INDICATIONS

- Known or suspected sensitivity to implant materials (markers) materials. Rampart One devices incorporate integrated fixation in the form of titanium alloy screws. Rampart One devices are provided in standard and oblique configurations. The standard device accommodates four screws, and the oblique device accommodates two screws. In each device, the screws are inserted through the anteriorly-located face plate into the adjacent vertebral bodies. Rampart One devices are provided in various heights and lordotic angles and contain a hollow cone to receive autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

Spineology Inc. disclaims all warranties, express or implied, including but not limited to any implied warranty of merchantability or fitness for a particular use.

CONTRAINDICATIONS

- Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
- It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the implant.
- The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.

INSTRUMENTS

- Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned and re-sterilized immediately after use.
- Note that instruments are provided sterile for single use only.
- Do not re-sterilize implants.

DEVICE RETRIEVAL

Contact Spineology to discuss Revision / Retrieval.

CLEANING AND DECONTAMINATION

- Cleaning and decontamination of surgical instruments are required before introduction into the sterile field.
- Following use, disassemble devices as instructed for cleaning. Preventing drying will facilitate cleaning.
- Soak in enzymatic detergent (mixed per manufacturer’s recommendations) for five (5) minute or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes.
- Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is acceptable.
- Rinse each part thoroughly under running water for one (1) minute or longer.
Sterilization

Instrument trays are provided for storing and sterilizing the instruments. Instrument trays do not provide a sterile barrier. Trays must be used with a sterilization wrap. Sterilization can be performed on wrapped trays with the following cycle parameters:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vac</td>
<td>270°F / 132°C</td>
<td>4 Minutes Minimum</td>
<td>30 Minutes Minimum</td>
</tr>
</tbody>
</table>

Cool-down time of 20 minutes is recommended.

Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

Further Information or Product Complaints

Contact Spineology at
Spineology Inc.
7800 3rd Street N., Suite 600
Saint Paul, MN 55128-5455
Phone: 1.651.256.8500
Fax: 1.651.256.8505

Please contact your local Spineology representative for a complete surgical technique manual or further cleaning instructions.

Manufactured by:
Spineology Inc.
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888-377-4633

Sterilized by gamma radiation

Do not reuse