stryker

URGENT
Medical Device Recall

Stryker Sonopet® 12cm iQ Claw

Attn: Risk Manager, Materials Manager, OR Director

Reference Number: RA2026-4365079

JUNE 10, 2026

Product affected

Catalog Number	Description	UDI	Affected Lot
550025B318	12cm iQ Claw	08858250000642RZ	24284027

Product description

Sonopet iQ Tips amplify and deliver ultrasonic energy to the target tissue while allowing for the removal of surgical waste from the surgical site using suction. 12cm iQ Claw is a hard tissue tip with teeth on one face pointing upwards.
They do not cut distally and have a blunt distal face.

Product issue

There is a potential that the device contained within the package does not correspond to the product description on the product label. Your carton of 12cm iQ Claws may contain products mislabeled as 12cm iQ Standard.

Potential risks

There is no potential harm associated with this issue.

Actions to be taken

1. Immediately review your inventory to locate and quarantine any affected products at your facility.
    a. For products in carton:
        i. The carton label and device in the packaging are correct; therefore, identify affected units by using the catalog and lot number listed in this notification
    b. For products removed from carton:
        i. Identify affected units by reviewing each product label which incorrectly identifies the product as "12cm iQ Standard" instead of "12 cm iQ Claw"
2. Please complete and return the enclosed Business Reply Form (BRF) to xxxx@stryker.com, even if the affected product is no longer in your inventory. Submitting the BRF prevents duplicate notices from being sent.
3. Once the completed Business Reply Form is received at XXXX@stryker.com, Stryker will issue a shipping label for the return of any recalled product currently 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 that Stryker can inform the recipients accordingly.
6. If you have further distributed the affected product, please notify the applicable parties. 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.
7. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations. For questions or concerns, please contact XXXX@stryker.com,

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: E-mail:

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,

Post Market Quality

Business Reply Form

Stryker Sonopet® 12cm iQ Claw

Attn: Risk Manager, Materials Manager, OR Director
Reference Number: RA2026-4365079
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Please choose the most appropriate option below and complete this form. Email the completed form to XXXX.recalls@stryker.com. RESPONSE IS REQUIRED.

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

☐ **I will return the following product(s) for replacement:**

Catalog Number	Description	Affected Lots	Affected Qty (EA)
550025B318	12cm iQ Claw	24284027	

Form completed by:

Facility Name			
Facility Address			
Printed Name		**Title**	
Email		**Phone**	
Signature		**Date**	
Stryker employees may not complete a Business Reply Form on behalf of the customer			

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			