

March 14, 2012

<Hospital Name>
 ATTN: <department [CCL, OR, Material Management]>
 <Address>
 <City>, <ST>, <Zip Code>

Dear Healthcare Professional:

We have identified a rare production issue affecting isolated lots of the **12Fr SLS® II** Laser Sheath that can result in a split in the outer jacket in an estimated 1% of affected devices. Consistent with our commitment to deliver the highest quality devices, Spectranetics is voluntarily recalling product as specified in Table 1. You are on record in our shipping database as having received one or more devices from the affected lots.

Table 1

Product Model Number	Product Name	Affected Lot Numbers			
500-001	12 Fr SLS II Laser Sheath	C	11	H	25B 25C 25D 29E 29F 29G
		C	11	J	All
		C	11	K	03E 06A 06B 06C
		F	11	J	19A 29F
		F	11	K	11D 25G
		F	11	L	03A 17A

We have received and confirmed two customer complaints of this issue, but no adverse events have been reported to Spectranetics. While we believe the probability of adverse health consequences is remote, there is potential for patient or user injury if broken fibers are exposed by a split outer jacket. We are initiating this voluntary action based on our internal quality processes. This voluntary action has been reported to the U.S. Food and Drug Administration and to the affected foreign Regulatory Bodies.

Requested Actions:

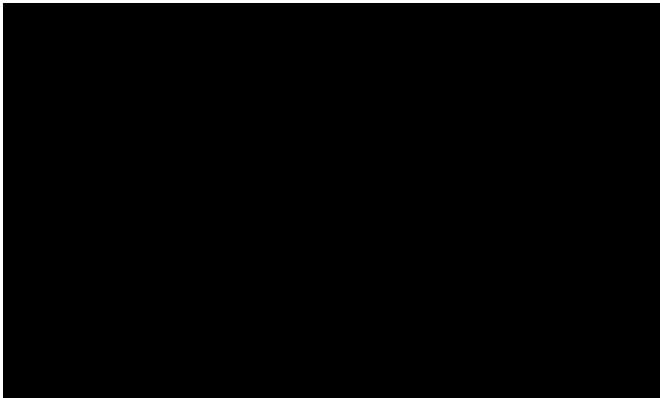
- For Model 500-001 SLS II 12Fr units in your inventory, please compare the lot number on the product label with lot numbers in Table 1 to determine if you have any affected devices

- Set-aside any affected 500-001 devices
- Contact **Customer Service at +31-33-4347-051** to arrange the product exchange at no cost to you
- Document the product to be returned on the enclosed **12Fr SLS II Laser Sheath Affected Lot List FAX** form. Your Spectranetics sales representative can assist you to expedite the product return and exchange.

Spectranetics values the trust you place in us for the delivery of safe, effective, high-quality products. This voluntary action is consistent with our commitment to you and your patients. If you have additional questions, please contact your local Spectranetics representative or me directly.

Sincerely,

The Spectranetics Corporation



12Fr SLS® II Laser Sheath Affected Lot List

>> Return to Spectranetics Customer Service <<
FAX NUMBER: +31-33-4347-051

Instructions

1. If you possess one or more affected devices, please complete the chart below per Table 1 - Affected Lot Numbers; go to #3
2. If no affected devices remain in your inventory, please mark the check box below
3. Please sign on the line provided
4. Please return this form to Spectranetics with EITHER the table completed OR the box checked

Spectranetics Lot #	Customer PO #(if available)	Qty on Shelf (record per Lot #)

- After verifying Affected Lot Numbers per Table 1, to my knowledge, there are not any devices remaining in the hospital's inventory.

>> **Customer Fax Number:** _____
-Please include for Spectranetics communication back to you on:
-product RMA#
-replenishment product orders

>> **Customer Signature:** _____
(or if applicable, Spectranetics Sales Representative)

Hospital Name: <Hospital Name>
Customer Number: <CustNum>