterations,

pelvic muscle training and exercise (see the following section), and medication as first steps.

Pelvic Floor Muscle Rehabilitation

Pelvic muscle training (Kegel exercises) is a simple, non-invasive intervention that may improve pelvic function. Whether Kegel exercises can resolve prolapse has not been studied since Kegel's original articles (20). Nevertheless, the benefit of pelvic floor muscle training has been clearly demonstrated for women with urinary or

fecal symptoms, especially incontinence. It is commonly recommended as adjunct therapy for women with prolapse and associated symptoms, often with symptom-directed therapy.

► ***What are effective surgical treatments for uterine or vaginal vault prolapse?***

Hysterectomy is often the traditional surgical approach for women with uterine or uterovaginal prolapse. However, because the uterus plays only a passive role in prolapse, hysterectomy alone or hysterectomy with anterior or posterior colporrhaphy does not address the underlying problem of deficient apical support. When hysterectomy is performed for uterine prolapse, attention must be directed toward restoration of apical support once the uterus is removed. Surgical options for patients with apical prolapse (when hysterectomy has been performed remotely or as part of the current procedure) include abdominal sacral colpopexy and transvaginal suspension procedures using pelvic structures for fixation, such as the sacrospinous ligament(s), uterosacral ligaments, and iliococcygeus fascia or muscle.

Multiple case series on vaginal and abdominal approaches to apical prolapse have been summarized in extensive reviews (21, 22). These predominantly retrospective studies demonstrate a wide range of effectiveness for surgical treatment of prolapse at the vaginal apex, with failure rates ranging from 0% to 20% for each type of procedure (sacrospinous ligament fixation, uterosacral ligament suspension, endopelvic fascial suspension by vaginal approach, or abdominal sacral colpopexy by open or laparoscopic approach). Whether abdominal sacral colpopexy offers advantages in outcomes over vaginal approaches to prolapse repair is controversial.

A 2005 Cochrane review (6) of surgical management of prolapse concluded that, based on a synthesis of three randomized trials (23–25), compared with vaginal sacrospinous ligament fixation, abdominal sacral colpopexy has less apical failure and less postoperative dyspareunia and stress incontinence, but is also associated with more complications. The reported recurrence for vault prolapse was 3 in 84 abdominal sacral colpopexies versus 13 in 85 vaginal surgeries (relative risk [RR], 0.23; 95% confidence interval [CI], 0.07–0.77). However, operating time and patient recovery was longer with abdominal sacral colpopexy compared with vaginal sacrospinous ligament fixation. Short-term and long-term complications, particularly related to intraabdominal adhesions and small-bowel obstruction, may be more frequent after abdominal sacral colpopexy compared with vaginal prolapse repair. Therefore, clinicians should carefully consider each patient's risk for complications and potential for

recurrent prolapse, along with the patient's preferences, when making recommendations for abdominal sacral colpopexy or vaginal sacrospinous ligament fixation.

Whether results are superior with uterosacral versus sacrospinous ligament suspension is unknown; the two procedures have never been compared in a controlled or randomized trial. From case series of sacrospinous and uterosacral ligament vaginal suspensions, risks common to surgery in general are similar probably because the two procedures share the vaginal approach. However, some risks are specific to each procedure. Ureteral injury rates as high as 11% have been reported with uterosacral ligament suspension (26). Cystoscopy should be performed intraoperatively to assess for bladder or ureteral damage after all prolapse or incontinence procedures during which the bladder or ureters may be at risk of injury. If promptly identified and treated, such injury usually requires only suture release and replacement to avoid serious morbidity. However, ureteral injury occasionally requires reimplantation, particularly if recognition of the injury is delayed. Hemorrhage from pudendal vessels injured in sacrospinous ligament suspension is rare but can be life-threatening and is technically challenging to address. Buttock pain after sacrospinous suspension occurs infrequently and usually is self-limited but may require reoperation for suture removal to resolve persistent pain.

Outcomes of laparoscopic sacral colpopexy have been reported in case series (27–29) and one comparative cohort study (30). Recurrent apical prolapse occurred in only 4–7%, but anterior or posterior vaginal prolapse recurred in up to 32%. Without randomized trials, it is not possible to draw conclusions of similar efficacy compared with abdominal sacral colpopexy, but it does seem that for surgeons with advanced laparoscopic skills, sacral colpopexy can be accomplished, thereby avoiding laparotomy. However, even in the hands of experienced laparoscopists, a protracted learning curve is described for laparoscopic sacral colpopexy (28), and average operative times are almost an hour longer than for open sacral colpopexy (30), although postoperative recovery may be shorter.

Reviews of several case series of uterosacral ligament suspension describe recurrent prolapse in 4–18% of patients after relatively short follow-up (up to 4 years), although conclusions are limited by the inherent weaknesses of uncontrolled studies (26, 31–35). In one study of 168 women, 11 (6.5%) had recurrent prolapse at follow-up from 6 months to 3 years (34). In 72 of those women monitored for a mean of 5.1 years (range, 3.5–7.5 years), 11 (15.3%) experienced symptomatic recurrent prolapse of stage II or greater, although only two women (3%) had apical prolapse (36). Alternative sites for apical

support, such as sacrospinous ligament(s) or iliococcygeus fascia, can be used when the uterosacral ligaments are not easily accessible or are attenuated and unable to provide adequate support. Use of the iliococcygeus fascia during vaginal surgery has been reported in case series (37, 38).

► ***What management options are recommended for women who are poor surgical candidates and who present with complete eversion of the vagina, with or without a uterus?***

In some cases, including women who are at such high risk of surgical or anesthetic complications that surgery is contraindicated, nonsurgical treatment will be first-line therapy. Expectant management, nonsurgical therapy, and surgery have not been directly compared for any patient population, including older or medically compromised women with advanced prolapse. In general, perioperative risk is increased in patients with concomitant medical problems. However, if surgery becomes necessary, limited data support its relative safety; morbidity occurs frequently but mortality is rare.

In 267 women aged 75 years or older, after primarily vaginal urogynecologic surgery, 26% had perioperative complications, most commonly blood loss, pulmonary edema, and congestive heart failure (39). In a study reviewing an administrative database of inpatient urogynecologic procedures in 264,340 women (40), mortality was increased in a nonlinear pattern with each decade of life: 1 in 10,000 for women younger than 60 years; 5 in 10,000 for women aged 60–69 years; 9 in 10,000 for those aged 70–79 years; and 28 per 10,000 for women aged 80 years and older. Complications were more frequent in women aged 80 years and older and in women who had reconstructive rather than obliterative surgery.

Colpocleisis (or colpectomy) can be offered to women who are at high risk for complications with reconstructive procedures and who do not desire vaginal intercourse. In a recent review, colpocleisis was reported as successful for prolapse repair in close to 100% of patients in modern retrospective series (41). However, the rate of reoperation for stress incontinence or recurrent prolapse after colpocleisis is unknown. Although complications are relatively common in this group of predominantly older patients, serious morbidity or mortality is uncommon. Concomitant hysterectomy is associated with increased blood loss, blood transfusion, and length of hospital stay, without known benefit. Few studies systematically assess pelvic symptoms, either before or after surgery. The Manchester procedure (amputation of the cervix combined with anterior and posterior colporrha-

phy) has been considered another option for older, frail women with prolapse, but it has been little used since the mid-1970s.

► ***Are effective surgical treatments available for a woman with pelvic organ prolapse who prefers to avoid hysterectomy?***

For women who choose surgical management and who prefer uterine conservation (which may or may not include interest in further childbearing), the same procedures performed for vaginal suspension (after either remote or concomitant hysterectomy) can be performed without hysterectomy: uterosacral or sacrospinous ligament fixation by the vaginal approach, or sacral hysteropexy by the abdominal approach. Limited data on pregnancy outcomes (42, 43) and even fewer data on prolapse outcomes are available. Ideally, childbearing should be complete before considering surgery for prolapse to avoid the theoretical but plausible risk of recurrent prolapse after subsequent pregnancy and delivery. For women who become pregnant after prolapse repair, decisions regarding mode of delivery should be made on a case-by-case basis; evidence to guide such decisions is lacking.

Hysteropexy

In retrospective series review, prolapse recurrence ranges from 6.6% to 23.5% after sacral hysteropexy or sacral colpopexy (abdominal attachment of the lower uterus or upper vagina to the sacral promontory with synthetic mesh) (44, 45), and up to 30% for sacrospinous hysteropexy (43, 46). Complications include hemorrhage, hematoma, wound infection, small-bowel obstruction, incisional hernia, and mesh erosion. The laparoscopic approach has been used for hysteropexy, but data are limited (47, 48). Hysteropexy should not be performed by using the ventral abdominal wall for support because of the high risk for recurrent prolapse, particularly enterocele.

Round Ligament Suspension

Round ligament suspension is not effective in treating uterine or vaginal prolapse. A retrospective case series review on laparoscopic suspension to the round ligament found that 90% of patients had already experienced recurrent prolapse by 3 months postoperatively (49).

Colpocleisis

Some patients do not desire vaginal function for sexual activity or future childbearing and prefer to avoid hysterectomy. For these women, colpocleisis is an option.

► ***Are effective surgical treatments available for a woman with anterior or posterior vaginal prolapse or both (ie, cystocele or rectocele or both)?***

Anterior vaginal prolapse (cystocele) may be repaired with traditional midline anterior colporrhaphy, with or without the addition of mesh or graft material, or by paravaginal repair, which can be accomplished vaginally or retropubically by open or laparoscopic access. No data are available on the effectiveness of laparoscopic paravaginal repair primarily for prolapse. Retrospective case series review regarding open retropubic and vaginal paravaginal repairs (in combination with other procedures for prolapse and often stress incontinence) show recurrent prolapse in 15–37% with relatively short follow-up up to 3 years (50–53). Controlled studies comparing open retropubic repair with vaginal paravaginal repair or studies comparing paravaginal repair by any approach with anterior colporrhaphy are lacking.

Posterior vaginal prolapse (rectocele) has traditionally been treated surgically by posterior colporrhaphy, with midline plication of the subepithelial vaginal tissue. Although in the past plication of the medial portion of the levator ani often was performed as an adjunct to posterior repair, its use has been largely abandoned because of postoperative dyspareunia except when postoperative sexual activity is not anticipated. Site-specific repair also can be accomplished, in which a specific “defect” in the vaginal muscularis or adventitia is visualized and repaired. Abdominal and laparoscopic approaches also have been suggested, usually in conjunction with sacral colpopexy, where mesh is placed along the posterior vagina, sometimes all the way to the perineal body (sacral colpoperineopexy).

No randomized trials compare posterior colporrhaphy with site-specific defect repairs; in one uncontrolled comparison (54), after site-specific repairs, prolapse recurred more frequently (33%) than after traditional midline plication (14%) within 1 year of follow-up. Dyspareunia remains a frequent and difficult postoperative problem, even when introital narrowing is avoided (55).

Colorectal surgeons have advocated the transanal approach to rectocele repair, with plication of redundant rectal mucosa and anterior rectal muscle. However, in a trial comparing transanal and transvaginal approaches (6, 56), transvaginal repair was more effective for subjective symptom relief and objective recurrence of posterior vaginal prolapse (rectocele and enterocele). The vaginal approach was associated with a smaller mean rectocele depth determined by defecography, and postoperative enterocele was less common, compared with

the transanal approach (6). Therefore, transvaginal posterior colporrhaphy is recommended over transanal repair for posterior vaginal prolapse.

► ***What can be recommended regarding currently available graft materials for use in prolapse surgery?***

Biologic and synthetic graft materials have been used to augment traditional prolapse repairs, such as anterior and posterior colporrhaphy, as a substitute or reinforcement for the original vaginal tissue. For apical prolapse, new techniques use materials mounted on trocars to bypass native supportive structures (eg, uterosacral–cardinal ligament complex) in order to provide vaginal support. Despite the lack of risk–benefit information, many new techniques and products are being incorporated rapidly into clinical practice, even while continuous modifications are taking place in an attempt to reduce complications, particularly those related to mesh erosion, contraction (resulting in vaginal shortening and narrowing), and fistula. Given the pace of change with new techniques and products, any publication attempting to provide a comprehensive list will be outdated even before publication. Clinicians should follow the emerging literature closely to remain knowledgeable about which techniques and products should be avoided and which are ultimately proved to be of benefit to patients. The topic of graft materials is well covered in a review by Silva and Karram (57).

Although synthetic mesh used in early reports of abdominal sacral colpopexy was associated with good prolapse outcomes, mesh erosion occurred in some cases. Most cases of mesh erosion can be managed successfully with limited vaginal excision, incurring minimal morbidity; however, in rare cases, the entire mesh must be removed via laparotomy, often in the setting of refractory peritoneal infection, severe adhesions, and high likelihood of bowel complications. In an effort to reduce the risk of mesh erosion, some surgeons switched from synthetic mesh to allograft (cadaveric) fascia for abdominal sacral colpopexy. However, high rates of prolapse recurrence after abdominal sacral colpopexy using cadaveric fascia were initially reported in case series review (58–60), followed by randomized trial evidence (61). The use of cadaveric fascia for abdominal sacral colpopexy should be abandoned.

When choosing the best material for specific procedures, it is critically important that surgeons understand how certain characteristics of materials play a key role in the risk–benefit ratio for various types of surgery. Pore size in surgical mesh is one of the most important factors

in determining risk of postoperative infection. In addition, chemical coatings of materials can markedly influence the risk of complications. For example, silicone-coated synthetic mesh was used in sacral colpopexy with an unacceptably high rate of erosion, 24% (62), even after high erosion rates were reported in slings of similar material (63). It should be noted that some synthetic materials when used in abdominal surgery, such as abdominal sacral colpopexy, have a low rate of complications such as erosion, compared with their use in vaginal surgery, where the complication rate may be higher.

Following the success of the new generation of midurethral slings (in which synthetic material, mounted on trocars, was put in place through tiny incisions with minimal dissection), several new products have been introduced to augment or replace traditional prolapse procedures. Analogous to abdominal sacral colpopexy in which synthetic material is used to bypass native supports, products designed for use in treating apical prolapse are intended to replace deficient apical support with synthetic or biologic material.

In 2001, investigators reported 75 cases of infracoccygeal sacropexy (also known as posterior intravaginal slingplasty), a technique that initially used nylon mesh inserted via the ischiorectal fossa into the posterior vaginal fornices, to treat vaginal vault prolapse (64). Despite encouraging initial results reported by the inventor, subsequent case series review has shown high rates of recurrent prolapse (65) and mesh complications (66) even after the material was changed to polypropylene.

Other devices for the placement of mesh to provide apical support have been developed and are currently being marketed in the United States. Long-term data are insufficient to make recommendations concerning these products.

Other products have been introduced for use with repair of anterior and posterior vaginal prolapse. Biologic graft material (xenograft or allograft) or synthetic material (absorbable or permanent) can be used in place of or in addition to traditional colporrhaphy (67). However, as with apical support materials, data are insufficient to determine risks or benefits. In one study of 312 patients undergoing vaginal surgery for prolapse repair, 98 (31.4%) with graft use did not have better prolapse outcomes than those without graft use, but complications (such as vaginal or graft infection) occurred much more frequently (68). A high rate of early failures has been reported after vaginal prolapse repair with porcine xenograft (69, 70). Although several studies have evaluated anterior colporrhaphy with and without mesh or graft materials of different types (71–79),

because of heterogeneity of material studied, small sample sizes, and short-term follow-up, it is not possible to draw definitive conclusions about the risk versus the benefit of absorbable or permanent synthetic materials in anterior colporrhaphy.

Given the limited data and frequent changes in the marketed products (particularly with regard to type of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion), the procedures should be considered **experimental** and patients should consent to surgery with that understanding.

► ***Can the occurrence of stress urinary incontinence after surgery for pelvic organ prolapse be anticipated and avoided?***

Many women with advanced prolapse, particularly prolapse involving the anterior vagina, will not have symptoms of stress urinary incontinence, either because the urethral sphincteric mechanism is in fact competent or because the advanced prolapse kinks the urethra, causing obstruction. Some of these stress-continent women will become stress incontinent after prolapse surgery. Subjectively stress-continent women with positive reduction stress test results (prolapse reduced) more frequently have stress urinary incontinence after prolapse repair if no antiincontinence procedure is performed; in small case series review, this ranges widely, from 8% to 60%. Until recently, clinicians were faced with a dilemma in trying to balance potential risks of an antiincontinence procedure without strong evidence of benefit. However, randomized trial evidence is now available to guide management decisions for apparently stress-continent women with prolapse.

In two randomized trials of women undergoing prolapse repair, postoperative stress incontinence was reduced significantly by the inclusion of an antiincontinence procedure. Improvement in stress incontinence was obtained without a concomitant worsening of voiding symptoms or impaired bladder emptying. In one trial of 50 women with a positive stress test result with prolapse reduction, tension-free vaginal tape (TVT) or suburethral plication was added to vaginal prolapse repair (80). With median follow-up of approximately 2 years, the TVT group had less stress incontinence, both subjectively (96% versus 64%) and objectively (92% versus 56%). For women with positive prolapse reduction stress test results who are planning vaginal prolapse repair, the TVT midurethral sling (rather than suburethral fascial plication) appears to offer better prevention from postoperative stress incontinence.

In the second trial, the Colpopexy and Urinary Reduction Efforts (CARE) trial, 322 women were randomly assigned to undergo either the Burch procedure or no antiincontinence procedure at the time of abdominal sacral colpopexy (81). Three months after surgery, fewer women in the Burch group (23.8%) had stress incontinence than in the no-Burch group (44.1%). In addition, among women with stress incontinence after surgery, fewer women in the Burch group were bothered (6.1%) by their symptoms, compared with 24.5% of women in the no-Burch group.

Although long-term data are not yet available, it seems evident that subjectively stress-continent women with positive stress test results (with prolapse reduced) benefit from the addition of an antiincontinence procedure at the time of prolapse repair. In making recommendations to women planning prolapse repair, clinicians should discuss the potential risks and benefits of adding an antiincontinence procedure, keeping in mind that prophylaxis against postoperative stress incontinence is not perfectly effective (just as antiincontinence procedures used for treatment are not perfectly effective). Even when antiincontinence procedures are performed, some women continue to have incontinence symptoms (both stress and urge) after surgery. Further study is needed to determine how to better prevent incontinence symptoms after prolapse repair, and whether more selective application of antiincontinence procedures will improve the risk–benefit ratio.

Women with negative stress test results despite prolapse reduction also may benefit from the addition of an antiincontinence procedure at the time of prolapse repair. In the CARE trial, women with negative stress test results (prolapse reduced) benefited from the addition of Burch colposuspension (20.8% with stress incontinence 3 months after surgery in the Burch group, compared with 38.2% in the no-Burch group). However, a smaller trial of women undergoing vaginal prolapse repair did not show a benefit from the addition of pubourethral ligament plication (82). Including only women with negative stress test results (prolapse reduced), 102 patients were randomly assigned to receive vaginal prolapse repair with or without pubourethral ligament plication. After 1 year, the proportion of women with stress incontinence was the same in both groups (8%). Until further data become available, clinicians should discuss with women the potential advantages and disadvantages of adding an antiincontinence procedure to prolapse repair when results of preoperative prolapse reduction stress testing are negative.

Summary of Recommendations and Conclusions

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- ▶ The only symptom specific to prolapse is the awareness of a vaginal bulge or protrusion. For all other pelvic symptoms, resolution with prolapse treatment cannot be assumed.
- ▶ Pessaries can be fitted in most women with prolapse, regardless of prolapse stage or site of predominant prolapse.
- ▶ Cadaveric fascia should not be used as graft material for abdominal sacral colpopexy because of a substantially higher risk of recurrent prolapse than with synthetic mesh.
- ▶ Stress-continent women with positive stress test results (prolapse reduced) are at higher risk for developing postoperative stress incontinence after prolapse repair alone compared with women with negative stress test results (prolapse reduced).
- ▶ For stress-continent women planning abdominal sacral colpopexy, regardless of the results of preoperative stress testing, the addition of the Burch procedure substantially reduces the likelihood of postoperative stress incontinence without increasing urgency symptoms or obstructed voiding.
- ▶ For women with positive prolapse reduction stress test results who are planning vaginal prolapse repair, TVT midurethral sling (rather than suburethral fascial plication) appears to offer better prevention from postoperative stress incontinence.

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- ▶ Clinicians should discuss the option of pessary use with all women who have prolapse that warrants treatment based on symptoms. In particular, pessary use should be considered before surgical intervention in women with symptomatic prolapse.
- ▶ Alternative operations for uterine preservation in women with prolapse include uterosacral or sacrospinous ligament fixation by the vaginal approach, or sacral hysteropexy by the abdominal approach.

- ▶ Hysteropexy should not be performed by using the ventral abdominal wall for support because of the high risk for recurrent prolapse, particularly enterocele.
- ▶ Round ligament suspension is not effective in treating uterine or vaginal prolapse.
- ▶ Compared with vaginal sacrospinous ligament fixation, abdominal sacral colpopexy has less apical failure and less postoperative dyspareunia and stress incontinence, but is also associated with more complications.
- ▶ Transvaginal posterior colporrhaphy is recommended over transanal repair for posterior vaginal prolapse.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- ▶ Clinicians should discuss with women the potential risks and benefits in performing a prophylactic anti-incontinence procedure at the time of prolapse repair.
- ▶ Women with prolapse who are asymptomatic or mildly symptomatic can be observed at regular intervals, unless new bothersome symptoms develop.
- ▶ For women who are at high risk for complications with reconstructive procedures and who no longer desire vaginal intercourse, colpocleisis can be offered.
- ▶ Cystoscopy should be performed intraoperatively to assess for bladder or ureteral damage after all prolapse or incontinence procedures during which the bladder or ureters may be at risk of injury.

Proposed Performance Measure

The percentage of women with diagnosed symptomatic pelvic organ prolapse who are offered pessary use as first-line treatment

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and August 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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The American College of Obstetricians and Gynecologists
409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920
 12345/10987

Pelvic organ prolapse. ACOG Practice Bulletin No. 79. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007; 109:461–73.

EXHIBIT H

Methods: A retrospective chart review of patients undergoing treatment of pelvic organ prolapse with placement of the Perigee and Apogee system from January 2005 to July 2007. The data analyzed outcomes and complications.

Results: A total of forty-one patients with a mean age of 61 (41-79) underwent the procedure. Twenty-two patients had placement of Perigee with Apogee repair, eighteen had Perigee alone, and one patient has Apogee performed. Follow-up ranged from 1 month to 15 months (mean = 5). The presenting symptoms were stress urinary incontinence (SUI) 34(83%), urge urinary incontinence (UII) 4(10%), and mixed urinary incontinence (MUI) 3(7%). Four patients (10%) had intraoperative bladder perforations from passage of the trocar and were treated with primary repair and extended foley catheter placement. Four patients (10%) experienced urinary retention immediately following the procedure requiring clean intermittent catheterization. Denovo detrusor instability at two weeks follow-up was seen in eight patients (20%) all were treated with anticholinergics. Dyspareunia was noted in three patients (7%) post-operatively. Pudendal neuropathy, was seen in three patients (7%) at 2 months follow-up, however at 9 months only one patient had occasional symptoms of pudendal neuropathy with the other two cases completely resolving. Two patients required excision of mesh, one patient had exposed mesh, the second patient had pain due to an Apogee web causing dyspareunia and postcoital bleeding. Symptoms resolved in both patients after excision. Two patients had interstim sacral nerve stimulators placed for severe frequency and urgency.

Conclusion: The use of the Perigee and Apogee systems for anterior and posterior repair is a safe, minimally invasive technique and is well tolerated. Detrusor instability, pudendal neuropathy, and dyspareunia were the most frequent post-operative complaints. Long-term results are needed to assess durability and efficacy, but initial findings are promising.

Disclosures: J.A. Califano, None; G. Slobodov, None; D.J. Culklin, None.

Presentation Number: Poster 24

Two Year Anatomical Outcome after Pelvic Organ Prolapse Repair with Prolift Transvaginal Mesh

E. Kulwa, B. Hines, and A. Yitzhack *Stamford Hospital, Stamford, CT*

Category: Vaginal Prolapse Repairs with Grafts.

Objective: To investigate long term (two year) anatomical outcomes after pelvic organ prolapse repair with prolift.

Methods: A retrospective chart review of 50 patients who underwent Prolift for repair of anterior and posterior compartments pelvic organ prolapse at one institution between May 2005 and April 2006 with 2 years of follow up was done. Pre- op and post-op POP Q scores were obtained for each patient at 6 week, 6 month, 1 year and 2 year follow up periods. The Pre op and 2 yr post-op POPQ scores were analyzed. Wilcoxon matched pairs signed rank test was used to compare the pre and 2 year post-op POP Q scores at points Aa, Ba, C, Ap, Bp and D.

Results: Prolift use was associated with statistically significant improvement in POP Q scores 2 years post-op at points Aa, Ba, Ap and Bp (Wilcoxon matched pair signed rank test p value <0.05). There was no difference in pre and post op POP Q scores at 2 year follow up at points C and D (Wilcoxon matched pair signed rank test p value > 0.05).

Conclusions: Prolift leads to good control of anterior and posterior prolapse in the long term but does not seem to have any effect on apical or uterine prolapse in the long term.

Disclosures: E. Kulwa, None; B. Hines, None; A. Yitzhack, None.

Presentation Number: Poster 25

Bilateral, Graft-Augmented Sacrospinous Hysteropexy: 1-Year Anatomical and Functional Outcomes Following Surgery for Uterine Preservation

T. L. Gamble,* S. O. Aschkenazi,* A. Nguyen,* Y. A. Liu,† J. Beaumont,‡ S. M. Botros,* P. K. Sand,* and R. P. Goldberg* **Evanston Northwestern Healthcare/Northwestern University Feinberg School of Medicine, Evanston, IL, †Northwestern University, Evanston, IL, ‡Center for Outcomes Research and Education/ Evanston Northwestern Healthcare, Evanston, IL*

Category: Vaginal Prolapse Repairs with Grafts.

Objective: To evaluate the 1 year anatomic and functional outcomes of a bilateral "anterior approach" sacrospinous hysteropexy with allograft-reinforcement for uterovaginal prolapse.

Methods: 39 consecutive women with Stage ≥ 2 uterine prolapse underwent a bilateral 'anterior approach' sacrospinous hysteropexy with acellular dermal graft reinforcement to the anterior and apical compartments. Subjects self-selected uterine preservation as an alternative to vaginal hysterectomy. Surgical technique: Through a vertical anterior vaginal incision, and limited dissection within the paravaginal space, the ischial spine and sacrospinous ligament were identified by palpation. Single permanent 00 Gore Tex sutures were placed 1.5 cm medial to the ischial spines on both the right and left sacrospinous ligament (SSL), using a push and catch suturing device (Capio, Boston Scientific Corporation, Marlborough MA). Each SSL suture was secured to an acellular allograft (4-5 cm \times 7-10 cm) sized to patients' dimensions. 'Arcus to arcus' paravaginal support and reinforcement of the anterior colporrhaphy was obtained by securing the graft at three levels along the arcus tendineus fascia pelvis. These sutures were then secured to a fixation point on the ipsilateral vaginal apex located 1 cm lateral to the cervix on both sides. Once tied, these SSL sutures establish apical fixation of the graft and both vaginal apices. Anterior and posterior colporrhaphy repairs were performed in the usual fashion. Changes in pre- and post-operative POPQ staging were assessed using McNemar's test. Paired t-tests were used to compare pre and post surgery PFDI and PISQ.

Results: Mean age was 57(range) years (36-78), BMI 27 (18-39), and mean parity 3.0 (1-8). Mean operative time and estimated blood loss were 146 minutes and 203 ml (range: 75-400) respectively. All 39 women had anterior colporrhaphy, 97% had posterior repair and 85% had concurrent midurethral slings. Mean interval of 13.8 (5-25) months was obtained in 33/39 (83%) of subjects. No erosions or significant complications were observed. POPQ staging was improved for all compartments ($p < 0.05$): Aa -3.1, Ba -3.1, C -4.1, Ap -1.8, Bp -1.7, D -3.0. The risk of recurrent uterine prolapse as defined as Baden-Walker stage 3-4 after one year was: uterine prolapse 2.6%, cystocele 4% and, rectocele 4.3%. Post-operative mean total PFDI scores were significantly improved (25.9 vs. 77.1, $p = 0.043$). Dyspareunia as measured by Likert scale {21% vs. 22% ($p = 0.706$)} and mean total PISQ scores {27.9 vs 29.1 ($p = 0.732$)} were not statistically different before and after surgery.

Conclusion: Bilateral sacrospinous hysteropexy with anterior graft-augmentation provides effective support and improved self-reported QOL without adverse effects on female sexual function at one year among women who desire uterine preservation.

Disclosures: T.L. Gamble, None; S.O. Aschkenazi, None; A. Nguyen, None; Y.A. Liu, None; J. Beaumont, None; S.M. Botros, None; P.K. Sand, Watson Pharmaceuticals, Inc; Indevus; Ortho-McNeil; Allergan, Grant/Research Support; Watson Pharmaceuticals, Inc; Indevus; Ortho-McNeil; Allergan, Consultant; Indevus; Ortho-McNeil; Speaker's Bureau; R.P. Goldberg, Boston Scientific, Consultant.

EXHIBIT I



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November 28, 2008

Ema Kulwa, M.D.
OB/GYN Department
Stamford Hospital
Stamford, Connecticut 06904

Re: Research Project: Efficacy and safety of prolift prolapse repair system in patients operated on in the year 2005 with a three year follow up.

Dear Dr. Kulwa:

The Institutional Review Board of the Stamford Hospital met on November 21, 2008, to review your letter dated October 31, 2008, along with a revised protocol dated November 3, 2008, asking for expansion of the original study plan.

After discussion about how this revision would change the study, including proposed telephone calls to patients, the IRB feels that such changes constitute a new study. The IRB requests that you submit this as a new protocol. Please note that this study will expire on February 28, 2009.

Thank you.

Sincerely,

Michael F. Parry, M.D., Chairman
Institutional Review Board

MFP:jo

cc Lance Bruck, M.D.

CONFIDENTIAL

RECEIVED
TSH IRB
STAMFORD, CT
11-4-08 DR

Stamford Hospital IRB
30 Shelburne Rd
Stamford, CT, 06901
10/31/2008

Ema Kulwa, MD, MPH
30 Shelburne Rd
Stamford, CT, 06901

Dear Sir/Madam

REF: Research project: Efficacy and safety of prolift prolapse repair system in patients operated on in the year 2005 with a three year follow up.

I would like to reopen the project "Efficacy and Safety of prolift prolapse repair system in patients operated on in the year 2005 with a two year follow up" with a continuation of the study extending to a three year follow up. As previously detailed in the closure letter, this was a retrospective chart review of patients who underwent ant/post Prolift prolapse repair (with/out concomitant SUI incontinence procedures) between May 2005 and May 2006 at Stamford hospital with 2 year follow up. Demographic data, complications and Pelvic Organ Prolapse Quantification (POP-Q) values at preoperative and postop periods (2 wk, 6 wk, 6 months, 1 year and 2 year post-op) were obtained. Mean POP Q scores and Wilcoxon signed matched pairs tests were used for comparison of pre- and post operative POP-Q data. The results showed that in patients who underwent anterior repair, the mean preop Ap and Bp were both 1, while post op the mean values were -3, -3 and -3 at 6 months, 1 yr and 2 yrs respectively. For patients who underwent posterior repair the mean preop C was -3.8, an -6, -4.5 and -2 at 6 months, 1 year and 2 years postoperatively. In patients who underwent anterior and posterior prolapse repair the mean preop Aa, Ba, Ap an Bp was 1, while it was -2.5, -3 and -3 at 6 months, 1 year and 2 years postoperatively respectively. After anterior repair, the 1 yr post op Aa and Ba was significantly different from preop Aa and Ba values (Wilcoxon mached pairs signed rank test $p < 0.01$) but not in 2 yrs ($p < 0.1$). After posterior repair, the post op Ap and Bp in 1 year were significantly different from the preop values ($p < 0.01$) but not statistically different in 2 yrs ($p < 0.01$). Prolift is associated with a low risk of complication: 4% rate of febrile morbidity, 6.1% UTI, 2% hematoma, 2% perineal laceration, 2% vaginal scar tissue formation and 4% mesh erosion. The conclusions of the study was that Prolift has excellent anatomical outcomes in 1 yr but not in 2 yrs in our study. The second conclusion was that Prolift was associated with low complication rates.

A major problem in this study was the poor follow up of patients with less than 10 patients available for analysis available at the 2 year follow up. In order to improve patient follow up in the study, I will make telephone calls to patients who have not yet presented for their third year follow up and ask them to present for follow up and physical exam at Dr. Hines office. Letters requesting follow up with Dr. Hines will be mailed out to patients who are unreachable by telephone. The patients will be examined by Dr. Hines at the office and POP-Q value assigned from the physical exams.

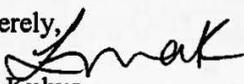
As in the parent study, the information that I will mainly extract from the charts will be the 3 year post-op stage of prolapse, intraop and post op complications such as damage to surrounding organs such as bladder and rectum, excessive blood loss and UTI. I will also look at the anatomical cure rate, rate of prolapse recurrence, rate of pre and post op dyspareunia. I will also assess how many patients who had recurrence of prolapse underwent repeat surgery. These patients are usually followed up at 2 weeks, 6 weeks, 6 month, 1 year and subsequently continued annual visits. This new study will therefore show longer post op follow up (3 years), have a larger number of participants and also have the advantage of having been done in one center under one main surgeon. These results will be presented during the Ob-GYN department Schiffer Day in May 2009 and subsequently to OB/GYN journals for publication.

This is an important area to investigate as the use of transvaginal polypropylene mesh for prolapse repair is relatively new and has not been extensively studied. Transvaginal polypropylene mesh prolapse repair developed partly due to dissatisfaction with the traditional methods of repair such as anterior and posterior colporrhaphy, abdominal sacrocolpopexy and uterosacral ligament fixation. These traditional methods have been associated with a high rate of prolapse recurrence.

There have been no rigorous controlled trials comparing the transvaginal mesh kits with the traditional methods. Most of the studies done have been retrospective chart reviews or prospective non-randomized studies. For example, de Tayrac et al (2007) conducted a prospective multicenter study that looked at 1 year functional and anatomical outcome in patients who underwent prolapse repair with polypropylene mesh. The anatomic success rate ranged from 75-100%, but there was also a high rate of mesh erosion (13%) and post op dyspareunia (de Tayrac et al, 2007). This study involved 230 women from 13 centers.

Below, please see the protocol that I will use for the current study that is very similar to the parent protocol. Please let me know if there is any more information needed.

Thank you,

Sincerely,
 · Beeper #350
Ema Kulwa .

Reference:

De Tayrac R, Devoldere G, Renaudie J, Villard P, Guilhaud O, Eglin G. Prolapse repair by vaginal route using a new protected low-weight polypropylene mesh: 1-year functional and anatomical outcome in a prospective multicentre study. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:251-256.

Protocol:

For this research project I will look at the medical record charts for the year 2005 of all the patients that Dr. Hines operated on. These records are available on HPF and also in the charts in Dr. Hines' private office. A list of patients that Dr. Hines operated on in 2005 will be obtained from his billing company and from medical records. The reason I will be using a list from the billing company is that they have a complete list of all the patients that Dr. Hines operated on. Getting a list of patients from medical records was the other option but I am convinced that the yield from this approach would be suboptimal secondary to inconsistent diagnosis and procedures coding.

I will then identify the cases that specifically involved repair of anterior or posterior prolapse using Prolift polypropylene mesh. I will collect data on the patients from the pre-op History and physical and then the progress notes written at the 2 week, 6 week, 6 month, 1 year, 2 year and 3 year follow up periods. Information that I will mainly focus on are the pre and post op stage of prolapse, intraop and post op complications such as damage to surrounding organs such as bladder and rectum, excessive blood loss and UTI. I will also look at the anatomical cure rate, rate of prolapse recurrence, rate of pre and post op dyspareunia. Below, please see a list of the other variables that I will be using below. I will also assess how many patients who had recurrence of prolapse underwent repeat surgery. Statistical analysis that I will use include the chi-squares and Fisher's exact test for categorical variables and t tests for continuous variables. These results will then be presented at the OB-GYN Schiffer Research day in 2009 and then submitted to journals for publication.

Other variables that I will use in data collection are:

Age

Parity

Preop diagnosis

Prior prolapsed/incontinence surgery

Procedure done

Operation time

Number of days in the hospital

Pre-op POP Q score

Post-op POP Q scores at 6 weeks, 6 months, 1 year and 2 years.

Preop complaints such as urge, stress incontinence, constipation, anal incontinence, urgency.

Post op complaints based on the above preop complaints

Preop urodynamics

Post op urodynamics

Preop dyspareunia, sexual activity (are they sexually active/ effect of prolapsed on activity?)

Postop dyspareunia, sexual activity (are they sexually active/ effect of prolapsed on activity?)

Intra op complications

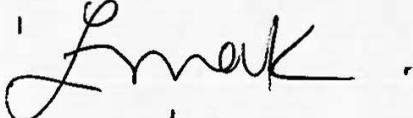
Post op complications

Recurrence of symptoms

Need for reoperation

Patient satisfaction/dissatisfaction with the procedure

Ema Kulwa


11/03/2008

Stamford Hospital IRB Continuing DB/Chart Review Request

Study ID: _____



Affiliate Columbia University College of Physicians & Surgeons
Member New York Presbyterian Healthcare System
A Planetree Hospital

Date of Initial IRB Approval:	
Date of Last Approval:	
Date of Expiration:	

Protocol #: _____

Principal Investigator (please complete all items)

Name:	Ena Kulwa
E-mail (required):	ekulwa@stamhealth.org

Research Project Title

Efficacy and Safety of Prolift Prolapse Repair System in Patients Operated on in 2005 with three year follow up.

Status of Chart or Database Review Research

<input type="checkbox"/>	Request or search for records not initiated/ Data collection NOT started
<input type="checkbox"/>	Initial data from db, registry, medical records, or charts made but no review has begun
<input checked="" type="checkbox"/>	Data collection ongoing
<input type="checkbox"/>	Data collection completed and in analysis

Changes in Study Plan

Any change to project?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes → changes must be submitted to IRB
Any change to data being collected?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes → changes must be submitted to IRB
Has the time period of data collection changed? (ex.- records from 1/1/01 - 12/31/02)	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes → changes must be submitted to IRB <i>01/1/05 → 10/31/2008</i>

Persons accessing/reviewing/collecting data (please list new) No Change

1. Name: Ena Kulwa	Phone: 646-251-6857
GCP Training: Y/N: YES Year: 2006 Program Name: CITI	
2. Name:	Phone:
GCP Training: Y/N: NO Year: Program Name:	

Stamford Hospital IRB Continuing DB/Chart Review Request

Study ID: _____

Research Coordinator (please complete all items)

Is there a research coordinator? <input type="checkbox"/> Yes, complete below <input checked="" type="checkbox"/> No	
Name:	
E-mail (required):	

Activity Summary for Chart or Database Review

	This Reporting Period	Total Since IRB Approval
# Records Identified	49	49
# Records Reviewed	49	49

Unanticipated Problems (UAP's) (not previously reported) None

UAP's are those events that involve risks to subjects or others (such as confidentiality).

Reports that occurred during this reporting period or not previously reported:

Date	Event

New Information (please attach as needed) None

<input type="checkbox"/>	Manuscript or publication
<input type="checkbox"/>	Revised Protocol (version date: __/__/__)
<input type="checkbox"/>	Revised Data Collection Tool (version date: __/__/__)

Risk benefit assessment

Are there any changes or new information that might change the risk/benefit assessment from last IRB review?

No
 Yes

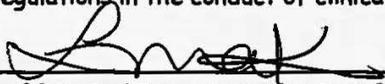
(please summarize below)

Comments / Supplemental Information None

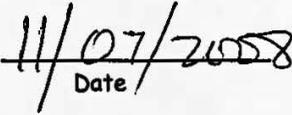
Stamford Hospital IRB Continuing DB/Chart Review Request

Study ID: _____

I certify that the information provided in this application is complete and accurate. I understand that as the Principal Investigator I have the ultimate responsibility for the protection of the rights and welfare of human subjects, and the strict adherence to any study specific requirements imposed by the approving IRB. I agree to comply with all IRB and Institutional policies and procedures, as well as all applicable federal, state, and local laws and regulations in the conduct of clinical research.



Signature of Principal Investigator at Stamford Hospital



Date

IRB / Privacy Board Continuing Review Approval - For IRB Use Only

Continuing approval for the above research activity has been granted by the Stamford Hospital IRB for the following time period: to .

Signature of IRB Chair (or Authorized Agent)

Date

EXHIBIT J

In The Matter Of:
FARRELL v.
JOHNSON & JOHNSON, ET AL

MICHELLE IRVIN
October 21, 2015

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1 SUPERIOR COURT: CLD
 2 J.D. OF WATERBURY
 3 AT WATERBURY
 4 D.N.: X06 UWY-CV-11-6014102-S
 5 -----x
 6 MARY BETH FARRELL, ET AL.,
 7 Plaintiff,
 8 vs.
 9 JOHNSON & JOHNSON, ET AL,
 10 Defendants.
 11 -----x
 12 DEPOSITION OF: MICHELLE IRVIN
 13 DATE TAKEN: OCTOBER 21, 2015
 14
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 16
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 18
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 21 COMPUTER-AIDED TRANSCRIPT PREPARED BY:
 22 FITZSIMMONS REPORTING & VIDEOCONFERENCE CENTER
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1 T R A N S C R I P T of the stenographic notes
 2 of the proceedings in the above-mentioned matter, as
 3 taken by and before GINA M. LAMM, a Certified Shorthand
 4 Reporter and Notary Public of the State of New Jersey,
 5 held at the Law Offices of RIKER, DANZIG, SCHERER,
 6 HYLAND & PERRETTI, LLP, Headquarters Plaza, One
 7 Speedwell Avenue, Morristown, New Jersey, on October
 8 21, 2015, commencing at approximately 10:30 in the
 9 a.m., pursuant to notice.
 10
 11 A P P E A R A N C E S:
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1 I N D E X

3 WITNESS	DIRECT	CROSS
4 MICHELLE IRVIN		
5 BY: MR. LEYDON	4	
6 BY: MR. ALLENTUCH		85
7 BY: MS. CILANO		93

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1 **MS. MAIMBOURG:** We have them. They
2 were part of the production today.
3 **BY MR. LEYDON:**
4 Q. Okay. And I was asking about
5 documents starting in 08256521, which is an email
6 from Michael Dill to C. Alvarez dated July 13th,
7 2012, and appears to have an attachment as well.
8 My first question is: Was 522 and 523, do those
9 go with that? Was that the attachment to 521?
10 **A. Yes, 523 would be what was pasted into the**
11 **email, and then 522 would be what was attached.**
12 Q. Okay. So, the box that's under
13 purchases as of February 1, is what's in 523?
14 **A. Correct. Yes.**
15 Q. And, so, Ethicon, we can see from
16 this, kept track of the use and sales of its
17 product at Stamford Hospital, correct?
18 **MR. ALLENTUCH:** Objection to form.
19 **A. Correct. We would know how much they**
20 **ordered and when they ordered the product.**
21 Q. And is that -- that's been something
22 that they've had in their system for some time.
23 So, monthly sales data, or however it's done,
24 quarterly, by Stamford Hospital of Prolift, would
25 be information available to Ethicon?

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1 **A. Correct. Prolift was a direct purchase**
2 **product only. So, as soon as the order was placed**
3 **with Ethicon it would be known within an hour that**
4 **they had placed the order.**
5 Q. And those records are maintained by
6 Ethicon?
7 **A. To my understanding, yes, we had a portal**
8 **that we could go to, to pull up the information of**
9 **when sales were done.**
10 Q. Now, when you say direct -- I'm
11 sorry, what did you say, direct, what was the
12 phrase you used there?
13 **A. It's a direct purchase. So, it cannot --**
14 **these products cannot be purchased through a**
15 **distributor. So, if a product is bought through a**
16 **distributor, we don't get the exact order date and**
17 **time necessarily. We are just given data by the**
18 **distributor, and it depends on the distributor of**
19 **what was purchased. So, since these were a direct**
20 **order, Johnson & Johnson Health Care Systems would**
21 **have an accurate representation of when it was**
22 **physically placed.**
23 Q. All right. Now, specifically with
24 regards to the Prolift, that could only be
25 purchased through a hospital, correct?

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1 **A. It could only be purchased through --**
2 **MR. ALLENTUCH:** Objection to form.
3 **A. -- a facility that was authorized, which**
4 **could include a hospital, potentially a surgery**
5 **center. So, it would be a health care facility**
6 **performing surgery.**
7 Q. A individual doctor with a regular
8 office would not be able to directly purchase
9 that, it would have to be either through a
10 hospital or an authorized surgery facility,
11 correct?
12 **A. Correct. Offices were not authorized to**
13 **purchase the Prolift procedure kits.**
14 Q. And why is that?
15 **A. The Prolift products were not an office**
16 **based procedure. They were procedures that were**
17 **performed in an operating room setting.**
18 Q. So then hospitals, by definition,
19 were part of the process any time Prolift would
20 have to be implanted?
21 **MR. ALLENTUCH:** Objection to form.
22 **A. Correct. The order would come through,**
23 **typically the purchasing department, through our**
24 **company.**
25 Q. This is an email, and then the power

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1 point that goes with it.
2 **A. Are we done with this?**
3 Q. Yes. That was her's.
4 **MS. MAIMBOURG:** I don't see
5 Dr. Hines's name on here. Oh, there he is. Did
6 you identify the document numbers already?
7 **MR. LEYDON:** I did not, no.
8 **MS. MAIMBOURG:** 1152074243 and 44.
9 So, I have 143. Then the other document he handed
10 her was a power point. It's native tissue.
11 Format 11520747, is the cover page and it looks
12 like this.
13 Q. So, I guess the first question I
14 just want to verify is --
15 **MS. CILANO:** I'm sorry, please give
16 me a minute. I don't have a 243. I have a 242.
17 **MS. MAIMBOURG:** You want to see 243?
18 **MS. CILANO:** Please.
19 **MS. MAIMBOURG:** How about, do you
20 have 44?
21 **MS. CILANO:** 20743. Okay.
22 **BY MR. LEYDON:**
23 Q. So, my first question is: That
24 power point is the one that goes with that email,
25 correct?

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1 **MS. CILANO:** Objection.
2 **A. So, it says at the bottom, attached is**
3 **some complication data for Prolift, looks like**
4 **Jeff Potcol mentions malpractice consulting, but I**
5 **don't see anything from Dr. Hines specifying what**
6 **it is. So, I would go off what Jeff put, but that**
7 **would be an assumption.**
8 Q. In any case, this was clearly sent
9 to Dr. Hines.
10 **A. Correct. Yup. He received it.**
11 Q. And he wrote back "thanks" in reply
12 to that, in the middle?
13 **A. Correct. Yup. Yup. So, he is confirming**
14 **that he received it.**
15 Q. And these complaint reporting
16 statements, are those things that you had seen
17 before this?
18 **A. I had seen these documents in review**
19 **yesterday. I can't confirm, when I was a sales**
20 **representative this is something I specifically**
21 **seen, but I did review it yesterday.**
22 Q. You think it's likely you might have
23 seen something like this and don't recall, or do
24 you have any recollection whatsoever?
25 **A. I know that in our training decks we would**

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1 **use in Prolift training, we would cover**
2 **complications. I don't know if I specifically saw**
3 **this format, and I'm not quite sure exactly where**
4 **all this information came from.**
5 Q. When you say "all this information"
6 you mean the data that's set forth in the charts
7 on those?
8 **A. Correct. Yeah. I can't conclude, based**
9 **on the notes at the bottom, whether, you know,**
10 **where this was pulled from, what studies, data**
11 **base, it's not clear, but it is a culmination of**
12 **complaints that is on our letterhead.**
13 Q. So, in any case, it's a document
14 produced and prepared by Ethicon, correct?
15 **A. Yes. I would agree to that. I do not see**
16 **a copy approval number. I don't know if this is**
17 **the whole document, but it looks like something**
18 **that was put together by Ethicon.**
19 Q. And turning to 58.
20 **A. Okay.**
21 Q. Which is the complications through
22 third quarter 2006, do you see that?
23 **A. Correct. Yup.**
24 Q. And it says, most significant
25 reported complications. And then there is a cross

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1 symbol. It says, per MBR reporting requirement,
2 and cites federal regulation, do you see that?
3 **A. Correct.**
4 Q. So, these are setting forth the
5 complications that are required to be reported
6 under that federal regulation, correct?
7 **MS. MAIMBOURG:** Objection.
8 **A. I don't know what all that means MVR, CFR,**
9 **I'm not privy to that legal terminology, but it is**
10 **some sort of reporting requirement, but I don't**
11 **know what that means.**
12 Q. In any case, it lists the
13 complications that were deemed most significant to
14 be reported, correct?
15 **A. Correct.**
16 **MS. MAIMBOURG:** Objection.
17 Q. And likewise, 59 takes it through
18 the 4th quarter of 2006, and at that point notes
19 that the 63,000 procedures with the university
20 this was drawn from, correct?
21 **A. Correct. Yup. Seems like the same data**
22 **base but just extending it three more months.**
23 Q. And, again, listing most significant
24 complications that ought to be reported with
25 regards to the Prolift?

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1 **A. Correct. As the document says, most**
2 **significantly reported.**
3 Q. To your knowledge, did Dr. Hines
4 himself ever report a complication to Ethicon?
5 **MR. ALLENTUCH:** Objection to form.
6 **A. I don't recall from the review of the**
7 **documents yesterday if there was any direct**
8 **communication from Dr. Hines to Ethicon about a**
9 **complication.**
10 Q. The expectation of Ethicon, if
11 they're giving these documents to people, would be
12 that doctors are reporting incidents such as
13 exposure, pain and dyspareunia.
14 **MS. CILANO:** Objection to form.
15 **MS. MAIMBOURG:** Objection to form.
16 **A. Correct. So, if a complication arises,**
17 **and it's brought to a sales representative's**
18 **attention, we immediately report it. Otherwise,**
19 **it is understood that if there is a complication**
20 **that a physician would report it.**
21 Q. And that's very important for
22 Ethicon in its feedback loop, to get that
23 information from its physicians, correct?
24 **MS. CILANO:** Objection to form.
25 **A. I would agree that it is important to know**

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1 if there are any complications that are occurring
2 with the product, which is why we, as a company,
3 take it very serious to obtain that information as
4 quickly as possible and to get as full of
5 information as we can when we find out that an
6 adverse event did occur.
7 Q. And you certainly wouldn't have
8 published things like this if there was a belief
9 that these types of injuries were being grossly
10 underreported, would Ethicon?
11 **MS. MAIMBOURG:** Objection. I have
12 no idea what that means.
13 **MS. CILANO:** Objection to form.
14 **MR. ALLENTUCH:** Objection.
15 **A. I can't make any statements around gross
16 underreporting as according to this document.
17 This just states what's in the MVR reporting.**
18 Q. Eighty-six through 89 is what I'm
19 asking about.
20 **A. Okay.**
21 **MS. MAIMBOURG:** 19301286 through
22 289.
23 **MR. LEYDON:** Is there another page
24 that goes with that?
25 **MS. MAIMBOURG:** What did you want

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1 her to look at, 286?
2 **BY MR. LEYDON:**
3 Q. My first question is going to be: Is
4 this a complete document?
5 **A. I think it goes to 285.**
6 Q. I think that's there any way. So,
7 why don't we start there.
8 **A. Yeah. So, it's going from 285 to 289.**
9 **MS. MAIMBOURG:** Okay, we're ready.
10 Q. The first, just to clarify, am I
11 correct that these go together, from 85 through
12 89?
13 **A. Yes, one is the request form to be a part
14 of patient builder, and the next one is the
15 agreement with regards to patient builder.**
16 Q. What is patient builder?
17 **A. I do not know. That's not something I had
18 experience with when I was a sales rep.**
19 Q. On 85 do you see that funds request
20 form?
21 **A. Yes.**
22 Q. Is that a document you're familiar
23 with?
24 **A. Again, we looked at one of these earlier.
25 I never did any co-op advertising, but I saw**

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1 several of these when we went through the
2 documents that were discovered.
3 Q. So, this related to cooperative
4 advertising with Dr. Hines. It also references
5 Stamford Hospital and the Gynecare Prolift,
6 correct?
7 **A. Correct.**
8 Q. And as we continue through to 89
9 there is a signature of 1/30/08, correct?
10 **A. Correct.**
11 Q. I am done with that one.
12 **A. Okay.**
13 **MS. MAIMBOURG:** One page document?
14 **MR. LEYDON:** Yes.
15 **MS. MAIMBOURG:** 19301284. It has a
16 fax date of February 8th, 2007.
17 Q. Have you seen that document before?
18 **A. Yes, this is one document I reviewed
19 yesterday.**
20 Q. And this relates to the actual
21 cooperative advertising we've been discussed, that
22 actually ran in the Stamford Advocate and the
23 Greenwich Times in various states in '07, is that
24 correct?
25 **MS. CILANO:** Objection to form.

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1 **MR. ALLENTUCH:** Objection to form.
2 **A. So, it looks -- it makes suggestions for
3 dates, and it identifies the Advocate and
4 Greenwich Times as being the publication where
5 they should be run.**
6 Q. And those were the types of
7 promotions we have been discussing that was going
8 on commonly at that time between Ethicon and
9 doctors and hospitals?
10 **MS. CILANO:** Objection to form.
11 **MR. ALLENTUCH:** Object to form.
12 **MS. MAIMBOURG:** Object to form.
13 **A. Yeah, I'm not comfortable with the term of
14 commonly. That's very vague. And you said
15 advertising. There are lots of different
16 components to that. So, this was one form of
17 co-op advertising that Ethicon would engage with
18 physicians in. That's what I would be comfortable
19 confirming.**
20 Q. Just the one page.
21 **A. Okay.**
22 **MS. MAIMBOURG:** So, it's 19869671.
23 At the top it says, "Physician education program
24 outline agreement". Looks like it was signed by
25 Brian Hines September 7th of 2010.

1 **A. Not to my knowledge.**
 2 Q. All right. You were not his sales
 3 representative, who, in any way, dealt with
 4 Dr. Hines, either through email or over the
 5 telephone, true?
 6 **A. True.**
 7 Q. You have no firsthand knowledge
 8 whatsoever of anything Dr. Hines may have said to
 9 anyone at Ethicon, correct?
 10 **A. True.**
 11 Q. Okay. And just so I'm clear, the
 12 documents that have been marked as exhibits here,
 13 do these documents comprise any and all
 14 correspondence or emails that would have been sent
 15 to Dr. Hines, correct?
 16 **MS. MAIMBOURG:** Well, I want to
 17 answer that question because she did not
 18 participate in the search. We did an extensive
 19 search of the global production using various
 20 search terms, and it is our belief that we
 21 identified all emails, either to or from
 22 Dr. Hines or his group with Ethicon.
 23 **MS. CILANO:** And all correspondence
 24 as well?
 25 **MS. MAIMBOURG:** Yes, we looked at

1 e-mails, word documents, spread sheets, we looked
 2 at different types of documents.
 3 **BY MR. CILANO:**
 4 Q. And do you have any reason to
 5 disagree with your counsel's representation that a
 6 search has been made for any and all communication
 7 between Ethicon and Dr. Hines?
 8 **A. I would not disagree with anything she**
 9 **said.**
 10 **MS. CILANO:** Okay. I don't have any
 11 other questions. Thank you.
 12 **THE REPORTER:** Mr. Allentuch, would
 13 you like a copy of the transcript?
 14 **MR. ALLENTUCH:** Yes, E-Tran, please.
 15 **MS. CILANO:** I would like a copy,
 16 E-Tran as well. Thank you.
 17 **MR. LEYDON:** I would like E-Tran and
 18 delivered by Monday. Thank you.
 19 **MS. MAIMBOURG:** E-Tran, please.
 20 (Deposition concluded.)
 21
 22
 23
 24
 25

1 C E R T I F I C A T E
 2
 3 I, GINA MARIE VERDEROSA-LAMM, a Certified
 4 Shorthand Reporter and Notary Public of the State of
 5 New Jersey, certify that the foregoing is a true and
 6 accurate transcript of the deposition of said
 7 witness(es) who were first duly sworn by me, on the
 8 date and place hereinbefore set forth.
 9 I FURTHER CERTIFY that I am neither attorney,
 10 nor counsel for, nor related to or employed by, any of
 11 the parties to the action in which this deposition was
 12 taken, and further that I am not a relative or employee
 13 of any attorney or counsel employed in this action, nor
 14 am I financially interested in this case.
 15

16
 17 GINA MARIE VERDEROSA-LAMM, C.S.R.
 18 LICENSE NO. XI2043
 19
 20
 21
 22
 23
 24
 25

EXHIBIT K

<p style="text-align: center;">A P P E A R A N C E S</p> <p>Page 2</p> <p>FOR THE PLAINTIFFS: TOOHER, WOCL & LEYDON, LLC 80 Fourth Street Stamford, Connecticut 06905 BY: JACQUELINE E. FUSCO, ESQUIRE</p> <p>FOR THE DEFENDANT, JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY, GYNECARE A DIVISION OF ETHICON, INC.: SHIPMAN & GOODWIN, LLP One Constitution Plaza Hartford, Connecticut 06103-1919 BY: CHRISTOPHER R. DRURY, ESQUIRE</p> <p>FOR THE DEFENDANT, STAMFORD HEALTH SYSTEM, INC. D/B/A STAMFORD HOSPITAL; UROGYNECOLOGY & PELVIC SURGERY, LLC: NEUBERT, PEPE & MONTEITH, PC 195 Church Street, 13th Floor New Haven, Connecticut 06510 BY: ERIC J. STOCKMAN, ESQUIRE</p> <p>FOR THE DEFENDANT, AMERICAN MEDICAL SYSTEMS, INC.: DISERIO, MARTIN, O'CONNOR & CASTIGLIONI, LLP One Atlantic Street Stamford, Connecticut 06901 BY: THOMAS P. O'DEA, JR., ESQUIRE -and- REED SMITH, LLP Three Logan Square 1717 Arch Street, Suite 3100 Philadelphia, Pennsylvania 19103 BY: MICHAEL SALIMBENE, ESQUIRE -via teleconference-</p>	<p style="text-align: center;">S T I P U L A T I O N S</p> <p style="text-align: right;">Page 4</p> <p>IT IS HEREBY STIPULATED AND AGREED by and between counsel for the parties that the proof of the official authority of the Notary Public before whom this deposition is taken is waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that the reading and signing of the deposition is not waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that notice of the time and place of the taking of the deposition is waived;</p> <p>IT IS FURTHER STIPULATED AND AGREED that all objections, except as to the form of the question, are reserved until the time of trial.</p> <p style="text-align: center;">* * *</p>
<p style="text-align: center;">A P P E A R A N C E S (Cont.d)</p> <p style="text-align: right;">Page 3</p> <p>SACHNER & O'CONNOR, LLC</p> <p>THE CROSSROADS WEST</p> <p>765 Straits Turnpike</p> <p>Building 2, Suite 2000</p> <p>Middlebury, Connecticut 06762</p> <p>BY: ILYSSA H. KELSON, ESQUIRE</p>	<p style="text-align: right;">Page 5</p> <p>1 (Plaintiff's Exhibits 1 through 2 3 marked for identification.) 3 THE COURT REPORTER: Are there any 4 stipulations for the record? 5 MR. STOCKMAN: We'd like to reserve the 6 right to read and sign. 7 MS. FUSCO: Usual stips? 8 MR. STOCKMAN: Other than that, usual 9 stips. 10 MR. DRURY: That includes objection by one 11 is objection for all? 12 MR. STOCKMAN: I don't know if that 13 includes that. 14 MS. FUSCO: It actually doesn't. 15 MR. DRURY: Right. I mean, that's what 16 we've done in the past, right, can we agree? 17 MR. STOCKMAN: That's fine. That's good 18 with me. Just means I get more objections. 19 R U T H C A R D I E L L O, 20 30 Shelburne Road, Stamford, Connecticut, 21 called as a witness, after having been duly sworn, was 22 examined and testified as follows: 23 DIRECT EXAMINATION 24 BY MS. FUSCO: 25 Q Good morning, Ms. Cardiello. My name is</p>

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1 A -- from 2012 to current. When we
2 transitioned that -- because I oversaw the
3 department during this transition -- we chose not to
4 try to integrate Peminic and QASYS. It was too
5 difficult to integrate all the data points in there.
6 So we put this information on the server. I don't
7 know how long -- how many years of data resides on
8 the server for Peminic.
9 Q Okay. So, in my limited technology, you
10 would have on your server a file for QASYS and a
11 file for Peminic?
12 A Yeah.
13 Q Okay.
14 A Essentially, Peminic is a static file.
15 Q Okay.
16 A It's an electronic storage file. We took
17 all the data, and said, okay, we're going to leave
18 it there in case it's ever needed.
19 Q Okay.
20 A And then QASYS is an online active, for
21 lack of a better word, database that's added to on a
22 daily basis.
23 Q So you could access QASYS for, I think,
24 2012 to the present --
25 A Uh-huh.

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1 Q -- for occurrences?
2 A Correct.
3 Q Okay. And that's something you could
4 easily do?
5 A Yes.
6 Q Okay. For medical devices?
7 A Yes.
8 Q Okay. Would it be easy to sort for mesh
9 devices?
10 A No, because I think the category would
11 probably be equipment related. So you don't have
12 it -- so if you think about any typical database you
13 have certain high level categories. So we'd have --
14 one of them would be type of event. So it might be
15 equipment related. But in the narrative text that
16 the staff might be completing, or a physician, it
17 would be -- if there's a -- the actual product would
18 be, more likely than not, in the narrative. There
19 isn't a "click and point" that you can say it's this
20 device, this device, this device.
21 Q But could you search QASYS for a
22 particular product and get all the reports related
23 to a particular product?
24 A We could search for -- by the type of
25 event, not by a product.

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1 Q Okay. And the category event?
2 A Would be equipment related.
3 Q Not surgery related?
4 A It could be.
5 Q Okay.
6 A I mean, you'd have to define your search
7 terms. It could be.
8 Q So did you educate the staff in any
9 particular way related to medical devices, how they
10 would report it?
11 A We educated them broadly on what needed to
12 be reported and how to report.
13 Q Okay. So you didn't say, hey, if we have
14 a medical device, you need to categorize it as this?
15 A We didn't go into that much detail, no.
16 Q Okay. So it was basically up to the
17 employee to characterize it based on what they
18 thought the problem might be?
19 A Yes.
20 Q Okay. And the same for the physicians?
21 A Yes.
22 Q Okay. Do you know if, in the QASYS
23 system, there are -- well, first of all, do you
24 monitor the QASYS -- well, you said you do monitor
25 it, correct? Or you get those reports?

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1 A We get -- when a report is submitted, we
2 get electronic copies. So it goes to the director
3 of the department that's involved --
4 Q Okay.
5 A -- or selected as the involved department,
6 and then it goes -- copies are sent to my team, and
7 myself as well.
8 Q Okay. The director of the department.
9 Does the director have a role in educating the
10 physicians in his department about adverse events?
11 A You mean as a physician chair?
12 Q As the director.
13 A I think they have a --
14 Q Now, the --
15 A Go ahead.
16 Q No. I was just going to say, the
17 director, not the chair, because I think you just
18 said "chair." Are we talking about two different
19 positions here?
20 A Well, there's -- there's directors who
21 are -- could be clinical staff. So there's nursing
22 directors, there's directors in facilities, and
23 materials management. There are division directors
24 in some of the medical departments, such as surgery.
25 And there are chairs. And I think we have eight

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1 chairs of the medical departments.
2 Q Okay.
3 A These are physicians. So, depending on
4 the department, they may not have physician division
5 directors, they may just have a chair.
6 Q Okay.
7 A Or they may have division directors who --
8 that would be responsible, as well, to educate.
9 But, again, if they had a question, those chairs
10 would also come to us in the department.
11 Q Okay. So let's talk about the chair of
12 the OB/GYN department. Is it correct that
13 urogynecology comes under the chair of the OB/GYN
14 department?
15 A Urogynecology, yes, they would.
16 Q Yes. So you work with the chair of the
17 OB/GYN department to educate the staff in OB/GYN
18 related to medical devices and what adverse events
19 would be reportable?
20 A No.
21 Q Does anybody educate them?
22 A Again, going back to those categories that
23 we talked about before, new employee orientation,
24 annual training would be our role.
25 Q Okay.

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1 A So we don't individually work with our
2 chairs or individually train departments.
3 Q So you don't train departments for devices
4 that are specific for that department?
5 A No.
6 Q It's more of a broad general training?
7 A Correct.
8 Q Okay. So do you know if, in your QASYS
9 reporting -- so it's 2012 to 2015 -- if any adverse
10 events have been reported related to the pelvic mesh
11 products?
12 A Well, in response to the litigation, we
13 reviewed that, and there are none.
14 Q There are none. Okay. Have you reviewed
15 cases to see if there were actually reportable
16 events that were not reported?
17 A No.
18 Q Do you know if removing a medical device,
19 so in this case the mesh, part of the pelvic mesh
20 that was implanted -- do you know if that's a
21 reportable adverse event?
22 MR. STOCKMAN: Objection.
23 You can answer, to the extent you don't
24 know based on conversation with counsel.
25 THE WITNESS: Yeah. We're getting pretty

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1 close to that line here. So I'm --
2 BY MS. FUSCO:
3 Q Well, while your conversations are
4 confidential, facts allow you to testify here are
5 not.
6 MR. STOCKMAN: Right. So my instruction
7 to you is, if you have an independent basis
8 beyond conversations with counsel you can
9 answer. If your response is based on
10 conversations with counsel you should not
11 answer.
12 MS. FUSCO: I think I disagree with that
13 because, you know, your obligation is to
14 prepare her to testify. So the facts --
15 MR. STOCKMAN: I know. But I don't think
16 you're asking her for facts. Because I don't
17 think it's black and white as to whether or not
18 removal of mesh is a reportable event. I
19 don't -- I don't think you're seeking a fact.
20 MS. FUSCO: I think I am seeking a fact.
21 MR. STOCKMAN: Okay. You may think you're
22 seeking a fact. I don't think you're seeking a
23 fact.
24 MS. FUSCO: And I may have it here, which
25 we can get to.

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1 MR. STOCKMAN: Okay.
2 MS. FUSCO: That's a good segue. Let's
3 see.
4 (Discussion off the record.)
5 MS. FUSCO: I do have it, but I don't have
6 it with me.
7 MR. STOCKMAN: Okay. Why don't we skip
8 this for now, and we'll come back to it.
9 THE WITNESS: Can I --
10 MR. STOCKMAN: Can you what?
11 MS. FUSCO: Okay.
12 THE WITNESS: Can you repeat the question?
13 MR. STOCKMAN: Yeah. Why don't we repeat
14 the question.
15 BY MS. FUSCO:
16 Q I will represent to you, subject to
17 looking at the regulations, because I didn't bring
18 them with me, the federal regulations -- I don't --
19 I can check on my computer at the break -- that
20 removing the mesh -- removing a part of a medical
21 device is a reportable event. Okay.
22 MR. STOCKMAN: So you're asking whether or
23 not she knows that?
24 BY MS. FUSCO:
25 Q Whether or not you know that. Correct.

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1 MR. STOCKMAN: I'll let her answer that.
2 MS. FUSCO: Yes.
3 MR. STOCKMAN: Objection. But I'll let
4 her answer that.
5 MS. FUSCO: Subject to confirmation that
6 my memory is intact.
7 MR. STOCKMAN: Okay.
8 THE WITNESS: So the question is, do I
9 know that removal of a --
10 BY MS. FUSCO:
11 Q Of mesh --
12 A -- mesh is a reportable --
13 Q Is a reportable event?
14 MR. STOCKMAN: Objection.
15 You can answer.
16 THE WITNESS: I don't know that.
17 BY MS. FUSCO:
18 Q You don't know that. Okay. If that was
19 in the regulations, who would be responsible for --
20 for conveying that information to the physician, so
21 that the physician could report it to the hospital,
22 so that the hospital could fulfill its mandatory
23 duty to report that event?
24 A Partly, certainly, in my department, as
25 well as the director or overseer of that department,

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1 as well if that's a chair.
2 Q So do you know if the chair of the
3 department -- and we'll just be specific to the
4 OB/GYN department -- do they have a responsibility
5 to review the regulations related to medical devices
6 that are implanted just within their department?
7 MR. STOCKMAN: Objection.
8 You can answer.
9 THE WITNESS: I don't know. I don't know
10 their job description, so I don't know if
11 that's part of it.
12 BY MS. FUSCO:
13 Q Okay. So just quickly back to Peminic --
14 MR. STOCKMAN: And whenever there's a
15 natural break point, just let us know --
16 MS. FUSCO: Okay.
17 MR. STOCKMAN: -- because I'd like to hit
18 the restroom.
19 MS. FUSCO: Okay. Let me just finish up
20 this one part.
21 MR. STOCKMAN: Sure.
22 BY MS. FUSCO:
23 Q So I think you said that you could easily
24 access Peminic?
25 A I can -- my IT staff can access Peminic.

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1 And I don't think I used the word "easily."
2 Q Okay.
3 A We have access to --
4 Q They can access it?
5 A -- data on a server, so, essentially, a
6 storage server.
7 Q Okay. And do you know if the
8 occurrences -- reportable occurrences are organized
9 the same way as they are in QASYS, meaning you've
10 got the categories?
11 A My recollection is they were similar. It
12 was type of event --
13 Q Okay.
14 A -- department involved, and then some
15 narrative.
16 Q Do you know if they could search for a
17 particular device in Peminic to see if there were
18 adverse events reported related to that?
19 A I don't know specifics. My recollection
20 is that they could search. But, again, it's the
21 same type, you'd have to search by events, and then,
22 more likely than not, the -- any device names are in
23 the narrative.
24 Q Right. And so, since you are here since
25 2006, to your knowledge, with your recollection,

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1 have any adverse events been reported related to
2 pelvic mesh products?
3 A No.
4 MS. FUSCO: Break time.
5 (Recess: 10:56 a.m. until 11:06
6 a.m.)
7 (Mr. O'Dea is now attending via
8 teleconference.)
9 MS. FUSCO: Okay. Back on the record.
10 BY MS. FUSCO:
11 Q One question in follow-up, because I just
12 want to clarify. I think you said that in the QASYS
13 there were no adverse events related to the pelvic
14 mesh products; is that correct?
15 A Correct.
16 MR. STOCKMAN: You asked about Peminic
17 too; right?
18 MS. FUSCO: Yes. There were none in
19 Peminic.
20 MR. STOCKMAN: Right.
21 MS. FUSCO: Did I ask QASYS? I couldn't
22 remember.
23 MR. STOCKMAN: Okay.
24 THE WITNESS: You did.
25 MS. FUSCO: There are none.

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1 can kind of move on.
2 MR. STOCKMAN: Because I do think,
3 frankly, it also comports with the practice
4 book to allow you to inspect, you know --
5 MS. FUSCO: But I --
6 MR. STOCKMAN: But you asked for it;
7 right? I mean --
8 MS. FUSCO: Well, we asked for it to be
9 produced, not made available in the warehouse.
10 MR. STOCKMAN: That's adequate production.
11 MS. FUSCO: So, I mean, I'd rather --
12 MR. STOCKMAN: It just is. It just is.
13 You know, there are --
14 MS. FUSCO: Specifically, for this
15 situation, I don't think it's adequate.
16 MR. STOCKMAN: No. In litigation -- I
17 mean, you know, I remember going to warehouses
18 in Indianapolis and sitting for months looking
19 for documents.
20 MS. FUSCO: But I'm talking about
21 specifically under this court order, the
22 documents --
23 MR. STOCKMAN: Oh, no. No. The document
24 -- it doesn't say anything about --
25 MS. FUSCO: Produce documents.

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1 MR. STOCKMAN: That's production. That's
2 production under any -- any court order. In
3 any event --
4 MS. FUSCO: We're not agreeing to that.
5 MR. STOCKMAN: Right, because -- well,
6 never mind. So we can clarify all of this
7 after the deposition is over. Are you finished
8 for today?
9 MS. FUSCO: Yes, I'm finished for today.
10 MR. STOCKMAN: Anyone?
11 MR. DRURY: No questions.
12 MR. STOCKMAN: I have follow-up.
13 CROSS EXAMINATION
14 BY MR. STOCKMAN:
15 Q I want you to assume that the 2008 notice
16 was sent via email to Liz McKinley. Does the fact
17 that you cannot find -- that the hospital can't find
18 any folder with the 2008 notice mean that it
19 definitively was not sent to her?
20 A No.
21 Q All right. Do you know whether or not
22 there would be any clinical follow-up with regard to
23 a update on serious complications associated with
24 transvaginal placement of surgical mesh -- I'm
25 sorry. That's the wrong title. Let me ask that

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1 again.
2 Do you know whether or not there
3 would be any kind of clinical communication between
4 risk management and either the surgical or
5 obstetrical department over an FDA public health
6 notification that concluded that there were
7 complications associated with transvaginal placement
8 of surgical mesh that were rare?
9 A I don't know.
10 Q In any event, if the department head -- if
11 the department chair already knew about it, would
12 risk management necessarily have to be involved?
13 MS. FUSCO: Objection.
14 THE WITNESS: No.
15 MR. STOCKMAN: I have nothing further.
16 MS. FUSCO: Okay. A follow-up.
17 MR. STOCKMAN: I knew you were going to
18 have a follow-up.
19 REDIRECT EXAMINATION
20 BY MS. FUSCO:
21 Q Who is Liz McKinley?
22 MR. STOCKMAN: Liz -- oh. You can ask
23 her.
24 THE WITNESS: Liz McKinley is the manager
25 of regulatory -- well, was the manager of

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1 regulatory affairs. Currently she is a
2 director in our nursing department for our
3 medical surgical units. She previously was in
4 the department as a manager, and then a
5 director of regulatory affairs.
6 BY MS. FUSCO:
7 Q And she was manager of regulatory affairs
8 when?
9 A I think she was hired in '05. I don't --
10 I'm -- that's my memory. She was in the department
11 when I started in December of 2006, and then she
12 left for that new position, I think it was January
13 2014.
14 Q So you did not know that this report was
15 sent via email to Liz McKinley in regulatory
16 affairs; is that correct? I believe that's what
17 counsel represented.
18 MR. STOCKMAN: Yeah.
19 MS. FUSCO: Right.
20 THE WITNESS: Yeah, I did not know.
21 BY MS. FUSCO:
22 Q Okay. Do you know what Liz McKinley would
23 have done with this notification?
24 A Generally what I outlined as the process
25 would apply here, which is, if -- if we got this

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1 type of public health notification on this device,
 2 or any other device, we are not the clinical
 3 experts, and we would have to go to the clinical
 4 experts and ask them for their guidance regarding
 5 what should be done with this type of alert or
 6 notice.
 7 Q And it starts with the chair of the
 8 department; is that correct?
 9 A Yeah. But it may not be the chair in
 10 certain areas. It may be the division director. If
 11 it's an orthopedic device, yes, we could start with
 12 the chair, but we may also ask the division
 13 director, because that is his or her specialty.
 14 Q Right. So if the division director -- if
 15 there was a division director of urogynecology who
 16 happened to be implanting pelvic mesh product, that
 17 physician would be the obvious person to go to to
 18 talk about this; is that right?
 19 A Right, in addition to or in conjunction
 20 with the chair, yes.
 21 Q Okay.
 22 MS. FUSCO: That's it.
 23 MR. STOCKMAN: Okay. I have nothing else.
 24 MS. FUSCO: Okay.
 25 MR. STOCKMAN: Thank you.

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1 MS. FUSCO: Thank you.
 2 (Time noted: 12:02 p.m.)
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 2
 3 I, RUTH CARDIELLO, have read the foregoing
 4 pages, and find the answers to the questions therein
 5 contained to be true and correct, with the exception of
 6 changes, if any, as may be noted on the Correction Page.
 7
 8
 9
 10 Dated _____ RUTH CARDIELLO
 11
 12 Subscribed and sworn to before me this ____ day
 13 of _____, 2015.
 14
 15
 16
 17
 18
 19 _____
 20 Notary Public
 21 My Commission Expires:
 22
 23
 24
 25

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1 STATE OF CONNECTICUT)
 2) SS: DANBURY
 3 COUNTY OF FAIRFIELD)
 4 I, Deborah R. Pomponio, a Registered Merit Reporter
 5 and Notary Public within and for the State of Connecticut,
 6 do hereby certify that the within deposition of RUTH
 7 CARDIELLO was held before me on the 29th day of June, 2015.
 8 I further certify that the witness was first sworn by
 9 me to tell the truth, the whole truth and nothing but the
 10 truth, and was examined by counsel, and his testimony was
 11 recorded stenographically by me, it was reduced to
 12 typewriting under my supervision, and I hereby submit that
 13 the within contents of said deposition are true and accurate
 14 to the best of my ability.
 15 I further certify that I am not a relative of nor an
 16 attorney for any of the parties connected with the aforesaid
 17 examination, nor otherwise interested in the testimony of
 18 the witness.
 19 Dated at Danbury, Connecticut, the 1st day of July,
 20 2015.
 21
 22 _____
 23 Deborah R. Pomponio, RMR
 24 Notary Public
 25 CT License No. 79
 (My Commission expires January 31, 2020.)

EXHIBIT L

Code of Conduct

at Stamford Hospital

STAMFORD HOSPITAL | Discover More The Regional Center for Health

Affiliate Columbia University-College of Physicians & Surgeons
Member NewYork-Presbyterian Healthcare System
A Planetree Hospital

As a Planetree hospital, we are committed to personalizing, humanizing and demystifying the healthcare experience for patients and their families. Our approach is holistic and encourages healing in all dimensions—mind, body and spirit.



Stamford Hospital
30 Shelburne Road
P.O. Box 9317
Stamford, CT 06904-9317
Phone: 203.276.1000

stamfordhospital.org



STAMFORD HOSPITAL | Discover More The Regional Center for Health

Affiliate Columbia University-College of Physicians & Surgeons
Member NewYork-Presbyterian Healthcare System
A Planetree Hospital





Dear Staff,

One of the principal guidelines we use as an organization to demonstrate our commitment to upholding the trust and confidence of our community, is the code of conduct we all adhere to on a daily basis. As part of our ongoing corporate compliance efforts, we spent the last year developing a code of conduct in order to enhance the organization's high-level of ethical standards.

This code has been developed and adopted by the Board of Directors to state clearly the behaviors we will each follow and look for in the conduct of others. It is grounded in our core values—teamwork, compassion, integrity, respect and accountability—with the understanding that those who follow its guidelines will truly be living those values in their activities at Stamford Hospital. The code impacts everyone associated with the hospital—employees, contractors, members of the medical staff, students and volunteers.

Over the next year, we will all become more familiar with the new code of conduct as it will be discussed at staff meetings, promoted in Newsline, introduced in new employee orientation and become part of the annual mandatory regulatory training for all employees. More importantly, it will be exemplified in all our behaviors.

As always, if you have any questions or concerns on any compliance matters, you can contact Ruth Cardiello, Corporate Compliance Officer at ext. 7533, or you can make an anonymous call through the confidential compliance hotline at 1.800.826.6762.

Brian Grissler
President & CEO

Introduction

Stamford Hospital is committed to ensuring that all employees share in the responsibility for keeping the Hospital in full compliance with all laws and regulations governing ethical business practices. This brochure explains the expected behavior and conduct of all employees, volunteers, members of the Board of Directors and members of the Hospital's medical staff in our workplace.

This is your copy of the System's Code of Conduct. It has been designed to be a clear and concise guide. Please familiarize yourself with it to ensure understanding.

This Code of Conduct addresses various issues including the following:

- Patient care
- Confidentiality
- Compliance with laws and regulations
- Conflicts of interest
- Coding and billing integrity
- Workplace safety
- Workplace conduct including discrimination
- Protection of assets
- Use of patient information

This Code of Conduct is a broad guideline which is reinforced in greater detail by the various policy and procedure manuals utilized throughout the Hospital. It is the responsibility of every employee, volunteer, member of the Board of Directors and medical staff member to act in a manner consistent with this Code, the values and principles it expresses, and its supporting policies.

The Hospital's Code of Conduct is a "living document" that will be updated periodically. If you have suggestions, recommendations or ideas for improving the Code, please contact the Corporate Compliance office at 203.276.7533.



Stamford Hospital will:

Provide Excellent Patient Care. Providing quality of care, while respecting the rights of patients, is the central focus of the Hospital. We are committed to providing services that meet and exceed patient expectations while focusing on continuous improvement of quality. Stamford Hospital employees will treat all with a spirit of kindness, patience and understanding. Each patient should be respected, with their needs and desires considered as health care decisions are made. Steps shall be taken so that each patient understands his or her treatment needs and options, treatment methods utilized, and treatment outcomes. Stamford Hospital will provide services in a manner that does not discriminate against any person because of age, race, religion, gender, sexual orientation, disability, national origin, ability to pay or for any other reason prohibited by applicable Federal and State law. At all times, competent and qualified individuals will provide appropriate, medically necessary care, while considering the safety and well being of the patients.

Stamford Hospital shall provide an appropriate medical screening examination to any individual who seeks emergency medical treatment, regardless of ability to pay, and such further medical examination or treatment as required to stabilize any emergency medical condition, or provide a medically appropriate transfer, and will not delay a medical screening examination, or any further examination and treatment required, in order to inquire about the individual's method of payment, ability to pay or insurance status.

Protect Confidential Information. Stamford Hospital is committed to maintaining the confidentiality of patient, personnel, financial and other proprietary information in accordance with applicable legal and ethical standards. Any use or disclosure of any patient information that is not in compliance with Federal and State law, and the Hospital's policies and procedures, is strictly prohibited.

Comply with the Laws, Regulations and Accreditation and Internal Standards.

Stamford Hospital is subject to numerous local, Federal and State laws, regulations and internal standards pertaining to all aspects of its operation. All employees are required to understand and abide by those laws, regulations and standards which are applicable to them in the performance of their jobs. All employees must be knowledgeable about, and ensure compliance with, all laws and regulations applicable to the performance of their job, and performance evaluations will take these factors into account. It is the responsibility of each employee to immediately report any violations or suspected violations of any legal requirements or accreditation standards to a supervisor, administrator and/or the Compliance Officer. All employees will deal with accrediting and regulatory bodies in a direct, open and honest manner.

Adhere to Anti-Referral and Health Care Fraud and Abuse Legislation.

All employees of Stamford Hospital are required to comply with any and all laws which prohibit health care fraud and abuse. We shall not engage in any illegal or unethical business practices. Contractual/financial arrangements with physicians, vendors, third party payors, managed care organizations or other referral sources will be structured to ensure compliance with applicable Federal and State laws and regulations, fulfill the mission of the Hospital, and be in the best interests of the Hospital and the patients we serve. Stamford Hospital expects employees to refrain from conduct that violates Federal and State anti-kickback statutes, as well as the "Stark" physician self-referral laws and regulations. Simply put, we do not pay for referrals or otherwise unlawfully attempt to induce referrals to the Hospital.



Activities that are prohibited include, but are not limited to:

- Intentionally or knowingly making false or fraudulent claims for payment or approval;
- Offering or receiving anything of value (cash or in kind) as an inducement to make a referral for the furnishing of any item or service;
- Offering or receiving anything of value (cash or in kind) as an inducement or in return for the purchasing, leasing, ordering, or arranging for or recommending the purchasing of any goods, facility, service or item; and,
- Submitting false information for the purpose of gaining or retaining the right to participate in a plan or obtain reimbursement for services.

Avoid Inappropriate Gifts & Gratuities. Employees are prohibited from soliciting or accepting tips, personal gratuities or gifts from patients, vendors, contractors and other third parties. Employees may, however, accept unsolicited non-monetary gratuities or gifts of a nominal value, such as cookies, flowers or candy if the gift would not influence, or reasonably appear to others to be capable of influencing, the employee's business judgment. If the value of the gifts are over \$300, as per Stamford Hospital policy, or there is any question regarding whether acceptance of the gift would comply with Stamford Hospital policies, the employee must seek prior approval from the Corporate Compliance Office or refuse the gift and promptly return the gift to the vendor or patient. Employees shall not offer or give money, services or other things of value with the expectation of influencing the judgment or decision making process of any purchaser, vendor, patient, governmental official or any other person.

Avoid Conflicts of Interest. It is the policy of Stamford Hospital to prohibit its employees and other associates from engaging in any activity, practice, or act which conflicts with, or appears to conflict with, the interests of Stamford Hospital, or its patients. Employees are expected to conduct the business of the Hospital to the best of their ability and for the benefit of the Hospital and its patients. Employees must be careful not to create any conflicts of interest (actual or perceived). The policy also requires board members, officers, senior leaders, medical staff leaders, committee members and other individuals as appropriate to disclose any potential conflict of interest they or their immediate family may have, including any interest in or relationship with any individual or organization which does business with Stamford Hospital or which competes with Stamford Hospital. Stamford Hospital manages its contractor and supplier relationships in a fair and reasonable manner, consistent with all applicable laws and good business practices. Our selection of contractors, suppliers, and vendors will be made on the basis of objective criteria, and not on personal relationships and friendships.

Coding and Billing Integrity. Stamford Hospital is committed to the proposition that all payments and other transactions must be properly documented and authorized by management. Employees are expected to adhere to the rules and regulations regarding documentation. All transactions must be accurately and completely supported in the Hospital's books and records. Further, all billing practices and compilation of, and filing of, cost reports must comply with all Federal and State laws and regulations. Activities that are prohibited, but not limited to, include:

- Knowingly submitting a claim or bill for services that were not rendered or accurately described on the claim form or statement, nor shall we misrepresent services which were rendered, or alter a medical record;



- Submitting a claim requesting payment or bill a third party for medically unnecessary services, or seek reimbursement for a service that is not warranted by the patient's current medical condition as documented in the medical record and physician's orders;
- Knowingly submitting claims for payment that have not been properly coded, documented or billed according to applicable laws and regulations;
- Submitting bills in a piecemeal or fragmented fashion to maximize reimbursement for various test or procedures that are required to be billed together and therefore at a reduced cost ("unbundling"), nor billing separately for each component of a group of procedures that are commonly used together for which Medicare and/or Medicaid provides a special reimbursement rate; or
- Submitting more than one claim for the same service or submitting a bill to more than one primary payor at the same time ("duplicate billing").

Employees shall assist Stamford Hospital in identifying and appropriately resolving any coding and billing issues or concerns identified. Stamford Hospital will refund overpayments made by a Federal health care program or other payor.

Keep Accurate and Complete Records. It is essential that Stamford Hospital report accurate information to governmental entities and other third parties. In order to meet this obligation, it is equally essential that every employee accurately and clearly report the relevant facts or the true nature of a transaction. No employee should knowingly or with reckless disregard for the truth make any false or misleading statement on any form or to any other officer, employee or auditor for Stamford Hospital. All patient records must meet the documentation standards required for quality care and to meet reimbursement regulations. Employee travel and entertainment related expenses

must be accurately documented and supported when seeking reimbursement from the hospital. All medical and business documents and records are retained in accordance with the law and Stamford Hospital's record retention policy.

Conduct Political Activities According to the Law. Stamford Hospital expects each of its employees to refrain from engaging in activity that may jeopardize the tax exempt status of the Hospital. Stamford Hospital funds or resources may not be used to contribute to political campaigns or for gifts or payment to any political party or any political organization. Stamford Hospital does not participate or intervene in (including the publishing or distributing of statements) any political campaign on behalf of or in opposition to any candidate for public office. While the Hospital supports employee participation in the political process, employees are not permitted to use positions in Stamford Hospital to try to influence the personal decisions of others to contribute or otherwise support political parties or candidates except as lawfully permitted through political action committees. Stamford Hospital may participate in lobbying activities or advocating the passage or defeat of certain legislation that pertains to issues that affect the healthcare community and as such complies with the state's ethics requirements. Lobbying activities, or advocating the passage or defeat of certain legislation, shall not constitute a substantial part of the activities of Stamford Hospital.

Protect the Environment. It is the policy of Stamford Hospital to comply with all Federal and State laws protecting the environment. Employees shall dispose of all waste and other materials and store all chemicals and substances in accordance with applicable laws and regulations. It is important to file all necessary environmental reports accurately and promptly and to cooperate fully with all governmental authorities in the event of an environmental incident.



Provide a Safe Workplace. It is the policy of Stamford Hospital to comply with all applicable Federal and State laws designed to improve workplace safety. Stamford Hospital is committed to training employees to carry out their work in a manner that is safe for them, their coworkers and the patients they serve. We shall ensure high-quality healthcare through the provision of educational training and teaching experiences for all employees.

Not Tolerate Harassment or Discrimination. Stamford Hospital recognizes that all employees, regardless of job classification, belong to a knowledgeable and skilled health team which contributes to patient care. We want to create a caring and positive environment in which all employees are treated fairly. It is Stamford Hospital's policy not to discriminate on the basis of race, color, religion, national origin, age, disability, sexual orientation or gender in providing services to patients or the public, nor in relation to employment practices. Furthermore, Stamford Hospital prohibits harassment of its employees in any form by supervisors, coworkers, patients, medical staff members or vendors.

Safeguard and Appropriately Use Assets. All employees are charged with protecting and preserving Stamford Hospital's assets and resources by following procedures to prevent their loss, theft or unauthorized use. Further, Stamford Hospital and its employees must make every effort possible to ensure that the property of our patients is safeguarded. Stamford Hospital shall ensure that the assets of the Hospital are used properly and in a manner that supports the best interests of the organization and its patients. No part of the net earnings of Stamford Hospital shall be used for the benefit of, or be distributed to, its Directors, Executive Staff, employees or other private persons having directly or indirectly any personal or private interest in the activities of Stamford Hospital, except to the extent that such payments constitute reasonable compensation for services rendered in the necessary course of Stamford Hospital's business.

Protect Access to Information Systems. Stamford Hospital is committed to protecting all aspects of its information systems. All employees and other associates with access to Stamford Hospital's computerized information system shall abide by Stamford Hospital's Policies, including the protection of confidential user-ids and passwords. All computers, PDA's, pagers, communication systems, electronic mail, fax, networks (including internet access) and voicemail are the property of Stamford Hospital and are to be used for business purposes only.

Adhere to Intellectual Property Laws. Stamford Hospital is committed to adhering to all applicable intellectual property laws. All software used in connection with Stamford Hospital's business must be properly licensed and used in accordance with that license. Additionally, Stamford Hospital will respect the intellectual property and copyright laws regarding books, trade journals, magazines and other applicable resources.

If anyone has any questions or concerns on any compliance matters, you may raise your concern to the Corporate Compliance office at 203.276.7533 or the Corporate Compliance Hotline at 1.800.826.6762. Retaliation for raising concerns is unlawful and will not be tolerated by Stamford Hospital.

EXHIBIT O

Anatomic outcomes and safety of prolift over 2 years

Ema Kulwa, PGY II
 OBGYN Department
 Schiffer day 05/30/2008

Background: Pelvic organ prolapse

- Up to 50% of women who have had a vaginal delivery have some degree of poor pelvic organ support
- About 20% of women who have had a vaginal delivery will have symptoms that require seeking medical care
- 11% of women will have surgery for POP by age of 80 years (300,000 procedures in USA/year)
- Traditional methods of uterine/vaginal vault prolapse:
 - Hysterectomy
 - Abdominal sacral colpopexy, sacrospinous ligament fixation, uterosacral ligaments and iliococcygeus fascia/muscle fixation
 - Failure rates 0% to 20% for above methods

Lee et al, 2007

Background: Pelvic organ prolapse

- Traditional methods for cystocele, rectocele
 - anterior colporrhaphy with/without addition of mesh/graft material
 - Paravaginal repair
 - Recurrent prolapse in 15-37 % in 3 years
 - posterior colporrhaphy, plication
 - 50% recurrence within a year of tx
 - site specific repair of defect
 - Recurrence 33% within a year of U/U

ACOG, 2007

Use of graft materials in prolapse surgery

- Grafts used to augment traditional prolapse repairs, substitute/reinforcement for original vaginal tissue
- Despite increased use of grafts, mesh there's lack of sufficient risk-benefit information
- Complications mesh erosion, vaginal contraction
- Synthetic mesh vs. cadaveric fascia

Studies of transvaginal repair with synthetic meshes

Author	Year	Mesh	N	f/u (months)	Asst success 100%	Vaginal intxn	Vaginal erosion
Julien	1996	Marlex	22	24	100	0	8.3%
Hicks	1998	Marlex	44	3	93.2%	0	2.3%
Flood et al	1998	Marlex	142	36	84.4	3.5%	2.1%
Mage	1999	Mersilene	66	26	100	0	2.2%
Migliari	2000	Prolene	12	20	75	0	0
Dwyer, O rally	2004	Atrium	47	29	94	0	7

Gynecare Prolift (Ethicon, USA) pelvic floor repair system

- Synthetic polypropylene mesh, trocar delivered
- Non- absorbable
- Tension free
- Can be used for all sites of vaginal vault prolapse
- Relatively quick procedure with quick recovery

EXHIBIT P

**Medical Device Safety**[Safety Communications](#)
[Public Health Notifications
\(Medical Devices\)](#)

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

For updated information about Surgical Mesh for Pelvic Organ Prolapse, see: [UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse, released July 13, 2011.](#)

Issued: October 20, 2008

Dear Healthcare Practitioner:

This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.

Nature of the Problem

Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement.

The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.

Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.

Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (e.g. hysterectomy), and possibly estrogen status.

Recommendations

Physicians should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.

[Additional patient information](#) can be found on the following FDA Consumer website.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of surgical mesh, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting. You can report directly to MedWatch, the FDA Safety Information and [Adverse Event Reporting program online](#), by phone at 1-800-FDA-1088, or obtain the [fillable form online](#), print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Getting More Information

[FDA Medical Device Public Health Notifications](#) are available on the Internet. You can also be notified through email each time a new Public Health Notification is added to our web page. To subscribe, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDA_39.

Sincerely,
Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health

Food and Drug Administration

If you have questions about this Notification, please contact FDA's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by e-mail at dsmica@fda.hhs.gov or by phone at 1-800-638-2041 or 301-796-7100

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FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

Date Issued: July 13, 2011

Audience:

- Health care providers who implant surgical mesh to repair pelvic organ prolapse and/or stress urinary incontinence
- Health care providers involved in the care of patients with surgical mesh implanted to repair pelvic organ prolapse and/or stress urinary incontinence
- Patients who are considering or have received a surgical mesh implant to repair pelvic organ prolapse and/or stress urinary incontinence

Medical Specialties: gynecology, urogynecology, urology, general surgery, internal medicine, family practice, emergency medicine

Device:

Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.

Background:

Pelvic Organ Prolapse

Pelvic organ prolapse (POP) occurs when the tissues that hold the pelvic organs in place become weak or stretched. Thirty to fifty percent of women may experience POP in their lifetime with 2 percent developing symptoms. When POP happens, the organs bulge (prolapse) into the vagina and sometimes prolapse past the vaginal opening. More than one pelvic organ can prolapse at the same time. Organs that can be involved in POP include the bladder, the uterus, the rectum, the top of the vagina (vaginal apex) after a hysterectomy, and the bowel.

Stress Urinary Incontinence

Stress urinary incontinence (SUI) is a leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercise.

Purpose:

On Oct. 20, 2008, the FDA issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat POP and SUL.

Based on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern.

The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. This Safety Communication provides updated recommendations for health care providers and patients and updates the FDA's activities involving surgical mesh for the transvaginal repair of POP.

The FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date.

For detailed information, please see: [Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse](#).

Summary of Problem and Scope:

In the Oct. 20, 2008 FDA Public Health Notification, the number of adverse events reported to the FDA for surgical mesh devices used to repair POP and SUI for the previous 3-year period (2005 – 2007) was “over 1,000.” Since then, from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, we are concerned that the number of adverse event reports remains high.

From 2008 – 2010, the most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization.

In order to better understand the use of surgical mesh for POP and SUI, the FDA conducted a systematic review of the published scientific literature from 1996 – 2011 to evaluate its safety and effectiveness. The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report about that usage at a later date.

In particular, the literature review revealed that:

- Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.
- Mesh placed abdominally for POP repair appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh.
- While transvaginal surgical repair to correct weakened tissue between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results.

The FDA's literature review found that *erosion* of mesh through the vagina is the *most common and consistently reported mesh-related complication* from transvaginal POP surgeries using mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication.

Mesh contraction (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 FDA Public Health Notification. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.

Both mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse. Also, men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion.

The complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh.

Recommendations for Health Care Providers:

As stated in the Oct. 20, 2008 Public Health Notification, the FDA continues to recommend that health care providers should:

- Obtain specialized training for each mesh placement technique, and be aware of the risks of surgical mesh.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh.
- Provide patients with a copy of the patient labeling from the surgical mesh manufacturer if available.

In addition, the FDA also recommends that health care providers:

- Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.
- Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives.
- Consider these factors before placing surgical mesh:
 - Surgical mesh is a permanent implant that may make future surgical repair more challenging.
 - A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.
 - Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.
 - Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
- Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used.
- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

Recommendations for Patients:

Before Surgery

Be aware of the risks associated with surgical mesh for transvaginal repair of POP. Know that having a mesh surgery may put you at risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

Ask your surgeon about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why your surgeon may be recommending treatment of POP with mesh.

In addition, ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:

- Are you planning to use mesh in my surgery?
- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?
- What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
- Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?
- If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
- What can I expect to feel after surgery and for how long?
- Which specific side effects should I report to you after the surgery?
- What if the mesh surgery doesn't correct my problem?
- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?
- If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

After Surgery

- Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.
- Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
- Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
- Talk to your health care provider about any questions you may have.

If you had POP surgery, but do not know whether your surgeon used mesh, ask your health care provider at your next scheduled visit.

FDA Activities:

The FDA is working in several areas to assess and improve the safety and effectiveness of urogynecologic mesh products. The FDA will:

- Convene the Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee, on September 8-9, 2011. The panel will discuss and make recommendations regarding the safety and effectiveness of transvaginal surgical mesh for POP and SUI.
- Explore regulatory solutions to answer questions about the safety and effectiveness of urogynecologic mesh products that are now being marketed and those that will be reviewed for marketing in the future.
- Continue to monitor adverse events reported to FDA associated with surgical mesh used to repair POP and SUI, as well as assessing any and all data as it becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with surgical mesh, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#). Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements](#) should follow the reporting procedures established by their facilities. Device manufacturers must comply with the [Medical Device Reporting \(MDR\) regulations](#).

To help us learn as much as possible about the adverse events associated with surgical mesh to repair POP and SUI, please include the following information in your reports, if available:

- Manufacturer's name
- Product name (brand name)
- Catalog number
- Lot number
- Size
- Date of implant
- Date of explant (if mesh was removed)
- Details of the adverse event and medical and/or surgical interventions (if required)
- Type of procedure (e.g., anterior or posterior repair, sacral colpopexy, sling procedure for SUI)
- Surgical approach: (e.g., vaginal, abdominal, laparoscopic)
- Reason for mesh implantation: (e.g., POP of the uterus, bladder, rectum, vaginal apex or bowel, SUI)
- Specific postoperative symptoms experienced by the patient with time of onset and follow-up treatment

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

Additional Information

- [Urogynecologic Surgical Mesh Implants](#)
- [Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse \(July 2011\)](#) (PDF - 243KB)
- [Press Release: Surgical placement of mesh to repair pelvic organ prolapse poses risks](#)
- [Federal Register Notice: Urogynecologic Surgical Mesh](#)
- [Federal Register Notice Amendment: Urogynecologic Surgical Mesh](#)

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