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URGENT:
MEDICAL DEVICE RECALL

AEQUALIS FLEX REVIVE

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

Recall Number: RA2023-3322296

Xxxx June 2023

Product affected

Catalog number	GTIN	Product description	Batch #	Distribution Dates
ARS655101	00846832069408	Aequalis Flex Revive Assembly Screw 0mm	Starting with **AZ1322077** (see **Attachment A: Product Affected)**	16/Mar/2023 – 22/Mar/2023
ARS655118	00846832093304	Aequalis Flex Revive Assembly Screw 0mm Short	Starting with **AZ1822082** (see **Attachment A: Product Affected)**	10/Mar/2023

The purpose of this notification is to advise you that Tornier Inc. (a wholly owned subsidiary of Stryker) is conducting a field action on two specific lots of Aequalis Flex Revive Assembly Screws. Please refer to Attachment A for a list of the serialized lot numbers that were identified as shipped to distributors and end users.

Product description

Aequalis Flex Revive Assembly Screws are used to connect the proximal body and distal stem components of the Aequalis Flex Revive Shoulder System.

Product issue

Stryker has identified a nonconformance in two specific lots of Aequalis Flex Revive Assembly Screws. Specifically, a comingle/swap resulted in the labeling and laser marking on the product to state it is a Aequalis Flex Revive Assembly Screw 0mm Standard (ARS655101) but it was a Aequalis Flex Revive Assembly Screw 0mm **Short** (ARS655118) & vice versa.

Potential risks

The short screw is 10mm shorter than the standard version. A short screw is unable to connect a standard proximal body to a stem, see Figure 1.
In a worst-case scenario (i.e. no backup device available), the surgeon will likely adjust the surgical method by changing components (proximal body/spacer/distal stem). This may lead to removal of more bone than was intended/needed initially), or a suboptimal fit of the prosthesis. Suboptimal fit may lead to the need for revision surgery.

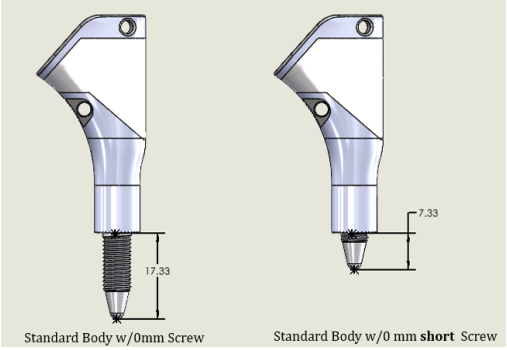

Figure 1

Actions needed

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Immediately check your internal inventory to locate the product(s) listed on the attached Business Reply Form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.
2. Sign and return the enclosed Business Reply Form by email to <xxx@stryker.com> to confirm receipt of this notification/documenting product disposition.
    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 eliminate the need for us to send 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. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details so that we can inform the recipients appropriately.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

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 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 and your expectations, remain on the market.

Sincerely,

Attachment A: Product Affected

Catalog number	Product Description	Lot/Serial #
ARS655118	Aequalis Flex Revive Assembly Screw 0mm Short	AZ1822082001, AZ1822082002, AZ1822082003, AZ1822082004, AZ1822082005, AZ1822082006, AZ1822082007, AZ1822082008, AZ1822082009, AZ1822082010, AZ1822082011, AZ1822082012, AZ1822082013, AZ1822082014, AZ1822082015, AZ1822082016, AZ1822082017, AZ1822082018, AZ1822082019, AZ1822082020, AZ1822082021, AZ1822082022, AZ1822082023, AZ1822082024, AZ1822082025, AZ1822082026, AZ1822082027, AZ1822082028, AZ1822082029, AZ1822082030, AZ1822082031, AZ1822082032, AZ1822082033, AZ1822082034, AZ1822082035, AZ1822082036, AZ1822082037, AZ1822082038, AZ1822082039, AZ1822082040, AZ1822082041, AZ1822082042, AZ1822082043, AZ1822082044, AZ1822082045, AZ1822082046, AZ1822082047, AZ1822082048, AZ1822082049, AZ1822082050, AZ1822082051, AZ1822082052, AZ1822082053, AZ1822082054, AZ1822082055
ARS655101	AEQUALIS FLEX REVIVE ASSEMBLY SCREW 0MM	AZ1322077001, AZ1322077002, AZ1322077003, AZ1322077004, AZ1322077005, AZ1322077006, AZ1322077007, AZ1322077008, AZ1322077009, AZ1322077010, AZ1322077011, AZ1322077012, AZ1322077013, AZ1322077014, AZ1322077015, AZ1322077016, AZ1322077017, AZ1322077018, AZ1322077019, AZ1322077020, AZ1322077021, AZ1322077022, AZ1322077023, AZ1322077024, AZ1322077025, AZ1322077026, AZ1322077027, AZ1322077028, AZ1322077029, AZ1322077030, AZ1322077031, AZ1322077032, AZ1322077033, AZ1322077034, AZ1322077035, AZ1322077036, AZ1322077037, AZ1322077038, AZ1322077039, AZ1322077040, AZ1322077041, AZ1322077042, AZ1322077043, AZ1322077044, AZ1322077045, AZ1322077046, AZ1322077047, AZ1322077048, AZ1322077049, AZ1322077050, AZ1322077051, AZ1322077052, AZ1322077053, AZ1322077054, AZ1322077055

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Business Reply Form

Account number:
Account name:
Account Address:

AEQUALIS FLEX REVIVE

Recall Number: RA2023-3322296
Xxxx June 2023

Please complete and sign this form. Email the completed form to **<xxx@stryker.com>** by **<MMM DD YYYY>.**

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product Description	Lot/Serial #	Quantity on hand*
ARS655101	Aequalis Flex Revive Assembly Screw 0mm		
ARS655101	Aequalis Flex Revive Assembly Screw 0mm		
ARS655118	Aequalis Flex Revive Assembly Screw 0mm Short		
ARS655118	Aequalis Flex Revive Assembly Screw 0mm Short		

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			

☐ **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 :