URGENT FIELD SAFETY NOTICE and MEDICAL DEVICE CORRECTION

stryker

Attn: OR Manager
Account Name
Account Address
Account Number

May 2026
Action Reference: RA2026- 4264880

Image 1:
Affected Component:
Soffit Ring

Purpose The purpose of this notification is to advise you that Stryker has initiated a voluntary recall for the device listed in Table 1 below.

Affected Product

Part Number	Product Description	GTIN	Affected Devices	Distribution Dates
CH00000001	Chromophare	07613327296167	Devices manufactured with Revision B Soffit Rings	April 30, 2024 - October 30, 2025

Product Description Chromophare surgical lights are medical lights used in hospital treatment rooms. The affected component is the soffit ring, which supports the Chromophare ceiling cover.

Reason for the Recall Stryker has discovered that certain lots of the soffit ring may not adequately support the weight of the ceiling cover. As a result, the cover may shift or slide down the ceiling tube. Movement of the ceiling cover can expose the area above the ceiling, which may allow particles, such as dust, debris, residue, or other contaminants, to enter the sterile field.

Potential Risks The ceiling cover sliding down the ceiling tube may lead to particles, such as debris and dust, falling into the surgical field or directly into patients. This could lead to infection, or intra-operative intervention. As of March 3rd, 2026, Stryker has received 141 complaints pertaining to this issue, one of which resulted in an adverse health event to the user.

Device Correction All soffit rings are inspected during the installation process to ensure they are mated tightly against the ceiling cover at the time of installation. An indication that the soffit ring is supporting the ceiling cover is that the ceiling cover sits flush with the ceiling per the Chromophare installation manual. Images of the soffit ring properly supporting the cover and not properly supporting the cover are shown in Attachment A.

Actions needed

1. Inform individuals within your organization who need to be aware of this action.
2. Check your internal inventory to locate the affected product.
3. Visually check the ceiling cover to ensure it is flush to the ceiling, using images in Attachment A.
    a. If a gap is observed, stop use and report this to Service immediately at xxxxxxxxxxx@stryker.com
    b. If no gap is observed, the product may continue to be used per the instructions for use.
4. A representative will contact affected accounts to schedule a field service visit to complete an inspection and replacement of the affected component.
5. Complete Attachment B, Business Reply Form, as an acknowledgement of this notice and return the completed form via email to xxxxxxxxxxx@stryker.com. Response is required.
6. Maintain awareness of this communication internally until all required actions have been completed within your facility.
7. 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 appropriately.

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 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,

Personal data

Personal data

Visual Check

Attachment A

Part Number: CH00000001
Product Description: Chromophare

Visually check the ceiling cover to ensure it is flush to the ceiling, using the images in Attachment A.

a. If a gap is observed, stop use and report this to Service immediately at xxxxxxxxxxx@stryker.com. Please see Image 3 below as an example.
b. If no gap is observed, the product may continue to be used per the instructions for use. Please see Image 2 below as an example.

Image 2: Example of a ceiling cover that is flush to the ceiling

Image 3: Example of a ceiling cover that is not flush with the ceiling

Attachment B

Business Reply Form

Chromophare – Soffit Ring
Action Reference: RA2026- 4264880
May 2026

Response is required; please complete and sign this form.
Email the completed form to xxxxxxxxxx@stryker.com by **May 31, 2026.**

Please indicate the part number, serial number(s), and quantity of this product your facility has on hand:

Part Number	Serial Number(s)	Quantity on hand
CH00000001		

If you no longer have the device on hand, please indicate the final disposition of the product:_____

_____

Please indicate your facility information and sign and date below:

Account Name			
Account Address			
Account Number			
Printed Name		Title	
Signature		Phone	
Email		Date	

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			