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URGENT:
MEDICAL DEVICE RECALL

INFINITY™ RESECTION GUIDE ADJUSTMENT BLOCK

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

Recall Number: RA2024-3551148

XX-March -2024

Product Affected

Catalog number	GTIN	Product description	Lot numbers	Distribution Dates
33600030	00889797004008	INFINITY™ RESECTION GUIDE ADJUSTMENT BLOCK	2656950 2762126 2796094	04-Aug-2023 to 06-Oct-2023

The purpose of this notification is to advise that Wright Medical Technology, Inc (a wholly owned subsidiary of Stryker) is conducting a field action for three lots of INFINITY™ Resection Guide Adjustment Blocks. Please refer to the table above for catalog and lot numbers within the scope of this field action that were identified as shipped to distributors and end users.

Product description

The Infinity™ Resection Guide Adjustment Block is a non-sterile instrument used in the INFINITY™ Instrument Kit. INFINITY™ Total Ankle instruments are intended to facilitate implantation of a total ankle arthroplasty device.

Product issue

Stryker has identified an issue that impacts specific lots of Infinity™ Resection Guide Adjustment Blocks. The parts within these three lots were found to have been missing an internal screw in the finished instrument assembly. The missing screw is used to lockout the Medial/Lateral adjustment on the INFINITY Resection Adjustment Guide. See Addendum A for images of the issue.

Potential risks

The hazard associated with this issue is the device is not fully functional due to the missing subcomponent. The product issue is detectable, see Addendum A. If the issue is detected intraoperatively, the potential harm is elongation of surgery time to obtain a replacement. If a replacement is not available, delay of procedure may be necessary.

Actions needed by Customers and Distributors

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 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. Proceed with a visual inspection according to the "visual inspection criteria" shown below in Addendum A (page 3) and document the inspection results in the corresponding table in the Business Reply Form (page 4 of this letter).
3. Return the enclosed business reply form by email to confirm receipt of this notification/document product segregation.
    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.
4. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return of your product(s) if non-conforming items are found in your inventory.
5. Maintain awareness of this communication internally until all required actions have been completed within your facility.
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:

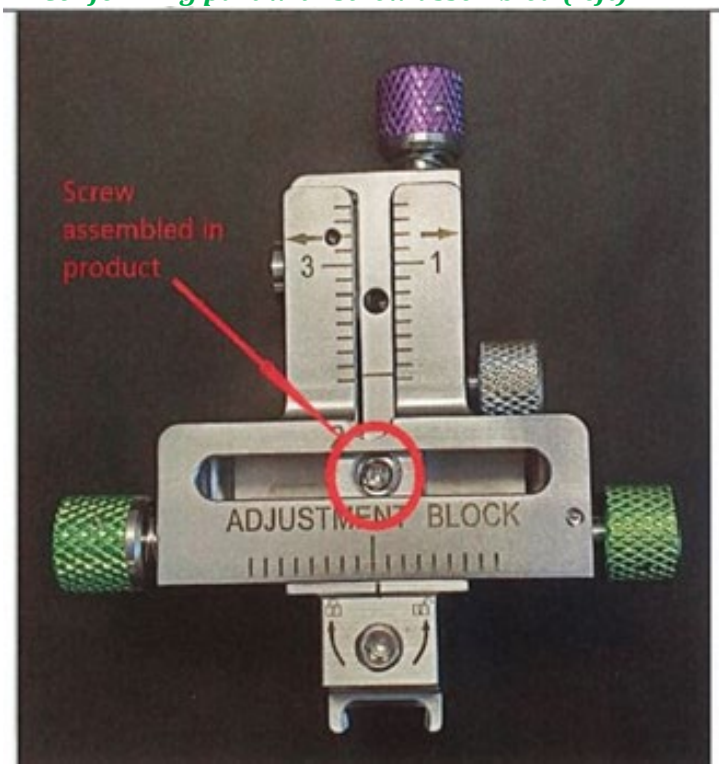
In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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.

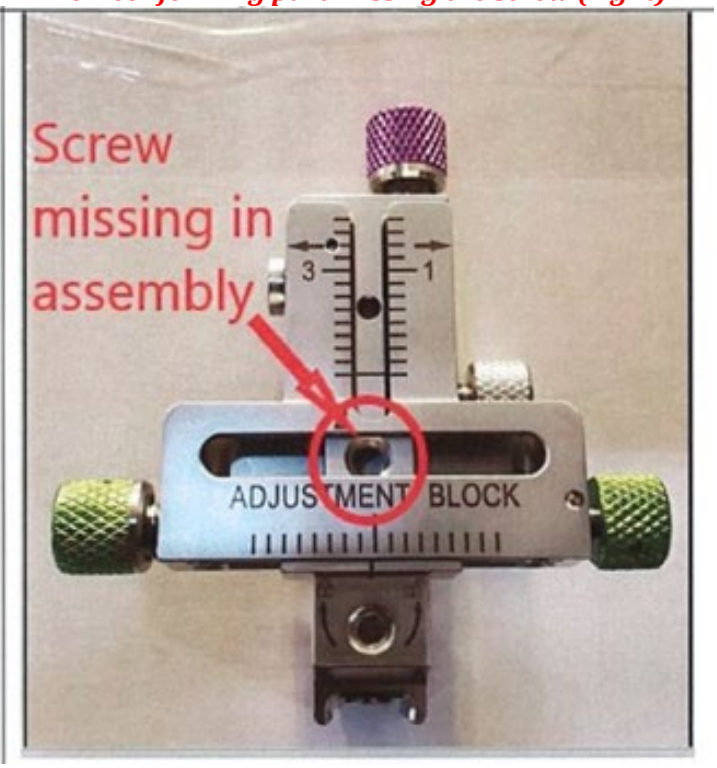
Sincerely,

Addendum A – Visual Inspection Criteria

Conforming part with screw assembled (left)



Non-conforming part missing the screw (right)



Please document the inspection results for each item you have on hand in the corresponding table in the Business Reply Form (page 4 of this letter).

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Business Reply Form

Account name:
Account Address:

INFINITY™ RESECTION GUIDE ADJUSTMENT BLOCK

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Please complete and sign this form. Email the completed form to **xxxx@stryker.com** by **XX-MAR-2024**.

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 number	Quantity on Hand Missing Screw (To be returned) *	Quantity on Hand Assembled with Screw (Not to be Returned) *
33600030	INFINITY™ RESECTION GUIDE ADJUSTMENT BLOCK	2656950		
		2762126		
		2796094		

*If all devices have already been returned and no affected devices are available, 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, if possible:

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 :