Field Safety Notice: RA2024-3589151

UPDATE

May XX, 2024

Affected product

Product Field Action #: **RA2024-3589151**

Product Name: **EXETER 2.5 IM PLUG**

Identification of the Affected Products:

Table 1

Catalog / Part #	Item Description	Lot #	GTIN
0939-0-108	EXETER 2.5 I M PLUG 8MM	N0398	04546540167200
0939-0-110	EXETER 2.5 I M PLUG 10MM	N0352	07613327051087
		N0397	
		N0388	
0939-0-112	EXETER 2.5 I M PLUG 12MM	N0329	04546540167224
		N0339	
		N0340	
		N0400	
		N0404	
0939-0-114	EXETER 2.5 I M PLUG 14MM	N0347	04546540167231
		N0345	
		N0346	

Dear Customer,

Stryker initiated a voluntary, lot number specific recall for the EXETER 2.5 I M PLUG on April 04, 2024. Stryker is providing this UPDATE communication to provide customers with more context around the intended use of the product and risk mitigations.

Product Description

The Exeter Intramedullary (IM) Plugs, also known as cement restriction plugs, are used in cemented hip arthroplasty, which is a surgical procedure in which bone cement (made from polymethylmethacrylate - PMMA) is used to secure hip implant components within the bone.

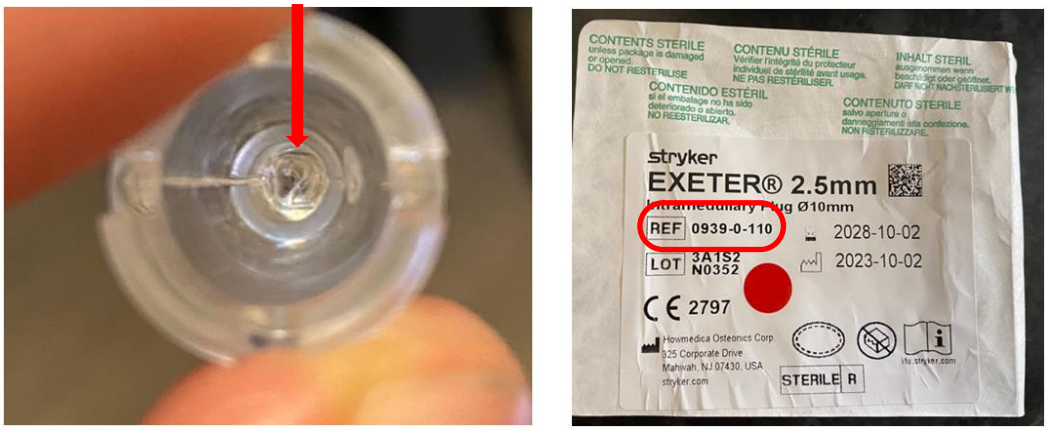
The Exeter IM Plug, which is also made of PMMA, is designed to control the flow of bone cement within the femoral canal during the implantation process.

Issue

Stryker has discovered the potential that the size on the package label of the EXETER 2.5 I M PLUG may not match the device within the packaging (see Figure 1 below).

Figure 1:

Images showing part marking for 12mm Exeter IM Plug found in package labelled for 10mm Exeter IM Plug



Potential Hazards

1. Failure to assemble: The Exeter IM Plug may fail to assemble to the appropriate adapter if it is the unintended size.
2. Foreign Object (Unintended): If a smaller than intended Exeter IM Plug is placed too deep into the femoral canal, it may potentially detach from the plug introducer and become lodged in the canal. This scenario may lead to exposure to the potential hazard of foreign object (unintended).
3. Malpositioned Implant: The use of a larger or smaller sized Exeter IM Plug than intended may not seat at the desired position in the bone canal.

Potential Harms

There are no identified harms associated with this issue which would lead to any known adverse health consequences.

All hazards above may lead to a delay in surgery to remove the unintended Exeter IM Plug from the femoral canal and/or retrieve a replacement device. There are no harms/complications associated with a delay in surgery to remove and/or replace an unintended Exeter IM Plug.

In addition, if an unintended smaller sized Exeter IM Plug becomes lodged in the canal, and cannot be retrieved, there would be no harms associated with leaving the smaller plug in the canal. The Exeter Plug is made from PMMA material (which is biocompatible and similar to bone cement), would remain lodged in the bone canal, and is provided sterile, therefore no other potential hazards/harms would arise.

Risk Mitigations

The hazards may be mitigated by the following:

- *Size Marking Present on Device*: Exeter IM Plugs have a size marking which is present on the inner surface of the device. The size marking might be utilized by the surgeon to confirm any potential mismatch in size marked on the product.
- *Surgical trialing steps*: During implantation, the surgeon will assess whether the non-conforming Exeter IM Plug (when attached to the Exeter IM Plug Introducer (P/N: 0939-0-002M) matches the same size and depth as that of the selected Exeter Plug Trial. The difference in depth as well as the fit due to the difference in size may raise awareness of the discrepancy to the user.
- *Compatibility of the Exeter IM Plug Introducer attachments*: Since the Exeter IM Plug must be assembled with the appropriate Adaptor Plug before the Exeter IM Plug is inserted into the femoral canal and before cement is applied, the discrepancy may be identified when the surgeon attempts to assemble a non-conforming Exeter IM Plug with the inappropriate Adaptor Plug.

Actions needed

Our records indicate that you may have received the affected product(s). It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Maintain awareness of this notice internally until all required actions have been completed within your facility.
3. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list (in Table 1, page 1) are at your facility.
4. Segregate all of the recalled devices identified in the affected product list (see *Table 1, page 1)* and notify your Stryker Representative of the identified inventory. Discard/dispose of the recalled device(s) following your appropriate internal process.
5. 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.
6. Please inform Stryker of any serious incidents concerning the use of the subject devices.
    a. Please comply with any local laws or regulations concerning the notification of serious incidents to your National Competent Authority.
7. 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.
8. 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 that you respond to this notice within 7 calendar days from the date of receipt.

Please respond event if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

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 and EU 2017/745, 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,

RA2024-3589151 - UPDATE
Business Reply Form - response required

Urgent Field Safety Notice: RA2024-3589151

May XX, 2024

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		N0345	
		N0346	

I have received the **Medical Device Recall** UPDATE letter from Stryker dated XX-May-2024 stating that the company has initiated a voluntary recall on the above referenced affected products in Table 1

Please complete the form even if you do not have inventory. This will preclude us from following up.

Customer information

Customer name: _____

Name of person completing this form: _____ Title: _____

Direct phone number: _____ Email _____

Address: _____ City: _____

Postal code: _____ Country:_____

If affected inventory, please provide the information below. Attach additional sheet if needed.

Product code	Lot number	Qty quarantined	Qty destroyed	Qty returned

We have not located any of these devices in our inventory *(please add check mark to box)*: ☐

If you have further distributed subject devices, please provide information below:

Facility Name	Facility Address	Contact person	Product code	Lot number	Qty

I have read and understand the instructions provided and acknowledge receipt of the subject Field Safety Notice. I also agree to further distribute and communicate this important information from this letter to those to whom I distributed any of the subject devices noted in this letter.

Name (print): _____ Signature: _____ Date: _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL _____ OR FAX _____