

# Urgent Field Safety Notice: RA2022-2911584

## Bilox® Delta Ceramic V40™ Femoral Head

**January 18, 2022**

### Product affected

Catalog Number	Product Description	GTIN	Lot Number
6570-0-032	Bilox® delta Ceramic V40™ Femoral Head 32/ -4.0mm	04546540608475	89648801 89648802 89648803 89648804 89648805
6570-0-136	Bilox® delta Ceramic V40™ Femoral Head 36/ +0.0mm	04546540608512	89549404
6570-0-232	Bilox® delta Ceramic V40™ Femoral Head 32/ +4.0mm	04546540608536	89546202

**Table 1**

Dear Customer,

Stryker has initiated a voluntary, lot number specific recall for the Bilox® delta Ceramic V40™ Femoral Head. The lot numbers impacted by this recall are included in Table 1 above.

### Product issue

Stryker has discovered a potential product mix where the size and/or offset of the Bilox® delta Ceramic V40™ Femoral Head inside the package does not match the package labeling.

### Potential hazard/harms

Technical and medical assessments are currently underway to determine any potential hazards and harms associated with the use of an impacted Bilox® delta Ceramic V40™ Femoral Head. An updated communication will be forwarded upon completion of the internal investigation on this issue.

### 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 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:** \_\_\_\_\_ **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,

**Business Reply Form-  
response required**

<Account number>  
January 18, 2022

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Catalog Number	Product Description	GTIN	Lot Number
6570-0-032	Biolog <sup>®</sup> delta Ceramic V40™ Femoral Head 32/ -4.0mm	04546540608475	89648801 89648802 89648803 89648804 89648805
6570-0-136	Biolog <sup>®</sup> delta Ceramic V40™ Femoral Head 36/ +0.0mm	04546540608512	89549404
6570-0-232	Biolog <sup>®</sup> delta Ceramic V40™ Femoral Head 32/ +4.0mm	04546540608536	89546202

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**