stryker

URGENT:
FIELD SAFETY NOTICE

UNIMA EVOLUTION SCREW

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Recall Number: PFA 3046986

xx July 2022

Product affected

Catalog number	Product description	GTIN	Lot Code	Distribution Dates
AA45AH560	Unima Evolution Screw Ø 4.5 mm x 60mm	00840420175038	0A40	21-Nov-2018 to 04-Oct-2021
AA45AH560	Unima Evolution Screw Ø 4.5 mm x 60mm	00840420175038	09HQ	
AA73AA565	Unima Evolution Screw Ø 7.3 mm x 65mm	00840420175380	0A6Q	
AA73AA570	Unima Evolution Screw Ø 7.3 mm x 70mm	00840420175397	0A45	

The purpose of this notification is to advise you that Stryker is conducting a voluntary recall regarding four specific lots of Unima Evolution Screw, which is manufactured by Stryker's wholly owned subsidiary Wright Medical Technology, Inc. Please refer to the table above for catalogue and lot number that were identified as shipped to distributors and end users.

Product description

The Unima Evolution Screws are compression screws of different diameters and lengths. They are manufactured from titanium alloy and provided sterile. The Unima Evolution compression screws are only indicated for use in the lower extremities. The Unima Evolution compression screws are recommended for the fixation of bone fractures and for bone reconstruction.

Product issue

Stryker has identified a nonconformance in four specific lots of Unima Evolution compression screws. Specifically, for the affected lots, the outer label does not match the device inside the package (example: label states Ø 4.5 mm but package contains Ø 7.3 mm).

Potential risks

The potential hazardous situation for an incorrectly labeled device is the wrong size and/or wrong product present in surgery. While the nonconformance is detectable (the screws are different size in diameter and color) this event could lead to surgical delay to obtain an alternative/back up device. While unlikely, if an alternative device is not available, change of surgery plan may be necessary.

Actions needed

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.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return and replacement of your product(s).
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 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:

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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

Account number:
Account name:
Account Address:

UNIMA EVOLUTION SCREW

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Please complete and sign this form within 7 Calendar Days. Email the completed form to xxxx@stryker.com by DD-MMM-2022.

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

Form completed by:

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 :