Norian CRS Fast Set Putty. Calcium phosphate bone cement.

Technique Guide

SYNTHES®

Table of Contents

Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Norian CRS Fast Set Putty. Calcium phosphate bone cement.

Norian Cranial Repair System (CRS) Fast Set Putty is a moldable, biocompatible bone cement that sets at body temperature. It is supplied in two containers:
– a cup containing sterile powder (calcium phosphate)
– a syringe containing sterile solution (dilute sodium phosphate).

When the two components are mixed together, the resultant putty is suitable for augmentation and restoration of the craniofacial skeleton. When fully cured, Norian CRS Fast Set Putty closely resembles the mineral phase of bone and is gradually resorbed and replaced with bone during the healing process.

Norian CRS Fast Set Putty is easily mixed within the sterile field. It is readily molded and shaped to fill the defect and sets in a moist environment.

Common applications include:
– Cranioplasty
– Cranial recontouring
– Cranial flap augmentation
– Augmentation genioplasty
– Skull base defect repair

Features		**Benefits**
Easily shapeable and moldable	→	Implantation into defects positioned at difficult angles
Hardens in a warm, wet environment	→	Reduced need to control moisture at the operative site
Isothermic hardening	→	Eliminate thermal injury to surrounding soft tissue
Fast setting time (3–6 minutes)	→	Minimizes procedure time
Maximum compressive strength of approx. 30 MPa within 24hours	→	Compressive strength is 2–6 times higher than compressive strength of cancellous bone
Resembles mineral phase of bone	→	Gradual resorbtion and replacement with bone during the healing process

Norian CRS Fast Set Putty is a self-setting calcium phosphate bone cement which:

- hardens isothermally in vivo to form carbonated apatite;
- closely resembles the mineral phase of bone;
- achieves a maximum compressive strength of approximately 30 MPa (4,350 psi) within 24 hours;
- gradually resorbs and is replaced with bone during the healing process;
- is isothermic during setting

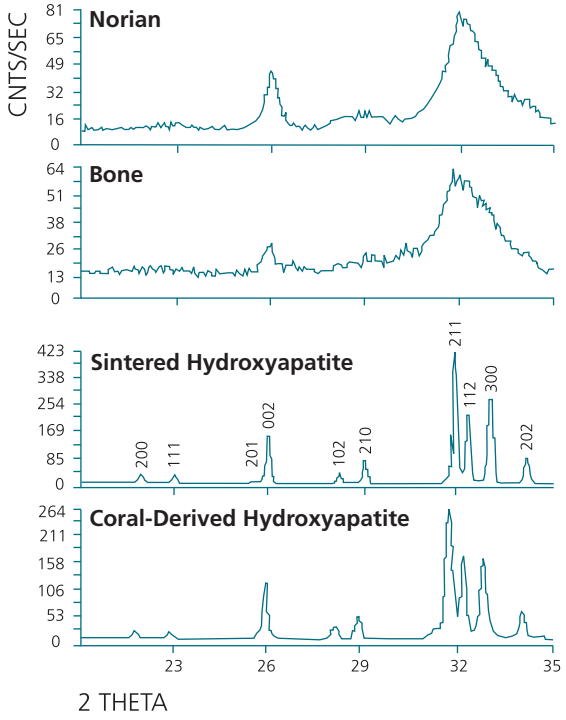
Although hydroxyapatite is commonly thought of as the mineral phase of bone, carbonated apatite actually constitutes 60–70% of total dry bone weight. The main distinction between hydroxyapatite and carbonated apatite is the presence of carbonate. While the carbonate content of hydroxyapatite is 0%, the carbonate content of the carbonated apatite contained in bone is 4–6%. Unlike hydroxyapatite, Norian CRS Fast Set Putty has a carbonate content of 5%, which closely resembles the composition of bone. The properties of bone and Norian CRS Fast Set Putty are compared in Table 1.

Properties of Norian CRS Fast Set Putty vs. Bone[1]

Characteristic	Bone	Norian CRS Fast Set Putty
Carbonate Content	4.0–6.0%	~5.0%
Ca/P Molar Ratio	1.33–1.73	1.67
Crystal Order	Low	Low
Perfect Crystal Size	~200 Å	~200 Å
Chemical Make-up	Inorganic/organic	Inorganic

Table 1

Crystallographic analysis by powder x-ray diffraction (XRD)



[1] B. Constantz, I.C. Ison, M.T. Fulmer, R.D. Poser, S.T. Smith, M. VanWagoner, J. Ross, S.A. Goldstein, J.B. Jupiter and D.I. Rosenthal. "Skeletal Repair by In Situ Formation of the Mineral Phase of Bone." Science 267. 1995. 1796–1799.

Indications and Contraindications

Indications
Norian CRS Fast Set Putty is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm^2. Norian CRS Fast Set Putty is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar and mental areas.

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

Relative Contraindications
The effect of Norian CRS Fast Set Putty is not known in:
- traumatic open injuries which are predisposed to infection
- stress bearing applications, such as the temporo-mandibular 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, vascular or severe neurological disease, infection, immunologic deficiencies)
- patients who have not reached an age at which skull and facial growth is essentially complete

Please see package insert for all necessary information, warnings, complications and precautions.

Timing Sequence

The handling properties of Norian CRS Fast Set Putty are governed primarily by the ambient temperature of the material as it is mixed 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	**Mixing phase** **45–90** seconds depending on vol.	**Working phase** **2** minutes	**Hardening/Setting phase** **3–6** minutes
Temperature	18–23°C	37°C	37°C
Surgical procedure	Mix until both of the components are fully integrated to produce a homegeneous putty	Apply CRS into surgical site Contour CRS	Do not manipulate the material after 2 minutes of contact with body to prevent disruption of the crystallisation process Keep the material moist

Caution: If insufficient amount of cement has been mixed to fill the defect, another pack may be mixed and added during the working phase. However, if the two-minute working phase has elapsed and the cement has hardened, additional material should not be applied.

Curing time, 24 hours
24 hours at body temperature (37°C). Norian CRS Fast Set Putty reaches its full compressive strength in 24 hours.

1

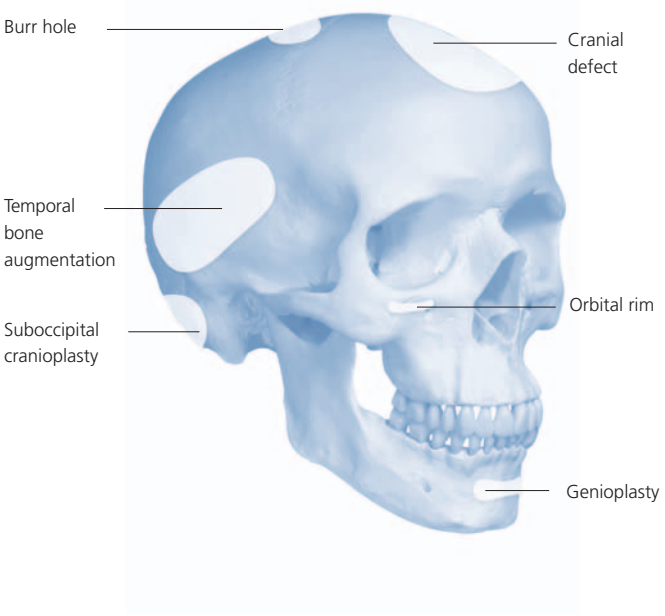
Prepare implant site

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 Norian CRS Fast Set Putty.

Caution: Norian CRS Fast Set Putty is not intended for use in defects with a surface area larger than 25 cm^2.

Indications



2
Mix components

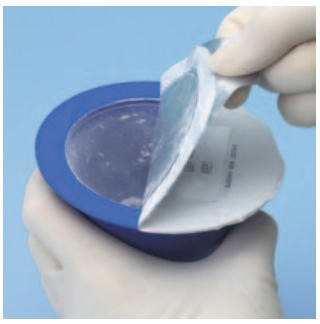
Transfer the tray containing the mixing cup and the tray containing the solution syringe to the sterile field using aseptic technique.

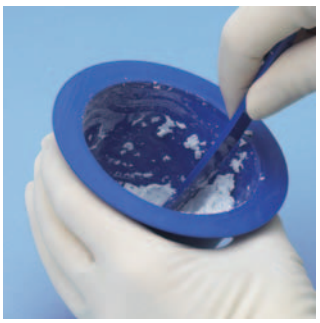
When the site is ready for implantation, prepare materials for mixing.
- Remove the cup containing powder from the tray
- Tap the cup on a hard surface to insure all powder is at the bottom of the cup
- Slowly and gently peel back the lid to expose the powder, making sure not to spill any powder

Caution: The tray and syringe package containing product cannot be stored once the outer pouches have been opened.

- Transfer the syringe foil pouch to the sterile field using aseptic technique.
- Remove the syringe from the foil pouch
- Pull off the silicone syringe cap and unthread the inner cap
- Deliver the liquid onto the powder, ensuring that all liquid is dispensed from the syringe

Using the spatula provided, mix the powder and liquid components together for 45–90 seconds, depending on the volume. Use a sweeping motion along the sides of the cup to incorporate all powder into the mix. Ensure that the components are fully integrated to produce a homogeneous putty.





3
Implant and contour material

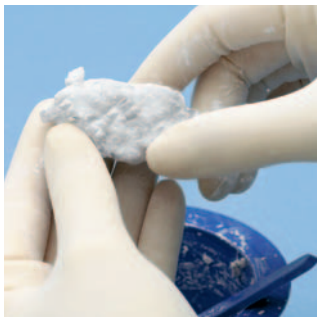
Immediately apply Norian CRS Fast Set Putty to the defect site with the spatula or by hand. Contour the putty manually, using a wet gloved finger or a surgical instrument.

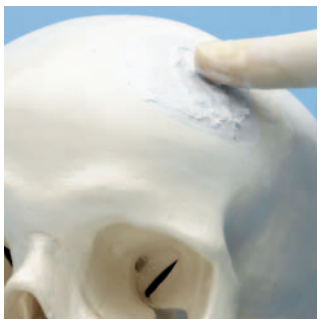
Complete all contouring within two minutes of implantation.

Norian CRS Fast Set Putty remains moldable for 2 minutes at room temperature (18–23°C). If two minutes have elapsed, the remaining putty that has not been implanted should be discarded.

Implantation of the material should be performed under direct visualization or under real-time image intensification.

Completely fill the void. Check the fill with multiple view. Remove excess material.





Caution: Layering of Norian CRS Fast Set Putty is not recommended. Should additional material be required, apply during the 2 minute implantation phase. (see Timing Sequence)

Caution: If Norian CRS Fast Set Putty is applied against the dura, the use of Synthes Titanium mesh is recommended as an underlay to protect the cement from potential micro fracture caused by dural pulsation.

4

Allow Norian CRS Fast Set Putty to harden

The putty will set within 3–6 minutes at normal body temperature (37° C). Once the putty begins to harden, it must be left undisturbed to set properly.

The Norian CRS Fast Set Putty should be kept moist by gently covering it with a wet warm lap sponge and carefully irrigating the cement with warm saline (approximately 37°C) twice per minute. Care should be taken not to disturb the cement. Do not tap the material during setting.

Norian CRS Fast Set Putty fully cures and reaches its ultimate compressive strength in 24 hours.

Technique tips: 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.

Note: Discard any unused material

Norian CRS Fast Set Putty

Norian CRS Fast Set Putty, sterile	
FSP-03-01	3 cc (6 grams)
FSP-05-01	5 cc (9 grams)
FSP-10-01	10 cc (17 grams)
FSP-15-01	15 cc (25 grams)

Manufacturer:
Norian Corporation
A Synthes Company
1230 Wilson Drive
West Chester, PA 19380
USA

EU Authorized Representative:
Synthes GmbH
Im Kirchenhürstle 4–6
D-79224 Umkirch
Germany