Understand. Innovate. Deliver.™

1600 West Merit Parkway
South Jordan, UT 84095 USA
PHONE 801.253.1600
FAX 801.253.1688
merit.com

URGENT FIELD SAFETY NOTICE (FSN)

Date:15-Mar-2017

Customer Name
Customer Address

ATTENTION: Hospital Administrator/Interventional Radiology Lab Manager/Risk Manager

Dear Sir or Madam,

Merit Medical Systems, Inc. is voluntarily conducting a recall of the Merit PreludeSYNC™ Radial Compression Device. This affects the lots identified in the table below. Particulate generated during the manufacturing process may enter the valve, preventing a complete seal of the inflation valve resulting in a slow balloon air leak. Merit has not received any reports of patient harm or injury as a result of this issue. Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lots and return them to Merit.

Catalog Numbers	Affected Lot Numbers
SRB24AC	H1068590S1 H1078177 H1078180 H1083628
SRB24MED	H1068587S1 H1073974 H1078179 H1078181 H1083629 H1083630

Catalog Numbers	Affected Lot Numbers
SRB29AC	H1068591S1 H1078183 H1083631
SRB29MED	H1068589S1 H1078184 H1078185 H1083633

Our records indicate that you have received affected lots.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form are within your facility, quarantine them, and discontinue use.
2. Ensure that all personnel to whom the devices were distributed are made aware of this field action.
3. Please fill out, scan and email the attached Customer Response Form to response@merit.com.
4. Please return all affected lots in your possession to Merit, per the instructions found in the Customer Response Form.

Note, continued clinical use of affected product may result in the following risks to the patient: hematoma (compartment syndrome and ischemia), hemorrhage (mild to moderate), and patient discomfort.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Michelle Savelkoul at +31 43 3588247 (Ext. 9007) or msavelkoul@merit.com.

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Kind Regards,

Mark Mullaney
Director, Regulatory Affairs
Merit Medical Ireland Ltd.
Phone #: +353 91 703 761 / Fax #: +353 91 771 888 / E-mail: mmullaney@merit.com

Enclosure

Urgent Product Recall Notice
Customer Response Form

Merit Medical Systems, Inc.

Merit Sales Rep: XXXXXXXXXXX

[Ship to Address]	Site Representative _____
	Title _____
	Phone # _____
Customer # Customer Phone Number	Date _____

THIS IS AN URGENT PRODUCT RECALL NOTICE:
Merit Medical Systems, Inc. is voluntarily conducting a recall of the Merit PreludeSYNC™ Radial Compression Device. This affects the lots identified in the table below. Particulate generated during the manufacturing process may enter the valve, preventing a complete seal of the inflation valve resulting in a slow balloon air leak. Merit has not received any reports of patient harm or injury as a result of this issue. Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lots and return them to Merit.

Please provide status on the following:

Lot #	Part #	Qty	Ship Date	Customer PO #	Merit Order #	RGA #	Qty Used /Distributed	Qty Unused and Being Returned

Please fill out and sign this Customer Response Form and complete the following steps. It is very important that you complete these steps in order to assist Merit in complying with applicable government regulations.

1. **Scan and email the completed Customer Response Form to Michelle Savelkoul at: msavelkoul@merit.com.**
2. **If you are returning product, place the original completed Customer Response Form with the products to be returned as below. The form must accompany all products being returned to Merit.**

Product Return Instructions
Return the affected products by shipping them back to Merit via UPS Standard Account Number 7619AE, include the assigned Field Report number on the outside of the box and ship to:

Merit Medical, Customer Service, Amerikalaan 42, 6199 AE Maastricht Airport, The Netherlands

If you have further questions, please contact Michelle Savelkoul at +31 43 3588247 (Ext. 9007) or msavelkoul@merit.com.

I certify that I received and understood this notice. I certify that the above listed products have been used, distributed, or returned to Merit Medical Systems, Inc. according to the notification instructions. Furthermore, if I have further distributed product listed on this form, I certify that a copy of this notice was provided to said consignee(s).

_____ _____

Signature of Site Representative **Date**