stryker

URGENT

Medical Device Recall

InterPulse® Irrigation System

Attn: Material Manager, OR Director, Risk Manager

Recall Number: RA2026-4218540

January XX 2026

The purpose of this letter is to inform you of a missing CE mark on the product label.

Products Affected

Catalog Number	Product Description	GTIN
0211-100-000	InterPulse Rechargeable Handpiece Set with Suction Tubing	04546540144331

Impacted Lot Numbers										
23053012	23107012	23131012	23206012	23345012	24009022	24046022	24129012	24173012	24235012	24285012
23054012	23110012	23150012	23207012	24003012	24011012	24051012	24129022	24173022	24283012	24318012
23058012	23114012	23164012	23276012	24008012	24011022	24051022	24130012	24199012	24283022	24318022
23089012	23115012	23164022	23313012	24008022	24012012	24052022	24172012	24199022	24284012	24319012
23090012	23116012	23205012	23319012	24009012	24012022	24053012	24172022	24200012	24284022	24352012

Product Description

The InterPulse Rechargeable Handpiece Set with Suction Tubing is a single-use disposable device intended for procedures such as wound or soft tissue debridement and cleansing of medical, clinical, or surgical sites.

Product Issue and Risk

The lots listed above were distributed to EU customers without the CE mark displayed on the product label. The CE mark is a mandatory requirement for medical devices marketed within the EU, as it signifies conformity with applicable regulatory standards. Consequently, these devices should not have been released for distribution in the EU without the CE mark present. There is no risk of harm associated with this nonconformance, and no complaints have been reported.

Actions Required

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> 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:

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

InterPulse® Irrigation System

Attn: Material Manager, OR Director, Risk Manager

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Please select from one of 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 replacements:

Catalog Number	Product Description	Affected Lots	Qty on hand*	
			EA	PACKS
0211-100-000	InterPulse Rechargeable Handpiece Set with Suction Tubing			

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

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

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:

Facility Name		**Contact Person**	
Full Address			