

Urgent Field Safety Notice: RA2021-2667189

DirectInject, 5cc

Attn:

April 01 2021



Product affected

Catalog number	UDI	Product description	Serial/Lot number(s)	Distribution Dates
79-45905	07613327123265 20311	DirectInject, 5cc	DI20311	21Dec2020 – 05Feb2021
79-45905	07613327123265 20307	DirectInject, 5cc	DI20307	06Jan2021 – 07Jan2021

Product description

DirectInject is a sterile, dual paste, calcium phosphate cement which is provided pre-filled in a double barrel Delivery Syringe system. Upon injection through the Mixer-Cannula, the two pastes form a cement which is moldable. The injected cement, as it is injected into a bone void, will harden under normal body conditions to form hydroxyapatite.

Primary clinical purpose of device(s)

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.

Product issue

We have received customer complaints that describe the inability of the user to push the paste through the Mixer-Cannula which prohibits the injection into a bone void. We have confirmed these complaints are isolated to the two lots identified above.

Potential hazard and risks

The hazard for the patient is that the device may not function as intended if the user is unable to eject the paste from the syringe. This result would require a second device or an alternative method be used to close the defect.

Actions needed

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
 - a. Please provide contact details so that Stryker can inform the recipients appropriately.
 - b. If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
 - a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
 - a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request your support in finalizing the required steps within 14 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: _____ **Position:** _____ **email:** _____

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,



Business Reply Form- response required

DirectInject, 5cc

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Please complete and sign this form. Email the completed form xxxx@Stryker.com by <MMM DD YYYY>

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product	Lot number(s)	Quantity on hand*
79-45905	DirectInject, 5cc	DI20311	
79-45905	DirectInject, 5cc	DI20307	

*If no affected devices are available for return please enter 0 (zero).

Form completed by:

Printed name		Title	
Signature		Phone	
Date		Email	

If you have further distributed any affected product, please indicate to whom:

Product(s) distributed		Quantity distributed	
Facility name		Contact person	
Full address			