URGENT MEDICAL DEVICE RECALL

December 30, 2021

Product Field Action #: 2847072

Product Name: Exeter® V40™ Cemented Hip Stem

Identification of the Affected Products:

Table 1

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.

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 PRIOR 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 AFTER 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.

Follow up:
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 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 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.
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. **Discontinue use** of the recalled Exeter V40 Cemented Hip Stems, Lots #G7900352 and #G7900236 and return the product.
4. **Hospitals/Branches/Agencies**: Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form and fax a copy to 1-866-660-8956 or email to strykerortho6067@sedgwick.com.

5. **Hospitals Only:** Please contact your Local Sales Office or your Stryker Sales Representative directly for product returns and inventory questions.
6. **Branches/Agencies Only**: Please forward this Urgent Medical Device Recall to the individuals or organizations who have consigned product, if applicable. Return all affected devices available at your location to the following address.

Att. Regina Short (Quality Manager) / PFA# 2847072
Stryker
Global Quality & Operations
Tullagreen Building, IDA Business & Technology Park,
Carrigtwohill, Cork, Ireland
T45 HE42

7. **Please contact your Local Sales Office or your Stryker Sales Representative directly for product replacement and inventory questions.**

Please assist us in meeting our regulatory obligation by emailing back the attached Urgent Medical Device Recall Business Reply Form within 5 days. A response is required, even though you may not have any physical inventory on site.

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Stryker informed of any adverse events associated with this product by emailing soprodexpreports@stryker.com.

We regret any inconvenience this action may cause. If you have any questions or concerns after reviewing this letter, please contact Customer Service at (888)-756-7846. For questions pertaining to the recall, email SO_M_PRODUCT_FIELD_ACTION_RESPONSE@stryker.com

Sincerely,

Dervillia Murphy
Vice President, Regulatory Interactions
Stryker
Joint Replacement Division
210 Centennial Park
Elstree, WD6 3SJ, United Kingdom

URGENT MEDICAL DEVICE RECALL
BUSINESS REPLY FORM

December 30, 2021

Product Field Action #: 2847072

Product Name: Exeter® V40™ Cemented Hip Stem

I have received the **Urgent Medical Device Recall** letter from Stryker dated December 30, 2021 stating that the company has initiated a voluntary recall on the above referenced affected products.

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

_____ _____

Hospital Name Date

_____

Hospital Address

_____

Hospital Rep
(Signature)

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL LISTED BELOW:

Fax: 1-866-660-8956 or email to strykerortho6067@sedgwick.com