Urgent Field Safety Notice: RA2022-2911584

Biolox® Delta Ceramic V40™ Femoral Head

March 16, 2022

Product affected

Catalog Number	Product Description	GTIN	Lot Number
6570-0-032	Biolox® delta Ceramic V40™ Femoral Head 32/ **-4.0mm**	04546540608475	**89648802**
6570-0-232	Biolox® delta Ceramic V40™ Femoral Head 32/ **+4.0mm**	04546540608536	**89546202**

Table 1

Dear Customer,

Stryker initiated an urgent, voluntary, lot-specific recall for the Biolox® delta Ceramic V40™ Femoral Head referenced above in January 2022. Stryker has completed the technical and medical assessments and is providing this follow-up communication to inform customers of the updated scope, potential hazards and harms, and any risk mitigation factors.

Scope Update

In the initial communication, Stryker included seven (7) lots potentially impacted by a product mix where the size and/or head offset of the Biolox® delta Ceramic V40™ Femoral Head inside the package did not match the package labeling. The investigation concluded that the scope of this issue is limited to catalog 6570-0-032, lot 89648802 and catalog 6570-0-232, lot 89546202, referenced in Table 1 above. The five (5) lots listed in Appendix A hereto are conforming and are no longer within the scope of the recall.

Product issue

Stryker has discovered that a product mix occurred between catalog 6570-0-032, lot 89648802 and catalog 6570-0-232, lot 89546202.

- Box labels with catalog 6570-0-232, lot 89546202 (Dia. 32mm, Head offset **+4.0mm**) have the potential to contain catalog 6570-0-032, lot 89648802 (Dia. 32mm, Head offset **-4.0mm**).
- Box labels with catalog 6570-0-032, lot 89648802 (Dia. 32mm, Head offset **-4.0mm**) have the potential to contain catalog 6570-0-232, lot 89546202 (Dia. 32mm, Head offset **+4.0mm**).
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Potential Hazards

In the event of a product mix between the Biolox® delta Ceramic V40™ Femoral Head, (32mm/ **+4.0mm** head offset) or (32mm/ **-4.0**mm head offset), the following potential hazard(s) have been identified:

- Delay in surgery of ≤15 minutes to retrieve a back-up device.
- Fractured device if an incorrect offset size Biolox® delta Ceramic V40™ Femoral Head is assembled to the stem trunnion, then intraoperatively replaced with another Biolox® delta Ceramic V40™ Femoral Head.
- Insufficient constraint/soft tissue tension if the incorrect offset size Biolox® delta Ceramic V40™ Femoral Head is implanted.

Potential Harms

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

- Leg length discrepancy
- Weakness of the abductor muscle
- Hip dislocation of femoral head from acetabular cup
- Pain and inability to walk leading to revision surgery

  Note: There are no harms associated with a delay in surgery ≤15 minutes to retrieve a back-up device.

Risk Mitigation

- Risks may be mitigated by performing a visual inspection of the device upon removal from its packaging as the device markings convey the size of the Biolox® delta Ceramic V40™ Femoral Head. These markings would be visible to the surgeon(s) and/or surgical staff. If the defect was identified the device could be replaced prior to implantation.
- Risks may be mitigated if the Instructions For Use (IFU) and Surgical Protocol are followed for femoral head replacement options for the Biolox® delta Ceramic V40™ Femoral Head. The IFU and Surgical Protocol informs the surgeon user that once a Biolox® delta Ceramic V40™ Femoral Head has been assembled to a femoral stem trunnion, a ceramic head should never be directly re-assembled to the same femoral stem trunnion. The Surgical Protocol further details acceptable femoral head replacement options for a Biolox® delta Ceramic V40™ Femoral Head, which include V40 metal heads, or an adapter sleeve in combination with Biolox C-taper or Universal taper ceramic heads.
- Risks may be mitigated if after impacting the femoral head onto a femoral stem, a visual inspection of the device seating is performed. For example, if a device with a -4.0mm head offset were assembled instead of an intended +4.0mm head offset, the unintended femoral head offset could be detected visually because the device would sit lower/proud on the femoral stem trunnion.
- Risks may be mitigated during an intraoperative range of motion assessment. This assessment may reveal a lack of joint tension and/or reveal inadequate joint constraint if the unintended device were used.

Recommendations for patients already implanted with an impacted device:

Patients treated with an impacted product identified in Table 1 should continue to be followed per the normal protocol established by his or her surgeon(s). There are no recommended changes to the frequency of the standard follow-up care protocol. Additional or more frequent patient monitoring or follow up may be required in accordance with clinical judgment.

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. 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 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.

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: 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>
March 16, 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

Appendix A

Biolox® delta Ceramic V40™ Femoral Heads no longer within scope of this recall.

Catalog Number	Product Description	GTIN	Lot Number
6570-0-032	Biolox® delta Ceramic V40™ Femoral Head 32/ -4.0mm	04546540608475	89648801 89648803 89648804 89648805
6570-0-136	Biolox® delta Ceramic V40™ Femoral Head 36/ +0.0mm	04546540608512	89549404