Scout Vessel Guard. A cover for vessels during anterior lumbar spine surgery.
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## Product Information

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Image intensifier control
Scout Vessel Guard. A cover for vessels during anterior lumbar spine surgery.

The Scout Vessel Guard is a flexible, nonabsorbable membrane, allowing it to contour to the anatomy. It is designed to be placed between the anterior spine and proximate vessels during anterior lumbar surgery.

The Scout Vessel Guard is a permanent implant. In cases of revision surgery or subsequent adjacent level surgery, the presence of the vessel guard will aid the surgeon in identifying the location of the index level, and in visualizing and identifying vessels and soft tissue structures.

The Scout Vessel Guard is MR Safe.

The safety and effectiveness of this device for reducing the incidence, severity and extent of postoperative adhesion formation have not been established.
The Scout Vessel Guard can be used over a variety of spinal implants:
- Total disc replacements (such as ProDisc-L) (Figure 1)
- Stand-alone ALIF devices (such as SynFix-LR) (Figure 2)
- Anterior plates (such as ATB, Antegra or Antegra-T) (Figure 3)
- ALIF spacers (such as FRA, ALIF or CC-ALIF) (Figure 4)

The Scout Vessel Guard is made from hydrogel (water, polyvinyl alcohol (PVA) and polyvinylpyrrolidone (PVP)) and packed wet in phosphate buffered saline (PBS).
Material Characteristics

Maximum pore size of 0.08 microns
– Particles larger than that cannot pass through

Hydrophilic
– Enhances fluid transport properties of the membrane
– Provided hydrated

Pliable
– Contours to anatomy

Homogeneous, translucent and white in color
– Able to maintain visualization of primary spine implant

Customizable footprint
– Can be trimmed intraoperatively to fit patient anatomy and application

1. Test data available on file at Synthes, West Chester, PA
Indications

The Scout Vessel Guard is indicated as a cover for vessels during anterior vertebral surgery.

Contraindications

Use of the Synthes Scout Vessel Guard is contraindicated for Reconstruction of:
- cardiovascular defects
- central nervous system defects
- peripheral nervous system defects
- hernias
- soft tissue deficiencies

Use of this product in applications other than those indicated has the potential for serious complications, such as pullout of the fixation or undesired healing to surrounding tissues.

Patients with infection, e.g., inflammatory, bacterial bone diseases (posttraumatic or chronic osteomyelitis) and soft-tissue infections at the site of proposed implantation.

Patients with demonstrated allergy or foreign body sensitivity to any of the implant materials.
One of the potential risks identified with any surgical procedure is death. Other potential risks associated with the use of this device which may require additional surgery, include:

- neurological injury
- vascular or visceral injury
- loss of fixation

Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.

DO NOT USE if there is loss of sterility of the device.
DO NOT USE if the device appears dehydrated or if moisture is not visible in the inner package.

The Synthes Scout Vessel Guards are sterilized by gamma radiation. DO NOT RESTERILIZE. CONTENTS STERILE UNLESS INNER PACKAGE IS OPENED OR DAMAGED.

Do not use the Scout Vessel Guard after the expiration date printed on the package label.

Product should be stored at room temperature, 15°C–30°C (59°F–86°F).

The safety and effectiveness of this device for reducing the incidence, severity and extent of postoperative adhesion formation have not been established.
Handling

03.650.008  Atraumatic DeBakey Forceps

Keep the sterile and hydrated product unopened in its protective packaging until ready to use (Figure 1).

A clear retainer is included in the package to keep the vessel guard flat during transit and storage. Remove the clear retainer from package before handling vessel guard (Figure 2).

To maintain flexibility of the implant, it is important to minimize dehydration, which can be caused by prolonged exposure to air. If the implant becomes dehydrated, soak it in sterile liquid (i.e., saline or water) until flexibility is restored. Sterile liquid can be added to the tray as needed to maintain hydration and keep the implant flat (Figure 3).

The vessel guard should be aseptically transferred from its tray directly to the site of application, using clean, sterile gloves and/or atraumatic instruments such as DeBakey forceps (Figure 4).

Maintain strict asepsis around the surgical site and avoid skin contact during transfer into the wound.

Avoid direct contact of the vessel guard with any sharp objects to protect the hydrogel material.
1

Select implant size

Choose the appropriate implant size based on patient anatomy and the surgical exposure. Ensure that the vessel guard will completely cover the desired area.

Vessel guards are shown actual size.
2

Size implant

Size the material using sharp, sterile scissors, such as Mayo scissors.

**Important:**
If the vessel guard is cut too small, excessive stress may be placed on the tissue or material and fixation pullout could occur. If the material is cut too large, excessive wrinkling may occur, compromising results.

Size the vessel guard appropriately for the intended area. Loose, fragmented pieces of the implant should not be used in the patient.
3
Insert implant

Instrument
03.650.008 Atraumatic DeBakey Forceps

Place the vessel guard over the spine in the exposed vessel area using clean, sterile gloves and/or atraumatic instruments such as DeBakey forceps (Figure 1).

Important: Using sharp instruments may damage the vessel guard and compromise vessel guard function.

Ensure that the implant is placed exterior to the disc space and without wrinkles (Figure 2).

Note: Retractor blades or other flat instruments placed near the application site may be used to facilitate smooth and even placement of the vessel guard (Figure 3).
Apply Fixation

4

Apply fixation

Fix the vessel guard in place to prevent migration.

Choose nonabsorbable sutures with a noncutting needle, such as a taper or piercing point.

Use the smallest needle appropriate for the application.

To avoid mechanical damage and suture hole elongation, smoothly pierce the vessel guard and follow the curve of the needle through the material.

Use minimal tension when pulling the suture line or when placing a knot.

Secure the vessel guard to adjacent nonvascular tissue using the fewest possible sutures, with a minimum of two points of fixation.

**Important:** Always fix the vessel guard in place to avoid implant migration.

Do not stretch the vessel guard while fixing in place; the implant should be smoothly placed without wrinkles or tension. Excessive tension on the implant or sutures may damage the implant and compromise vessel guard function.

Using fixation means other than those listed above is not recommended, as they may cause damage to the implant or surrounding anatomy.
Final Position

5
Release vessels
Release retraction on the vessels so they lay in their natural position. Take care not to place excessive force on the vessel guard while the vessels move into position over the implant.

6
Verify final position
The vessel guard should be positioned between the vessels and the spine.
To reposition the vessel guard, remobilize the vessels, and cut and remove sutures. Adjust the position and resuture.
Implant Removal

In the event that the vessel guard must be removed, remobilize the vessels, cut the sutures and remove the implant and sutures.

Properly discard any implant materials after removal.

**Important:**
All loose, fragmented pieces of the vessel guard should be removed and discarded.

Do not resterilize or reuse the vessel guard after removal.

The vessel guard should be removed in the event of unresolved infection.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>08.650.101S</td>
<td>Scout Vessel Guard, 65 mm width x 55 mm height x 1 mm thick, sterile</td>
</tr>
<tr>
<td>08.650.102S</td>
<td>Scout Vessel Guard, 65 mm width x 110 mm height x 1 mm thick, sterile</td>
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03.650.008  Atraumatic DeBakey Forceps

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions for the Atraumatic DeBakey Forceps, please refer to http://www.synthes.com/sites/NA/MedicalCommunity/Pages/Cleaning_and_Sterilization.aspx or to the below listed insert, which will be included in the shipping container:
- Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305