



USER: JOHNSON, SHEVON E (sxj)

FOLDER: K051503 - 86 pages (FOI:09004691)

COMPANY: SOFRADIM PRODUCTION (SOFRPROD)

PRODUCT: MESH, SURGICAL, POLYMERIC (FTL)

SUMMARY: Product: UGYTEX SUAL KNIT MESH

DATE REQUESTED: Wed Nov 17 24:00:00 2010

DATE PRINTED: Fri Jan 14 06:01:48 2011

Note: Releasable Version

Table of Contents

| | |
|--|-----------|
| 510K SUMMARY - 5 pages | 1 |
| CORRESPONDENCE - 6 pages | 6 |
| ORIGINAL - 63 pages | 12 |
| REVIEWER INFORMATION - 10 pages | 75 |

K051503
1/2

AUG 5 - 2005
510(k) Summary
for
UGYTEX® Dual Knit Mesh

1. SPONSOR

Sofradim Production
116 Avenue du formans
01600 Trevoux
France

Contact: Christophe Cosson
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name: UGYTEX® Dual Knit Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim UGYTEX® Mesh K033376

4. DEVICE DESCRIPTION

The Sofradim UGYTEX® Dual Knit Mesh is a monofilament, polypropylene mesh coated in the central portion with an absorbable hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

The UGYTEX Dual Knit Mesh will be offered in various configurations which may include a rectangular sheet, anterior repair system and posterior repair system.

1051503
2/2

5. INDICATIONS FOR USE

The UGYTEX® Dual Knit Mesh 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The UGYTEX® Dual Knit Mesh is substantially equivalent in material, function, performance and design to the predicate UGYTEX® Mesh.

7. PERFORMANCE TESTING

The appropriate testing was performed to determine the performance characteristics of the mesh. The test results showed that the Sofradim UGYTEX® Dual Knit Mesh is substantially equivalent to the predicate device.



AUG 5 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sofradim Production
c/o Pamela Papineau, RAC
Consultant to Sofradim Production
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K051503
Trade/Device Name: UGYTEX® Dual Knit Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 6, 2005
Received: June 7, 2005

Dear Ms. Papineau:

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.

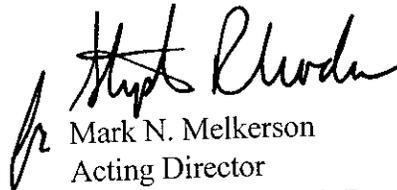
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

K051503

510(k) Number (if known):

Device Name: UGYTEX® Dual Knit Mesh

Indications For Use:

The UGYTEX Dual Knit Mesh 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)

OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K051503



AUG 5 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sofradim Production
c/o Pamela Papineau, RAC
Consultant to Sofradim Production . . .
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K051503
Trade/Device Name: UGYTEX[®] Dual Knit Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 6, 2005
Received: June 7, 2005

Dear Ms. Papineau:

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.

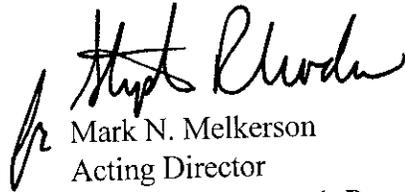
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

K051503

510(k) Number (if known):

Device Name: UGYTEX® Dual Knit Mesh

Indications For Use: _____

The UGYTEX Dual Knit Mesh 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)

OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K051503

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

June 09, 2005

SOFRADIM PRODUCTION
C/O DELPHI MEDICAL DEVICE CONSULTAN
5 WHITCOMB AVENUE
AYER, MA 01432
ATTN: PAMELA PAPINEAU

510(k) Number: K051503
Received: 08-JUN-2005
Product: UGYTEX SUAL KNIT
MESH

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

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 premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

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

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

June 07, 2005

SOFRADIM PRODUCTION
C/O DELPHI MEDICAL DEVICE CONSULTAN
5 WHITCOMB AVENUE
AYER, MA 01432
ATTN: PAMELA PAPINEAU

510(k) Number: K051503
Received: 07-JUN-2005
Product: UGYTEX SUAL KNIT
User Fee ID Number: 6021177

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

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

K051503

Delphi Medical Device Consulting, Inc.

June 6, 2005

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

RE: 510(k) Premarket Notification (Traditional) for UGYTEX® Mesh

Dear Sir/Madam:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR 807, Sofradim Production hereby submits this 510(k) Premarket Notification.

Sofradim intends to introduce into interstate commerce a polypropylene surgical mesh with hydrophilic film for use in the repair of damaged or ruptured soft tissue in the pelvic floor. This proposed device is substantially equivalent to the currently marketed Sofradim UGYTEX surgical mesh that was cleared for marketing by FDA in K033376.

Sofradim Production has submitted the required Premarket Notification review fee as required under the Medical Device User Fees and Modernization Act of 2002 (MDUFMA). The payment identification number associated with this submission is (b) (4); a copy of the User Fee Cover Sheet is included with this submission package.

The information provided in this Premarket Notification is **detailed in nature and is considered proprietary and confidential to Sofradim Production**. For this reason, we are requesting the right to review this document and redact all confidential and proprietary information prior to its release to any third party.

If you have any questions about this notification or require further information, please contact me at (978) 772-3552.

Sincerely,


Pamela Papineau, RAC
Consultant to Sofradim Production

Submitted in Duplicate
Attachment

5 Whitcomb Avenue
Ayer, MA 01432

Phone (978) 772-3552
Fax (978) 772-3557
delphi@ids.net

17

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

| | | | |
|--|--|---|-------------|
| 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"> Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 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. 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.) 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.) 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. 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) SOFRADIM PRODUCTION 116 AVENUE DU FORMANS TREVOUX NO DATA 01600 FR 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA | | 2. CONTACT NAME CHRISTOPHE COSSON 2.1 E-MAIL ADDRESS c.cosson@sofradim.com 2.2 TELEPHONE NUMBER (include Area code) 33-474089000 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 33-474089001 | |
| 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"/> 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) | | 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: null | | | |
| 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"/> The sole purpose of the application is to support conditions of use for a pediatric population | |
| <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 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 (FOR FISCAL YEAR 2005) \$3,502.00 | | | |
| | | | 03-Jun-2005 |

Form FDA 8601 (08/2003)

Close Window

Print Cover sheet

18
J-22
5H

**Traditional 510(k) Premarket Notification
for
UGYTEX[®] Dual Knit Mesh**

June 6, 2005

**Sofradim Production
Trevoux, France**

**Traditional 510(k) Premarket Notification
for
UGYTEX® Dual Knit Mesh**

Table of Contents

| <i>Section</i> | <i>Page</i> |
|--|-------------|
| 510(k) Checklist..... | ii |
| Indications for Use Statement | vi |
| Truthful and Accurate Statement | vii |
| 1 Purpose of Premarket Notification..... | 1 |
| 2 Company Name and Address..... | 1 |
| 2.1 Sponsor/Manufacturer..... | 1 |
| 2.2 Consultant/Contact..... | 1 |
| 3 Subject Device | 2 |
| 4 Predicate Device | 2 |
| 5 Establishment Registration Number | 2 |
| 6 Device Classification / Regulation Number / Product Code | 2 |
| 7 Performance Standards | 2 |
| 8 Proposed Labeling | 3 |
| 9 Device Description..... | 3 |
| 9.1 Intended Use | 3 |
| 9.2 Indications for Use..... | 3 |
| 9.3 Device Design..... | 3 |
| 9.4 Device Materials | 5 |
| 9.5 Modifications Addressed In This Submission..... | 5 |
| 9.6 Packaging/Stability | 6 |
| 9.7 Sterilization..... | 6 |
| 10 Testing..... | 7 |
| 10.1 Biocompatibility | 7 |
| 10.2 Performance Testing..... | 7 |
| 11 Substantial Equivalence | 9 |
| 12 510(k) Summary | 10 |

APPENDICES

- Appendix A - Proposed Labeling
- Appendix B - Technical Information
- Appendix C - Performance Testing
- Appendix D - Product Information for Predicate Devices
- Appendix E - 510(k) Summary
- Appendix F - Kit Component Certification

510(k) Screening Checklist for UGYTEX® Dual Knit Mesh

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k).....Do Sections 1 and 2
 Abbreviated 510(k).....Do Sections 1, 3 and 4
 Traditional 510(k) or no identification providedDo Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

| | Present | Inadequate or Missing |
|--|-------------------------|-----------------------|
| Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual. | Yes | |
| Table of Contents. | Page i | |
| Truthful and Accurate Statement. | Page vii | |
| Device's Trade Name, Device's Classification Name and Establishment Registration Number. | Sections 2-4 | |
| Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified). | Section 4 | |
| Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual. | Section 6 & APPENDIX A | |
| Statement of Indications for Use that is on a separate page in the premarket submission. | Page vi | |
| 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 9 | |
| 510(k) Summary or 510(k) Statement. | Section 10 & APPENDIX E | |
| Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals. | Section 7 & APPENDIX B | |
| Identification of legally marketed predicate device.* | Section 9 & APPENDIX D | |
| Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).] | Section 5 | |
| Class III Certification and Summary. ** | | NA |
| Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)] | | NA |
| 510(k) Kit Certification. *** | APPENDIX F | |

- * May not be applicable for Special 510(k)s.
** Required for Class III devices, only.
*** See pages 3 -12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

**510(k) Screening Checklist
for
UGYTEX® Dual Knit Mesh
(Continued)**

Section 2: Required Elements for a SPECIAL 510(k) submission:

| | Present | Inadequate or Missing |
|---|----------------------|-----------------------|
| Name and 510(k) number of the sponsor's own, unmodified predicate device. | | |
| A description of the modified device and a comparison to the sponsor's predicate device. | | |
| 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. | | |
| A statement that the modification has not altered the fundamental technology of the sponsor's predicate device. | | |
| A Design Control Activities Summary that includes the following elements (a-c): | <i>No entry here</i> | <i>No entry here</i> |
| 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 required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. | | |
| c. A Declaration of Conformity with design controls that includes the following statements: | | |
| 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. | | |
| A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in CFR 21 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities. | | |

510(k) Screening Checklist
for
UGYTEX® Dual Knit Mesh
(Continued)

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

| | Present | Inadequate or Missing |
|--|---------|-----------------------|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) | | |
| For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive.] | | |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has <i>not</i> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <i>and</i> any additional information requested by the reviewer in order to determine substantial equivalence. | | |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence. | | |

* When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

510(k) Screening Checklist
for
UGYTEX® Dual Knit Mesh
(Continued)

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL
510(k) submissions (If Applicable):**

| | Present | Inadequate or Missing |
|---|-------------|--------------------------|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation | Section 8.1 | |
| b) Sterilization and expiration dating information: | Section 7.4 | |
| i) sterilization process | Section 7.4 | |
| ii) validation method of sterilization process | Section 7.4 | |
| iii) SAL | Section 7.4 | |
| iv) packaging | Section 7.3 | |
| v) specify pyrogen free | Section 7.4 | |
| vi) ETO residues | Section 7.4 | |
| vii) radiation dose | | NA |
| c) Software Documentation | | NA |

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

APPENDIX E

510(k) Summary

510(k) Number (if known):

Device Name: UGYTEX® Dual Knit Mesh

Indications For Use:

The UGYTEX Dual Knit Mesh 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)

OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Premarket Notification
Truthful and Accurate Statement
For
UGYTEX[®] Dual Knit Mesh**

I certify that, in my capacity as Chairman and Chief Executive Officer of SOFRADIM Production, I believe to the best of my knowledge, that all data and information submitted in this premarket notification for UGYTEX[®] Dual Knit Mesh are truthful and accurate and that no material fact has been omitted.

François - Régis Orly
Signature

05/30/2005
Date
(mm/dd/yyyy)

François-Régis ORY
Chairman and Chief Executive Officer



**510(k) Premarket Notification
for
UGYTEX® Dual Knit Mesh**

1 PURPOSE OF PREMARKET NOTIFICATION

The purpose of this premarket notification is to notify FDA of the Sofradim UGYTEX Dual Knit Mesh which is a line extension of Sofradim's existing UGYTEX Mesh that involves a design change with no changes in materials. Furthermore, both the subject and predicate devices share the same intended use, indications for use and fundamental scientific technology.

2 COMPANY NAME AND ADDRESS

2.1 Sponsor/Manufacturer

Sofradim Production
116 Avenue du formans
01600 Trevoux
France

Telephone: 33(0)4 74 08 90 00
Facsimile : 33(0)4 74 08 90 02

2.2 Consultant/Contact

Sofradim Production's authorized contact person for this 510(k) Premarket Notification is as follows:

Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
Email : delphi@ids.net
Telephone: 978-772-3552
Facsimile: 978-772-3557

3 SUBJECT DEVICE

Proprietary Name: UGYTEX® Dual Knit Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

4 PREDICATE DEVICE

Proprietary Name: UGYTEX® Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh
Premarket Notification: K033376, Clearance date – January 15, 2004

5 ESTABLISHMENT REGISTRATION NUMBER

The establishment registration number for Sofradim Production is 9615742.

6 DEVICE CLASSIFICATION / REGULATION NUMBER / PRODUCT CODE

Surgical meshes have been classified as Class II devices under the classification name surgical mesh (21 CFR 878.3300, Product Code FTL) and are reviewed by the General and Plastic Surgery Devices Panel.

7 PERFORMANCE STANDARDS

No performance standards applicable to this device have been adopted under Section 514 of the Act.

Where applicable, testing of the UGYTEX® Dual Knit Mesh was performed in accordance with the following FDA Guidance and industry standards. Results of these tests are discussed in Section 10.2.

| | |
|-------------|--|
| ISO 3801 | Determination of Mass per Unit Length and Mass per Unit Area |
| ISO 5084 | Determination of Thickness of Woven and Knitted Fabrics |
| ISO 13934-1 | Determination of Breaking Strength and Elongation |
| ISO 4674 | Determination of Tear Resistance of Coated Fabrics |

ISO13938-1 Determination of Bursting Strength and Bursting Distension

FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 2, 1999)

FDA Guidance for Medical Devices Containing Materials Derived from Animal Sources (November 6, 1998)

8 PROPOSED LABELING

Proposed labeling for the UGYTEX Dual Knit Mesh is provided in APPENDIX A.

9 DEVICE DESCRIPTION

9.1 Intended Use

The UGYTEX Dual Knit Mesh is intended for reinforcement of tissue during surgical repair.

9.2 Indications for Use

The UGYTEX Dual Knit Mesh 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.

9.3 Device Design

The Sofradim UGYTEX Dual Knit Mesh is a monofilament, nonabsorbable, polypropylene mesh which provides long-term reinforcement for support structures. UGYTEX Dual Knit Mesh has a soft knit in the central section for compliant organ support and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh (see section 10.2). The open weave design offers multidirectional elasticity that allows UGYTEX Dual Knit Mesh to be cut into any desired shape or size without unraveling and to adapt to various body stresses.

The central soft knit section is coated with the same hydrophilic, collagen film as the predicate UGYTEX Mesh cleared in K033376. The film minimizes visceral attachment to the mesh, which may occur during the healing process, without affecting physical performance characteristics. The

central collagen-coated, soft-knit section should be positioned next to the organ to be supported. The central soft knit is similar to that described in 510(k) K033376 for the predicate Sofradim UGYTEX Mesh.

The lateral, strong knit sections allow tension-free fixation of the mesh. These sections of the UGYTEX Dual Knit Mesh are not coated to maximize the mesh fixation immediately post-implantation.

The UGYTEX Dual Knit Mesh will be offered in various configurations, according to user preference, which may include the following:

9.3.1 UGYTEX Dual Knit Mesh

The UGYTEX Dual Knit Mesh, like the predicate UGYTEX Mesh, is a rectangular sheet that is trimmed to the desired size and shape by the physician prior to implantation. An introducer of the physician's choice may be used to implant and position the UGYTEX Dual Knit Mesh, if desired.

Please refer to APPENDIX B for a visual depiction of UGYTEX Dual Knit Mesh.

9.3.2 UGYTEX Dual Knit - Anterior Repair System

As an added convenience to the physician, the UGYTEX Dual Knit Anterior Repair System consists of a pre-cut UGYTEX Dual Knit Mesh graft for anterior vaginal wall prolapse repair and an introducer to help facilitate placement of the graft. Based on clinical experience with the predicate UGYTEX Mesh, the pre-cut graft provides a general shape requiring less physician trimming, though the graft may be further trimmed by the physician to achieve the final desired geometry for the procedure.

The UGYTEX Dual Knit Mesh and the disposable introducer are supplied in two separate sterile packages in a common cardboard box (kit package). The introducer is a Class I, exempt, manual surgical instrument (21 CFR 878.4800) used to place the implant. The introducer is comprised of a handle and a stainless steel needle. Please refer to APPENDIX F for a signed kit certification.

Please refer to APPENDIX B for a visual depiction of UGYTEX Dual Knit Mesh for Anterior Repair

9.3.3 UGYTEX Dual Knit - Posterior Repair System

As an added convenience to the physician, the UGYTEX Dual Knit Posterior Repair System consists of a pre-cut UGYTEX Dual Knit Mesh graft for posterior vaginal wall prolapse repair and an introducer to help facilitate placement of the graft. Based on clinical experience with the predicate UGYTEX Mesh, the pre-cut graft provides a general shape that requires less physician trimming, though the graft may be further trimmed by the physician to achieve the final desired geometry for the procedure.

The UGYTEX Dual Knit Mesh and the disposable introducer are supplied in two separate sterile packages in a common cardboard box (kit package). The introducer is a Class I, exempt, manual surgical instrument (21 CFR 878.4800) used to place the implant. The introducer is comprised of a handle and a stainless needle. Please refer to APPENDIX F for a signed kit certification.

Please refer to APPENDIX B for a visual depiction of UGYTEX Dual Knit Mesh for Posterior Repair.

9.4 Device Materials

The UGYTEX Dual Knit Mesh is composed of the same materials (polypropylene and a hydrophilic, collagen film) as the predicate device cleared in Sofradim 510(k) K033376. Please reference the predicate 510(k) for specific details on these materials.

9.5 Modifications Addressed In This Submission

The subject and predicate device are of the same general design in that both are composed of a biosynthetic mesh of the same materials with the same intended use and indications for use. Both devices rely on the same fundamental scientific technology.

The primary differences are in the varying knit and shape of the mesh:

- Knit – The subject UGYTEX Dual Knit Mesh has a collagen-coated soft knit in the central section and an uncoated stronger knit in the lateral sections whereas the predicate UGYTEX Mesh is entirely collagen-coated soft knit.

- Shape – The subject device will be offered in various configurations including a rectangular sheet and pre-cut versions for convenience in anterior and posterior vaginal wall prolapse repairs. The predicate device is offered in a rectangular sheet which is cut to shape by the physician for anterior repair, posterior repair or other vaginal wall prolapse repairs.

9.6 **Packaging/Stability**

UGYTEX Dual Knit Mesh:

The packaging of the UGYTEX Dual Knit Mesh is identical to that described in 510(k) K033376 for the cleared Sofradim UGYTEX Mesh. UGYTEX Dual Knit Mesh is packaged in a single blue-tinted PETG blister, inside a single Tyvek pouch, and placed in an aluminum bag. Only the blister and the Tyvek pouches are sterile, the aluminum bag is not sterile (see warning label in APPENDIX A). Its purpose is to preserve the device from humidity and light. Data to support a shelf life of five years for UGYTEX Mesh were provided in K033376.

Introducer:

The introducers will be manufactured per SOFRADIM Production specifications by a contract manufacturer. The introducers are purchased bulk, nonsterile and packaged, tray sealed with a Tyvek® lid, by SOFRADIM Production.

Kit Packaging:

After sterilization of the implant package (UGYTEX Dual Knit Mesh) and the introducer package, both products and the Instructions for Use are placed in a kit package (cardboard box).

9.7 **Sterilization**

The sterilization parameters summarized below are applicable to the mesh and introducers:

| | |
|-------------------------------|---|
| Sterilization Method | Ethylene Oxide |
| Validation Method | (b) (4) - Medical Devices Validation and Routine Control of Ethylene Oxide Sterilization and (b) (4) - Sterilization of Medical Devices to be Labeled "Sterile" |
| Sterilization Assurance Level | 10 ⁻⁶ |
| Residuals | Ethylene Oxide: (b) (4) Ethylene Chlorohydrin: (b) (4) Ethylene Glycol: (b) (4) |

Sterilization of the Mesh has not changed from K033376. The introducers are sterilized by Sterigenics, Rantigny, France, FDA Registration #3002807106.

10 TESTING

10.1 Biocompatibility

As stated in Section 9.4 above, The UGYTEX Dual Knit Mesh is composed of the same materials (polypropylene and hydrophilic, collagen film) as the predicate Sofradim UGYTEX Mesh device cleared in 510(k) K033376. Please reference K033376 for biocompatibility testing.

10.2 Performance Testing

The mechanical performance of the UGYTEX Dual Knit Mesh is determined by the polypropylene mesh material. Mechanical testing has been performed to determine the density, thickness, elongation, breaking strength, pore size, tear resistance, burst resistance, and tensile strength of the UGYTEX Dual Knit Mesh and the results for this testing are summarized in Table 1 below. Please refer to APPENDIX C for a copy of the study report.

Table 1. Test Results

| Characteristics | UGYTEX Mesh (Excerpt from K033376) | | UGYTEX Dual Knit Mesh (proposed) | | | |
|--|--|---------|---|---------|--|---------|
| | | | central section ⁽¹⁾ (soft knit) | | lateral sections ⁽¹⁾ (strong knit) | |
| Mesh Density (g/m ²) | (b) (4) | | (b) (4) | | (b) (4) | |
| Mesh Thickness (mm) | (b) (4) | | (b) (4) | | (b) (4) | |
| Mesh Pore Size (mm) | (b) (4) | | (b) (4) | | (b) (4) | |
| | Warp | Weft | Warp | Weft | Warp | Weft |
| Tensile/Breaking Strength (daN) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| Stiffness/Elongation at rupture (%) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| Tear Resistance (N) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | 53 | 46 |
| Suture Pull Out Strength (daN) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| Burst resistance/Breaking Pressure (kPa) | (b) (4) | | (b) (4) | | (b) (4) | |

⁽¹⁾ As stated in Section 9.3 above, UGYTEX Dual Knit Mesh has a soft knit in the central section for compliant organ support and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh.

(b) (4)

(b) (4)

(b) (4)

(b) (4)

The data summarized in the table above demonstrate that the proposed UGYTEX Dual Knit Mesh is substantially equivalent to the predicate device in terms of physical and mechanical properties:

- Central Section: the results show that the physical and mechanical properties are similar to the predicate UGYTEX Mesh. The small differences are not significant and the equivalence is demonstrated.
- Lateral section: the aim of the lateral sections is to provide improved strength in the areas used to provide tension free fixation of the mesh. The results show that the mechanical properties, in particular the Breaking Strength, the Tear Resistance and the Suture Pull Out Strength are meaningfully higher for the lateral sections than for the predicate UGYTEX Mesh.

11 SUBSTANTIAL EQUIVALENCE

The Sofradim UGYTEX Dual Knit Mesh is substantially equivalent to the cleared Sofradim UGYTEX Mesh. (K033376). Product literature for the predicate device is provided in APPENDIX D.

The Sofradim UGYTEX Dual Knit Mesh has the same intended use as the predicate Sofradim UGYTEX Mesh. (K033376). They are both 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 Sofradim UGYTEX Dual Knit Mesh and the Sofradim UGYTEX Mesh (K033376) are both made from the identical polypropylene raw material and include the same hydrophilic, collagen film. In both cases, the film helps minimize visceral attachment to the mesh which may occur during the healing process. The predicate UGYTEX Mesh is collagen coated over the entire surface, while only the central section of the subject UGYTEX Dual Knit Mesh is collagen coated. The lateral segments of UGYTEX Dual Knit Mesh are not coated to maximize the mesh fixation immediately post-implantation.

The predicate UGYTEX Mesh is offered in bulk sheets of various sizes which are trimmed by the physician to the desired size and shape prior to implantation. The subject UGYTEX Dual Knit Mesh will be offered in multiple configurations which may include similar trimmable, rectangular, bulk sheets (UGYTEX[®] Dual Knit Mesh) and trimmable, pre-cut configurations (UGYTEX[®] Dual Knit Anterior Repair System or UGYTEX[®] Dual Knit Posterior Repair System).

All of the proposed and predicate device may be fixed to the patient either by staples or sutures and are single-use devices only. Additionally, the lateral, strong knit sections of the subject device may be used to provide tension-free fixation of the mesh.

As outlined in Table 1 above, the physical performance characteristics of the proposed Sofradim UGYTEX soft mesh are equivalent to those of the predicate Sofradim UGYTEX Mesh (K033376).

Table 2 below compares the characteristics of the Sofradim UGYTEX Dual Knit Mesh to the predicate device. Sofradim believes that the above rationale and the

comparison table below demonstrate substantial equivalence of the Sofradim UGYTEX Dual Knit Mesh to the predicate device.

Table 2. Substantial Equivalence Comparison Chart

| Similarities and Differences | Sofradim UGYTEX Mesh | Sofradim UGYTEX Dual Knit Mesh |
|------------------------------|---|---|
| Indications | 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 |
| Intended Use | reinforcement of tissue during surgical repair | Same |
| Materials | Polypropylene Hydrophilic film (porcine collagen, glycerol, PEG) | Same |
| Shape | Rectangular | Rectangular : UGYTEX Dual Knit Mesh Pre-cut : Examples include UGYTEX Dual Knit Anterior Repair System and UGYTEX Dual Knit Posterior Repair System (see Appendix B) |
| Sizes | various size ranging from 2 x 4 cm to 30 x 30 cm | Please refer to Appendix B for visual depictions |
| Texture | Sealed open worked monofilament knit (soft knit) | Sealed open worked monofilament knit Soft knit in the central section, strong knit in the lateral sections |
| Method of Fixation | Staples or sutures | Staples, sutures or tension free |
| Sterile | EtO | Same |
| Packaging | Single blister, tyvek pouch and aluminium bag | Same |
| Regulatory Status | K033376 | Proposed |

12 510(k) SUMMARY

In accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92, a 510(k) Summary for this premarket notification submission is provided in APPENDIX E.

APPENDIX A

Proposed Labeling

- Package labels
- Package Insert

UGYTEX Dual Knit Mesh

Instructions for Use

(Page 1)



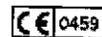
P-239-01
2005-05-20

GB UGYTEX® DUAL KNIT MESH
US INSTRUCTIONS FOR USE

DRAFT



116, avenue du Formans
01600 Trégnoux . FRANCE
Tel. +33 4 74 08 90 00
Fax +33 4 74 08 90 01



UGYTEX Dual Knit Mesh

Instructions for Use

(Page 2)

ENGLISH/US

DESCRIPTION

Ugytex® Dual Knit Mesh is a monofilament, polypropylene mesh coated with an absorbable, hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

Ugytex® Dual Knit Mesh has a soft knit in the central section for compliant organ support and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open weave design offers multidirectional elasticity that allows Ugytex® Dual Knit Mesh to be cut into any desired shape or size without unraveling and to adapt to various body stresses. Ugytex® Dual Knit Mesh also has an absorbable, hydrophilic film of porcine collagen that covers the soft-knit central section of the mesh to minimize visceral attachments in this area. The lateral segments of Ugytex® Dual Knit Mesh are not coated to maximize mesh fixation immediately post-implantation.

Ugytex® Dual Knit Mesh is supplied as a rectangular sheet that is trimmed to the desired size and shape by the physician prior to implantation. The central collagen-coated, soft-knit section should be positioned next to the organ to be supported. The lateral, uncoated segments may be trimmed to provide tension-free fixation of the mesh. An introducer of the physician's choice may be used to implant and position the Ugytex® Dual Knit Mesh, if desired.

INDICATIONS

Ugytex® Dual Knit Mesh 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

Ugytex® Dual Knit Mesh 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

- Ugytex® Dual Knit Mesh 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 Ugytex® Dual Knit Mesh implantation procedure requires diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- Excessive tension should be avoided on the Ugytex® Dual Knit Mesh and suture attachment points to account for wound shrinkage during the healing process.
- Ugytex® Dual Knit Mesh is provided in a sterile blister tray within a double-pouched package. Do not place either pouch in the sterile field. The sterile blister tray may be placed in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh 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.

IMPLANT PROCEDURES

Preparation of Ugytex® Dual Knit Mesh for Implantation:

At the time of implantation, Ugytex® Dual Knit Mesh must be hydrated. To hydrate, place Ugytex® Dual Knit Mesh into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for approximately 30 seconds or until the mesh recovers its conformability and flexibility.

Ugytex® Dual Knit Mesh is more easily trimmed prior to hydration, but may be trimmed after hydration if desired.

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 Ugytex® Dual Knit Mesh:

Ugytex® Dual Knit Mesh should be trimmed to the desired size and shape for the procedure by the physician. An introducer of the physician's choice may be used to facilitate implantation of the mesh. The central collagen-coated, soft-knit section should be positioned between the organ to be supported and the vaginal mucosa. The lateral, uncoated segments may be trimmed to provide tension-free fixation of the mesh. The surgeon's preferred suturing technique can be used to secure the mesh with a tension-free technique. Anchoring points should be positioned at least 1 cm from the edge of the mesh. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth.

STERILIZATION TECHNIQUE

Ugytex® Dual Knit Mesh is intended as a single-use device. The mesh is sterilized by ethylene oxide. Do not resterilize. Discard any unused mesh following the procedure.

STORAGE

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

DRAFT

UGYTEX Dual Knit Mesh

Instructions for Use

(Page 3)

GUARANTEE

SOFRADIM Production certifies that all precautions have been taken in the choice of materials and manufacturing methods for this product. SOFRADIM Production disclaims all liability in case of loss, damage or costs directly or indirectly linked to the use of the product. The guarantee terms or restrictions listed here cancel and replace any guarantee which does not appear in the present document, whether express or tacit by means of legislation or any other means whatsoever. SOFRADIM Production is not liable for any other action taken on its behalf by any party with regard to the product and hereby forbids any party to do so.

Manufacturer:

Sofradim Production
116, avenue du Formans
01600 Trévoux, France

DRAFT

UGYTEX Dual Knit Mesh

Instructions for Use

(Page 4)

SYMBOLS USED



Refer to instructions for use



SINGLE USE

Single Use only



Do not re-sterilize

STERILE



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



Sterile unless package is opened or damaged.

Rx only

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

DRAFT

UGYTEX Dual Knit Mesh

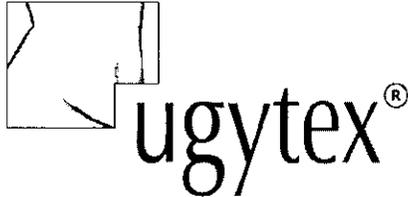
External label
(on cardboard box)



UGYTEX DUAL KNIT MESH

LOT XXXXXXXX

REF UGY XXXX



UGYTEX DUAL KNIT MESH

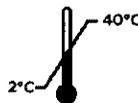
REF UGY XXXX
(XX x XX cm)

Monofilament polypropylene mesh coated with an absorbable hydrophilic film of porcine collagen.

DRAFT

E-1462-01 . 2005-05-27

Rx only



STERILE EO

CE 0459

UGYTEX Dual Knit Mesh

Internal labels
(on the aluminum bag)

ugytex[®]

UGYTEX DUAL KNIT MESH
REF UGY XXXX
(XX x XX cm)

UGYTEX DUAL KNIT MESH
LOT XXXXXXXX XXXX-XX
REF UGY XXXX XXXX-XX

UGYTEX DUAL KNIT MESH
LOT XXXXXXXX XXXX-XX
REF UGY XXXX XXXX-XX

UGYTEX DUAL KNIT MESH
LOT XXXXXXXX XXXX-XX
REF UGY XXXX XXXX-XX

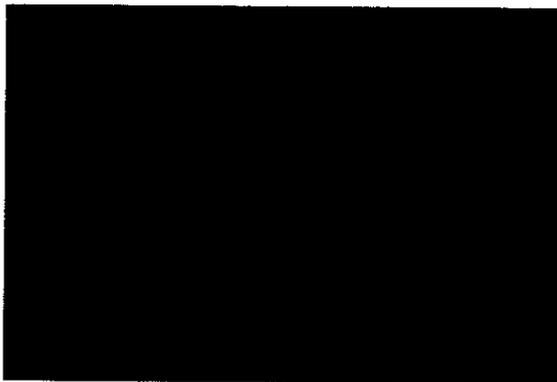
UGYTEX DUAL KNIT MESH
LOT XXXXXXXX XXXX-XX
REF UGY XXXX XXXX-XX

STERILE EO Rx only CE 0459

SOFRADIM PRODUCTION

116, avenue du Formans
C1660 TRÉVOUX - FRANCE
Tel: (33) (0)4 74 08 90 00 - Fax: (33) (0)4 74 08 90 01

E: 1462-01 2006-06-07



DRAFT

44

UGYTEX Dual Knit - Anterior Repair System
UGYTEX Dual Knit Posterior Repair System

Instructions for Use
(Page 1)



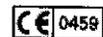
P-240-01
2005-05-30

GB UGYTEX® DUAL KNIT ANTERIOR REPAIR SYSTEM
US UGYTEX® DUAL KNIT POSTERIOR REPAIR SYSTEM
INSTRUCTIONS FOR USE

DRAFT



116, avenue du Formans
01600 Trévoux . FRANCE
Tel. +33 4 74 08 90 00
Fax +33 4 74 08 90 01



45

UGYTEX Dual Knit - Anterior Repair System UGYTEX Dual Knit Posterior Repair System

Instructions for Use (Page 2)

ENGLISH/US

DESCRIPTION

Ugytex® Dual Knit Mesh is a monofilament, polypropylene mesh coated with an absorbable, hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

Ugytex® Dual Knit Mesh has a soft knit in the central section for compliant organ support and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open weave design offers multidirectional elasticity that allows Ugytex® Dual Knit Mesh to be cut into any desired shape or size without unraveling and to adapt to various body stresses. Ugytex® Dual Knit Mesh also has an absorbable, hydrophilic film of porcine collagen that covers the soft-knit central section of the mesh to minimize visceral attachments in this area. The lateral segments of Ugytex® Dual Knit Mesh are not coated to maximize mesh fixation immediately post-implantation.

As a convenience to the physician, the Ugytex® Dual Knit Anterior Repair System consists of a pre-cut Ugytex® Dual Knit Mesh graft for anterior 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.

As a convenience to the physician, the Ugytex® Dual Knit Posterior Repair System consists of a pre-cut Ugytex® Dual Knit Mesh graft for posterior 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.

INDICATIONS

Ugytex® Dual Knit Mesh 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

Ugytex® Dual Knit Mesh 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

- Ugytex® Dual Knit Mesh 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 Ugytex® Dual Knit Mesh implantation procedure requires diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- Excessive tension should be avoided on the Ugytex® Dual Knit Mesh and suture attachment points to account for wound shrinkage during the healing process.
- Ugytex® Dual Knit Mesh is provided in a sterile blister tray within a double-pouched package. Do not place either pouch in the sterile field. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Ugytex® Anterior and Posterior Repair Systems are provided in a double-packaged tray. Do not place the outer tray in the sterile field. The inner tray is sterile and may be placed 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.

IMPLANT PROCEDURES

Preparation of Ugytex® Dual Knit Mesh for Implantation:

At the time of implantation, Ugytex® Dual Knit Mesh must be hydrated. To hydrate, place Ugytex® Dual Knit Mesh into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for approximately 30 seconds or until the mesh recovers its conformability and flexibility. Ugytex® Dual Knit Mesh is more easily trimmed prior to hydration, but may be trimmed after hydration if desired. 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 Ugytex® Dual Knit Anterior Repair System:

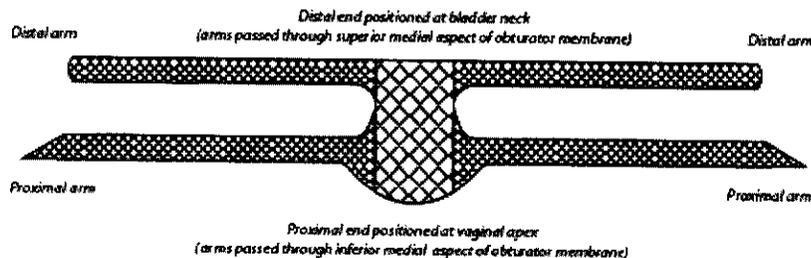


FIGURE 1. Example of Pre-Cut Ugytex® Dual Knit Mesh Anterior Graft

UGYTEX Dual Knit - Anterior Repair System UGYTEX Dual Knit Posterior Repair System

Instructions for Use (Page 3)

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 along the superior medial obturator fossa lateral to the inferior portion of the clitoris for the distal arm of the mesh. Make a second vertical 1.5 cm incision at the inferior border of the obturator fossa approximately lateral to the vaginal cuff and 3 cm below and 1-2 cm lateral to the first incision for the proximal arm of the mesh. Repeat on the contralateral side.
4. Insert the tip of the anterior introducer 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. Continue pivoting the introducer to exteriorize the needle tip at the vaginal introitus.
5. Pass the proximal arm (pointed end) of the mesh 3-4 cm through the eyelet in the needle tip. 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.
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. Insert the tip of the anterior introducer into the superior groin incision and gently puncture through the superior medial aspect of 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, and then exteriorize the tip at the vaginal introitus.
8. Pass a distal arm (rounded end) of the mesh 3-4 cm through the eyelet in the needle tip. 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. 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.
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 Ugytex® Dual Knit Posterior Repair System:

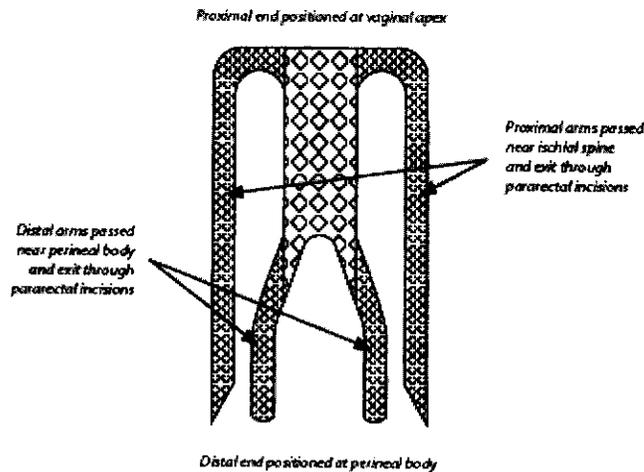


FIGURE 2. Example of Pre-Cut Ugytex® Dual Knit Mesh Posterior Graft

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 2-3 cm lateral and 2-3 cm posterior to the anus.
4. Orient the posterior introducer 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 1-2 cm anterior to the ischial spine and out through the posterior vaginal wall incision (use a vaginal finger to help guide the needle tip during passage). Continue moving the introducer handle downwards to direct the needle tip towards the vaginal introitus. Use a vaginal finger to help guide and exteriorize the needle tip. Exercise care not to tear the pelvic tissue during passage. Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.

UGYTEX Dual Knit - Anterior Repair System
UGYTEX Dual Knit Posterior Repair System

Instructions for Use
(Page 4)

5. Pass the proximal mesh arm (pointed end) 3-4 cm through the eyelet in the needle tip. 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.
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. Insert the tip of the posterior introducer 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 exteriorize the tip at the vaginal introitus.
8. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. 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. Ensure the central mesh lays flat 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.
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

Ugytex® Dual Knit Anterior Repair System and Ugytex® Dual Knit Posterior Repair System are intended as single-use devices. The mesh and introducers are sterilized by ethylene oxide. Do not resterilize. Discard introducers and any unused mesh following the procedure.

STORAGE

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

GUARANTEE

SOFRADIM Production certifies that all precautions have been taken in the choice of materials and manufacturing methods for this product. SOFRADIM Production disclaims all liability in case of loss, damage or costs directly or indirectly linked to the use of the product. The guarantee terms or restrictions listed here cancel and replace any guarantee which does not appear in the present document, whether express or tacit by means of legislation or any other means whatsoever. SOFRADIM Production is not liable for any other action taken on its behalf by any party with regard to the product and hereby forbids any party to do so.

Manufacturer:

Sofradim Production
116, avenue du Fomans
01600 Trévoux, France

P R A F T

UGYTEX Dual Knit - Anterior Repair System
UGYTEX Dual Knit - Posterior Repair System

Instructions for Use
(Page 5)

SYMBOLS USED



Refer to instructions for use



Single Use only

SINGLE USE



Do not resterilize

STERILE



Recommended storage conditions: between 2°-40°C (36°-103°F), in a dry area.



Sterile unless package is opened or damaged.

Rx only

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

DRAFT

UGYTEX Dual Knit - Anterior Repair System

External label
(on cardboard box)



UGYTEX DUAL KNIT
ANTERIOR REPAIR SYSTEM

REF UGY ARS

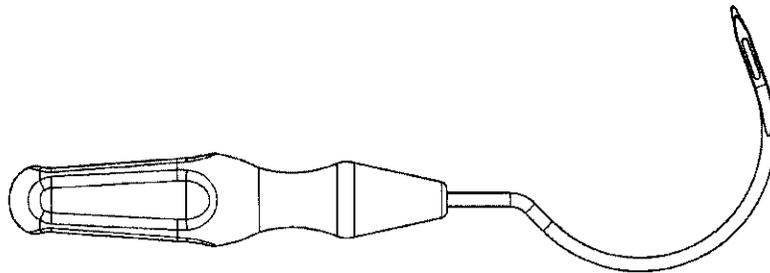
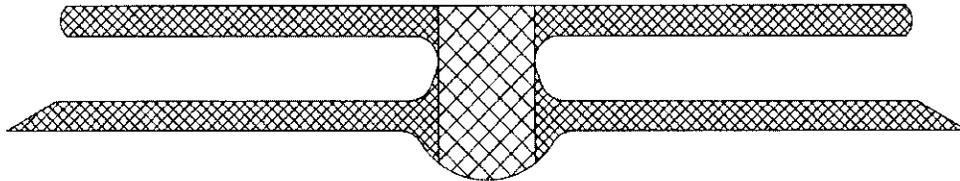
LOT XXXXXXXX
XXXX-XX



ugytex[®]

UGYTEX DUAL KNIT
ANTERIOR REPAIR SYSTEM

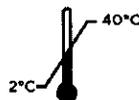
REF UGY ARS



DRAFT

E-1458-01 . 2005-05-27

Rx only



STERILE EO

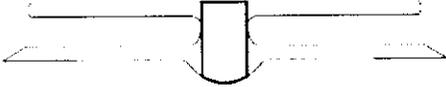
CE 0459

50

UGYTEX Dual Knit - Anterior Repair System

Internal labels
(on the aluminum bag)

 **UGYTEX DUAL KNIT ANTERIOR REPAIR SYSTEM**
REF UGY ARS



UGYTEX DUAL KNIT ANTERIOR REPAIR SYSTEM
LOT XXXXXXXX  XXXX-XX
REF UGY ARS  XXXX-XX

UGYTEX DUAL KNIT ANTERIOR REPAIR SYSTEM
LOT XXXXXXXX  XXXX-XX
REF UGY ARS  XXXX-XX

UGYTEX DUAL KNIT ANTERIOR REPAIR SYSTEM
LOT XXXXXXXX  XXXX-XX
REF UGY ARS  XXXX-XX

UGYTEX DUAL KNIT ANTERIOR REPAIR SYSTEM
LOT XXXXXXXX  XXXX-XX
REF UGY ARS  XXXX-XX

STERILE **EO**   **Rx only**   **CE 0459**

SOFRADIM  **PRODUCTION**

116, avenue du Formans
01600 TREVOUX - FRANCE
Tel (33) (0)4 74 06 90 00 - Fax (33) (0)4 74 06 90 01

F-468-01 0005-05-07

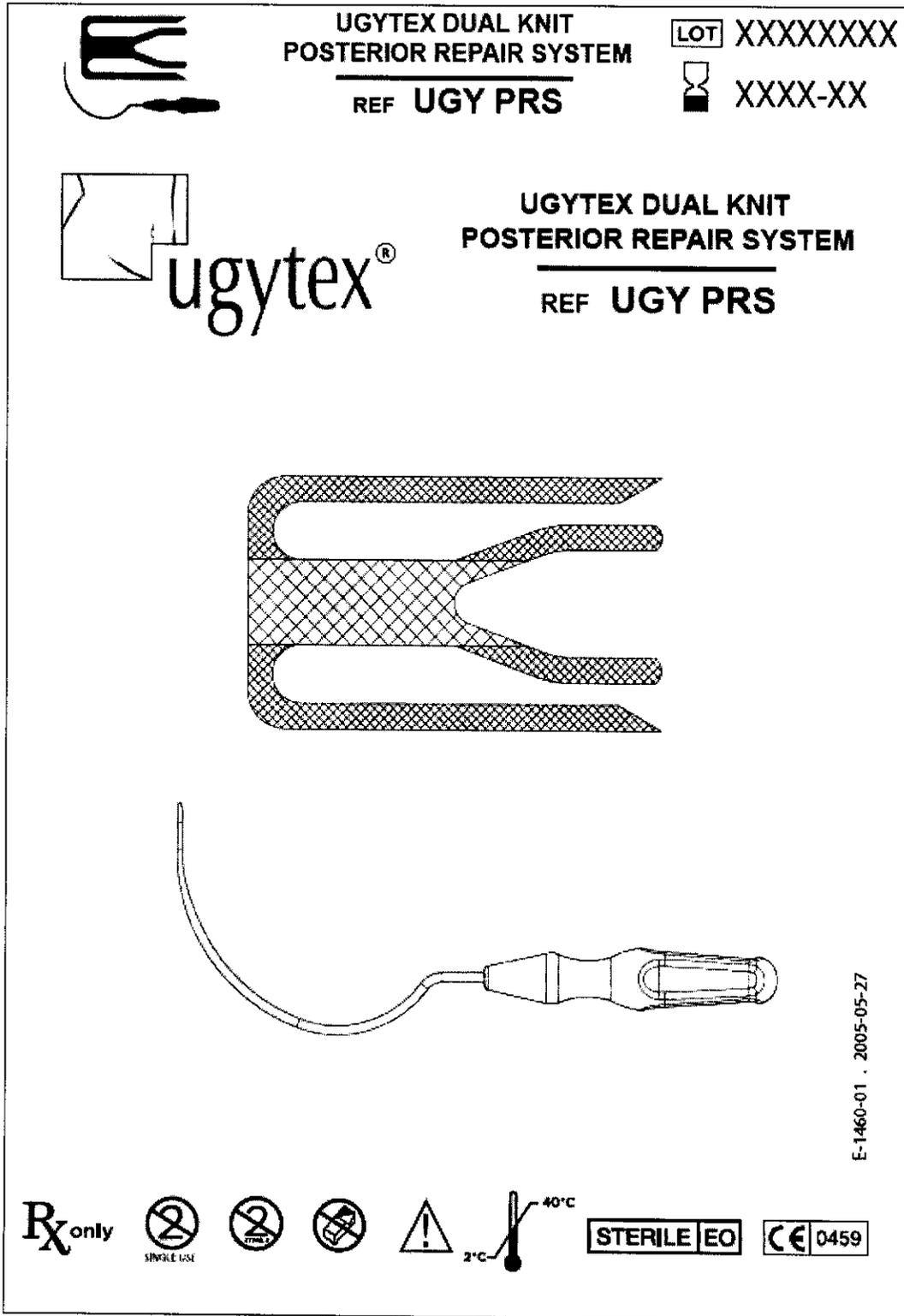


DRAFT

57

UGYTEX Dual Knit Posterior Repair System

External label
(on cardboard box)



DRAFT

52

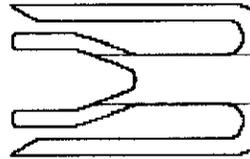
UGYTEX Dual Knit - Posterior Repair System

Internal labels
(on the aluminum bag)



UGYTEX DUAL KNIT
POSTERIOR REPAIR SYSTEM

REF UGY PRS



UGYTEX DUAL KNIT POSTERIOR REPAIR SYSTEM

LOT XXXXXXXX

XXXX-XX

REF UGY PRS

XXXX-XX

UGYTEX DUAL KNIT POSTERIOR REPAIR SYSTEM

LOT XXXXXXXX

XXXX-XX

REF UGY PRS

XXXX-XX

UGYTEX DUAL KNIT POSTERIOR REPAIR SYSTEM

LOT XXXXXXXX

XXXX-XX

REF UGY PRS

XXXX-XX

UGYTEX DUAL KNIT POSTERIOR REPAIR SYSTEM

LOT XXXXXXXX

XXXX-XX

REF UGY PRS

XXXX-XX

STERILE EO



Rx only

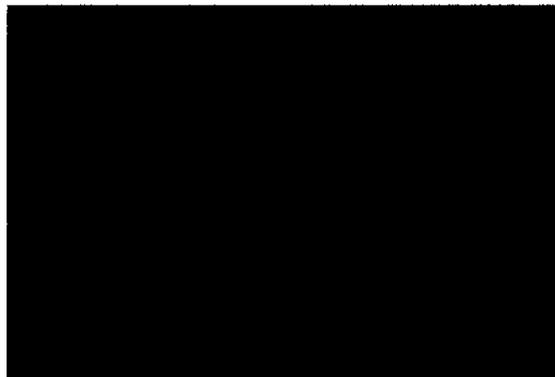


CE 0459

SOFRADIM
PRODUCTION

115, avenue de Fontaines
D1502 TRÉVOUX - FRANCE
Tel. (33) 04 74 09 92 00 - Fax (33) 04 74 09 92 01

F-146141 2003-02-07



DRAFT

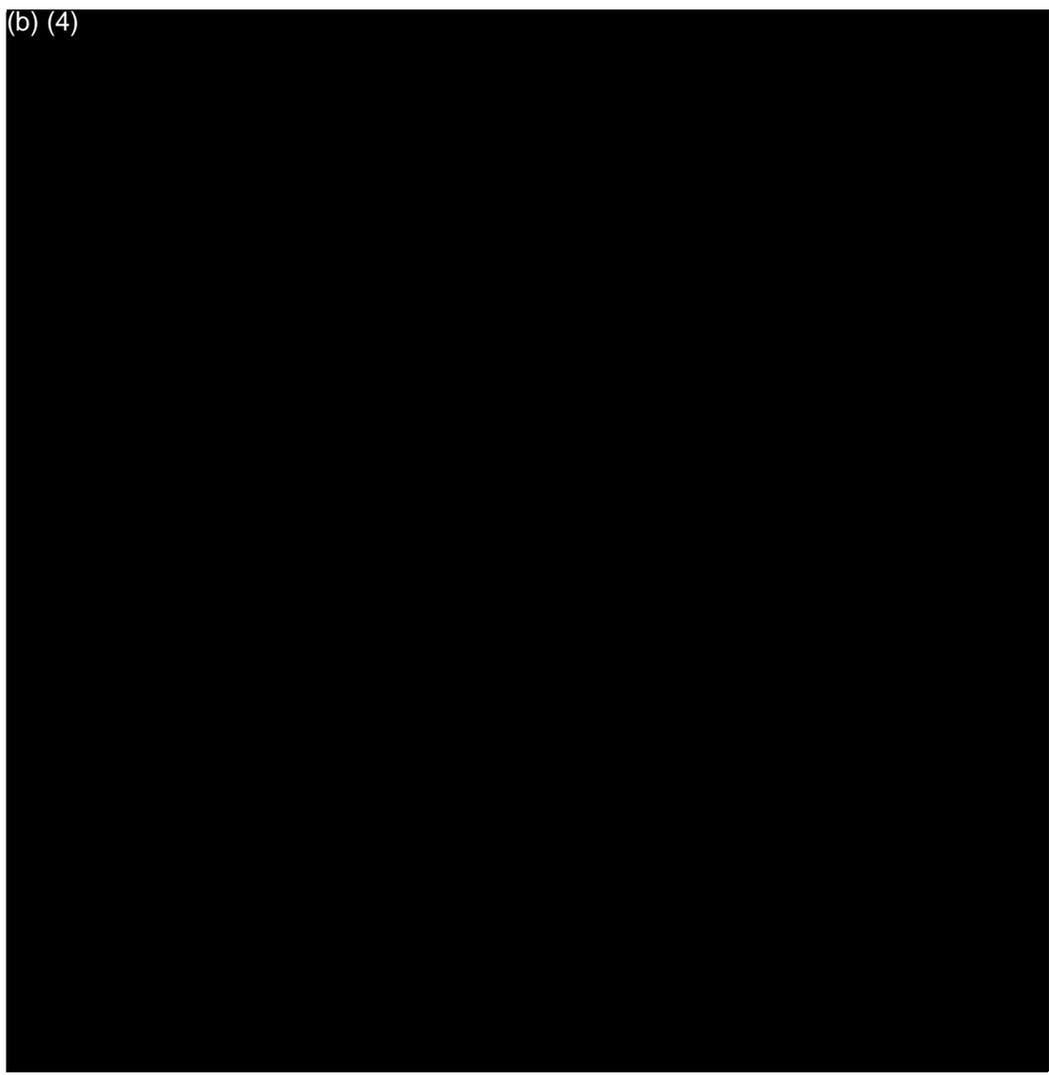
53

APPENDIX B

Technical Information

DRAFT

(b) (4)



UGYTEX DUAL KNIT MESH

Ref: (b) (4)

Date: (b) (4)

(b) (4)

DRAFT

(b) (4)

UGYTEX DUAL KNIT MESH

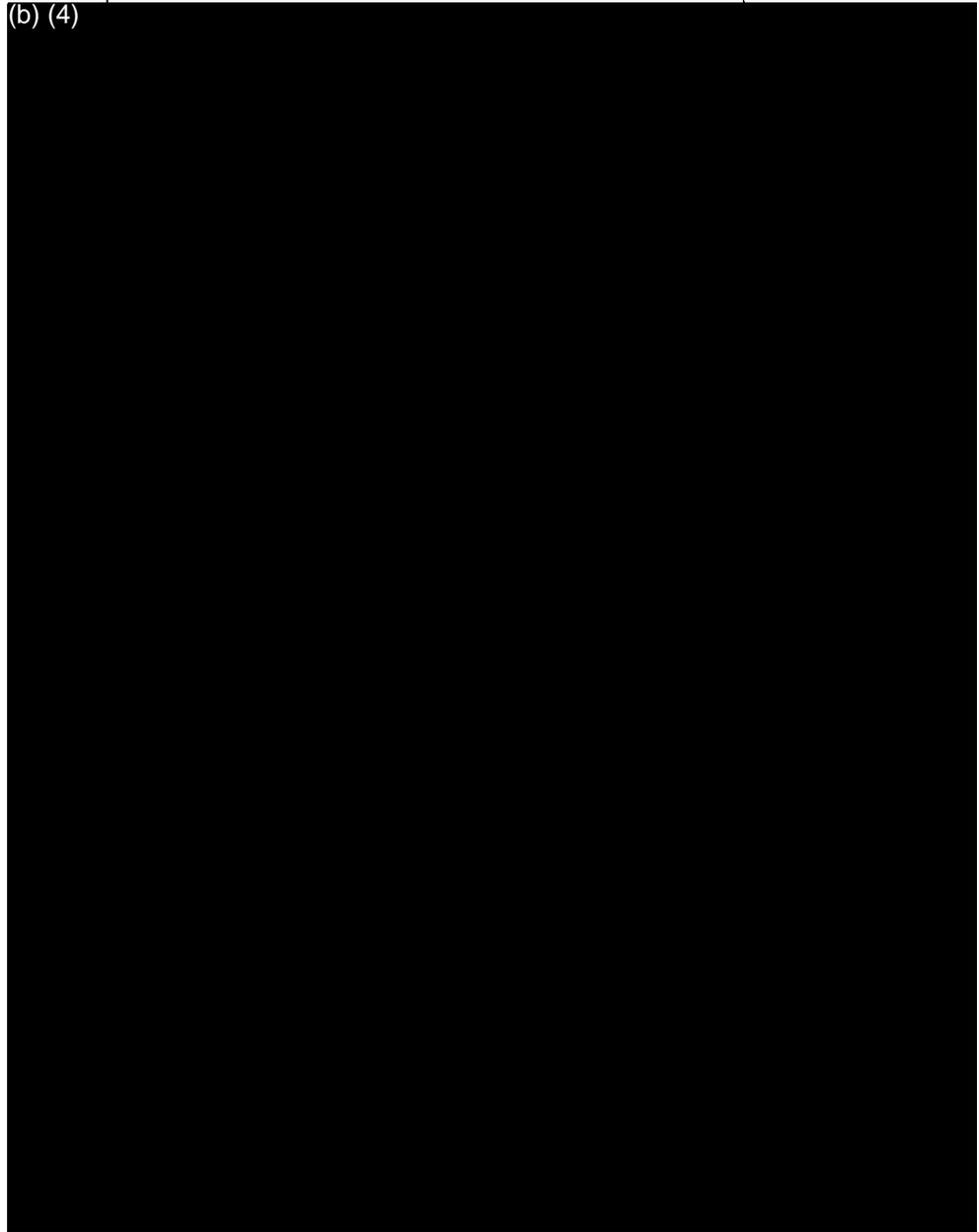
Ret: (b) (4)

Date: (b) (4)

DRAFT

(b) (4)

(b) (4)



UGYTEX DUAL KNIT MESH
Ref: (b) (4)
Date: (b) (4)

57

**Ugytex Dual Knit Mesh characterization:
Comparison Ugytex Dual Knit Mesh textile vs Ugytex Mesh textile**

I. INTRODUCTION

The Ugytex Dual Knit Mesh is made out of a bi-dimensional textile, which is called PLB.

The PLB textile is designed as an evolution of the PPL textile, which is the textile part of the currently marketed Sofradim Ugytex Mesh. As a matter of fact, the PLB textile is composed of two different sections:

- A central soft knit section based on PPL knitting pattern
- Lateral strong knit sections designed to secure mesh fixation



Knitting pattern of the central section



Knitting pattern of the lateral sections

Both PLB and PPL textiles are made out of knitted polypropylene thread (b) (4) (b) (4) mm diameter).

The width of the PLB textile central section is (b) (4) mm. However in another embodiment of this textile, the central section width could be either inferior to or superior to that of the PLB textile. The width of the central section can be easily modified thanks to knitting facilities (modification of the threading pattern). It has no influence on the mechanical properties of both central soft knit section and lateral strong knit section.

The aim of this study is to compare the mechanical properties of the PLB textile (Ugytex Dual Knit Mesh textile) to those of the PPL textile (textile part of the Sofradim Ugytex Mesh currently available on the market).

II. MATERIALS AND METHODS

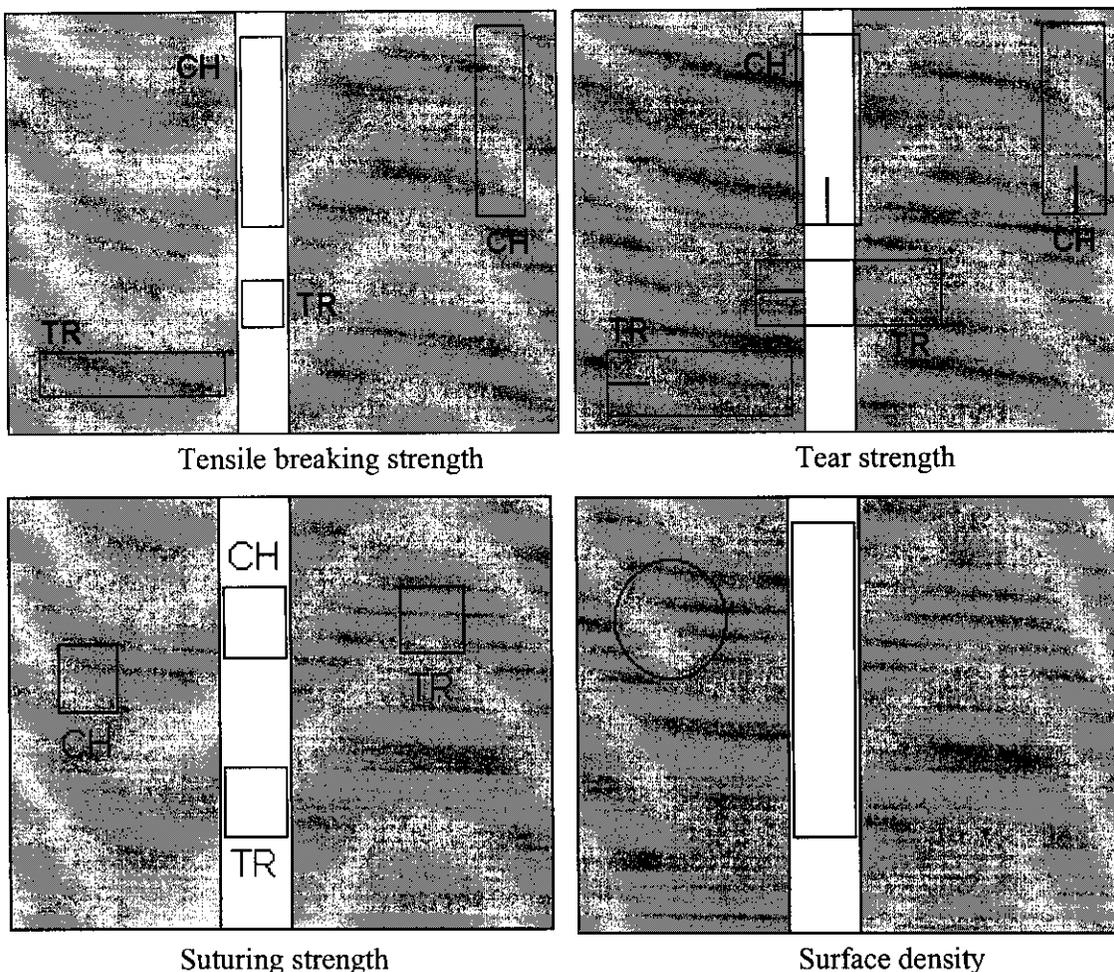
II.1. Test articles

The characterization tests are performed on the PLB and PPL textiles, (b) (4) and (b) (4) respective lot numbers, except from suturing strength and tensile breaking strength special samples tests, which were performed on (b) (4) PPL textile lot number.

II.2. Equipments and methods

Tests were performed by Sofradim qualified staff according to standards listed in table below. Samples sizes were either standard or special due to PLB textile special design. For comparative purpose, the same sample's dimensions of PPL textile were used.

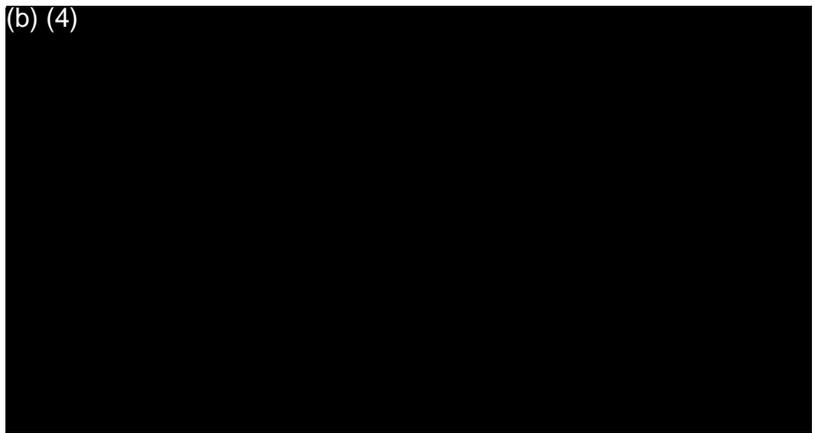
PLB textile sampling patterns:



| Tests | Standard | Sample dimensions and testing parameters | | | Number of samples | Material |
|--|--|---|-----------------------------------|------------------------|-------------------|--|
| | | PPL | PLB Central section | PLB Lateral section | | |
| Surface density ⁽¹⁾ | ISO 3801 "Determination of Mass per Unit Length and Mass per Unit Area" | (b) (4) | Width: (b) (4) Length: (b) (4) | (b) (4) | 1 | Scale - (b) (4) (b) (4) (b) (4) |
| Thickness ⁽²⁾ | ISO 5084 "Determination of Thickness of Woven and Knitted Fabrics" | (b) (4) | Width: (b) (4) Length: (b) (4) | (b) (4) | 1 | Micrometer Caliper - (b) (4) (b) (4) |
| Pore size ⁽²⁾ | N/A | (b) (4) | Width: (b) (4) Length: (b) (4) | (b) (4) | 1 | Profile Projector - (b) (4) (b) (4) |
| Bursting strength | ISO 13938-1 "Determination of Bursting Strength and Bursting Distension" | Standard | N/A ⁽³⁾ | Standard | 5 | Bursting Strength Tester - (b) (4) (b) (4) |
| Tensile breaking strength and elongation: warp and weft directions | ISO 13934-1 "Determination of Breaking Strength and Elongation" | Width: (b) (4) Length between the jaws: - warp: (b) (4) - weft: (b) (4) - weft: (b) (4) Crosshead speed: (b) (4) | | | 5 | Traction testing machine - (b) (4) (b) (4) (b) (4) |
| Tear strength: warp and weft direction | ISO 4674: 1977 (Method A2) "Determination of Tear Resistance of Coated Fabrics" | Width: (b) (4) Tear length: (b) (4) Crosshead speed: (b) (4) | | | 5 | Traction testing machine - (b) (4) (b) (4) (b) (4) |
| Suturing strength ⁽⁴⁾ : warp and weft direction | N/A | Width: (b) (4) Length: (b) (4) Overcasting seam type: (b) (4) | | | 5 | Traction testing machine - (b) (4) (b) (4) (b) (4) |

69

- (1) Surface density is roughly measured by weighing the sample.
- (2) Thickness and pore size are measured at different places of a single sample. There is no need in this study for an accurate value of the thickness and the pore size. However an evaluated measurement is enough to compare the 2 textiles. Thickness is measured using a micrometer caliper. Pore size is measured using a profile projector.
- (3) Bursting strength of the PLB central section cannot be measured because the section width is smaller than the bursting tester diaphragm diameter.
- (4) Suturing strength is the ability for a textile to be sutured without breaking or tearing. It is evaluated via the measurement of the tensile breaking strength of samples sewn with a suture or suture-like yarn. For this study, suturing strength samples are made out of 2 pieces of textile sampled in the same direction (i.e. either warp or weft direction), and sewn together using green PTFE coated polyester suture yarn, size (b) (4).
(b) (4) The seam type is overcasting, (b) (4)



III. RESULTS

Detailed results of the different tests which were performed are supplied in appendix to this document. Mean results and standard deviations for each test can be consulted in the table below.

| Characteristics | | PPL | | PLB Central soft knit section | | PLB Lateral strong knit section | | Comparison |
|-------------------------------------|------------------------|---------|---------|----------------------------------|---------|------------------------------------|---------|--|
| Surface density (g/m ²) | | (b) (4) | | (b) (4) | | (b) (4) | | PPL and PLB central soft knit section physical properties are roughly similar, whereas PLB lateral strong knit section is heavier. |
| Thickness (mm) | | (b) (4) | | (b) (4) | | (b) (4) | | |
| Pore size (mm) | | (b) (4) | | (b) (4) | | (b) (4) | | |
| | | Warp | Weft | Warp | Weft | Warp | Weft | Mechanical properties |
| Bursting strength (kPa) | | (b) (4) | | / | | (b) (4) | | <p>- No significant difference is observed between the mechanical properties of PLB central soft knit section and PPL textile. The equivalence of these two textile sections is demonstrated.</p> <p>- The mechanical properties of the PLB lateral strong knit section are significantly superior to that of the PPL textile, particularly in weft direction.</p> |
| Tensile breaking strength (N) | Sample size : Standard | (b) (4) | (b) (4) | (b) (4) | / | (b) (4) | (b) (4) | |
| | Sample size : Special | / | (b) (4) | / | (b) (4) | / | / | |
| Tensile breaking elongation (%) | | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | |
| Tear strength (N) | | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | |
| Suturing strength (N) | | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) | |

62

CONCLUSION

The textile component of the Ugytex Dual Knit Mesh, i.e. PLB textile, is composed of two distinct sections:

- The central soft knit section, which is to be compared to the Sofradim Ugytex Mesh textile (PPL). Physical and mechanical properties of both PPL and PLB central soft knit section are similar. Thus, the equivalence is demonstrated.
- The lateral strong knit section is designed to secure mesh fixation. Mechanical properties of the PLB lateral strong knit section are enhanced to provide a stronger textile in order for the physician to trim in these sections of the mesh if desired.

J LECUIVRE

APPENDIX C

Performance Testing

APPENDIX D

Product Information for Predicate Device

65

K033376
P/2

JAN 15 2004

**510(k) Summary
for
UGYTEX® Mesh**

1. SPONSOR

Sofradim Production
116 Avenue du formans
01600 Trevoux
France

Contact: Christophe Cosson
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name: UGYTEX® Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

| | |
|-----------------------------------|---------|
| Sofradim Parietex® Composite Mesh | K002699 |
| Sofradim Parietene® Mesh | K991400 |
| Ethicon Gynemesh Prolene Soft | K013718 |

4. DEVICE DESCRIPTION

The UGYTEX Mesh is a surgical mesh used during open or laparoscopic procedures. The UGYTEX Mesh is made from polypropylene and a collagen based hydrogel component. The hydrophilic collagen film does not affect the physical performance characteristics of the mesh but serves to temporary separate the mesh from adjacent organs to minimize visceral attachment to the mesh, which may occur during the healing process. The UGYTEX Mesh is offered in several sizes and shapes to accommodate the type and approach of the operation.

K033326
P2/2

5. INTENDED USE

The UGYTEX Mesh 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sofradim UGYTEX Mesh is composed of two biocompatible components: polypropylene mesh and a hydrophilic collagen film. The polypropylene material used in the UGYTEX Mesh is identical to the polypropylene used in Sofradim's Parietene polypropylene mesh, which received FDA marketing clearance under K991400. The UGYTEX Mesh is constructed of reduced diameter monofilament fibers, knitted into a design identical to the Parietene polypropylene mesh. This mesh with large pores allows fast tissue ingrowth and exhibits more flexibility than standard Parietene mesh. The collagen component of the Sofradim UGYTEX Mesh is derived from a Porcine source and meets all the requirements in the FDA collagen guidance documents. In addition, the Sofradim mesh and predicate devices are available in various sizes and shapes to accommodate different surgical procedures and/or surgeon's choice.

7. PERFORMANCE TESTING

Biocompatibility testing demonstrates that the materials used in the Sofradim UGYTEX Mesh are biocompatible and safe for its intended use.

Testing was performed to determine the performance characteristics of the Mesh. The density, thickness, elongation, breaking strength, tear resistance, burst resistance, and tensile strength were all evaluated. The test results showed that the Sofradim UGYTEX Mesh has similar performance characteristics as previously cleared surgical meshes.

67



JAN 15 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sofradim Production
c/o Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K033376
Trade/Device Name: UGYTEX[®] Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 21, 2003
Received: October 23, 2003

Dear Ms. McNamara-Cullinane:

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.

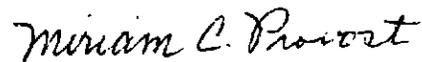
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

68

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033376

510(k) Number (if known): K033376

Device Name: UGYTEX® Mesh

Indications for Use:

The UGYTEX Mesh 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
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
 (Division Sign-Off)
 Division of General, Restorative
 and Neurological Devices

Page 1 of 1

(k) Number K033376

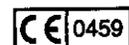
70



US MONOFILAMENT POLYPROPYLENE MESH COATED WITH AN
ABSORBABLE HYDROPHILIC FILM
INSTRUCTIONS FOR USE

 **SOFRADIM**  **PRODUCTION**

116, avenue du Formans . 01600 Trévoux . FRANCE
Tel. (33) 04 74 08 90 00 . Fax (33) 04 74 08 90 01



71

DESCRIPTION

UGYTEX® is a monofilament, polypropylene mesh coated with an absorbable, hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

UGYTEX® has an open weave design that offers homogeneous, multidirectional elasticity. This design allows the mesh to be cut into any desired shape or size without unraveling. The multidirectional elasticity enables the mesh to adapt to various body stresses.

INDICATIONS

UGYTEX® is indicated for use in the surgical repair of damaged or ruptured soft tissue in the pelvic floor where reinforcing or bridging materials are needed to provide reinforcement and long lasting stabilization of fascial structures.

CONTRAINDICATIONS

UGYTEX® 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, infection, inflammation, sensitization, adhesion formation, fistula formation, extrusion and recurrence.

PRECAUTIONS

- UGYTEX® 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.
- UGYTEX® is provided in a sterile blister tray within a double, pouched package. Do not place either pouch in the sterile field.
- Check the integrity of the packaging before use.
- Do not use the mesh 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.

IMPLANT PROCEDURES

Before handling, UGYTEX® must be hydrated. To hydrate, place UGYTEX® into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for approximately 30 seconds or until the mesh recovers its conformability and flexibility. The surgeon's preferred fixation technique can be utilized to secure the device tension free. Anchoring points should be positioned at least one cm from the edge of the mesh. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth.

STERILIZATION TECHNIQUE

UGYTEX® is intended as a single-use device. The mesh is sterilized by ethylene oxide. Do not resterilize. Discard opened, unused mesh.

STORAGE

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

GUARANTEE

SOFRADIM PRODUCTION certifies that all precautions have been taken in the choice of materials and manufacturing methods for this product. SOFRADIM PRODUCTION disclaims all liability in case of loss, damage or costs directly or indirectly linked to the use of the product. The guarantee terms or restrictions listed here cancel and replace any guarantee which does not appear in the present document, whether express or tacit by means of legislation or any other means whatsoever.

SOFRADIM PRODUCTION is not liable for any other action taken on its behalf by any party with regard to the product and hereby forbids any party to do so.

CAUTION : Federal law (USA) restricts this device to sale by or on the order of a physician.

Ugytex is a trademark of SOFRADIM PRODUCTION.

Manufacturer:

 SOFRADIM
PRODUCTION

116, avenue du Formans
01600 Trévoux
France
Tel. (33) 04 74 08 90 00
Fax (33) 04 74 08 90 01

72

- It is recommended to store the mesh at ambient temperature, away from direct heat.
- Do not use the device if the packaging is opened or damaged.
- Do not use the device past the last day of the labeled month of expiration.
- This device is intended as a single-use, disposable device. Do not reuse.
- The device is sterilized by ethylene oxide. Do not resterilize any portion of the device.
- **CAUTION** : Federal law (USA) restricts this device to sale by or on the order of a physician.

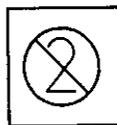
SYMBOLS USED



Warning, see the Instructions for Use.



Lot number.



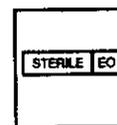
Do not reuse.



Use before.



Sterile, except if packaging is open or damaged.

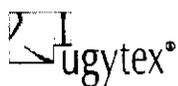


Sterile. Sterilized by ethylene oxide.



Manufacturing date.

**External label
(on cardboard box)**



**UGY 2415
(24 x 15 cm)**

LOT 20355UGY05
2008-03



**UGY 2415
(24 x 15 cm)**

- F** Renfort en polypropylène monofilament imprégné d'un film hydrophile résorbable.
Température de conservation : +2°C / +40°C (36°/105°F), dans un endroit sec.
- GB** Monofilament polypropylene mesh impregnated with a resorbable hydrophilic film.
To be stored between +2°C / +40°C (36°/105°F), in a dry area.
US *CAUTION : Federal (USA) Law restricts this device to sale by or on the order of a physician.*
- D** Monofilament Polypropylen-Netz, imprägniert mit einem resorbierbaren hydrophilen Film.
Zu lagern bei +2°C bis +40°C (36°/105°F), in einem trockenem Bereich.
- E** Malla de monofilamentos de polipropileno impregnada con una película hidrofílica resorbible.
Almacenar entre +2°C/+40°C (36°/105°F), en un lugar seco.
- I** Maglia monofilamentosa di polipropilene impregnata con una pellicola idrofila riassorbibile.
Da conservare a +2°C/+40°C (36-105°F), in un luogo asciutto.
- NL** Monofilament polypropyleen mesh geïmpregneerd met een resorbeerbare hydrofiele film.
Bewaren bij +2° C / +40° C (36°/105°F), op een droge plaats.
- P** Rede de monofilamento de polipropileno impregnada com uma película hidrofílica reabsorvível.
Deve conservar-se entre +2°C / +40°C (36°/105°F) em local seco.
- DK** Monofilament polypropylen net imprægneret med en resorberbar hydrofil film.
Opbevares tørt og ved mellem +2°C / +40°C (36°/105°F)
- S** Nät av monofilament-polypropylen imprægnerat med en resorberbar hydrofil film.
Förvaras torrt, mellan +2°C/+40°C (36°/105°F).
- FIN** Yksisäikeinen polypropyleeni-verkko, joka on kyllästetty resorboituvalle hydrofiilisellä kalvolla.
Säilytettävä kuivassa paikassa +2°C / +40°C (36°/105°F) n lämpötilassa.
- GR** Πλέγμα από πολυπροπυλένιο μονού νηματίου εμποτισμένο με απορροφούμενο υδρόφιλο υμένιο.
Πρέπει να φυλάσσεται σε θερμοκρασία μεταξύ +2 °C / +40°C (36°/105°F) σε ξηρό χώρο.

LOT 20355UGY05

2003-03

2008-03

E:1248-02 0903

STERILE EO



CE 0459

74

Internal label



UGY 2415
(24 x 15 cm)

UGYTEX 2415

LOT 20355UGY05



2003-03

2008-03

UGYTEX 2415

LOT 20355UGY05



2003-03

2008-03

UGYTEX 2415

LOT 20355UGY05



2003-03

2008-03

UGYTEX 2415

LOT 20355UGY05



2003-03

2008-03

4 repositionnable
stickers

STERILE EO



CE 0459

*Fabricant
Manufacturer*

SOFRADIM
PRODUCTION

116, avenue du Formans
01600 TRÉVOUX - FRANCE
Tel. (33) (0)4 74 08 90 00 - Fax (33) (0)4 74 08 90 01

E:1248-02 09/03

75

5. INDICATIONS FOR USE

The UGYTEX® Dual Knit Mesh 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The UGYTEX® Dual Knit Mesh is substantially equivalent in material, function, performance and design to the predicate UGYTEX® Mesh.

7. PERFORMANCE TESTING

The appropriate testing was performed to determine the performance characteristics of the mesh. The test results showed that the Sofradim UGYTEX® Dual Knit Mesh is substantially equivalent to the predicate device.

APPENDIX F

Kit Certification

**510(k) Premarket Notification
UGYTEX[®] Dual Knit Mesh**

Kit Certification

The introducers provided in UGYTEX Dual Knit Mesh kits are comprised of a handle and a stainless steel needle.

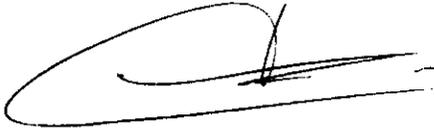
I certify that the introducers are Class I, exempt, manual surgical instruments (21 CFR 878.4800), consistent with the exemption criteria described in the classification regulation and the limitations of exemptions from 21 CFR Parts 862-892.

The introducers are purchased bulk, non-sterile. The introducers are packaged and sealed by SOFRADIM Production and sterilized.

François-Régis ORY
Signature

05/30/2005
Date
(mm/dd/yyyy)

François-Régis ORY
Chairman and Chief Executive Officer



Internal Administrative Form

| | YES | NO |
|---|-----|----|
| 1. Did the firm request expedited review? | | ✓ |
| 2. Did we grant expedited review? | N/A | |
| 3. Have you verified that the Document is labeled Class III for GMP purposes? | N/A | |
| 4. If, not, has POS been notified? | ✓ | |
| 5. Is the product a device? | | ✓ |
| 6. Is the device exempt from 510(k) by regulation or policy? | ✓ | |
| 7. Is the device subject to review by CDRH? | | ✓ |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | ✓ |
| 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? | N/A | |
| 10. Are you aware of the submitter being the subject of an integrity investigation? | | ✓ |
| 11. If, yes, consult the ODE Integrity Officer. | | ✓ |
| 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991. | N/A | |

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: *[Signature]* K 051503
 Division/Branch: OGEND/PRESB
 Device Name: Ughex Mal Knut Niesl
 Product To Which Compared (510(K) Number If Known): K033376

| | YES | NO | |
|--|-------------------------------------|-------------------------------------|--------------------------------------|
| 1. Is Product A Device | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | If NO = Stop |
| 2. Is Device Subject To 510(k)? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | If NO = Stop |
| 3. Same Indication Statement? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | If YES = Go To 5 |
| 4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | <input type="checkbox"/> | <input type="checkbox"/> | If YES = Stop NE |
| 5. Same Technological Characteristics? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | <input type="checkbox"/> | <input type="checkbox"/> | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | If NO = Go To 10 If YES = Stop SE |
| 8. New Types Of Safety Or Effectiveness Questions? | <input type="checkbox"/> | <input type="checkbox"/> | If YES = Stop NE |
| 9. Accepted Scientific Methods Exist? | <input type="checkbox"/> | <input type="checkbox"/> | If NO = Stop NE |
| 10. Performance Data Available? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | If NO = Request Data |
| 11. Data Demonstrate Equivalence? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Final Decision: |

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

new device design - I mesh with i comparison to 1

6. Explain how new characteristics could or could not affect safety or effectiveness: *but in their own predicate*

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

5 1 0 (K) M E M O R A N D U M

TO: K051503

FROM: Peter L. Hudson, Ph.D.
ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

J. Rhoda 8/5

DATE: 8/5/05

SUBJ: Ugytex Dual Knit Mesh
Sofradim Production
Ms. Pamela Papineau

PHONE: 978-772-3552

FAX: 978-772-3557

Email: delphi@ids.net

Recommendation: Substantially equivalent
Procode: FTL
Class: II
Regulation Number: 878.3300
Regulation Name: Surgical mesh

REVIEW:

1. Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)

Subject Device

The [subject device] 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.

Predicate device(s)

The Ugytex Mesh (K033376) 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.

Discussion of whether the intended use/indications are the same

The indications for use are identical to the predicate device and therefore are substantially equivalent.

2. Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.) of the Subject Device and Predicate(s)

Subject Device

The device is a monofilament, nonabsorbable, polypropylene mesh. It has a soft knit in the

central section and a strong knit in the lateral sides. The central, soft section is coated with a hydrophilic, collagen film used previously in the predicate comparator, K033376. The lateral sections of the mesh are not coated with the film. The following device configurations will be provided:

- Dual knit mesh: a rectangular sheet that can be trimmed to a desired size and shape
- Dual knit, anterior repair system: a pre-cut device for anterior vaginal wall prolapse repair accompanied by an introducer to facilitate placement
- Dual knit, posterior repair system: a pre-cut device for posterior vaginal wall prolapse repair accompanied by an introducer to facilitate placement
- The introducer provided with the meshes is a Class I, exempt, manual surgical instrument (21 CFR 878.4800). The sponsor has provided the kit certification statement.

Predicate Device(s)

The device materials are the same as that identified in the predicate application, K033376, i.e., polypropylene and a collagen film.

The differences between the subject device and the sponsor's own predicate product are the following:

- Varying knit of the mesh: the subject device has a collagen-coated soft knit in the central section and an uncoated stronger knit in the lateral sections whereas the predicate mesh is uniformly collagen-coated and is of a soft knit.
- Varying shape of the mesh: the subject device is offered in various configurations including a rectangular sheet and pre-cut versions for convenience in anterior and posterior prolapse repair procedures. The predicate is offered in solely a rectangular sheet.

Discussion of whether the subject device has a significant change in technological characteristics

Technologically, the subject device differs in that instead of consisting of a uniform soft knit, collagen-coated mesh, it now has lateral stronger knit sections that are not collagen-coated. I discussed the differences with Dr. Herb Lerner, General Surgeon. Dr. Lerner stated that the devices were essentially the same and that the new design did not raise new concerns regarding intended use or anticipated safe use and effectiveness. The devices are substantially equivalent.

3. Comparative Data (in vitro, animal and/or clinical)

Safety Data - Subject Device

The device consists of the same components as those in the predicate device, K033376 and therefore pose no new biocompatibility issues.

Safety Data - Predicate Device(s)

The Sofradim predicate Ugytex Mesh is made of a polypropylene mesh and contains a thin hydrophilic collagen-based film. The mesh material used is identical to that described in K991400 for the cleared Sofradim Parietene mesh. (b) (4)

(b) (4) This film is similar to the cleared Parietex mesh except that the collagen (b) (4) (b) (4)

| Test | Performed On | Laboratory Results |
|---------------------------------------|------------------|--------------------|
| Cytotoxicity Study | Hydrophilic Film | Passed |
| Immediate Sensitization Study | Hydrophilic Film | Passed |
| Delayed Sensitization Study | Hydrophilic Film | Passed |
| Systemic Toxicity Study | Hydrophilic Film | Passed |
| Genotoxicity Ames test | Hydrophilic Film | Passed |
| Implantation tests: Subcutaneous | Ugytex Mesh | Passed |
| Hemolysis Study | Hydrophilic Film | Passed |
| Pyrogenicity (LAL test) on each batch | Ugytex Mesh | (b) (4) |

Effectiveness Data – Subject Device

| Characteristics | Ugytex predicate | Ugytex dual knit mesh | |
|--|------------------|-----------------------|---------|
| | | Central | Lateral |
| Mesh Density (g/m) | (b) (4) | | |
| Mesh Thickness mm | | | |
| Mesh Pore Size (mean) mm | | | |
| Tensile/Breaking Strength (mean) daN | | | |
| Stiffness/Elongation at rupture (mean) % | | | |
| Tear Resistance (mean) N | | | |
| Suture Pull Out Strength (daN) | | | |
| Burst* | | | |
| Resistance/ Breaking Pressure (mean) kPa | (b) (4) | | |

* values determined on evaluations conducted with control to size

the burst resistance of the central soft knit section was considered NA because the section was too small for accurate comparison to the soft knit of the predicate device.

Effectiveness Data - Predicate Device(s)

The sponsor's most similar predicate device (Ugytex) was compared to other predicate surgical meshes in K033376:

| Characteristics | Parietex | Ugytex | Gynemesh |
|--|----------|---------|----------|
| Mesh Density (g/m) | (b) (4) | (b) (4) | (b) (4) |
| Mesh Thickness mm | (b) (4) | (b) (4) | (b) (4) |
| Mesh Pore Size (mean) mm | (b) (4) | (b) (4) | (b) (4) |
| Tensile/Breaking Strength (mean) daN | (b) (4) | (b) (4) | (b) (4) |
| Stiffness/Elongation at rupture (mean) % | (b) (4) | (b) (4) | (b) (4) |
| Tear Resistance (mean) N | (b) (4) | (b) (4) | (b) (4) |
| Suture Pull Out Strength (daN) Burst | (b) (4) | (b) (4) | (b) (4) |
| Resistance/ Breaking Pressure (mean) kPa | (b) (4) | (b) (4) | (b) (4) |

Discussion of whether the data demonstrate that the subject device is as safe and effective as the predicate(s)

As can be concluded from the data provided above in the effectiveness evaluations section, the subject device has physical characteristics that are equivalent if not stronger, in certain respects, than the predicate. The predicate device was evaluated for biocompatibility and found to be substantially equivalent to predicate surgical mesh products. The subject device contains the same material components and therefore does not pose new biocompatibility issues.

4. Does the product contain drugs or biologicals?

a. **If yes, what drug(s)/biologic(s): No**

5. Sterilization

| | |
|-----------------------------|--|
| Method - | Ethylene oxide |
| Validation - | (b) (4) – Medical devices, validation and routine control of ethylene oxide sterilization, and (b) (4) – Sterilization of medical devices to be labeled sterile |
| Residuals - | (b) (4) |
| Sterility Assurance Level - | 10 ⁻⁶ |
| Packaging - | PETG blister inside a single Tyvek pouch within an aluminum bag for the meshes. The packaging is identical to the sponsor's predicate device. The introducers will be purchased as bulk, non-sterile and packaged, tray-sealed with a Tyvek lid by the sponsor. After sterilization of the implant |

Pyrogenicity claims -

and the introducer packages, both products are placed into a kit package (cardboard box).
The sponsor conducts an LAL endotoxin evaluation on each product lot and meets the recommended medical device specification of (b) (4)

6. Is the Labeling Adequate?

(Prescription)
Package Insert (appendix A, page 2)
Carton/Pouch Labels (appendix A, page 5)

7. Claims

No specific claims are made, such as improved repair, etc. The label does describe what the central and lateral sections of the mesh are intended to do, or how they're to be used, i.e., the central-coated section is to be placed next to the organ so that the hydrophilic film will minimize visceral attachment to the device and the lateral sections are uncoated to encourage tissue fixation. The description regarding the hydrophilic film minimizing visceral attachment is in the predicate label.

8. Has sponsor provided all administrative requirements?

- Truthful and Accurate Statement (pg. vii)
- 510(k) Summary (appendix E, pg. 1)
- Indication for Use Page (pg. vi)

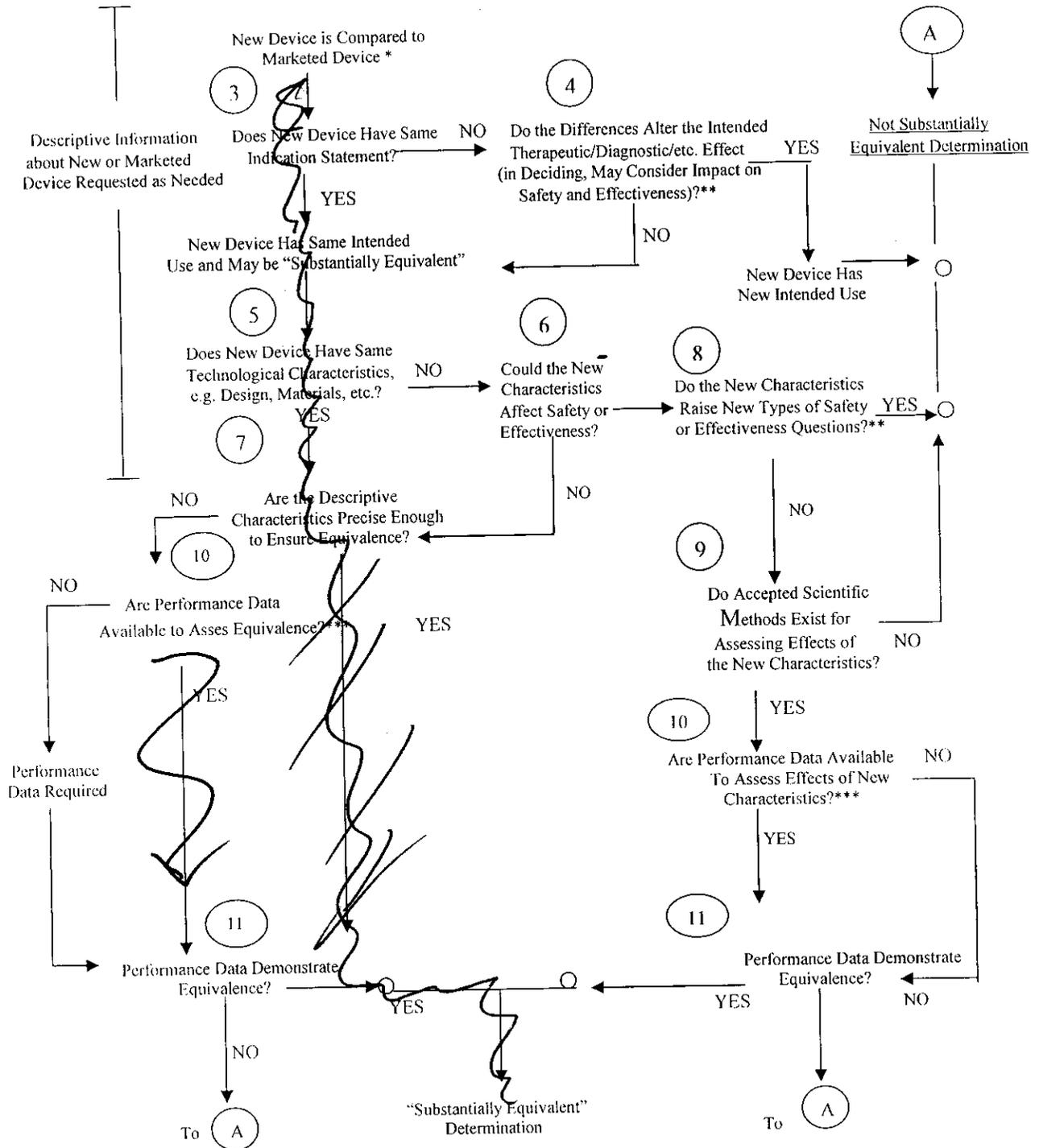
9. Analysis of the Equivalence of the Subject and Predicate(s)

The subject device indications for use, technology and safety and effectiveness evaluations all clearly indicate that the device is substantially equivalent. In the case of the indications, the statements are identical. The device differs subtly from the predicate, technologically in that it is now composed of a central soft knit section and a lateral strong knit dual sections. I've consulted with Dr. Lerner regarding the design change and he believed that the device does not raise new safety and effectiveness questions in comparison to standard surgical mesh devices. I recommend that the device be found substantially equivalent.

10. Contact History/Requests for More Information:


 Name _____ Date 8/5/06
 Plastic and Reconstructive Surgery Devices Branch

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



- ❖ 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.