Instructions for Use
RapidSorb Resorbable Fixation System

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Instructions for Use

RapidSorb Resorbable Fixation System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique. Sufficient experience in the field of the use of biomaterials is highly recommended before using the RapidSorb Resorbable Fixation System.

Material(s)

Material(s):	Standard(s):
85:15 poly(L-lactide-co-glycolide)	ASTM F1925

Description
The RapidSorb Resorbable Fixation System consists of implants (plates, meshes, foils, and screws), instruments and cases.
The material of the RapidSorb implants is made of resorbable 85:15 poly(L-lactide-co-glycolide) copolymer. RapidSorb implants retain their stability for at least 8 weeks during the critical bone healing phase.
In vivo degradation occurs by hydrolysis to lactic acid, which is then metabolized into carbon dioxide and water. Both end products will be absorbed and excreted by the body. The RapidSorb implants will degrade within approximately 12 months depending on secondary factors like implant site and condition of patient.

Intended use
The RapidSorb Resorbable Implants are intended for use in fracture repair or reconstructive procedures or graft containment of the craniomaxillofacial skeleton in pediatric and adult populations.

Indications
The RapidSorb Resorbable Plates, Meshes, Foils and Screws are indicated for bone fixation in the management of fractures or reconstructions of the craniofacial skeleton.
The RapidSorb Resorbable Meshes, Foils and Screws are indicated for graft containment in craniofacial or mandibular areas (in non-load-bearing applications only).
The RapidSorb Resorbable Plates, Meshes, Foils and Screws should only be used in locations subject to non-load-bearing osteosynthesis.

Contraindications
The RapidSorb Resorbable Fixation System should not be used in the following circumstances:
- Loadbearing and unstable applications
- Resection of a mandibular tumor
- Blood supply limitations or reduced blood circulation
- Insufficient quantity and quality of bone
- Situations in which internal fixation is contraindicated for other reasons or in patients with compromised health (e.g. metabolic, vascular, or severe neurological disease, infection, immunologic deficiencies, inadequate quantity or quality of bone) and/or lack of willingness to cooperate (e.g. alcoholism)
- Active, acute, latent, potential or chronic infections
- In cases of established intolerance/allergy to poly(lactides) and/or poly(glycolides)

Possible side effects
- Nonunion or delayed union, which may lead to breakage of the implant
- Pain, discomfort, abnormal sensation, or palpability due to the presence of the device
- Increased fibrous tissue response around fracture site and/or the implant
- Necrosis of bone
- In general, good tissue receptivity of resorbable implants made of poly(L-lactide-co-glycolide) copolymer is supported by experimental and clinical data. Nevertheless, the following complications are possible: Fragment displacement as a result of use in inappropriate indications and foreign body reactions

Possible general complications caused by invasive surgery including:
- Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.)
- Thrombosis, embolism or injury of other critical structures including blood vessels
- Neurovascular injuries
- Excessive bleeding
- Allergic reactions
- Inflammatory reactions
- Infections can lead to failure of the procedure
- Damage to soft tissues including swelling
- Abnormal scar formation
- Functional impairment of the musculoskeletal system

Sterile device

STERILE R Sterilized using gamma-irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or passed expiry date.

Do not re-sterilize

Single-use device

Do not re-use

Products intended for single-use must not be reused. Re-use or reprocessing (e.g. cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

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

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

Combination of medical devices
The RapidSorb Resorbable Implants should only be used with the specially developed instruments. The manufacturer does not accept any liability for complications that may arise from the use of other instruments. RapidSorb Resorbable Plates and Meshes should only be fixed with RapidSorb Screws.
Due to the material similarities, no negative interactions between RapidSorb implants and sutures based on poly(lactide), poly(glycolide), or their co-polymers, e.g. Vicryl®, are expected. When using the RapidSorb implants in conjunction with adjunctive materials, the instructions and cautions provided by each manufacturer should be followed.

Magnetic resonance environment
The RapidSorb Resorbable Implants are of non-metallic, organic origin. This material is inherently non-magnetic and cannot be heated up or act as an antenna either by bringing the patients into the MRI magnet or during the MRI examinations.

Special operating instructions
The right choice of implant (size, shape and adaptation) and correct positioning and fixation is crucially important to the success of osteosynthesis. The operating surgeon should be thoroughly familiar with the implants, instruments and relevant aseptic surgical techniques.
Open reduction of the fracture or osteotomy is followed by insertion of the implants as described below.

1) Select and prepare plates/meshes/foils
If desired, use the bending templates to determine the optimal plate shape and size, especially where direct access is limited. Bending templates may be cut to size. If necessary cut the selected plates/meshes/foils to the desired length or shape using the Cutter or Scissors for Resorbable Plates.
When cutting a resorbable plate/mesh/foil, heat it in 65 °C – 75 °C sterile water or sterile saline. Open the Scissors for Resorbable Plates 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/foils
The resorbable plates/meshes/foils should be heated (approximately 15 seconds, between 65 °C – 75 °C) before bending/contouring. By using the Synthes Water Bath Unit (i.e. Compact Water Bath System) only sterile water or sterile saline must be used. The heated plate/mesh/foil can be removed with the Holding Forceps for Plates.
Contouring is possible by either laying the plate/mesh/foil directly onto the bone or by using the contoured bending template.
Be sure that the hole taper is facing the proper direction before contouring/implanting 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 screws
Choose the appropriate screw length and diameter. Please select screw length carefully as a too long screw could possibly cause injury to the dura.

4) Select tap
Select the appropriate self-drilling tap dependent on the selected RapidSorb Screw (1.5/2.0).

5) Tap holes for 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.
If the tap selected is too short, it will not be possible to countersink the screw completely in the plate/mesh 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.

6) Insert screws
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.
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/mesh.
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.

7) Emergency screw placement
If the screw breaks or the bone strips out 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.

Device-related storage an handling information

Upper limit of temperature: 25 °C


Keep dry


Keep away from sunlight

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Additional device-specific information

Reference number

Lot or batch number


Manufacturer


Expiration date

Notified Body


Caution, see instruction for use


Do not use if the packaging is damaged

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