

Keri Medical SAS
ACTIPRO – 219 RUE LASZLO BIRO
74610 ARCHAMPS
France

URGENT: FIELD SAFETY NOTICE

FSN-2019-001

It has come to our attention that your company received incorrectly labelled products from Swemac Innovation AB. Our supplier has unfortunately labeled the article, 40-1015S, Radius Cup ø15mm, batch 178733, with 'CrN'. The label incorrectly states that the product is coated with CrN (Chromium Nitride). Batch 178733 is not coated with CrN.

This event does not pose any patient risk, nor does it affect the safety or performance of the product. No injury or harm has been reported for this event.

Swemac Innovation AB is performing a mandatory recall of all articles from the affected batch for re-labeling with a correct label.

Note! No actions are needed for already implanted devices.

Affected devices

Catalogue number	Product Name	Batch number
40-1015S	Radius Cup ø15mm	178733

Actions needed from distributors

Please determine if you have affected products in your inventory. If you do, stop using and/or distributing the product(s) and do the following:

1. Perform a physical count of your inventory.
2. Record this data on the survey found on page 2 of this FSN letter.
3. Fill out the rest of the survey form and return it via email to: quality@swemac.com by Friday the 1st of February.
4. For any products that need to be returned, please contact via email at karina.schollhammer@swemac.com or via phone +45 41 66 44 87

Please do not hesitate to contact Swemac if you have any questions. Thank you for your cooperation.

Best regards,



Andreas Sundberg
Quality and Regulatory Manager
Swemac Innovation AB

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SURVEY

Distributor company name:	
Address:	
Phone:	
Email:	
Contact person:	

We have identified the following number of articles to return to Swemac.

Please note how many items that will be returned in total in the rightmost column of the table below.

Catalogue number	Product Name	Batch number	Number of items to return
40-1015S	Radius Cup ø15mm	178733	

This survey was completed by: _____

Date: _____

Title: _____