Understand. Innovate. Deliver.™

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URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: Prelude SNAP™ Splittable Sheath Introducer

Field Safety Corrective Action (FSCA) Identifier: 1721504-XX/XX/XX-XXXR

Action Required: Return Device(s) to Merit

Date

ATTENTION: Risk Manager/Cardiac Catheter Lab or Electrophysiology Manager

Dear Sir or Madame,

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of Prelude SNAP™ Splittable Sheath Introducers due to an intermittent failure of the splittable hub. Merit Medical has received complaints indicating that the wings on certain lots of the Prelude SNAP™ have broken off the sheath hub during splitting. This will likely result in a minor delay in procedure. Although extremely rare, this could also result in a pacing lead/catheter displacement, air embolus, or minor hemorrhage. Merit has received no reports of patient harm or injury as a result of this issue. It is unlikely that any patient harm would result from this issue. Merit has identified the affected lots and catalog numbers as detailed in the table below. Merit has chosen to remove the affected units from the market and requests that you immediately stop using the affected lots and return them to Merit.

Catalog Numbers	Lot Numbers	Catalog Numbers	Lot Numbers	Catalog Numbers	Lot Numbers
PLS-1006	Q1175809 Q1190096 Q1194040 Q1194662 Q1194666 Q1213044 Q1228355	**PLS-1012.5**	Q1235166	**PLSH-1007**	Q1195096 Q1189781

Catalog Numbers	Lot Numbers	Catalog Numbers	Lot Numbers	Catalog Numbers	Lot Numbers
PLS-1007	Q1176348 Q1178762 Q1194660 Q1206565 Q1201803 Q1209475 Q1213042 Q1228339 Q1234189X1 Q1234639	**PLS-2506**	Q1205118	**PLSH-1009**	Q1161477
PLS-1008	Q1182862 Q1190097 Q1194661 Q1197055 Q1202959 Q1213024 Q1215467 Q1234979	**PLS-2507**	Q1175815 Q1194665 Q1197054	**PLSX-1006**	Q1185050 Q1234958
PLS-1009	Q1174112 Q1197331 Q1176349 Q1213048	**PLS-2508**	Q1193985	**PLSX-1007**	Q1176345 Q1193391 Q1228356
PLS-1009.5	Q1182863 Q1228338	**PLS-2509**	Q1193397 Q1209478 Q1228340	**PLSX-1009**	Q1175817 Q1194663 Q1215702 Q1228354
PLS-1010	Q1194041 Q1206577 Q1214620	**PLS-2510**	Q1176347 Q1204708	**PLSX-1009.5**	Q1201789
PLS-1010.5	Q1184987 Q1194664 Q1213051 Q1237072	**PLS-2510.5**	Q1182836		
PLS-1011	Q1213018	**PLSH-1006**	Q1170938		

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 individuals within your organization are made aware of this field action.
3. Please complete, scan and email the attached Customer Response Form to RESPONSE-EMEA@merit.com within 5 days.
4. Please return all affected lots in your possession to Merit within 10 days, per the instructions found in the Customer Response Form.

Note, the relevant National Competent Authorities have been advised of this FSN.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Customer Service at +31 43 3588 233 or CustomerService-Maastricht@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,

Signature Block

Enclosure: Customer Response Form

Urgent Product Field Safety 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 FIELD SAFETY NOTICE:

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of Prelude SNAP™ Splittable Sheath Introducers due to an intermittent failure of the splittable hub. Merit Medical has received complaints indicating that the wings on certain lots of the Prelude SNAP™ have broken off the sheath hub during splitting. This will likely result in a minor delay in procedure. Although extremely rare, this could also result in a pacing lead/catheter displacement, air embolus, or minor hemorrhage.
Merit has received no reports of patient harm or injury as a result of this issue. It is unlikely that any patient harm would result from this issue. Merit has identified the affected lots and catalog numbers as detailed in the attached table. Merit has chosen to remove the affected units from the market and requests that you immediately stop using 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	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 RESPONSE-EMEA@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 7619AE, include the assigned RGA number (see above table) 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 Customer Service at +31 43 3588 233 or CustomerService-Maastricht@merit.com.

I certify that I received and understood this notice. I certify that the above listed products have been used or returned to Merit Medical Systems, Inc. according to the notification instructions.

_____ _____
Signature of Site Representative Date