Instructions for Use
Norian Reinforced Fast Set Putty (Bone Void Filler)

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

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Jan 16, 2023

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

SE_441873 AD 04/2020

Instructions for Use

Norian Reinforced Fast Set Putty (Bone Void Filler)
CRS-0300-FRP Norian Reinforced Fast Set Putty (Bone Void Filler), 3 cc
CRS-0500-FRP Norian Reinforced Fast Set Putty (Bone Void Filler), 5 cc
CRS-1000-FRP Norian Reinforced Fast Set Putty (Bone Void Filler), 10 cc

Introduction
Norian Reinforced Fast Set Putty (Bone Void Filler) is a moldable bone cement with added reinforcing fibres that sets at body temperature. The addition of reinforcing fibres allows Norian Reinforced Fast Set Putty (Bone Void Filler) to resist cracking during the setting process*.
Norian Reinforced Fast Set Putty (Bone Void Filler) is supplied in two containers; the mixing cup holds powder (calcium phosphate with resorbable polylactide/glycolide co-polymer fibres) and the solution syringe holds sterile solution (dilute sodium phosphate with sodium hyaluronate).
When the powder and solution are mixed together using the provided cup and spatula, the resultant putty material is suitable for restoration of the craniofacial skeleton.
At body temperature (37 °C), Norian Reinforced Fast Set Putty (Bone Void Filler) begins to harden after two minutes and sets in approximately six minutes. When fully cured, the calcium phosphate phase of the composition formed closely approximates the mineral phase of bone. Norian Reinforced Fast Set Putty (Bone Void Filler) is slowly resorbed and replaced with bone during the healing process.
Important note for medical professionals and OR staff: Please read the instructions for use, the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical technique procedure.

* Data on file at DePuy Synthes (FRN Test #103 and FRN Test #82). Bench test results may not necessarily be indicative of clinical performance.

Material(s)

Material(s):	Standard(s):
Carbonated Apatite ($Ca_5(PO_4)_3OH$) with 2 % poly(L-lactide-co-glycolide) Fibres and 0.2 % Sodium Hyaluronate	N/A

Intended use
Norian Reinforced Fast Set Putty (Bone Void Filler) is intended for repairing and restoration of the craniofacial skeleton.

Indications
Norian Reinforced Fast Set Putty (Bone Void Filler) is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm^2. Norian Reinforced Fast Set Putty (Bone Void Filler) is also indicated for the restoration of bony contours of the craniofacial skeleton including the fronto-orbital area.

Contraindications
Norian Reinforced Fast Set Putty (Bone Void Filler) is contraindicated for use in spinal applications. Norian Reinforced Fast Set Putty (Bone Void Filler) should not be used in the presence of active or suspected infection.

Norian Reinforced Fast Set Putty (Bone Void Filler) is not for use in:
- Patients with traumatic open injuries that are predisposed to infection
- Stress bearing applications, such as the temporomandibular joint or anchoring of endosseous implants
- 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
- Sinus obliteration

Intended User
This device is intended to be used by qualified health care professionals e.g. CMF and neuro-surgeons, OR staff, and professionals involved in preparation of the device. All personnel handling the device should be fully aware of the intended use of the products, the applicable surgical procedure and the Synthes "Important Information" brochure.

Performance Characteristics of the Device
Synthes has established the performance and safety of all variants of Norian Reinforced Fast Set Putty (Bone Void Filler), and that they represent state of the art medical devices for the restoration of bony contours of the craniofacial skeleton including the fronto-orbital area, when used according to their instructions for use and labeling.

Potential Side Effects
- Pain
- Systemic infection/Sepsis
- Damage to vital organs/surrounding structures
- Malunion/Non-union
- 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; and foreign body reactions.

Possible general complications caused by invasive surgery including:
- Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.)
- Thrombosis, embolism or injury of other critical structures including blood vessels
- Neurovascular injuries caused by surgical trauma
- Excessive bleeding
- Allergic reactions
- Inflammatory reactions
- Infections can lead to failure of the procedure
- Damage to soft tissues including swelling
- Abnormal scar formation
- Functional impairment of the musculoskeletal system, pain

Sterile device

STERILE R — Sterilized using gamma-irradiation (Norian Reinforced Powder Component).

STERILE A — Sterilized using aseptic techniques (Norian Reinforced Solution Component).

STERILE EO — Sterilized using ethylene oxide (Outer Surface of the Solution Syringe only).

- Norian Reinforced Fast Set Putty (Bone Void Filler) is supplied sterile.
- 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 if the sterile barrier has been compromised. When removing the implant from its packaging, strictly observe the instruction concerning asepsis.

Do not resterilize

- This product is intended for single use and must not be re-used. Re-use or reprocessing (e.g. cleaning and/or re-sterilization) may compromise the sterility or integrity of the device which may lead to infection, device failure and/or contamination.

Single-use device

Do not re-use

- This product is intended for single use and must not be re-used. Re-use or reprocessing (e.g. cleaning and/or re-sterilization) may compromise the sterility or integrity of the device which may lead to infection, device failure and/or contamination.
- The contents of an opened or damaged outer protective packaging may no longer be used and must be destroyed.
- Once the packaging has been opened, the content must be used immediately. Any unused parts, fragments or modified parts must be discarded in an approved biohazard waste container.
- Do not use after the expiry date.

Warnings and Precautions
- Norian Reinforced Fast Set Putty (Bone Void Filler) must not be used in combination with hydrophilic materials.
- Familiarity with the use of bone substitutes for filling defects in bone, and the use of Norian Reinforced Fast Set Putty (Bone Void Filler) are required prior to treatment.
- The size or nature of the void or defect may require more than one package. If so, the total volume of Norian Reinforced Fast Set Putty (Bone Void Filler) implanted in that void or defect must be implanted within the two-minute period commencing at the moment when the Norian Reinforced Fast Set Putty (Bone Void Filler) from the first package begins to be implanted. Disturbing the first Norian Reinforced Fast Set Putty (Bone Void Filler) implanted after that two-minute period may damage the construct.
- Due to the radiopacity of the materials, anomalies may not be detected.
- Norian Reinforced Fast Set Putty (Bone Void Filler) attains a physiological pH after components are mixed, but the mixing cup, spatula and syringe components may be independent irritants. Proper eye protection and surgical gloves should be worn when cleaning up the components. 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: Rinse thoroughly with running water.
- Unused Norian Reinforced Fast Set Putty (Bone Void Filler) should be discarded. Before disposal of the material, mix according to the Instructions for Use to render the contents pH neutral.
- Norian Reinforced Fast Set Putty (Bone Void Filler) should be implanted within two minutes after mixing.
- The effect of layering Norian Reinforced Fast Set Putty (Bone Void Filler) is not known.
- Mix materials into a homogeneous putty prior to implantation.
- Remove excess material in adjacent soft tissue.
- 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 post-operative period.
- Excess fluids at the surgical site could result in device malfunction (e.g. washing away prior to setting).
- When using Norian Reinforced Fast Set Putty (Bone Void Filler), some of the material may extrude into the surrounding soft tissues. The surgeon should minimize extrusion by observing the implantation of Norian Reinforced Fast Set Putty (Bone Void Filler) and remove the extruded cement when possible. The effect of extrusion in craniofacial applications is not yet established.
- Norian Reinforced Fast Set Putty (Bone Void Filler) components should be equilibrated to 18 °C – 23 °C prior to mixing.
- Do not manipulate site during the six-minute setting time at body temperature (37 °C).
- Do not overfill the defect site.
- Do not mix Norian Reinforced Fast Set Putty (Bone Void Filler) with any other substance.
- Do not drill Norian Reinforced Fast Set Putty (Bone Void Filler) during surgery.
- Do not attempt to re-sterilize the unused contents of an opened pack but dispose of such remnants.
- Re-sterilising of Norian Reinforced Fast Set Putty (Bone Void Filler) can result in product not being sterile, and/or not meeting mechanical properties.

Adjunct mechanical support (i.e. fixators such as Synthes titanium mesh devices) may be used at the surgeon's discretion to provide additional support and protection against possible reinjury. Please refer to corresponding device's specific instructions for use for comprehensive indications, contraindications, warnings and precautions.
The effect of Norian Reinforced Fast Set Putty (Bone Void Filler) on patients with the following indications or conditions is not known:
- Individuals who will not or cannot follow a prescribed rehabilitation course such as with alcohol or drug abusers
- Defects due to congenital malformation
- Documented renal disease
- Alveolar ridge reconstruction or augmentation
- Interpositional osteotomy segmental graft
- Pregnancy/nursing
- Cardiovascular disease precluding elective surgery
- Fractures or defects of the malar or mental regions, alveolar ridge re-construction or augmentation, anchoring of endosseous implants, or fracture stabilization and interpositional osteotomy segmental graft
- In patients having received or scheduled to receive chemotherapy or radiation therapy at or near the implant site
- When combined with bone, muscle grafts, dura, fascia, abdominal fat, acrylic, silicone, or polymer not supplied as part of the Norian Reinforced Fast Set Putty (Bone Void Filler) implant
- Intradural placement

Magnetic Resonance (MR) Environment
Norian Reinforced Fast Set Putty (Bone Void Filler) is of non-metallic inorganic 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.
Surgeons have the discretion to use Norian Reinforced Fast Set Putty (Bone Void Filler) in combination with adjunct mechanical support (i.e. fixators such as Synthes titanium mesh devices). In these clinical situations, please refer to the corresponding device's labelling for additional instructions or information essential to safe use in the MR environment.

Handling/Special Operating Instructions
The Norian Reinforced Fast Set Putty (Bone Void Filler) is supplied sterile and non-pyrogenic. Remove products from the package in an aseptic manner.
Norian Reinforced Fast Set Putty (Bone Void Filler) is provided in two components; the mixing cup holds the sterile powder component. The aseptic filtered solution component is in solution syringes ("Solution Syringe").
Do not open the package until ready to use. Examine the package for damage before using the sterile bone substitute, as damage might impair sterility. Do not attempt to re-sterilise the unused contents of an opened package, but dispose of it. This applies to both the inner primary and the outer secondary package.
Do not use Norian Reinforced Fast Set Putty (Bone Void Filler) after expiration of the use-by date printed on the package.
Before using Norian Reinforced Fast Set Putty (Bone Void Filler) the surgeon should develop a preoperative plan. This requires understanding the method, sequences, and estimated volume of Norian Reinforced Fast Set Putty (Bone Void Filler) needed to fill the void.

Prepare Implant Site
- Remove blood clots and tissue debris; lavage and/or suction instruments may be used. Control active bleeding.
- Prepare the void by compacting the cancellous bone with a curette elevator or similar instrument.

If bone wax or gelfoam is used, it should be removed prior to implanting Norian Reinforced Fast Set Putty (Bone Void Filler).

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

Important: The tray containing product cannot be stored once the outer pouch has been opened.
Important: Norian Reinforced Fast Set Putty (Bone Void Filler) kit should be equilibrated to 18 °C – 23 °C.

- When the site is ready for implantation, prepare materials for mixing. Remove the cup from the tray, tap the cup on a hard surface and slowly peel back the lid to expose the powder. Take care not to spill any powder.
- Remove the syringe from the tray and deliver the liquid onto the powder, ensuring that all liquid is removed from the syringe.
- Using the spatula provided, mix the powder and liquid components together for 45–90 seconds, depending on volume. Use a sweeping motion along the side of the cup to incorporate all powder into the mix. Ensure that the components are fully integrated to produce homogenous putty.

Implant and contour material
- Immediately apply the putty to the defect site using the spatula or by hand. Contour the putty manually, using a wet gloved finger or surgical instrument.
- Complete all contouring within two minutes of implantation.
- Norian Reinforced Fast Set Putty Bone Void Filler remains moldable for 2 minutes at room temperature (18 °C – 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.

Surgeons have the discretion to use Norian Reinforced Fast Set Putty (Bone Void Filler) in combination with adjunct mechanical support (i.e. fixators such as Synthes titanium mesh devices). In these clinical situations, please refer to the corresponding device's labelling for comprehensive indications, contraindications, warnings and precautions.

Allow Fast Set Putty to harden
The fast set putty will set within six minutes at normal body temperature, 37 °C. Drip irrigate with warm water during the six-minute setting period. Once the cement begins to harden, it must be left undisturbed to avoid cracking and/or crumbling.
Norian Reinforced Fast Set Putty Bone Void Filler remains moldable for 2 minutes at room temperature (18 °C – 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.

Discard any unused material

Cure Time
24 hours at body temperature, 37 °C: Norian Reinforced Fast Set Putty (Bone Void Filler) reaches its ultimate compressive strength by 24 hours.

Implant Removal
Norian Reinforced Fast Set Putty (Bone Void Filler) is for permanent implantation and not intended for removal once implanted.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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.
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Device Related Storage and Handling Information
Keep the sterile bone substitute in its protective package in a dry place at 5 °C – 25 °C. Exposure during transit may exceed this range.

Temperature limitation


Keep dry


Keep away from sunlight

Additional Instructions for Use
For additional information, please contact your local Synthes representative.

Interpretation of Symbols

Reference Number

Lot or Batch Number


Manufacturer


Expiration Date


Do not use when packaging is damaged

Sterile

Notified Body

Not all products are currently available in all markets.

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.jnjmedicaldevices.com