stryker

Urgent Field Safety Notice: RA2023-3238368

May 18, 2023

Product Field Action # **RA2023-3238368**

Product Name: **Exeter V40 Trial Head**

Identification of the Affected Products:

Table 1

Catalog Number	Product Description	Lot Number	GTIN
6364-8-026	Exeter V40 Trial Head, 26mm, -3	G7207242	07613327188660

Dear Customer,

Stryker has initiated a voluntary, lot-specific recall for the Exeter V40 Trial Head listed in Table 1. The intent of this letter is to list all known hazards and harms potentially associated with the below noted issue and list the risk mitigation factors associated with the use of the product.

Issue:

Stryker has discovered that the Exeter V40 Trial Head, catalog number 6364-8-026 (size 26mm, -3) may appear green, when it is meant to be a blue color. Green signifies a size 26mm, +3 Trial Head. This issue only impacts the Exeter V40 Trial Head, 26mm, -3 (catalog number 6364-8-026, lot G7207242).

Potential Hazards:

In the event a miscolored Exeter V40 Trial Head is received, the following potential hazards may occur:

- Incorrect or inappropriate output or functionality
- Incorrect trialing assessment
- Incorrect choice of implant

Potential Harms:

The potential hazards may result in the following potential harm(s):

- Instability with potential for dislocation
- Leg length inequality
- Revision surgery

Risk Mitigations:

- Although miscolored, the Exeter V40 Trial Head is engraved with the correct size, part number, and offset marking.
- The Exeter V40 Trial Heads have specific markings that will be compared with the artwork on the Exeter V40 Trial Head Tray during kitting.

- The difference in head offset between Exeter V40 Trial Heads 26mm, -3 (nonconforming green) and 26mm, +4 (conforming green), is a total of 7mm. This magnitude of difference would affect the leg length/offset and tension in the soft tissues during range of motion assessment.
- In the Exeter surgical technique, there are two distinct trialing checks that may mitigate an incorrect trialing assessment.
- A final reduction step is performed with implants to ensure soft tissue tension, offset, and leg length are acceptable while using the selected Femoral Head implant.

Recommendations for patients already treated with an affected device:

Patients treated with an affected product should continue to be followed per the normal protocol. There are no recommended changes to the frequency of the standard follow-up care protocol.

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. Please inform users of this Urgent Medical Device Recall and forward this notice to all individuals who need to be made aware or organizations who have consigned product.
2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility.
3. Quarantine and discontinue use of the recalled devices identified in the affected product list.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility.
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 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.
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 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: Nina Goddard
Position: Senior Manager RAQA
email: nina.goddard@Stryker.com

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,

Nina Goddard
Regulatory Affairs and Quality Assurance

Urgent Field Safety Notice: RA2023-3238368
Business Reply Form - response required

May 18, 2023

Product Field Action # **RA2023-3238368**

Product Name: **Exeter V40 Trial Head**

I have received the **Urgent Medical Device Recall** letter from Stryker dated May 18, 2023, stating that the company has initiated a voluntary recall on the above-referenced affected products in *Table 1:*

Catalog Number	Product Description	Lot Number	GTIN
6364-8-026	Exeter V40 Trial Head, 26mm, -3	G7207242	07613327188660

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

Customer information

Hospital name_____

Name of person completing this form_____

Title_____ Direct phone #_____ Email_____

Address_____ City_____ Postal code _____

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

Product code	Serial/Lot number	Qty quarantined	Qty destroyed/returned

No affected product in inventory (please check) ☐

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 this Field Safety Notice. I also agree to further distribute and communicate this important information from this letter to those to whom I have distributed any of the subjected devices noted in this letter.

Name (print)_____Signature_____Date _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL nby_qara@stryker.com