ORTHOMESH® RESORBABLE GRAFT CONTAINMENT SYSTEM

For maintaining the position of bone graft or bone graft substitute
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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\(^1\)
- 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)\(^2,3\)
- Proven biocompatible material\(^4\)
- Radiolucent polymer does not interfere with intraoperative or postoperative radiographs\(^5,6\)
- Polymer strength is not affected by radiation therapy\(^7,8\)

1. Average strength retention data on file at DePuy Synthes Companies of Johnson & Johnson.
4. Based on biocompatibility testing per ISO10993-1:1997(E) conducted by DePuy Synthes Companies of Johnson & Johnson.
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.9

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INDICATIONS AND CONTRAINDICATIONS

**Indications**
The 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**
The 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
PREPARATION

In preparation for contouring resorbable plates, meshes, and sheets, set up Water Bath in advance. There are two DePuy Synthes Companies Water Bath options. The Compact Water Bath System (05.725.010) is used with a Sterile Drape. The Water Bath System (530.509) has a Tray and Sterility Cover that must be sterilized before each use. An optional technique of a Sterile Drape is also available for the Water Bath System.

COMPACT WATER BATH SYSTEM ASSEMBLY

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<td>05.725.010 Compact Water Bath</td>
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Compact Water Bath System setup*

The Compact Water Bath System must be set up and turned on at least 15 minutes before anticipated use.

1

Insert power cord

Place the Compact Water Bath on a level, stable, nonsterile surface. Ensure the power switch is in the OFF position. Confirm that the power cord is firmly inserted into the Compact Water Bath.

Note: Ensure that there is a grounded electrical outlet within reach of the power cord from where the Compact Water Bath is placed.

*For additional information, please refer to Instructions For Use.
Preparation
Compact Water Bath System Assembly

2

Fill to PREFILL line

Fill the pan basin with approximately 50 mL of room temperature sterile water or sterile saline to the PREFILL Line.
Preparation
Compact Water Bath System Assembly

3
Insert sterile drape

While using sterile technique, unfold the Sterile Drape to locate the center. Hold the center of the drape over the Compact Water Bath and unfold completely. The entire Compact Water Bath should be covered by the Sterile Drape.

Caution: Be careful to maintain drape sterility on the upward-facing side of the drape. The Compact Water Bath and surface under the Compact Water Bath is not sterile.

Note: Instructions for inserting the Sterile Drape are also included in the Sterile Drape packaging.
4

Fill

Press the drape down into the basin with one hand while pouring approximately 450 mL of room-temperature sterile water or sterile saline so that the liquid level is between the MIN line and MAX line.

**Note:** To reduce heat-up time, ensure the Sterile Drape contacts the prefill liquid or walls of the Compact Water Bath basin.
5 Heat liquid

Plug power cord into a grounded power outlet. Switch the Power Switch to the ON position. The blue WARMING indicator on the front of the Compact Water Bath will illuminate, signifying that the liquid is heating up.

After approximately 15 minutes the green READY FOR USE indicator will illuminate, signifying that the liquid is heated to 149°F-167°F (65°C-75°C) and is ready for use.

The Compact Water Bath will maintain at temperature during operation. If the liquid level drops below the MIN fill line, additional sterile water or sterile saline must be added. Additional time may be required to heat the water back up to temperature, as indicated by the WARMING indicator.

Note: If the READY FOR USE indicator does not illuminate after 20 minutes, adjust drape to ensure contact with prefill liquid or walls of the Compact Water Bath basin.
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.

*For additional information, please refer to Instructions For Use.*
2
Create sterile barrier

**Instruments**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>530.512</td>
<td>Water Bath Tray</td>
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<tr>
<td>530.514</td>
<td>Water Bath Sterility Cover</td>
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</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. Place the Water Bath Tray into the well of the Water Bath Heater. Add 5 mL–10 mL 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 sterile saline solution into the Water Bath Tray up to the “water level line” (approximately 500 mL).

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 and contouring

**Instrument**

| 05.725.010 | Compact Water Bath |
| 08-CC184 | Sterile Drape |

or

| 530.509 | Water Bath System |

Place the resorbable mesh in the Water Bath System. Allow the resorbable mesh to become malleable before contouring.
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.
5

Secure mesh

The resorbable mesh can be fixated using resorbable screws.

**Drill/Tap hole**

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<tr>
<th>Instruments</th>
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<tbody>
<tr>
<td>311.03</td>
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<tr>
<td>311.035.97S</td>
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</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.
Secure Mesh

<table>
<thead>
<tr>
<th>Insert screw</th>
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<tr>
<td>Instruments</td>
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<td>314.431 or 314.432</td>
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<tr>
<td>314.686 or 314.687</td>
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</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 2-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.
Secure Mesh

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, ie, 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.

Emergency screw placement

If the 1.5 mm screw breaks during screw insertion, either remove the screw or tap through the screw with the 2.0 mm self-drilling tap.
COMPACT WATER BATH SYSTEM DISASSEMBLY

1 Cool unit

Switch the Power Switch to the OFF position and disconnect the unit from the electrical outlet. Allow the unit to cool for approximately 25 minutes to room temperature.

2 Dispose of liquid and drape

Empty liquid out of Compact Water Bath and dispose of drape.

Important:
• Do not use the drape as a container to transport the liquid.
• Disposal of contaminated material/fluids should be in accordance with all applicable regulations.

3 Wipe down

Due to the use of the disposable Sterile Drape, the Compact Water Bath does not have patient contact and does not contact bodily fluids during normal use. The Compact Water Bath can be wiped with a damp cloth and a solution of water with soap.

Important:
• Do not sterilize, immerse, or place the Compact Water Bath under running water.
• Solvents and aggressive chemicals should not be used to wipe down the unit.
Disassembly

WATER BATH SYSTEM DISASSEMBLY

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<th>Instrument</th>
<th>Description</th>
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<td>Water Bath Heater</td>
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<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>

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.

   **Important:** Disposal of contaminated material/fluids should be in accordance with all applicable regulations.

3. **Clean**
   
   The Water Bath Heater can be wiped with a damp cloth and a solution of water with soap. After cleaning, the tray and cover can be wrapped, sterilized, and stored as a unit.

   **Important**
   - Do not sterilize, immerse, or place the Water Bath Heater under running water.
   - Solvents and aggressive chemicals should not be used to wipe down the unit.

4. **Sterilize**
   
   Sterilize the Water Bath Tray and Sterility Cover.*

   **Caution:** Do not sterilize the Water Bath Heater.

*For additional information, please refer to Instructions For Use.
The DePuy Synthes Companies ORTHOMESH Resorbable Graft Containment System is not intended for use in load-bearing indications unless it is used in conjunction with traditional rigid fixation devices. The ORTHOMESH Implants can break or bend as a result of stress, activity, or full load-bearing and could result in failure of the device or treatment.

The surgeon is to be thoroughly familiar with the devices, the method of application, instruments and the surgical procedure. The surgeon must select the type or types of internal fixation devices appropriate for treatment.

1. Improper selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results.
2. Resorbable devices provide fixation and are not intended to replace normal healthy bone or withstand the stress of full load-bearing.
3. The implants can break or be damaged due to excessive activity or trauma. This could lead to failure of the implant construct, which could require additional surgery and device removal.
4. Discard and do not use previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.
6. Do not use if the temperature indicator located on the packaging is black.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>851.711.97S</td>
<td>1.5 mm ORTHOMESH Resorbable Straight Row Mesh, 50 mm x 50 mm x 0.5 mm, sterile</td>
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<tr>
<td>851.712.97S</td>
<td>1.5 mm ORTHOMESH Resorbable Straight Row Mesh, 100 mm x 100 mm x 0.5 mm, sterile</td>
</tr>
<tr>
<td>803.605.02S</td>
<td>1.5 mm ORTHOMESH Resorbable Cortex Screw, 5 mm, sterile, pkg. of 2</td>
</tr>
<tr>
<td>804.006.02S</td>
<td>2.0 mm ORTHOMESH Resorbable Cortex Screw, 6 mm, sterile, pkg. of 2</td>
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## INSTRUMENTS

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<td>Handle, with mini quick coupling</td>
<td><img src="image1.png" alt="Image" /></td>
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<tr>
<td>311.03</td>
<td>Handle, with mini quick coupling, small</td>
<td><img src="image2.png" alt="Image" /></td>
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<tr>
<td>311.035.97S</td>
<td>Tap for 1.5 mm Resorbable Cortex Screw, self-drilling, 5 mm, sterile</td>
<td><img src="image3.png" alt="Image" /></td>
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<tr>
<td>311.056.97S</td>
<td>Tap for 2.0 mm Resorbable Cortex Screw, self-drilling, 6 mm, sterile</td>
<td><img src="image4.png" alt="Image" /></td>
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<tr>
<td>314.431</td>
<td>1.5 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, mini quick coupling, for resorbable screws</td>
<td><img src="image5.png" alt="Image" /></td>
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<tr>
<td>314.432</td>
<td>1.5 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, long, for resorbable screws</td>
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<tr>
<td>314.686</td>
<td>2.0 mm Cruciform Screwdriver Blade, with spring holding sleeve, mini quick coupling, for resorbable screws</td>
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<tr>
<td>347.98</td>
<td>Plate Holding Forceps</td>
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<tr>
<td>391.964</td>
<td>Scissors for Resorbable Mesh Plates</td>
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### Compact Water Bath System

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### Water Bath System

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<td>530.512</td>
<td>Water Bath Tray</td>
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<tr>
<td>530.514</td>
<td>Water Bath Sterility Cover</td>
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</table>
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 Companies 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.

Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

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