URGENT FIELD SAFETY NOTICE: RA2019-1937561

STRYKER: Chromophare F 528/F 628 Surgical Lights, Light Head Cover

ATTN: Operating Room Director, Risk Manager, Materials Manager

April, 2019

FSCA identification: Field Safety Corrective Action RA2019-1937561
Action type: Device Correction
Catalogue Numbers: 83282 and 83283
Product description: Light Head Cover, Printed, F 528 and Light Head Cover, Printed, F 628
Part of the device: CH00000001
Chromophare F 528-F 628 - Ceiling Mounted Surgical Light System
Legal manufacturer : BERCHTOLD
Serial Numbers: See Appendix A

Dear Device Customer/Distributor,

The purpose of this notification is to advise you that Stryker Communications is voluntarily correcting the above affected F 528/F 628 Light Head Covers, which are a part of Stryker's Berchtold Chromophare Surgical Lighting System.

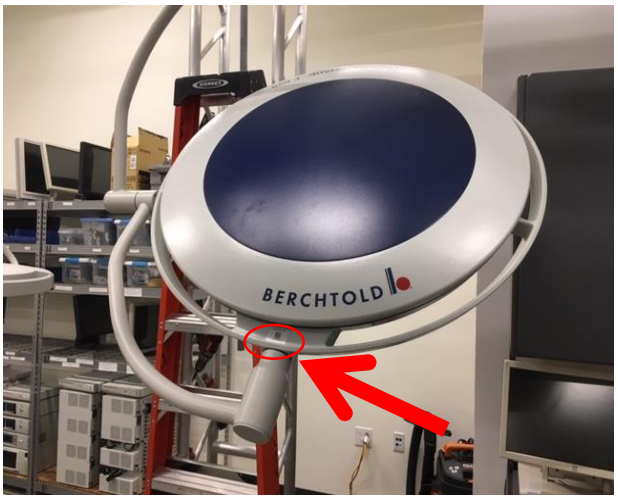

Figure 1: F 528/F 628 Light Head with attached affected Light Head Cover

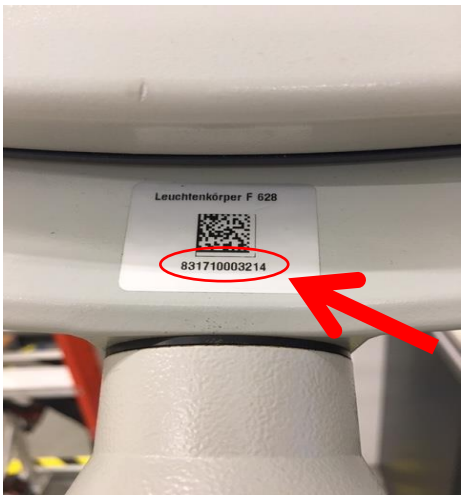

Figure 2: serial number of the F 528/F 628 Light Head Cover

Product Description:
The surgical lights for Berchtold Chromophare F 528 and F 628 are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light. The major components of system are the ceiling down tube, a swivel arm support and the light head.

Reason for the Voluntary Recall:
Stryker has become aware that there is a remote likelihood that the Berchtold Chromophare F 528 and F 628 Light Head Cover (Manufactured from September 21st, 2017 to November 13th, 2018) may have an insufficiently assembled component on the back cover. If this component on the Chromophare Light Head Cover disengages, it could potentially fall off the light and cause temporary or reversible injuryto HealthCare Providers and/or patients. To date, there have been no adverse events reported for this issue.

Risk to Health:
If this component on the Chromophare Light Head Cover disengages, it could potentially fall off the light and cause temporary or reversible injury to HealthCare Providers and/or patients. To date, there have been no adverse events reported for this issue.

Actions to be taken by the Customer/User:
Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.
We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory. Please note that the lights can continue to remain in full use.
2. Circulate this Field Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form. 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 negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) A Stryker Representative will begin replacements for customer facilities in April. For the replacement, the Stryker Representative will perform an onsite rework of the Berchtold Chromophare F 528 and F 628 Light Head Cover. In the meantime, the lights can continue to remain in full use.

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 Meddev Vigilance Guidance document Ref 2.12-1, 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 within the target date 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, remain on the market.

Yours Sincerely,

XXXXXX

URGENT FIELD SAFETY NOTICE: RA2019-1937561
APPENDIX A
STRYKER: Chromophare F 528/F 628 Surgical Lights, Light Head Cover

Part Number	Serial Number
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CUSTOMER RESPONSE FORM: RA2019-1937561

STRYKER: Chromophare F 528/F 628 Surgical Lights, Light Head Cover

FSCA identification: Field Safety Corrective Action RA2019-1937561
Action type: Device Correction
Catalogue Numbers: 83282 and 83283
Product description: Light Head Cover, Printed, F 528 and Light Head Cover, Printed, F 628
Part of the device: CH00000001
Chromophare F 528-F 628 - Ceiling Mounted Surgical Light System
Legal manufacturer : BERCHTOLD
Serial Numbers: See Appendix A

I received and understood the Field Safety Notice for RA2019-1937561 and have followed the instructions in the Notice.

We have not located any of these devices in our inventory: *(please delete if not applicable)*	

We have located the following devices:			
Product Reference	Serial Number	Qty on hand	Qty scrapped before receiving this Notice

We have further distributed subject devices to the following organizations:	
Facility Name	
Facility Address	

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO _____
OR EMAIL TO _____