Field Safety Notice: RA2024-3589151

April 30, 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,

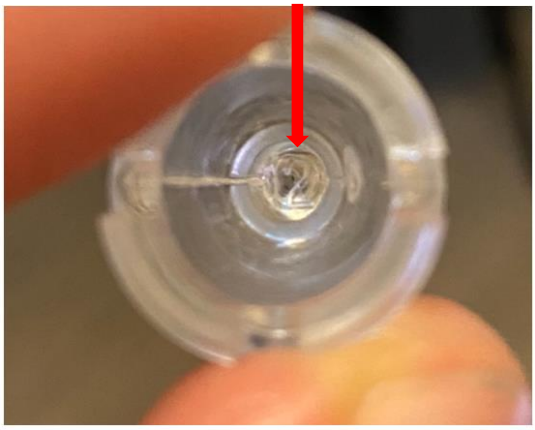
Stryker has initiated a voluntary, lot number specific Recall for the EXETER 2.5 I M PLUG. The lot numbers impacted by this recall are included in Table 1 above.

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 (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.

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. 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.

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 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.
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 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: Marius Ciocanau Position: Lead PMS Specialist email: marius.ciocanau@stryker.com

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,

Marius-Alexandru Ciocanau

Lead Post Market Surveillance Specialist

Stryker

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