RAPIDSORB® RAPID RESORBABLE FIXATION SYSTEM

For craniofacial reconstruction
Features
Rapid resorbable implants maintain appropriate fixation for bone healing for approximately 8 weeks postoperatively.\(^1\)

- Resorbs in approximately 12 months\(^1\)
- Degradates without late inflammatory complications and foreign-body responses that have been observed with semicrystalline structures such as poly (L-lactide)\(^2,3\)
- Eliminates concerns for potential migration and translocation associated with metallic implants\(^4,5\)
- Eliminates secondary surgeries for implant removal
- Proven biocompatible material\(^6\)
- Radiolucent polymer does not interfere with intraoperative or postoperative radiographs\(^7,8\)
- Polymer strength is not affected by radiation therapy\(^9,10\)
- Full line of instrumentation and customizable trays

References:
1. Average strength retention data on file at DePuy Synthes Companies of Johnson & Johnson.
6. 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.11

INDICATIONS AND CONTRAINDICATIONS

Indications
The DePuy Synthes Companies RAPIDSORB 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 Companies RAPIDSORB 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.

12. Please see Instructions For Use for complete contraindications, warnings and precautions.
The wide assortment of implants in the DePuy Synthes Companies 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

**Plate/screw profiles**
Low plate and screw profile minimizes soft tissue irritation, palpability, and the amount of material to be resorbed.

- Implants are available in a range of sizes

**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 screw
RAPIDSORB Implants

**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
Preshaped orbital floor plate can be quickly and easily contoured.

Contourable mesh permits optimal anatomic conformity without cutting or kinking.
The solid sheet allows customization of hole size and location.

Straight row mesh can be cut into desired plate geometries.
A full line of instrumentation and trays meets the needs of both surgeons and operating room personnel.

Please refer to the RAPIDSORB Rapid Resorbable Fixation Technique Guide for a complete listing of instruments and contouring systems.

**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
Both the Compact Water Bath System and the Water Bath System warm a bath of sterile water or sterile saline solution to quickly heat resorbable plates, meshes, and sheets to a malleable state.

**Compact Water Bath System**
- Smaller footprint takes up less surface area in Operating Room and in storage
- Required custom sterile drape allows for quick set up and use of the Compact Water Bath

**Water Bath System**
- Removable water tray and sterility cover can be cleaned and sterilized
- Reusable sterility cover or disposable sterile drape allows use in the sterile field
Limited Warranty and Disclaimer: DePuy Synthes Companies 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.

Rx only

Some devices listed in this brochure may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.