stryker

URGENT

MEDICAL DEVICE RECALL

Blade Mount Geometry Out of Tolerance/ Precision Thin Blades

Attn: Materials Manager, Risk Manager, OR Director

February xx, 2025

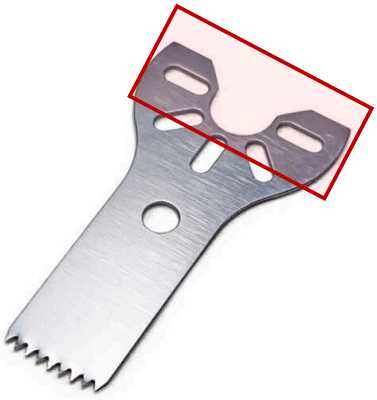
Recall Number: RA2024- 3846155

This notification is to inform you that Stryker Instruments is voluntarily recalling specific products and lots of the Precision Thin blades.

Catalog number	Product description	GTIN	Lot number
2296-003-155	PREC THIN 9.0 X 0.38 X 18.5MM	04546540466549	23070017
2296-003-108	PREC THIN 13.0 X 0.38 X 39.0MM	04546540046482	22298017

Product description

The Stryker Micro-Oscillating and Sagittal Blades are intended for use with compatible handpieces for cutting, drilling, decorticating, and smoothing of bone and other bone-related tissue in a variety of surgical procedures.



Product issue

Precision Thin blade attachments have a potential to be out of measurement specifications, preventing them from securely fitting into the compatible handpiece. See image for slot misalignment.

Potential risks

An incomplete fit into the handpiece may result in a decrease in device performance, caused by inhibited holding force by the user or inability to insert blade into the handpiece. An ill-fit may also cause the blade to disengage from the handpiece.

Actions needed

1. Immediately review your inventory to locate and quarantine any affected products at your facility.
2. Return the enclosed Business Reply Form (BRF), even if the affected product is no longer in inventory, to the email xxx@stryker.com.
3. Upon receipt of the completed BRF, Stryker will provide a shipping label to return recalled product on-hand.
4. A replacement will be provided upon receipt of the recalled product.
5. Maintain awareness of this communication internally and inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so Stryker can inform the recipients accordingly..

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:

We request that you respond to this notice within 10 calendar days from the date of receipt

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 by 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.

Yours Sincerely,

Sincerely,

Business Reply Form

Blade Mount Geometry Out of Tolerance / Precision Thin Blades

February X 2025

Recall Number: RA2024- 3846155

Please select from the options below and complete this form. Email the completed form to: xxx@stryker.com.

RESPONSE IS REQUIRED.

☐ **No remaining affected products on-hand.**

☐ **I, the customer, choose to return the following product(s) for replacement:**

Catalog number	Product	Lot number(s)	Quantity on hand (EA)*
2296-003-155	PREC THIN 9.0 X 0.38 X 18.5MM	**23070017**	
2296-003-108	PREC THIN 13.0 X 0.38 X 39.0MM	**22298017**	

*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, if possible:

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

☐ **I have received the Medical Device Notification from Stryker dated February , 2025**

☐ **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 :