Instructions for Use
RapidSorb Cranial Clamp

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

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DePuy Synthes
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Instructions for Use

RapidSorb Cranial Clamp

Introduction
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 Cranial Clamp.

Material(s)

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

Description
The RapidSorb Cranial Clamp is a sterile cranial fixation clamp designed for quick and stable fixation of cranial bone flaps. The cranial clamp consists of two disks connected by a ratcheting shaft.
The RapidSorb Cranial Clamp 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 Cranial Clamp will degrade within approximately 12 months depending on secondary factors like implant site and condition of patient.

Intended use
The intended use of the RapidSorb Cranial Clamps is to cover burr holes and to fix cranial bone flaps in pediatric and adult populations.

Indications
The RapidSorb Cranial Clamps are indicated for fixation of cranial bone flaps and covering burr holes generated during craniotomy procedure in paediatric and adult populations.

Contraindications
The RapidSorb Cranial Clamp should not be used in the following circumstances:
– For kerf widths less than 1.5 mm or greater than 4 mm and for burr holes larger than 10 mm in diameter
– As an internal fixation other than indicated
– If the dura is missing
– For viscerocranial use
– Situations in which internal fixation is contra-indicated 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)

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

Apart from these side effects there are always possible complications of any surgical procedure such as infection, nerve damage and pain which may not be related to the implant.

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
– Neurovascular injuries caused by surgical trauma
– Foreign body reactions
– Allergic reactions
– Inflammatory reactions
– Infections can lead to failure of the procedure
– General complications caused by invasive surgery

General adverse Events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

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 resterilize

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
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, re-use 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
– The RapidSorb Cranial Clamps can break or bend as a result of stress or excessive activity, which could cause failure of the device and/or the treatment
– The RapidSorb Cranial Clamp must not to be heated by any means

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

Magnetic Resonance Environment
RapidSorb Cranial Clamps are of non-metallic, organic origin. This material is inherently diamagnetic 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

1) Place Clamps

With the cranial bone flap removed, an appropriate number of the RapidSorb Cranial Clamps have to be positioned equidistant around the opening. The bottom disks are placed between the dura and the skull. A minimum of three RapidSorb Cranial Clamps are recommended for a secure fixation of cranial bone flaps in pediatric patients and a minimum of four in adult patients. Depending on the patient and bone-flap size, more fixation points may be required.

2) Replace the Cranial Bone Flap

The cranial bone flap is then replaced in its original position, ensuring the shafts of the cranial clamps remain vertical in the kerf. Pre-tension each clamp by pressing the top disk manually to the cranial surface. The disk should always be in a perpendicular position to the shaft. A 2-finger pinching technique is suggested.
When using more than three RapidSorb Cranial Clamps, it is highly recommended to lower the top disks of the clamps in a crisscross pattern modus manually.

3) Engage application Forceps

The use of the specific application device is mandatory. With the ratchet mechanism engaged, the application device is placed perpendicular (all the time) over the RapidSorb Cranial Clamp shaft and the application device is lowered to the top disk.

4) Apply Tension

The application device handles are pulled to put tension on the RapidSorb Cranial Clamp. If the clamps were not pre-tensioned as described in step 2, the tensioning step may be repeated to fully fixate the clamps.

5) Cut the Stem

While maintaining tension of the clamp, the shaft is cut by pulling the cutting trigger. After cutting the shaft, the ratcheting mechanism on the application device is released.
Repeat steps 3–5 until all clamps have been secured.
The RapidSorb Cranial Clamp can be used in combination with other closure techniques in neurosurgery.

6) Removal

In cases where postoperative re-entering to the cranium is required, forceps are used to grasp the top disk of the clamp along the kerf. The disk is released by lifting and rotating it parallel to the kerf. In such cases it is recommended to completely remove the RapidSorb Cranial Clamps. Repeat this procedure with the remaining clamps. The bone flap can now be removed.

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.

Device-Related Storage and Handling Information

Upper limit of temperature: 25 °C


Keep dry


Keep away from sunlight

Additional Device-Specific Information

Reference Number

Lot or Batch Number


Manufacturer


Expiration Date

Notified Body


Caution, see instructions for use


Do not use when packaging is damaged

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