RAPIDSORB RESORBABLE FIXATION SYSTEM

Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.
TABLE OF CONTENTS

INTRODUCTION

Product Features and Benefits  2
Indications and Contraindications  3
Warnings and Precautions  4
Material/Basic Science  6

SURGICAL TECHNIQUE

Compact Water Bath Instructions  8
Surgical Technique  14
Compact Water Bath Disassembly Instructions  21

BIBLIOGRAPHY  23

Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
**RapidSorb Resorbable Fixation System**
RapidSorb is a resorbable fixation system, which was developed for fracture stabilization and craniofacial reconstruction. By using a bioresorbable L-lactide-co-glycolide polymer, it presents an attractive alternative to permanent metal implants.

### RapidSorb Features
- Resorbable
- Radiolucent
- 2nd generation material

### RapidSorb Benefits
- No lifelong implants; No secondary surgery for implant removal; Eliminates potential growth restriction; No stress shielding
- No interference with radiographic imaging or therapeutic irradiation
- Proven safety

### Screw hole design
Improved screw plate contact offers optimal load transfer

### Cross slots
Improved bendability

### Straight edged design
Higher overall stability

### Top side indicator
Beveled outer edges reduce the palpability and facilitate the identification of the topside during implanting

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**Product portfolio**

- **Meshes/Foils**
- **Screws**
- **Plates**
INDICATIONS AND CONTRAINDICATIONS

Rapid Sorb Resorbable Fixation System

Indications
The Synthes resorbable plate, mesh, foil and screw system is used for bone fixation in the management of fractures or reconstructions of the craniofacial skeleton and as graft containment. The plates, meshes, foils and screws should only be used in locations subject to low biomechanical loading, i.e. non-load-bearing osteosynthesis exclusively.

Examples of appropriate indications include:
• Trauma repair and reconstructive procedures in the mid facial area, maxilla and cranium.
• Containment of bone grafts or bone graft substitutes in other parts of the body in non-load-bearing indications.

Contraindications
The Synthes Resorbable Fixation System should not be used in the following circumstances:
• Mandibular fractures subject to high biomechanical loading
• Resection of a mandibular tumor
• Any fracture outside the area of craniofacial surgery with load-bearing osteosynthesis situations
• Synthes Resorbable Fixation System is not indicated for use in loadbearing and unstable indications for graft containment, unless used in conjunction with appropriate osteosynthesis fixation systems
• Blood supply limitations or reduced blood circulation
• Insufficient quantity and quality of bone
• Active, acute, latent, potential or chronic infections
• Situations in which internal fixation is contra-indicated for other reasons, e.g. in patients with bone disorders or lack of willingness to cooperate (e.g. alcoholism)
• Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.

Compact Water Bath System
• The DePuy Synthes Compact Water Bath, used along with the sterile drape, is intended to provide a 149°F–167°F/65°C–75°C temperature controlled basin of sterile water or sterile saline for use in conjunction with DePuy Synthes implants intended for thermal contouring.
WARNINGS AND PRECAUTIONS

RAPIDSORB RESORBABLE FIXATION SYSTEM

Warnings
- Do not attempt to re-sterilize the unused contents of an opened pack, but dispose of such remnants: this applies to both the inner primary and the outer secondary packaging. Re-sterilization of RapidSorb Implants can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.
- Do not use Synthes Resorbable Implants after the expiry date printed on the packaging.
- Improper selection, placement, positioning and fixation of the implant can cause a subsequent undesirable result.
- These resorbable devices provide fixation and are not intended to replace normal healthy bone or withstand stress of full load bearing.
- These devices are resorbable and do not provide permanent fixation. Do not use in procedures where a permanent implant is needed.
- The plates and meshes should be heated using the corresponding Synthes water bath unit before contouring them. In case that an alternative Operating Room (O.R.) appropriate sterile water bath will be used please make sure that the water temperature stays between 65°C–75°C. Only sterile water or sterile saline must be used. Screws are not to be heated or reshaped by any means.

Precautions
The use of Synthes Resorbable Fixation System has a more restricted indication in:
- Poor bone quality.
- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization or infection can cause loosening, bending cracking or fracture of the device.
COMPACT WATER BATH SYSTEM

Warnings
- To avoid loss of sterility of the implant, do not use without the Sterile Drape or with sterile drapes not approved by DePuy Synthes.
- Do not operate without sterile water or sterile saline.
- Do not use sharp instruments to retrieve implants.
- Do not sterilize the CWB. Sterilization can damage internal components and lead to equipment malfunction and electric shock.
- Do not use with liquid media other than sterile water or sterile saline.
- The stainless steel basin is hot during operation and contains hot liquid (149°F–167°F/65°C–75°C).

Precautions
- To avoid burns and rupture of the drape, use a blunt instrument to insert and retrieve an implant from the heated liquid.
- Only use with DePuy Synthes implants which are intended for thermal contouring (please refer to product labeling of implant).
- To avoid equipment malfunction, do not use with preheated sterile water or sterile saline >158°F/70°C.
- Do not use with medicinal, therapeutic or other additives.
- To avoid risk of electric shock, do not open the device.
- To prevent risk of fire, do not operate the device in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
- The CWB is intended to be used in an O.R. environment. It cannot be used or stored outdoors. Failure to comply may result in equipment malfunction, electric shock or fire.
- To avoid the potential of electric shock, the operator should not touch the CWB and the patient simultaneously.
- For proper operation, the CWB should be monitored during use to ensure the liquid level remains between the MIN FILL LINE and MAX FILL LINE.
- The CWB is not intended for continuous operation longer than 24 hours.
- Medical Electrical Equipment needs special precautions regarding EMC (electro-magnetic compatibility) and needs to be installed and put into service according to the EMC information provided in these Instructions for Use.
- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.
- The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- The equipment or system should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
The implants of the RapidSorb Resorbable Fixation 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 craniofacial fracture stabilization¹ and reconstruction² (Figure 1).

85:15 poly (L-lactide-co-glycolide) is a linear, substantially amorphous, random copolymer. RapidSorb implants made of it retain at least 60% and approximately 85% of its initial bending strength after 8 weeks; e.g. in a four point bending test on 8-hole plates (Figure 2)*. Thus it ensures proper stability during the critical bone healing phase before the implants are completely resorbed after approximately 12 months.

* Mechanical test data on file at DePuy Synthes. Mechanical test data are not necessarily indicative of clinical performance.

1. C.A. Landes et al., 2005; C.A. Landes et al., 2006
2. R. Guzman et al., 2011

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**Figure 1**

L-Lactide (85%) L-lactide polymers are semicrystalline, characterized by high strength and a long degradation time.

Glycolide (15%) Glycolide polymers are amorphous, characterized by lower strength and more rapid degradation.

**Figure 2**

<table>
<thead>
<tr>
<th>Degradation Time</th>
<th>Strength Retention (%)</th>
<th>Molecular Weight (%)</th>
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</thead>
<tbody>
<tr>
<td>0h</td>
<td>110%</td>
<td>110%</td>
</tr>
<tr>
<td>1h in vitro</td>
<td>110%</td>
<td>110%</td>
</tr>
<tr>
<td>2w in vitro</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>4w in vitro</td>
<td>90%</td>
<td>80%</td>
</tr>
<tr>
<td>8w in vitro</td>
<td>80%</td>
<td>70%</td>
</tr>
</tbody>
</table>

**Figure 2:** Degradation behavior of adaption plates 8 holes (851.008.015) showing Strength Retention and Molecular Weight.
The main degradation mechanism of poly(lactides) and poly(glycolides), and their co-polymers is random hydrolytic chain scission.\(^3\) There is some evidence for enzymatic degradation of the polymers and acceleration of the breakdown by free radicals released from activated phagocytic cells (macrophages and neutrophils).\(^4\) No matter which form of degradation occurs, the intermediate products of poly(lactides), poly(glycolides) and their co-polymers are \(\text{L-lactic acid and glycolic acid.} \) They are present in the human body and are actively metabolized by cells surrounding the implant, by means of the citrate cycle, to water and carbon dioxide, which is finally eliminated by respiration.\(^5\)

\(^1\) J. M. Schakenraad et al., 1990  
\(^2\) S. A. Ali et al., 1993; D. F. Williams and E. Mort, 1977  
\(^3\) M. Vert et al., 1992
PREPARATION

In preparation for contouring plates and meshes, set up the Compact Water Bath system in advance.

Compact Water Bath System

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.725.010</td>
<td>Compact Water Bath</td>
</tr>
<tr>
<td>08-CC184</td>
<td>Sterile Drape</td>
</tr>
</tbody>
</table>

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 surface. Ensure the power switch is in the OFF position. Confirm that the power cord is firmly inserted into the Compact Water Bath.

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

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

Heat Water

Plug in the power cord to 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 65–75°C and is ready for use.

The Compact Water Bath will maintain 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.

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

Select and prepare plates

If desired, use the bending templates to determine the optimal plate shape and size, especially where direct access is limited.

Templates may be cut to size.

If necessary cut the selected plate to the desired length or shape using the Cutter or Scissors for Resorbable Plates (391.980 and 391.964 respectively).

When cutting a resorbable mesh plate, heat it in 65–75°C sterile water or sterile saline. Open the Scissors for Resorbable Plates (391.964) wide and place the mesh plate at the very back of the scissor blades. This provides the most leverage and control for a clean cut.
2 Heating and contouring of plates/meshes

The resorbable plates/meshes should be heated (approximately 15 seconds) before contouring. By using the Compact Water Bath System only sterile water or sterile saline must be used. The heated plate/mesh can be removed with the Holding Forceps for Plates (347.981).

Contouring is possible by either laying the plate directly onto the bone or by using the contoured bending template.

Be sure that the hole taper is facing the proper direction before contouring the plate.

Depending upon operating room temperature, the heated plate will have approximately 10 seconds of working time before becoming rigid. Reduced finger contact with the plate will extend working time.

The implants must never be bent, notched or scratched in their cold, rigid state, as this may result in surface damage or internal load concentrations, providing possible starting points for product failure.

• Plates may be heated and contoured up to three times.
• Bending must not be repeated more than three times.
• Do not store the implant(s) in the hot water bath.
3
Select tap

Self drilling taps for 1.5 System (color coded in red)

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
<th>Length</th>
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<tr>
<td>311.033</td>
<td>1.5 mm</td>
<td>3 mm</td>
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<td>311.031</td>
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<td>1.5 mm</td>
<td>6 mm</td>
</tr>
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<td>311.037</td>
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Self drilling taps for 2.0 System (color coded in blue)

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
<th>Length</th>
</tr>
</thead>
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<tr>
<td>311.034</td>
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<td>4 mm</td>
</tr>
<tr>
<td>311.036</td>
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<td>6 mm</td>
</tr>
<tr>
<td>311.038</td>
<td>2.0 mm</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

Select the appropriate self-drilling tap dependant on the selected implant (1.5/2.0).
4

Tap holes for resorbable screws

Drill the holes at a 90° angle to the plate surface if possible until the stop of the drill bit/tap rests against the plate surface.

**Important:** If the tap selected is too short, it will not be possible to countersink the screw completely in the plate hole and further screwing in will inevitably lead to breakage of the screw. This can also occur if tapping is terminated before the tap shoulder has reached the plate surface.

Clean tap threads and flutes of debris prior to tapping the next hole.

When preparing screw holes in the cranium, it is advisable to place a suitable instrument between the inner cortical surface and the dura to protect the dura against possible injury.

In case of dense, solid cortical bone or in areas of extreme comminution, predrill the hole before tapping.
5

Select screws

RapidSorb Cortex Screw Ø 1.5 mm

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Length</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>805.603.02S</td>
<td>3 mm</td>
<td>2 units</td>
</tr>
<tr>
<td>805.603.04S</td>
<td>3 mm</td>
<td>4 units</td>
</tr>
<tr>
<td>805.604.02S</td>
<td>4 mm</td>
<td>2 units</td>
</tr>
<tr>
<td>805.604.04S</td>
<td>4 mm</td>
<td>4 units</td>
</tr>
<tr>
<td>805.604.10S</td>
<td>4 mm</td>
<td>10 units</td>
</tr>
<tr>
<td>805.605.02S</td>
<td>5 mm</td>
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</tr>
<tr>
<td>805.605.04S</td>
<td>5 mm</td>
<td>4 units</td>
</tr>
<tr>
<td>805.606.02S</td>
<td>6 mm</td>
<td>2 units</td>
</tr>
<tr>
<td>805.606.04S</td>
<td>6 mm</td>
<td>4 units</td>
</tr>
<tr>
<td>805.606.10S</td>
<td>6 mm</td>
<td>10 units</td>
</tr>
<tr>
<td>805.608.02S</td>
<td>8 mm</td>
<td>2 units</td>
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<tr>
<td>805.608.04S</td>
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<td>4 units</td>
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RapidSorb Cortex Screw Ø 2.0 mm

<table>
<thead>
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<th>Product Code</th>
<th>Length</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>806.004.02S</td>
<td>4 mm</td>
<td>2 units</td>
</tr>
<tr>
<td>806.004.04S</td>
<td>4 mm</td>
<td>4 units</td>
</tr>
<tr>
<td>806.004.10S</td>
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<td>806.006.02S</td>
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<td>806.006.04S</td>
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<td>806.006.10S</td>
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<tr>
<td>806.008.02S</td>
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<td>2 units</td>
</tr>
<tr>
<td>806.008.04S</td>
<td>8 mm</td>
<td>4 units</td>
</tr>
</tbody>
</table>

Choose the appropriate screw length and diameter.

Attach the appropriate Ø 1.5 or 2.0 mm cruciform screwdriver shaft with holding sleeve to the handle. Align the screwdriver shaft 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 oblique angle.

If too much force is used to insert the screwdriver shaft into the screw head, the cruciform slot could be damaged, resulting in poor screw pick-up and insertion.

Slide the screwdriver holding sleeve completely down over the screw head to securely grasp the screw.
6

Insert screws

Screw driver shaft for 1.5 system (color coded in red)

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Cortex Screws</th>
<th>Ø mm</th>
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<tbody>
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<td>66</td>
</tr>
<tr>
<td>314.432</td>
<td></td>
<td>92</td>
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</table>

Screw driver shaft for 2.0 system (color coded in blue)

<table>
<thead>
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<th>Product Code</th>
<th>Cortex Screws</th>
<th>Ø mm</th>
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<td>314.687</td>
<td></td>
<td>92</td>
</tr>
</tbody>
</table>

Carefully insert the selected screw, using the appropriate screwdriver, until the screw is countersunk in the plate. Use a light, two-finger approach (thumb and index finger) to insert the screw. To prevent breakage, do not overtighten the screws. Stop immediately when the screw has made full contact with the plate.

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

If screw insertion proves difficult, this is most probably due to an insufficiently tapped hole. In such cases, carefully withdraw the screw and re-tap the hole, ensuring that the tap is fully inserted and sufficiently sharp.

Replace the screw if the screw or screw head is damaged. If the screw head breaks or the bone strips out during screw insertion, an emergency screw must be inserted.

Insert the remaining screws in the same way until accurate reduction and stable fixation of the fracture is achieved. It is recommended to insert at least two screws on either side of the fracture or osteotomy line.
Emergency screw placement

Self drilling emergency taps for 1.5 System (color coded in red)

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
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<tr>
<td>311.056</td>
<td>2.0 mm</td>
<td>6 mm</td>
</tr>
<tr>
<td>311.058</td>
<td>2.0 mm</td>
<td>8 mm</td>
</tr>
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</table>

Self drilling taps for 2.0 System (color coded in blue)

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
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<td>311.046</td>
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</tr>
<tr>
<td>311.048</td>
<td>2.5 mm</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

If the bone strips out or the screw breaks during screw insertion, an emergency screw must be inserted. Remove the screw to be replaced and tap the hole for the emergency screw. If the screw to be replaced cannot be removed, tap through the screw with the next-larger diameter tap and insert the corresponding emergency screw. For example, if the bone strips out with a 1.5 × 4 mm screw, use a 2.0 × 4 mm self-drilling tap and then a 2.0 × 4 mm screw.
Compact Water Bath System Disassembly

05.725.010  Compact Water Bath
08-CC184  Sterile Drape

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.

Sterile Drape: CE0050
Manufactured by: AdvanceTM Medical Designs Inc., 1241 Atlanta Industrial Drive, Marietta, GA 30066
EU Representative: MDS5 GmbH, Schiffgraben 11, 30175 Hanover, Germany
Distributed by: Synthes GmbH, Eimattstrasse 3, 4436 Oberdorf, Switzerland
3

Wipe down

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.
- 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.
- Solvents and aggressive chemicals should not be used to wipe down the unit.


