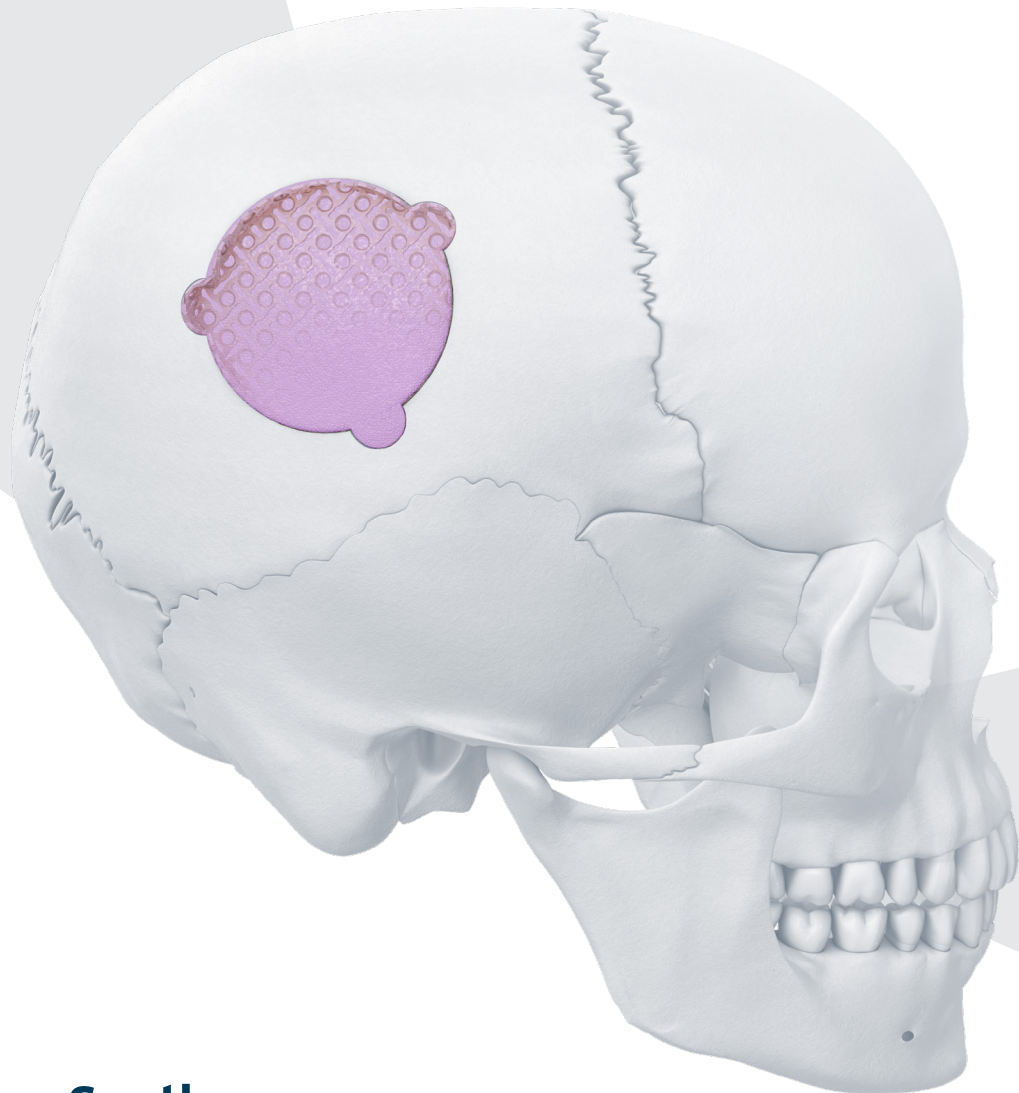


The tougher bone cement

# CRANIOS REINFORCED<sup>®</sup> Fast Set Putty

Surgical Technique





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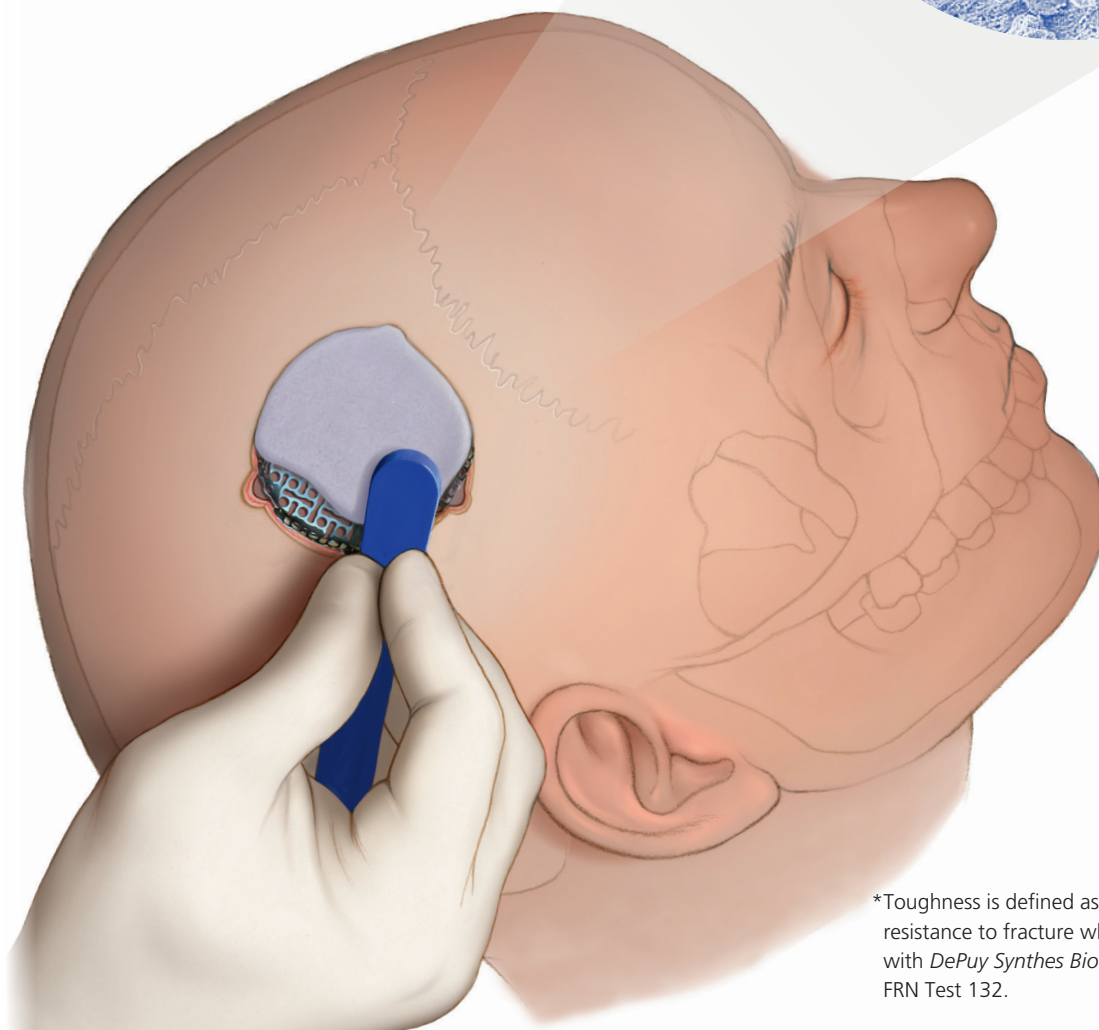
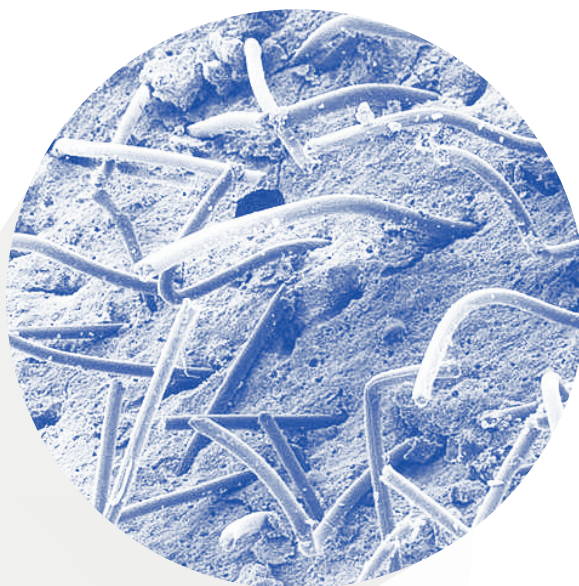
# CRANIOS REINFORCED® Fast Set Putty

The tougher bone cement

CRANIOS REINFORCED Fast Set Putty is a moldable, 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 and handling properties.

CRANIOS REINFORCED Fast Set Putty is easily mixed within the sterile field. It is molded and shaped to fill the defect, 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
Easily shaped and molded	Allows for customization of implant
Sets in a warm, wet environment	Reduced need to limit moisture at the operative site
Isothermic hardening	No thermal injury to surrounding soft tissue
Fast setting time (3-6 minutes)	Minimizes procedure time
Maximum compressive strength of approximately 25 MPa within 24 hours	Compressive strength is 2– 6 times higher than compressive strength of cancellous bone <sup>1</sup>
Resembles mineral phase of bone	Gradual resorption and replacement with bone during the bone healing process

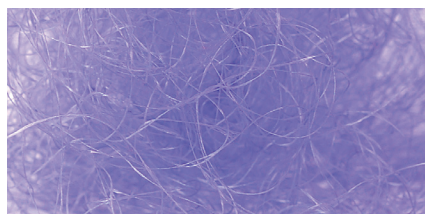
### Calcium phosphate powder



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.<sup>2,3</sup>

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### 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. Cowin SC, ed. *Bone Mechanics Handbook*. 2nd ed. New York, NY: CRC Press, 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 Nov; 85 (11):2127-37. 2003;85-A:2127-2137.  
 3. Chang BS, Lee CK, Hong KS, Youn HJ, Ryu HS, Chung SS, et al. Osteoconduction at porous hydroxy-apatite 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 Fast Set Putty 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 Fast Set Putty has a carbonate content of approximately 4–5%, more closely resembling the mineral phase of bone. The properties of bone and CRANIOS REINFORCED Fast Set Putty are compared in the adjacent table.

Once CRANIOS REINFORCED Fast Set Putty 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 Fast Set Putty

Characteristic	Bone <sup>4</sup>	CRANIOS REINFORCED Fast Set Putty
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)

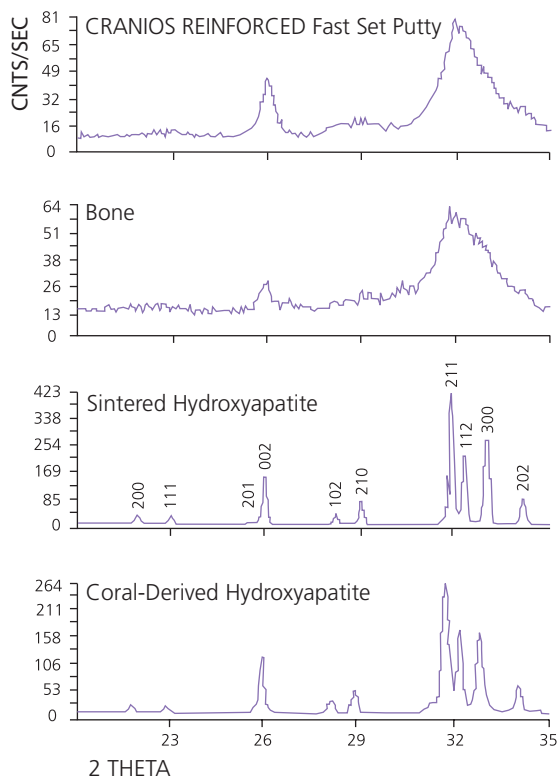


Figure 1

4. Constantz BR, Ison IC, 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.

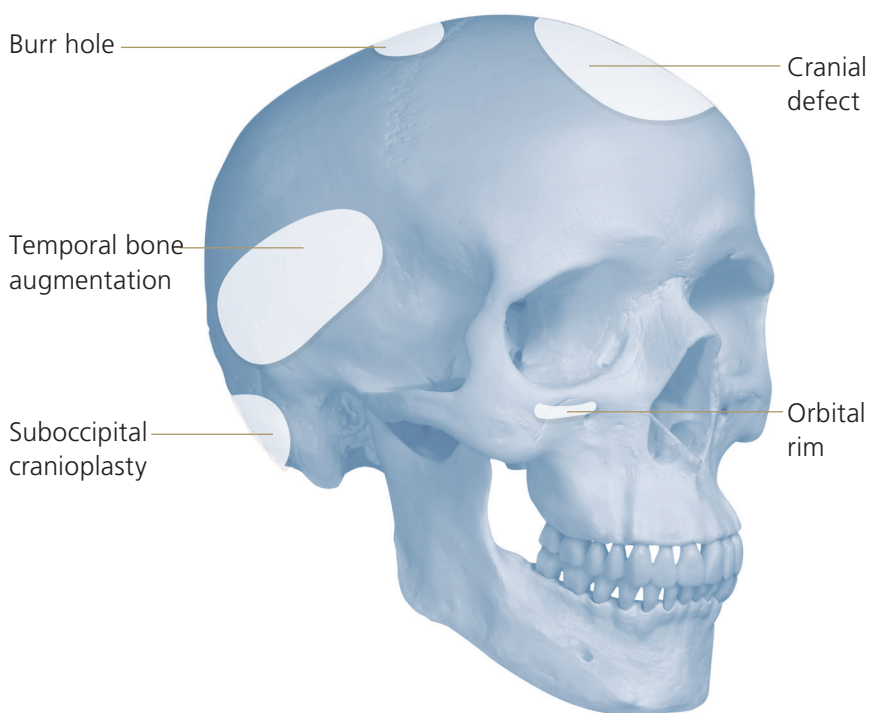


# Indications and Contraindications

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## Indications

CRANIOS REINFORCED Fast Set Putty is indicated for repairing or filling cranial defects and craniotomy cuts with a surface area no larger than 25 cm<sup>2</sup>. CRANIOS REINFORCED Fast Set Putty 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

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## Contraindications

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

CRANIOS REINFORCED Fast Set Putty 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<sup>2</sup>

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

# Timing Sequence

## Time and temperature properties

The handling properties of CRANIOS REINFORCED Fast Set Putty are governed primarily by the mixing technique and ambient temperature of the material as it is prepared and delivered to 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.

Timing sequence	<b>Mixing</b> <b>45–90 seconds</b>	<b>Implantation time</b> <b>2 minutes</b> maximum	<b>Setting time</b> <b>3–6 minutes</b> at body temperature
Temperature	18–23°C / 64°–73°F	37°C / 98.6°F	37°C / 98.6°F
Procedure	<p><b>Mix</b> the contents of the package for 45–90 seconds until a cohesive putty is formed.</p> <p><b>Note: Mixing time is dependent on the size of the package being applied.</b></p>	<p><b>Deliver</b> the material either with the spatula or by hand into the prepared bone void and contour as necessary. Product should only be manipulated during this 2-minute window.</p> <p><b>Layering precaution:</b> <b>If more than 1 pack is required, the total volume of CRANIOS REINFORCED Fast Set Putty should be implanted within the same 2-minute implantation time.</b></p>	<p><b>Irrigate</b> the bone void filler with warm, sterile saline, or place a warm, wet sponge over the implant site to bring the site back to body temperature.</p>

Curing time: 24 hours at body temperature (37°C/98.6°F)  
 CRANIOS REINFORCED Fast Set Putty reaches its full compressive strength of approximately 25 MPa in 24 hours.



# Surgical Technique

## 1

### 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 Fast Set Putty.

**Contraindication:** CRANIOS REINFORCED Fast Set Putty is not for use in defects greater than 25 cm<sup>2</sup>.

## Mixing Time

## 2

### Transfer components to sterile field

Open the outer pouch containing the CRANIOS REINFORCED Fast Set Putty tray and aseptically transfer the tray containing the cup and spatula to the sterile field. Open the outer tray containing the solution and aseptically transfer the inner tray to the sterile field.

**Important:** The trays containing the mixing cup and the solution cannot be stored once the seal on the outer packaging has been removed.



## 3

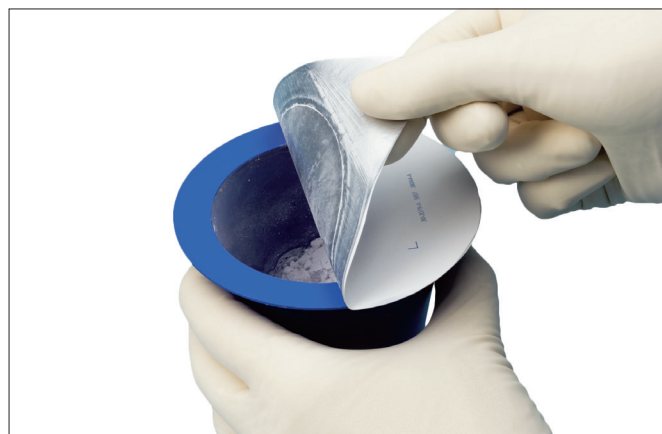
### Prepare components for mixing

When the site is ready for implantation, prepare materials for mixing. Remove the cup, spatula, and solution from the inner trays.

## 4

### Remove the lid of the CRANIOS REINFORCED Fast Set Putty cup

Tap the cup on a hard surface and slowly peel back the lid to expose the powder. Take care not to spill any powder.



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

**5**

**Mix components (45–90 seconds)**

Remove the cap from the solution syringe by turning the gray silicone cap counterclockwise. Carefully deliver the liquid onto the powder in the cup, ensuring that all liquid is expelled from the syringe.

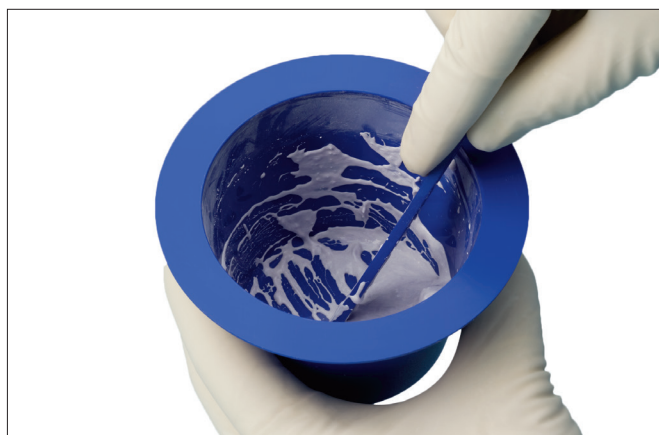
Using the spatula provided, mix the powder and liquid components together for 45–90 seconds, depending on volume. Using a sweeping motion at first, slowly mix the components until the liquid and powder components are incorporated.

Once the powder and solution mimic a putty material, begin to vigorously mix the putty in a circular motion, using the spatula and side of the cup to apply shear force to the material.

At the completion of the mixing period ensure that the components are fully integrated to produce a homogenous putty.

**Notes**

- **The putty will not become smooth until mixing is complete.**
- **During mixing, the initial stage will appear dry and crumbly. Adequate mixing is required (45-90 seconds) to achieve a smooth putty.**



# Implantation Time

## 6

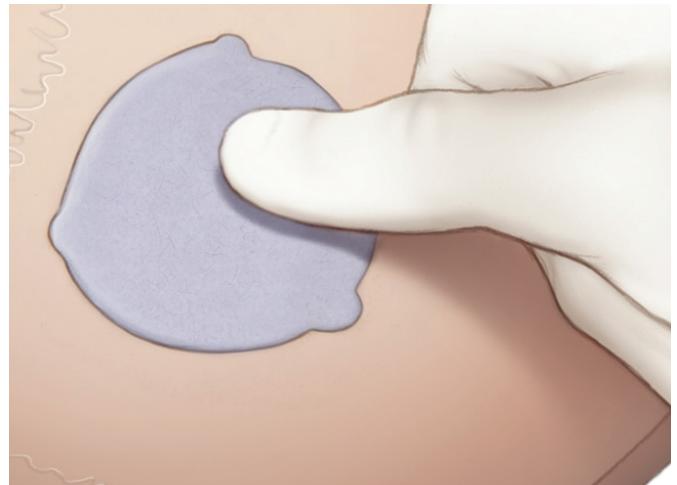
### Implant and contour material

Immediately apply CRANIOS REINFORCED Fast Set Putty to the defect site with the spatula or by hand. Contour the putty manually, using a wet-gloved finger or a surgical instrument.

Complete all contouring within 2 minutes of implantation.

Ensure that the putty is completely contained within the defect.

CRANIOS REINFORCED Fast Set Putty remains moldable for 2 minutes at room temperature (18°–23°C/64°–74°F). If 2 minutes have elapsed, the remaining putty that has not been implanted should be discarded.



### Warnings

- **The effect of layering CRANIOS REINFORCED Fast Set Putty is unknown. If more than one package is required to fill a defect, the total volume of CRANIOS REINFORCED Fast Set Putty should be implanted within the 2-minute Implantation Time, beginning with the moment that the first unit of CRANIOS REINFORCED Fast Set Putty is implanted.**
- **If CRANIOS REINFORCED Fast Set Putty 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

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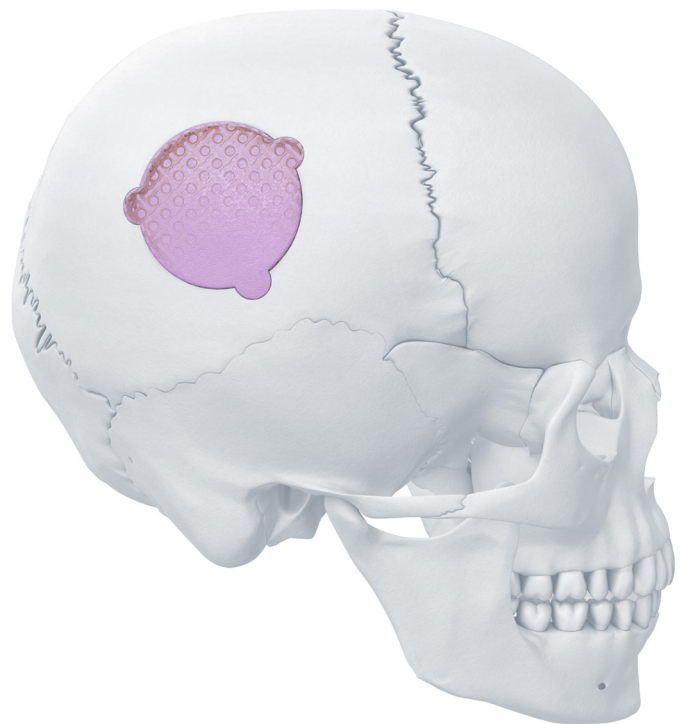
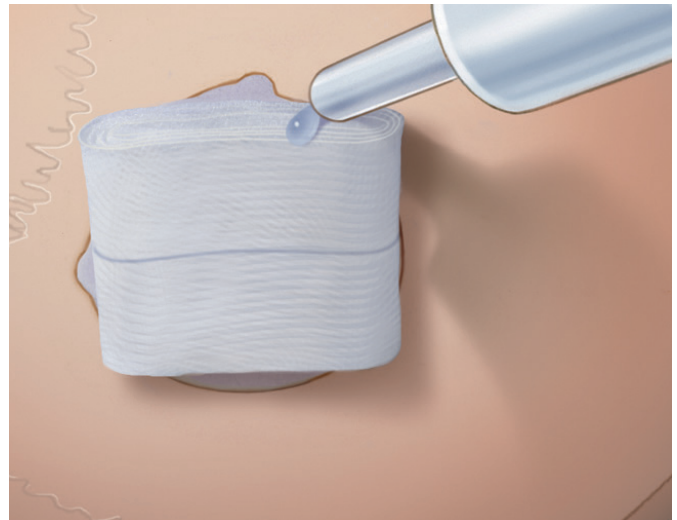
## Setting

CRANIOS REINFORCED Fast Set Putty sets within 3–6 minutes at normal body temperature (37°C/98.6°F). Once the cement begins to harden, it must be left undisturbed to set properly.

CRANIOS REINFORCED Fast Set Putty 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 Fast Set Putty fully cures and reaches its ultimate compressive strength of approximately 25 MPa in 24 hours.

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



# Product Information

CRANIOS REINFORCED Fast Set Putty, sterile

615.03.01S	3 cc (6 grams)
615.05.01S	5 cc (9 grams)
615.10.01S	10 cc (17 grams)



Also Available

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)

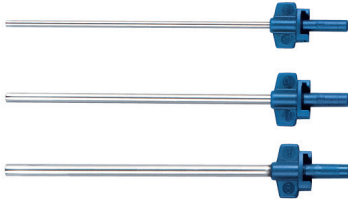


MXR-US-2000 Rotary Mixer



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



# Warnings

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- Do not resterilize.
- Do not manipulate site during the 6-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 Fast Set Putty is provided sterile and is a single use only device. If integrity of the package is compromised, the product must be assumed nonsterile and appropriately discarded. Before disposal of the material, mix according to the Directions For Use to render the contents pH neutral.
- CRANIOS REINFORCED Fast Set Putty must be implanted within 2 minutes after mixing. Discard any unused material.
- The safety and effectiveness of CRANIOS REINFORCED Fast Set Putty 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 Fast Set Putty 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 Fast Set Putty in defects which would result in intradural placement are not yet established.
- The effect of layering CRANIOS REINFORCED Fast Set Putty is not known. If more than one package is required to fill a defect, the total volume of CRANIOS REINFORCED Fast Set Putty should be implanted within the 2-minute Implantation Time, beginning with the moment that the first unit of CRANIOS REINFORCED Fast Set Putty is implanted.
- Do not mix CRANIOS REINFORCED Fast Set Putty 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, implantation time, setting time and cure times are required prior to treatment. Prior to mixing CRANIOS REINFORCED Fast Set Putty, the surgeon should develop a preoperative plan for augmentation or restoration. This requires understanding the method, sequence, and estimated volume of CRANIOS REINFORCED Fast Set Putty to be administered. The plan should be confirmed intraoperatively by direct visualization or under real-time image intensification.
  - The CRANIOS REINFORCED Fast Set Putty 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 Fast Set Putty does not attain a physiological pH until components are mixed. Therefore, 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 Fast Set Putty 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<sup>2</sup>, closed suction or drainage is recommended to prevent wound fluid accumulation in the immediate post-operative 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 Fast Set Putty, some of the material may extrude into the surrounding soft tissues. The surgeon should minimize extrusion by observing the implantation of CRANIOS REINFORCED Fast Set Putty, and removing the extruded cement when possible. The effect of extrusion in cranial applications is not yet established.

Note: For additional information, please refer to the package insert or [www.e-ifu.com](http://www.e-ifu.com).

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

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

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**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.**

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