Urgent Field Safety Notice: RA2024-3559587

March xx, 2024

Affected product

Product Name: **Trident II Hemispherical and PSL Shells**

Identification of the Affected Products: **Table 1**

Catalog Number	Lot Number	Product Description
702-11-44B	14974852	TRIDENTII HEMI CLUSTER44B
702-11-48D	14875651	TRIDENTII HEMI CLUSTER48D
702-11-48D	15005253	TRIDENTII HEMI CLUSTER48D
702-11-48D	16044255	TRIDENTII HEMI CLUSTER48D
702-11-50D	14629051	TRIDENTII HEMI CLUSTER50D
702-11-50D	14628851	TRIDENTII HEMI CLUSTER50D
702-11-50D	15175654	TRIDENTII HEMI CLUSTER50D
702-11-50D	15610452	TRIDENTII HEMI CLUSTER50D
702-11-52E	14875853	TRIDENTII HEMI CLUSTER52E
702-11-52E	14875852	TRIDENTII HEMI CLUSTER52E
702-11-54E	15293151	TRIDENTII HEMI CLUSTER54E
702-11-54E	15293153	TRIDENTII HEMI CLUSTER54E
702-11-54E	15293152	TRIDENTII HEMI CLUSTER54E
702-11-54E	15432252	TRIDENTII HEMI CLUSTER54E
702-11-54E	15432254	TRIDENTII HEMI CLUSTER54E
702-11-54E	15432451	TRIDENTII HEMI CLUSTER54E
702-11-54E	15432351	TRIDENTII HEMI CLUSTER54E
702-11-54E	15432251	TRIDENTII HEMI CLUSTER54E
702-11-54E	15432253	TRIDENTII HEMI CLUSTER54E
702-11-54E	16265752	TRIDENTII HEMI CLUSTER54E
702-11-58F	15854353	TRIDENTII HEMI CLUSTER58F
702-11-66H	15445252	TRIDENTII HEMI CLUSTER66H
742-11-48D	16311453	TRIDENTII PSL CLUSTER48D
742-11-50D	14593551	TRIDENTII PSL CLUSTER50D
742-11-50D	15432653	TRIDENTII PSL CLUSTER50D
742-11-50D	15432651	TRIDENTII PSL CLUSTER50D
742-11-52E	14876553	TRIDENTII PSL CLUSTER52E
742-11-52E	14876552	TRIDENTII PSL CLUSTER52E
742-11-58F	13927651	TRIDENTII PSL CLUSTER58F
742-11-64H	15611151	TRIDENTII PSL CLUSTER64H

Dear Customer,

Stryker has initiated a voluntary, lot number specific recall for Trident II Hemispherical and PSL Shells. The lot numbers impacted by this recall are included in Table 1 above.

Issue

Stryker has discovered a potential issue with Trident II Hemispherical and PSL Shells where the acetabular shell may have excessive deburring, resulting in a smooth surface on the edge of the shell.

Potential Hazards/Harms

Technical and medical assessments are currently underway to determine any potential hazards and harms associated with the use of an impacted Trident II Acetabular Shell.

An updated communication will be forwarded upon completion of the internal investigation of this issue.

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. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

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)* and notify your Stryker Representative of the identified inventory. Your Representative will organize all the returns of the devices.
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 it 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 even 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:
e-mail: xxxx@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,

RA2024-3559587
Business Reply Form - response required

Urgent Field Safety Notice: RA2024-3559587

March xx, 2024

Product Family Names:	**Trident II Hemispherical and PSL Shells**
Identification of the Affected Products:	**See *Table 1* on page 1**

I have received the **Field Safety Notice** letter from Stryker dated March XX, 2024, stating that the company has initiated a voluntary recall on the above-referenced affected products.

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 an 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 XXXX@stryker.com