RapidSorb Resorbable Fixation System

Surgical Technique

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products 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 DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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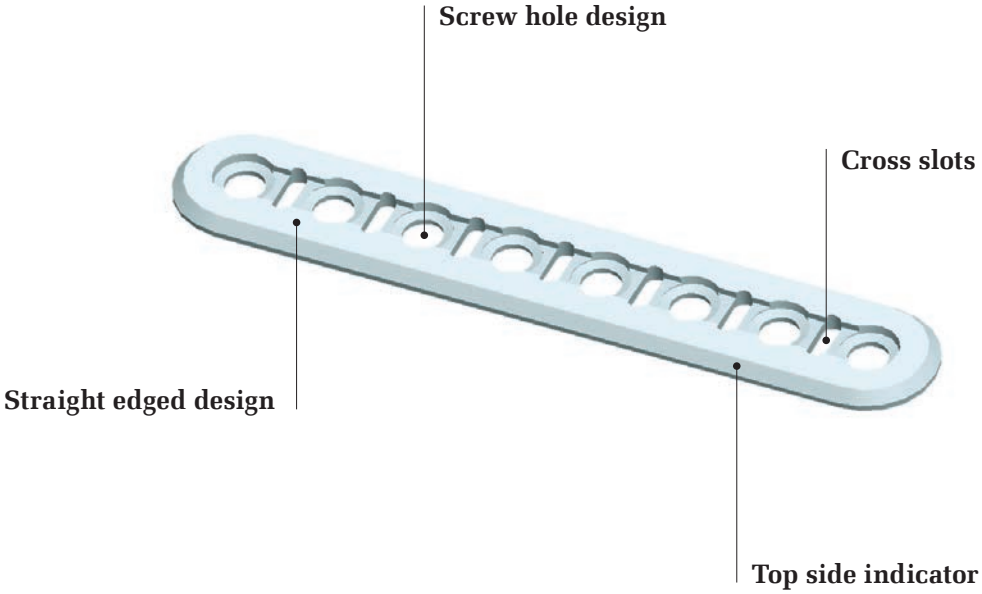
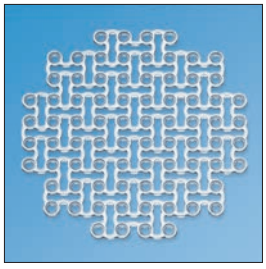
Overview

RapidSorb Resorbable Fixation System
RapidSorb is a resorbable fixation system, which is intended for fracture repair and craniofacial reconstruction. It is made of bioresorbable L-lactide-co-glycolide polymer. Rapidsorb Resorbable Fixation system is radiolucent.

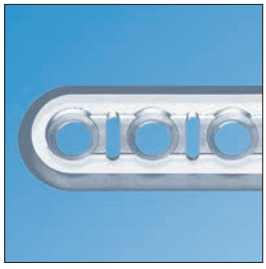


Intended Use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

Product portfolio


Meshes/Foils


Screws


Plates

Warnings and Precautions

Rapidsorb Resorbable Fixation System

Warnings:
- Do not use in procedures where a permanent implant is needed.
- Improper selection, placement, positioning and fixation of the implant can cause a subsequently undesirable result.
- Do not bend/contour plates, meshes or foils in the cold state.
- The plates, meshes and foils 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.
- Do not store the implants in the hot water bath.
- Screws must not be heated or reshaped by any means.

Precautions:
- These devices are resorbable and do not provide permanent fixation.
- These resorbable devices provide fixation and are not intended to replace normal healthy bone or withstand stress of full load bearing.

Foreign body sensitivity: where material sensitivity is suspected, testing is to be completed prior to implantation.

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 (65 °C–75 °C [149 °F–167 °F]).

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 >70 °C (158 °F).
- 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.
- To prevent risk of fire, do not operate device in an oxygen rich environment (oxygen concentrations greater than 25%).
- To prevent equipment malfunction, do not operate close to magnetic fields (e.g., MRI).
- To prevent risk of electric shock, do not overfill or spill liquid on the exterior of the CWB. Liquid added to the CWB basin prior to drape placement should not exceed the PREFILL LINE. Final liquid volume should not exceed the MAX FILL LINE.
- The CWB is to be used only on a flat, even surface with sufficient strength to support the device. To ensure proper operation and to prevent electric shock due to ingress of liquid, ensure the CWB is level before filling with liquid.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- To prevent electric shock, before inspecting or replacing fuse, disconnect device from supply mains.
- To prevent risk of fire, only replace fuse(s) with the same type (250V 5A fast-acting, low-breaking).
- Do not position the device so that it is difficult to disconnect the power cord from the supply mains.
- No modification of this equipment is allowed. Modification of this equipment can result in significant injury to operators, patients and bystanders.
- To prevent risk of equipment malfunction, electric shock or fire, only replace a lost or damaged power cord with a power cord type SJT, rated at 13A or higher and rated for the appropriate local mains voltage.
- 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.

Compact Water Bath Instructions

Preparation

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

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

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.

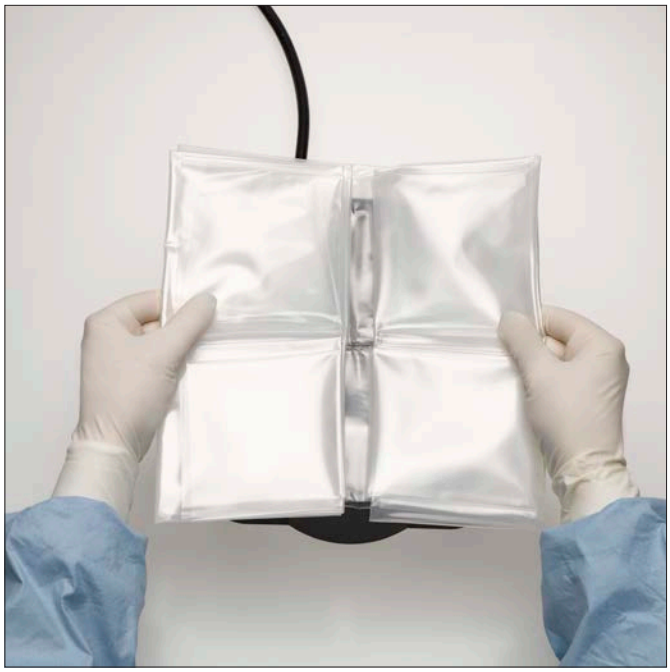
Ensure that there is a grounded electrical outlet within reach of the power cord from where the Compact Water Bath is placed.

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.

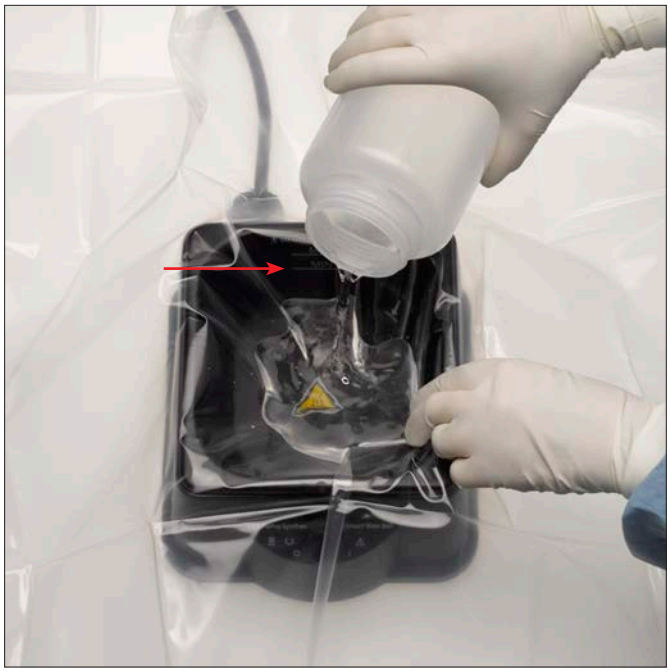


Precaution: **Be careful to maintain drape sterility on the upward-facing side of the drape. The Compact Water Bath and surface under the Compact Water Bath is not sterile.**

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.



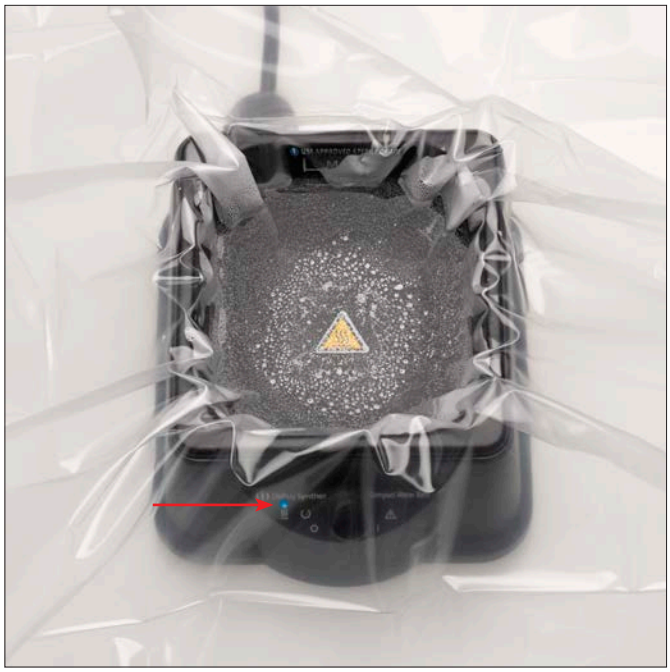
5. Heat Water

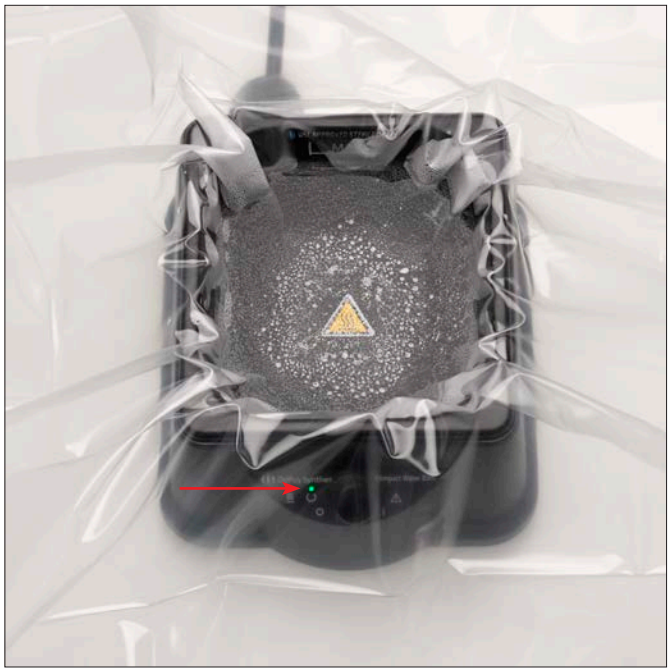
Plug in the power cord to a grounded power outlet. Switch the Power Switch to the ON position. The blue WARMING indicator on the front of the Compact Water Bath will illuminate, signifying that the liquid is heating up.

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.





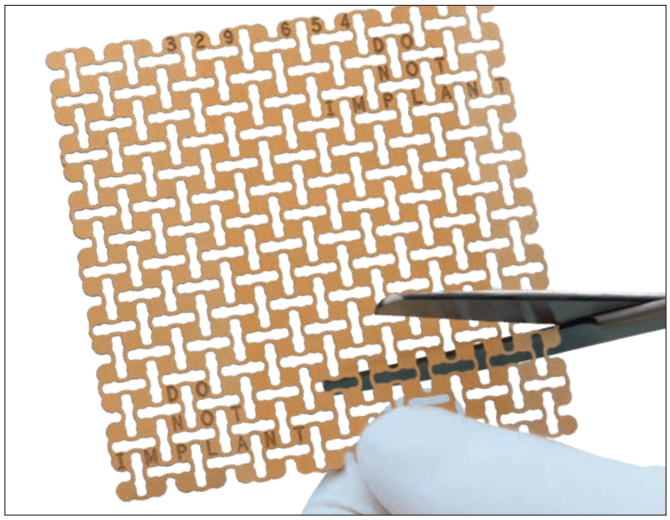
1. Select and prepare plates

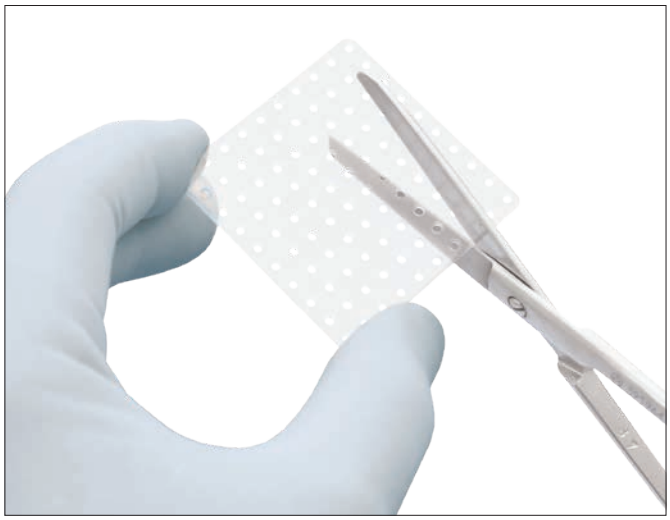
If desired, use the bending templates to determine the plate shape and size, especially where direct access is limited.

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).

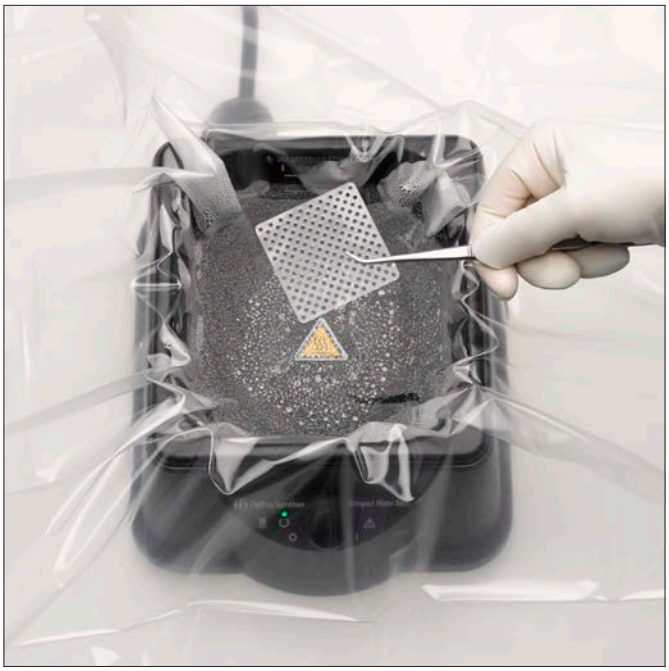
Contouring is possible by either laying the plate directly onto the bone or by using the contoured bending template.

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/contouring of plates, meshes and foils 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)

Product Code	Diameter	Length
311.033	1.5 mm	3 mm
311.031	1.5 mm	4 mm
311.032	1.5 mm	6 mm
311.037	1.5 mm	8 mm

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

Product Code	Diameter	Length
311.034	2.0 mm	4 mm
311.036	2.0 mm	6 mm
311.038	2.0 mm	8 mm

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.

Note: **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 ∅ 1.5 mm

Product Code	Length	Pack
805.603.02S	3 mm	2 units
805.603.04S	3 mm	4 units
805.604.02S	4 mm	2 units
805.604.04S	4 mm	4 units
805.604.10S	4 mm	10 units
805.605.02S	5 mm	2 units
805.605.04S	5 mm	4 units
805.606.02S	6 mm	2 units
805.606.04S	6 mm	4 units
805.606.10S	6 mm	10 units
805.608.02S	8 mm	2 units
805.608.04S	8 mm	4 units

RapidSorb Cortex Screw ∅ 2.0 mm

Product Code	Length	Pack
806.004.02S	4 mm	2 units
806.004.04S	4 mm	4 units
806.004.10S	4 mm	10 units
806.006.02S	6 mm	2 units
806.006.04S	6 mm	4 units
806.006.10S	6 mm	10 units
806.008.02S	8 mm	2 units
806.008.04S	8 mm	4 units

Choose the appropriate screw length and diameter.

Attach the appropriate ∅ 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)

Product Code	Cortex Screws ∅ mm
314.431	66
314.432	92

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

Product Code	Cortex Screws ∅ mm
314.686	66
314.687	92

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)

Product Code	Diameter	Length
311.054	2.0 mm	4 mm
311.056	2.0 mm	6 mm
311.058	2.0 mm	8 mm

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

Product Code	Diameter	Length
311.044	2.5 mm	4 mm
311.046	2.5 mm	6 mm
311.048	2.5 mm	8 mm

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 Disassembly Instructions

Compact Water Bath System Disassembly

05.725.010	Compact Water Bath
08-CC184	Sterile Drape[6]

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.

Disposal of waste:

- **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.**

[6] Sterile Drape: CE0050
Manufactured by: AdvanceTM Medical Designs Inc., 1241 Atlanta Industrial Drive, Marietta, GA 30066
EU Representative: MDSS 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.

Cleaning and Shut down:

- **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.**

Product Information

Plates

851.002.01S	Plate 1.5, straight, RapidSorb, 2 holes, 0.8 mm
851.004.01S	RapidSorb Plate 1.5, straight, 4 holes, thickn. 0.8 mm
851.008.01S	RapidSorb Adaption Plate 1.5, 8 holes, thickn. 0.8 mm
851.020.01S	Adaption Plate 1.5, RapidSorb, 20 holes, 0.8 mm
851.110.01S	RapidSorb Orbital Rim Plate 1.5, 10 holes, th. 0.8 mm
851.320.01S	Double Y-Plate 1.5, RapidSorb, 10 holes, 0.8 mm
851.343.01S	Y-Plate 1.5, RapidSorb, 10 holes, 0.8 mm
851.420.01S	Strut Plate 1.5, RapidSorb, 2 × 10 holes, 0.8 mm
851.421.01S	Strut Plate 1.5, RapidSorb, 2 × 18 holes, 0.8 mm
851.510.01S	RapidSorb Mesh Plate 1.5, 50 × 50 mm, thickness 0.5 mm
851.512.01S	RapidSorb Mesh Plate 1.5, 100 × 100 mm, thickn. 0.5 mm
851.520.01S	Mesh Plate 1.5, RapidSorb, 50 × 50 mm, 0.8 mm
851.521.01S	RapidSorb Mesh Plate 1.5, 100 × 100 mm, thickness 0.8 mm
851.540.01S	Orbital Floor Plate 1.5, RapidSorb, small, 0.5 mm
851.541.01S	RapidSorb Orbital Floor Plate 1.5, medium, th. 0.5 mm
851.542.01S	RapidSorb Orbital Floor Plate 1.5, lrg., thickn. 0.5 mm
851.604.01S	RapidSorb X-Plate 1.5, 4 holes, thickness 0.8 mm
851.651.01S	Mesh Plate 1.5, RapidSorb, ∅ 50 mm, 0.5 mm
851.652.01S	Mesh Plate 1.5, RapidSorb, ∅ 100 mm, 0.5 mm
851.661.01S	Mesh Plate 1.5, RapidSorb, ∅ 50 mm, 0.8 mm
851.662.01S	RapidSorb Mesh Plate 1.5, thickn. 0.8 mm, contourable
851.711.01S	RapidSorb Mesh Plate 1.5, 50 × 50 mm, thickness 0.5 mm
851.712.01S	RapidSorb Mesh Plate 1.5, 100 × 100 mm, thickness 0.5 mm
851.721.01S	Mesh Plate 1.5, RapidSorb, 50 × 50 mm, 0.8 mm
851.722.01S	RapidSorb Mesh Plate 1.5, 100 × 100 mm, thickness 0.8 mm
852.002.01S	RapidSorb Plate 2.0, straight, 2 holes, th. 1.2 mm
852.004.01S	Plate 2.0, straight, RapidSorb, 4 holes, 1.2 mm
852.008.01S	RapidSorb Adaption Plate 2.0, 8 holes, th. 1.2 mm
852.020.01S	RapidSorb Adaption Plate 2.0, 20 holes, th. 1.2 mm
852.110.01S	Orbital Rim Plate 2.0, RapidSorb, 10 holes, 1.2 mm
852.263.01S	RapidSorb L-Plate 2.0, left, 10 holes, th. 1.2 mm
852.264.01S	RapidSorb L-Plate 2.0, right, 10 holes, th. 1.2 mm
852.343.01S	Y-Plate 2.0, RapidSorb, 10 holes, 1.2 mm
852.420.01S	RapidSorb Strut Plate 2.0, 2 × 10 holes, th. 1.2 mm
852.421.01S	RapidSorb Strut Plate 2.0, 2 × 18 holes, th. 1.2 mm
852.520.01S	RapidSorb Mesh Plate 2.0, 48 × 48 mm, thickness 1.2 mm
852.521.01S	Mesh Plate 2.0, RapidSorb, 78 × 78 mm, 1.2 mm
852.641.01S	RapidSorb Mesh Plate 2.0, ∅ 50 mm, contourable

Screws

805.603.02S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 3 mm
805.603.04S	RapidSorb Cortex Screw ∅ 1.5 mm, L 3 mm
805.604.02S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 4 mm
805.604.04S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 4 mm
805.604.10S	RapidSorb Cortex Screw ∅ 1.5 mm, L 4 mm
805.605.02S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 5 mm
805.605.04S	RapidSorb Cortex Screw ∅ 1.5 mm, L 5 mm
805.606.02S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 6 mm
805.606.04S	RapidSorb Cortex Screw ∅ 1.5 mm, L 6 mm
805.606.10S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 6 mm
805.608.02S	RapidSorb Cortex Screw ∅ 1.5 mm, L 8 mm
805.608.04S	MF Cortex Screw ∅ 1.5 mm, RapidSorb, L 8 mm
806.004.02S	MF Cortex Screw ∅ 2.0 mm, RapidSorb, L 4 mm
806.004.04S	RapidSorb Cortex Screw ∅ 2.0 mm, L 4 mm
806.004.10S	RapidSorb Cortex Screw ∅ 2.0 mm, L 4 mm
806.006.02S	MF Cortex Screw ∅ 2.0 mm, RapidSorb, L 6 mm
806.006.04S	RapidSorb Cortex Screw ∅ 2.0 mm, L 6 mm
806.006.10S	RapidSorb Cortex Screw ∅ 2.0 mm, L 6 mm
806.008.02S	RapidSorb Cortex Screw ∅ 2.0 mm, L 8 mm
806.008.04S	RapidSorb Cortex Screw ∅ 2.0 mm, L 8 mm
806.044.02S	RapidSorb Emergency Screw ∅ 2.5 mm, L 4 mm
806.046.02S	Emergency Screw ∅ 2.5 mm, RapidSorb, L 6 mm
806.048.02S	RapidSorb Emergency Screw ∅ 2.5 mm, L 8 mm

Burr Hole Cover

851.506.01S	RapidSorb Burr Hole Cover 1.5, 8 ho., ∅ 21 mm, th.0.5 mm
851.508.01S	RapidSorb Burr Hole Cover 1.5, 10 ho., ∅ 30 mm, th.0.8 mm

Rapidsorb Foil

851.532.01S	RapidSorb Foil, 50 × 50 mm , thickness 0.5 mm
851.534.01S	RapidSorb Foil, 50 × 50 mm, thickness 0.8 mm

DePuy Synthes
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Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

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