



USER: JOHNSON, SHEVON E (sxj)

FOLDER: K082571 - 92 pages (FOI:09003755)

COMPANY: C.R. BARD, INC. (CRBARD)

PRODUCT: MESH, SURGICAL, POLYMERIC (FTL)

SUMMARY: Product: AVAULTA SUPPORT SYSTEM

DATE REQUESTED: Tue Nov 09 24:00:00 2010

DATE PRINTED: Fri Jan 14 06:04:01 2011

Note: Releasable Version

Table of Contents

510K SUMMARY - 5 pages	1
ADMIN - 1 pages	6
CORRESPONDENCE - 5 pages	7
ORIGINAL - 75 pages	12
REVIEWER INFORMATION - 4 pages	87

SEP 30 2008

K082571

1/2

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name: C. R. Bard, Inc.
Bard Urological Division
Address: 13183 Harland Drive
Covington, GA 30014

Contact Person: John C. Knorpp
Contact Person's Telephone Number: 678-342-4920
Contact Person's Fax: 770-788-5513

B. DEVICE NAME:

Trade Name(s): Avaulta™ Solo Support System
Avaulta™ Plus Biosynthetic Support System
Common/Usual Name: Surgical Mesh
Classification Names: 79 FTL – Mesh, Surgical, Polymeric
CFR Reference: 21 CFR 878.3300
Classification Panel: General and Plastic Surgery

C. PREDICATE DEVICE NAME:

Trade Names: Avaulta™ Solo Support System
Avaulta™ Plus Biosynthetic Support System
K063712

D. DEVICE DESCRIPTION:

The Avaulta™ Support System includes a sterile, single use, permanent implant that provides long term reinforcement to support structures in the correction of anterior or posterior vaginal wall prolapse. The central soft knit section provides compliant organ support while the strong knit arms provide improved strength for tension free fixation of the implant.

The Avaulta™ Plus Biosynthetic Support System and Avaulta™ Solo support system both utilize a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. The Avaulta™ Plus Biosynthetic Support System adds a porous, acellular, ultra-thin sheet of crosslinked collagen attached to the polypropylene mesh which serves to establish a protective barrier between mucosal tissue and

K082571
2/2

the polypropylene mesh and contains apertures uniformly sized to allow for ingrowth of host tissue and capillary vessels.

E. INTENDED USE:

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject Avaulta™ Support System has the same intended use, general design and fundamental scientific technology as the predicate device.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing to determine substantial equivalence was completed. This includes testing in accordance with *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (March 22, 1999).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2008

C.R. Bard, Incorporated
Mr. John C. Knorpp, RAC
Director, Regulatory Affairs
Bard Urological Division
13183 Harland Drive
Covington, Georgia 30014

Re: K082571
Trade/Device Name: Avaulta™ Support System
Regulation Number: 878.3300
Regulation Name: Surgical Mash
Regulatory Class: II
Product Code: FTL
Dated: September 3, 2008
Received: September 5, 2008

Dear Mr. Knorpp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082571

1.4 Indications for Use Statement

510(k) Number (if known): K082571

Device Name: Avaulta™ Support System

Indications for Use:

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Neil R. Dyck for man

Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082571

(Recommended Format 11/13/2003)

Document Cover Sheet:

K082571-K7010

FSR0801-000

Date of Submission:	03-SEP-2008
Description:	AVAULTA SUPPORT SYSTEM
Date of Scan:	20-NOV-2008
Document Prep:	TKK 11/20/08
Scanner:	TKK 11/21/08
Image Quality Reviewer:	



Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Decision Letter 30-SEP-2008	1	2	3	<input type="checkbox"/>
Indications for Use 30-SEP-2008	3	3	2	<input type="checkbox"/>
Reviewer Memorandum 30-SEP-2008	4	5	3	<input type="checkbox"/>
Reviewer Notes 19-SEP-2008	6	7	3	<input type="checkbox"/>
Acknowledgement Letter 05-SEP-2008	8	9	3	<input type="checkbox"/>
Total documents: 5				<input type="checkbox"/>
Total document pages: 9				<input type="checkbox"/>
Total separator pages: 5				<input type="checkbox"/>
Total Scan pages: 15				<input type="checkbox"/>

QC Signature _____

QC Bar Code Sticker



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2008

C.R. Bard, Incorporated
Mr. John C. Knorpp, RAC
Director, Regulatory Affairs
Bard Urological Division
13183 Harland Drive
Covington, Georgia 30014

Re: K082571
Trade/Device Name: Avaulta™ Support System
Regulation Number: 878.3300
Regulation Name: Surgical Mash
Regulatory Class: II
Product Code: FTL
Dated: September 3, 2008
Received: September 5, 2008

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Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.4 Indications for Use Statement

510(k) Number (if known): K082571

Device Name: Avaulta™ Support System

Indications for Use:

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Neil R. Dyer for name
Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082571

(Recommended Format 11/13/2003)

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 05, 2008

C.R. BARD, INC.
UROLOGICAL DIVISION
13183 HARLAND DRIVE
COVINGTON, GA 30014
ATTN: JOHN C. KNORPP

510(k) Number: K082571
Received: 05-SEP-2008
Product: AVAULTA SUPPORT
SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued

8

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (<http://www.fda.gov/oc/initiatives/fdaaa/guidance/certifications.html>). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Bard Urological Division
C. R. Bard, Inc.
13183 Harland Dr.
Covington, GA 30014

SUT/DGRND

K082571

BARD

September 3, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FDA CENTER FOR DEVICES AND RADIATION HEALTH

SEP - 5 2008

Re: Special Premarket 510(k) Notification
Avaulta Support System

Received K-13

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Urological Division, C.R. Bard, Inc., is submitting two copies of this 510(k) notification of changes to Bard's Avaulta Support System and two copies of this cover letter. One copy of the 510(k) notification is being provided in electronic format per FDA's web instructions and is an exact duplicate of the paper copy. The purpose of this 510(k) submission is to notify FDA of a minor design change to the Avaulta Support System Implant.

Device Name:	Avaulta Support System
Trade Name(s):	Avaulta Solo™ Synthetic Support System Avaulta Plus™ Biosynthetic Support System
Common/Usual Name:	Surgical Mesh
Classification Names:	79 FTL – Mesh, Surgical, Polymeric
CFR Reference:	21 CFR 878.3300
Classification Panel:	General and Plastic Surgery

There are no FDA document numbers associated with this submission other than the predicate 510(k), K063712.

The terms "substantially equivalent", "similar" and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

Exhibit 1 contains a copy of a completed CDRH Premarket Review Submission Cover Sheet. Section 1.0 contains Screening Checklists for Special Premarket Notification [510(K)] Submissions with references to the sections of this document that contain the required information, the Premarket Notification Truthful and Accurate Statement and the 510(k) Indications for Use Statement. The 510(k) Summary of Safety and Effectiveness Information can be found as Exhibit 2. The general design and use of the device is indicated in the table below:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biologic source?	X	
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does the device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

C. R. Bard, Inc. has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C. R. Bard, Inc. requests that FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b).

C. R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, the Contact Person is:

John C. Knorpp
john.knorpp@crbard.com

678-342-4920
770-788-5513 (fax)

I hereby authorize the FDA to communicate with me regarding this submission via phone, fax and/or email as indicated above. Thank you in advance for your consideration of our application.

Sincerely,



John C. Knorpp, RAC
Director, Regulatory Affairs
Bard Urological Division

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:	
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) C R BARD INC 13183 Harland Drive Covington GA 30014 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)	2. CONTACT NAME John Knorpp 2.1 E-MAIL ADDRESS john.knorpp@crbard.com 2.2 TELEPHONE NUMBER (include Area code) 678-342-4920 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 770-788-5513
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)	
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)	
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4) 22-May-2008	

Bard Urological Division
C. R. Bard, Inc.
13183 Harland Dr.
Covington, GA 30014



September 3, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Special Premarket 510(k) Notification
Avaulta Support System

Dear Sir/Madam:

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Classification Panel:	General and Plastic Surgery

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Special Premarket Notification [510(k)]

C.R. Bard, Inc.
Bard Urological Division (BUD)

Avaulta™ Support System

TABLE OF CONTENTS

Avaulta Support System

Special Premarket Notification [510(k)]

	<u>Page</u>
1.0 REGULATORY INFORMATION	1
1.1 Regulatory Forms	1
1.2 Screening Checklists For Special Premarket Notification [510(K)] Submissions	1
1.3 Premarket Notification Truthful and Accurate Statement	3
1.4 Indications for Use Statement	4
2.0 INTRODUCTION	5
2.1 Purpose of Premarket Notification	5
2.2 General Information	5
2.3 Intended Use	6
2.4 Indications for Use	6
2.5 Device History	7
3.0 DEVICE DESCRIPTION	8
3.1 Device Principles of Operation	8
3.2 Device Design and Materials	8
3.3 Design Modifications Addressed In This Submission	9
3.4 Packaging	10
3.5 Sterilization	11
3.6 Stability	11
3.7 Labeling	11
4.0 SUMMARY OF DESIGN CONTROL ACTIVITIES	12
4.1 User Needs	12
4.2 Design Inputs	12
4.3 Risk Analysis	12
4.4 Summary of Design Verification and Validation Activities	12
4.5 Conclusion	13
5.0 SUBSTANTIAL EQUIVALENCE	14

EXHIBITS

Exhibit 1 – Regulatory Forms

Exhibit 2 – 510(k) Summary of Safety and Effectiveness

Exhibit 3 – Subject Device Drawings

Exhibit 4 – Proposed IFUs

Exhibit 5 – Current IFUs

Exhibit 6 – 510(k) Substantial Equivalence Decision Tree

Exhibit 7 – Declaration of Conformity with Design Controls

1.0 REGULATORY INFORMATION

1.1 Regulatory Forms

Exhibit 1 contains the following regulatory forms:

- FDA-3514: CDRH Premarket Review Submission Cover Sheet
- FDA-3674: Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank

1.2 Screening Checklists For Special Premarket Notification [510(K)] Submissions

Table 1.2.1: Required Elements for all Types of 510(k) Submissions

Required Element	Location
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual	Cover Letter
Table of Contents	Table of Contents
Truthful and Accurate Statement	Section 1.3
Device Trade Name, Device's Classification Name and Establishment Registration Number	Section 2.2
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Section 2.2
Proposed Labeling including the materials listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Exhibit 4
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 1.4
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Section 3.3
510(k) Summary	Exhibit 2
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Exhibit 3
Identification of legally marketed predicate device.	Section 2.2
Compliance with performance standards.	Section 2.2
Class III Certification and Summary	N/A (Class II Device)
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. [See 21 CFR 807.87(l)]	N/A (No clinical studies)
510(k) Kit Certification	N/A (No changes affecting kit)

Table 1.2.2: Additional Requirements for a SPECIAL 510(k) Submissions

Required Element	Location
Name and 510(k) number of the sponsor's own, unmodified predicate device.	Section 2.2
A description of the modified device and a comparison to the sponsor's predicate device.	Section 3.0
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.	Sections 2.3 and 2.4
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	Section 3.1
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 1.4
A design Control Activities Summary that includes the following elements (a-c below):	
<ul style="list-style-type: none"> a. Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. 	Section 4.3
<ul style="list-style-type: none"> b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. 	Sections 4.3 and 4.4
<ul style="list-style-type: none"> c. A Declaration of Conformity with design controls that includes the following statements: 	Exhibit 7
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities. 	Exhibit 7
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities. 	Exhibit 7

1.3 Premarket Notification Truthful and Accurate Statement

I certify that, in my capacity as Director, Regulatory Affairs of C.R. Bard, Inc., Bard Urological Division I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.

Signature: 

Typed Name: John C. Knorpp
Director, Regulatory Affairs

Date: 8-26-08

510(k) Number:
(if applicable) _____

1.4 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Avaulta™ Support System

Indications for Use:

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Recommended Format 11/13/2003)

2.0 INTRODUCTION

2.1 Purpose of Premarket Notification

The purpose of this Special 510(k) submission is to notify FDA of a minor design change to the posterior Avaulta Plus™ Implant and revisions to the IFUs for the Avaulta Plus and Avaulta Solo™ Implants. There are no changes being made to the Avaulta Solo Implant. These devices are covered under K063712.

The modified Avaulta Plus Implant has the same intended use, general design, materials and fundamental scientific technology as the predicate device. The decision tree and guidance included in *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications* was used to determine that a Special 510(k) is appropriate for these changes.

2.2 General Information

Subject Device Information

Device Name: Avaulta Support System
Trade Name(s): Avaulta Solo™ Synthetic Support System
Avaulta Plus™ Biosynthetic Support System
Common/Usual Name: Surgical Mesh
Classification Names: 79 FTL – Mesh, Surgical, Polymeric
CFR Reference: 21 CFR 878.3300
Classification Panel: General and Plastic Surgery

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, where applicable, adherence to the following guidance has been maintained:

- Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, issued March 2, 1999

Predicate Device Information

Device Name: Avaulta Support System
Trade Name(s): Avaulta Solo™ Synthetic Support System
Avaulta Plus™ Biosynthetic Support System
Common/Usual Name: Surgical Mesh
Classification Names: 79 FTL – Mesh, Surgical, Polymeric
CFR Reference: 21 CFR 878.3300
Classification Panel: General and Plastic Surgery
Premarket Notification: K063712, clearance date – March 12, 2007.

Manufacturer/Submitter

Manufacturer Name: Bard Urological Division (BUD)
[a division of C.R. Bard, Inc.]
Address: 13183 Harland Drive
Covington, GA 30014
Contact Person: John C. Knorpp
Telephone Number: 678-342-4920
Fax Number: 770-788-5513
Registration Number: 1018233
Additional Registration Numbers:
C.R. Bard: 2212754

Sterilization Sites

Name: Bard Medical Division (BMD)
[a division of C.R. Bard, Inc.]
Address 1: 8195 Industrial Blvd.
Covington, GA 30014
Registration Number: 1018233
Address 2: 1211 Mary Magnan Blvd.
Madison, GA 30650
Registration Number: 3006082230

2.3 Intended Use

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

The intended use has not changed.

2.4 Indications for Use

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

The indications for use have not changed.

2.5 Device History

Subsequent to FDA clearance for commercial distribution on March 12, 2007, some minor changes were made to the predicate Avaulta Support System. After consulting the FDA's guidance document, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, these changes were determined to be non-significant, and therefore did not require the submission of a 510(k). The changes were as follows:

- Dimensional tolerances were modified to more closely match the product tested during design qualification.
- Arm tensile strength specifications were restated as minimum quantitative requirements rather than relying on a comparison to a similar product.
- A caution was added to the IFU relative to post-operative patient activity consistent with other mesh implants.
- Sterilization of the Avaulta Solo Implant now occurs in the final kit configuration with the introducer as opposed to individually packaged subassemblies prior to kitting. This change was made for logistical reasons and did not affect packaging, only the order of operations.
- Shelf life was extended to 2 years based on a combination of real time and accelerated aging studies, consistent with K063712.
- The IFU was revised to include procedural clarifications regarding graft preparation and placement.

3.0 DEVICE DESCRIPTION

3.1 Device Principles of Operation

As explained in K063712, the Avaulta Support System includes a sterile, single use, permanent implant that provides long term reinforcement to support structures in the correction of vaginal wall prolapse. The central soft knit section provides compliant organ support while the strong knit arms provide improved strength for tension free fixation of the implant. Each implant is accompanied by a sterile, single use, Class I, Exempt introducer used for placement of the implant.

The Avaulta Support System is offered in multiple configurations:

- Avaulta Solo Synthetic Support System for Anterior Repair
- Avaulta Solo Synthetic Support System for Posterior Repair
- Avaulta Plus Biosynthetic Support System with Porcine Graft for Anterior Repair
- Avaulta Plus Biosynthetic Support System with Porcine Graft for Posterior Repair

The fundamental technology of the implant has not changed.

3.2 Device Design and Materials

The Avaulta Solo Synthetic Support System implant is composed of a pre-cut synthetic mesh implant. The Avaulta Plus Biosynthetic Support System implant is composed of the same pre-cut synthetic mesh implant with a porcine collagen sheet covering one side of the central section. The arms are not covered to maximize mesh fixation immediately post implant. The primary support mechanism is the mesh beneath the collagen sheet (see Figure 1).

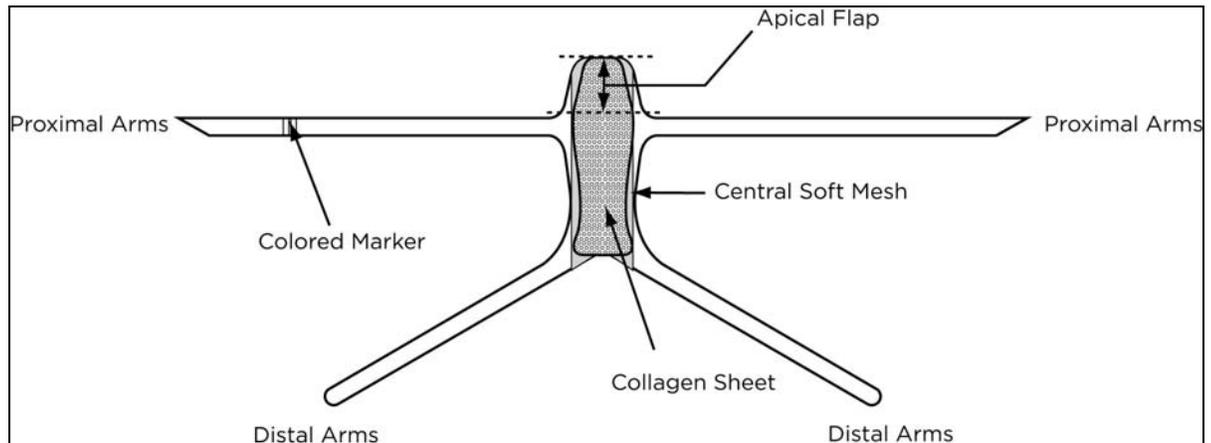


Figure 1: Predicate Avaulta Plus Posterior Implant

The collagen sheet is pre-attached to the central soft knit section to provide a protective barrier between the polypropylene mesh and pelvic tissues. The

collagen sheet encourages fibroblast infiltration and revascularization so that the implant gradually becomes incorporated in the surrounding tissue.

The overall design, including device materials, performance specifications and dimensional specifications, has not changed.

3.3 Design Modifications Addressed In This Submission

(b) (4)

[REDACTED] (see Figure 2).

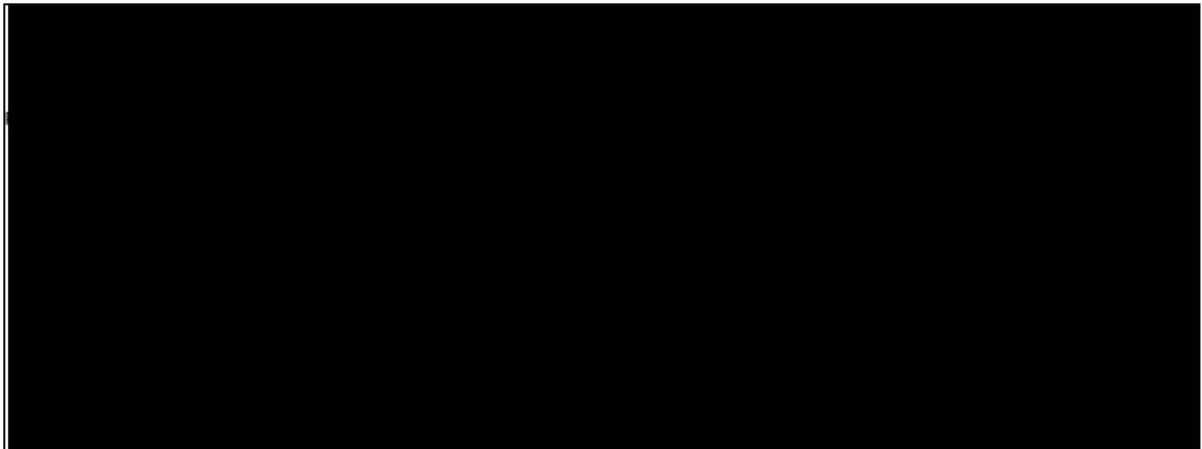


Figure 2: Subject Avaulta Plus Posterior Implant

The current posterior Avaulta Plus Implant can be trimmed, at the physician's discretion, after implantation and before tensioning. In most cases, a small midline or wedge cut is made between the two distal arms in the central soft mesh/collagen sheet area in order to match the anatomy, ensure the implant lays flat against the mucosa and to obtain proper tension. The subject design modification will provide additional flexibility to remove this section of the collagen during this trimming step. Doing so will better facilitate adjustment of the implant to more closely match the patient's anatomy.

This change only applies to the posterior Avaulta Plus Implant but it does not affect the size or shape of the implant. The attached portion of the collagen sheet will remain fastened to the mesh without change. There are no changes to the anterior Avaulta Plus Implant or posterior and anterior Avaulta Solo Implants.

See Exhibit 3 for further graphical representations of the posterior implant.

The following table provides a comparison between the predicate and subject devices.

NOTE: **Bold Type – Indicates a difference between predicate as currently marketed and subject device.**
Plain Type – Indicates the subject device attribute is the same as that of the predicate device as currently marketed.

Attribute	Predicate Device Avaulta Support System K063712	Subject Device Avaulta Support System
Intended Use	Reinforcement of tissue during surgical repair.	Same
Indications for Use	Tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.	Same
Mesh central section	Avaulta Solo: Soft knit mesh Avaulta Plus: Soft knit mesh with porcine collagen sheet fully attached to one side of the mesh	Avaulta Solo: Soft knit mesh Avaulta Plus: Soft knit mesh with porcine collagen sheet fully attached to one side of the mesh except for the distal 3cm on the posterior implant
Mesh markers	Blue markers on the midline and in lateral arms	Same
Mesh lateral arms	Strong knit mesh	Same
Mesh characteristics	Porous, open, monofilament knit that allows trimming of the implant and tissue ingrowth	Same
Collagen	Crosslinked, acellular, lyophilized porcine dermal collagen sheet	Same
Collagen thickness	0.5mm	Same
Collagen porosity	1.8mm holes	Same
Implant shape	Precut for anterior and posterior repair with apical flap on both	Same
Implant method of fixation	Staples, sutures or tension free	Same
Implant sterilization	EtO	Same

3.4 Packaging

There are no changes to packaging. The Avaulta Implant is packaged in a thermoformed blister tray with a Tyvek® lid. The sealed tray is placed in one of two pouches:

- The Avaulta Plus synthetic/collagen implant tray is placed in a foil/foil pouch with a Tyvek® header. After sterilization, the pouch is sealed below the Tyvek® header (i.e. foil to foil) which is then removed. The foil pouch with foil to foil heat seal provides a long-term moisture barrier while maintaining sterility of the contents.
- The Avaulta Solo synthetic implant tray is placed in Tyvek®/film pouch.

The packaged implant and separately packaged Class I, Exempt introducer are placed in a corrugate box.

3.5 Sterilization

There are no changes to sterilization method or cycle. The Avaulta Support System is supplied as a sterile, single use device sterilized by EtO.

3.6 Stability

The Avaulta Support System is offered with a 2 year shelf life. This is based on accelerated aging studies conducted on polypropylene mesh which demonstrate a 5 year shelf life and real time aging studies conducted on the Collamend Implant (Collamend was the original predicate device referenced in K063712 upon which shelf life was determined) which demonstrate a 2 year shelf life.

3.7 Labeling

The Avaulta Plus and Solo Implant IFUs have been modified to better ensure consistency between and within the IFUs, allow procedural flexibility based on physician discretion, include further information regarding general surgical practice and include additional instructions pertinent to the subject design change.

Copies of the draft proposed IFUs have been included in Exhibit 4 and the current IFUs in Exhibit 5.

4.0 Summary of Design Control Activities

4.1 User Needs

As part of its ongoing product line improvement process, Bard Urological Division identified an opportunity to allow for greater flexibility in physician modifications of the posterior Avaulta Plus Implant. Physician feedback indicated that the central section was longer than necessary for many patients. By removing the stitching from the distal section of the collagen sheet, physicians would be able to more easily customize the graft based on the specific patient anatomy.

Currently, the posterior Avaulta Plus Implant can be trimmed by physicians after implantation and before tensioning. In most cases, a small midline or wedge cut is made between the two distal arms in the central soft mesh/collagen sheet area in order to match the anatomy, ensure the implant lays flat against the mucosa and to obtain proper tension. The subject design modification will provide additional flexibility, at the physician's discretion, to remove this section of the collagen during this trimming step.

4.2 Design Inputs

The user needs identified were translated into design input requirements for the posterior Avaulta Plus Implant. It was determined that the stitching should be removed from the distal 3cm of the graft to allow for removal of the collagen, if so desired. This modification allows the complete graft to be implanted with the entire collagen sheet, as with the current design, or it allows the physician the flexibility to remove some or all of the 3cm collagen flap based on an assessment of patient anatomy.

4.3 Risk Analysis

A design failure modes and effects analysis (DFMEA) of the modified posterior Avaulta Plus Implant was conducted in accordance with an internal procedure based on EN/ISO 14971 *Medical Devices – Application of Risk Management to Medical Devices* to assure that risks posed by the modified device are acceptable. The analysis did not raise any new types of safety or effectiveness questions.

4.4 Summary of Design Verification and Validation Activities

The materials of construction, manufacturing methods, performance specifications and overall design of the posterior Avaulta Plus Implant have not changed. The only change is to remove the stitching from the distal 3cm of the collagen sheet. The Risk Summary Table below specifically identifies the potential risks associated with the change and risk mitigation steps taken. Because there were no new types of safety or effectiveness questions, there were no design verification tests required to specifically address the risks identified. However, for an added measure of confidence and in accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," the following design

verification activities were conducted: Visual, dimensional and implant tensile strength. The testing demonstrated that the modified device was substantially equivalent to the predicate and met the predetermined acceptance criteria.

Risk Summary Table for Sewing Change to the Posterior Avaulta Plus Implant				
Technical Feature	Original Design	Change	Potential Risk	Mitigation of Risk
(b) (4)				

(b) (4)

4.5 Conclusion

The subject posterior Avaulta Plus Implant has been evaluated in both design verification and validation tests and determined to meet all predetermined acceptance criteria and is substantially equivalent to the predicate device.

5.0 SUBSTANTIAL EQUIVALENCE

BUD intends to modify the posterior Avaulta Plus Implant originally cleared under K063712.

The "510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree" was used in determining the substantial equivalence of the Avaulta Support System implant to the predicate device.

A copy of this decision tree is provided as Exhibit 6. Additionally, the answers to the following questions on the decision tree confirm substantial equivalence to the predicate device.

1. Does new device have same indication statements?

Yes. The indications for use statement has not changed.

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

2. Does new device have same technological characteristics, e.g., design, materials, etc.?

No. The subject and predicate device have the same general design features and rely on the same fundamental scientific technology, however the subject posterior Avaulta Plus incorporates a sewing pattern change that will allow for the distal 3cm section of the mesh sheet to be free. There are no materials changes.

3. Could the new characteristics affect safety or effectiveness?

Yes. A design change could affect safety and effectiveness.

4. Do the new characteristics raise new types of safety or effectiveness questions?

No. Both the subject and predicate device perform their intended function in the same manner using the same fundamental scientific technology. The change provides more flexibility to the physician.

5. Do accepted scientific methods exist for assessing effects of new characteristics?

Yes. Functional performance has been addressed by conducting relevant testing as determined by the risk analysis and in consideration of FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," as appropriate.

6. Are performance data available to assess effects of new characteristics?

Yes. Design verification and validation activities have been summarized herein.

7. Performance data demonstrate equivalence?

Yes. The testing summarized herein demonstrates that the subject device met all predetermined acceptance criteria and is substantial equivalent to the predicate.

Based on the answers to the above questions, the subject Avaulta Support System is substantially equivalent to the predicate Avaulta Support System (K063712).

Exhibit 1

Regulatory Forms

- FDA-3514: CDRH Premarket Review Submission Cover Sheet
- FDA-3674: Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 9/3/2008	User Fee Payment ID Number MD6036608-956733	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	<input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name C.R. Bard, Inc.		Establishment Registration Number (if known) 1018233	
Division Name (if applicable) Bard Urological Division (BUD)		Phone Number (including area code) (678) 342-4920	
Street Address 13183 Harland Drive		FAX Number (including area code) (770) 788-5513	
City Covington	State / Province GA	ZIP/Postal Code 30014	Country USA
Contact Name John C. Knorpp			
Contact Title Director, Regulatory Affairs		Contact E-mail Address john.knorpp@crbard.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Change in Design		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	79 FTL	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K063712	1	Avaulta Support System	1	C.R. Bard, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Surgical Mesh

	Trade or Proprietary or Model Name for This Device		Model Number
1	Avaulta Support System	1	Multiple
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code 79 FTL	C.F.R. Section (if applicable) 21 CFR 878.3300	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 1018233		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name C.R. Bard, Inc.			Establishment Registration Number 1018233		
Division Name (if applicable) Bard Urological/Medical Division			Phone Number (including area code) (678) 342-4820		
Street Address 8195 Industrial Blvd.			FAX Number (including area code) () N/A		
City Covington		State / Province GA	ZIP/Postal Code 30014	Country USA	
Contact Name Al Jacks		Contact Title Vice President, QA/RA		Contact E-mail Address al.jacks@crbard.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3006082230		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name C.R. Bard, Inc.			Establishment Registration Number Pending		
Division Name (if applicable) Bard Medical Division			Phone Number (including area code) (770) 784-6120		
Street Address 1211 Mary Magnan Blvd.			FAX Number (including area code) (770) 784-6340		
City Madison		State / Province GA	ZIP/Postal Code 30650	Country USA	
Contact Name Mary Mayo		Contact Title Staff Vice President, Quality Assurance		Contact E-mail Address mary_mayo@crbard.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3005636544		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name C.R. Bard, Inc.			Establishment Registration Number 3005636544		
Division Name (if applicable) Bard Shannon Limited			Phone Number (including area code) (787) 656-5500		
Street Address San Geronimo Industrial Park, Lot #1, Road #3, km 79.7			FAX Number (including area code) () N/A		
City Humacao		State / Province PR	ZIP/Postal Code 00791	Country USA	
Contact Name Dan Gregoire		Contact Title Plant QA Manager		Contact E-mail Address dan.gregoire@crbard.com	

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Original
 Add Delete

Facility Establishment Identifier (FEI) Number
N/A

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name
(b) (4)

Establishment Registration Number
N/A

Division Name (if applicable)
N/A

Phone Number (including area code)
(b) (4)

Street Address
(b) (4)

FAX Number (including area code)
(b) (4)

City
(b) (4)

State / Province
(b) (4)

ZIP/Postal Code
(b) (4)

Country
USA

Contact Name
(b) (4)

Contact Title
President

Contact E-mail Address

Original
 Add Delete

Facility Establishment Identifier (FEI) Number

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name

Establishment Registration Number

Division Name (if applicable)

Phone Number (including area code)
()

Street Address

FAX Number (including area code)
()

City

State / Province

ZIP/Postal Code

Country

Contact Name

Contact Title

Contact E-mail Address

Original
 Add Delete

Facility Establishment Identifier (FEI) Number

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name

Establishment Registration Number

Division Name (if applicable)

Phone Number (including area code)
()

Street Address

FAX Number (including area code)
()

City

State / Province

ZIP/Postal Code

Country

Contact Name

Contact Title

Contact E-mail Address

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

1	Standards No. 14971	Standards Organization EN/ISO	Standards Title Medical Devices--Application of Risk Management to Medical Devices	Version 2007	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER John C. Knorpp	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 09/03/2008
3. ADDRESS (Number, Street, State, and ZIP Code) C.R. Bard, Inc. Bard Urological Division 13183 Harland Drive Covington, GA 30014	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 678-342-4920 (Fax) 770-788-5513

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Avaulta Solo Synthetic Support System	Surgical Mesh
Avaulta Plus Biosynthetic Support System	

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
N/A

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
TBD

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.**

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) John C. Knorpp (Title) Director, Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) C.R. Bard, Inc. Bard Urological Division 13183 Harland Drive Covington, GA 30014	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 678-342-4920 (Fax) 770-788-5513
	15. DATE OF CERTIFICATION

Exhibit 2

510(k) Summary of Safety and
Effectiveness

Bard Urological Division
C. R. Bard, Inc.
13183 Harland Dr.
Covington, GA 30014



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc. Bard Urological Division
Address:	13183 Harland Drive Covington, GA 30014
Contact Person:	John C. Knorpp
Contact Person's Telephone Number:	678-342-4920
Contact Person's Fax:	770-788-5513

B. DEVICE NAME:

Trade Name(s):	Avaulta™ Solo Support System Avaulta™ Plus Biosynthetic Support System
Common/Usual Name:	Surgical Mesh
Classification Names:	79 FTL – Mesh, Surgical, Polymeric
CFR Reference:	21 CFR 878.3300
Classification Panel:	General and Plastic Surgery

C. PREDICATE DEVICE NAME:

Trade Names:	Avaulta™ Solo Support System Avaulta™ Plus Biosynthetic Support System K063712
--------------	--

D. DEVICE DESCRIPTION:

The Avaulta™ Support System includes a sterile, single use, permanent implant that provides long term reinforcement to support structures in the correction of anterior or posterior vaginal wall prolapse. The central soft knit section provides compliant organ support while the strong knit arms provide improved strength for tension free fixation of the implant.

The Avaulta™ Plus Biosynthetic Support System and Avaulta™ Solo support system both utilize a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. The Avaulta™ Plus Biosynthetic Support System adds a porous, acellular, ultra-thin sheet of crosslinked collagen attached to the polypropylene mesh which serves to establish a protective barrier between mucosal tissue and

the polypropylene mesh and contains apertures uniformly sized to allow for ingrowth of host tissue and capillary vessels.

E. INTENDED USE:

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject Avaulta™ Support System has the same intended use, general design and fundamental scientific technology as the predicate device.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing to determine substantial equivalence was completed. This includes testing in accordance with *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (March 22, 1999).

Exhibit 3

Subject Device Drawings

POSTERIOR CONFIGURATION

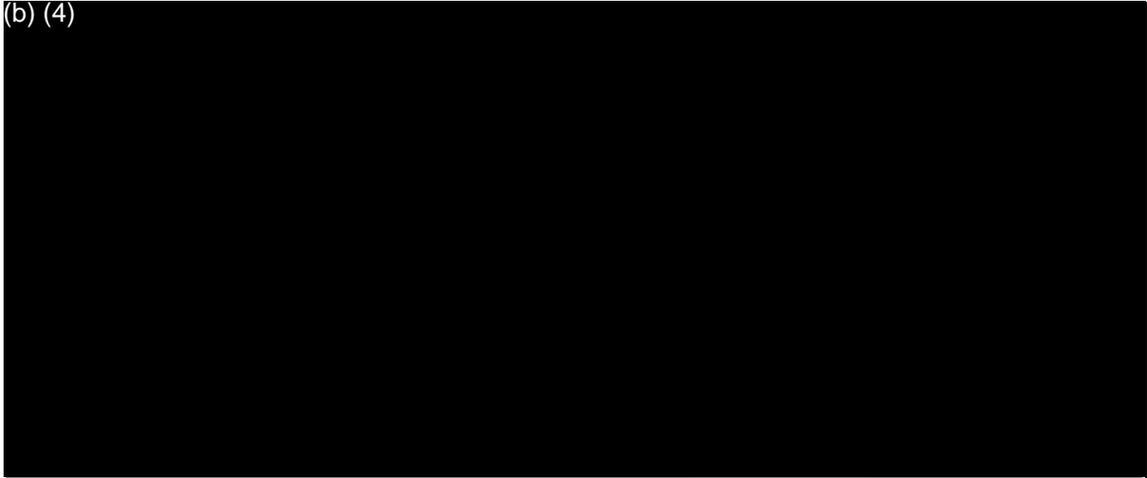


Figure 3: Avaulta Plus and Solo Implant Dimensions (b) (4)



Figure 4: Avaulta Solo Synthetic Support System (b) (4)

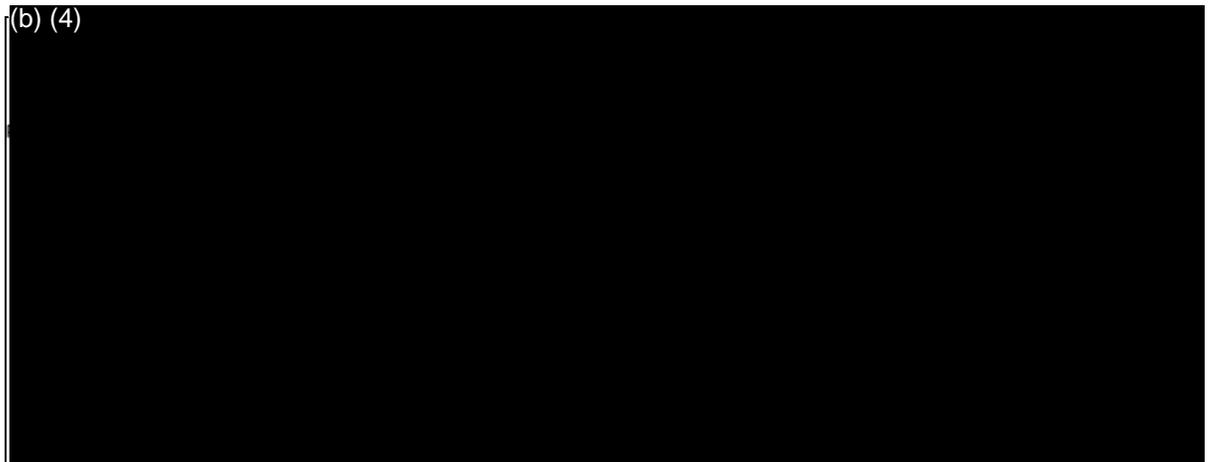


Figure 5: Subject Posterior Avaulta Plus Biosynthetic Support System

Exhibit 4

Proposed IFUs

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Avaulta Plus™

Biosynthetic Support System

INSTRUCTIONS FOR USE

4-ENGLISH
9-FRENCH/FRANÇAIS
15-GERMAN/DEUTSCH
21-ITALIAN/ITALIANO
27-SPANISH/ESPAÑOL
33-DUTCH/NEDERLANDS
39-PORTUGUESE/PORTUGUÊS
45-GREEK/ΕΛΛΗΝΙΚΑ
51-DANISH/DANSK
56-SWEDISH/SVENSKA
61-FINNISH/SUOMI
67-NORWEGIAN/NORSK
72-POLISH/POLSKI
77-HUNGARIAN/MAGYAR
82-CZECH/ČESKY
87-TURKISH/TÜRKÇE



BARD

C. R. Bard, Inc.
Covington, GA 30014 USA
1-888-367-2273
www.bardurological.com



Bard Limited, Forest House
Brighton Road
Crawley, West Sussex
RH11 9BP, UK
0044 1293 527 888



PK0302004 5/2008

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STERILE EO

Sterilized by Ethylene Oxide
Stérilisé à l'oxyde d'éthylène
Sterilisiert mit Ethyloxid
Sterilizato con ossido di etilene
Esterilizado con óxido de etileno
Gesteriliseerd met behulp van ethyleenoxide
Esterilizado por óxido de etileno
Αποστειρωμένο με οξείδιο του αιθυλενίου
Steriliseret med ethylenoxid
Steriliserat med etylenoxid
Steriloitu etyleenioksidilla
Steriliseret med etylenoksid
Steryliowany tlenkiem etylenu
Etílenoxidál sterilizálva
Sterilizováno ethylenoxidem
Etilen Oksitle sterilize edilmiştir



Read instructions for use
Se reporter au mode d'emploi
Gebrauchsanweisung lesen
Leggere le istruzioni per l'uso
Leer las instrucciones de uso
Voorzichtig, raadpleeg de gebruiksaanwijzing
Leia as instruções de utilização
Διαβάστε τις οδηγίες χρήσης
Læs brugsanvisningen
Läs anvisningarna före användning.
Lue käyttöohjeet
Les bruksanvisningen
Przed użyciem zapoznaj się z instrukcją
Olvassa el a használati útmutatót
Přečtěte si pokyny k použití
Kullanma talimatını okuyun



Single use only. Do not reuse.
Réservé à un usage unique. Ne pas réutiliser.
Nur für den einmaligen Gebrauch bestimmt. Nicht wiederverwenden.
Solo monouso. Non riutilizzare.
Un solo uso. No reutilizar.
Uitsluitend voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para utilização única. Não reutilizar.
Για μία μόνο χρήση. Μην επαναχρησιμοποιείτε.
Kun til engangsbrug. Må ikke genbruges.
Endast för engångsbruk. Får ej återanvändas.
Vain kertakäyttöön. Ei saa käyttää uudelleen.
Ikke til gjenbruk.
Wyłącznie do jednorazowego użytku. Nie używać powtórnie.
Kizárólag egyszéri használatra. Ne használja fel újra.
Pouze k jednorázovému použití. Nepoužívejte opakovaně.
Sadece tek kullanımlık. Tekrar kullanmayın.



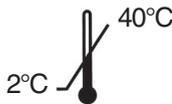
Do Not Resterilize
Ne pas procéder à une nouvelle stérilisation
Nicht resterilisieren
Non risterilizzare
No reesterilizar
Niet opnieuw steriliseren
Não reesterilizar
Μην επαναποστειρώνετε.
Må ikke gensteriliseres
Får ej omsteriliseras.
Ei saa steriloida uudelleen
Skal ikke resteriliseres.
Nie sterylizować ponownie
Ne sterilizálja újra
Neprovádějte resterilizaci
Tekrar Sterilize Etmeyin.



Sterile unless package is opened or damaged.
Stérile sauf si l'emballage est ouvert ou endommagé.
Steril, sofern nicht offen oder beschädigt.
Sterile solo se la confezione non è aperta o danneggiata.
Estéril a menos que el envase esté abierto o dañado.
Steriel tenzij de verpakking geopend of beschadigd is.
Estéril a menos que a embalagem esteja aberta ou danificada.
Αποστειρωμένο εφόσον η συσκευασία δεν έχει ανοιχτεί και δεν έχει υποστεί ζημιά.
Steril medmindre emballagen er åbnet eller beskadiget.
Steril om förpackningen inte har öppnats eller skadats.
Sterilii mikáli pakkkaus on avaamaton ja ehjä.
Steril med mindre forpakningen er åbnet eller skadet.
Produkt sterylnoy, o ile opakowanie nie zostało otwarte lub uszkodzone.
Steril, kivéve ha a csomagolás nyitott vagy károsodott.
Sterilní, pokud není balení otevřeno či poškozeno.
Ambalaj açılmadığı ve hasarlı olmadığı sürece sterildir.



Use by date
Date de péremption
Verfallsdatum
Data di scadenza
Usar antes de
Houdbaar tot
Utilizar até
Ημερομηνία λήξης
Anvendes inden
Används senast
Viimeinen käyttöajankohta
Brukes innen:
Data ważności
Lejárati idő
Použijte do
Son kullanma tarihi



Recommended storage conditions: between 2°-40°C (36°-105°F), in a dry area.
Conditions de conservation recommandées : Conserver entre 2° et 40°C, dans un lieu sec.
Empfohlene Lagerungsbedingungen: zwischen 2°-40°F, in trockener Umgebung lagern.
Condizioni di conservazione consigliate: temperatura compresa tra 2°-40°C in luogo asciutto.
Condiciones de almacenamiento recomendadas: entre 2°-40°C, en un lugar seco.
Aanbevolen bewaarcondities: 2 - 40 °C (36 - 105 °F), op een droge plaats.
Condições de conservação recomendadas: entre 2°-40°C (36°-105°F), num local seco.
Συνιστώμενες συνθήκες φύλαξης: μεταξύ 2 °C 40 °C (36 °F 105 °F), σε ξηρό χώρο.
Anbefalede opbevaringsbetingelser: mellem 2°-40°C i et tørt område.
Rekommenderade förvaringsvillkor: mellan 2°-40 °C på ett torrt ställe.
Suositeltavat säilytysolosuhteet: 2-40 °C (36-105 °F), kuivassa paikassa.
Anbefales oppbevar: tørt, mellom 2 °C -40 °C (36 °F -105 °F).
Zalecane warunki przechowywania: temperatura w zakresie 2°-40°C, w suchym miejscu.
Javasolt tárolási környezet: 2°-40°C között, száraz helyen.
Doporučované podmínky skladování: mezi 2°-40°C, v suchém prostředí.
Önerilen saklama koşulları: Kuru bir yerde, 2° 40°C (36° 105°F) arası sıcaklıklarda saklayınız.

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Date of Manufacture
Date de fabrication
Herstellungsdatum
Data di produzione
Fecha de fabricación
Productiedatum
Data da produção
Ημερομηνία κατασκευής
Fremstillingsdato
Tillverkningsdatum
Valmistuspäivämäärä
Produksjonsdato:
Data produkcji
Gyártás dátuma
Datum výroby
Üretim Tarihi



Batch code
Code de lot
Chargenbezeichnung
Codice batch
Código del lote
Lotnummer
Código do lote
Κωδικός παρτίδας
Batch nummer
Batchkod
Eräkoodi
Bartch-kode:
Numer serii
Gyártási szám
Kód šarže
Parti kodu



Manufacturer
Fabricant
Hersteller
Produttore
Fabricante
Fabrikant
Fabricante
Κατασκευαστής
Producent
Tillverkare
Valmistaja
Produsent
Gyártó
Výrobce
Üretici



Catalogue number
Numéro de catalogue
Katalog-Nummer
Numero di catalogo
Número de catálogo
Catalogusnummer
Referència de catàlego
Αριθμός καταλόγου
Katalog number
Katalognummer
Luettelonumero
Katalognummer
Numer katalogowy
Katalógusszám
Katalogové číslo
Katalog numarası



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
Attention: Selon la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.
Achtung: Gemäß US-Bundesgesetzgebung darf der Verkauf dieses Systems nur durch einen Arzt oder auf Veranlassung eines Arztes erfolgen.
Attenzione: le leggi federali degli Stati Uniti limitano la vendita di questo dispositivo ai soli medici o su prescrizione medica.
Precaución: Las leyes federales (EE.UU.) limitan la venta de este dispositivo a médicos o bajo prescripción facultativa.
Opgelet: Krachtens de federale wetgeving (VS) mag dit product alleen door of in opdracht van een arts worden verkocht.
Cuidado: A Lei Federal (EUA) limita a venda deste dispositivo a um médico ou por ordem de um médico.
Προσοχή: Η ομοσπονδιακή νομοθεσία (Η.Π.Α.) επιτρέπει την πώληση της συσκευής αυτής μόνον από ιατρό ή κατόπιν εντολής ιατρού.
Forsigtig: Amerikansk lovgivning begrænser denne anordning til salg a feller efter ordination af en læge.
Varning: Enligt federal lag (USA) får denna utrustning endast säljas av eller på ordination av läkare.
Huomio: Yhdysvaltojen lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.
Forsiktig: I henhold til føderal lov i USA kan dette utstyret kun selges av eller etter henvisning fra en lege.
Uwaga: Prawo federalne USA ogranicza sprzedaż tego urządzenia do sprzedaży przez lub na zamówienie lekarza.
Figyelem: A szövetségi (USA) törvények értelmében ezen eszköz kizárólag orvos által, illetve orvosi rendelvényre árusítható.
Upozornění: Federální zákony (USA) omezují prodej tohoto prostředku na prodej lékařem nebo na lékařský předpis.
Dikkat: ABD federal kanunlarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir.



Authorized Representative
Représentant autorisé
Autorisierter Vertreter
Rappresentante autorizzato
Representante autorizado
Gemachtigde vertegenwoordiger
Representante autorizado
Εξουσιοδοτημένος αντιπρόσωπος
Autoriseret repræsentant
Auktoriserad representant
Valtuutettu edustaja
Autorisert representant
Autoryzowany przedstawiciel
Felhatalmazott képviselő
Autorizovaný zástupce
Yetkilil Temsilci

Avaulta Plus™ Biosynthetic Support System

Instructions for Use

DESCRIPTION

The Avaulta Plus™ Biosynthetic Support System utilizes a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. Additionally, the Avaulta Plus™ Biosynthetic Support System features a porous, acellular, ultra-thin sheet of crosslinked collagen attached to the polypropylene mesh which serves to establish a protective barrier between mucosal tissue and the polypropylene mesh and contains apertures uniformly sized to allow the ingrowth of host tissue and capillary vessels.

The monofilament, polypropylene mesh used in the Avaulta Plus™ Biosynthetic Support System has a soft knit in the central section for compliant organ support and host tissue ingrowth, and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open knit design offers multidirectional strength and elasticity that allows the synthetic mesh to be trimmed at the physician's discretion without unraveling and to adapt to various body stresses.

The pre-attached collagen sheet on the Avaulta Plus™ Biosynthetic Support System covers the soft-knit central section of the mesh to provide both a thin collagen plane for ingrowth of native tissue as well as a protective mucosal tissue barrier. The lateral segments of the Avaulta Plus™ Biosynthetic Support System are not covered to maximize mesh fixation immediately post-implantation.

As a convenience to the physician, the Avaulta Plus™ Biosynthetic Support System consists of a pre-cut graft for vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

The instrumentation included in the Avaulta Plus™ Biosynthetic Support System features a unique, patent-pending flexible snare system designed to minimize tissue trauma during implantation and allow for easier tip exteriorization and mesh arm capture.

INDICATIONS

Avaulta Plus™ Biosynthetic Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

Avaulta Plus™ Biosynthetic Support System is contraindicated for patients who are pregnant or may become pregnant, have a urinary tract infection, have an infection in the operative field, or patients in a period of growth because the mesh may not stretch significantly.

Avaulta Plus™ Biosynthetic Support System with acellular dermal tissue has material derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage.

PRECAUTIONS

- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- The Avaulta Plus™ Biosynthetic Support System should only be used by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction and the implantation of nonabsorbable meshes and biologic materials.

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- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.
- The Avaulta Plus™ Biosynthetic Support System implantation procedures require diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- The Avaulta Plus™ Biosynthetic Support System is provided in a sterile blister tray within a sterile pouch. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Anterior and Posterior Support Systems are provided in a sterile blister tray. Transfer the introducer to the sterile field using aseptic techniques. Do not place the tray in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh or introducers if the packaging is opened or damaged.
- As for any implantable material, it is recommended to open the blister tray at the time of implantation.
- After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month.

IMPLANT PROCEDURES

Preparation of Avaulta Plus™ Biosynthetic mesh for Implantation:

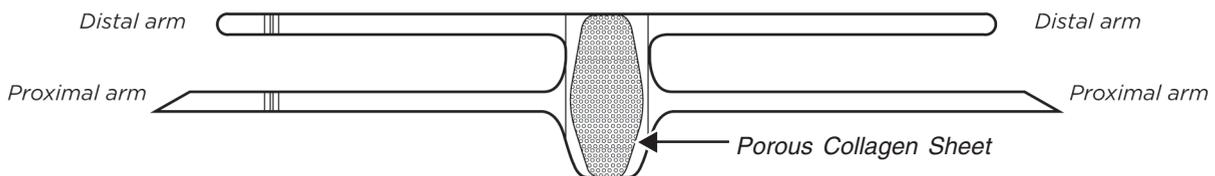
At the time of implantation, Avaulta Plus™ Biosynthetic Support System mesh must be hydrated. To hydrate, place the Avaulta Plus™ Biosynthetic Support System mesh into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for at least 3 minutes.

Avaulta Plus™ Biosynthetic Support System mesh is more easily trimmed prior to hydration, but may be trimmed after hydration if desired, to approximate the total vaginal length over which the graft will provide support. If necessary, the proximal portion of the graft (apical extension) may be removed.

CAUTION: The mesh should not be trimmed to a width less than 1 cm in order to maintain sufficient strength and prevent unraveling.

Implantation Technique for the Avaulta Plus™ Biosynthetic Anterior Support System:

*Distal end positioned at bladder neck
(arms passed through superior medial aspect of obturator membrane)*



*Proximal end positioned at vaginal apex
(arms passed through inferior medial aspect of obturator membrane)*

- Note: When using the Avaulta Plus™ Biosynthetic Support System, the tissue layer of the graft may be oriented to face the vaginal mucosal tissue or the visceral side at the discretion of the physician. To help facilitate the desired orientation, the colored markers on the arms should be positioned on the patient's right side for the tissue layer to be positioned on the vaginal mucosal side. Conversely, the arm markers should be oriented on the patient's left side for the tissue layer to face the visceral side.
- Proximal end with apical flap positioned at vaginal apex
- Proximal arms (long arms with pointed ends) passed through inferior medial aspect of obturator membrane
- Distal end positioned at bladder neck
- Distal arms (short arms with rounded ends) passed through superior medial aspect of obturator membrane

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1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
2. Make an incision in the anterior vaginal wall through the vaginal mucosa and into the fascial plane between the mucosa and the bladder. Dissect the vaginal mucosa away from the bladder laterally to the obturator internus at the level of the bladder neck and proximally to the ischial spine on both sides. Ensure a thick dissection is created, leaving as much endopelvic fascia on the mucosa as possible.
3. Identify the obturator fossa by grasping the adductor longus at its insertion to the pubic tubercle. Using the thumb to palpate under the adductor longus insertion, the superior medial aspect of the obturator fossa is identified. Palpate and draw the medial border of the obturator fossa to its inferior medial border. Make a vertical incision ≥ 1 cm approximately 1 cm below the superior medial border of the obturator fossa and lateral to the bladder neck for the distal arm of the mesh. Make a second vertical incision ≥ 1 cm at the inferior medial border of the obturator fossa and approximately lateral to the vaginal cuff. Repeat on the contralateral side.
4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the inferior medial groin incision to puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle tip towards the ischial spine or top of the vaginal cuff. Identify the tip of the introducer before puncturing through the obturator internus muscle. With a gentle rotation of the introducer push through the obturator muscle and use the vaginal finger to guide the needle tip through the fascial wall to exit proximally at the vaginal apex, exposing at least 1-2 cm of the needle tip. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself.
5. Pass the proximal arm (pointed end) of the mesh up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the inferior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.

6. Apply traction to draw the proximal (inferior) arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Be sure the graft is tension-free.
7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the superior groin incision and gently puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle towards the level of the bladder neck. Use a vaginal finger to guide the needle tip through the obturator internus as before, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
8. Pass a distal arm (rounded end) of the mesh up to the fold (about 4 cm) through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the superior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
9. Apply traction to draw the distal (superior) arms of the graft into the desired position such that the distal end of the central graft is positioned near the bladder neck. If significant folds are observed, scissors may be used to cut a small section out of the midline of the graft under the bladder neck. Apply additional traction to the distal (superior) arms to help take up the slack and flatten the mesh under the bladder. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. A cystoscopy should be performed to confirm integrity of the bladder after the mesh has been positioned.
10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. Extra care should be used when positioning the Avaulta Plus™ Biosynthetic Support System implant to prevent tearing of the acellular collagen sheet. After desired positioning is complete, at the physician's discretion, the entire graft and incision line may be irrigated with an appropriate antibiotic solution. Trimming of the vaginal mucosa should be limited to only mucosal edges damaged by instruments.

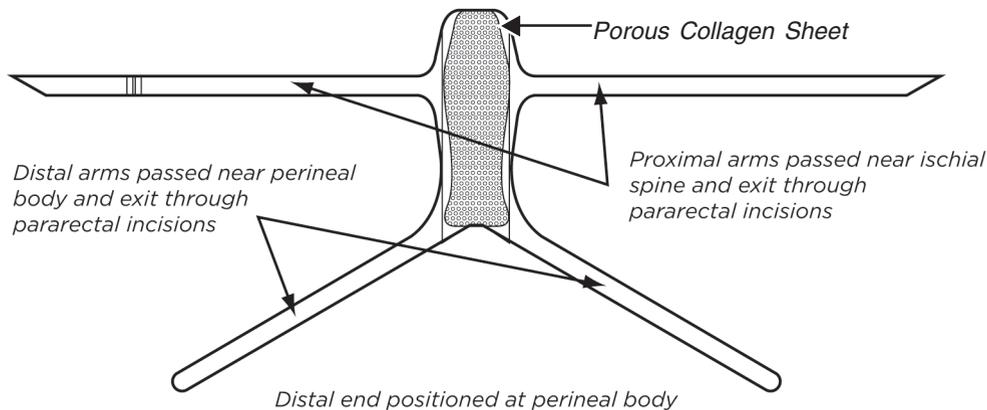
Caution: Excessive tension should be avoided on the mesh and suture attachment points to account for wound shrinkage during the healing process.

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11. Close the anterior vaginal wall incision using a running stitch. It is advised to use a monofilament suture for closure, though it is not advised to use an interrupted or locking stitch as this may cause excessive hemostasis, resulting in delayed closure. Trim all ends of the mesh arms below the level of the skin and close skin incisions.

Implantation Technique for the Avaulta Plus™ Posterior Support System:

Proximal end positioned at vaginal apex



- Note: When using the Avaulta Plus™ Biosynthetic Support System, the tissue layer of the graft may be oriented to face the vaginal mucosal tissue or the visceral side at the discretion of the physician. To help facilitate the desired orientation, the colored markers on the arms should be positioned on the patient's right side for the tissue layer to be positioned on the vaginal mucosal side. Conversely, the arm markers should be oriented on the patient's left side for the tissue layer to face the visceral side.
- Proximal end with apical flap positioned at vaginal apex
- Proximal arms (long arms with pointed ends) passed through ischiorectal fossa
- Distal end positioned at perineal body
- Distal arms (short arms with rounded ends) passed through ischiorectal fossa

1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
2. Make an incision in the posterior vaginal wall through the vaginal mucosa and into the fascial plane between the mucosa and the rectum. Use blunt and sharp dissection to dissect the vaginal mucosa away from the rectum laterally to the pelvic sidewalls and proximally to the ischial spine on both sides. Ensure a thick dissection is created, leaving as much endopelvic fascia on the mucosa as possible.
3. Make two small pararectal incisions (≥ 1 cm) approximately 3 cm lateral and 3 cm posterior to the anus.
4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Orient the introducer needle with the handle positioned vertically and the needle tip horizontal and parallel to the vaginal floor. Insert the needle tip into one of the pararectal incisions, aiming the needle tip towards the ischial spine. Pass the introducer through the ischiorectal fossa passing lateral to the posterior wall of the rectum until the needle tip nears the ischial spine, so that the proximal arms of the graft can be placed at or just cephalad to the level of the ischial spine. Move the handle downwards to direct the needle tip upwards approximately 1 cm proximal to the ischial spine and out through the posterior vaginal wall incision, exposing at least 1-2 cm of the needle tip. At the physician's discretion, the proximal arms may be secured through the sacrospinous ligament using a similar motion. Exercise care not to tear the pelvic tissue during passage. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself. *Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.*
5. Pass the proximal mesh arm (pointed end) up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.

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6. Apply traction to draw the proximal arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Avoid placing excessive tension on the graft.
7. Approximate the total vaginal length over which the graft will provide support. If necessary, use scissors to remove as much of the distal portion of the collagen sheet as is necessary so that the collagen terminates inside the vaginal introitus. Make a vertical cut along the blue center line of the polypropylene mesh to just inside the vaginal introitus to allow the graft to lie flat over the rectum once the distal arms are placed.
8. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the same pararectal incision created in Step 3 and orient the needle tip towards the vaginal introitus. Exercise care to stay lateral to the anal sphincter and rectum during passage. Use a vaginal finger to guide the needle tip through the posterior vaginal wall incision at the perineal body and at the most lateral portion of the dissection (the junction of the transverse perineal and bulbocavernosus muscles), exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
9. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 8 and 9 on the contralateral side.
10. Apply traction to draw the distal arms of the graft into the desired position such that the distal end of the central graft is positioned next to the perineal body. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central mesh lays over the rectum without excessive tension. A digital rectal exam should be performed to confirm integrity of the rectum after the mesh is positioned.
11. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. Extra care should be used when positioning the Avaulta Plus™ Biosynthetic Support System implant to prevent tearing of the acellular collagen sheet. After desired positioning is complete, at the physician's discretion, the entire graft and incision line may be irrigated with an appropriate antibiotic solution. Trimming of the vaginal mucosa should be limited to only mucosal edges damaged by instruments.

Caution: Excessive tension should be avoided on the mesh and suture attachment points to account for wound shrinkage during the healing process.
12. Close the posterior vaginal wall incision using a running stitch. It is advised to use a monofilament suture for closure, though it is not advised to use an interrupted or locking stitch as this may cause excessive hemostasis, resulting in delayed closure. Trim all ends of the mesh arms below the level of the skin and close skin incisions.

STERILIZATION TECHNIQUE

Avaulta Plus™ Biosynthetic Support System is a single-use device. The implant and introducers are sterilized by ethylene oxide. Do not resterilize.

STORAGE

Recommended storage conditions: between 2°-40°C (36°-105°F) in a dry area.

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Patent pending.

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Avaulta Solo™ Synthetic Support System

INSTRUCTIONS FOR USE

4-ENGLISH
9-FRENCH/FRANÇAIS
14-GERMAN/DEUTSCH
19-ITALIAN/ITALIANO
24-SPANISH/ESPAÑOL
29-DUTCH/NEDERLANDS
34-PORTUGUESE/PORTUGUÊS
39-GREEK/ΕΛΛΗΝΙΚΑ
45-DANISH/DANSK
50-SWEDISH/SVENSKA
55-FINNISH/SUOMI
60-NORWEGIAN/NORSK
65-POLISH/POLSKI
69-HUNGARIAN/MAGYAR
74-CZECH/ČESKY
79-TURKISH/TÜRKÇE



BARD

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1-888-367-2273
www.bardurological.com



Bard Limited, Forest House
Brighton Road
Crawley, West Sussex
RH11 9BP, UK
0044 1293 527 888



PK0302005 5/2008

STERILE EO

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 Stérilisé à l'oxyde d'éthylène
 Sterilisiert mit Ethyloxid
 Sterilizzato con ossido di etilene
 Esterilizado con óxido de etileno
 Gesteriliseerd met behulp van ethyleenoxide
 Esterilizado por óxido de etileno
 Αποστειρωμένο με οξειδίο του αιθυλενίου
 Steriliseret med ethylenoxid
 Steriliserat med etylenoxid
 Steriloitu etyleenioksidilla
 Steriliseret med etylenoksid
 Sterylizowany tlenkiem etylenu
 Etilénoxiddal sterilizálva
 Sterilizovano ethylenoxidem
 Etilen Oksitle sterilize edilmiştir



Read instructions for use
 Se reporter au mode d'emploi
 Gebrauchsanweisung lesen
 Leggere le istruzioni per l'uso
 Leer las instrucciones de uso
 Voorzichtig, raadpleeg de gebruiksaanwijzing
 Leia as instruções de utilização
 Διαβάστε τις οδηγίες χρήσης
 Læs brugsanvisningen
 Läs anvisningarna före användning.
 Lue käyttöohjeet
 Les bruksanvisningen
 Przed użyciem zapoznać się z instrukcją
 Olvassa el a használati útmutatót
 Přečtěte si pokyny k použití
 Kullanna talimatini okuyun



Single use only. Do not reuse.
 Réserve à un usage unique. Ne pas réutiliser.
 Nur für den einmaligen Gebrauch bestimmt. Nicht wiederverwenden.
 Solo monouso. Non riutilizzare.
 Un solo uso. No reutilizar.
 Uitsluitend voor eenmalig gebruik. Niet opnieuw gebruiken.
 Apenas para utilização única. Não reutilizar.
 Για μία μόνο χρήση. Μην επαναχρησιμοποιείτε.
 Kun til engangsbrug. Må ikke genbruges.
 Endast för engångsbruk Får ej återanvändas.
 Vain kertakäyttöön. Ei saa käyttää uudelleen.
 Ikke til gjenbruk.
 Wyłącznie do jednorazowego użytku. Nie używać powtórnie.
 Kizárólag egyszeri használatra. Ne használja fel újra.
 Pouze k jednorázovému použití. Nepoužívejte opakovaně.
 Sadece tek kullanımlık. Tekrar kullanmayın.



Do Not Resterilize
 Ne pas procéder à une nouvelle stérilisation
 Nicht reesterilisieren
 Non risterilizzare
 No reesterilizar
 Niet opnieuw steriliseren
 Não reesterilizar
 Μην επαναποστειρώνετε.
 Må ikke gensteriliseres
 Får ej omsteriliseras.
 Ei saa steriloida uudelleen
 Skal ikke reesteriliseres.
 Nie sterylizować ponownie
 Ne sterilizálja újra
 Neprovádějte reesterilizaci
 Tekrar Sterilize Etmeyin.



Sterile unless package is opened or damaged.
 Stérile sauf si l'emballage est ouvert ou endommagé.
 Steril, sofern nicht offen oder beschädigt.
 Sterile solo se la confezione non è aperta o danneggiata.
 Estéril a menos que el envase esté abierto o dañado.
 Steriel tenzij de verpakking geopend of beschadigd is.
 Estéril a menos que a embalagem esteja aberta ou danificada.
 Αποστειρωμένο εφόσον η συσκευασία δεν έχει ανοιχτεί και δεν έχει υποστεί ζημιά.
 Steril med mindre emballagen er åbnet eller beskadiget.
 Steril om förpackningen inte har öppnats eller skadats.
 Steriili mikäli pakkaus on avaaaton ja ehjä.
 Steril med mindre förpackningen er åpnet eller skadet.
 Produkt sterylno, o ile opakowanie nie zostało otwarte lub uszkodzone.
 Steril, kivéve ha a csomagolás nyitott vagy károsodott.
 Sterilní, pokud není balení otevřeno či poškozeno.
 Ambalaj açılmadığı ve hasarlı olmadığı sürece sterilidir.



Use by date
 Date de péremption
 Verfallsdatum
 Data di scadenza
 Usar antes de
 Houdbaar tot
 Utilizar até
 Ημερομηνία λήξης
 Anvendes inden
 Används senast
 Viimeinen käyttöajankohta
 Brukes innen:
 Data ważności
 Lejárati idő
 Použijte do
 Son kullanma tarihi



Recommended storage conditions: between 2°-40°C (36°-105°F), in a dry area.
 Conditions de conservation recommandées : Conserver entre 2° et 40°C, dans un lieu sec.
 Empfohlene Lagerungsbedingungen: zwischen 2°-40°C, in trockener Umgebung lagern.
 Condizioni di conservazione consigliate: temperatura compresa tra 2°-40°C in luogo asciutto.
 Condiciones de almacenamiento recomendadas: entre 2°-40°C, en un lugar seco.
 Aanbevolen bewaarcondities: 2 - 40 °C (36 - 105 °F), op een droge plaats.
 Condições de conservação recomendadas: entre 2°-40°C (36°-105°F), num local seco.
 Συνιστώμενες συνθήκες φύλαξης: μεταξύ 2 °C 40 °C (36 °F 105 °F), σε ξηρό χώρο.
 Befølede opbevaringsbetingelser: mellem 2°-40°C i et tørt område.
 Rekommenderade förvaringsvillkor: mellan 2°-40 °C på ett torrt ställe.
 Suositeltavat säilytysolosuhteet: 2–40 °C (36–105 °F), kuivassa paikassa.
 Anbefales oppbevar: tørt, mellom 2 °C -40 °C (36 °F -105 °F).
 Zalecane warunki przechowywania: temperatura w zakresie 2°-40°C, w suchym miejscu.
 Javasolt tárolási környezet: 2°-40°C között, száraz helyen.
 Doporučované podmínky skladování: mezi 2°-40°C, v suchém prostředí.
 Önerilen saklama koşulları: Kuru bir yerde, 2° 40°C (36° 105°F) arası sıcaklıklarda saklayınız.

DRAFT



Date of Manufacture
Date de fabrication
Herstellungsdatum
Data di produzione
Fecha de fabricación
Productiedatum
Data da produção
Ημερομηνία κατασκευής
Fremstillingsdato
Tillverkningsdatum
Valmistuspäivämäärä
Produksjonsdato:
Data produkcji
Gyártás dátuma
Datum výroby
Üretim Tarihi



Batch code
Code de lot
Chargenbezeichnung
Codice batch
Código del lote
Lotnummer
Código do lote
Κωδικός παρτίδας
Batch nummer
Batchkod
Eräkoodi
Batch-kode:
Numer serii
Gyártási szám
Kód šarže
Parti kodu



Manufacturer
Fabricant
Hersteller
Produttore
Fabricante
Fabrikant
Fabricante
Κατασκευαστής
Producent
Tillverkare
Valmistaja
Produzent
Producent
Gyártó
Výrobce
Üretici



Catalogue number
Numéro de catalogue
Katalog-Nummer
Numero di catalogo
Número de catálogo
Catalogusnummer
Referència de catàlego
Αριθμός καταλόγου
Katalog nummer
Katalognummer
Luettelonumero
Katalognummer
Numer katalogowy
Katalógusszám
Katalogové číslo
Katalog numarası



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
Attention: Selon la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.
Achtung: Gemäß US-Bundesgesetzgebung darf der Verkauf dieses Systems nur durch einen Arzt oder auf Veranlassung eines Arztes erfolgen.
Attenzione: le leggi federali degli Stati Uniti limitano la vendita di questo dispositivo ai soli medici o su prescrizione medica.
Precaución: Las leyes federales (EE.UU.) limitan la venta de este dispositivo a médicos o bajo prescripción facultativa.
Opgelet: Krachtens de federale wetgeving (VS) mag dit product alleen door of in opdracht van een arts worden verkocht.
Cuidado: A Lei Federal (EUA) limita a venda deste dispositivo a um médico ou por ordem de um médico.
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Figyelem: A szövetségi (USA) törvények értelmében ezen eszköz kizárólag orvos által, illetve orvosi rendelvényre árusítható.
Upozornění: Federální zákony (USA) omezují prodej tohoto prostředku na prodej lékařem nebo na lékařský předpis.
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Valtuutettu edustaja
Autorisert representant
Autoryzowany przedstawiciel
Felhatalmazott képviselő
Autorizovaný zástupce
Yetkili Temsilci

Avaulta Solo™ Synthetic Support System

Instructions for Use

DESCRIPTION

The Avaulta Solo™ Synthetic Support System utilizes a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. The monofilament, polypropylene mesh used in the Avaulta Solo™ Support System has a soft knit in the central section for compliant organ support and host tissue ingrowth, and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open knit design offers multidirectional strength and elasticity that allows the synthetic mesh to be trimmed at the physician's discretion without unraveling and to adapt to various body stresses.

As a convenience to the physician, the Avaulta Solo™ Synthetic Support System consists of a pre-cut graft for vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

The instrumentation included in the Avaulta Solo™ Synthetic Support System features a unique, patent-pending flexible snare system designed to minimize tissue trauma during implantation and allow for easier tip exteriorization and mesh arm capture.

INDICATIONS

Avaulta Solo™ Synthetic Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

Avaulta Solo™ Synthetic Support System is contraindicated for patients who are pregnant or may become pregnant, have a urinary tract infection, have an infection in the operative field, or patients in a period of growth because the mesh may not stretch significantly.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage.

PRECAUTIONS

- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Avaulta Solo™ Synthetic Support System should only be used by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction and the implantation of nonabsorbable meshes.
- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.
- Avaulta Solo™ Synthetic Support System implantation procedures require diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- The Avaulta Solo™ Synthetic Support System is provided in a sterile blister tray within a sterile pouch. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Anterior and Posterior Synthetic Support Systems are provided in a sterile blister tray. Transfer the introducer to the sterile field using aseptic techniques. Do not place the tray in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh or introducers if the packaging is opened or damaged.
- As for any implantable material, it is recommended to open the blister tray at the time of implantation.
- After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling jogging) for at least three to four weeks and intercourse for one month.

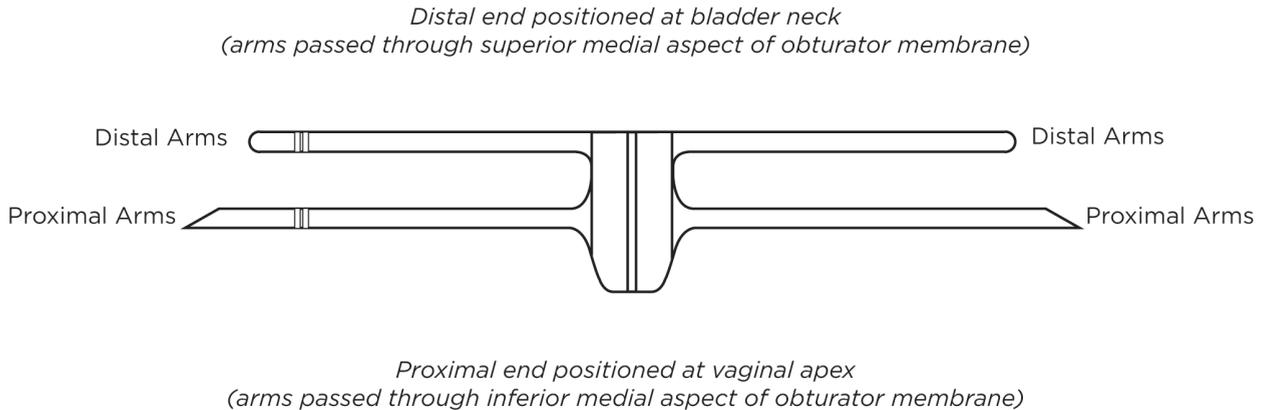
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IMPLANT PROCEDURES

Avaulta Solo™ Synthetic Support System mesh may be trimmed to approximate the total vaginal length over which the graft will provide support. If necessary, the proximal portion of the graft (apical extension) may be removed.

CAUTION: The mesh should not be trimmed to a width less than 1 cm in order to maintain sufficient strength and prevent unraveling.

Implantation Technique for the Avaulta Solo™ Anterior Support System:



- Note: The Avaulta Solo™ Support System does not require a particular orientation with respect to mucosal or visceral sidedness.
 - Proximal end with apical flap positioned at vaginal apex
 - Proximal arms (long arms with pointed ends) passed through inferior medial aspect of obturator membrane
 - Distal end positioned at bladder neck
 - Distal arms (short arms with rounded ends) passed through superior medial aspect of obturator membrane
1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
 2. Make an incision in the anterior vaginal wall through the vaginal mucosa and into the fascial plane between the mucosa and the bladder. Dissect the vaginal mucosa away from the bladder laterally to the obturator internus at the level of the bladder neck and proximally to the ischial spine on both sides. Ensure a thick dissection is created, leaving as much endopelvic fascia on the mucosa as possible.
 3. Identify the obturator fossa by grasping the adductor longus at its insertion to the pubic tubercle. Using the thumb to palpate under the adductor longus insertion, the superior medial aspect of the obturator fossa is identified. Palpate and draw the medial border of the obturator fossa to its inferior medial border. Make a vertical incision ≥ 1 cm approximately 1 cm below the superior medial border of the obturator fossa and lateral to the bladder neck for the distal arm of the mesh. Make a second vertical incision ≥ 1 cm at the inferior medial border of the obturator fossa and approximately lateral to the vaginal cuff. Repeat on the contralateral side.
 4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the inferior medial groin incision to puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle tip towards the ischial spine or top of the vaginal cuff. Identify the tip of the introducer before puncturing through the obturator internus muscle. With a gentle rotation of the introducer push through the obturator muscle and use the vaginal finger to guide the needle tip through the fascial wall to exit proximally at the vaginal apex, exposing at least 1-2 cm of the needle tip. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself.
 5. Pass the proximal arm (pointed end) of the mesh up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from

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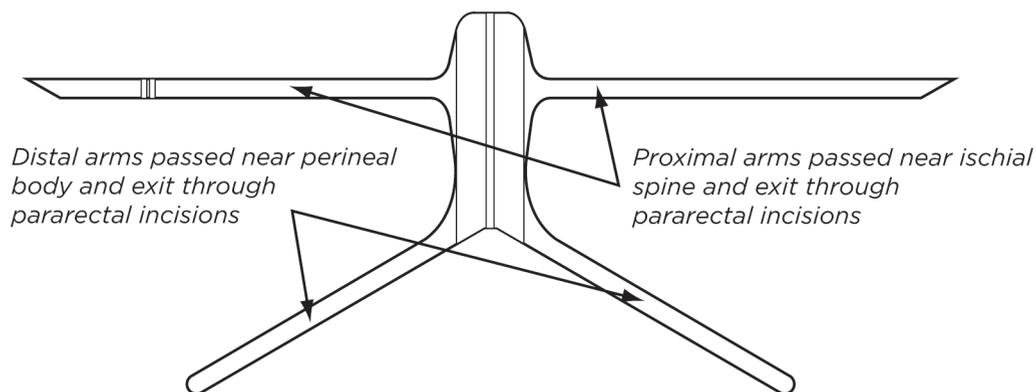
getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the inferior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.

6. Apply traction to draw the proximal (inferior) arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Be sure the graft is tension-free.
 7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the superior groin incision and gently puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle towards the level of the bladder neck. Use a vaginal finger to guide the needle tip through the obturator internus as before, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
 8. Pass a distal arm (rounded end) of the mesh up to the fold (about 4 cm) through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the superior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
 9. Apply traction to draw the distal (superior) arms of the graft into the desired position such that the distal end of the central graft is positioned near the bladder neck. If significant folds are observed, scissors may be used to cut a small section out of the midline of the graft under the bladder neck. Apply additional traction to the distal (superior) arms to help take up the slack and flatten the mesh under the bladder. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. A cystoscopy should be performed to confirm integrity of the bladder after the mesh has been positioned.
 10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, at the physician's discretion, the entire graft and incision line may be irrigated with an appropriate antibiotic solution. Trimming of the vaginal mucosa should be limited to only mucosal edges damaged by instruments.
- Caution: Excessive tension should be avoided on the mesh and suture attachment points to account for wound shrinkage during the healing process.
11. Close the anterior vaginal wall incision using a running stitch. It is advised to use a monofilament suture for closure, though it is not advised to use an interrupted or locking stitch as this may cause excessive hemostasis, resulting in delayed closure. Trim all ends of the mesh arms below the level of the skin and close incisions.

Implantation Technique for the Avaulta Solo™ Synthetic Posterior Support System:

Proximal end positioned at vaginal apex



Distal end positioned at perineal body

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- Note: The Avaulta Solo™ Support System does not require a particular orientation with respect to mucosal or visceral sidedness.
 - Proximal end with apical flap positioned at vaginal apex
 - Proximal arms (long arms with pointed ends) passed through ischiorectal fossa
 - Distal end positioned at perineal body
 - Distal arms (short arms with rounded ends) passed through ischiorectal fossa
1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
 2. Make an incision in the posterior vaginal wall through the vaginal mucosa and into the fascial plane between the mucosa and the rectum. Use blunt and sharp dissection to dissect the vaginal mucosa away from the rectum laterally to the pelvic sidewalls and proximally to the ischial spine on both sides. Ensure a thick dissection is created, leaving as much endopelvic fascia on the mucosa as possible.
 3. Make two small pararectal incisions (≥ 1 cm) approximately 3 cm lateral and 3 cm posterior to the anus.
 4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Orient the introducer needle with the handle positioned vertically and the needle tip horizontal and parallel to the vaginal floor. Insert the needle tip into one of the pararectal incisions, aiming the needle tip towards the ischial spine. Pass the introducer through the ischiorectal fossa passing lateral to the posterior wall of the rectum until the needle tip nears the ischial spine, so that the proximal arms of the graft can be placed at or just cephalad to the level of the ischial spine. Move the handle downwards to direct the needle tip upwards approximately 1 cm proximal to the ischial spine and out through the posterior vaginal wall incision, exposing at least 1-2 cm of the needle tip. At the physician's discretion, the proximal arms may be secured through the sacrospinous ligament using a similar motion. Exercise care not to tear the pelvic tissue during passage. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself. *Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.*
 5. Pass the proximal mesh arm (pointed end) up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.
 6. Apply traction to draw the proximal arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Avoid placing excessive tension on the graft.
 7. Approximate the total vaginal length over which the graft will provide support. If necessary, make a vertical cut along the blue center line of the polypropylene mesh to just inside the vaginal introitus to allow the graft to lie flat over the rectum once the distal arms are placed.
 8. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the same pararectal incision created in Step 3 and orient the needle tip towards the vaginal introitus. Exercise care to stay lateral to the anal sphincter and rectum during passage. Use a vaginal finger to guide the needle tip through the posterior vaginal wall incision at the perineal body, and at the most lateral portion of the dissection (the junction of the transverse perineal and bulbocavernosus muscles), exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.

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9. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 8 and 9 on the contralateral side.
10. Apply traction to draw the distal arms of the graft into the desired position such that the distal end of the central graft is positioned next to the perineal body. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central mesh lays over the rectum without excessive tension. A digital rectal exam should be performed to confirm integrity of the rectum after the mesh is positioned.
11. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, at the physician's discretion, the graft and incision line may be irrigated with an appropriate antibiotic solution. Trimming of the vaginal mucosa should be limited to only mucosal edges damaged by instruments.

Caution: Excessive tension should be avoided on the mesh and suture attachment points to account for wound shrinkage during the healing process.

12. Close the posterior vaginal wall incision using a running stitch. It is advised to use a monofilament suture for closure, though it is not advised to use an interrupted or locking stitch as this may cause excessive hemostasis, resulting in delayed closure. Trim all ends of the mesh arms below the level of the skin and close incisions.

STERILIZATION TECHNIQUE

Avaulta Solo™ Support System is a single-use device. The implant and introducers are sterilized by ethylene oxide. Do not resterilize.

STORAGE

Recommended storage conditions: between 2°-40°C (36°-105°F) in a dry area.

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Patent pending.

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Exhibit 5

Current IFUs

Avaulta Plus™

Biosynthetic Support System

INSTRUCTIONS FOR USE

4-ENGLISH
9-FRENCH/FRANÇAIS
15-GERMAN/DEUTSCH
21-ITALIAN/ITALIANO
27-SPANISH/ESPAÑOL
33-DUTCH/NEDERLANDS
39-PORTUGUESE/PORTUGUÊS
45-GREEK/ΕΛΛΗΝΙΚΑ
51-DANISH/DANSK
56-SWEDISH/SVENSKA
61-FINNISH/SUOMI
67-NORWEGIAN/NORSK
72-POLISH/POLSKI
77-HUNGARIAN/MAGYAR
82-CZECH/ČESKY
87-TURKISH/TÜRKÇE



BARD

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Covington, GA 30014 USA
1-888-367-2273
www.bardurological.com



Bard Limited, Forest House
Brighton Road
Crawley, West Sussex
RH11 9BP, UK
0044 1293 527 888

STERILE EO

Sterilized by Ethylene Oxide
Stérilisé à l'oxyde d'éthylène
Sterilisiert mit Ethyloxid
Sterilizato con ossido di etilene
Esterilizado con óxido de etileno
Gesteriliseerd met behulp van ethyleenoxide
Esterilizado por óxido de etileno
Αποστειρωμένο με οξείδιο του αιθυλενίου
Steriliseret med ethylenoxid
Steriliserat med etylenoxid
Steriloitu etyleenioksidilla
Steriliseret med etylenoksid
Steryliowany tlenkiem etylenu
Etílenoxidál sterilizálva
Sterilizováno etylenoxidem
Etilen Oksitle sterilize edilmiştir



Read instructions for use
Se reporter au mode d'emploi
Gebrauchsanweisung lesen
Leggere le istruzioni per l'uso
Leer las instrucciones de uso
Voorzichtig, raadpleeg de gebruiksaanwijzing
Leia as instruções de utilização
Διαβάστε τις οδηγίες χρήσης
Læs brugsanvisningen
Läs anvisningarna före användning.
Lue käyttöohjeet
Les bruksanvisningen
Przed użyciem zapoznać się z instrukcją
Olvassa el a használati útmutatót
Přečtěte si pokyny k použití
Kullanma talimatını okuyun



Single use only. Do not reuse.
Réservé à un usage unique. Ne pas réutiliser.
Nur für den einmaligen Gebrauch bestimmt. Nicht wiederverwenden.
Solo monouso. Non riutilizzare.
Un solo uso. No reutilizar.
Uitsluitend voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para utilização única. Não reutilizar.
Για μία μόνο χρήση. Μην επαναχρησιμοποιείτε.
Kun til engangsbrug. Må ikke genbruges.
Endast för engångsbruk. Får ej återanvändas.
Vain kertakäyttöön. Ei saa käyttää uudelleen.
Ikke til gjenbruk.
Wyłącznie do jednorazowego użytku. Nie używać powtórnie.
Kizárólag egyszéri használatra. Ne használja fel újra.
Pouze k jednorázovému použití. Nepoužívejte opakovaně.
Sadece tek kullanımlık. Tekrar kullanmayın.



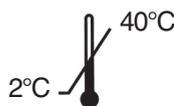
Do Not Resterilize
Ne pas procéder à une nouvelle stérilisation
Nicht reesterilisieren
Non risterilizzare
No reesterilizar
Niet opnieuw steriliseren
Não reesterilizar
Μην επαναποστειρώνετε.
Må ikke gensteriliseres
Får ej omsteriliseras.
Ei saa steriloida uudelleen
Skal ikke reesteriliseres.
Nie sterylizować ponownie
Ne sterilizálja újra
Neprovádějte resterilizaci
Tekrar Sterilize Etmeyin.



Sterile unless package is opened or damaged.
Stérile sauf si l'emballage est ouvert ou endommagé.
Steril, sofern nicht offen oder beschädigt.
Sterile solo se la confezione non è aperta o danneggiata.
Estéril a menos que el envase esté abierto o dañado.
Steriel tenzij de verpakking geopend of beschadigd is.
Estéril a menos que a embalagem esteja aberta ou danificada.
Αποστειρωμένο εφόσον η συσκευασία δεν έχει ανοιχτεί και δεν έχει υποστεί ζημιά.
Steril medmindre emballagen er åbnet eller beskadiget.
Steril om förpackningen inte har öppnats eller skadats.
Sterilii mikáli pakkaus on avaamaton ja ehjä.
Steril med mindre forpakningen er åbnet eller skadet.
Produkt sterylony, o ile opakowanie nie zostało otwarte lub uszkodzone.
Steril, kivéve ha a csomagolás nyitott vagy károsodott.
Sterilní, pokud není balení otevřeno či poškozeno.
Ambalaj açılmadığı ve hasarlı olmadığı sürece sterildir.



Use by date
Date de péremption
Verfallsdatum
Data di scadenza
Usar antes de
Houdbaar tot
Utilizar até
Ημερομηνία λήξης
Anvendes inden
Används senast
Viimeinen käyttöajankohta
Brukes innen:
Data ważności
Lejárati idő
Použijte do
Son kullanma tarihi



Recommended storage conditions: between 2°-40°C (36°-105°F), in a dry area.
Conditions de conservation recommandées : Conserver entre 2° et 40°C, dans un lieu sec.
Empfohlene Lagerungsbedingungen: zwischen 2°-40°F, in trockener Umgebung lagern.
Condizioni di conservazione consigliate: temperatura compresa tra 2°-40°C in luogo asciutto.
Condiciones de almacenamiento recomendadas: entre 2°-40°C, en un lugar seco.
Aanbevolen bewaarcondities: 2 - 40 °C (36 - 105 °F), op een droge plaats.
Condições de conservação recomendadas: entre 2°-40°C (36°-105°F), num local seco.
Συνιστώμενες συνθήκες φύλαξης: μεταξύ 2 °C-40 °C (36 °F-105 °F), σε ξηρό χώρο.
Anbefalede opbevaringsbetingelser: mellem 2°-40°C i et tørt område.
Rekommenderade förvaringsvillkor: mellan 2°-40 °C på ett torrt ställe.
Suositeltavat säilytysolosuhteet: 2-40 °C (36-105 °F), kuivassa paikassa.
Anbefales oppbevar: tørt, mellom 2 °C -40 °C (36 °F -105 °F).
Zalecane warunki przechowywania: temperatura w zakresie 2°-40°C, w suchym miejscu.
Javasolt tárolási környezet: 2°-40°C között, száraz helyen.
Doporučované podmínky skladování: mezi 2°-40°C, v suchém prostředí.
Önerilen saklama koşulları: Kuru bir yerde, 2°-40°C (36°-105°F) arası sıcaklıklarda saklayınız.



Date of Manufacture
Date de fabrication
Herstellungsdatum
Data di produzione
Fecha de fabricación
Productiedatum
Data da produção
Ημερομηνία κατασκευής
Fremstillingsdato
Tillverkningsdatum
Valmistuspäivämäärä
Produksjonsdato:
Data produkcji
Gyártás dátuma
Datum výroby
Üretim Tarihi



Batch code
Code de lot
Chargenbezeichnung
Codice batch
Código del lote
Lotnummer
Código do lote
Κωδικός παρτίδας
Batch nummer
Batchkod
Eräkoodi
Bartch-kode:
Numer serii
Gyártási szám
Kód šarže
Parti kodu



Manufacturer
Fabricant
Hersteller
Produttore
Fabricante
Fabrikant
Fabricante
Κατασκευαστής
Producent
Tillverkare
Valmistaja
Produsent
Producent
Gyártó
Výrobce
Üretici



Catalogue number
Numéro de catalogue
Katalog-Nummer
Numero di catalogo
Número de catálogo
Catalogusnummer
Referència de catàlego
Αριθμός καταλόγου
Katalog number
Katalognummer
Luettelonumero
Katalognummer
Numer katalogowy
Katalógusszám
Katalogové číslo
Katalog numarası



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
Attention: Selon la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.
Achtung: Gemäß US-Bundesgesetzgebung darf der Verkauf dieses Systems nur durch einen Arzt oder auf Veranlassung eines Arztes erfolgen.
Attenzione: le leggi federali degli Stati Uniti limitano la vendita di questo dispositivo ai soli medici o su prescrizione medica.
Precaución: Las leyes federales (EE.UU.) limitan la venta de este dispositivo a médicos o bajo prescripción facultativa.
Opgelet: Krachtens de federale wetgeving (VS) mag dit product alleen door of in opdracht van een arts worden verkocht.
Cuidado: A Lei Federal (EUA) limita a venda deste dispositivo a um médico ou por ordem de um médico.
Προσοχή: Η ομοσπονδιακή νομοθεσία (Η.Π.Α.) επιτρέπει την πώληση της συσκευής αυτής μόνον από ιατρό ή κατόπιν εντολής ιατρού.
Forsigtig: Amerikansk lovgivning begrænser denne anordning til salg a feller efter ordination af en læge.
Varning: Enligt federal lag (USA) får denna utrustning endast säljas av eller på ordination av läkare.
Huomio: Yhdysvaltojen lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.
Forsiktig: I henhold til føderal lov i USA kan dette utstyret kun selges av eller etter henvisning fra en lege.
Uwaga: Prawo federalne USA ogranicza sprzedaż tego urządzenia do sprzedaży przez lub na zamówienie lekarza.
Figyelem: A szövetségi (USA) törvények értelmében ezen eszköz kizárólag orvos által, illetve orvosi rendelvényre árusítható.
Upozornění: Federální zákony (USA) omezují prodej tohoto prostředku na prodej lékařem nebo na lékařský předpis.
Dikkat: ABD federal kanunlarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir.



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Autorisierter Vertreter
Rappresentante autorizzato
Representante autorizado
Gemachtigde vertegenwoordiger
Representante autorizado
Εξουσιοδοτημένος αντιπρόσωπος
Autoriseret repræsentant
Auktoriserad representant
Valtuutettu edustaja
Autorisert representant
Autoryzowany przedstawiciel
Felhatalmazott képviselő
Autorizovaný zástupce
Yetkilil Temsilci

Avaulta Plus™ Biosynthetic Support System

Instructions for Use

ENGLISH/US

DESCRIPTION

The Avaulta Plus™ Biosynthetic Support System utilizes a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. Additionally, the Avaulta Plus™ Biosynthetic Support System features a porous, acellular, ultra-thin sheet of crosslinked collagen attached to the polypropylene mesh which serves to establish a protective barrier between mucosal tissue and the polypropylene mesh and contains apertures uniformly sized to allow the ingrowth of host tissue and capillary vessels.

The monofilament, polypropylene mesh used in the Avaulta Plus™ Biosynthetic Support System has a soft knit in the central section for compliant organ support and host tissue ingrowth, and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open knit design offers multidirectional strength and elasticity that allows the synthetic mesh to be trimmed at the physician's discretion without unraveling and to adapt to various body stresses.

The pre-attached collagen sheet on the Avaulta Plus™ Biosynthetic Support System covers the soft-knit central section of the mesh to provide both a thin collagen plane for ingrowth of native tissue as well as a protective mucosal tissue barrier. The lateral segments of the Avaulta Plus™ Biosynthetic Support System are not covered to maximize mesh fixation immediately post-implantation.

As a convenience to the physician, the Avaulta Plus™ Biosynthetic Support System consists of a pre-cut graft for vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

The instrumentation included in the Avaulta Plus™ Biosynthetic Support System features a unique, patent-pending flexible snare system designed to minimize tissue trauma during implantation and allow for easier tip exteriorization and mesh arm capture.

INDICATIONS

Avaulta Plus™ Biosynthetic Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

Avaulta Plus™ Biosynthetic Support System is contraindicated for patients who are pregnant or may become pregnant, have a urinary tract infection, have an infection in the operative field, or patients in a period of growth because the mesh may not stretch significantly.

Avaulta Plus™ Biosynthetic Support System with acellular dermal tissue has material derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage.

PRECAUTIONS

- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- The Avaulta Plus™ Biosynthetic Support System should only be used by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction and the implantation of nonabsorbable meshes.
- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.

- The Avaulta Plus™ Biosynthetic Support System implantation procedures require diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- The Avaulta Plus™ Biosynthetic Support System is provided in a sterile blister tray within a sterile pouch. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Anterior and Posterior Support Systems are provided in a sterile blister tray. Transfer the introducer to the sterile field using aseptic techniques. Do not place the tray in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh or introducers if the packaging is opened or damaged.
- As for any implantable material, it is recommended to open the blister tray at the time of implantation.
- After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month.

IMPLANT PROCEDURES

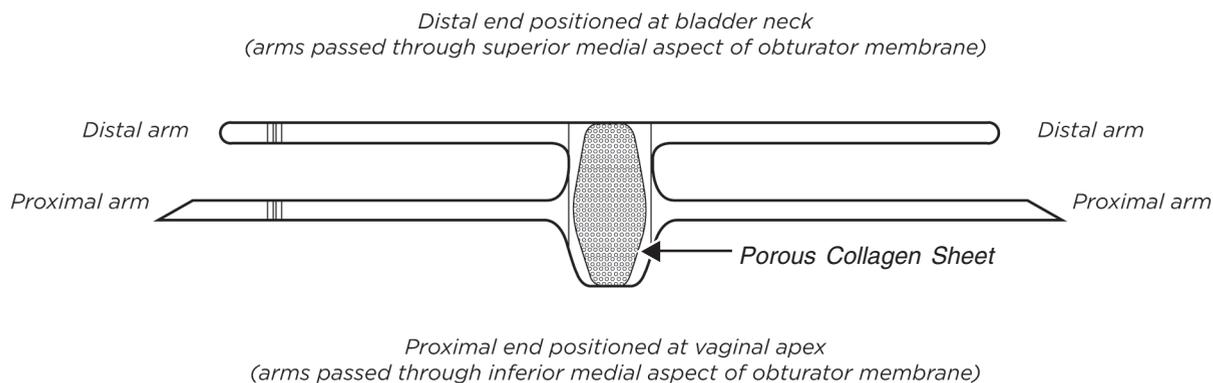
Preparation of Avaulta Plus™ Biosynthetic mesh for Implantation:

At the time of implantation, Avaulta Plus™ Biosynthetic Support System mesh must be hydrated. To hydrate, place the Avaulta Plus™ Biosynthetic Support System mesh into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for at least 3 minutes.

Avaulta Plus™ Biosynthetic Support System mesh is more easily trimmed prior to hydration, but may be trimmed after hydration if desired, to approximate the total vaginal length over which the graft will provide support. If necessary, the proximal portion of the graft (apical extension) may be removed.

CAUTION: The mesh should not be trimmed to a width less than 1 cm in order to maintain sufficient strength and prevent unraveling.

Implantation Technique for the Avaulta Plus™ Biosynthetic Anterior Support System:



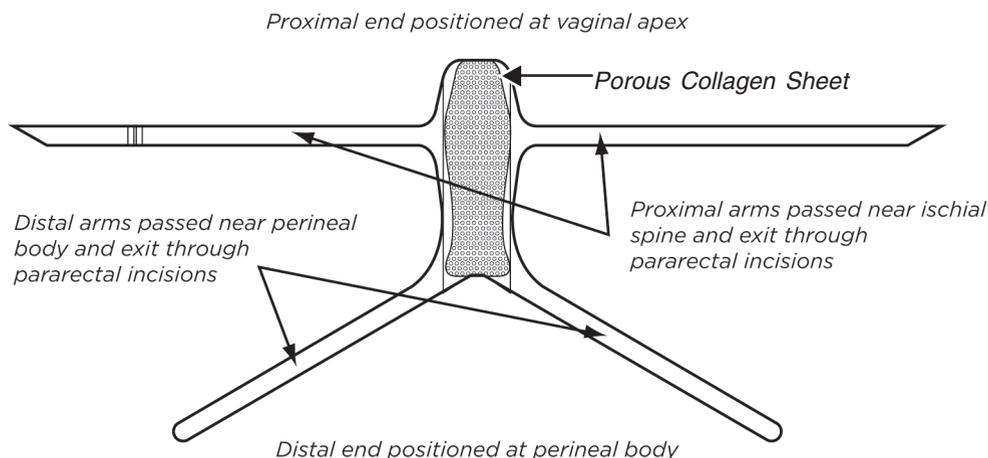
- Note: When using the Avaulta Plus™ Biosynthetic Support System, the tissue layer of the graft may be oriented to face the vaginal mucosal tissue or the visceral side at the discretion of the physician. To help facilitate the desired orientation, the colored markers on the arms should be positioned on the patient's right side for the tissue layer to be positioned on the vaginal mucosal side. Conversely, the arm markers should be oriented on the patient's left side for the tissue layer to face the visceral side.
 - Proximal end with apical flap positioned at vaginal apex
 - Proximal arms (long arms with pointed ends) passed through inferior medial aspect of obturator membrane
 - Distal end positioned at bladder neck
 - Distal arms (short arms with rounded ends) passed through superior medial aspect of obturator membrane
1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.

2. Make a midline incision in the anterior vaginal wall starting 1 cm below the urethral meatus and extending to the vaginal cuff. Dissect the vaginal mucosa away from the bladder laterally to the obturator internus at the level of the bladder neck and proximally to the ischial spine on both sides.
3. Identify the obturator fossa by grasping the adductor longus at its insertion to the pubic tubercle. Using the thumb to palpate under the adductor longus insertion, the superior medial aspect of the obturator fossa is identified. Palpate and draw the medial border of the obturator fossa to its inferior medial border. Make a vertical 1.5 cm incision approximately 1 cm below the superior medial border of the obturator fossa and lateral to the bladder neck for the distal arm of the mesh. Make a second vertical 1.5 cm incision at the inferior medial border of the obturator fossa and approximately lateral to the vaginal cuff. Repeat on the contralateral side.
4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the inferior medial groin incision to puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle tip towards the ischial spine or top of the vaginal cuff. Identify the tip of the introducer before puncturing through the obturator internus muscle. With a gentle rotation of the introducer push through the obturator muscle and use the vaginal finger to guide the needle tip through the fascial wall to exit proximally at the vaginal apex, exposing at least 1-2 cm of the needle tip. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself.
5. Pass the proximal arm (pointed end) of the mesh up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the inferior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.
 Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.
6. Apply traction to draw the proximal (inferior) arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Be sure the graft is tension-free.
7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the superior groin incision and gently puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle towards the level of the bladder neck. Use a vaginal finger to guide the needle tip through the obturator internus as before, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
8. Pass a distal arm (rounded end) of the mesh up to the fold (about 4 cm) through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the superior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
9. Apply traction to draw the distal (superior) arms of the graft into the desired position such that the distal end of the central graft is positioned near the bladder neck. If significant folds are observed, scissors may be used to cut a small section out of the midline of the graft under the bladder neck. Apply additional traction to the distal (superior) arms to help take up the slack and flatten the mesh under the bladder. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. A cystoscopy should be performed to confirm integrity of the bladder after the mesh has been positioned.
10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.

Caution: Excessive tension should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process.

- Close the anterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

Implantation Technique for the Avaulta Plus™ Posterior Support System:



- Note: When using the Avaulta Plus™ Biosynthetic Support System, the tissue layer of the graft may be oriented to face the vaginal mucosal tissue or the visceral side at the discretion of the physician. To help facilitate the desired orientation, the colored markers on the arms should be positioned on the patient's right side for the tissue layer to be positioned on the vaginal mucosal side. Conversely, the arm markers should be oriented on the patient's left side for the tissue layer to face the visceral side.
 - Proximal end with apical flap positioned at vaginal apex
 - Proximal arms (long arms with pointed ends) passed through ischiorectal fossa
 - Distal end positioned at perineal body
 - Distal arms (short arms with rounded ends) passed through ischiorectal fossa
- Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
 - Make a midline incision in the posterior vaginal wall starting at the vaginal introitus and extending to the vaginal apex. Starting at the perineal body, use blunt and sharp dissection to dissect the vaginal mucosa away from the rectum laterally to the pelvic sidewalls and proximally to the ischial spine on both sides.
 - Make two small pararectal incisions (1-2 cm) approximately 3 cm lateral and 3 cm posterior to the anus.
 - Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Orient the introducer needle with the handle positioned vertically and the needle tip horizontal and parallel to the vaginal floor. Insert the needle tip into one of the pararectal incisions, aiming the needle tip towards the ischial spine. Pass the introducer through the ischiorectal fossa passing lateral to the posterior wall of the rectum until the needle tip nears the ischial spine, so that the proximal arms of the graft can be placed at or just cephalad to the level of the ischial spine. Move the handle downwards to direct the needle tip upwards approximately 1 cm proximal to the ischial spine and out through the posterior vaginal wall incision, exposing at least 1-2 cm of the needle tip. At the physician's discretion, the proximal arms may be secured through the sacrospinous ligament using a similar motion. Exercise care not to tear the pelvic tissue during passage. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself. *Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.*
 - Pass the proximal mesh arm (pointed end) up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.

6. Apply traction to draw the proximal arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Avoid placing excessive tension on the graft.
7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the same pararectal incision created in Step 3 and orient the needle tip towards the vaginal introitus. Exercise care to stay lateral to the anal sphincter and rectum during passage. Use a vaginal finger to guide the needle tip through the posterior vaginal wall incision at the perineal body and at the most lateral portion of the dissection (the junction of the transverse perineal and bulbocavernosus muscles), exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
8. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
9. Apply traction to draw the distal arms of the graft into the desired position such that the distal end of the central graft is positioned next to the perineal body. If necessary, use scissors to make a small (≤ 2 cm) midline wedge or "V" cut in the distal edge of the central graft to approximate the length from the vaginal apex to the perineal body. Apply additional traction to the distal arms to position the central mesh as desired. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central mesh lays over the rectum without excessive tension. A digital rectal exam should be performed to confirm integrity of the rectum after the mesh is positioned.
10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.

Caution: Excessive tension should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process.

11. Close the posterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

STERILIZATION TECHNIQUE

Avaulta Plus™ Biosynthetic Support System is a single-use device. The implant and introducers are sterilized by ethylene oxide. Do not resterilize.

STORAGE

Recommended storage conditions: between 2°-40°C (36°-105°F) in a dry area.

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Patent pending.

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Avaulta Solo™ Support System

INSTRUCTIONS FOR USE

4-ENGLISH
9-FRENCH/FRANÇAIS
14-GERMAN/DEUTSCH
19-ITALIAN/ITALIANO
24-SPANISH/ESPAÑOL
29-DUTCH/NEDERLANDS
34-PORTUGUESE/PORTUGUÊS
39-GREEK/ΕΛΛΗΝΙΚΑ
45-DANISH/DANSK
50-SWEDISH/SVENSKA
55-FINNISH/SUOMI
60-POLISH/POLSKI
64-HUNGARIAN/MAGYAR
69-CZECH/ČESKY
74-TURKISH/TÜRKÇE



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www.bardurological.com



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Brighton Road
Crawley, West Sussex
RH11 9BP, UK
0044 1293 527 888



PK0301743 2/07

STERILE EO

Sterilized by Ethylene Oxide
Stérilisé à l'oxyde d'éthylène
Sterilisiert mit Ethyloxid
Sterilizato con ossido di etilene
Esterilizado con óxido de etileno
Gesteriliseerd met behulp van ethyleenoxide
Esterilizado por óxido de etileno
Αποστειρωμένο με οξειδίο του αιθυλενίου
Steriliseret med ethylenoxid
Steriliserat med etylenoxid
Steriloitu etyleenioksidilla
Steryliowany tlenkiem etylenu
Etilénoxidall sterilizálva
Sterilizovano ethylenoxidem
Etilen Oksitle sterilize edilmiştir



Read instructions for use
Se reporter au mode d'emploi
Gebrauchsanweisung lesen
Leggere le istruzioni per l'uso
Leer las instrucciones de uso
Voorzichtig, raadpleeg de gebruiksaanwijzing
Leia as instruções de utilização
Diaβάστε τις οδηγίες χρήσης
Læs brugsanvisningen
Läs anvisningarna före användning.
Lue käyttöohjeet
Przed użyciem zapoznać się z instrukcją
Olvassa el a használati útmutatót
Přečtěte si pokyny k použití
Kullanma talimatını okuyun



Single use only. Do not reuse.
Réservé à un usage unique. Ne pas réutiliser.
Nur für den einmaligen Gebrauch bestimmt. Nicht wiederverwenden.
Solo monouso. Non riutilizzare.
Un solo uso. No reutilizar.
Uitsluitend voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para utilização única. Não reutilizar.
Για μία μόνο χρήση. Μην επαναχρησιμοποιείτε.
Kun til engangsbrug. Må ikke genbruges.
Endast för engångsbruk. Får ej återanvändas.
Vain kertakäyttöön. Ei saa käyttää uudelleen.
Wyłącznie do jednorazowego użytku. Nie używać powtórnie.
Kizárolag egyszeri használatra. Ne használja fel újra.
Pouze k jednorázovému použití. Nepoužívejte opakovaně.
Sadece tek kullanımlık. Tekrar kullanmayın.



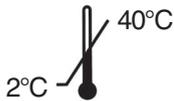
Do Not Resterilize
Ne pas procéder à une nouvelle stérilisation
Nicht reesterilisieren
Non risterilizzare
No reesterilizar
Niet opnieuw steriliseren
Não reesterilizar
Μην επαναποστειρώνετε.
Må ikke gensteriliseres
Får ej omsteriliseras.
Ei saa steriloida uudelleen
Nie steryliować ponownie
Ne sterilizálja újra
Neprovádějte resterilizaci
Tekrar Sterilize Etmeyin.



Sterile unless package is opened or damaged.
Stérile sauf si l'emballage est ouvert ou endommagé.
Steril, sofern nicht offen oder beschädigt.
Sterile solo se la confezione non è aperta o danneggiata.
Estéril a menos que el envase esté abierto o dañado.
Steriel tenzij de verpakking geopend of beschadigd is.
Estéril a menos que a embalagem esteja aberta ou danificada.
Αποστειρωμένο εφόσον η συσκευασία δεν έχει ανοιχτεί και δεν έχει υποστεί ζημιά.
Steril med mindre emballagen er åbnet eller beskadiget.
Steril om förpackningen inte har öppnats eller skadats.
Steriili mikäli pakkaus on avaamaton ja ehjä.
Produkt sterylony, o ile opakowanie nie zostało otwarte lub uszkodzone.
Steril, kivéve ha a csomagolás nyitott vagy károsodott.
Sterilní, pokud není balení otevřeno či poškozeno.
Ambalaj açılmadığı ve hasarlı olmadığı sürece sterildir.



Use by date
Date de péremption
Verfallsdatum
Data di scadenza
Usar antes de
Houdbaar tot
Utilizar até
Ημερομηνία λήξης
Anvendes inden
Används senast
Viimeinen käyttöajankohta
Data ważności
Lejárati idő
Použijte do
Son kullanma tarihi



Recommended storage conditions: between 2°-40°C (36°-105°F), in a dry area.
Conditions de conservation recommandées : Conserver entre 2° et 40°C, dans un lieu sec.
Empfohlene Lagerungsbedingungen: zwischen 2°-40°C, in trockener Umgebung lagern.
Condizioni di conservazione consigliate: temperatura compresa tra 2°-40°C in luogo asciutto.
Condiciones de almacenamiento recomendadas: entre 2°-40°C, en un lugar seco.
Aanbevolen bewaarcondities: 2 - 40 °C (36 - 105 °F), op een droge plaats.
Condições de conservação recomendadas: entre 2°-40°C (36°-105°F), num local seco.
Συνιστώμενες συνθήκες φύλαξης: μεταξύ 2 °C 40 °C (36 °F 105 °F), σε ξηρό χώρο.
Anbefalede opbevaringsbetingelser: mellem 2°-40°C i et tørt område.
Rekommenderade förvaringsvillkor: mellan 2°-40 °C på ett torrt ställe.
Suositeltavat säilytysolosuhteet: 2–40 °C (36–105 °F), kuivassa paikassa.
Zalecane warunki przechowywania: temperatura w zakresie 2°-40°C, w suchym miejscu.
Javasolt tárolási környezet: 2°-40°C között, száraz helyen.
Doporučované podmínky skladování: mezi 2°-40°C, v suchém prostředí.
Önerilen saklama koşulları: Kuru bir yerde, 2° 40°C (36° 105°F) arası sıcaklıklarda saklayınız.



Date of Manufacture
Date de fabrication
Herstellungsdatum
Data di produzione
Fecha de fabricacion
Productiedatum
Data da producao
Ημερομηνία κατασκευής
Fremstillingsdato
Tillverkningsdatum
Valmistuspäivämäärä
Data produkci
Gyártás dátuma
Datum výroby
Üretim Tarihi



Batch code
Code de lot
Chargenbezeichnung
Codice batch
Código del lote
Lotnummer
Código do lote
Κωδικός παρτίδας
Batch nummer
Batchkod
Eräkoodi
Numer serii
Gyártási szám
Kód šarže
Parti kodu



Manufacturer
Fabricant
Hersteller
Produttore
Fabricante
Fabrikant
Fabricante
Κατασκευαστής
Producent
Tillverkare
Valmistaja
Producent
Gyártó
Výrobce
Üretici



Catalogue number
Numéro de catalogue
Katalog-Nummer
Numero di catalogo
Número de catálogo
Catalogusnummer
Referència de catàlego
Αριθμός καταλόγου
Katalog nummer
Katalognummer
Luettelonumero
Numer katalogowy
Katalógusszám
Katalogové číslo
Katalog numarası



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
Attention: Selon la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.
Achtung: Gemäß US-Bundesgesetzgebung darf der Verkauf dieses Systems nur durch einen Arzt oder auf Veranlassung eines Arztes erfolgen.
Attenzione: le leggi federali degli Stati Uniti limitano la vendita di questo dispositivo ai soli medici o su prescrizione medica.
Precaución: Las leyes federales (EE.UU.) limitan la venta de este dispositivo a médicos o bajo prescripción facultativa.
Opgelet: Krachtens de federale wetgeving (VS) mag dit product alleen door of in opdracht van een arts worden verkocht.
Cuidado: A Lei Federal (EUA) limita a venda deste dispositivo a um médico ou por ordem de um médico.
Προσοχή: Η ομοσπονδιακή νομοθεσία (Η.Π.Α.) επιτρέπει την πώληση της συσκευής αυτής μόνον από ιατρό ή κατόπιν εντολής ιατρού.
Forsigtig: Amerikansk lovgivning begrænser denne anordning til salg a feller efter ordination af en læge.
Varning: Enligt federal lag (USA) får denna utrustning endast säljas av eller på ordination av läkare.
Huomio: Yhdysvaltojen lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.
Uwaga: Prawo federalne USA ogranicza sprzedaż tego urządzenia do sprzedaży przez lub na zamówienie lekarza.
Figyelem: A szövetségi (USA) törvények értelmében ezen eszköz kizárólag orvos által, illetve orvosi rendelvényre árusítható.
Upozornění: Federální zákony (USA) omezují prodej tohoto prostředku na prodej lékařem nebo na lékařský předpis.
Dikkat: ABD federal kanunlarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir.



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Representante autorizado
Εξουσιοδοτημένος αντιπρόσωπος
Autoriseret repræsentant
Auktoriserad representant
Valtuutettu edustaja
Autoryzowany przedstawiciel
Felhatalmazott képviselő
Autorizovaný zástupce
Yetkili Temsilci

Avaulta Solo™ Support System

Instructions for Use

DESCRIPTION

The Avaulta Solo™ Support System utilizes a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. The monofilament, polypropylene mesh used in the Avaulta Solo™ Support System has a soft knit in the central section for compliant organ support and host tissue ingrowth, and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open knit design offers multidirectional strength and elasticity that allows the synthetic mesh to be trimmed at the physician's discretion without unraveling and to adapt to various body stresses.

As a convenience to the physician, the Avaulta Solo™ Support System consists of a pre-cut graft for vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

The instrumentation included in the Avaulta Solo™ Support System features a unique, patent-pending flexible snare system designed to minimize tissue trauma during implantation and allow for easier tip exteriorization and mesh arm capture.

INDICATIONS

Avaulta Solo™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

Avaulta Solo™ Support System is contraindicated for patients who are pregnant or may become pregnant, have a urinary tract infection, have an infection in the operative field, or patients in a period of growth because the mesh may not stretch significantly.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage.

PRECAUTIONS

- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Avaulta Solo™ Support System should only be used by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction and the implantation of nonabsorbable meshes.
- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.
- Avaulta Solo™ Support System implantation procedures require diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- The Avaulta Solo™ Support System is provided in a sterile blister tray within a sterile pouch. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Anterior and Posterior Support Systems are provided in a sterile blister tray. Transfer the introducer to the sterile field using aseptic techniques. Do not place the tray in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh or introducers if the packaging is opened or damaged.
- As for any implantable material, it is recommended to open the blister tray at the time of implantation.
- After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

IMPLANT PROCEDURES

CAUTION: The mesh should not be trimmed to a width less than 1 cm in order to maintain sufficient strength and prevent unraveling.

ADDENDUM

ENGLISH: Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month.

FRENCH/FRANÇAIS: Après l'opération, il est recommandé au patient de s'abstenir de soulever de lourdes charges et/ou de faire de l'exercice intensif (par ex., vélo, jogging) pendant au moins trois à quatre semaines et d'avoir des relations sexuelles pendant un mois.

GERMAN/DEUTSCH: Es wird empfohlen, dass der Patient nach der Operation mindestens drei bis vier Wochen keine schweren Gegenstände hebt und/oder starke körperliche Anstrengungen (d.h. Radfahren, Joggen) vermeidet und einen Monat auf Geschlechtsverkehr verzichtet.

ITALIAN/ITALIANO: Dopo l'intervento chirurgico, si raccomanda alla paziente di evitare il sollevamento di oggetti pesanti e/o l'attività fisica (es. andare in bicicletta, fare jogging) per almeno tre - quattro settimane e di astenersi dai rapporti sessuali per un mese.

SPANISH/ESPAÑOL: Después de la operación, se recomienda al paciente que se abstenga de levantar mucho peso y/o hacer ejercicio (es decir, ciclismo, footing) durante al menos tres o cuatro semanas y de mantener relaciones sexuales durante un mes.

DUTCH/NEDERLANDS: De patiënt wordt aangeraden om na de operatie gedurende ten minste drie à vier weken geen zware voorwerpen te tillen en/of zware inspanningen te leveren (d.w.z. fietsen, joggen) en om gedurende één maand geen geslachtsgemeenschap te hebben.

PORTUGUESE/PORTUGUÊS: No pós-operatório o doente é aconselhado a abster-se de levantar pesos e/ou fazer exercício pesado (i.e., ciclismo, jogging) durante pelo menos três a quatro semanas e de ter relações sexuais durante um mês.

GREEK/ΕΛΛΗΝΙΚΑ: Μετεγχειρητικά ο ασθενής συνιστάται να απέχει από άρση βαρών ή και άσκηση (π.χ. ποδηλασία, τζόγκινγκ) για τουλάχιστον τρεις σε τέσσερις εβδομάδες και από τη σεξουαλική επαφή για ένα μήνα.

DANISH/DANSK: Postoperativt anbefales patienten at afholde sig fra tung løften og/eller motion (dvs. cyklen, jogging) i mindst tre til fire uger og samleje i en én måned.

SWEDISH/SVENSKA: Efter operationen bör patienten avstå från tunga lyft och/eller motion (dvs. cykling, jogging) under minst tre till fyra veckor samt avhålla sig från samlag under en månad.

FINNISH/SUOMI: Leikkauksen jälkeen on suositeltavaa, ettei potilas nosta painavia esineitä ja/tai harrasta liikuntaa (esim. pyöräile, juokse) vähintään kolmeen neljään viikkoon eikä ole yhdynnässä yhteen kuukauteen.

POLISH/POLSKI: Po operacji pacjent powinien powstrzymać się od podnoszenia ciężkich przedmiotów i/lub aktywności fizycznej (tj. jazdy na rowerze, biegania) przez przynajmniej trzy-cztery tygodnie oraz od aktywności seksualnej przez jeden miesiąc.

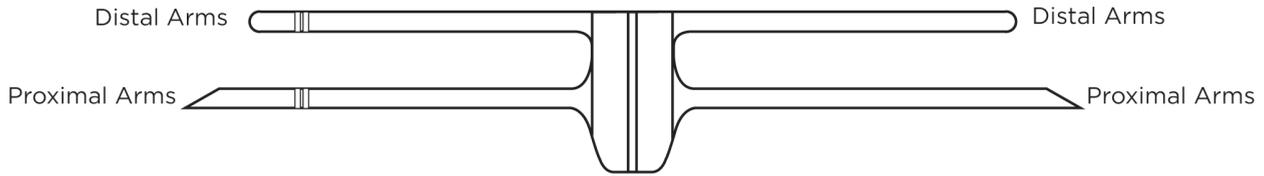
HUNGARIAN/MAGYAR: A műtét után javasoljuk, hogy a beteg legalább három-négy hétig ne emeljen nehéz tárgyakat, és/vagy ne végezzen nehéz testmozgást (pl. kerékpározás vagy futás), valamint egy hónapig tartózkodjon a szexuális aktivitástól.

CZECH/ČESKY: Doporučuje se, aby se pacient po operaci vyvaroval zvedání těžkých břemen a/nebo cvičení (např. jízdy na kole, běhání) minimálně po dobu tří až čtyř týdnů a také pohlavnímu styku po dobu jednoho měsíce.

TURKISH/TÜRKÇE: Postoperatif olarak hastanın ağır yük kaldırmak ve/veya egzersiz yapmaktan (yani bisiklete binmek, koşmak) en az üç dört hafta ve cinsel ilişkidен en az bir ay kaçınması istenir.

Implantation Technique for the Avaulta Solo™ Anterior Support System:

*Distal end positioned at bladder neck
(arms passed through superior medial aspect of obturator membrane)*



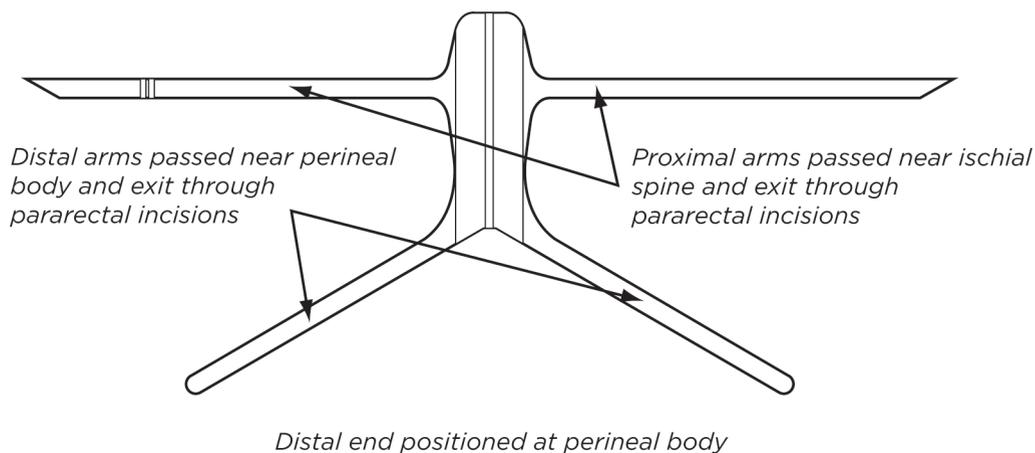
*Proximal end positioned at vaginal apex
(arms passed through inferior medial aspect of obturator membrane)*

- Note: The Avaulta Solo™ Support System does not require a particular orientation with respect to mucosal or visceral sidedness.
 - Proximal end with apical flap positioned at vaginal apex
 - Proximal arms (long arms with pointed ends) passed through inferior medial aspect of obturator membrane
 - Distal end positioned at bladder neck
 - Distal arms (short arms with rounded ends) passed through superior medial aspect of obturator membrane
1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
 2. Make a midline incision in the anterior vaginal wall starting 1 cm below the urethral meatus and extending to the vaginal cuff. Dissect the vaginal mucosa away from the bladder laterally to the obturator internus at the level of the bladder neck and proximally to the ischial spine on both sides.
 3. Identify the obturator fossa by grasping the adductor longus at its insertion to the pubic tubercle. Using the thumb to palpate under the adductor longus insertion, the superior medial aspect of the obturator fossa is identified. Palpate and draw the medial border of the obturator fossa to its inferior medial border. Make a vertical 1.5 cm incision approximately 1 cm below the superior medial border of the obturator fossa and lateral to the bladder neck for the distal arm of the mesh. Make a second vertical 1.5 cm incision at the inferior medial border of the obturator fossa and approximately lateral to the vaginal cuff. Repeat on the contralateral side.
 4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the inferior medial groin incision to puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle tip towards the ischial spine or top of the vaginal cuff. Identify the tip of the introducer before puncturing through the obturator internus muscle. With a gentle rotation of the introducer push through the obturator muscle and use the vaginal finger to guide the needle tip through the fascial wall to exit proximally at the vaginal apex, exposing at least 1-2 cm of the needle tip. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself.
 5. Pass the proximal arm (pointed end) of the mesh up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the inferior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.
Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.

6. Apply traction to draw the proximal (inferior) arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Be sure the graft is tension-free.
 7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the superior groin incision and gently puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle towards the level of the bladder neck. Use a vaginal finger to guide the needle tip through the obturator internus as before, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
 8. Pass a distal arm (rounded end) of the mesh up to the fold (about 4 cm) through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the superior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
 9. Apply traction to draw the distal (superior) arms of the graft into the desired position such that the distal end of the central graft is positioned near the bladder neck. If significant folds are observed, scissors may be used to cut a small section out of the midline of the graft under the bladder neck. Apply additional traction to the distal (superior) arms to help take up the slack and flatten the mesh under the bladder. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. A cystoscopy should be performed to confirm integrity of the bladder after the mesh has been positioned.
 10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.
- Caution: Excessive tension should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process.
11. Close the anterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

Implantation Technique for the Avaulta Solo™ Posterior Support System:

Proximal end positioned at vaginal apex



- Note: The Avaulta Solo™ Support System does not require a particular orientation with respect to mucosal or visceral sidedness.
- Proximal end with apical flap positioned at vaginal apex
- Proximal arms (long arms with pointed ends) passed through ischiorectal fossa
- Distal end positioned at perineal body
- Distal arms (short arms with rounded ends) passed through ischiorectal fossa

1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
2. Make a midline incision in the posterior vaginal wall starting at the vaginal introitus and extending to the vaginal apex. Starting at the perineal body, use blunt and sharp dissection to dissect the vaginal mucosa away from the rectum laterally to the pelvic sidewalls and proximally to the ischial spine on both sides.
3. Make two small pararectal incisions (1-2 cm) approximately 3 cm lateral and 3 cm posterior to the anus.
4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Orient the introducer needle with the handle positioned vertically and the needle tip horizontal and parallel to the vaginal floor. Insert the needle tip into one of the pararectal incisions, aiming the needle tip towards the ischial spine. Pass the introducer through the ischiorectal fossa passing lateral to the posterior wall of the rectum until the needle tip nears the ischial spine. Move the handle downwards to direct the needle tip upwards approximately 1 cm proximal to the ischial spine and out through the posterior vaginal wall incision, exposing at least 1-2 cm of the needle tip. At the physician's discretion, the proximal arms may be secured through the sacrospinous ligament using a similar motion. Exercise care not to tear the pelvic tissue during passage. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself. *Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.*
5. Pass the proximal mesh arm (pointed end) up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Take care to prevent the surrounding tissue from getting caught in the snare during retraction. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.
Note: If substantial resistance is felt during retraction of the introducer needle, ensure that no tissue has been caught in the needle during the snare retraction. Should this occur, re-extend the snare using the thumb slider mechanism, remove the trapped tissue, and re-retract the snare.
6. Apply traction to draw the proximal arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Avoid placing excessive tension on the graft.
7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the same pararectal incision created in Step 3 and orient the needle tip towards the vaginal introitus. Exercise care to stay lateral to the anal sphincter and rectum during passage. Use a vaginal finger to guide the needle tip through the posterior vaginal wall incision at the perineal body, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.
8. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
9. Apply traction to draw the distal arms of the graft into the desired position such that the distal end of the central graft is positioned next to the perineal body. Use scissors to make a small midline cut in the central graft to approximate the length from the vaginal apex to the perineal body. Apply additional traction to the distal arms to position the central mesh as desired. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. Ensure the central mesh lays over the rectum without excessive tension. A digital rectal exam should be performed to confirm integrity of the rectum after the mesh is positioned.

10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.

Caution: Excessive tension should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process.

11. Close the posterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

STERILIZATION TECHNIQUE

Avaulta Solo™ Support System is a single-use device. The implant and introducers are sterilized by ethylene oxide. Do not resterilize.

STORAGE

Recommended storage conditions: between 2°-40°C (36°-105°F) in a dry area.

Bard is a registered trademark of C. R. Bard, Inc. or an affiliate. Avaulta Solo is a trademark of C. R. Bard, Inc. or an affiliate.

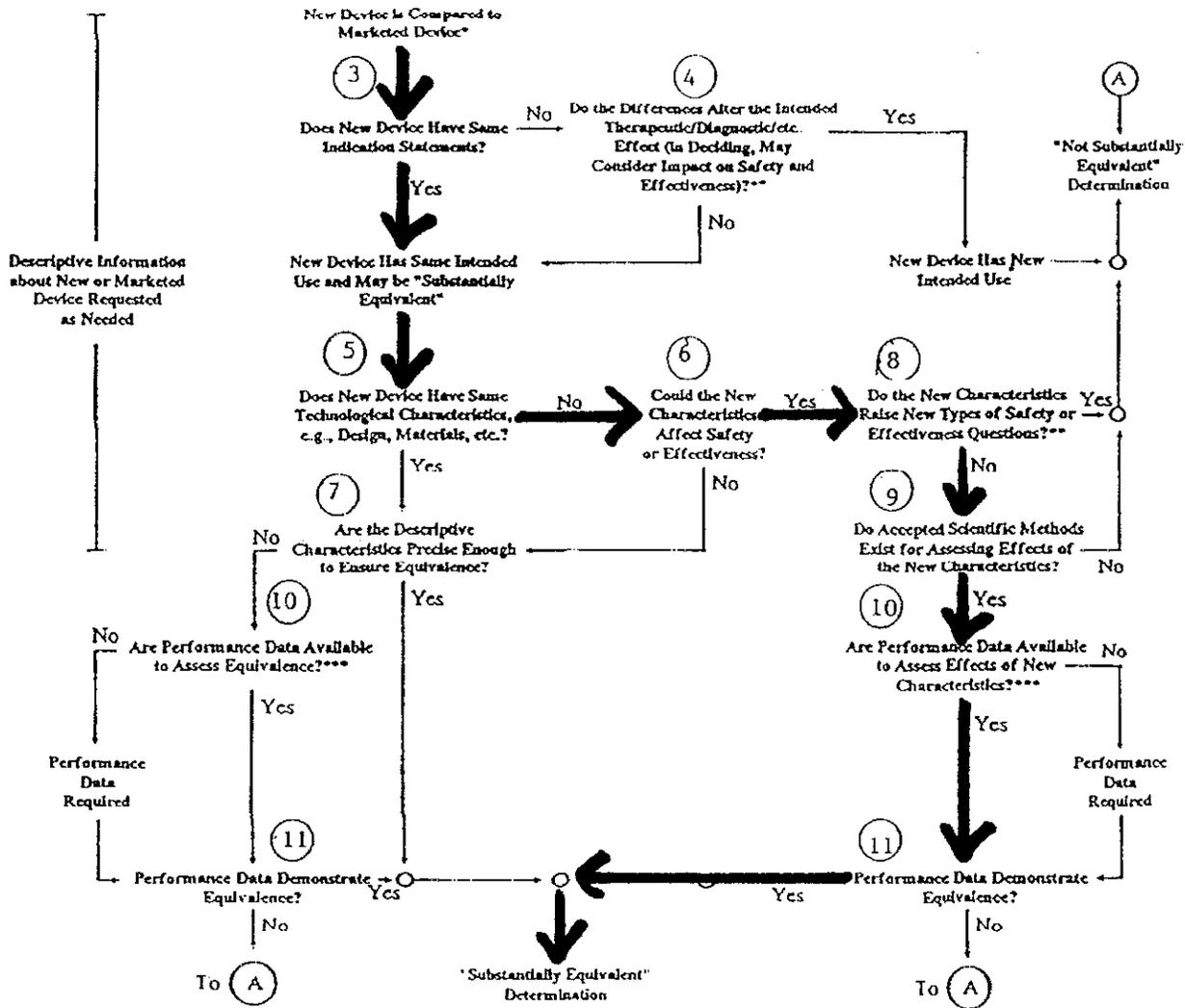
Patent pending.

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Exhibit 6

510(k) Substantial Equivalence Decision Tree

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



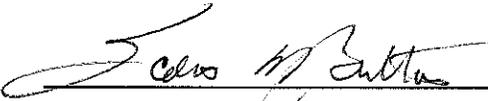
- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Exhibit 7

Declaration of Conformity
with Design Controls

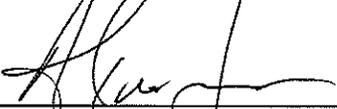
DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

I certify that, in my capacity as Vice President of Research and Development of Bard Urological Division, I believe to the best of my knowledge, that as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.

Signature:  Date: 9/2/08

Typed Name: Scott Britton
Vice President of Research and Development

I certify that, in my capacity as Vice President of Quality Assurance and Regulatory Affairs of Bard Urological Division, I believe to the best of my knowledge, that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Signature:  Date: 9/2/08

Typed Name: Al Jacks
Vice President of Quality Assurance and Regulatory Affairs



COVER SHEET MEMORANDUM

From: Reviewer Name
Subject: 510(k) Number
To: The Record

Ch. Juday Ph.D.
K082571

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary / 510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	X
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?		X	
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		X	X
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)		X	
Nanotechnology			X

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER K082571

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: K063712, Avaulta Support System, **79 FTL, 878.3300 – Mesh, Surgical, Polymeric.**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** (statements on pg. 5 and 6 - confirmed) along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed** (pg. 5).

The Avaulta Support System is a collection of surgical meshes intended for the reinforcement of soft tissues in the pelvic floor in cases of vaginal wall prolapse. There are 4 device forms:

- Avaulta Solo Synthetic Support System for anterior repair
- Avaulta Solo Synthetic Support System for posterior repair
- Avaulta Plus Biosynthetic Support System with Porcine Graft for anterior repair
- Avaulta Plus Biosynthetic Support System with Porcine Graft for posterior repair

(b) (4)



4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics. Verification activities included visual, dimensional and implant tensile strength assessments.
5. A **Design Control Activities Summary** which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis

- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
- c) A declaration of conformity with design controls (Exhibit 7). The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A Truthful and Accurate Statement (pg. 3), a 510(k) Summary (exhibit 2) and the Indications for Use Enclosure (pg. 4).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Clifford, M.D.
 (Reviewer's Signature)

9/19/08
 (Date)

*I concur,
 Daniel Krone
 9/22/2008*