Reclassification of Urogynecologic Surgical Mesh Instrumentation

Food and Drug Administration
Executive Summary

Gastroenterology-Urology Medical Devices Advisory Committee Panel

February 26, 2016

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I. Introduction

The Food and Drug Administration (FDA) is convening the Gastroenterology-Urology Devices Advisory Panel (the Panel) to obtain recommendations regarding the reclassification of urogynecologic surgical mesh instrumentation. Urogynecologic surgical mesh instrumentation are class I medical devices. The FDA is proposing to reclassify these devices into class II and establish special controls.

The FDA is seeking Panel input on the risks to health and benefits of urogynecologic surgical mesh instrumentation and whether class II is the appropriate regulatory class for these devices. If the Panel believes that class II is appropriate, the FDA requests the Panel recommend special controls that mitigate the risks to health.

II. Device Description

Urogynecologic surgical mesh instrumentation is specifically designed for use during urogynecologic surgical mesh procedures. Urogynecologic surgical mesh are intended to treat pelvic organ prolapse (POP) and female stress urinary incontinence (SUI). Urogynecologic surgical mesh procedures include transvaginal POP repair, transabdominal POP repair (i.e., sacrocolpopexy), retropubic sling placement for SUI, and transobturator sling placement for SUI.. Please see **Attachment 1** for an overview of urogynecologic mesh, including the device design and placement.

Implantation of urogynecologic surgical mesh is a complex procedure. It is performed ‘‘blind,’’ meaning the surgeon cannot directly visualize placement of the surgical mesh and relies on the urogynecologic surgical mesh instrumentation, palpation of anatomic landmarks, and experience to access critical ligaments and attach anchors and other devices needed to secure the mesh. Urogynecologic surgical mesh instrumentation aids in insertion, placement, fixation, and/or anchoring of the urogynecologic surgical mesh and is typically composed of a stainless-steel needle attached to a plastic handle. The design of the instrumentation is dependent upon the urogynecologic surgical mesh procedure.

Figure 1 provides examples of urogynecologic surgical mesh instrumentation designed for use with urogynecologic surgical mesh.

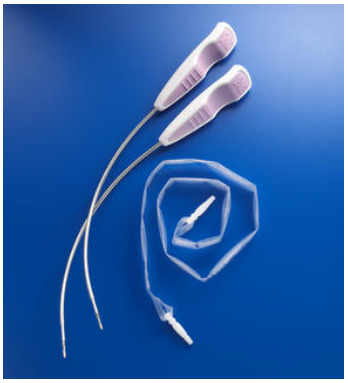
(a)  (b)  (c) 

Figure 1 (a) Capio needle used for transvaginal POP procedures, (b) instrumentation for retropubic sling placement, and (c) instrumentation for transobturator sling placement

Figure 2 depicts use of instrumentation during two urogynecologic surgical mesh procedures.

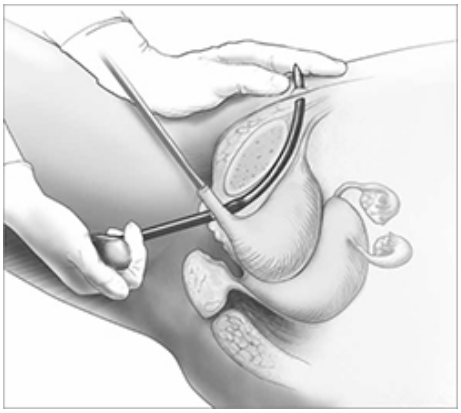
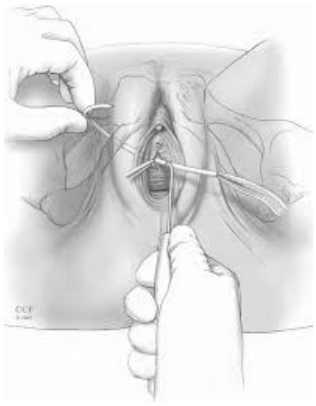
(a)  (b) 

Figure 2 (a) Using instrumentation to place retropubic sling and (b) using instrumentation to place a transobturator sling

Instrumentation specifically designed for use with urogynecologic surgical mesh can be placed into one of the following categories:

1. Designed, packaged, and indicated for use with one specific urogynecologic surgical mesh device. The packaged combination of mesh and instrumentation is referred to as a urogynecologic surgical mesh kit.

2. Designed and indicated for use with multiple urogynecologic surgical mesh devices. The instrumentation is packaged and marketed separately from the mesh devices.

3. Designed and indicated for use with a urogynecologic surgical mesh device but also indicated for non-mesh urogynecologic procedures, e.g., pelvic floor repair procedures

Please note that the FDA is not proposing to reclassify general instrumentation used during urogynecologic surgical mesh procedures. The FDA is only proposing to reclassify urogynecologic surgical mesh instrumentation that is designed to be used with urogynecologic surgical mesh. General instrumentation will remain in class I.

III. Regulatory History

Section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act; 21 U.S.C.360c) establishes three categories (classes) of devices based on the risks to health posed by the devices and the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. Class I devices are low risk and require less regulatory control whereas class III devices are high risk and require the most regulatory control. Class II devices are intermediate with respect to both risk and regulatory control. Please see **Attachment 2** for an overview of the risk based classification and regulation of medical devices.

Urogynecologic surgical mesh indicated for transvaginal POP repair are class III devices, and urogynecologic surgical mesh for all other indications (i.e., transabdominal POP repair and female stress urinary incontinence) are class II devices. Urogynecologic surgical mesh instrumentation is regulated as a class I device under 21 CFR 876.4730 (manual gastroenterology-urology surgical instrument and

accessories) and 21 CFR 878.4800 (manual surgical instrument for general use). Urogynecologic surgical mesh instrumentation is exempt from premarket notification procedures; and therefore, their design, biocompatibility, sterilization method, etc. are not reviewed by the FDA prior to being marketed. However, when instrumentation is packaged with the surgical mesh in an urogynecologic surgical mesh kit, the FDA has reviewed the instrumentation as part of the premarket notification (510(k)) submitted for the urogynecologic surgical mesh. The FDA is proposing to reclassify urogynecologic surgical mesh instrumentation into class II so that all new instrumentation will be subject to premarket notification (510(k)) requirements and special controls.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final reclassification order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) publication of a proposed order in the Federal Register; (2) consideration of comments to a public docket; and (3) meeting of a device classification panel described in section 513(b) of the FD&C Act.

The FDA completed the first step on May 1, 2014, by publishing a proposed order titled "Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair and Surgical Instrumentation for Urogynecologic Surgical Mesh Procedures; Designation of Special Controls for Urogynecologic Surgical Mesh Instrumentation." In this proposed order, the FDA proposed to reclassify (1) surgical mesh indicated for transvaginal POP repair from class II to class III and (2) urogynecologic surgical mesh instrumentation from class I to class II. The FDA also proposed to develop new regulations for these devices under Part 884, Obstetrical and Gynecological Devices.

The FDA received public comments regarding the urogynecologic surgical mesh instrumentation reclassification as part of the May 1, 2014, 513(e) proposed order, satisfying the second step of the reclassification process. The FDA will complete the third step of the reclassification process by convening the Panel on February 26, 2016.

[Please note that the Obstetrics and Gynecology Medical Devices Advisory Committee Panel discussed the proposed reclassification of surgical mesh indicated for transvaginal POP repair on September 8, 2011. The FDA reclassified surgical mesh indicated for transvaginal POP repair to class III in a final order dated January 5, 2016.]

The FDA received thirteen public comments related to reclassification of urogynecologic surgical mesh instrumentation following publication of the May 1, 2014 513(e) proposed order as follows:

- Six comments from patients supported reclassification for urogynecologic surgical mesh instrumentation to class II or class III.
- One comment from a consumer group requested that urogynecologic surgical mesh instrumentation have the same classification as the surgical mesh device with which it is indicated to be used.
- Three comments from consumer groups (Patient, Consumer & Public Health Coalition, National Center for Health Research, and the Consumers Union) supported reclassification for urogynecologic surgical mesh instrumentation to class II.
- Two comments from clinical organizations (American College of Obstetricians and Gynecologists and the American Urogynecologic Society) supported reclassification for urogynecologic surgical mesh instrumentation to class II.
- One comment from industry (American Medical Systems) stated that the scope of instrumentation reclassification was unclear, and it appeared the reclassification could apply to

instrumentation used for POP repair or to instruments used for all urogynecologic surgical mesh procedures. The comments also stated that data provided to support instrumentation reclassification was based on POP procedures, valid scientific evidence had not been provided to support instrumentation reclassification, and no evidence was provided to support identified risks. The comment further stated that the proposed order should be withdrawn until Panel input was obtained.

Regarding the comment from a consumer group requesting that urogynecologic surgical mesh instrumentation have the same classification as the surgical mesh device with which it is indicated to be used, the FDA believes that classification of accessory devices should reflect the risks of the accessory device when used as intended and the level of regulatory controls necessary to assure safety and effectiveness. Accessory devices can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class. The FDA believes that the risks associated with urogynecologic surgical mesh instrumentation (accessory device) can be mitigated through special controls; and accordingly, the FDA believes class II is the most appropriate regulation for these devices. Therefore, the FDA does not believe it is appropriate to classify urogynecologic surgical mesh instrumentation in the same regulatory class as the surgical mesh with which it is intended to be used in all cases.

Regarding the comment from American Medical Systems, the scope of the reclassification is limited to urogynecologic surgical mesh instrumentation that is designed to be used with urogynecologic surgical mesh. The FDA believes that the information provided in the May 1, 2014, 513(e) proposed order and in Section IV of this executive summary provide valid scientific evidence per 21 CFR 860.7(c)(2) to support reclassification of urogynecologic surgical mesh instrumentation from class I to class II. In addition, as required by Section 513(e) of the Act, the FDA is convening a device classification panel to obtain recommendations regarding the appropriate classification for urogynecologic surgical mesh instrumentation.

IV. Summary of Clinical Evidence

Adverse events related to an urogynecologic surgical mesh procedure, and that might be attributable to the instrumentation used in the procedure, are typically submitted or described with reference to the surgical mesh and not the instrumentation. Therefore, it can be difficult to distinguish adverse events related to the urogynecologic surgical mesh instrumentation from those directly related to the surgical mesh. The FDA believes that intra-operative and peri-operative adverse events, such as organ injury and perforation, hemorrhage and bleeding, and nerve injury and pain can be reasonably attributed to the urogynecologic surgical mesh instrumentation and not the surgical mesh. The FDA believes it is unlikely the surgical mesh itself caused those adverse events.

Although the previously described adverse events are inherent to urogynecologic surgical mesh procedures, the FDA believes they can be mitigated through well designed instrumentation and appropriate labeling. In addition, the use of urogynecologic surgical mesh instrumentation may lead to adverse tissue reaction as a result of using non-biocompatible materials. It may also lead to infection due to inadequate sterilization, inadequate reprocessing procedures, or use beyond the labeled expiration date. These are general risks that apply to devices that have patient contact, are provided sterile, and are reusable; and therefore, it is challenging to identify adverse events in the MDR database and published literature specifically related to those risks.

The FDA searched the Medical Device Report (MDR) Database and the published literature for adverse events that can be reasonably attributed to urogynecologic surgical mesh instrumentation. The results of these analyses are described in the sections immediately following.

A. Medical Device Report (MDR) Database

Each year, the FDA receives several hundred thousand MDRs of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. Medical device manufacturers, importers, and device user facilities are required to report known adverse events as part of the general controls, and health care professionals, patients, and consumers are encouraged to voluntarily report adverse events. MDRs provide a qualitative snapshot of adverse events for a specific device or device type when they are being used in a "real world" setting/environment. However, it is a passive surveillance system, and therefore MDRs can contain incomplete, inaccurate, untimely, unverified, or biased data. The incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Please see **Attachment 3** for additional information regarding the MDR database and its strengths and limitations.

The FDA searched all MDRs reported from January 1, 2008, to December 2, 2015 to find those associated with urogynecologic surgical mesh instrumentation. The FDA identified MDRs that were associated with at least 1 of 9 different product codes assigned to urogynecologic surgical mesh. The FDA filtered the resulting injury and death reports using the following criteria: problem types such as bleed, hemorrhage, irritation, inflammation, obstruction, perforation, migration, laceration, and dislodgement, and device terms such as tension, correction, trocar, anchor, and needle. The FDA then removed reports that included the terms attorney and plaintiff, as such reports typically contain few details and stem from patient litigation. The FDA reviewed the results to identify those reports which described instrumentation device problems associated with the intra-operative placement of the urogynecologic surgical mesh and to conduct a detailed analysis of these MDRs. Please see **Attachment 4** for additional information regarding the MDR database search methods.

The FDA identified a total of 463 MDRs using the described search methods described above. A total of 438 MDRs were submitted by manufacturers, 14 by a user facility, and 11 were voluntary. The event types were listed as 339 malfunctions and 124 injuries. The MDRs were identified under six product codes: FTL, FTM, OTN, OTP, OTO, and PAH. **Table 1** provides the total MDR count by product code.

Product Code	Total MDR Count
OTP - Mesh, surgical, synthetic, Urogynecologic, for Pelvic Organ Prolapse, Transvaginally Placed	186
FTL - Mesh, Surgical, Polymeric	114
OTN - Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic or Transobturator	92
PAH - Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Mini-Sling	46
FTM - Mesh, Surgical	23
OTO - Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal and Uterine Prolapse, Transabdominally Placed	2

Table 1 Total MDR count by product code

Figure 3 summarizes the total MDRs received by year.

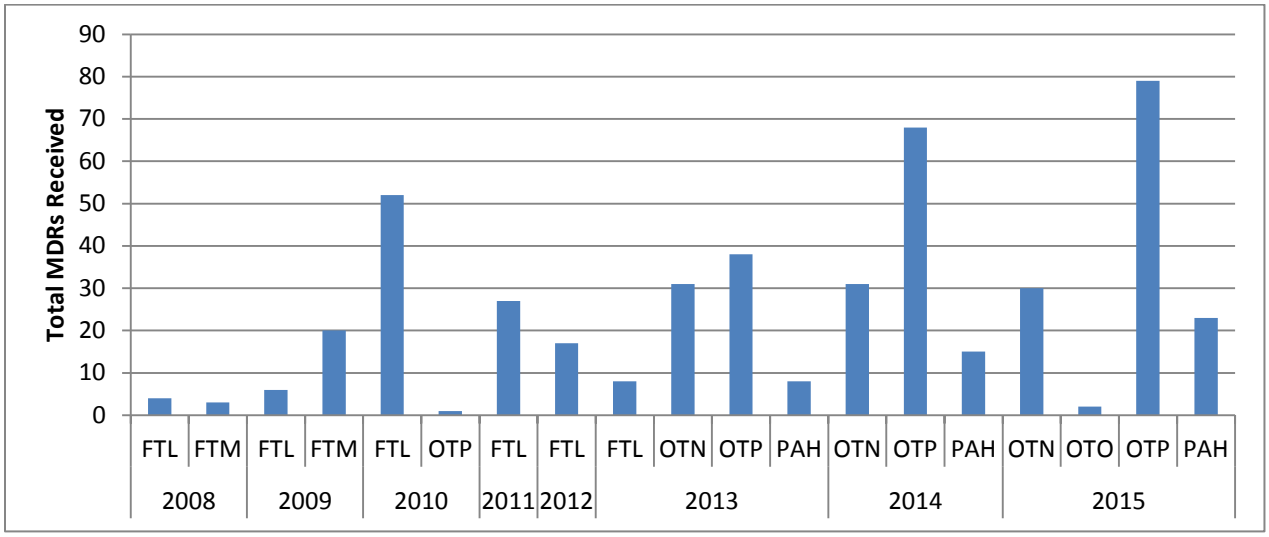


Figure 3 Total MDRs received by year and procode

Table 2 summarizes the submitted MDRs by manufacturer and brand name. Please note that the brand names listed in **Table 2** are of the surgical mesh, as the instrumentation used to implant the surgical mesh devices are often part of surgical mesh kits. Identification of specific instruments associated with the problems reported in the MDRs is discussed later in this executive summary.

Manufacturer and Brand Name	MDR Count
AMERICAN MEDICAL SYSTEMS, INC.	**12**
AMS ELEVATE ANTERIOR PROLAPSE REPAIR SYSTEM WITH INTEPRO LITE	4
AMS MONARC SLING SYSTEM	2
AMS RETROARC RETROPUBIC SLING SYSTEM	2
AMS SPARC SLING SYSTEM	1
APOGEE SYSTEM WITH INTEXEN	1
SACRAL COLPOPEXY SYSTEM	1
MINI ARC PRECISE	1
BOSTON SCIENTIFIC CORPORATION	**316**
ADVANTAGE FIT SYSTEM	2
LYNX SYSTEM	1
OBTRYX SYSTEM	7
PINNACLE PELVIC FLOOR REPAIR KIT	134
SOLYX SIS SYSTEM	5
UPHOLD VAGINAL SUPPORT SYSTEM	167
C.R. BARD, INC.	**38**
AJUST HELICAL ADJUSTABLE SINGLE-INCISION SLING	35
ALIGHN TRANS-OBTURATOR URETHRAL SUPPORT	2
PELVILACE BIOURETHRAL SUPPORT SYSTEM	1

Manufacturer and Brand Name	MDR Count
CL MEDICAL	**1**
I-STOP	1
COLOPLAST MANFACTURING US, LLC	**6**
ALTIS	3
EXAIR ANTERIOR MESH	1
T-SLING UNIVERSAL SLING	2
ETHICON, INC.	**90**
ENDOLOOP* LIGATURE	1
GYNECARE TVT SYSTEM	65
SUTURE UNKNOWN	10
TENSION FREE VAGINAL TAPE	14
Total	**463**

Table 2 Total MDR count by manufacturer and brand name

Table 3 summarizes the patient problem codes. The FDA identified 30 patient problem codes with a total of 485 reported occurrences in 463 MDRs. (A single MDR may contain more than one patient problem code.) There were 356 problem codes of "no consequence or impact to patient" or "no known impact or consequence to patient." This represented 317 out of 463 MDRs (68%). The most frequently reported patient problem code with impact to the patient was "device fragments in patient" (45).

Patient Problem	Total MDR Count
No Consequence or Impact to Patient	302
No Known Impact or Consequence to Patient	54
Device Fragments in Patient	45
No Information	21
Nonresorbable Materials, Unretrieved in body	10
Foreign Body, Removal of	8
No Code Available	6
Pain	4
Organ(s), Perforation of	3
Perforation	3
Surgery, Prolonged	3
Blood Loss	2
Foreign Body in Patient	2
Hemorrhage	2
Injury	2
No Patient Involvement	2
Surgical Procedure	2
Urinary Retention	2
Abscess	1
Dissection	1
Fever	1
Headache	1
Implant, Failure of	1

Patient Problem	Total MDR Count
Incontinence	1
Surgical Procedure, Additional	1
Surgical Procedure, Repeated	1
Test Result	1
Tissue Damage	1
Treatment with Medication(s)	1
Weakness	1

Table 3 Total number of reported patient problem codes

Table 4 summarizes the 10 most frequently cited device problem codes. The FDA identified 51 total device problem codes with a total of 616 reported occurrences in 463 MDRs (a single MDR may contain more than one device problem code). **Tables 5-12** summarize the MDRs related to device problem codes.

Device Problem	Total MDR Count
Detachment of Device, or Device Component	259
Break	141
Needle	52
Suture	40
Difficult to Insert	16
Retraction Problem	13
Other (for use when an appropriate device code cannot be identified)	11
Carrier	8
Difficult to Advance	6
Bent	5
Device or Device Fragments Location Unknown	5

Table 4 Top 10 reported device problem codes

MDRs Related to Sutures and Needles

Suture and needle issues, including detachment, break (suture and needle tip), frayed, and puncture, were listed in 265 of 463 reports (85 injury and 180 malfunction reports). Overall, needle detachment was the primary device issue reported with the majority of MDRs submitted from devices manufactured by Boston Scientific Corporation (BSC). Needle detachment and suture break was noted to occur after placement through the sacrospinous ligament or other tissues, while loading into the BSC Capio device, by failure of the Capio device or needle holder to capture the needle and/or suture, or for unknown reasons.

Other needle issues identified included bent needle tip (noted during placement attempt), broken needle tip (often noted following initial placement of device), unsterile needle tip (following the tip puncturing through package), and two reports of perforation (vaginal wall and bladder). Issues similar to those reported for needle detachment were also noted for reports related to broken sutures including: resistance when pulling the suture through the sacrospinous ligament or other tissues, or other placement issues.

Table 5 provides a summary of MDRs related to needle devices, and **Table 6** provides a summary for MDRs related to broken sutures.

Device Problem/Issue	MDR Event Types	Manufacturer	Brand Names	Product Code	MDR Total Count
Needle Detachment	Injury (54) Malfunction (84)	Boston Scientific Corporation	Pinnacle System; Uphold System; Solyx SIS System	FTL-42 FTM-3 OTP-86 PAH-2	133
		Ethicon	Unknown Suture Product	OTN-2 OTP-2 PAH-1	5
Needle Tip Bent or Broke	Injury (4) Malfunction (9)	American Medical Systems, Inc.	Elevate System	OTP-1	2
		Ethicon, Inc.	TVT System; Unknown Suture Product	OTN-6	6
		Boston Scientific Corporation	Pinnacle System; Uphold System	FTM-1 FTL-1 OTP-3	5
Needle Tip Unsterile	Malfunction (4)	Ethicon, Inc.	Gynecare TVT System	OTN-1	1
		Boston Scientific Corporation	Uphold System	OTP-3	3
Needle Perforation	Injury (2)	American Medical Systems, Inc.	Elevate System, AMS Retroarc Retropubic Sling System	OTN-1 OTP-1	2
Needle/Hook Break	Malfunction (4)	Ethicon, Inc.	Tension Free Vaginal Tape; Gynecare TVT System	OTN-2	4
		Boston Scientific Corporation	Obtryx Sling System	FTL-1	
		C.R. Bard	Ajust Single-Incision Sling	PAH-1	

Table 5 MDRs related to needle devices

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	MDR Total Count
Broken Suture	Injury (25)	Boston Scientific Corporation	Pinnacle System Uphold System	FTL-10 FTM-3 OTP-1 OTP-11	25

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	MDR Total Count
	Malfunction (79)	Boston Scientific Corporation	Pinnacle System Uphold System	FTL-35 FTM-4 OTP-5 OTP-29	73
		Ethicon, Inc.	Unknown Suture Product Endoloop Ligature Gynecare TVT System	OTN-1 OTO-1 PAH-1 OTO-1	4
		Coloplast Manufacturing US, LLC	Altis Single Incision Sling System	PAH-1	1
		American Medical Systems, Inc.	Sacral Colpopexy System	OTN-1	1

Table 6 MDRs related to broken suture

MDRs Related to Cover Sheath and Needle Passer Insertion Tool

Covering sheath and needle passer/insertion tool (often referred to as a trocar) issues including break, detachment, retained, bent tip, and other miscellaneous problems were listed in 70 of the 463 MDRs (15 injury and 55 malfunction reports). The primary manufacturer which listed these issues was Ethicon, Inc. with 55 MDRs. The primary device issue noted was the break or tearing of the covering sheath during placement of the device. All but three of the MDRs noted that the procedure was completed either with the same or second device. Where noted, patient outcomes were reported as "with no adverse patient consequence." Of the device issues which noted a retained covering sheath, it was reported that a portion was left in two patients, another patient needed further dissection to remove the broken portion, and the fourth patient required a laparoscopic procedure for removal of the retained sheath. The miscellaneous needle passer/insertion tool issues noted included the connector/tubing between the needle passer and mesh breaking off, cracking of the tubing that is connected to the needle passer/insertion tool and mesh, difficulty experienced by the physician to maneuver the needle passer/insertion tool, and wire noted protruding through the needle passer/insertion tool upon insertion.

Table 7 summarizes the MDRs related to the covering sheath, and **Table 8** summarizes the MDRs related to the needle passer/insertion tool (trocar).

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	Total MDR Count
Covering Sheath Break/Torn	Injury (4)	American Medical Systems, Inc.	AMS Sparc Sling System	OTN-1	1
		Ethicon, Inc.	Gynecare TVT System	OTN-2`	2

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	Total MDR Count
		Coloplast Manufacturing US, LLS	T-Sling System	OTN-1	1
	Malfunction (29)	Ethicon, Inc.	Tension Free Vaginal Tape Gynecare TVT System	FTL-2 OTN-1 OTN-24	29
		C.R. Bard, Inc.	Align Transobturator Urethral Support System	OTN-1	
		Coloplast Manufacturing US, LLC	T-Sling System	OTN-1	
Covering Sheath Retained	Injury (5)	Ethicon, Inc.	Gynecare TVT System	OTN-2 FTL-1	5
		Boston Scientific Corporation	Obtryx Mesh System Pinnacle System	FTL-1 FTM-1	
Covering Sheath Detached	Injury (2)	Boston Scientific Corporation	Pinnacle System	FTL-1	2
		American Medical Systems, Inc.	Apogee System	FTL-1	
	Malfunction (1)	Ethicon, Inc.	Tension Free Vaginal Tape	OTN-1	1
Covering Sheath Kinks	Malfunction (2)	Ethicon, Inc.	Gynecare TVT System	OTN-2	2

Table 7 MDRs related to covering sheath

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	Total MDR Count
Needle Passer/Insertion Tool (Trocar) Tip Break	Injury (3) Malfunction (12)	Ethicon, Inc.	Tension Free Vaginal tape	OTN-8 FTL-5	15
		American Medical Systems, Inc.	Elevate System AMS Monarc Sling System	OTP-1 OTN-1	
Needle Passer/Insertion Tool (Trocar) Bent	Malfunction (6)	Ethicon, Inc.	Gynecare TVT System	OTN-5	6
		Boston Scientific Corporation	Advantage Fit System	OTN-1	
Miscellaneous Needle	Injury (1) Malfunction (4)	Coloplast Manufacturing	Exair Anterior Mesh	OTP-1	5

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	Total MDR Count
Passer/Insertion Tool (Trocar) Issues		US, LLC			
		Ethicon, Inc.	Gynecare TVT	OTN-2	
		C.R. Bard, Inc.	Pelvilace Biourethral Support System	FTL-1	
		Boston Scientific Corporation	Obtryx Halo System	FTL-1	
Needle Passer/Insertion Tool (Trocar) Pierced Sheath	Malfunction (1)	Ethicon, Inc.	Gynecare TVT System	OTN-1	1

Table 8 MDRs related to needle passer/insertion tool (trocar)

MDRs Related to Capio Needle

Device issues with the Capio needle were listed in 45 of the 463 MDRs, with 8 injury and 37 malfunctions reports. Device issues included failure to catch or pass the needle during mesh insertion; device would not retract during use or locked during use, and break of the device or handle during use. One report stated that the surgeon felt the device was "unstable" and the patient's urethra was perforated during the initial implant. No further information was reported with that event. Overall the procedures were completed with the opening of another device when necessary and there were no adverse patient consequences reported, other than the urethra perforation and one complaint of urinary retention.

Table 9 summarizes the MDRs related to the Capio needle.

Device Problem/Issue	MDR Event Type	Manufacturer	Brand Name	Product Code	Total MDR Count
Capio/Needle Holder Failure	Injury (5) Malfunction (25)	Boston Scientific Corporation	Uphold System Pinnacle System	OTP-23 OTN-2 FTL-2 FTM-2	30
		American Medical Systems, Inc.	AMS Retroarc Retropubic Sling System	OTN-1	
Capio/Needle Holder Break	Malfunction (8)	Boston Scientific Corporation	Uphold System	OTP-8	8
Capio/Needle Holder Bent	Injury (3) Malfunction (4)	Boston Scientific Corporation Boston Scientific Corporation	Uphold System Pinnacle System Uphold System	OTP-3 FTM-2` OTP-2	7

Table 9 MDRs related to Capio needle

MDRs Related to Introducer/Dilator

Introducer/dilator device issues were noted in 33 of 463 MDRs; with 10 injuries and 23 malfunction reports. Device issues of break, detachment, and "bunched" were noted following passage through the sacrospinous ligament, when an increased insertion force was needed (especially when resistance was encountered during the initial placement of the dilator/introducer), and after initial placement of the device.

Table 10 summarizes the MDRs related to introducer/dilator devices.

Device Problem/Issues	**MDR Event Type**	**Manufacturer**	**Brand Name**	**Product Code**	**Total MDR Count**
Introducer/Dilator Break	Injury (3) Malfunction (9)	Coloplast Manufacturing US, LLC	Altis Single Incision Sling System	PAH-2	12
		Boston Scientific Corporation	Uphold System	OTP-1	
		Ethicon, Inc.	Gynecare TVT System Tension Free Vaginal Tape	OTN-5 FTL-1	
		Boston Scientific Corporation	Pinnacle System Uphold System	FTM-2 OTP-1	
Detached Dilator	Injury (3) Malfunction (4)	Boston Scientific Corporation	Pinnacle System Obtryx System Lynx System	FTL-4 FTM-1 OTN-2	7
Dilator Kinked/ Bunched	Injury (4) Malfunction (3)	Boston Scientific Corporation	Pinnacle System	FTL-3 FTM-4	7
Bent Introducer	Malfunction (4)	Ethicon, Inc.	Gynecare TVT System	OTN-4	4
Introducer Punctured Sheath	Malfunction (3)	Ethicon, Inc. Boston Scientific Corporation	Gynecare TVT System Advantage Fit System	OTN-2 OTN-1	3

Table 10 MDRs related to introducer/dilatordevices

MDRs Related to Anchor Devices

Anchor device issues including break and detachment were noted in 31 of 463 MDRs with 30 malfunction and 1 injury report. All but one report listed C.R. Bard as the manufacturer. Anchor break was the primary device issue noted (n=27). Anchor breaks were noted during the procedure/initial implant attempt, after implant and during anchor fixation, and after completion of anchor fixation.

Table 11 summarizes the MDRs related to anchoring devices.

Device Problem/Issues	**MDR Event Type**	**Manufacturer**	**Brand Name**	**Product Code**	**Total MDR Count**
Anchor Break	Injury (1)	C.R. Bard, Inc.	Ajust Single Incision Sling	PAH-1	1
	Malfunction (26)	C.R. Bard, Inc.	Ajust Single Incision Sling Align Transobturator Urethral Support	PAH-25 OTN-1	26
Anchor Detachment	Malfunction (3)	C.R. Bard, Inc.	Ajust Single Incision Sling	PAH-3	3
	Malfunction (1)	AMS	Mini Arc Precise	PAH-1	1

Table 11 MDRs related to anchoring devices

MDRs Related to Miscellaneous Device Problems

Miscellaneous device issues were seen in 10 of 463 MDRs: 5 injury and 5 malfunction reports. Device issues included: the fixation end was noted broken after device placement, connector tube noted damaged during procedure, device detached after placement, and difficulty with device placement following multiple attempts (heavy bleeding due to trauma was noted). Urethral perforation (procedure was not completed), prolonged surgery, bleeding, and urinary retention were several patient complaints noted with these reported issues. Deployment issues were seen in 9 of 463 MDRs with all reports listed as malfunctions. Device issues included: lever did not release prior to insertion, delivery device would not release anchoring tip following insertion, bullet was noted distorted and would not deploy the device, mesh loop detached from the assembly during placement, and mesh assembly misfired during initial placement.

Table 12 summarizes the MDRs related to miscellaneous/deployment issues.

Device Problem/Issues	MDR Event Type	Manufacturer	Brand Name	Procode	Total MDR Count
Miscellaneous Issues	Injury (5)	Ethicon, Inc.	Gynecare TVT System	OTN-1	5
		Boston Scientific Corporation	Pinnacle System Uphold System	OTP-2	

Device Problem/Issues	MDR Event Type	Manufacturer	Brand Name	Procode	Total MDR Count
		American Medical Systems, Inc.	AMS Monarc Sling System	OTN-1	
		C.R. Bard, Inc.	Ajust Single-Incision Sling	PAH-1`	
	Malfunction (5)	C.R. Bard, Inc.	Ajust Single-Incision Sling	PAH-3`	5
		Ethicon, Inc.	Gynecare TVT System	OTN-2	
Deployment Issues	Malfunction (9)	Boston Scientific Corporation	Solyx SIS System Uphold System Obtryx System	PAH-3` OTP-2 FTL-2	9
		C.R. Bard, Inc.	Ajust Single Incision Sling	PAH-1	
		CL Medical	I-Stop	OTN-1	

Table 12 MDRs related to miscellaneous/deployment issues

Manufacturers' Conclusions

Table 13 summarizes the manufacturers' conclusions provided in the MDRs.

Manufacturer Conclusion	Total MDR Count
Device not Returned	231
Unable to Confirm Complaint	161
Conclusion not yet Available-Evaluation in Progress	92
Operational Context Caused or Contributed to Event	73
Other (code unspecified)	32
Device Failure Occurred and was Related to Event	21
Device Discarded by User, Unable to Follow-Up	13
Human Factors Issue	7
Use Error Caused or Contributed to Event	7
No Device Failure	5
Device Failure Occurred by not Related to Event	4
Operational Context Caused Event	4
Use Error Caused Event	3
Design Deficiency	1
Device Was Out of Specification in a Manner That Relates to Event	1
Erroneous Data	1
Invalid Data	1
Known Inherent Risk of Procedure	1
Manufacturing Deficiency	1

Table 13 Manufacturer conclusion

For those reports where the device was not returned or the manufacturers stated they were unable to confirm the complaint, the reports did not include information which aided in the analysis as to the cause of the reported problems.

For 39 of the 92 reports which listed that the device evaluation was still in progress at the time of initial MDR submission, supplemental reports were later submitted with an analysis result. The manufacturers' responses in such cases included:

- "the most probable root cause classification is operational context"
- "the complaint is associated with a product that meets the design and manufacturing specification but due to anatomical/procedural factors encountered during the procedure, performance was limited"
- "a root cause classification of handling damage indicates the complaint was caused by handling of the device or portion of the device without direct patient contact"
- "the device history record review found the device met all manufacturing specifications"
- Re-stating the device's Instructions for Use with warnings and contraindications address the proper use of the device, and possibly problems that may be encountered if not adhered to

One supplement report for an Uphold Lite device manufactured by Boston Scientific Corporation stated that a possible supplier manufacturing issue of improper crimping of the suture may be related to the reported event of the suture detaching from the needle. The supplier has completed an investigation to address this issue. Additionally, a review of the device history was performed with no anomalies noted.

The manufacturing conclusion, "device failure occurred and was related to event", was provided in MDRs following a visual analysis of returned product and confirmed the original complaint such as: "tip of used needle was found bent and broken", "tip of needle was damaged", "tip of trocar sheath broke", and "sheath around mesh was broken." Additionally "batch met all finished goods release criteria" was also provided in a number of the supplemental reports as a manufacturing conclusion statement.

The MDR listing "device was out of specification in a manner that relates to event" as a conclusion involved a bent needle tip from a Tension Free Vaginal Tape device manufactured by Ethicon, Inc. The manufacturer additionally stated that the "batch met all finished goods release criteria."

The MDR which listed "design deficiency" as a conclusion involved an Uphold Lite device manufactured by Boston Scientific Corporation. The manufacturer stated that the most probable root cause for the event of "Capio device would deploy at a slight angle" was "design." Further analysis for needle detachment could not be determined. Additionally, the manufacturer stated that the device history record review found that the device met all manufacturing specifications.

The MDR which listed "manufacturing deficiency" as a conclusion involved a needle detachment from a Boston Scientific Corporation Uphold Lite device. It was further stated in the report that the conclusion was not yet available as the evaluation was still in progress.

FDA Conclusions

Based on the information provided in the MDR database, the FDA draws the following conclusions:

- Boston Scientific Corporation (n=316) and Ethicon Inc. (n=90) were the two manufacturers which had the highest number of MDRs.
- The top reported instrumentation problems were issues noted with the suture and needle detaching or breaking. These two device issues were seen predominantly with Boston Scientific Corporation's two products, the Pinnacle and Uphold Systems.
- Other instrumentation problems included issues with the covering sheath either tearing or "breaking" during device placement, primarily noted with Ethicon, Inc.'s Gynecare TVT System, and the Capio/Needle holder failing to capture or pass the needle during mesh insertion (all but one seen with Boston Scientific Corporation's Uphold and Pinnacle Systems).
- Additional instrumentation issues included anchor breaks noted with the Ajust Sling System manufactured by C.R. Bard, Inc., introducer/dilator breaks and "kinking/bunching," as well as deployment of various mesh components.
- "Device fragments in patient" can be clinically significant in that device fragments left inside a patient may not be retrieved or found, possibly leading to a need for later surgical retrieval if the fragment(s) lead to patient problems. Even when identified and retrieved during the initial mesh implant procedure, there is typically an increase in overall surgical time.
- The devices were reported as not returned in 231 MDRs; therefore, a thorough analysis and determination of likely contributing cause(s) could not be completed for the reported events. Additionally, the manufacturer conclusion in 161 reports was listed as "unable to confirm complaint," again not providing a possible or likely cause for the reported event.
- Of the reports which listed that an evaluation was in progress at the time of initial MDR submission, only one MDR, involving the Uphold Lite Device manufactured by Boston Scientific Corporation, stated that a design issue was the most probable cause for the event, with no further information provided.
- The primary patient problem code, "no consequence or impact to patient/no known impact or consequence to patient" was listed in 317 out of 463 MDRs (68%), indicating that in the majority of reports, the device problems experienced did not lead to significant adverse patient consequences.

Overall, the FDA believes the MDR data demonstrate that failures of urogynecologic surgical mesh instrumentation occur and have the potential to adversely affect patients. These data support the need for well-designed instrumentation evaluated to ensure adequate performance, specifications, and labeling.

B. Published Literature

The FDA completed a literature search on December 8, 2015 using the PubMed and Embase online databases. The search criteria consisted of a combination of terms related to adverse events (type, timing with respect to surgery), type of urogynecologic condition, type of surgical instrumentation, study design, device name, and manufacturer name. This search resulted in 255 references. These references were analyzed if they evaluated human subjects, were written in English, and were published between 1997 and 2015. References were excluded from the study if they evaluated male subjects, included only information on non-primary procedures, did not include a discussion of intraoperative and perioperative

adverse events, included previously published data already included in the literature review, or were case reports or review articles. Following application of the inclusion and exclusion criteria, a total of 207 references remained. Please see **Attachment 5** for additional information regarding the methods used to search the published literature.

The FDA reviewed references that included the following urogynecologic procedures:

- SUI – retropubic procedure (n=74)
- SUI – tranobturator procedure (n=65)
- SUI – mini-sling procedure (n=32)
- POP – transvaginal repair (n=33)
- POP – sacrocolpopexy (n=3)

The FDA extracted data from the published literature for three major categories of adverse events related to urogynecologic surgical mesh instrumentation:

- Organ perforation and injury
- Vascular injury and bleeding
- Nerve injury and pain

Organ perforation and injury includes adverse events captured in the literature as organ perforation, organ injury, urethral injury, ureteral injury, bladder injury, bladder perforation, rectal injury, cystotomy, and enterotomy. Please see **Attachment 6** for a table of organ perforation and injury outcomes from the published literature.

For adverse events related to **organ perforation and injury**:

- **SUI, retropubic procedures**: 54 of 74 references reported adverse events, with rates between 0.3-23.8%. Bladder perforation appeared to be the most common adverse event in this category.
- **SUI, transobturator procedures**: 25 of 65 references reported adverse events, with rates between 0.2-5.8%.
- **SUI, mini-sling**: 6 of 32 references reported adverse events, with rates between 0.2-2.6%.
- **POP, transvaginal repair**: 16 of 33 references reported adverse events, with rates between 0.7-13.1%.
- **POP, sacrocolpopexy**: 1 of 3 references reported adverse events, with a rate of 3.6%.

Vascular injury and bleeding include adverse events such as hemorrhage, vascular injury, hematoma, and blood transfusion. Please see **Attachment 7** for a table of vascular injury and bleeding outcomes from the published literature.

For adverse events related to **vascular injury and bleeding**:

- **SUI, retropubic procedures**: 38 of 74 references reported adverse events, with rates between 0.4-29.4%.
- **SUI, transobturator procedures**: 19 of 65 references reported adverse events, with rates between 0.2-11.9%.

- **SUI, mini-sling**: 6 of 32 references reported adverse events, with rates between 1.0-20.5%.
- **POP, transvaginal repair**: 15 of 33 references reported adverse events, with rates between 0.7-7.7%.
- **POP, sacrocolpopexy**: 1 of 3 references reported adverse events, with a rate of 2.8%.

Nerve injury and pain events include adverse events such as nerve injury, nerve damage, leg pain, thigh pain, buttock pain, and neurological symptoms. Please see **Attachment 8** for a table of vascular injury and bleeding outcomes from the published literature.

For adverse events related to **nerve injury and pain**:

- **SUI, retropubic procedures**: 5 of 74 references reported adverse events, with rates between 0.1-5.3%.
- **SUI, transobturator procedures**: 11 of 65 references reported adverse events, with rates between 0.8-30.8%.
- **SUI, mini-sling**: 5 of 32 references reported adverse events, with rates between 1.1-4.1%.
- **POP, transvaginal repair**: 15 of 33 references reported adverse events, with rates between 6.0-39.1%.
- **POP, sacrocolpopexy**: 1 of 3 references reported adverse events, with a rate of 14.9%.

Overall, the review of the published literature demonstrates that adverse events can occur as a result of urogynecologic surgical mesh instrumentation and at potentially high rates. These data support the need for well-designed instrumentation evaluated to ensure adequate performance, specifications, and labeling.

V. Risks to Health and Proposed Mitigations

In the May 1, 2014 513(e) proposed order, the FDA identified the following risks to health associated with urogynecologic surgical mesh instrumentation:

1. *Perioperative risks*. Organ perforation or injury and bleeding (including hemorrhage/hematoma).

2. *Damage to blood vessels, nerves, connective tissue, and other structures*. This may be caused by improperly designed and/or misused surgical mesh instrumentation. Clinical sequelae include pelvic pain and neuromuscular problems.

3. *Adverse tissue reaction*. This may be caused by non-biocompatible materials.

4. *Infection*. This may be due to inadequate sterilization and/or reprocessing instructions or procedures.

The FDA is seeking Panel input on the identified risks to health for urogynecologic surgical mesh instrumentation. The Panel should assess whether this list completely and accurately identifies the risks to health presented by urogynecologic surgical mesh instrumentation and whether any other risks should be included in the overall risk assessment of the device type.

Table 14 lists the identified risks to health associated with urogynecological surgical mesh instrumentation and the proposed special controls to mitigate them.

Identified Risk	Special Controls
Perioperative injury	Non-clinical performance testing[2] Labeling Shelf life testing
Damage to blood vessels, nerves, connective tissue, and other structures[1]	Non-clinical performance testing[2] Labeling Shelf life testing
Adverse tissue reaction	Biocompatibility
Infection	Sterilization validation Reprocessing validation[3] Shelf life testing Labeling

[1] This risk was identified as "pelvic pain and neuromuscular problems" in the proposed order.
[2] This special control was described as "bench and/or cadaver testing" in the proposed order.
[3] Reprocessing validation was not identified as a special control in the proposed order.

Table 14 Health risks and mitigation measures for urogynecologic surgical mesh instrumentation

Per **Table 14**, the FDA believes that the risks to health associated with urogynecologic surgical mesh instrumentation can be mitigated through the special controls. The FDA does not believe the general controls alone are sufficient to mitigate the risks associated with urogynecologic surgical mesh instrumentation.

VI. Proposed Classification and Special Controls

The FDA has determined that valid scientific evidence demonstrates that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for urogynecologic surgical mesh instrumentation. Accordingly, the FDA believes that urogynecologic surgical mesh instrumentation should be classified from class I to class II (special controls).

The FDA is seeking Panel input on the proposed reclassification of urogynecologic surgical mesh from class I to class II. The Panel should assess whether general controls alone or the combination of general and special controls are needed to provide reasonable assurance of safety and effectiveness of urogynecologic surgical mesh instrumentation.

The FDA believes that the following special controls, in addition to general controls, are sufficient to mitigate the risks to health attributable to urogynecologic surgical mesh instrumentation:

- The device must be demonstrated to be biocompatible;
- The device must be demonstrated to be sterile, including adequate reprocessing for reusable devices;
- Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;

- Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and
- Labeling must include:
    - Information regarding the mesh design that may be used with the device;
    - Detailed summary of the clinical evaluations pertinent to use of the device;
    - Expiration date; and
    - Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.

The FDA believes the risk of adverse tissue reaction as a result of using non-biocompatible materials can be mitigated by biocompatibility testing.

The FDA finds that the risk of infection due to inadequate sterilization and/or reprocessing instructions/procedures can be mitigated through sterilization validation, reprocessing validation, and the inclusion of validated reprocessing instructions in the device labeling.

The FDA believes that shelf life testing and inclusion of an expiration date on the labeling will mitigate the risk of infection by ensuring that the device maintains its sterility over the duration of its shelf life. Shelf life testing demonstrating that the device maintains its functionality over the duration of its shelf life will also mitigate damage to blood vessels, nerves, connective tissue, and other structures, and perioperative risks. The expiration date is intended to prevent use of the device after its validated shelf life.

The FDA believes that bench and/or cadaver testing can help ensure that urogynecologic surgical mesh instrumentation is appropriately designed and limits damage to blood vessels, nerves, connective tissue, and other structures. Such evaluation may help limit the adverse events, such as perioperative injury (organ perforation or injury and bleeding), pelvic pain, and neuromuscular problems. In addition, labeling specifying the mesh type that may be used with the device and provision of a detailed summary of the clinical evaluations pertinent to use of the device will also mitigate these risks.

In addition, the FDA believes that the sale, distribution, and use of urogynecologic surgical mesh instrumentation should be restricted to prescription use in accordance with 21 CFR 801.109.

If the Panel finds that class II regulatory controls are needed to provide reasonable assurance of safety and effectiveness for urogynecologic surgical mesh instrumentation, the FDA seeks Panel input on the proposed special controls for urogynecologic surgical mesh instrumentation. The Panel should assess whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are needed.

VII. Proposed Regulation

The FDA proposes to add the following regulation to Subpart E for Part 884, Obstetrical and Gynecological Devices. As described in Table 14, the following special controls have been revised from those included in the May 1, 2014 513(e) proposed order.

§ 884.4910 Specialized surgical instrumentation for use with urogynecologic surgical mesh.

(a) *Identification*. Surgical instrumentation for use with surgical mesh for urogynecological procedures is a prescription device used to aid in insertion, placement, fixation, or anchoring of surgical mesh for procedures including transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of such surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors. This device does not include manual gastroenterology-urology surgical instrument and accessories (§ 876.4730) nor manual surgical instrument for general use (§ 878.4800).

(b) *Classification*. Class II (special controls). The special controls for this device are:
- (1) The device must be demonstrated to be biocompatible;
- (2) The device must be demonstrated to be sterile, including adequate reprocessing for reusable devices;
- (3) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;
- (4) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and
- (5) Labeling must include:
  - (i) Information regarding the mesh design that may be used with the device;
  - (ii) Detailed summary of the clinical evaluations pertinent to use of the device;
  - (iii) Expiration date; and
  - (iv) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.

VIII. Conclusion

The FDA proposes that urogynecologic surgical mesh instrumentation are reclassified from class I to class II with special controls and be subject to premarket notification requirements. The FDA also recommends a new regulation for these devices under Subpart E of Part 884, Obstetrical and Gynecological Devices.

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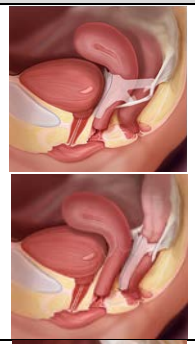
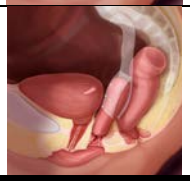
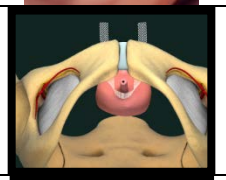
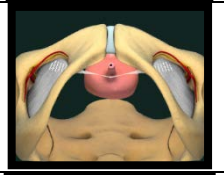
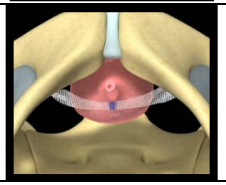
Attachment 1 – Overview of Urogynecologic Surgical Mesh

Procedure	Device Description	Placement of Mesh
Transvaginal prolapse repair	Typically pre-configured to repair specific vaginal compartment (apical, anterior, posterior, total)	
Abdominal prolapse repair (Sacrocolpopexy)	"Y-shaped"; typically sutured to anterior and posterior vaginal wall and to sacral promontory	
Retropubic sling for treatment of stress urinary incontinence	"Tape" ~40 cm x ~1 cm; no tissue anchors; typically requires three incisions (1 vaginal and 2 abdominal)	
Transobturator sling for treatment of stress urinary incontinence	"Tape" ~40 cm x ~1 cm; no tissue anchors; typically requires three incisions (1 vaginal and 2 upper thigh/groin)	
Mini-sling for treatment of stress urinary incontinence	"Tape" ~10 cm x ~1 cm; typically includes tissue anchors; typically single-incision (1 vaginal)	

Attachment 2 –Classification and Regulation of Medical Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act; 21 U.S.C.360c) establishes three categories (classes) of devices, reflecting the risks to health posed by the devices and the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act provides the following definitions for each class:

(A) CLASS I, GENERAL CONTROLS

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS

A device which cannot be classified as a Class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL

A device which because

(i) it (I) cannot be classified as a Class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a Class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness."

In summary, general controls apply to all three device classes and include, for example, establishment registration and device listing with the FDA, requirements for reporting and keeping records of adverse events, and compliance with the Quality System regulation (21 CFR 820).

Special controls apply only to class II devices. Special controls may include one or more of the following:

- specific labeling information
- premarket studies, e.g., bench studies, animal studies, clinical studies
- performance standard(s)
- guidelines (formerly special control guidance documents)
- postmarket surveillance
- patient registry

Class III devices are subject to an independent assessment of safety and effectiveness during premarket review. This includes the following premarket and postmarket controls:

- Premarket submission of valid scientific evidence to allow FDA to determine reasonable assurance of safety and effectiveness of the device as described in 21 CFR 860.7.
- Premarket review of manufacturing information and pre-approval manufacturing inspection
- Post-approval studies to obtain long-term and real-world safety and effectiveness data (if needed)
- Annual reporting
- Postmarket device and labeling changes must be reported to FDA (significant changes require approval by the FDA prior to implementation)

Attachment 3 – Overview of the MDR Database and its Strengths and Limitations

The MDR database is maintained by the Office of Surveillance and Biometrics. This database contains adverse events and reportable product problems with medical devices. The database was fully implemented in August 1996 and contains individual adverse event reports submitted by manufacturers, user facilities, importers, and voluntary reporters. Medical device manufacturers, importers, and device user facilitates are required to report known adverse events as part of the general controls, and health care professionals, patients, and consumers are encouraged to voluntarily report adverse events.

Each year, the FDA receives several hundred thousand MDRs of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

MDRs provide a qualitative snapshot of adverse events for a specific device or device type when they are being used in a "real world" setting/environment, including rare, serious, or unexpected adverse events, adverse events that occur during long-term device use, adverse events associated with vulnerable populations, off-label use, and use errors.

However, it is a passive surveillance system, and therefore MDRs can contain incomplete, inaccurate, untimely, unverified, or biased data. The incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. As such, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.

Other limitations of MDRs include but are not necessarily limited to:

- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
- Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MDR data is subjected to reporting bias, attributable to potential causes such as reporting practice, increased media attention, and/or other agency regulatory actions.
- MDR data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.

Attachment 4 – MDR Database Search Methods

The FDA searched the MDR database on December 3, 2015 using the dates of January 1, 2008 to December 2, 2015 and the following procodes:

- OTN – Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic or Transobturator
- OTO – Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal and Uterine Prolapse, Transabdominally Placed
- OTP – Mesh, surgical, synthetic, Urogynecologic, for Pelvic Organ Prolapse, Transvaginally Placed
- PAG – Mesh, Surgical, Non-Synthetic, Urogynecologic, for Stress Urinary Incontinence, Retropubic or Transobturator
- PAH – Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Mini-Sling
- PAI – Mesh, surgical, Non-Synthetic, Urogynecologic, for Pelvic Organ Prolapse, Transvaginally Placed
- PAJ – Mesh, Surgical, Non-Synthetic, Urogynecologic, for Apical Vaginal and Uterine Prolapse, Transabdominally Placed
- FTL – Mesh, Surgical, Polymeric
- FTM – Mesh, Surgical

The FDA filtered the latter two product codes using brand names previously identified as being urogynecologic surgical mesh.

The FDA filtered the resulting injury and death reports using the following criteria: problem types such as bleed, hemorrhage, irritation, inflammation, obstruction, perforation, migration, laceration, and dislodgement, and device terms such as tension, correction, trocar, anchor, and needle. The FDA then removed reports that included the terms attorney and plaintiff, as such reports typically contain few details and stem from patient litigation. The FDA included all malfunction reports for further individual review.

The FDA reviewed the results to identify those reports which described instrumentation device problems associated with the intra-operative placement of the urogynecologic surgical mesh and to conduct a detailed analysis of these MDRs.

The completed analysis for urogynecologic surgical mesh instrumentation applied a number of filters for device problem codes and specific text terms to narrow the initial search results to those MDRs that were most likely to be relevant to instrumentation and not the surgical mesh devices themselves. It is possible that some MDRs that may involve instrumentation were not identified in the final data set used in the analysis. However, the FDA does not expect the number of any such reports to be significant and does not believe that their possible exclusion will alter the analysis, findings and observations in any significant way.

Attachment 5 – Published Literature Search Methods

The FDA completed a literature search on December 8, 2015 using the PubMed and Embase online databases. The search criteria consisted of a combination of terms related to adverse events (type, timing with respect to surgery), type of urogynecologic condition, type of surgical instrumentation, study design, device name, and manufacturer name. This search resulted in 255 references.

References were included if they evaluated human subjects, were written in English, and were published between 1997 and 2015. References were excluded from the study if they evaluated male subjects, included only information on non-primary procedures, did not include a discussion of intraoperative and perioperative adverse events, or were case reports or review articles. Following application of the inclusion and exclusion criteria, a total of 207 references remained.

The following data elements were extracted from the references:

- Author
- Year
- Reference Type (Randomized Clinical Trial, Retrospective Review, Case series, Review Article, etc.)
- Procedure (Sacrocolpopexy, Transvaginal POP repair (anterior), Transvaginal POP Repair (posterior), Transvaginal POP Repair (apical), Minisling, Retropubic, Transobturator, etc.)
- Multicenter study (Y, N)
- Adverse Events assessed as primary endpoint (Y, N)
- Mesh Trade Name
- Instrumentation Trade Name or Type (Examples: Capio, Trocar, Anchor)
- Number of patients at baseline
- Number of patients who underwent a procedure
- Age (in years)
- Body mass index (kg/m^2); Parity
- Follow-up duration
- Number Adverse Events for Organ perforation, Organ injury, Urethral injury, Ureteral injury, Bladder injury, Bladder perforation, Rectal injury, Hemorrhage, Vascular injury, Hematoma, Nerve injury, Nerve damage, Leg pain, Thigh pain, Buttock pain, Other pain, Abscess, Infection, Cystotomy, Enterotomy, Blood transfusion and Neurologic Symptoms; Additional Comments.

Following extraction of the above data from the references, the FDA determined three major categories of adverse events as follows:

- Organ perforation and injury
- Vascular injury and bleeding
- Nerve injury and pain

The number and percentage of these adverse events were reported for each reference that included such data.

Attachment 6 – Organ Perforation and Injury

Organ injury and perforation includes organ perforation, organ injury, urethral injury, ureteral injury, bladder injury, bladder perforation, rectal injury, cystotomy, and enterotomy.

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Stress Urinary Incontinence					
Retropubic Sling					
Andonian	2005	TVT, Sparc	84	20	23.8
Niemczyk	2001		100	23	23.0
McLennan	2012	Lynx	206	47	22.8
Campeau	2007	TVT	34	7	20.6
Stavros	2012		265	39	14.7
Tsivian	2004		55	7	12.7
Jeffry	2001		112	13	11.6
Potic	2014	TVT	30	3	10.0
Barber	2008	TVT	88	8	9.1
Ustun	2003	TVT	23	2	8.7
Zullo	2007		35	3	8.6
El-Barky	2005		25	2	8.0
Neuman	2007		75	6	8.0
Hodroff	2005	Sparc	348	27	7.8
Deffieux	2010	TVT	75	5	6.7
Kristensen	2010		778	51	6.6
Barry	2008	TVT	107	7	6.5
Minassian	2005	TVT	79	5	6.3
Liapis	2001		68	4	5.9
Guerrero	2010	TVT	72	4	5.6
Paraiso	2004	TVT	36	2	5.6
Castillo-Pino	2010	TVT	55	3	5.5
Karram	2003	TVT	350	19	5.4
Cetinel	2004		75	4	5.3
Sola	2007	TVT	76	4	5.3

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Allahdin	2004B		159	8	5.0
Pushkar	2011	TVT	207	10	4.8
Sanses	2010	TVT	279	13	4.7
Dalpiaz	2006	SPARC	43	2	4.7
Kokturk	2015		129	6	4.7
Fischer	2005	TVT	220	10	4.5
Meschia	2005	TVT	264	12	4.5
Yoon	2007		66	3	4.5
Meschia	2007		114	5	4.4
Hamer	2011	TVT	69	3	4.3
Kuuva	2002		1455	57	3.9
Gold	2007		460	18	3.9
Allahdin	2004A	TVT	179	7	3.9
Aigmuller	2014	TVT	285	11	3.9
Skriapas	2005		83	3	3.6
Houwert	2010	TVT	257	9	3.5
Meschia	2006		95	3	3.2
Jomaa	2001		32	1	3.1
Celebi	2008	TVT	563	17	3.0
Ghezzi	2005		149	4	2.7
Meltomma	2004		150	4	2.7
Tincello	2011		437	10	2.3
Gungorduk	2009	TVT	180	4	2.2
Arrabal-polo	2012	SPARC	50	1	2.0
Palomba	2013	Sparc	120	2	1.7
Lord	2006	TVT, SPARC	301	4	1.3
Luo	2014	TVT	105	1	1.0
Wang	2004	TVT	600	5	0.8
Gordon	2005		331	1	0.3
Transobturator Sling					
But	2008	TVT-O, Monarc	120	10	8.3
Abdel-Fattah	2010	TVT-O; Aris	341	23	6.7

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Barber	2006	Monarc	205	12	5.9
Bozkurt	2015		156	9	5.8
El-Hefnawy	2010	TVT, TOT	21	1	4.8
Stavros	2012		193	8	4.1
Canel	2015	TVT-O, TVT Abbrevo	100	4	4.0
Pushkar	2011	TVT-O	570	18	3.2
Poza	2008	TVT-O, Uretex	254	8	3.1
Zugor	2010		108	3	2.8
Deffieux	2010	TVT-O	74	2	2.7
Laurikainen	2007		131	3	2.3
Costa	2004	Uratape	183	4	2.2
Feng	2008	TVT-O	102	2	2.0
Sivaslioglu	2007		60	1	1.7
Barry	2008	MONARC	80	1	1.3
Cindolo	2003	Uratape	80	1	1.3
Barber	2008	Monarc	82	1	1.2
Brito	2013	Safyre	94	1	1.1
Abdel-Fattah	2006	Obtape, Aris, Obtryx, Monarc	389	4	1.0
Martinez-Franco	2015	TVT-O	108	1	0.9
Liapis	2008	Monarc, TVT-O	120	1	0.8
Fischer	2005	Monarc	220	1	0.5
Tincello	2011		238	1	0.4
Collinet	2008		984	2	0.2
Minisling					
Presthus	2012	MiniArc	38	1	2.6
Hamer	2011	TVT-Secur	64	1	1.6
Stavros	2012	MiniArc, TVT Secur, Needleless Sling, Tissue Fixation System	73	1	1.4
Moore	2013	MiniArc	142	1	0.7
Kennelly	2010	Miniarc	188	1	0.5
Tincello	2011	TVT Secur	659	1	0.2

Pelvic Organ Prolapse					
Sacrocolpopexy					
McDermott	2013	Gynemesh	56	2	3.6
Transvaginal Prolapse Repair					
Aungst	2009	Prolift	335	44	13.1
McDermott	2013	Prolift	35	3	8.6
Ganj	2009	Gynemesh	127	8	6.3
Kato	2009	Gynemesh	300	12	4.0
Cho	2012	Prolift	60	2	3.3
Demirci	2014	Prolift	43	1	2.3
Alperin	2008	Prolift	100	2	2.0
Khan	2014	Prolift	106	2	1.9
Wong	2013		1282	24	1.9
Argirovic	2010	Prolift	67	1	1.5
Mahdy	2013	Perigee	69	1	1.4
Nguyen	2012		4142	56	1.4
Wang	2013	Prolift	80	1	1.3
Bjelic-Radisic	2014	Prolift, Gynemesh, Apogee, Perigee, Seratom, Other	723	8	1.1
McLennan	2013	Prolift, Elevate	220	2	0.9
Samour	2015	Gynemesh	152	1	0.7

Attachment 7 – Vascular Injury and Bleeding

Vascular injury and bleeding includes hemorrhage, vascular injury, hematoma, and blood transfusion.

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Stress Urinary Incontinence					
Retropubic Sling					
Campeau	2007	TVT	34	10	29.4
Stavros	2012		265	72	27.2
Paraiso	2004	TVT	36	4	11.1
El-Hefnawy	2010	TVT, TOT	19	2	10.5
Andonian	2005	TVT, Sparc	84	7	8.3
Pushkar	2011	TVT	207	17	8.2
Potic	2014	TVT	30	2	6.7
Barber	2006	TVT	213	13	6.1
Ito	2011		38	2	5.3
Zugor	2010		100	5	5.0
Kuuva	2002		1455	63	4.3
Arrabal-polo	2012	SPARC	50	2	4.0
Neuman	2007		75	3	4.0
Skriapas	2005		83	3	3.6
Jeffry	2001		112	4	3.6
Lord	2006	TVT, SPARC	301	10	3.3
Kobashi	2003	Sparc, TVT	140	4	2.9
Zullo	2007		35	1	2.9
Ghezzi	2005		149	4	2.7
Barber	2008	TVT	88	2	2.3
Allahdin	2004B		159	3	1.9
Castillo-Pino	2010	TVT	55	1	1.8
Allahdin	2004A	TVT	179	3	1.7
Meschia	2005	TVT	264	4	1.5
Kristensen	2010		778	11	1.4
Meschia	2006		95	1	1.1

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Niemczyk	2001		100	1	1.0
Siddiqui	2008	Sparc	100	1	1.0
Fischer	2005	TVT	220	2	0.9
Lasala	2006	TVT	340	3	0.9
Karram	2003	TVT	350	3	0.9
Palomba	2013	Sparc	120	1	0.8
Aigmuller	2014	TVT	285	2	0.7
Tincello	2011		437	3	0.7
Meltomma	2004		150	1	0.7
Hodroff	2005	Sparc	348	2	0.6
Houwert	2010	TVT	257	1	0.4
Sanses	2010	TVT	279	1	0.4
Transobturator Sling					
Stavros	2012		193	23	11.9
Zugor	2010		108	10	9.3
Abdel-Fattah	2010	TVT-O; Aris	341	26	7.6
Bozkurt	2015		156	11	7.1
Poza	2008	TVT-O, Uretex	254	13	5.1
But	2008	TVT-O, Monarc	120	6	5.0
Tang	2014	TVT-O	48	2	4.2
Potic	2014	Herniamesh	34	1	2.9
Barber	2006	Monarc	205	6	2.9
Ito	2011		45	1	2.2
Arrabal-polo	2012	MONARC	125	2	1.6
Pushkar	2011	TVT-O	570	8	1.4
Barry	2008	MONARC	80	1	1.3
Aigmuller	2014	TOT	269	3	1.1
Martinez-Franco	2015	TVT-O	108	1	0.9
Davila	2006	Monarc	200	1	0.5
Tincello	2011		238	1	0.4
Abdel-Fattah	2006	Obtape, Aris, Obtryx, Monarc	389	1	0.3
Collinet	2008		984	2	0.2

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Minisling					
Stavros	2012	MiniArc, TVT Secur, Needleless Sling, Tissue Fixation System	73	15	20.5
Lim	2010	TVT Secur	42	3	7.1
Palomba	2013	MiniArc, TVT Secur, Adjust	120	3	2.5
Tincello	2011	TVT Secur	659	9	1.4
Tommaselli	2013	TVT Secur	77	1	1.3
Neuman	2008	TVT Secur	100	1	1.0
Pelvic Organ Prolapse					
Sacrocolpopexy					
Agarwala	2007	Gynemesh	72	2	2.8
Transvaginal Prolapse Repair					
Vaiyapuri	2012	Prolift	169	13	7.7
Ganj	2009	Gynecare	127	9	7.1
Alperin	2008	Prolift	100	4	4.0
Cho	2012	Prolift	60	2	3.3
Chen	2012	Prolift	92	3	3.3
McLennan	2013	Prolift, Elevate	220	7	3.2
Wong	2013		1282	31	2.4
Demirci	2014	Prolift	43	1	2.3
Chen	2012	Gynemesh	131	3	2.3
Bjelic-Radisic	2014	Prolift, Gynemesh, Apogee, Perigee, Seratom, Other	723	16	2.2
Takahashi	2010	Gynemesh PS	138	3	2.2
Stanford	2015	Elevate	142	3	2.1
Fatton	2007	Prolift	110	2	1.8
Sekiguchi	2014	Tissue Fixation System	60	1	1.7
Kato	2009	Gynemesh	300	2	0.7

Attachment 8 – Nerve Injury and Pain

Nerve injury and pain includes nerve injury, nerve damage, leg pain, thigh pain, buttock pain, and neurological symptoms.

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Stress Urinary Incontinence					
Retropubic Sling					
El-Hefnawy	2010	TVT, TOT	19	1	5.3
Barber	2006	TVT	213	5	2.3
Stavros	2012		265	2	0.8
Meltomma	2004		150	1	0.7
Kuuva	2002		1455	1	0.1
Transobturator Sling					
Bozkurt	2015		156	48	30.8
Feng	2008	TVT-O	102	17	16.7
Tang	2014	TVT-O	48	8	16.7
El-Hefnawy	2010	TVT, TOT	21	3	14.3
Ark	2010	Safyre	210	25	11.9
Stavros	2012		193	11	5.7
Meschia	2007		117	6	5.1
Abdel-Fattah	2010	TVT-O; Aris	341	15	4.4
Liapis	2008	Monarc, TVT-O	120	4	3.3
Barber	2006	Monarc	205	3	1.5
But	2008	TVT-O, Monarc	120	1	0.8
Minisling					
Stavros	2012	MiniArc, TVT Secur, Needleless Sling, Tissue Fixation System	73	3	4.1
Moore	2013	MiniArc	142	5	3.5
Presthus	2012	MiniArc	38	1	2.6
Tang	2014	TVT Secur	46	1	2.2
Natale	2014	Adjust	92	1	1.1
Pelvic Organ Prolapse					
Sacrocolpopexy					
Unger	2014		242	36	14.9

Author	Year	Mesh Trade Name	Number of Subjects	Number of Events	Percentage
Transvaginal Prolapse Repair					
Vaiyapuri	2012	Prolift	169	66	39.1
Jeffry	2014	Pinnacle	23	6	26.1
Ganj	2009	Gynecare	127	31	24.4
Gabriel	2010	Prolift	62	9	14.5
Lo	2010	Prolift	42	4	9.5
Alperin	2008	Prolift	100	6	6.0