Urgent Field Safety Notice: RA2022-2895948

Exeter® V40™ Cemented Hip Stem

January 6, 2022

Product affected

Part Number	Product Description	Lot	GTIN
0580-1-044	Exeter® V40™ Cemented Hip Stem	G7900236	04546540509048
0580-1-440	Exeter® V40™ Cemented Hip Stem	G7900352	04546540153296

Dear Customer,

Stryker has initiated a voluntary, catalog and lot number specific recall for the Exeter® V40™ Cemented Hip Stems. 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.

Product issue

Stryker has discovered that a potential label mix has occurred between Exeter® V40™ Cemented Hip (125mm) Stem, P/N 0580-1-044, Lot #G7900236 and Exeter® V40™ Cemented Hip (150mm) Stem, P/N 0580-1-440, Lot #G7900352.

One or more of the five outer box labels of the Exeter® V40™ Cemented Hip Stem, P/N 0580-1-044, Lot #G7900236, may be labeled incorrectly as the Exeter® V40™ Cemented Hip Stem, P/N 0580-1-440, Lot #G7900352. The patient label set, provided in the product box, may also be labeled incorrectly.

Similarly, one or more of the five outer box labels, and/or the patient label set, of the Exeter® V40™ Cemented Hip Stem, P/N 0580-1-440, Lot #G7900352 may be labeled incorrectly as the Exeter® V40™ Cemented Hip Stem, P/N 0580-1-044, Lot #G7900236.

Stryker is aware of complaints associated with the issue. There have been no reports of serious injuries.

Potential hazard

Potential delay in surgery time of up to 60 minutes due to additional bone preparation required to accommodate the Exeter® V40™ Cemented Hip (150mm) stem, P/N 0580-1-440.

Potential harms

The aforementioned potential hazard may result in the following potential harm:

•Complications associated with extended surgery time of up to 60 minutes.

Risk mitigation

If issue is identified <u>PRIOR</u> to commencement of surgery

- During typical pre-surgical preparation, all planned implants, instruments, and ancillary equipment are checked to be available and ready for use. During this step, the issue could be identified, mitigating the potential for exposure of the hazard during surgery.

If issue is identified <u>AFTER</u> the commencement of surgery

- The following product information is present in product markings on the necks of all implants in scope of this Product Field Action: catalogue number, lot code, offset, size, trunnion taper, and stem length. These product markings can clarify the identity of the stem and help to reduce the risk of instrument misidentification due to one or more labels potentially being incorrect.

- There is an easily recognizable difference in Exeter V40 Cemented Hip Stem, P/N: 0580-1-044 (125mm) from P/N: 0580-1-440 (150mm) in both length and body geometry in the medial/lateral profile. The physical difference would be identified, and the surgeon and/or surgical staff would refer to the stem markings for confirmation.

<u>Follow up:</u>
Patients should continue to be followed per the normal protocol established by his/her surgeon. There are no recommended changes to the frequency of the standard follow-up care protocol.

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. **<u>Discontinue use</u>** of the recalled Exeter V40 Cemented Hip Stems, Lots #G7900352 and #G7900236 and return the product.

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 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:

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,

stryker

Business Reply Form- response required

<Account number>
January 6, 2022

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

Customer information

Customer name _____

Name of person completing this form_____Title_____

Direct phone #_____Email_____

Address_____City_____State____ Postal code _____

Country _____

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	Serial/Lot number	QTY

I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of 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, XX, OR FAX, X