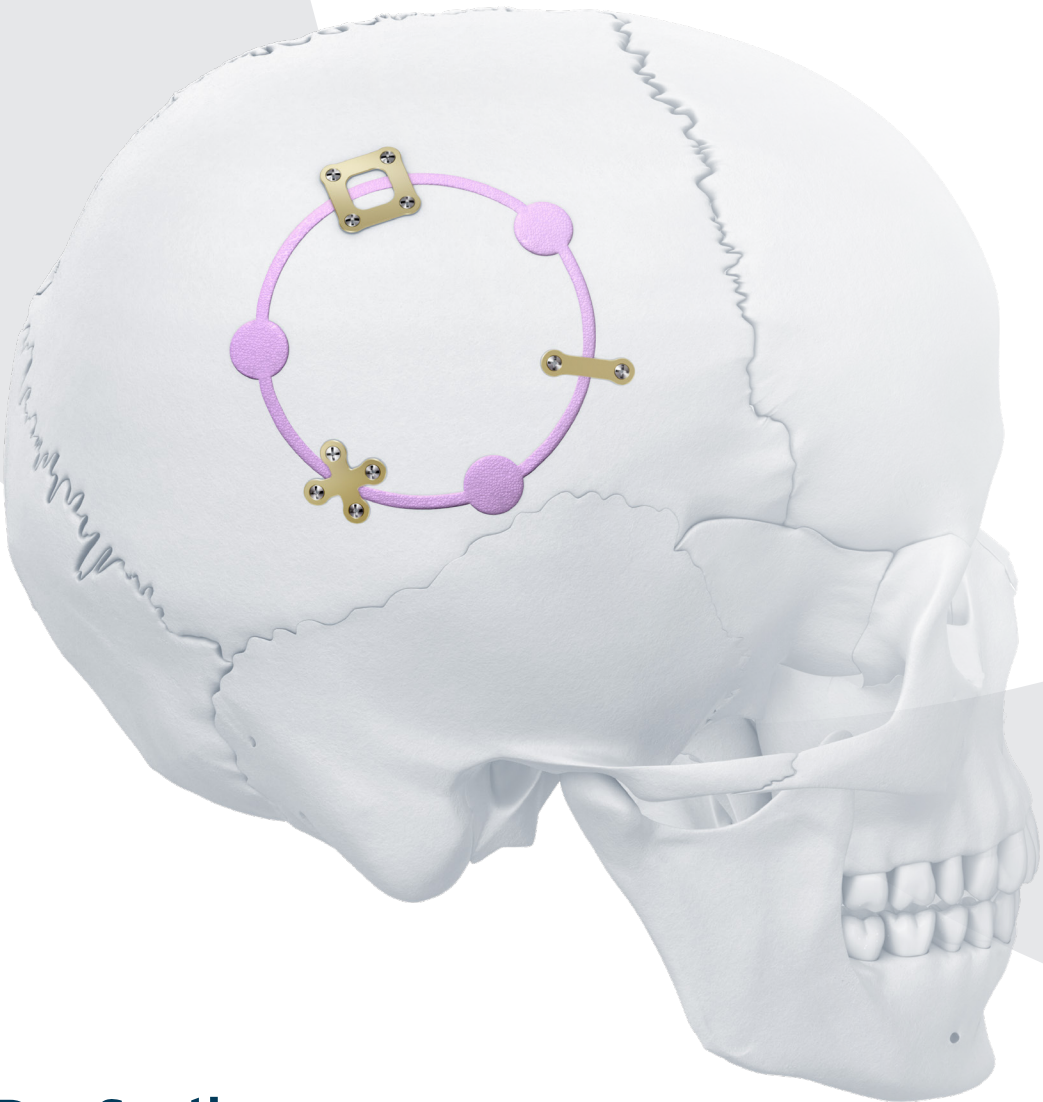
The tougher bone cement

CRANIOS REINFORCED® Rotary Mix

Surgical Technique



DePuy Synthes

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Image intensifier control

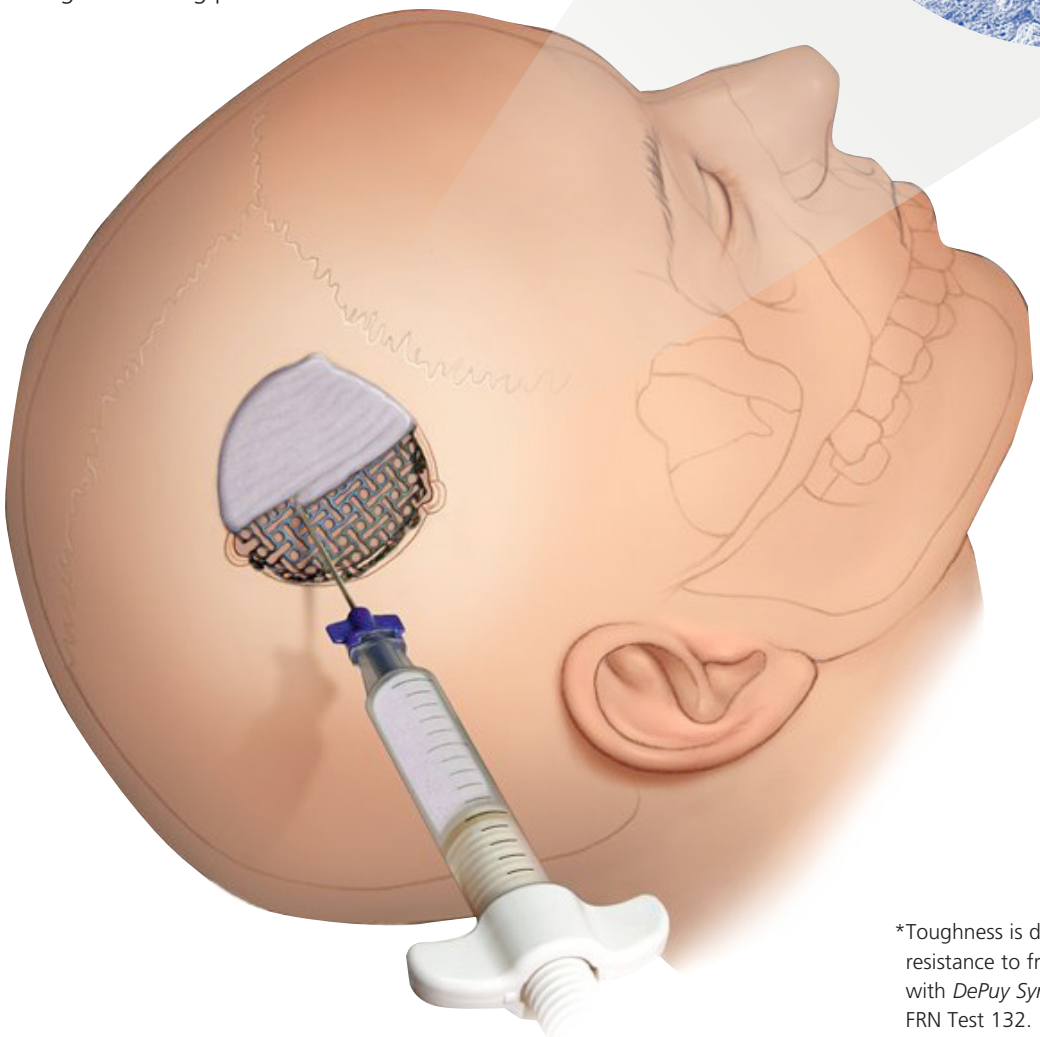
Cranios Reinforced® Rotary Mix

The tougher bone cement

CRANIOS REINFORCED® Rotary Mix is an injectable, biocompatible calcium phosphate bone cement with reinforcing fibers added for increased toughness* that sets at body temperature.

Due to its special composition, the reinforced cement resists cracking during the setting process. The addition of sodium hyaluronate solution provides enhanced mixing, handling, and injection properties.

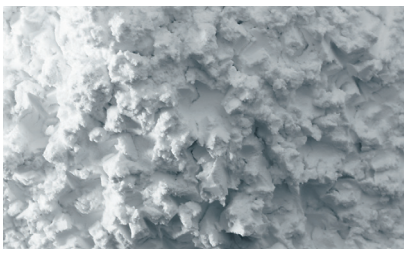
CRANIOS REINFORCED Rotary Mix is an injectable option suitable for bony defects positioned at difficult angles, and sets in a wet environment. When fully cured, the composition closely approximates the mineral phase of bone. It is gradually resorbed and replaced with bone during the healing process.



*Toughness is defined as a measure of a material's resistance to fracture when stressed. Data on file with *DePuy Synthes Biomaterials*, mechanical test FRN Test 132.

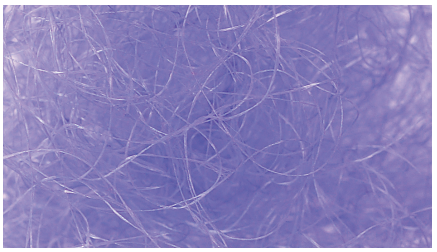
Features	Benefits
Reinforcing fibers	Material resists cracking during the setting process
Sodium hyaluronate solution	Enhanced mixing, handling, and flow properties
Injectability	Controlled injection and optimal defect filling
Sets in a warm, wet environment	Reduced need to limit moisture at the operative site
Isothermic hardening	No thermal injury to surrounding soft tissue
Maximum compressive strength of approximately 35 MPa within 24 hours	Compressive strength is 2– 6 times higher than compressive strength of cancellous bone[1]
Resembles mineral phase of bone	Gradual resorption and replacement with bone during the bone healing process
Resembles mineral phase of bone	Gradual resorption and replacement with bone during the bone healing process

Calcium phosphate powder



Calcium phosphate has been widely used in clinical applications for decades. There are a number of publications and clinical cases available which demonstrate its safety and effectiveness to address bone regeneration.[2,3]

Bioresorbable fibers



The bioresorbable Poly (lactide co-glycolide) polymer fibers are randomly oriented and uniformly distributed throughout the material to impart an increase in material toughness.* This incorporation of fibers into the matrix increases the material's resistance to cracking during the setting process.

Sodium hyaluronate solution

Sodium hyaluronate is a pH-neutral solution that increases viscosity, which leads to enhanced mixing and flow properties.

1. Cowen SC, ed. *Bone Mechanics Handbook*. 2nd ed. New York, NY: CRC Pross, 2001. 16–3. Print.
2. Cassidy C, Jupiter JB, Cohen M, Delli-Santi M, Fennell C, Leinberry C, et al. Norian SRS cement compared with conventional fixation in distal radial fractures. A randomized study. *J Bone Joint Surg Am.* 2003;85-A:2127-2137.
3. Chang BS, Lee CK, Hong KS, Youn HJ, Ryu HS, Chung SS, et al. Osteoconduction at porous hydroxyapatite with various pore configurations. *Biomaterials.* 2000;21:1291-1298.

*Toughness is defined as a measure of a material's resistance to fracture when stressed. Data on file with *DePuy Synthes Biomaterials*, mechanical test FRN Test 132.

CRANIOS REINFORCED Rotary Mix is a self-setting, calcium phosphate bone void filler which:

- Contains resorbable poly (lactide co-glycolide) polymer fibers which reduce crack propagation
- Hardens *in vivo* to form carbonated apatite, closely resembling the mineral phase of bone
- Gradually resorbed and replaced with bone during the healing process
- Biocompatible and isothermic

Although hydroxyapatite is commonly thought of as the mineral phase of bone, carbonated apatite actually constitutes 60–70% of total dry bone weight. The main distinction between hydroxyapatite and carbonated apatite is the presence of carbonate. Hydroxyapatite does not contain any carbonate. In contrast, CRANIOS REINFORCED Rotary Mix has a carbonate content of approximately 4–5%, more closely resembling the mineral phase of bone. The properties of bone and CRANIOS REINFORCED Rotary Mix are compared in the adjacent table.

Once CRANIOS REINFORCED Rotary Mix is fully set, it has a crystallographic characteristic and chemical composition similar to bone, as demonstrated in Figure 1.

Properties of Bone vs. Cranios Reinforced Rotary Mix

Characteristic	Bone[4]	CRANIOS REINFORCED Rotary Mix
Carbonate content	4.0–6.0%	4.0–5.0%
Ca/P molar ratio	1.33–1.73	1.60
Crystal order	Low	Low
Optimal crystal size	~200 Å	~200 Å
Chemical make-up	Inorganic/ organic	Inorganic/ organic

Table 1

Crystallographic analysis by powder x-ray diffraction (XRD)

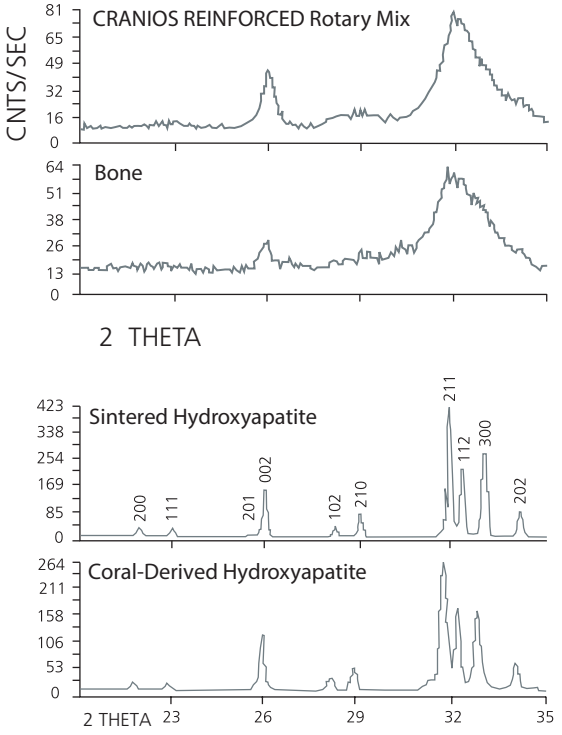


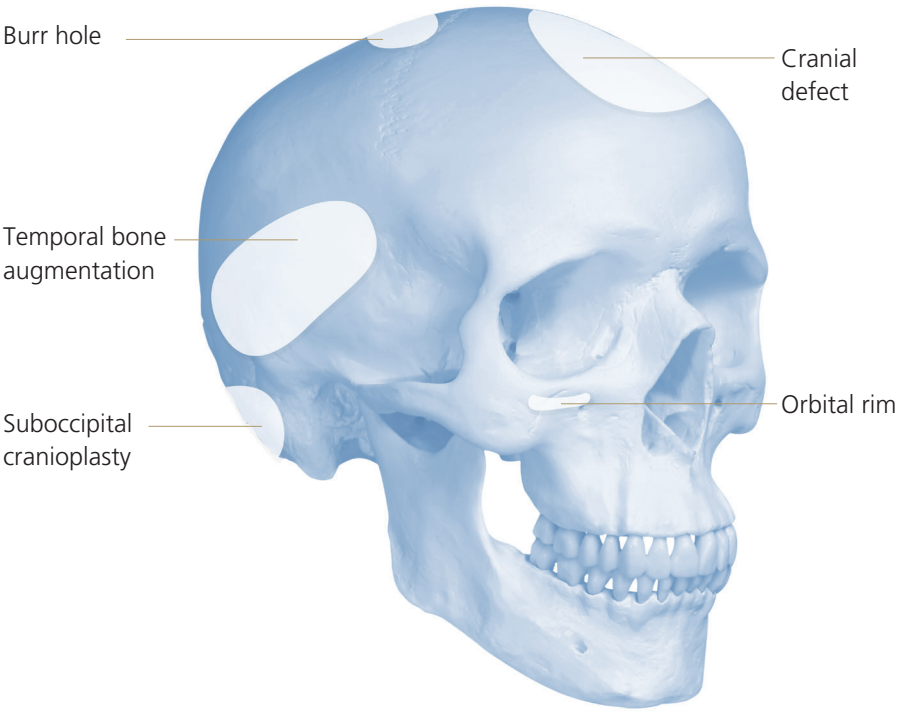
Figure 1

4. Constantz B, Ison LC, Fulmer MT, Poser RD, Smith ST, Vanwagoner M, et al. Skeletal repair by in situ formation of the mineral phase of bone. *Science*. 1995;267:1796–1799.

Indications and Contraindications

Indications

CRANIOS REINFORCED Rotary Mix is indicated for repairing or filling cranial defects and craniotomy cuts with a surface area no larger than 25 cm^2. CRANIOS REINFORCED Rotary Mix is also indicated for the restoration or augmentation of bony contours of the cranial skeleton (including fronto-orbital areas) such as burr hole voids and other cranial defects.



Clinical applications include:

- Cranioplasty
- Cranial recontouring
- Cranial flap augmentation
- Skull base defect repair
- Onlay grafting

Contraindications

CRANIOS REINFORCED Rotary Mix is **not intended for use in the spine** and should not be used in the presence of active or suspected infection.

CRANIOS REINFORCED Rotary Mix is not for use in:

- patients with traumatic open injuries that are predisposed to infection
- stress-bearing applications, such as the temporomandibular joint
- areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implant
- patients with compromised health (e.g., abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site
- patients who have not reached an age at which skull/facial growth is essentially complete
- defects contiguous with any of the paranasal sinuses
- defects greater than 25 cm^2

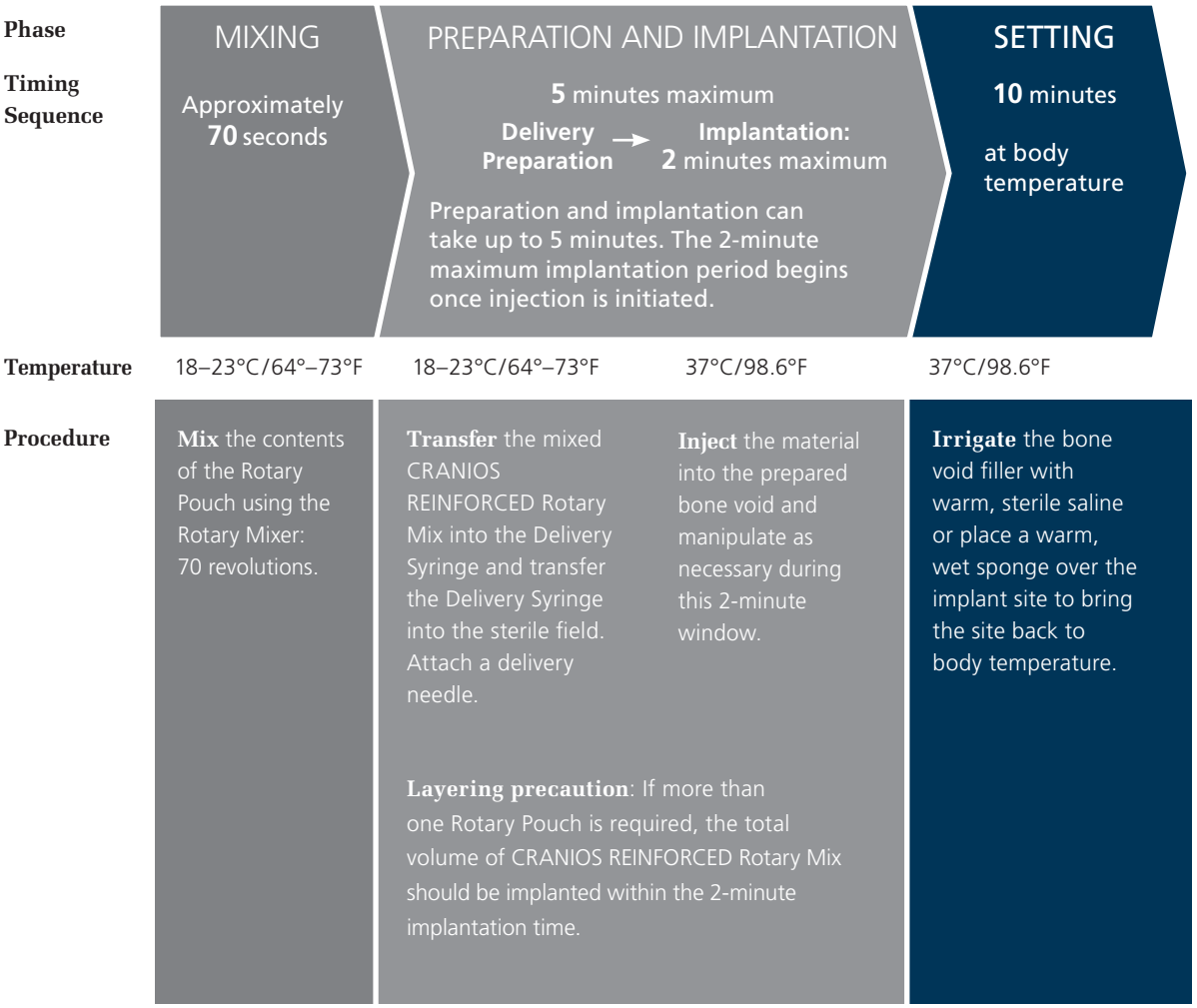
Please refer to package insert for complete indications, contraindications, warnings and precautions.

Timing Sequence

Time and temperature properties

The handling properties of CRANIOS REINFORCED Rotary Mix are governed primarily by the mixing technique and ambient temperature of the material as it is prepared and injected into the surgical site.

The following timing sequence refers to the specific time and temperature relationships that must be followed for the material to set properly.



Curing Time: 24 hours at body temperature

(37°C/ 98.6°F). CRANIOS REINFORCED Rotary Mix reaches its full compressive strength of approximately 35 MPa in 24 hours.

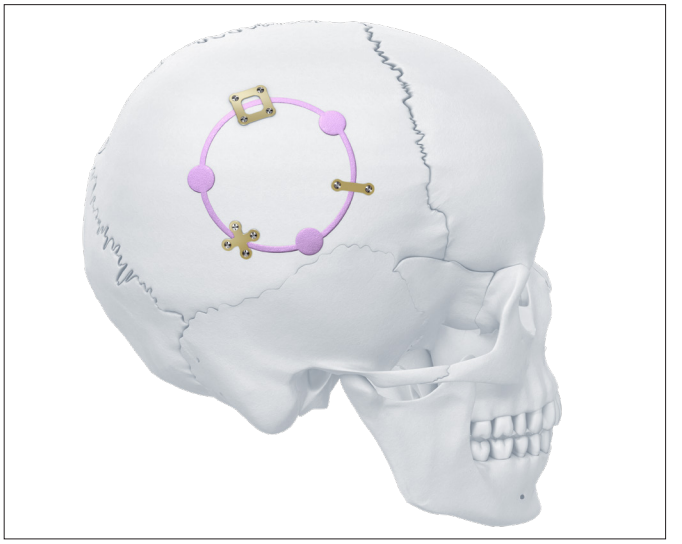
Rotary Mixer Powered Operation

Prepare implant site

Using lavage and/or suction instruments, remove blood clots and tissue debris while controlling active bleeding.

Note: **If bone wax or Gelfoam® is used, it should be removed prior to implanting Cranios Reinforced Rotary Mix.**

Contraindication: **CRANIOS REINFORCED Rotary Mix is not for use in defects greater than 25 cm².**



Note: **The following steps are performed outside the sterile field by a hospital employee.**

1

Connect the power cord

Unwrap the power cord and connect to an appropriate hospital grade outlet. Once connected, the "Standby" indicator will illuminate, indicating that the unit is ready for operation.

Gelfoam is a registered trademark of Pfizer Inc. or its affiliates.

2

Open Rotary Mixer lid

Open the lid by depressing the thumb latch on the right corner of the lid.

3

Position Rotary Pouch

Position the Rotary Pouch on the Mixer by aligning the arrows on the Rotary Pouch and Mixer. Press the Pouch over the center post of the Mixer.

4

Inject solution

Remove the solution syringe from the tray.

Using aseptic technique, remove the cap from the solution syringe by turning the gray silicone cap counter-clockwise.

Using aseptic technique, remove the cap from the Rotary Pouch injection port.

Connect the solution syringe to the injection port by turning clockwise.

Inject the entire contents of the solution syringe. Remove the solution syringe after injection is complete.

Note: Once the solution has been injected into the Rotary Pouch, the remaining steps must be completed immediately.

5

Remove pouch clip

Remove the pouch clip from the Rotary Pouch and unfold the Delivery Syringe to the right of the Rotary Mixer.

6

Close lid and start the Rotary Mixer

Close the lid and secure it by depressing the thumb latch.

Depress the "Start" button. A single brief beep will be heard, the "Standby" indicator will turn off, and the "Mixing" indicator will illuminate.

After 70 revolutions, the mixing cycle is complete. An extended beep will be heard and the "Complete" indicator will slowly flash. The Rotary Mixer will continue to beep every five seconds until the lid is opened.

Note: **If the Rotary Mixer fails to complete the mixing cycle, or the lid is opened before the cycle is complete, an audible alarm will sound and all function indicators will flash. Using a new Rotary Pouch, return to Step 2, or mix using manual operation.**

Rotary Mixer Manual Operation

Note: **The following steps are performed outside the sterile field by a hospital employee.**

1

Initial steps

Follow Steps 2–5 in the Rotary Mixer Powered Operation section.

2

Close the Rotary Mixer lid

Close the lid and secure by depressing the thumb latch.

3

Operate Rotary Mixer manually

To operate the Rotary Mixer manually, lift up on the handle located on the Mixer lid until it locks in the upright position. Rotate the top disk 70 revolutions clockwise (approximately one revolution per second).

Note: **The counter operates on battery power and will advance when rotating the top disk, without the Rotary Mixer plugged in.**

When mixing is complete, lower the handle on the Rotary Mixer lid by pulling it up and pushing the handle to the side.

Preparation TIME

1

Open Rotary Mixer lid

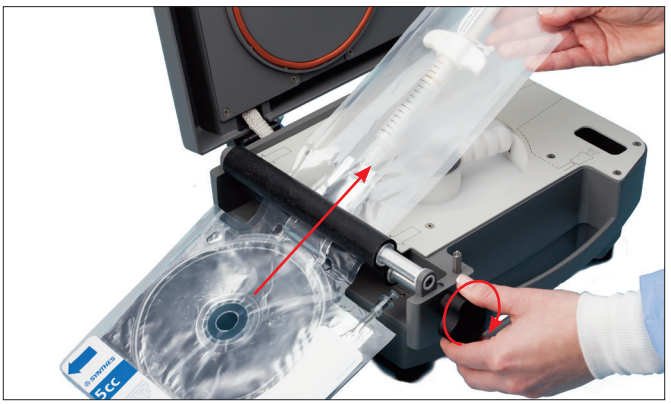
Open the lid and lift the mixed Rotary Pouch from the center post.

2

Transfer paste into Delivery Syringe

Guide the Rotary Pouch and turn the knob counterclockwise to feed the Rotary Pouch into the transfer roller. The material will be expelled from Rotary Pouch into the Delivery Syringe.

Once the material is completely transferred, turn the transfer knob clockwise to remove the Rotary Pouch.

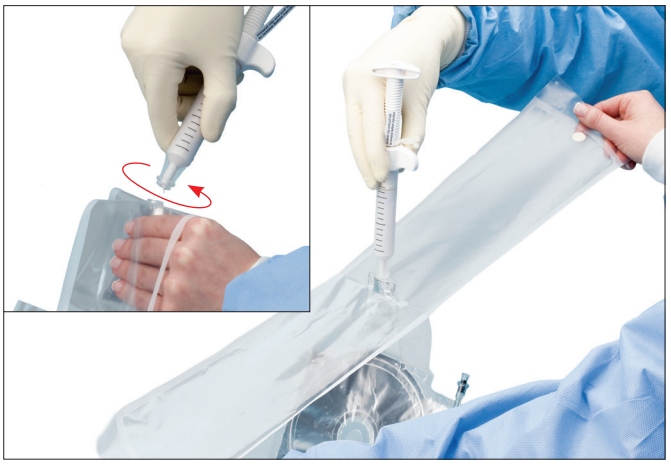


Note: **The following steps are performed inside the sterile field by a hospital employee.**

3

Transfer Delivery Syringe into the sterile field

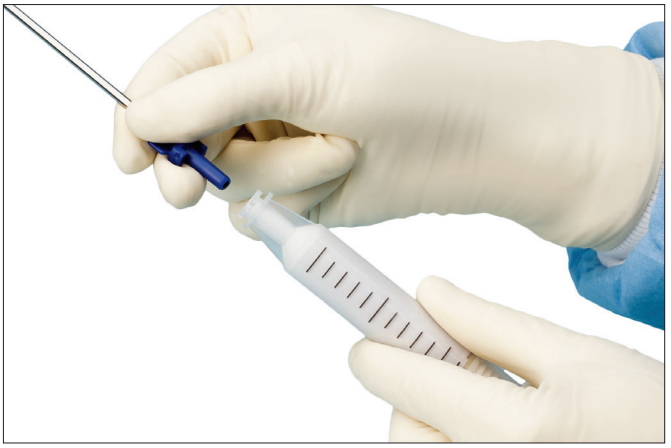
Using aseptic technique, peel back the outer pouch to expose the sterile Delivery Syringe. A sterile person should grasp the handle of the Delivery Syringe and detach the Syringe with one-quarter turn counterclockwise, and complete the transfer to the sterile field.



4

Attach Delivery Needle

Insert a Delivery Needle into the connection port at the tip of the Delivery Syringe and attach by rotating one-quarter turn clockwise to lock in place.

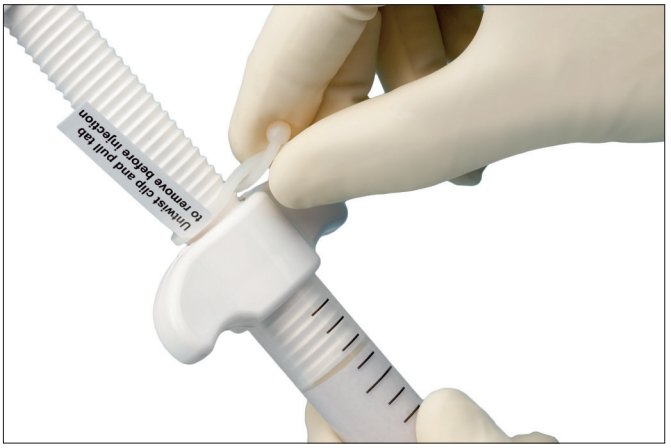


5

Remove clip from plunger

Remove the clip from the plunger. Slowly depress the plunger to evacuate air from the Delivery Syringe barrel until a small amount of paste is ejected.

The material is now ready for implantation.



Implantation Time

6

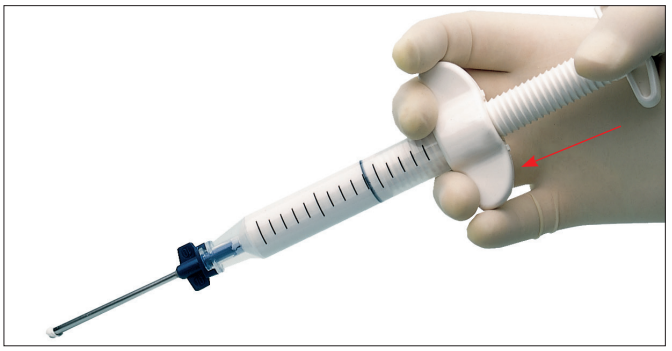
Implant and contour material

Calibration marks on the Delivery Syringe are spaced at 1 cc increments.

Inject the material by 1 of the 2 methods:

1. Standard injection

Slowly push the plunger. Every click corresponds to approximately 0.5 cc of injected material.



2. Injection under resistance

If you encounter resistance to injection before satisfactory defect filling is achieved, additional injection pressure can be applied by slowly turning the plunger knob clockwise. One full rotation of the knob injects 0.5 cc of material.

Note: **At no time during injection should excessive pressure or force be used because this may result in occlusion of the needle or syringe. If resistance is encountered, pull the syringe back slightly and rotate the knob one-half turn counterclockwise to relieve the pressure; then, continue injection.**

7

Implant and contour material continued

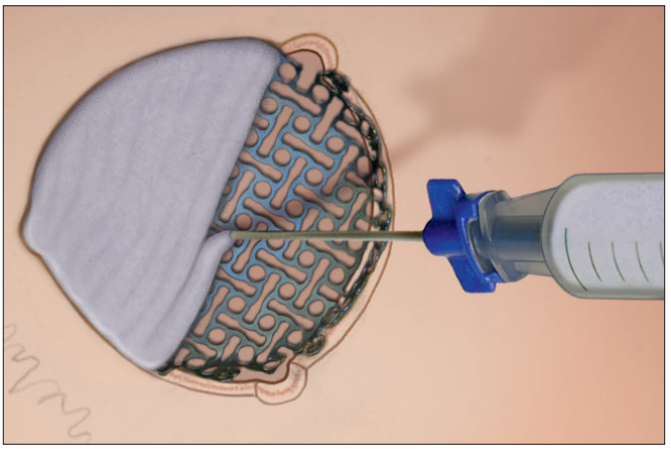
Cranios Reinforced Rotary Mix remains injectable for 2 minutes at room temperature (18°–23°C/64°–73°F). If 2 minutes have elapsed, the remaining material that has not been implanted should be discarded.

Start filling the defect at 1 side and completely fill the void. Remove excess material and move smoothly across the defect. Ensure that the material is completely contained within the defect.

Discard any unused material.

Layering precaution: Layering of Cranios Reinforced Rotary Mix is not recommended. Should additional material be required, apply during the same 2-minute implantation time (see Time and temperature properties, pg 6).

Warning: If the cement is applied against the dura, the use of DePuy Synthes CMF Titanium Mesh is recommended as an underlay to protect the cement from potential microfracture caused by dural pulsation.



Setting Time

8

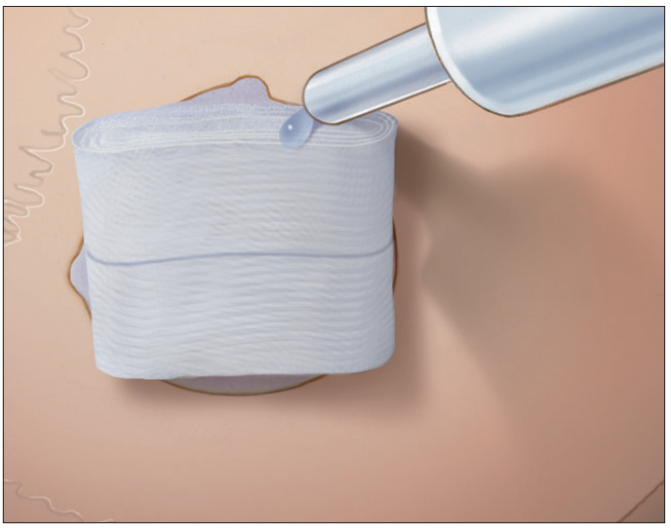
Setting

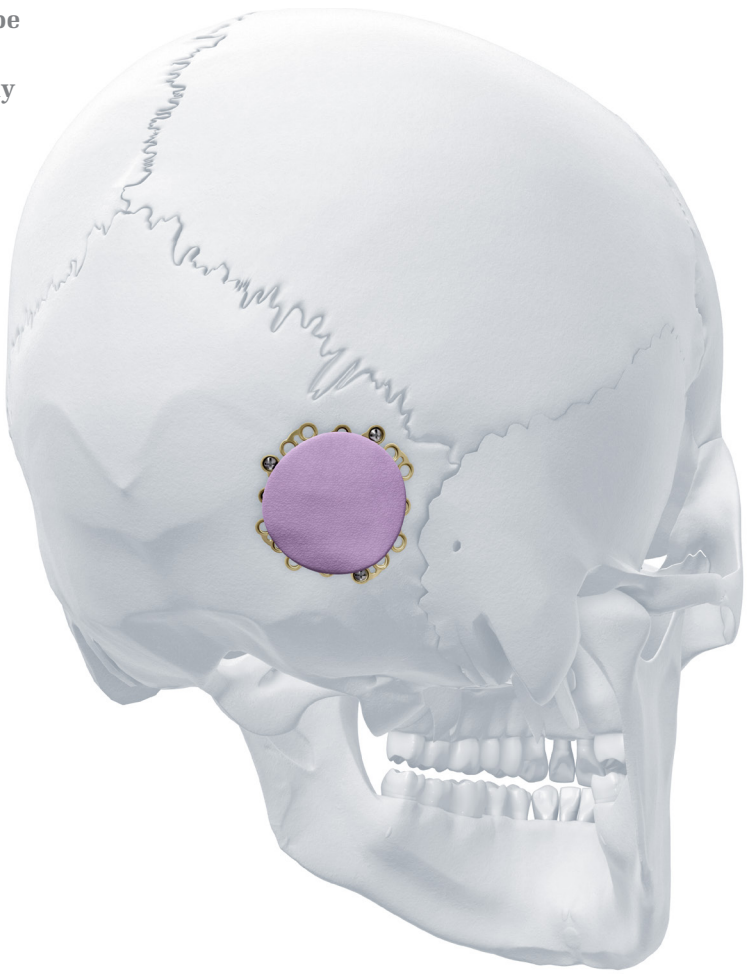
Cranios Reinforced Rotary Mix sets within 10 minutes at normal body temperature (37°C/98.6°F). Once the material begins to harden, it must be left undisturbed to set properly.

CRANIOS REINFORCED Rotary Mix should be kept moist during the setting process. It is recommended to gently cover it with a warm, wet lap sponge and carefully irrigate it with warm saline (approximately 37°C/98.6°F).

CRANIOS REINFORCED Rotary Mix fully cures and reaches its ultimate compressive strength of approximately 35 MPa in 24 hours.

Note: **Once the cement begins to harden it must be left undisturbed to set properly. Additional time maybe required if the operative site is not at body temperature.**





Product Information

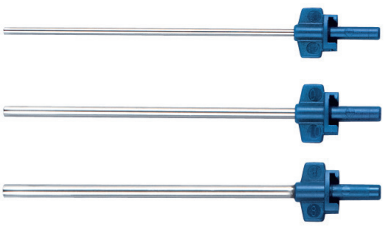
CRANIOS REINFORCED Rotary Mix, sterile

616.03.01S	3 cc (6 grams)
616.05.01S	5 cc (9 grams)
616.10.01S	10 cc (17 grams)

MXR-US-2000 Rotary Mixer

Delivery Needles, sterile

Single Pack	5 Pack	
612.40.01S	n/a	8 gauge X 10 cm
612.41.01S	612.41.05S	10 gauge X 10 cm
612.42.01S	n/a	12 gauge X 10 cm



Also Available:

CRANIOS REINFORCED Fast Set Putty, Sterile

615.03.01S	3 cc
615.05.01S	5 cc
615.10.01S	10 cc

Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuysynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Warnings

- Do not resterilize.
- Do not manipulate site during the 10-minute setting time at body temperature (37°C/98.6°F).
- Do not overfill the defect site.
- Remove excess material in adjacent soft tissue.
- CRANIOS REINFORCED Rotary Mix is provided sterile and is a single use only device. If integrity of the package is compromised, the product must be assumed non-sterile and appropriately discarded. Before disposal of the material, mix according to the Directions For Use to render the contents pH neutral.
- CRANIOS REINFORCED Rotary Mix must be implanted within 5 minutes after mixing. Discard any unused material.
- The safety and effectiveness of CRANIOS REINFORCED Rotary Mix when used in patients having received or to receive chemotherapy or radiation therapy at or near the implant site are not known.
- The safety and effectiveness of CRANIOS REINFORCED Rotary Mix when combined with bone, muscle grafts, dura, fascia, abdominal fat, acrylic, silicone, or polymer are not yet established.
- The safety and effectiveness of CRANIOS REINFORCED Rotary Mix in defects which would result in intradural placement are not yet established.
- The effect of layering CRANIOS REINFORCED Rotary Mix is not known. If more than one package is required to fill a defect, the total volume of CRANIOS REINFORCED Rotary Mix should be implanted within the 2-minute Implantation Time, beginning with the moment that the first unit of CRANIOS REINFORCED Rotary Mix is implanted.
- Do not mix CRANIOS REINFORCED Rotary Mix with any other substance.
- If the cement is applied against the dura, the use of *DePuy Synthes CMF* Titanium Mesh is recommended as an underlay to protect the cement from potential microfracture caused by dural pulsation.
- Mix materials into a homogenous putty prior to implantation.
- Do not use if temperature indicator has been activated (as shown by indicator dot turning black).

Precautions

- The medical professional is responsible for using his/her best medical judgment prior to using this or any other medical device. In particular, familiarity with surgical principles, mixing instructions, instrumentation, injection technique, preparation time and implantation time, setting time, and cure times are required prior to treatment. Prior to mixing CRANIOS REINFORCED Rotary Mix, the surgeon should develop a preoperative plan for augmentation or restoration. This requires understanding the method, sequence, and estimated volume of CRANIOS REINFORCED Rotary Mix to be administered. The plan should be confirmed intraoperatively by direct visualization or under real-time-image intensification.
- The CRANIOS REINFORCED Rotary Mix components should be equilibrated to 18°–23°C / 64°–73°F prior to mixing.
- Due to the radiopacity of the materials, anomalies may not be detected.
- CRANIOS REINFORCED Rotary Mix does not attain a physiological pH until components are mixed, proper eye protection and surgical gloves should be worn during clean-up of the unmixed components or component containers. Seek medical attention if the components are ingested or inhaled. If skin or eye contact occurs, do the following and seek medical attention if irritation occurs:
  - **Skin exposure**: Wash area with soap and water.
  - **Eye exposure**: Flush thoroughly with running water.
- The effect of CRANIOS REINFORCED Rotary Mix on patients with the following indications or conditions is not known:
  - Individuals who will not or cannot follow a prescribed rehabilitation course such as alcohol or drug abusers
  - Defects due to congenital malformation or metabolic disease
  - Documented renal disease
  - Pregnancy / nursing
  - Cardiovascular disease precluding elective surgery
  - Sinus obliteration, fractures or defects of the malar or mental regions, alveolar ridge reconstruction or augmentation, anchoring of endosseous implants, or fracture stabilization and interpositional osteotomy segmental graft
- A successful result is not achieved in every surgical case. If reoperation is required, the device should be removed and the surrounding bone should be re-evaluated to make sure it is still viable.
- In defects equal to or larger than 4 cm^2, closed suction or drainage is recommended to prevent wound fluid accumulation in the immediate postoperative period.
- Excess fluids at the surgical site could result in device malfunction (e.g. washing away of implant material prior to setting).
- When using CRANIOS REINFORCED Rotary Mix, some of the material may extrude into the surrounding soft tissues. The surgeon should minimize extrusion by observing the implantation of CRANIOS REINFORCED Rotary Mix, and remove the extruded cement when possible. The effect of extrusion in cranial applications is not yet established.

Store at room temperature (5°C – 25°C). Avoid excessive heat or humidity. Maximum shipping exposure 43°C.

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.

Some devices listed in this Technique Guide 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

DePuy Synthes

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4528 Zuchwil, Switzerland

To order (USA): 800-523-0322
To order (Canada): 844-243-4321

Note: For recognized manufacturer, refer to the product label.

www.depuysynthes.com

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