Laparoscopic Ventral Hernia Repair

Technique Guide

VENTRALIGHT™ ST Mesh - Lightweight Absorbable Barrier Composite Mesh
SEPRAMESH™ IP Composite - Absorbable Barrier Composite Mesh
COMPOSIX™ L/P Mesh - Permanent Barrier Composite Mesh
The techniques presented herein are for informational purposes only. The decision of which technique to use in a surgical application lies with the surgeon based on patient profile and previous surgical history.
# LAPAROSCOPIC VENTRAL HERNIA REPAIR

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Absorbable Barrier

Ventralight™ ST Mesh and Sepramesh™ IP Composite

- Built on the foundation of Sepra® technology, with over 13 years of proven clinical success.
- Unique hydrogel bioresorbable coating resorbs within 30 days.
- Monofilament polypropylene mesh allows for rapid and complete tissue ingrowth and incorporation.
  - Sepramesh™ IP Composite: monofilament polypropylene mesh.
  - Ventralight™ ST Mesh: low profile, polypropylene mesh, approximately 50% lighter than traditional polypropylene mesh.
- Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding to the polypropylene mesh.
- Mesh can easily be cut to customize shape and size.
Composix™ L/P Mesh

- **BARD®** submicronic ePTFE permanent barrier with over 13 years of proven clinical success.
- Lightweight monofilament polypropylene mesh allows for rapid and complete tissue ingrowth and incorporation.
- Low profile, large pore polypropylene Soft Mesh is approximately 60% lighter than **BARD®** Mesh.
- Optional complementary Introducer Tool further facilitates laparoscopic introduction.
Basic Steps To The Repair

1. Ports are placed.
2. The contents of the sac are reduced and the defect is located.
3. The defect is measured.
4. The properly sized prosthesis is selected.
5. The mesh is introduced into the abdomen.
6. The mesh is secured into place against the abdominal wall with a fixation device and/or sutures.
Patient and Monitor Positioning

The patient should be placed in the low lithotomy position with arms out. This allows access to all quadrants and allows for a very lateral port placement. A towel roll may be placed under the costal margin on the “working” side to elevate the costal margin, making it easier to insert the initial port in obese patients and to introduce mesh into the abdomen.

Monitors should be placed 180 degrees apart, one directly in front of the surgeon and one behind, in case it is necessary to insert an accessory port on the opposite side to evaluate incarcerated hernia sac contents from a different angle. For very large defects, it may be necessary to move to the opposite side to accurately complete fixation of the mesh to the abdominal wall.
**Trocar Size Recommendations**

### VENTRALIGHT™ ST Mesh

<table>
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<th>Size (Minimum)</th>
<th>Trocar Size*</th>
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<tr>
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<tr>
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### SEPRAMESH™ IP Composite

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### COMPOSIX™ L/P Mesh

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<td>0134610</td>
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<td>0134790</td>
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<td>0134810</td>
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*If a proximal cap is available on the trocar, removing the proximal cap can help facilitate deployment. Deployment capability may vary depending on rolled patch size and graspers / trocars used.
A camera port is placed laterally in the upper left or right quadrant of the abdomen in order to allow for complete vision internally. This is done so the ports can be placed on both sides and no opposition of view is encountered. The additional ports are then placed as far lateral as possible in the remaining three quadrants. This allows one to reach up to the abdominal wall and to be able to work all sides of the mesh.
If you have to rely upon reticulating instruments or angled cameras to complete the task, it typically means that the trocars have been placed too close to the hernia itself. A towel roll under the working side facilitates lateral port placement.
The first step in repairing these defects is to gain adequate visualization of the task. If you are unable to see the defect and any incarcerated contents, additional ports can be added.
Make sure that all contents are dissected off the hernia sac. No attempt should be made to excise the hernia sac itself. This is done because there is very little to protect the mesh from the skin except for a very thin layer of subcutaneous tissue in the hernia sac itself.

Once all of the contents of the hernia sac have been reduced, it is critical that the surgeon evaluate what has been removed to ensure:

- That there is no evidence of bowel injury.
- That all adhesions that could be lysed have been lysed.
3 Defect Measurement

Measuring the Defect Internally
The defect can be measured internally by cutting a non-paper ruler to a small size and deploying it down the 5 mm trocar or by using an instrument to measure.

Measuring the Defect Externally
The defect can be measured externally with a spinal needle by going around the outside of the defect and making marks on the abdominal wall to correspond with the internal opening or the internal facial ring. Once this is complete, there is an outline on the abdominal wall of the defect.
The mesh should overlap the defect(s) 3–5 cm on all sides. For larger defects, the overlap should be at least 5 cm.

**For Ventralight™ ST Mesh / Sepramesh™ IP Composite Techniques,**
*turn to page 13.*

**For Composix™ L/P Mesh Technique,**
*turn to page 25.*
VENTRALIGHT™ ST Mesh and SEPRAMESH™ IP Composite Technique
With Ventralight™ ST Mesh / Sepramesh™ IP Composite, the mesh can be tailored without fraying or unraveling. To minimize the chance of recurrence, trim the prosthesis so that it extends at least 3–5 cm beyond the margins of the defect. For larger defects, the overlap should be at least 5 cm. If the material is cut too small, tension may be placed on the fixation line, which may result in a recurrence of the original defect.
To ensure that Ventralight™ ST Mesh / Sepramesh™ IP Composite is properly oriented, an asymmetrical mark, such as the letter “R,” can be drawn on the coated side of the mesh with a surgical marker prior to hydration.

Alternatively, suture knots can be tied on the uncoated polypropylene to assist with orientation (see step 7).
Prior to rolling and inserting the Ventralight™ ST Mesh / Sepramesh™ IP Composite Mesh, one of the following steps may be taken:

- A center orientation suture may be placed. Ensure that this suture is placed through the anterior layer of polypropylene.
- Transfascial/orientation sutures may be placed. Ensure any knots are on the polypropylene side to assist with orientation once in the abdomen.
6 Mesh Hydration

Completely immerse Ventralight™ ST Mesh / Sepramesh™ IP Composite for no more than 1-3 seconds in sterile saline* just prior to placement in order to maximize the flexibility of the prosthesis. In order to preserve the integrity of the bioresorbable coating, it is not advisable to over stretch the prosthesis during handling.

* The safety and effectiveness of Ventralight™ ST Mesh / Sepramesh™ IP Composite in combination with solutions other than saline have not been tested.
Immediately following hydration, roll the mesh along its long axis (lengthwise) with the bioresorbable coating inside to protect the coating when going through a trocar.

Do not force the prosthesis through the trocar. If Ventralight™ ST Mesh / Sepramesh™ IP Composite does not easily deploy down the trocar, replace the trocar and retry with the next available larger sized trocar, or place the mesh through the trocar incision site and re-insert trocar.
Once the mesh is inserted, unroll the mesh and, if necessary, flip the mesh over to ensure that the uncoated polypropylene side faces the abdominal wall and the hydrogel coated side is against bowel or other visceral structures.
Once the mesh is properly positioned in the abdomen:

- If a center orientation suture was placed, a suture passer device is inserted through the center of the defect and the suture is hoisted up.
- If transfascial sutures were placed, a suture passer device is inserted through the abdominal wall and the sutures are hoisted up.
When using a mechanical fixation device such as a Bard® SorbaFix® Absorbable Fixation System depicted above, the trocar in which you are inserting the fixation device should be in the quadrant of the body 180 degrees away from the area in which the mesh is being attached. First place fasteners around the edge of the patch to set the location (1–4), then use counter pressure to allow the abdominal wall to be pushed down perpendicular to the fixation device; thus securing the mesh to the abdominal wall.*

* Review and follow the mechanical fixation device’s instructions for use.
Next, fixate around the perimeter of the Ventralight™ ST Mesh / Sepramesh™ IP Composite.
Once the outer row of fasteners is secured, place a second row around the margin of the defect. Fasteners should be placed about 1–2 cm apart. Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used.

- The center stitch can then be cut and thrown away.
- Any transfascial sutures can be cut and thrown away or tied off.
Completion of the Repair

Once the mesh is secured, remove all ports under direct vision to ensure there is no bleeding. Evaluate the mesh as the pneumoperitoneum is released. The mesh must lay flat and should not droop on the edges.
Composix™ L/P Mesh Technique
If the mesh must be trimmed, cut only between the stitch lines. Trim approximately 1 cm out from the stitching ring (see dotted line above), then fold back the edge of the ePTFE layer and perform a second trim of the polypropylene mesh. This will ensure ePTFE overlap around the edges of the mesh.

Trim the mesh just outside the stitching. If an overlap is desired, trim further out from stitching (approximately 1 cm) then fold back the edge of the ePTFE layer and perform a second trim of just the polypropylene mesh. To minimize the chance of recurrence, trim the prosthesis so that it extends at least 3 - 5 cm beyond the margins of the defect. If the material is cut too small, tension may be placed on the fixation line, which may result in a recurrence of the original defect. For larger defects, the overlap should be at least 5 cm.
Prior to rolling and inserting **Composix™** L/P Mesh, the following steps may be taken:

- A suture may be placed in the center of the mesh through the anterior layer of polypropylene.
- Transfascial sutures may be placed.*

* However, due to the uncoated polypropylene side of the mesh providing rapid tissue ingrowth, permanent transfascial sutures may not be required as determined by the operating surgeon.
The optional complementary Introducer Tool allows for easy and consistent rolling of larger pieces of mesh.

To use the Introducer Tool:

- Wrap mesh between the two tines on the Introducer Tool along the long axis approximately 1 to 2 inches from the edge of the mesh. Ensure that the polypropylene mesh side faces outward.
- Attach T-Cap.

* The Introducer Tool comes pre-packaged with catalog numbers: 0134610, 0134790, 0134810, 0134113, 0134114.
• Hold the mesh tightly in the center of the tines as you roll.
• Continue rolling mesh with firm grip.
When finished rolling, continue holding mesh firmly. Remove T-Cap and begin to insert into trocar.
• Twist in the same direction in which the mesh was rolled and push downward until the handle touches the top of the trocar.
• Holding fingers tightly over the trocar entry site, twist the Introducer Tool 1/2 turn in the opposite direction, withdraw 2/3 of the tine length from the trocar, twist again in direction of mesh roll, and push downward until mesh falls off of tine inside of the abdominal cavity. Do not completely remove the tines from the prosthesis until the prosthesis has completely passed through the trocar.

• After the prosthesis had cleared the trocar, remove the Introducer Tool.
Mesh Insertion – Option #2 (without Introducer Tool)

- Roll mesh along the long axis with polypropylene side facing out.
- Grasp end of mesh and guide through trocar.
Once the mesh is inserted, unroll the mesh and if necessary flip over mesh to ensure that the uncoated polypropylene side faces the abdominal wall and the ePTFE side is against bowel or other visceral sutures.
Once the mesh is properly positioned in the abdomen, insert a suture passer in one of two ways, depending on the method chosen for orientation.

- If a center orientation suture was placed, a suture passer device is inserted through the center of the defect and the suture is hoisted up.
- If transfascial sutures were placed, a suture passer device is inserted through the abdominal wall and the sutures are hoisted up.
When using a mechanical fixation device such as a Bard® SorbaFix® Absorbable Fixation System, the trocar in which you are inserting the fixation device should be in the quadrant of the body 180 degrees away from the area in which the mesh is being attached. First place fasteners around the edge of the patch to set the location (1–4), then use counter pressure to allow the abdominal wall to be pushed down perpendicular to the fixation device; thus securing the mesh to the abdominal wall.*

*Review and follow the mechanical fixation device’s instructions for use.
Next, fixate around the perimeter of the Composix™ L/P Mesh.
Once the initial outer row of fasteners is secured, place a second row around the margin of the defect. Fasteners should be placed about 1–2 cm apart. Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used.

Depending on the orientation method chosen:

- The center stitch can then be cut and thrown away.
- Any transfascial sutures can be cut and thrown away or tied off.
Completion of the Repair

Once the mesh is secured, remove all ports under direct vision to ensure there is no bleeding. Evaluate the mesh as the pneumoperitoneum is released. The mesh must lay flat and should not droop on the edges.
**Indications**

Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

**Contraindications**

Do not use Ventralight™ ST Mesh in infants or children, whereby future growth will be compromised by use of such mesh material.  
Do not use Ventralight™ ST Mesh for the reconstruction of cardiovascular defects.  

Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

**Warnings**

1. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.  
2. This device has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging 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 diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user.  
3. Product should be used once exterior foil pouch has been opened. Do not store for later use. Unused portions of the prosthesis should be discarded.  
4. If unused prosthesis has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections.  
5. Ensure proper orientation; the coated side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera. (Reference Surface Orientation section.)
Warnings (cont.)

6. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.

7. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the prosthesis. Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

8. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect at least 3 to 5 cm.

Precautions

1. Please read all instructions prior to use.

2. Only physicians qualified in the appropriate surgical techniques should use this prosthesis.

3. The safety and effectiveness of Ventralight™ ST Mesh has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.

Adverse Reactions

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect.

Fixation

BARD® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the prosthesis. If other fixation devices are used, they must be indicated for use in hernia repair. The method of securing the prosthesis should be determined by surgeon preference and the nature of the reconstruction to provide for adequate tissue fixation and to prevent reherniation. Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary additional fasteners and/or sutures should be used.

IFU Part # PK3797001
Sepramesh™ IP Composite Indications, Contraindications and Warnings

Indications
Sepramesh™ IP Bioresorbable Coating/Permanent Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

Contraindications
1. Do not use Sepramesh™ IP Bioresorbable Coating/Permanent Mesh in infants or children, whereby future growth will be compromised by use of such mesh material.
2. Do not use Sepramesh™ IP Bioresorbable Coating/Permanent Mesh for the reconstruction of cardiovascular defects.
3. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

Warnings
1. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
2. This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization or repackaging 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 diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. Product should be used once exterior foil wrapper has been broken. Do not store for later use. Unused portions of the prosthesis should be discarded.
3. If unused prosthesis has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections.
4. Ensure proper orientation; the coating side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a
Warnings (cont.)

4. The possibility for adhesion formation when the prosthesis is placed in direct contact with the bowel or viscera.

5. The use of any permanent prosthesis in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.

6. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the prosthesis. Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

7. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.

Precautions

1. Please read all instructions prior to use.

2. Only physicians qualified in the appropriate surgical techniques should use this prosthesis.

3. The safety and effectiveness of SEPRAMESH™ IP Biodegradable Coating / Permanent Mesh has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.

Adverse Reactions

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.
Composix™ L/P Mesh

Indications

Composix™ L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

Contraindications

1. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.
2. Do not use the Composix™ L/P Mesh in infants or children whereby future growth will be compromised by use of such material.
3. Do not use Composix™ L/P Mesh for the reconstruction of cardiovascular defects.

Warnings

1. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
2. This device is for single use only. Do not resterilize. After opening, discard unused portions of the prosthesis.
3. Ensure proper orientation; the solid, white surface (ePTFE) must be oriented against the bowel or sensitive organs. Do not place the polypropylene mesh surface against the bowel. There may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.
4. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.
5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device.
6. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.
Warnings (Cont)

7. Discard Introducer Tool after use. This product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Precautions

1. Please read all instructions prior to use.

2. Only physicians qualified in the appropriate surgical techniques should use this prosthesis.

3. Davol™ fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the prosthesis. If other fixation devices are used, they must be indicated for use in hernia repair. Care should be taken to ensure that the prosthesis is adequately fixated to the abdominal wall. If necessary additional fasteners and/or sutures should be used.

Fixation

Davol permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the prosthesis. If absorbable fixation devices are used, they must be indicated for use in hernia repair. To ensure a strong repair, sutures, or tacks should be placed at least 1/2 cm inside the outermost row of stitching. Suturing or tacking only on sealed edge of mesh is not recommended. Suture and/or fixation device choice, size and spacing should be determined by surgeon preference.

Adverse Reactions

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.
### Composix™ L/P Mesh

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<th>Quantity</th>
<th>Shape</th>
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<td>4.5” (11.4 cm)</td>
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<td>1/cs.</td>
<td>Ellipse</td>
<td>4.2” x 6.2” (10.8 cm x 15.9 cm)</td>
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<td>Ellipse</td>
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<td>1/cs.</td>
<td>Oval</td>
<td>6.2” x 10.2” (15.9 cm x 26.1 cm)</td>
</tr>
<tr>
<td>0134790</td>
<td>1/cs.</td>
<td>Ellipse</td>
<td>7.2” x 9.2” (18.4 cm x 23.5 cm)</td>
</tr>
<tr>
<td>0134810</td>
<td>1/cs.</td>
<td>Ellipse</td>
<td>8.2” x 10.2” (21.0 cm x 26.1 cm)</td>
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<tr>
<td>0134113</td>
<td>1/cs.</td>
<td>Ellipse</td>
<td>10.2” x 13.2” (26.1 cm x 33.7 cm)</td>
</tr>
<tr>
<td>0134114</td>
<td>1/cs.</td>
<td>Rectangle</td>
<td>10.2” x 14.2” (26.1 cm x 36.2 cm)</td>
</tr>
</tbody>
</table>

- Please add the Composix™ L/P Mesh to my preference card.
- I would like to have the Composix™ L/P Mesh in stock.  
  *(Reference sizes checked above)*

Surgeon’s Signature ________________________________

Purchase Order Number ________________________________

Catalog Number ________________________________

Date ____________________ Quantity ________________

For Ventralight™ ST Mesh and Sepramesh™ IP Composite ordering information, please see back cover.
### VENTRALIGHT™ ST Mesh

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Quantity</th>
<th>Shape</th>
<th>Size</th>
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</thead>
<tbody>
<tr>
<td>5954450</td>
<td>1/cs.</td>
<td>Circle</td>
<td>4.5&quot; (11.4 cm)</td>
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<tr>
<td>5954460</td>
<td>1/cs.</td>
<td>Ellipse</td>
<td>4&quot; x 6&quot; (10.2 cm x 15.2 cm)</td>
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<tr>
<td>5954600</td>
<td>1/cs.</td>
<td>Circle</td>
<td>6&quot; (15.2 cm)</td>
</tr>
<tr>
<td>5954680</td>
<td>1/cs.</td>
<td>Ellipse</td>
<td>6&quot; x 8&quot; (15.2 cm x 20.3 cm)</td>
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<tr>
<td>5954610</td>
<td>1/cs.</td>
<td>Oval</td>
<td>6&quot; x 10&quot; (15.2 cm x 25.4 cm)</td>
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<td>Ellipse</td>
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<td>5954800</td>
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<td>Circle</td>
<td>8&quot; (20.3 cm)</td>
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<td>1/cs.</td>
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<td>5954113</td>
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<td>Ellipse</td>
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<td>12&quot; x 14&quot; (30.5 cm x 35.6 cm)</td>
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</table>

- Please add the VENTRALIGHT™ ST Mesh to my preference card.
- I would like to have the VENTRALIGHT™ ST Mesh in stock.
  *(Reference sizes checked above)*

### SEPRAMESH™ IP Composite

<table>
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<th>Catalog Number</th>
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<td>5959680</td>
<td>1/cs.</td>
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<td>1/cs.</td>
<td>Rectangle</td>
<td>12&quot; x 14&quot; (30.5 cm x 35.6 cm)</td>
</tr>
</tbody>
</table>

- Please add the SEPRAMESH™ IP Composite to my preference card.
- I would like to have the SEPRAMESH™ IP Composite in stock.
  *(Reference sizes checked above)*

---

Surgeon’s Signature ________________________________

Purchase Order Number ________________________________

Catalog Number ________________________________

Date ________________________________ Quantity ________________________________

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Warwick, RI 02886 • 1.800.556.6275 • www.davol.com

Medical Services & Support 1.800.562.0027

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