

## Medical Device Recall

**Stryker Performance Series® Sagittal Blade****Attn: Risk Manager, Materials Manager/Director****Recall Number: RA2026-4201404****January 12th, 2026****Product affected**

Catalog Number	Description	GTIN	Affected Lot
6125-127-100	Stryker Performance Series Sagittal Blade	04546540501523	24236057
2108-140-000	Stryker 2108 Series Sagittal Blade	04546540042118	24233017

**Product description**

The Stryker Performance Blades are single use disposable devices intended for use with compatible handpieces for cutting, drilling, decorticating and smoothing of bone and other bone related tissues in a variety of surgical procedures.

**Product issue**

There is a potential that the device contained within the package does not correspond to the product description on the outer label. The label may indicate Stryker 2108 Series Sagittal, while the actual device inside is a Stryker Performance Series Sagittal Blade or vice versa

1 complaint was received for this issue, and 0 adverse events were reported.

**Potential risks**

There is no potential harm associated with this issue.

**Actions to be taken**

Our records indicate that you may have received one or more of the applicable products. It is Stryker's responsibility as the manufacturer of the products to ensure that customers who may have received the 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 [<XXXX@stryker.com>](mailto:<XXXX@stryker.com>) to confirm receipt of this notification/documenting 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 eliminate the need for us to send further unnecessary communication on this matter. Therefore, please complete the form even if you no longer have any of the subject devices in your physical inventory.
3. Upon receipt of the complete Business Reply Form, Stryker will contact you to arrange for the return of your affected product(s). A replacement will be provided upon receipt of the recalled product.
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

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:
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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,

# Business Reply Form

## Stryker Performance Series® Sagittal Blade

Recall Number: RA2026-4201404

January 12th, 2026

Please choose the most appropriate option below and complete this form. Email the completed form to [XXXX@stryker.com](mailto:XXXX@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	Description	Affected Lots	Affected Qty (EA)
6125-127-100	Stryker Performance Series Sagittal Blade	24236057	
2108-140-000	Stryker 2108 Series Sagittal Blade	24233017	

Form completed by:

Facility Name			
Facility Address			
Printed Name		Title	
Email		Phone	
Signature		Date	

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

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

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