stryker®

REF 3cc, 79-45903
REF 5cc, 79-45905
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DirectInject
Instructions for Use

STERILE R

Rx Only

CE 0197


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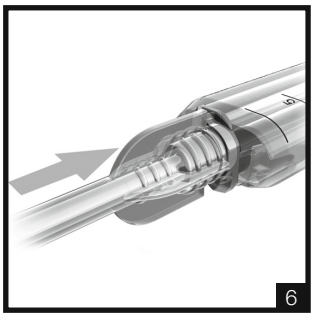
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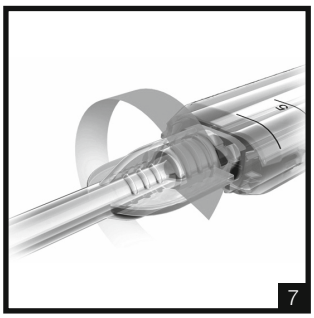
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Kit description

1. Delivery Syringe, containing two pastes
2. Mixer-Cannula; the blister includes two items
3. Spatula

Product Description

DirectInject consists of a sterile dual paste system which is calcium phosphate based. Upon injection through the Mixer-Cannula, the two pastes form a cement paste which is moldable.
The injected cement paste will harden under normal body conditions to form hydroxyapatite.
DirectInject is provided pre-filled in a double barrel Delivery Syringe system. The Delivery Syringe, prefilled with two pastes, is presented within a double blister tray along with two Mixer-Cannulae and a Spatula. When the Delivery Syringe system is assembled, the pastes are injected through a Mixer-Cannula which forms a homogenous blend of the two pastes, referred to as the "cement". A second Mixer-Cannula is provided for use when delays in surgery prevent full use of the product during the first injection period. The user replaces the Mixer-Cannula and can resume injecting the remaining cement from the syringe for additional defect sites. The contents of the sealed outer blister are supplied sterile for single patient use.

Intended Use/ Indications for Use

DirectInject is a self-setting, calcium phosphate cement intended to repair neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects not intrinsic to the stability of the bony structure. It is also intended for augmentation or restoration of bony contour in the craniofacial skeleton to include the cranial and zygomatic bones.
DirectInject is intended to repair cranial defects with a surface area of 4cm² or less. DirectInject is indicated for patients in whom skeletal growth is complete. It can be used in patients with surgically created bone defects.

Contraindications

DirectInject is not designed or sold for any use except as indicated. Do not use DirectInject in the presence of any contraindication. Contraindications include but are not limited to:

- Use in Vertebroplasty or Kyphoplasty.
- Use in load bearing applications, such as mandibular segment replacement.
- Use in a currently infected field or surgical site near an infection.
- Use in areas where surrounding bone is avascular or is incapable of supporting or anchoring the implant.
- Use in patients with the following: abnormal calcium metabolism, impaired kidney and liver function, metabolic bone disease, a recent untreated infection, immunologic abnormalities and systemic disorders which result in poor wound healing or will result in tissue deterioration over the implant site.
- Use in patients who have not reached an age at which skeletal system growth is essentially complete.
- Use in patients with acute traumatic injuries with open wounds near the defect that are likely to become infected.
- Use in patients with open fractures.
- Use in patients with fractures or voids that link joint spaces and/or articulating surfaces.

Possible Adverse Effects

The occurrence of any of the following complications is possible and may require reoperation and/or removal of the implant. Complications may include but are not limited to:

- Tissue thinning over implant site
- Tenderness, redness, edema
- Seroma, hematoma or infection
- Swelling, fluid collection
- Loss of contour
- Implant fracture, migration

Precautions

- Only use a fully functional product. If a defect is confirmed or suspected, do not use the product and return to the manufacturer.
- Always have a second product available within easy reach to be able to complete the initial surgical procedure safely in case of an unexpected product failure during operation.
- If a product is to be returned, contact the Stryker facility from which it was received.
- Ensure that you store and operate DirectInject according to the specifications listed in this manual.
- DirectInject is provided sterile and should be considered sterile unless the outer blister has been opened or damaged. Do not use if there is loss of sterility of DirectInject.
- The safety and effectiveness of the cement when combined with bone grafts, muscle grafts, dura fascia or dura synthetic substitutes, abdominal fat, acrylic, silicone or Dacron is not yet established. Dacron is a registered trademark of E.I. du Pont de Nemours.
- Only use the provided cannulae when using DirectInject. Use of nonstandard cannulae may result in insufficiently mixed cement, which may lead to undesirable DirectInject properties.
- DirectInject is a temperature sensitive product. Do not expose DirectInject to temperatures greater than 44 °C.
- Do not use opened or expired products.

Preoperative Warnings

- Aseptic handling techniques are required during all phases of device handling. Implant the cement only in a sterile field.
- Only experienced healthcare professionals fully trained in the safe and effective use of the product are allowed to use it in a sterile operating room environment. Failure to follow these instructions will void your warranty.
- DirectInject is single use only. The device must be used only once. Reuse may lead to diminished safety, performance, and/ or compliance with relevant specifications. Do not attempt to re-sterilize or use leftover material. Failure to comply may result in infection.

- The effects of preparing DirectInject with any other substance, including antibiotics and blood, are not known.
- DirectInject should only be used in accordance with the instructions for use contained in this manual.
- Surgeons should counsel patients regarding potential adverse effects.
- Before using this product or any component compatible with this product, read and understand all supplied instructions for use. Pay special attention to warning information, intended uses, indications, contraindications, compatibility and correct handling of the implant, instruments and accessories.

Intraoperative Warnings

- Do not mix DirectInject with any other substance or drug, such as antibiotics, serum or blood. Potential side effects are not known and could put the health of the patient at risk.
- Avoid over-pressurizing the defect site when applying the cement as this may lead to extrusion of the cement beyond the site of its intended application and damage to the surrounding tissues.
- Remove gel foam and bone wax prior to implantation.
- Placement over inadequate or non vascularized tissues or allograft material may put the health of the patient at risk.
- The safety and effectiveness of the cement in defects that would result in subdural placement is not known. Brain pulsations may cause DirectInject to crack.
- Do not manipulate site during intraoperative set time.
- Avoid fixation of hardware into the cement as this may lead to cement cracking or chipping.
- The cement can only be used after the pastes have passed through the Mixer-Cannula.
- Ensure that the cement is set at the defect site before closing.
- When closing the defect, do not disrupt the cement setting and stability of the implant.
- Suction drainage of accumulated fluid in the surrounding area is recommended prior to placement of the cement.
- Meticulously remove all mucosa where contact is expected between the cement and mucosa within the sinus cavities.
- Avoid over-pressurizing the defect site when applying the cement as this may lead to fat embolization or embolization of the cement material into the bloodstream.
- Avoid contact of the cement with the skin or the eyes. In case of contact refer to the MSDS (Material Safety Data Sheet, supplied by the manufacturer upon request).
- Use caution when irrigating the defect site. Over irrigating the defect site could cause the cement to washout or lose dimensional stability during the setting period.
- Avoid over-pressurizing the syringe when applying the cement as this may lead to failure of the product and resulting interruption of the procedure.
- Avoid extended working time as the fast setting nature of the cement could impart undesirable shaping or defect filling characteristics.
- The effects of DirectInject on patients with the following conditions are not known:
  - ♦ Documented renal disease
  - ♦ Metabolic bone disease
  - ♦ Pregnancy/nursing
  - ♦ Defects due to disease or congenital malformation
  - ♦ Cardiovascular disease precluding elective surgery
  - ♦ Infection during the last three months and/or a history of chronic infection.

  DirectInject should not be used in these instances, as it may pose a risk to patients.
- Do not overfill the defect site with excessive amounts of the DirectInject material, as it may result in undesirable effects to the healing progress, the final result of the procedure or the health of the patient.

Postoperative Warnings

- The surgeon must instruct the patient about post operative behavior.
- The safety and effectiveness of DirectInject is not known when used in patients who have undergone or who are to undergo radiation therapy at or near the implant site.
- Successful results may not be achieved in every surgical case. If additional surgery is required, the cement should be removed and the surrounding bone should be re-evaluated to ensure that it is still viable.

MR MRI Safety Information

The DirectInject is MR Safe.

NOTE

The DirectInject delivery system is MR Unsafe. Do not bring the DirectInject delivery system into the MR environment.

Use of Original Products

Implants and instruments are produced and designed to be used together. The use of products from other manufacturers along with Stryker products can involve incalculable risks and/or contamination of the material and misalignments of implant to instrument, thereby endangering the patient, user or third parties.

Instructions

NOTE

The product is temperature sensitive. Ideal product and operating room temperature ranges from 15 °C – 25 °C (59 °F – 77 °F). Use of DirectInject below this temperature will result in a softer cement and longer set time. Use of DirectInject above this temperature will result in a stiffer cement, reduced sculpting time and shorter set time.

1. Unpack the DirectInject Components

1.1. Check the packaging and the DirectInject for damage prior to use/surgery.

1.2. Peel back the outer blister lid. Remove the inner blister and transfer to sterile field.

1.3. Peel back and dispose of the sterile inner blister lid.

1.4. Remove the Delivery Syringe and one Mixer-Cannula from the inner blister.

2. Attach the Mixer-Cannula

NOTE

Do not push the plunger attached to the Delivery Syringe when you remove the Transit Cap.

NOTE

Do not dispose of the inner blister kit containing the additional Mixer-Cannula and Spatula until the surgical procedure is complete.

2.1. Remove the Transit Cap: rotate by 90° in a counterclockwise direction, then pull away from Delivery Syringe and dispose. Shown in Figure 4, cover page.

2.2. Attach the Mixer-Cannula to the end of the Delivery Syringe. Attach the Mixer-Cannula connection with the Delivery Syringe connection points. Shown in Figure 5, cover page.

2.3. Press the Mixer-Cannula into position. Shown in Figure 6, cover page.

2.4. Rotate the Mixer-Cannula by 90° in a clockwise direction to lock into position. Shown in Figure 7, cover page.

3. Injection

CAUTION

The cement can only be used after passing through the Mixer-Cannula. Do not inject the pastes through the Mixer-Cannula until ready for injection into the void.

NOTE

If the injection of the cement is not possible, remove the Mixer-Cannula and proceed from step 2.2 with another Mixer-Cannula.

3.1. The Delivery Syringe is now ready for use. Shown in Figure 8, cover page.

4. Implantation

NOTE

Prior to injection, control active bleeding at the implant site.

4.1. Use the Delivery Syringe to inject and implant the cement.

NOTE

If the volume of DirectInject contained in one syringe is insufficient to fill the defect completely, it is possible to apply the contents of further syringes into the partially filled defect. The time period between these applications should, however, not exceed 2 minutes, in order to avoid separation of subsequent applications.

4.2. Sculpt the cement with the Spatula provided.

5. Set time

CAUTION

Do not disturb the cement (over the 10 minutes of setting time) once it begins to harden.

5.1. Allow cement to set undisturbed.

5.2. The cement is fully set by 10 minutes after application.

Technical Specifications

Material:
Stainless steel, plastic

Storage: 

Warranty

Suitability for use of the medical device or any surgical procedure shall be determined by the health care provider. The manufacturer shall not be liable for incidental or consequential damages of any kind.

Overview of the DirectInject timeline

When the operating room temperatures are 15 °C – 25 °C (59 °F – 77 °F):

No.	Action	Total elapsed time	Total duration time of step
1	Injection complete	0	0
2	Sculpting cement	0 sec - 2 min 30 sec	2 min 30 sec
3	Setting time	2 min 30 sec - 10 min	7 min 30 sec

Symbol Definition

Symbol	Definition
	This is the general warning sign. It is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm.
	Date of Manufacture
	Manufacturer
	Do not reuse
	Do not resterilize
STERILE R	Sterilization by radiation
Rx Only	Federal law in the USA restricts this device to sale by or on order of a physician.
	Do not use if package is damaged.
	Use by date
LOT	Batch code
	Consult instructions for use
	Temperature limitation
REF	Catalogue number
HA	Hydroxyapatite
MR	MR Safe
CE	Conformity with Annex I of Medical Device Directive 93/42/EEC
	Discard device if dot turned black. A black dot indicates that the storage temperature has been exceeded and therefore the device may be damaged.

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