

Field Safety Notice - Customer Reply

1. Field Safety Notice (FSN) Information	
FSN Reference Number	3014526664-1/17/21-001-R
FSN Date	March 2, 2021
Product/ Device Name	ENROUTE® TRANSCAROTID STENT SYSTEM
Product Code(s)	SRE-0740-CS
Batch/Serial Number (s)	301330

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer Action Undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I have quarantined the affected devices - enter number of devices returned and date complete	Qty:	Lot Number:	Date Returned (DD/MMM/YYYY):
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/destruction	Comments:		
Print Name				
Signature				
Date				

4. Return Acknowledgement to Sender	
Deadline for returning the customer reply form	31 MAR 2021

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

FSN Ref: 3014526664-1/17/21-001-R

FSCA Ref: MDD21.069

Date: 02:MAR:2021

Urgent Field Safety Notice

ENROUTE[®] TRANSCAROTID STENT SYSTEM

Sent via Email

For Attention of:

To whom it may concern:

Contact Details of Local Representative (name, e-mail, telephone, address etc.)
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HealthLink Europe B.V.

Address: De Tweeling 20-22 5215 MC 's-Hertogenbosch The Netherlands
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Email: silkroad@healthlinkeurope.com
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Phone: +31 73 303 0500

Fax: +31 13 547 9301

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FSCA Ref: MDD21.069

Urgent Field Safety Notice (FSN)

ENROUTE[®] TRANSCAROTID STENT SYSTEM

Product Problem: Detachment of components during use.

1: Information on Affected Devices

1. Device Type	The Silk Road Medical ENROUTE Transcarotid Stent System consists of a nitinol self-expanding stent preloaded on a 5F (0.065 inch /1.65 mm) sheathed delivery system and is supplied sterile.
2. Commercial Name	ENROUTE [®] TRANSCAROTID STENT SYSTEM
3. Unique Device Identifier(s) (UDI-DI)	(01)00811311020652 (17)210930 (10)301330
4. Primary Clinical Purpose of Device	The stent delivery system is intended for the treatment of carotid artery stenosis.
5. Device Model/Catalogue/Part Number	Model number SRE-0740-CS.
6. Affected Serial or Lot Number Range	Lot number 301330.
7. Associated Devices	The ENROUTE Transcarotid Stent System is used in conjunction with the ENROUTE Transcarotid Neuroprotection System and is indicated for use in patients with stenotic lesions of the carotid artery(ies).

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2: Reason for Field Safety Corrective Action (FSCA)

1. Description of the Product Problem
The Nosecone (Distal Tip) may detach from the Delivery System during use of the ENROUTE Stent Delivery System.
2. Hazard Giving Rise to the FSCA
In instances where the detached tip is detected, there may be a need for intervention (e.g., use of a snare or conversion to carotid endarterectomy) and is the likely outcome of the failure. There is a potential for serious injury (embolization or stroke) as the result of this failure if the detached tip is not detected by the end user. Though no patient has experienced an adverse event associated with the complaints, if the tip detachment were to go undetected, it could result in an adverse event as significant as a stroke.
3. Probability of Problem Arising
Based on the total procedures performed and the number of complaints received, the probability of the respective problem arising is 0.206% (7 complaints, 3400 procedures).
4. Predicted Risk to Patient/Users
There is a remote probability of a serious adverse health consequence or a medically reversible or transient adverse health consequence.
5. Further Information to Help Characterise the Problem
The overall rate for tip dislodgement remains low, however there is a shift in frequency since market release in 2016. Therefore, out of an abundance of caution, Silk Road is voluntarily recalling the implicated lots from the field.
6. Background on Issue
Nosecone detachment has been reported in seven (7) customer complaint reports in the U.S. since September of 2020.
7. Other Information Relevant to FSCA
Out of an abundance of caution, a voluntary recall of the implicated lot has been initiated.

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3: Type of Action to Mitigate the Risk

1. Action to be Taken by the User <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions for Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Immediately upon receipt of this email, record the number of units from the corresponding lots that remain at your facility, ensure they are adequately quarantined to prevent use, and reply to this email (recall@silkroadmed.com). If no impacted product remains at your facility, please indicate so in the attachment. Please include your complete contact information in your reply including your name, title, and phone number. Return all pages in the attachment. Upon receipt of your response, a Silk Road Medical representative will reach out directly to coordinate return and replacement of the affected product.	
2. By when should the action be completed?	User actions should be completed as soon as possible.
3. Particular Considerations for:	<input checked="" type="checkbox"/> Implantable device <input type="checkbox"/> Diagnostic imaging device <input type="checkbox"/> IVD Is follow-up of patients or review of patients' previous results recommended? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
4. Is Customer Reply Required?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
6. By when should the action be completed?	Completion of all actions are expected by June 2021.
7. Is the FSN required to be communicated to the patient /lay user?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Appended to this FSN <input type="checkbox"/> Not appended to this FSN	

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4: General Information

1. FSN Type	<input checked="" type="checkbox"/> New <input type="checkbox"/> Update
2. For Updated FSN, Reference Number, and Date of Previous FSN	N/A
3. For Updated FSN, Key New Information as Follows:	N/A
4. Further advice or information already expected in follow-up FSN?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not planned yet
5. If follow-up FSN expected, what is the further advice expected to relate to:	N/A
6. Anticipated Timescale for Follow-Up FSN	N/A
7. Manufacturer Information (For contact details of local representative refer to page 1 of this FSN)	
a. Company Name	Silk Road Medical, Inc.
b. Address	1213 Innsbruck Avenue, Sunnyvale, CA 94089 USA
c. Website Address	www.silkroadmed.com
d. Phone	+1-855-410-8227
8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
9. List of Attachments/Appendices:	Customer FSN
10. Name/Signature	Shari Rideout Vice President, Quality and Regulatory Compliance
	 Electronically signed by: Shari Rideout Reason: Approved By Date: Mar 2, 2021 08:07 PST
	02-Mar-2021

* The relevant National Competent Authorities have been advised of the FSCA.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor, or local representative, and the national Competent Authority if appropriate, as this provides important feedback.