stryker

URGENT

MEDICAL DEVICE RECALL

iBur™ Distal Bend Cutting Accessories

Attn: Materials Manager, Risk Manager, OR Director

PFA Number: RA2024-3697148

xx-July , 2024

Catalog number	Product description	GTIN	Lot number
8431009030	3.0mm Precision Round, Distal Bend	07613327501247	Refer to **Appendix A**
8431009040	4.0mm Precision Round, Distal Bend	07613327501223	
8431012020D	2.0mm Diamond Round, Distal Bend	07613327501261	
8431012030D	3.0mm Diamond Round, Distal Bend	07613327501230	
8431012040D	4.0mm Diamond Round, Distal Bend	07613327501278	
8431013030DC	3.0mm Coarse Diamond Round, Distal Bend	07613327501209	
8431013040DC	4.0mm Coarse Diamond Round, Distal Bend	07613327501155	
8431013050DC	5.0mm Coarse Diamond Round, Distal Bend	07613327501186	
8431107030D	3.0mm Diamond Match Head, Distal Bend	07613327509229	
8431107530	3.0mm Precision Match Head, Distal Bend	07613327501193	

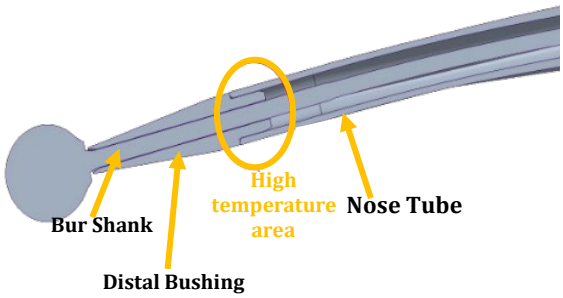
The purpose of this notification is to inform you that Stryker Instruments is voluntarily recalling specific products and lots of the **iBur Distal Bend Cutting Accessories**.

Product description

The iBur hubs and cutting accessories are intended to be used with the Stryker Consolidated Operating Room Equipment Console and electric and pneumatic motors. When used with these motors, the iBur hubs and cutting accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/ Otorhinolaryngology; and Endoscopic applications.

Product issue

There is a potential for the product to exhibit temperatures higher than specification where the bur shank meets the distal bushing.



Potential risks

Temperatures higher than specification may lead to the potential for minor tissue/structure damage or tissue/structure damage from thermal injury which may need medical/surgical intervention.

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 <xxxxxx@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.
    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 Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 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 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,

Appendix A

A total of 97 lot numbers across ten product numbers are listed below. Distribution dates for products in scope range from 08/25/2022– 04/08/2024.

Precision Round, Distal Bend (84310090X0)

3.0mm Precision Round, Distal Bend (8431009030)		4.0mm Precision Round, Distal Bend (8431009040)
22224017	22299017	22245017
22234017	23157017	22248017
22234027	23179017	22270017
22250017	23179027	22299017
22293017	23299017	22306027
		23188017

Diamond Round, Distal Bend (84310120X0D)

2.0mm Diamond Round, Distal Bend (8431012020D)	3.0mm Diamond Round, Distal Bend (8431012030D)		4.0mm Diamond Round, Distal Bend (8431012040D)
22237017	22216017	23009017	22334017
22241017	22230017	23157017	22339017
22334017	22334017	23208017	23004017
23085017	23004017	23233017	23016017
23179017	23004027	23233027	23085017
23213017		24003017	23115017
24003017			23195017
24015017			23299017

Coarse Diamond Round, Distal Bend (84310130X0DC)

3.0mm Coarse Diamond Round, Distal Bend (8431013030DC)		4.0mm Coarse Diamond Round, Distal Bend (8431013040DC)		5.0mm Coarse Diamond Round, Distal Bend (8431013050DC)
22230017	23172017	22248017	23179017	22224017
22333017	23188017	22263017	23205017	22227017
22342017	23221017	22334017	23205027	23087017
23011017	23311017	22348017	23205037	23157017
23093017	24004027	22348027	23221017	23188017
		23016027	23311017	23342017
		23095027	24004017	
		23128017	24004027	
		23163017	24004037	

Precision Match Head, Distal Bend (8431107XXX)

3.0mm Diamond Match Head, Distal Bend (8431107030D)	3.0mm Precision Match Head, Distal Bend (8431107530)		
22334017	22228017	23095017	23198017
23047017	22257017	23157017	23213017
23095017	22269017	23157027	23221017
23198017	22276017	23179017	23299017
	23085017	23179027	23345017
			23345027

Business Reply Form

iBur ™ Distal Bend Cutting Accessories

PFA Number: RA2024-3697148

Xx July , 2024

Please select from the options below and complete this form. Email the completed form to XXXXXXX@stryker.com > by <MMM DD YYYY>.

RESPONSE IS REQUIRED.

- ☐ **No remaining affected products onhand.**
- ☐ **I, the customer, choose to return the following product(s) for credits:**

Catalog number	Product Description	Lot number(s)	Quantity on hand *
8431009030	3.0mm Precision Round, Distal Bend		
8431009040	4.0mm Precision Round, Distal Bend		
8431012020D	2.0mm Diamond Round, Distal Bend		
8431012030D	3.0mm Diamond Round, Distal Bend		
8431012040D	4.0mm Diamond Round, Distal Bend		
8431013030DC	3.0mm Coarse Diamond Round, Distal Bend		
8431013040DC	4.0mm Coarse Diamond Round, Distal Bend		
8431013050DC	5.0mm Coarse Diamond Round, Distal Bend		
8431107030D	3.0mm Diamond Match Head, Distal Bend		
8431107530	3.0mm Precision Match Head, Distal Bend		

*If all devices have been used and none remain for return, please indicate 0 (zero) for quantity on hand.

Form completed by:

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

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

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 :