ORTHOMESH®
RESORBABLE GRAFT
CONTAINMENT SYSTEM

For maintaining the position of bone graft
or bone graft substitute
# TABLE OF CONTENTS

## INTRODUCTION
- ORTHOMESH Resorbable Graft Containment System 2
  - Basic Science 3
  - Indications and Contraindications 4

## SURGICAL TECHNIQUE
- Preparation 5
- Select and Prepare Mesh 7
- Contour Mesh 8
- Secure Mesh 9
- Water Bath System Disassembly 12

## PRODUCT INFORMATION
- Implants 13
- Instruments 14
- Instrument Trays 16
ORTHOMESH RESORBABLE GRAFT CONTAINMENT SYSTEM

Features

- Helps to ensure bone graft or bone graft substitute will remain in position
- Allows proliferation of new blood vessels into bone graft, bone graft substitute, or newly regenerated bone
- Restricts the ingrowth or prolapse of soft tissue, which could inhibit bone regeneration
- Resorbs in approximately 12 months
- Eliminates secondary surgeries for implant removal
- Degrades without late inflammatory complications and foreign-body responses that have been observed with semicrystalline structures such as poly(L-lactide)
- Proven biocompatible material
- Radiolucent polymer does not interfere with intraoperative or postoperative radiographs
- Polymer strength is not affected by radiation therapy

3. Based on biocompatibility testing per ISO10993-1:1997(E) conducted by Synthes (USA).
Basic Science

The implants of the ORTHOMESH Resorbable Graft Containment System are manufactured from 85:15 poly (L-lactide-co-glycolide). This copolymer is formed by combining L-lactide and glycolide, which maximizes the advantageous characteristics of each component and provides a material well suited for trauma bone graft containment (Figure 1).

85:15 poly (L-lactide-co-glycolide) is a linear, substantially amorphous, random copolymer, and retains approximately 85% of its initial bending strength after 8 weeks (Figure 2).

A significant benefit of this composition is the amorphous microstructure, which is readily resorbed by the body (Figure 3). First, water penetrates the bulk of the device and breaks the chemical bonds along the backbone of the polymer chains in a process called hydrolysis. As the bonds are broken, producing shorter polymer chains, the molecular weight of the polymer decreases, and the strength of the material decreases.

Eventually, the material loses its integrity and breaks down into smaller and smaller particles. These smaller pieces are then phagocytized (ingested and digested by the cells of the body). The polymer is broken down into lactic and glycolic acids, which are subsequently eliminated through natural body metabolism in the form of water and CO₂, without toxic tissue accumulation.  

**Indications***
The DePuy Synthes Trauma ORTHOMESH Resorbable Graft Containment System is indicated for use in maintaining the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures.

ORTHOMESH Resorbable Graft Containment System implants may be used alone (without traditional rigid fixation) to maintain the relative position of bone grafts, bone graft substitutes, or bone fragments in non-load-bearing reconstructive procedures involving areas where bone stability has not been compromised, such as tumor resections and iliac crest graft harvest sites.

The implants must be used in conjunction with traditional rigid fixation in load bearing applications to maintain the relative position of bone grafts, bone graft substitutes, or bone fragments in reconstructive procedures involving long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax. These devices are not intended for use in the spine. The devices are not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

**Contraindications***
DePuy Synthes ORTHOMESH Resorbable Graft Containment System is not intended for:

- Active infection
- Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections
- Load bearing indications unless used in conjunction with traditional rigid fixation
- Use in the spine

*Please see Directions for Use for complete contraindications, warnings, precautions, and possible adverse events.*
In preparation for contouring mesh, set up water bath heater in advance.

Water Bath System (530.509) includes:
530.510 Water Bath Heater
530.512 Water Bath Tray
530.514 Water Bath Sterility Cover

**Water Bath System setup**
The water bath tray and sterility cover must be sterilized before each use.* The water bath system must be set up and turned on at least 20 minutes before anticipated use.

1
**Plug in power cord**

**Instrument**

| 530.510 | Water Bath Heater |

Place the nonsterile water bath heater on a stable, nonsterile surface. Connect the power cord to an appropriate power supply.

**Caution:** Do not pour water directly into open well.

*Note: For additional information, please refer to package insert.*
2
Create sterile barrier

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.512</td>
<td>Water Bath Tray</td>
</tr>
<tr>
<td>530.514</td>
<td>Water Bath Sterility Cover</td>
</tr>
</tbody>
</table>

Place the sterilized plastic water bath sterility cover over the water bath heater. Place the sterilized water bath tray into the sterility cover.

Optional technique
A disposable, heat-resistant, clear sterile drape may be used in place of the water bath sterility cover. Place the water bath tray into the well of the water bath heater. Add 5 cc–10 cc of sterile water to the tray. Place the sterile drape over the entire assembly and press it down into the four corners of the water bath tray, then fill the covered tray with sterile water or saline solution. When disassembling the system, remove the water bath tray and the sterile drape together.

3
Fill
Pour room temperature sterile water or saline solution into the water bath tray up to the “water level line” (approximately 500 cc).

4
Heat water
Switch the water bath heater on. In about 18 minutes, the “Ready” indicator will light, indicating the unit is ready for use. The approximate temperature will be displayed.
The surgeon must be familiar with resorbable implants, the method of application, instruments, and the surgical procedure. The surgeon must determine whether a defect needs a bone graft and when in the surgical procedure the graft should be placed.

1 Select and prepare resorbable mesh

Instrument

| 391.964 | Scissors for Resorbable Mesh Plates |

If necessary, cut the resorbable mesh to the desired shape and size to fit the defect. This can be done using scissors.

Open the scissors wide and place the resorbable mesh at the very back of the scissor blades. This provides the most leverage and control for a clean cut.

2 Heat for contouring

Instrument

| 530.509 | Water Bath System |

Place the resorbable mesh in the water bath system. Allow the resorbable mesh to become malleable before contouring.
CONTOUR MESH

3 Contour mesh

Instrument

| 347.98 | Plate Holding Forceps |

Using the plate holding forceps, remove the resorbable mesh from the water bath. Contour by hand or by laying the resorbable mesh onto the bone.

The resorbable mesh may be reheated and recontoured up to 10 times. Depending on room temperature, the heated resorbable mesh will have approximately 7 seconds of working time prior to becoming rigid. Reduced finger contact will extend working time.

4 Place contoured mesh

Place the contoured mesh over the defect with some overlap of the surrounding bone for fixation.

According to proper ORIF technique, ORTHOMESH Resorbable Graft Containment System implants must be used in conjunction with traditional rigid fixation in load bearing applications.
Secure mesh
ORTHOMESH Resorbable Graft Containment System can be fixated using resorbable screws.

Drill/Tap hole

**Instruments**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.03</td>
<td>Handle, with mini quick coupling, small</td>
</tr>
<tr>
<td>or 311.01.96</td>
<td>Handle, with mini quick coupling</td>
</tr>
<tr>
<td>311.035.97S</td>
<td>Tap for 1.5 mm Resorbable Cortex Screw, self-drilling, 5 mm, sterile</td>
</tr>
<tr>
<td>or 311.056.97S</td>
<td>Tap for 2.0 mm Resorbable Cortex Screw, self-drilling, 6 mm, sterile</td>
</tr>
</tbody>
</table>

Select the appropriate tap. Taps are intended for single-procedure use only.

Insert the tap into the desired handle.

While maintaining the tap perpendicular to the mesh surface, tap through the mesh hole into the bone until the tap shoulder stops against the mesh surface.

Clean the tap threads and flutes of debris before tapping the next hole.
Insert screw

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>314.431 or 314.432</td>
<td>1.5 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling</td>
</tr>
<tr>
<td>314.686 or 314.687</td>
<td>2.0 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling</td>
</tr>
</tbody>
</table>

Select the appropriate screw.

Attach the cruciform screwdriver blade with spring holding sleeve to the selected handle. Fully retract the holding sleeve to spread prongs. Orient the blade directly above the screw head so that screw and screwdriver interaction is clearly visible. Insert the screwdriver tip into the cruciform drive of the screw head with the holding sleeve retracted. Do not insert at an angle.

Slide the screwdriver holding sleeve down completely over the screw head to securely grasp the screw.

Insert the screw through the hole in the mesh and into the tapped hole in the bone. Use a light two-finger technique (thumb and index finger) to insert the screw. Be sure to retract the holding sleeve before fully seating the screw. Stop immediately when the screw makes full contact with the plate. Do not overtighten.

Insert additional screws as needed.
Technique tips

- If screw insertion is difficult, the difficulty may be due to an insufficiently tapped hole. Back the screw out and retap the hole, being sure to fully insert the tap, i.e., the tap shoulder stops against the plate surface. If the original screw threads are damaged, insert a new screw.
- If the screw head breaks off before seating the screw, the tap may have not been fully inserted. Proceed with emergency screw placement.

**Important:** If too much force is used to insert the blade into the screw head, the cruciform slots could be damaged, resulting in poor screw pickup and insertion.

Overinsertion of the screw beyond its initial contact with the plate may result in breakage or deformation of the screw head.
Water Bath System Disassembly

**Instruments**

- 530.510 Water Bath Heater
- 530.512 Water Bath Tray
- 530.514 Water Bath Sterility Cover

1. **Cool unit**
   Turn the unit to "Standby" and allow it to cool for about 5 minutes.

2. **Drain water**
   Remove the water bath tray and pour out the water or saline. Remove the sterility cover.

3. **Clean**
   Wipe the water bath heater with a damp cloth and a water-soluble cleaning agent. After cleaning, the tray and cover can be wrapped, sterilized, and stored as a unit.

4. **Sterilize**
   Sterilize the water bath tray and sterility cover.*

**Caution:** Do not sterilize the water bath heater.

*Note: For additional information, please refer to package insert.*
### IMPLANTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>851.711.97S</td>
<td>ORTHOMESH Resorbable Graft Containment System &lt;br&gt; Straight Row Resorbable Mesh, &lt;br&gt; 50 mm x 50 mm x 0.5 mm, sterile</td>
</tr>
<tr>
<td>851.712.97S</td>
<td>ORTHOMESH Resorbable Graft Containment System &lt;br&gt; Straight Row Resorbable Mesh, &lt;br&gt; 100 mm x 100 mm x 0.5 mm, sterile</td>
</tr>
<tr>
<td>803.605.02S</td>
<td>ORTHOMESH Resorbable Graft Containment System &lt;br&gt; 1.5 mm Resorbable Cortex Screw, &lt;br&gt; 5 mm, sterile, pkg. of 2</td>
</tr>
<tr>
<td>804.006.02S</td>
<td>ORTHOMESH Resorbable Graft Containment System &lt;br&gt; 2.0 mm Resorbable Cortex Screw, &lt;br&gt; 6 mm, sterile, pkg. of 2</td>
</tr>
</tbody>
</table>
## INSTRUMENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.01.96</td>
<td>Handle, with mini quick coupling</td>
</tr>
<tr>
<td>311.03</td>
<td>Handle, with mini quick coupling, small</td>
</tr>
<tr>
<td>311.035.97S</td>
<td>Tap for 1.5 mm Resorbable Cortex Screw, self-drilling, 5 mm, sterile</td>
</tr>
<tr>
<td>311.056.97S</td>
<td>Tap for 2.0 mm Resorbable Cortex Screw, self-drilling, 6 mm, sterile</td>
</tr>
<tr>
<td>314.431</td>
<td>1.5 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, for resorbable screws</td>
</tr>
<tr>
<td>314.432</td>
<td>1.5 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, long, for resorbable screws</td>
</tr>
</tbody>
</table>
## Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>314.686</td>
<td>2.0 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, for resorbable screws</td>
</tr>
<tr>
<td>314.687</td>
<td>2.0 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, long, for resorbable screws</td>
</tr>
<tr>
<td>347.98</td>
<td>Plate Holding Forceps</td>
</tr>
<tr>
<td>391.964</td>
<td>Scissors for Resorbable Mesh Plates</td>
</tr>
<tr>
<td>530.509</td>
<td>Water Bath System</td>
</tr>
<tr>
<td></td>
<td>includes:</td>
</tr>
<tr>
<td>530.510</td>
<td>Water Bath Heater</td>
</tr>
<tr>
<td>530.512</td>
<td>Water Bath Tray</td>
</tr>
<tr>
<td>530.514</td>
<td>Water Bath Sterility Cover</td>
</tr>
</tbody>
</table>
INSTRUMENT TRAYS

Customizable Instrument Trays

305.806  Small Instrument Tray Lid, for Resorbable Fixation System
305.807  Small Instrument Tray Base, for Resorbable Fixation System
305.811  Instrument Insert, for Resorbable Instrument Trays
305.814  Finger Mat Insert, for Resorbable Instrument Trays
Limited Warranty and Disclaimer: DePuy Synthes Trauma products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

Legal manufacturer in Canada:

Synthes (Canada) Ltd.
2566 Meadowpine Boulevard
Mississauga, Ontario L5N 6P9
Telephone: (905) 567-0440
To order: (800) 668-1119
Fax: (905) 567-3185