Upsylon™ Y-Mesh and Colpassist™ Vaginal Positioning Device

Product Review for the Purchasing Committee
Product Review for the Purchasing Committee

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Product Overview

**Upsylon™ Y-Mesh**

**Colpassist™ Vaginal Positioning Device**
Product Overview: 
Upsylon Y-Mesh

The Upsylon Y-Mesh features lightweight, low surface area technology to minimize mesh contact with the vaginal wall. The mesh handling characteristics, large pores and blue color are designed to ease positioning and fixation to assist with placement.

- Mesh characteristics designed to provide stability for positioning and fixation
- Large pores for ease of suture passing and visibility
- Blue color designed to provide enhanced visualization of mesh against tissue

Figure 1: Picture of Upsylon Y-Mesh shows contrast of blue mesh and surrounding anatomy.
Product Overview: Colpassist™ Vaginal Positioning Device

The Colpassist Vaginal Positioning Device is the first device specifically designed for vaginal positioning in gynecologic procedures and as a suturing platform for vaginal wall fixation during sacrocolpopexy.

- Two size end options create a flat suturing surface
- Multi-direction vaginal manipulation during dissection and mesh placement

Figure 2: Picture of posterior dissection performed with Colpassist Vaginal Positioning Device providing positioning.
## Comprehensive Mesh Specs

It's more than light-weight mesh, It's ease of positioning and fixation.

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesh Weight (g/m²)</td>
<td>25</td>
<td>20</td>
<td>33.5</td>
<td>16.5</td>
<td>28*</td>
<td>52</td>
</tr>
<tr>
<td>Pore Size (mm²)</td>
<td>2.8</td>
<td>3.0</td>
<td>2.9***</td>
<td>2.9***</td>
<td>3.9**</td>
<td></td>
</tr>
<tr>
<td>Fiber Diameter (microns)</td>
<td>100</td>
<td>75</td>
<td>90</td>
<td>90</td>
<td>100</td>
<td>100</td>
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<tr>
<td>Length of Fiber (cm/cm²)</td>
<td>35.4</td>
<td>48.7</td>
<td>58.5</td>
<td>28.8</td>
<td>39.6</td>
<td>73.6</td>
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<tr>
<td>Surface Area Ratio</td>
<td>1.11</td>
<td>1.17</td>
<td>1.65</td>
<td>.81</td>
<td>1.24*</td>
<td>2.31</td>
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<tr>
<td>Thickness (microns)</td>
<td>200</td>
<td>305</td>
<td>377</td>
<td>287</td>
<td>533</td>
<td>527</td>
</tr>
<tr>
<td>Pliability (ASTM Standard D-4032 Stiffness (N))</td>
<td>0.53</td>
<td>0.11</td>
<td>Not Tested</td>
<td>0.15</td>
<td>0.71**</td>
<td>Not Tested</td>
</tr>
<tr>
<td>Suture Pull-Out (Machine Direction) Strength (N)</td>
<td>18.3</td>
<td>11.5</td>
<td>18.3</td>
<td>8.8</td>
<td>13.5</td>
<td>23.3</td>
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<tr>
<td>Color</td>
<td>Mesh Color</td>
<td>Blue w/ Natural Center Stripe</td>
<td>Natural</td>
<td>Natural w/Blue Stripe</td>
<td>Natural w/Blue Stripes</td>
<td>Natural</td>
</tr>
</tbody>
</table>

* Post-absorption  ** Pre-absorption  *** Including Cross Fiber  Data on file at Boston Scientific
Leg Attachment Strength and Elongation Profile

**Leg Attachment Strength and Method**
Comparison to Restorelle Y Mesh and 13 knot suture pattern.

**Mesh Attachment Strength (Average)**

<table>
<thead>
<tr>
<th>Mesh Type</th>
<th>N</th>
<th>Strength (lbs)</th>
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<tbody>
<tr>
<td>Upsylon™ Y-Mesh</td>
<td>30</td>
<td>23.2</td>
</tr>
<tr>
<td>Restorelle™ Y Mesh</td>
<td>9</td>
<td>16.5</td>
</tr>
</tbody>
</table>

Data on file at Boston Scientific
Results based on bench testing. Bench testing may not be necessarily indicative of clinical performance.

The leg attachment suture is knotted at 11 locations across the mesh. In addition, there are two back stitches for a total of 13 knots.

**Elongation Profile: Y-Mesh**
Benchmark Comparison of Upsylon Y-Mesh to Restorelle™ Y Mesh

<table>
<thead>
<tr>
<th>% ELONGATION at:</th>
<th>@ 0 Load</th>
<th>@ 1lbf Load</th>
<th>@ 3lbf Load</th>
<th>@ 5lbf Load</th>
<th>@ MAX Load</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upsylon Y-Mesh STERILE (avg of n=15)</td>
<td>0.0</td>
<td>5.29</td>
<td>13.88</td>
<td>19.56</td>
<td>49.84</td>
</tr>
<tr>
<td>Restorelle Y Mesh STERILE (avg of n=15)</td>
<td>0.0</td>
<td>3.83</td>
<td>9.57</td>
<td>15.68</td>
<td>50.17</td>
</tr>
</tbody>
</table>

Data on file at Boston Scientific
Results based on bench testing. Bench testing may not be necessarily indicative of clinical performance.
December 18, 2012

Boston Scientific Corporation
Urology/Women’s Health
% Ms. Lauren B. Anderson, RAC
Senior Specialist, Regulatory Affairs
100 Boston Scientific Way
MARLBOROUGH MA  01752

Re:  K122794
Trade/Device Name: Upsylon Y-mesh
Regulation Number: 21 CFR§ 873.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: November 28, 2012
Received: November 29, 2012

Dear Ms. Anderson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.
Product Review for the Purchasing Committee

Page 2 – Ms. Lauren B. Anderson, RAC

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICE/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/SafetyReportingProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
February 2, 2013

Dear Valued Customer,

Thank you for your inquiry regarding the Colpassist™ Vaginal Positioning Device. This information is provided in response to your direct request for regulatory information and may not be used for any other purpose without the expressed written permission of Boston Scientific Corporation.

The Colpassist™ Vaginal Positioning Device, order number M0068318210 complies with US Federal Regulation 21 CFR 884.4520, Instrument, Manual, General Obstetric-Gynecologic, and is 510(k) exempt. FDA does not require a 510(k) premarket notification for this device type.

Please feel free to your local sales representative or Boston Scientific directly should you have any additional questions or require additional information.

Sincerely,

Boston Scientific Regulatory Affairs
Pages 2

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in performing mesh procedures for surgical repair of pelvic organ prolapse.

**WARNING**
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

**DEVICE DESCRIPTION**
Upsylon Mesh is a preformed Y shaped lightweight polypropylene mesh consisting of two vaginal mesh arms and one sacral mesh arm. The Upsylon Mesh is blue in color with a non-colored centering line.

**INTENDED USE**
Upsylon Mesh is intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

**CONTRAINDICATIONS**
Upsylon Mesh is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients include those with:
- Pathology of the soft tissue into which the synthetic mesh is to be placed.
- Patients with future growth potential, pregnant patients, or patients that are considering future pregnancies.
- An anatomy that compromises device implant or pathology that limits blood supply or compromises healing.
- Autoimmune connective tissue disease.
- Pre-existing local or systemic infection.
- Blood coagulation disorder.

**WARNINGS**
- The effectiveness of this product has not been evaluated in a prospective randomized clinical trial.
- The implant procedure carries risk of infection and bleeding, inherent with open, laparoscopic, or robotic procedures.
- In the event of post procedure infection, the entire mesh may have to be removed.
Product Review Upsylvania Y-Mesh and Colpassist Vaginal Positioning Device

DFU: Upsylvania Y-Mesh (cont.)

- Perforations or lacerations of vessels, nerves, bladder, ureters, urethra or bowel may occur during placement and may require surgical repair.
- As with all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.

PRECAUTIONS
- Physicians should be trained in the placement of surgical mesh devices for treatment of pelvic floor disorders and in management of complications resulting from these procedures.
- Standard surgical practices should be followed for pelvic floor procedures as well as for the management of contaminated or infected wounds.
- An assessment of each patient should be made to determine their suitability for a synthetic mesh procedure, considering the patient’s prior abdominal or pelvic surgeries.
- Aseptic technique must be adhered to throughout procedure.
- Do not use product if past the date of expiration.
- It is recommended that patients be counseled to refrain from heavy lifting, exercise, and intercourse for a minimum of six (6) weeks after the procedure. Follow physician’s recommendations.
- It is recommended that patients be counseled to contact their physician in the case of post-operative bleeding, dysuria or other problems.
- There should be an appropriate margin of mesh extending beyond the suture line. Inadequate suturing of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.
- Future pregnancy may negate the effect of surgical repair.

ADVERSE EVENTS
- Adhesion formation
- Allergic reaction (hypersensitivity)
- Constipation
- Dystocia
- Erosion or extrusion
- Fistula formation
- Granulation tissue formation
- Hemorrhage
- Infection
- Inflammation (acute or chronic)
- Injury to ureter
- Mesh and or tissue contracture
- Necrosis
- Nerve injury
- Organ perforation
- Pain
- Prolapse/Recurrent prolapse
- Urinary and or fecal incontinence
- Urinary retention
- Vaginal shortening or stenosis

HOW SUPPLIED
Upsylvania™ Synthetic Mesh is supplied sterile in single use, single peel packages.
Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

OPERATIONS INSTRUCTIONS
1. Prepare anatomy using a laparotomy, laparoscopic or robotic approach. Surgical preparation for mesh attachment should be performed on the vaginal walls and the anterior longitudinal ligament overlying the sacral promontory.
2. Insert the Y mesh into the pelvic cavity, ensuring that the anterior and posterior arms are oriented to the corresponding anatomy. A non-colored centering line appears on the posterior arm and sacral arm of the Y mesh.

Note: The order of vaginal mesh attachment, ie. anterior before posterior/posterior before anterior, is at the discretion of the implanting physician, (but the vaginal attachments should be placed before securing the mesh to the sacrum).

3. Using standard fixation techniques, sutures may be used to fix the mesh to the vaginal walls per physician preference. Ensure that fixation is placed with at least two rows of empty pores (4 mm) from any mesh edge. Excess mesh beyond 4 mm from any mesh edge may be trimmed.
4. Ensuring appropriate tension, attach the sacral arm of the Y mesh to the anterior longitudinal ligament of the sacral promontory. Excess mesh beyond 4 mm from any mesh edge may be trimmed.
5. Reperitonealization over the mesh is recommended.
WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.
Product Review Upysylon™ Y-Mesh and Colpassist™ Vaginal Positioning Device

DFU: Upysylon Y-Mesh

Do not resterilize
Ne resteriliser
Nicht erneut sterilisieren
Ne pas résteriliser
Nicht erneut sterilisieren
Nel prodotto non è consentito
Niet te resteriliseren
Não resterilize

Do not use if package is damaged.
Ne pas utiliser si l'emballage est endommagé.
Nicht verwenden, wenn Verpackung beschädigt ist.
Non utilizzare se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l’oxyde d’éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.

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Legal Manufacturer
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Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.
Recyclable Package

CE 0197

English DFU for illustrative purposes only. Please refer to current version of the DFU.
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not re-use, re-process or re-sterilize. Re-use, re-processing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-processing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION
The Colpassist Vaginal Positioning Device is a vaginal positioning device molded from blue acrylonitrile butadiene styrene (ABS) material with a curved shaft and two uniquely sized end options. Each sized end features a flat surface, which may be used to facilitate suturing. The surgeon will choose the appropriate sized end based on vaginal width.

INTENDED USE / INDICATIONS FOR USE
The Vaginal Positioning Device is intended for use in general gynecological surgery to assist in the positioning and manipulation of the vagina during the procedure. It may also be used as support/back-stop for potential vaginal attachment during sacrocolpopexy. The device can be used with tactile feedback and/or direct visualization.

CONTRAINDICATIONS
None known.

WARNINGS
• Do not use excessive force during the insertion and movement of the device within the vagina.

PRECAUTIONS
• Aseptic technique must be adhered to throughout procedure.

ADVERSE EVENTS
• Tissue Damage
• Perforation

HOW SUPPLIED
The Colpassist Vaginal Positioning Device is supplied sterile in single use, single peel packages. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage
Store in a cool, dry, dark place.

English DFU for illustrative purposes only. Please refer to current version of the DFU.
**Product Review Up**

**sylon™ Y-Mesh and Colpassist™ Vaginal Positioning Device**

### DFU: Colpassist Vaginal Positioning Device (cont.)

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#### OPERATIONAL INSTRUCTIONS

Examine packaging and reject product if packaging is damaged or has been previously opened.

Peel open pouch and aseptically deliver product to sterile field.

Based on the patient’s anatomy, the surgeon should choose the appropriately sized Colpassist end.

The Colpassist™ Vaginal Positioning Device can be used with lubricating gels to facilitate insertion and movement.

#### WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use.

BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

---

**English DFU for illustrative purposes only. Please refer to current version of the DFU.**
Do not resterilize.

No reesterilizar.

Ne pas restériliser.

Nicht erneut sterilisieren.

Non risterilizzare.

Niet opnieuw steriliseren.

Não reesterilize.

Do not use if package is damaged.

No usar si el envase está dañado.

Ne pas utiliser si l'emballage est endommagé.

Bei beschädigter Verpackung nicht verwenden.

Non usare il prodotto se la confezione è danneggiata.

Niet gebruiken als de verpakking is beschadigd.

Não utilize se a embalagem estiver danificada.

STERILE EO

Sterilized using ethylene oxide.

Esterilizado por óxido de etileno.

Stérilisé à l'oxyde d'éthylène.

Mit Ethylenoxid sterilisiert.

Sterilizzato con ossido di etilene.

Gesteriliseerd met ethyleenoxide.

Do not use if package is damaged.

Esterilizado por óxido de etileno.

Please refer to current version of the DFU.

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### Reimbursement Guide: Upsylon Y-Mesh and Colpassist Vaginal Positioning Device

**Is this product reimbursable by insurance?**
The procedures for which it is used are reimbursable. Billing guides with respective coding and estimated Medicare reimbursement for relevant sacrocolpopexy procedures are available online at [www.bostonscientific.com/reimbursement](http://www.bostonscientific.com/reimbursement). For additional coding and reimbursement information, contact your local Territory Manager or the Women’s Health Reimbursement Help Desk at UnoWH.reimb@bsci.com or (800) 683-4022.

**What is the Medicare Pass-Through Code (aka C-Code or HCPCS)?**
The Medicare Pass-Through Code for Upsylon™ Y-Mesh is C1763 (Connective tissue, non-human (includes synthetic)).

**Is this a patient-chargeable product?**
Yes. The appropriate Revenue Code for Upsylon™ Y-Mesh is 272 – Medical/Surgical Supplies and Devices-Sterile Supply. Medicare does not dictate a provider’s charge structure or how it itemizes those charges. Section 2202.B of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g., operating room) does not specifically address which items are part of the basic “routine” charge and which are charged in addition to the basic charge. Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific supply. However, Medicare does require that charges billed on the CMS-1500 form (aka UB-04) be aggregated under the appropriate Revenue Code.

**Relevant Reimbursement Codes:**
Provider policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

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</thead>
<tbody>
<tr>
<td>Level II Laparoscopy</td>
<td>0131</td>
<td>57425 – Laparoscopy, surgical, colpopexy (susension of vaginal apex)</td>
<td>70.79 – Vaginal suspension and fixation with graft or prosthesis</td>
<td>$180.00 – Unspecified proloapse of vaginal walls</td>
<td>748 – Female reproductive system reconstructive procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>57280 – Colpopexy, abdominal approach (inpatient only procedure)</td>
<td></td>
<td>$180.09 – Other prolapse of vaginal walls without mention of stetine prolapse</td>
<td>662 – Minor bladder procedures with major complication or comorbidity (MCC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$180.50 – Prolapse of vaginal vault after hysterectomy</td>
<td>663 – Minor bladder procedures with complication or comorbidity (CC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>664 – Minor bladder procedures without CC/MCC</td>
</tr>
</tbody>
</table>

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*The patient’s medical record must support the existence and treatment of the complication or comorbidity.*
Ordering Information

**Upsylon™ Y-Mesh and Colpassist™** Vaginal Positioning Device

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Unit</th>
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<tbody>
<tr>
<td>M0068318200</td>
<td>Upsylon Y-Mesh</td>
<td>Each</td>
</tr>
<tr>
<td>M0068318210</td>
<td>Colpassist Vaginal Positioning Device</td>
<td>Each</td>
</tr>
<tr>
<td>M0068318220</td>
<td>Upsylon Y-Mesh and Colpassist Vaginal Positioning Device Kit</td>
<td>Each</td>
</tr>
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