stryker

# RA2024-3716835 URGENT:
## Field Safety Notice

## Sterilizable Internal Defibrillation Paddles

**Attn:**

**Recall Number:** FA-307/RA20247-3716835

**September 2024**

**Product affected**

| Catalog number | GTIN | Product description | Serial/Lot number(s) |
|---|---|---|---|
| 11131-000040<br>11131-000041<br>11131-000042<br>11131-000043<br>11131-000044<br>11131-000045<br>11131-000046<br>11131-000047 | 00883873863558<br>00883873863534<br>00883873863527<br>00883873863510<br>00883873863503<br>00883873863497<br>00883873863480<br>00883873863213 | **Sterilizable Internal Defibrillation Paddles** | 105817428<br>107124605<br>107124577<br>107445069<br>107556560 |

**Product description**

The Sterilizable Internal Defibrillation Paddles are intended for use with LIFEPAK defibrillators to internally detect ECG rhythm and provide defibrillation or synchronized cardioversion directly to the surgically exposed heart within a sterile use environment.

**Product issue**

Stryker has received several complaints indicating issues with the Internal Paddles. There have been 62 product complaints which state that the paddles are not reaching the expected cleaning and sterilization cycle count designated in the Instructions for Use and are showing signs of cracking. Please refer to the figures below for examples of the cracks.

In addition, there are 6 complaints of Internal Paddles having a noticeable material separation between the white and gray silicone overmold material on the grip of the handle. Please refer to the figures below for examples of the overmold separation.

## Potential risks

There is a possibility that if paddles are used when the cracks are present, it has the potential to result in an impact to electrical function or it may affect the efficacy of sterilization. Usage of the cracked paddles during patient events may also result in laceration of tissue due to the sharp edges created.

To date, there have been no adverse events reported to Stryker due to this issue.

Please keep Stryker informed of any serious incidents associated with this product by using Stryker's online reporting site: https://www.stryker.com/productexperience .

## Actions needed

1. Immediately check your internal inventory to locate the product listed on the attached business reply form.
2. It is important to follow the step 2 as outlined in the Pre-Surgical Check section of the Instructions for Use (IFU). If any damage or malfunction is found, remove the internal paddles from use immediately and contact your local Stryker representative below for assistance.
3. To confirm receipt of this Medical Device Notice and understanding of the provided information, please email the enclosed Business Reply Form (BRF) by **XXXX** to XXXX
4. Please continue to follow the Instructions for Use for the Sterilizable Internal Defibrillation Paddles for additional troubleshooting steps.

5. If you have further distributed this product to other organizations, proceed to inform them about the present Field Safety Notice.

Please respond even if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

The Stryker Representative for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: XXXX Position: XXXXX Email: XXXX

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 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 and your expectations, remain on the market.

Sincerely,

stryker

# Business Reply Form

**Account number:**
**Account name:**
**Account Address:**

## Sterilizable Internal Defibrillation Paddles

**Recall Number:** FA-307/RA2024-3716835
**September 2024**

Response is required; Please complete and sign this form.
Email the completed form to XXXX by **XXXX**

☐ I have read and understood the enclosed notification and performed all the actions requested.

| **If you no longer have the device on hand, what was the final disposition of the product:** |
|---|
| |
| **Additional Comments:** |
| |

**Form completed by:**

| | | | |
|---|---|---|---|
| **Printed Name** | | **Title** | |
| **Signature** | | **Phone** | |
| **Date** | | **Email** | |

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

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