

stryker®

DirectInject™

Stryker CMF

Craniomaxillofacial



Operative Technique



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 is designed to 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 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.

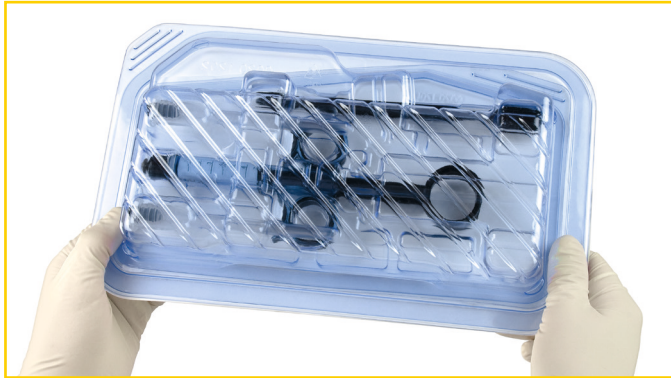
Important Information

The materials contained in this booklet have been provided for general education information purposes only. The information contained in this booklet cannot and should not replace the independent medical judgement of the treating physician.

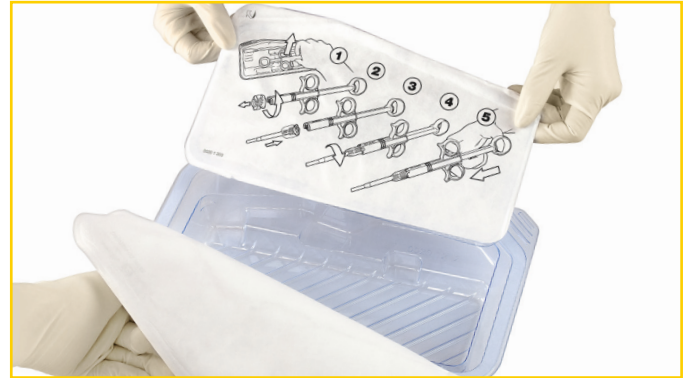
As a manufacturer, Stryker does not provide medical advice or services and does not recommend specific technique or instruction. It is always the responsibility of treating physician to determine the appropriate treatment and technique, based on the physician's medical knowledge and the individual circumstances of the particular case. It is also the treating physician's sole responsibility to inform the patient about potential risks, complications, and benefits of certain products and procedures.

Operative Technique

Step 1 - Unpack the DirectInject Components



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



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



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



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

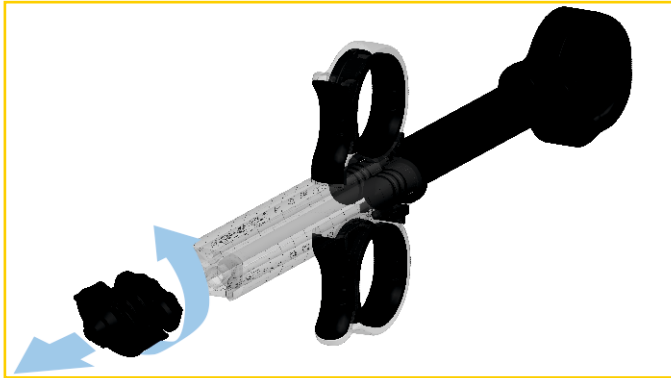
NOTE

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

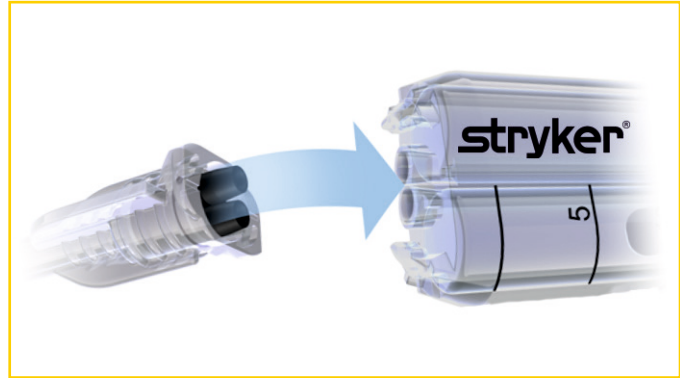
NOTE

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.

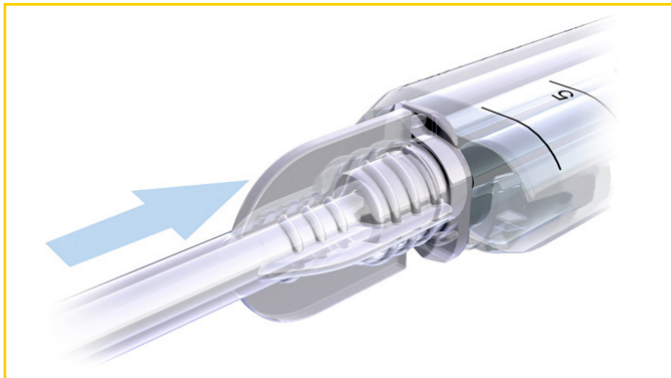
Step 2 - Attach the Mixer-Cannula



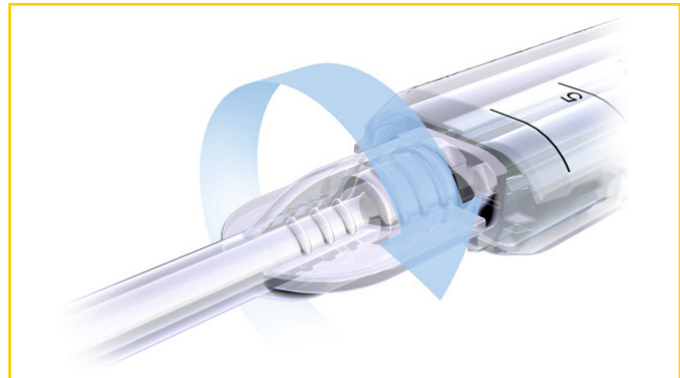
1. Remove the Transit Cap: rotate by 90° in a counterclockwise direction, then pull away from Delivery Syringe and dispose.



2. Attach the Mixer-Cannula to the end of the Delivery Syringe. Attach the Mixer-Cannula connection with the Delivery Syringe connection points.



3. Press the Mixer-Cannula into position.



4. Rotate the Mixer-Cannula by 90° in a clockwise direction to lock into position.

NOTE

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

Step 3 - Injection

1. The Delivery Syringe is now ready for use.



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.

Step 4 - Implantation

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.

2. Sculpt the cement with the Spatula provided.

NOTE

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

Step 5 - Set time

1. Allow cement to set undisturbed.

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

CAUTION

Do not disturb the cement (over the 7 minutes and 30 seconds of setting time) once it begins to harden.

Overview of the DirectInject timeline (10 minutes total elapsed time)

1. Injection complete



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2. Sculpting cement



2 min. and 30 sec.

3. Setting time



7 min. and 30 sec.



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