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Synthes
Synthes is a global medical device company and a market leader in craniofacial bone fixation.

Features
The RapidSorb Rapid Resorbable Fixation System can be used for bone graft containment in the anterior maxilla or mandible and can be cut and contoured in a hot water bath to fit the bony anatomy. Rigid meshes are a natural choice for ridge augmentation due to their space-maintaining properties.

Rapid resorbable implants maintain appropriate fixation for bone healing for approximately eight (8) weeks postoperatively.
- Resorbs in 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 secondary surgeries for implant removal
- Proven biocompatible material3
- Radiolucent polymer does not interfere with intra- or postoperative radiographs4,5
- Polymer strength is not affected by radiation therapy6,7

3. Based on biocompatibility testing per ISO10993-1:1997(E) conducted by Synthes (USA).
Case Study
Intraoperative photo of horizontal and vertical augmentation of mandibular central incisors, using RapidSorb mesh and screws. 1.5 mm RapidSorb contourable mesh, 0.5 mm thick is fixated with two resorbable screws apical to teeth #23 and #26.

Results from case studies are not predictive of results in other case studies. Results in other case studies may vary.

RapidSorb Implants

Screws
- Available in 1.5 mm and 2.0 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

Contourable Meshes
- Permit optimal anatomic conformity without cutting or kinking
- Reduce the time required to shape the mesh
- Maintain their integrity after contouring
- Are available in a variety of configurations to accommodate various dentoalveolar defect sites
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.⁸

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Indications and Contraindications

**Indications**
The 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**
Rapid resorbable devices are not intended for use in full load-bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. These devices are not intended for areas with active or latent infection, or for limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

**Note:** Please see Directions for Use for complete contraindications, warnings and precautions.
Preoperative Considerations

- Use appropriate diagnostic radiographs to determine the locations of the apices of adjacent teeth, concavities, site anatomy, and anatomic areas of concern such as the mental foramen. The minimum radiographs should include a pan and periapical. CT is recommended on an as-needed basis.
- Assess surgical access and visibility prior to treatment (beware of patient with limited opening).
- Assess medical status of the patient. Is patient medically fit to have surgery? (Poorly controlled diabetes, anti-coagulants, infection, patients considered ineligible for oral surgery).
- Avoid temporary dentures or other devices that may apply pressure to the site postoperatively.
- Anticipate tension-free primary closure.

Postoperative Considerations

Patients should receive appropriate postoperative instructions from their doctor regarding medications and antibiotics, oral hygiene regimen (including rinsing), diet (soft foods for an appropriate period of time), treatment of swelling and bleeding.
**Water bath system preparation**
The water bath tray and sterility cover must be sterilized prior to beginning the procedure. The water bath system must be set up and turned on at least 20 minutes prior to anticipated use.

Refer to water bath system section for more information.

1

**Expose defect**
Create a full thickness mucoperiosteal flap to expose the dentoalveolar defect.

**Note:** Periosteal releasing incisions may be required to obtain tension-free primary closure.
Select the appropriate size mesh to fit the defect

Meshes are available in two thicknesses, 0.25 mm and 0.5 mm. Both thicknesses are easily contourable in 70°C sterile water.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>851.611.01s</td>
<td>RapidSorb contourable mesh, 50 mm x 50 mm x 0.25 mm thick</td>
</tr>
<tr>
<td>851.634.01s</td>
<td>RapidSorb contourable mesh, 30 mm x 40 mm x 0.25 mm thick</td>
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<tr>
<td>851.635.01s</td>
<td>RapidSorb contourable mesh, 20 mm x 30 mm x 0.25 mm thick</td>
</tr>
<tr>
<td>851.636.01s</td>
<td>RapidSorb contourable mesh, 15 mm x 25 mm x 0.25 mm thick</td>
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<tr>
<td>851.621.01s</td>
<td>RapidSorb contourable mesh, 50 mm x 50 mm x 0.5 mm thick</td>
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<tr>
<td>851.637.01s</td>
<td>RapidSorb contourable mesh, 30 mm x 40 mm x 0.5 mm thick</td>
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</tr>
<tr>
<td>851.639.01s</td>
<td>RapidSorb contourable mesh, 15 mm x 25 mm x 0.5 mm thick</td>
</tr>
</tbody>
</table>
3
Shape and contour bending template

Instrument

| 329.654 | Bending Template for 1.5 mm/2.0 mm Resorbable Mesh Plates 75 x 75 |

Trim the bending template to the optimal size and shape to fit the defect.

Contour the bending template directly on the bone until it conforms to the bony anatomy.
4. **Cut mesh**

**Instrument**

| 391.964 | Scissors for Resorbable Mesh Plates |

**Note:** Before cutting a mesh plate, preheat it in 70°C sterile water for approximately 15 seconds. 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.

Cut the selected mesh to the shape of the defect using scissors and the previously shaped bending template as a guide.

**Note:** Cutting the mesh along the long slots gives the user a smooth edge with which to work (recommended minimum plate size after cutting is 2 round holes x 3 round holes).

5. **Contour mesh**

**Instrument**

| 530.510 | Water Bath Heater |

Using forceps, place the mesh into 70°C sterile water until mesh is malleable, for approximately 15 seconds. Refer to water bath system section for setup and operation.

Remove the mesh from the 70°C water and immediately contour by laying mesh on the contoured bending template as a guide. Allow mesh to become rigid as it cools.

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9. RapidSorb mesh may be reheated and contoured up to ten times.
10. Depending upon room temperature, the heated mesh will have approximately 7 seconds of working time before becoming rigid. Reduced finger contact with the mesh will extend working time.
Alternative technique tip: The mesh and contoured bending template can be held together using forceps and placed into 70°C sterile water until mesh contours to the bending template, approximately 15 seconds. While still holding the mesh and bending template together, remove them from the water bath. Allow mesh to become rigid as it cools.

Caution: Do not attempt to bend mesh without first heating it in 70°C sterile water for approximately 15 seconds, as mesh will break.

6 Prepare bone graft material and fill defect
Prepare the bone graft material as directed by the manufacturer's labeling. If bleeding bone is not observed, perforate the native cortical bone, to promote bleeding and vascularity to the bone graft site. Pack bone graft material into the defect.
Secure mesh using RapidSorb cortex screws

Instruments

<table>
<thead>
<tr>
<th>Instrument Code</th>
<th>Screwdriver Handle, with mini-quick coupling, small</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.03</td>
<td>Screwdriver Handle, with mini-quick coupling, small</td>
</tr>
</tbody>
</table>

Select the appropriate self-drilling tap from the chart below. Retract handle collar and insert tap shaft into the handle.

**Note:** Align flat on tap shaft with arrow on collar.

Release collar and pull on tap shaft to ensure tap is locked into place.

Self-Drilling Taps with Mini Quick Coupling (sterile)

<table>
<thead>
<tr>
<th>Screw diameter</th>
<th>Length (mm)</th>
</tr>
</thead>
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<tr>
<td>311.033.01S</td>
<td>1.5 mm 3</td>
</tr>
<tr>
<td>311.031.01S</td>
<td>1.5 mm 4</td>
</tr>
<tr>
<td>311.035.01S</td>
<td>1.5 mm 5</td>
</tr>
<tr>
<td>311.032.01S</td>
<td>1.5 mm 6</td>
</tr>
<tr>
<td>311.037.01S</td>
<td>1.5 mm 8</td>
</tr>
<tr>
<td>311.054.01S</td>
<td>2.0 mm 4</td>
</tr>
<tr>
<td>311.056.01S</td>
<td>2.0 mm 6</td>
</tr>
<tr>
<td>311.058.01S</td>
<td>2.0 mm 8</td>
</tr>
</tbody>
</table>

**Note:** Taps are intended for single-procedure use only.

Position the formed mesh over the defect.
Align tap with a mesh screw hole that is 3 mm–5 mm apical to the tooth roots referring to all appropriate radiographs.

Stay at least 1 mm–2 mm away from the defect walls when tapping the hole to avoid breaking through the wall.

While maintaining the tap perpendicular to the mesh surface and bone, apply firm pressure and turn tap clockwise into the bone until the tap stop contacts the plate surface. The tap MUST be fully inserted to the stop for proper screw insertion. Care must be taken NOT to over tighten the tap past the point where the stop seats onto the mesh surface.

Reverse tap by gently turning tap counterclockwise until it is fully disengaged from the bone.

**Caution:** Take care to keep the tap stable during insertion and removal. Failure to do so will damage the threads in the bone.

Clean tap threads and flutes of debris before tapping the next hole.
**Graft Containment with RapidSorb Mesh**

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**Alternative instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>317.24</td>
<td>1.1 mm Drill Bit, with 4 mm Stop, mini quick coupling</td>
</tr>
<tr>
<td>317.26</td>
<td>1.1 mm Drill Bit, with 6 mm Stop, mini quick coupling</td>
</tr>
<tr>
<td>317.28</td>
<td>1.1 mm Drill Bit, with 8 mm Stop, mini quick coupling</td>
</tr>
</tbody>
</table>

**Technique tip — method for denser D1 or D2 bone**

In the case of extremely hard or dense cortical bone, pre-drilling the hole with the appropriate length 1.1 mm diameter drill bit with stop before tapping may be required.

Align drill with a mesh screw hole that is 3 mm–5 mm apical to the tooth roots referring to all appropriate radiographs.

While maintaining the drill perpendicular to the mesh surface, insert drill until the stop contacts the mesh surface.

Tap as previously described using the 1.1 mm diameter hole as a guide.
Insert screw

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.03</td>
<td>Screwdriver Handle, with mini quick coupling, small</td>
</tr>
<tr>
<td>314.431</td>
<td>1.5 mm Cruciform Screwdriver Blade, with Spring Holding Sleeve, mini quick coupling</td>
</tr>
</tbody>
</table>

Attach the 1.5 mm cruciform screwdriver blade to the handle. Retract handle collar and insert screwdriver blade into the handle.

**Note:** Align flat on screwdriver blade shaft with arrow on collar.

Release collar and pull on screwdriver blade to ensure blade is locked in place.

Fully retract the holding sleeve to spread the holding prongs before inserting the blade into the screw head.

Choose the appropriate length screw. Place the screw holder on stable surface. Rotate lid to expose a screw in the hole in the lid.

Orient the blade directly above the screw head so that screw and screwdriver interaction is clearly visible. Maintain the blade at a 90° angle to the screw head. Insert the screwdriver tip into the cruciform drive of the screw head.

**Note:** Rotate the blade until it aligns with the cruciform drive of the screw head. Be careful not to apply too much force while inserting the blade into the screw head, as the cruciform slots could be damaged.
After the blade is seated in the cruciform, slide the holding sleeve down completely over the screw head to securely grasp the screw.

**Note:** Maintain screwdriver in a perpendicular position while removing the screw from the holder.

Insert the screw into the mesh screw hole which is aligned with the previously taped hole in the bone.

To insert the screw, turn screw clockwise using a light, two-finger approach (thumb and index finger).

**Note:** DO NOT apply downward pressure. Allow the screw to follow the threads into the hole.

Be sure to retract the holding sleeve approximately 1 mm–2 mm before fully seating the screw head on the mesh. Stop immediately when the screw head has made full contact with the mesh.

**Note:** A slight squeak may be heard at the time of contact. This is normal and is a good indicator that the screw is fully seated.

**Caution:** DO NOT over tighten. Over-tightening of the screw beyond its initial contact with the mesh will result in breakage or deformation of the screw head.

Secure the mesh to the bony anatomy by tapping additional holes in the bone and placing at least two screws buccally through the mesh into the native bone. Lingual screws may be used based upon the nature of the defect, access and surgeon preference.
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.

Insert replacement screw as described earlier.

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 using the original tap, being sure to fully insert the tap, i.e., the tap stop seats against the mesh surface. If the original screw is damaged, insert a new screw.
– If the screw head breaks off prior to seating the screw, the most likely cause is that the tap was not fully inserted. This will cause the screw to bottom out in the hole and break. Proceed with emergency screw placement as described above.
11 Healing
Allow the tissue to heal.

Postoperative Considerations
Patients should receive appropriate postoperative instructions from their doctor regarding medications and antibiotics, oral hygiene regimen (including rinsing), diet (soft foods for an appropriate period of time), treatment of swelling and bleeding.

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9 Closure
If needed, further release the flap and gingiva with periosteal releasing incisions to obtain tension-free primary closure.

10 Suture
Place interrupted sutures on either side of the defect, and suture the remaining flap using the preferred method of closure.

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Note: This mesh will not prevent the migration of epithelial cells into the graft area.
Water Bath System for Resorbable Fixation

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 prior to anticipated use.

**Instrument**

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>530.510</td>
<td>Water Bath Heater</td>
</tr>
</tbody>
</table>

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

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

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 well of the water bath heater.

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

**Heat water**
Switch the water bath heater to “ON.” In about 18 minutes, the “Ready” indicator will light, indicating the unit is ready for use. The approximate temperature will be displayed.

11. For additional information, please refer to the package insert.
Optional technique
A disposable, heat-resistant, clear sterile drape or bag 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 up to the “water level line” (approximately 500 cc) with sterile water or saline solution.

**Important:**
Squeeze out any air bubbles from under the drape or the water may not reach the operating temperature of 70°C.

When disassembling the system, remove the water bath tray and the sterile drape together.

Water bath system disassembly

**Cool unit**
Turn unit to “STANDBY” and allow it to cool for about 5 minutes.

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

Remove sterility cover.

**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.

Caution: Do not sterilize the water bath heater.
## Product Information

### Implants

<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Size</th>
<th>Code</th>
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<tbody>
<tr>
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<td>2.0 mm Rapid Resorbable Cortex Screws, sterile (2/pkg)</td>
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<td>806.008.02s</td>
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<tr>
<td>1.5 mm Rapid Resorbable Contourable Mesh Plates, sterile</td>
<td>50 mm x 50 mm x 0.25 mm thick</td>
<td>851.611.01s</td>
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<tr>
<td>1.5 mm Rapid Resorbable Contourable Mesh Plates, sterile</td>
<td>30 mm x 40 mm x 0.25 mm thick</td>
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### Drills

<table>
<thead>
<tr>
<th>Drill Bits with Stop, mini quick coupling, 44.5 mm long</th>
<th>1.1 mm Drill Bit, with 4 mm Stop</th>
</tr>
</thead>
<tbody>
<tr>
<td>317.24</td>
<td>317.26</td>
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<tr>
<td>317.28</td>
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### Instrument Trays

<table>
<thead>
<tr>
<th>Instrument Tray</th>
<th>Code</th>
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<tbody>
<tr>
<td>Small Instrument Tray Lid, for Resorbable Fixation System</td>
<td>305.806</td>
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<tr>
<td>Small Instrument Tray Base, for Resorbable Fixation System</td>
<td>305.807</td>
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<tr>
<td>Instrument Insert, for Resorbable Instrument Trays</td>
<td>305.811</td>
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<tr>
<td>Finger Mat Insert, for Resorbable Instrument Trays</td>
<td>305.814</td>
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### Accessories

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.509</td>
<td>Water Bath System includes:</td>
<td></td>
</tr>
<tr>
<td>530.510</td>
<td>Water Bath Heater</td>
<td></td>
</tr>
<tr>
<td>530.512</td>
<td>Water Bath Tray</td>
<td></td>
</tr>
<tr>
<td>530.514</td>
<td>Water Bath Sterility Cover</td>
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</table>

Please contact your Synthes Sales Representative for additionally available implants and instrumentation.

For more information, call the Dentoalveolar Surgery Hotline at (800) 824-2020.