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RAPIDSORB RAPID RESORBABLE FIXATION SYSTEM

Reshapes—Restores—Resorbs.
RAPIDSORB is a resorbable fixation system which was developed for fracture stabilization and craniofacial reconstruction. The implants provide appropriate fixation for bone healing and are gradually resorbed by the body. RapidSorb presents an attractive alternative to metal implants.

Advantages of RapidSorb implants:
• Adapts easily to complex anatomy
• Maintains appropriate fixation for bone healing for approximately 8 weeks postoperatively
• Resorbs in approximately 12 months
• Degrades without late inflammatory complications and foreign-body responses that have been observed with semicrystalline structures such as poly (L-lactide)\(^1\),\(^2\)
• Eliminates concern for potential migration and translocation associated with metallic implants\(^3\),\(^4\)
• Eliminates secondary surgeries for implant removal
• Proven biocompatible material\(^5\)
• Radiolucent polymer does not interfere with intraoperative or postoperative radiographs\(^6\),\(^7\)
• Polymer strength is not affected by radiation therapy\(^8\),\(^9\)

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

The implants of the RAPIDSORB Rapid 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 reconstruction (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.10

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**Indications**
The DePuy Synthes Rapid Resorbable Fixation System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations.

In addition, resorbable meshes, sheets, screws, and tacks may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

**Contraindications**
These devices are not intended for use in load-bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. The DePuy Synthes Rapid Resorbable System is not intended for areas with active or latent infection, or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

11 Please see Directions for Use for complete contraindications, warnings and precautions.

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Intraoperative photos of metopic synostosis reconstruction using Rapid Resorbable Fixation System

AP view—Frontal bar advanced and fixated with two 2 x 18 hole strut plates (circled)

Lateral view—Frontal bone fragments reconstructed using contourable mesh (circled)
FEATURES AND BENEFITS

RAPIDSORB PLATES

The wide assortment of implants in the DePuy Synthes RAPIDSORB Rapid Resorbable Fixation System incorporates a plate design with many features and benefits:

- Beveled edge for reduced palpability
- Optimized screw recess for low profile
- Straight-edged design for greater strength
- Groove identifies top surface
- Cross-slots between holes facilitate bending

**Specialized Plating Platforms**

Preshaped orbital floor plate can be quickly and easily contoured (Figure 1).

Contourable mesh permits optimal anatomic conformity without cutting or kinking (Figure 2).

The solid sheet allows customization of hole size and location (Figure 3).

Straight row mesh can be cut into desired plate geometries (Figure 4).
**Features and Benefits**

**Screws**
- Available in 1.5 mm, 2.0 mm, and 2.5 mm diameters
- Cruciform recess allows easy pickup, insertion, and removal
- Emergency screws can be placed easily by tapping through the original screw
- 2.0 mm screws can be used with 1.5 mm plates as primary or emergency screws

**Plate/screw profiles**

**1.5 mm Plates**
- 0.25 mm thick plate with 1.5 mm screw
- 0.5 mm thick plate with 1.5 mm screw
- 0.8 mm thick plate with 1.5 mm screw

**2.0 mm Plate**
- 1.2 mm thick plate with 2.0 mm or 2.5 mm screw
RAPIDSORB RAPID RESORBABLE FIXATION INSTRUMENTS

A full line of instrumentation and trays meets the needs of both surgeons and operating room personnel.

Customizable instrument trays
- Two customizable resorbable fixation instrument trays allow storage of preferred instrument combinations
- Translucent lid for visualization of contents
- Optional bending template module snaps onto either lid for storage

Taps
- Available with self-drilling tips
- Choice of hex or mini quick coupling
- Available in adjustable or fixed stop lengths

Self-drilling tap
Hex coupling
Mini quick coupling
Adjustable stop length, self-drilling tap
Fixed stop length, self-drilling tap
In preparation for contouring plates and mesh, set up water bath heater in advance.

**Water Bath System (530.509)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>

**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**

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

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 that the water has reached the recommended 70° C and the unit is ready for use. The approximate temperature will be displayed.
1
Select and prepare plates

Instrument

| 391.964 | Scissors |

If desired, use the bending templates to determine the optimal plate shape and size. Templates may be cut to size.

If necessary, cut the selected plate to the desired length or shape using the scissors.

Before cutting a mesh plate, heat it in 70°C sterile water. Open the scissors wide and place the mesh at the very back of the scissor blades. This provides the most leverage and control for a clean cut.
2

Heat and contour

Place the resorbable plate or mesh in the water bath system until the implant becomes malleable, approximately 15 seconds.

Using forceps, remove the plate from the water bath.

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

Contour by laying the plate onto the bone (Figure 1) or using a precontoured bending template as a guide (Figure 2).

Depending upon operating room temperature, the heated plate will have approximately 7 seconds of working time before becoming rigid. Reduced finger contact with the plate will extend working time.

**Note:** Plates may be heated and contoured up to ten times.
Tap hole for resorbable screw

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

Insert the tap into the preferred handle.

Technique tips

- When using a non-self-drilling tap, or in areas of dense cortical bone, or in cases of extreme comminution, predrill the hole with the appropriate length and diameter drill bit with stop.
- In extremely thin (less than 3 mm) or soft bone, such as in pediatric patients 4–6 months old, it may be possible to drill and not tap; use the 1.1 mm drill bit for 1.5 mm screws, 1.5 mm drill bit for 2.0 mm screws.
- When in the cranium, place a narrow brain ribbon retractor between the inner cortical surface and the dura to prevent potential contact between the tap and the dura.

While maintaining the tap perpendicular to the plate surface, tap through the plate hole into the bone, until the tap shoulder contacts the plate surface. The tap MUST be fully inserted to the stop for proper screw insertion.

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

### Tap hole for resorbable screw

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

Insert the tap into the preferred handle.

**Technique tips**

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While maintaining the tap perpendicular to the plate surface, tap through the plate hole into the bone, until the tap shoulder contacts the plate surface. The tap MUST be fully inserted to the stop for proper screw insertion.

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

**Self-drilling taps (sterile)**

<table>
<thead>
<tr>
<th>Screw diameter/ Color code</th>
<th>Tap depth below plate</th>
<th>Screw depth below plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 mm</td>
<td>0.5 mm</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>1.1 mm</td>
<td>1.2 mm</td>
<td>1.2 mm</td>
</tr>
<tr>
<td>2.0 mm</td>
<td>1.5 mm</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>2.5 mm (Emergency)</td>
<td>1.8 mm</td>
<td>1.8 mm</td>
</tr>
</tbody>
</table>

While maintaining the tap perpendicular to the plate surface, tap through the plate hole into the bone, until the tap shoulder contacts the plate surface. The tap MUST be fully inserted to the stop for proper screw insertion.

Clean tap threads and flutes of debris before tapping the next hole.
4

**Insert screw**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.006</td>
<td>Screwdriver Handle, with hex coupling, medium</td>
</tr>
<tr>
<td>314.436</td>
<td>1.5 mm Cruciform Screwdriver Blade, with Self-retaining Center Pin, hex coupling</td>
</tr>
<tr>
<td>314.696</td>
<td>2.0 mm Cruciform Screwdriver Blade, with Self-retaining Center Pin, hex coupling</td>
</tr>
</tbody>
</table>

Choose the appropriate length and diameter screw. Place the screw holder on a stable surface.

Attach the appropriate self-retaining 1.5 mm or 2.0 mm cruciform screwdriver blade to the handle. 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. Do not insert at an angle.

**Technique Tips**

- For screwdriver blades with retaining sleeves, fully retract the holding sleeve to spread the prongs before inserting the blade into the screw head. Once the blade is seated, slide the holding sleeve down completely over the screw head to securely grasp the screw.
- Self-retaining blades use a friction fit. To ensure that the blade is seated properly, spin the screw with the blade before removing the screw from the screw holder.

Insert the screw into the plate hole. Use a light, two-finger approach (thumb and index finger) to insert the screw. Do not over-tighten. Be sure to retract the holding sleeve before fully seating the screw. Stop immediately when the screw has made full contact with the plate.

Insert additional screws until accurate reduction and stable fixation are achieved. It is recommended to insert at least two screws on each side of the defect or fracture.
Emergency screw placement
If the bone strips out or the screw breaks during screw insertion, either remove the screw or tap through the screw with the next-larger-diameter tap. For example, if the bone strips out with a 1.5 mm x 4 mm screw, use a 2.0 mm x 4 mm self-drilling tap and then a 2.0 mm x 4 mm screw.

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.

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

Technique Tips
• If screw insertion is difficult, it is most likely due to an insufficiently tapped hole. Back out the screw 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 prior to seating the screw, the most likely cause is the tap not being fully inserted. Proceed with emergency screw placement.
Water Bath System Disassembly

<table>
<thead>
<tr>
<th>Code</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<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>

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.

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*Note: For additional information, please refer to package insert.*
Instructions for adjustable stop length taps

To adjust a tap to the desired screw length, hold the black stop collar in place and turn the clear locking collar to loosen (Figure 1).

Slide the black stop collar along the tap shaft until the length indicator aligns with the desired screw length setting on the tap body. The collar features a ratcheting mechanism that provides tactile and audible feedback that the collar has clicked into the proper location (Figure 2).

**Note:** The length indicator of the black stop collar should align with the etched marks on either side of the desired length setting. Even and odd lengths are on opposite sides of the tap (Figure 3).

Once the black stop collar has been adjusted to the desired screw length, hold it firmly in place and turn the clear locking collar until it is securely seated against the black stop collar (Figure 4).

Insert the tap into the appropriate handle (hex or mini quick coupling).
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.01.98</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>311.005</td>
<td>Screwdriver Handle with hex coupling, small</td>
</tr>
<tr>
<td>311.006</td>
<td>Screwdriver Handle with hex coupling, medium</td>
</tr>
<tr>
<td>311.007</td>
<td>Screwdriver Handle with hex coupling, large</td>
</tr>
</tbody>
</table>
### Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
</table>
| 311.031.01S–311.058.01S | Self-Drilling Taps, sterile  
(see chart on page.5)  
Mini quick coupling |
| 311.060.01S–311.073.01S | Hex coupling |
| 311.100.01S–311.102.01S | Self-Drilling Taps, adjustable stop length, sterile  
Mini quick coupling |
| 311.110.01S–311.112.01S | Hex coupling |
| 314.412 | 1.5 mm Cruciform Screwdriver Blades  
with Holding Sleeve, mini quick coupling |
| 314.425 | with Spring Holding Sleeve, hex coupling |
| 314.431 | with Spring Holding Sleeve, mini quick coupling |
| 314.432 | with Spring Holding Sleeve, mini quick coupling, long |
| 314.433 | Self-retaining, hex coupling |
| 314.434 | Self-retaining, mini quick coupling |
| 314.436 | 1.5 mm with Self-retaining center pin, hex coupling |
| 314.671 | 2.0 mm Cruciform Screwdriver Blades  
with Holding Sleeve, mini quick coupling |
| 314.677 | with Spring Holding Sleeve, hex coupling |
| 314.686 | with Spring Holding Sleeve, mini quick coupling |
| 314.687 | with Spring Holding Sleeve, mini quick coupling, long |
| 314.693 | Self-retaining, hex coupling |
| 314.694 | Self-retaining, mini quick coupling |
| 314.696 | 2.0 mm with Self-retaining center pin, hex coupling |
| 317.14 | Drill Bits, Stryker J-latch coupling, 44.5 mm  
1.1 mm dia., 4 mm stop |
| 317.16 | 1.1 mm dia., 6 mm stop |
| 317.64 | 1.5 mm dia., 4 mm stop |
| 317.66 | 1.5 mm dia., 6 mm stop |
| 317.68 | 1.5 mm dia., 8 mm stop |
Bending Templates for 1.5 mm
Resorbable Plates

329.408 For Adaption Plate, 8 holes
329.411 For Orbital Rim Plate
329.412 For Adaption Plate, 20 holes
329.421 For Strut Plate, 2 x 10 holes
329.422 For Strut Plate, 2 x 18 holes
329.433 For Oblique L-Plate
329.443 For Y-Plate
329.444 For Double Y-Plate
329.632 For Orbital Floor Plate, 24 mm
329.633 For Orbital Floor Plate, 30 mm
329.634 For Orbital Floor Plate, 35 mm
329.650 For Strut Plate, 2 x 36 holes
329.651 For T-Plate
329.652 For Box Plate
329.659 For X-Plate

Bending Templates for 2.0 mm
Resorbable Plates

329.458 For Adaption Plate, 8 holes
329.459 For Adaption Plate, 20 holes
329.461 For Orbital Rim Plate
329.471 For Strut Plate, 2 x 10 holes
329.483 For Oblique L-Plate
329.493 For Y-Plate

Bending Templates for 1.5 mm/2.0 mm
Resorbable Mesh Plates and Sheets

329.481 50 mm x 50 mm
329.654 75 mm x 75 mm
329.655 100 mm x 100 mm
329.656 150 mm x 150 mm
329.657 50 mm diameter
329.658 100 mm diameter
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>347.98</td>
<td>Plate Holding Forceps for 1.5 mm, 2.0 mm, and 2.4 mm plates</td>
<td><img src="image1.png" alt="Plate Holding Forceps" /></td>
</tr>
<tr>
<td>391.964</td>
<td>Scissors for Resorbable Mesh Plates</td>
<td><img src="image2.png" alt="Scissors" /></td>
</tr>
<tr>
<td>391.98</td>
<td>Plate Cutter for 1.0 mm, 1.3 mm, 1.5 mm, and 2.0 mm plates</td>
<td><img src="image3.png" alt="Plate Cutter" /></td>
</tr>
</tbody>
</table>
PLATE CONTOURING SYSTEMS

Water Bath System

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

* Available while supplies last.
RESORBABLE FIXATION INSTRUMENT CASES AND TRAYS

Customizable Instrument Trays
Select either a small or large tray, lid, and basic instrument insert.

305.806 Small Instrument Tray Lid, for Resorbable Fixation System
305.807 Small Instrument Tray Base, for Resorbable Fixation System
305.809 Large Instrument Tray Lid, for Resorbable Fixation System
305.810 Large Instrument Tray Base, for Resorbable Fixation System
305.811 Instrument Insert, for Resorbable Instrument Trays (includes label sheets 305.816 and 305.817)

Note: For additional information, please refer to package insert.
**Instrument Tray Options**

305.814  Finger Mat Insert for Resorbable Instrument Trays

305.815  Bending Template Module for Resorbable Fixation System (compatible with 305.807 and 305.806 or 305.810 and 305.809)

305.816  Label Sheet for Resorbable Instrument Trays

305.817  Drill Bit Label Sheet for Resorbable Instrument Trays
Limited Warranty and Disclaimer: DePuy Synthes CMF 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.