stryker

URGENT:
MEDICAL DEVICE RECALL

INFINITY™ ALIGNMENT FRAME DISTAL ASSEMBLY

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

Recall Number: RA2023-3314276

XX-June-2023

Product affected

Catalog number	GTIN	Product description	Lot numbers	Distribution Dates
33600020	00889797003926	INFINITY™ Alignment Frame Distal Assembly	2656815 2762126	2-May-2022 to 17-Mar-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 of two lots of Infinity™ Alignment Frame Distal Assemblies. 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™ Alignment Frame Distal Assembly is a non-sterile instrument used in the Infinity Total Ankle System. It is used in conjunction with the pin sleeves to place pins that are used for alignment and then subsequently resection while performing a total ankle replacement during a standard instrumentation INFINITY Total Ankle surgery.

Product issue

Stryker has identified an issue that impacts two specific lots of Infinity™ Alignment Frame Distal Assemblies. The parts within these two lots were found to have been manufactured with the pin sleeve holes too narrow to allow for the pin sleeves to pass through, resulting in assembly difficulties.

Potential risks

The hazard associated with this issue is the device is not fully functional due to the narrow pin sleeve holes. The product issue is detectable, see Figure 1. If the issue is detected intraoperatively, the potential harm is elongation of surgery time to obtain a replacement. If a replacement is not available, this could lead to a change of surgical method to ankle arthrodesis, potentially resulting in a longer recovery period and limited mobility.

Figure 1: *Pin sleeve unable to fit the Infinity™ Alignment Frame Distal Assembly*

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. 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.
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 event 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,

stryker

Business Reply Form

Account name:
Account Address:

INFINITY™ ALIGNMENT FRAME DISTAL ASSEMBLY

Recall Number: RA2023-3314276

XX-June-2023

Please complete and sign this form. Email the completed form to XXXXX@stryker.com by XX-JUN-2023.

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
33600020	INFINITY™ ALIGNMENT FRAME DISTAL ASSEMBLY	2656815	
		2762126	

*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, 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 :