stryker

URGENT:
MEDICAL DEVICE VOLUNTARY Recall
Recall Number: RA2022-3037482

Guider Softip™ XF Guide Catheter

Attn: Risk Management/ Recall Coordinator/ Inventory Manager

Boston Scientific has initiated a Voluntary Field Action – Removal on one lot of the Guider Softip™ XF Guide Catheter. The Guider Guide Catheter is manufactured by Boston Scientific Corporation and distributed by Stryker Neurovascular. Our records indicate that you have been supplied with the subject devices. We therefore request that you read this notice carefully and complete the actions requested.

Product affected:

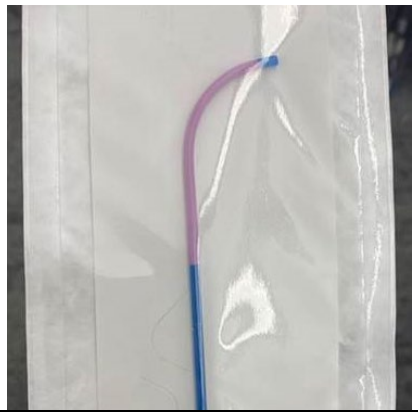
Please cease further distribution or use of any remaining product affected by this removal immediately.

Catalog number	Universal Device Identifier (UDI) Number	Product description	Lot Number
H965100440	(01)08714729202486(17)240518(10)27339850	Guider/40XF/8FR/90CM	27339850

Product description The Boston Scientific Guider Softip™ XF Guide Catheter is a neurovascular access catheter that creates a stable conduit through which interventional devices can pass. It is constructed with a polymer liner on the inside diameter for lubricity, stainless steel wire reinforcement within the wall for torque transmission and strength, and polymer materials along the length of the catheter for support and flexibility. The catheter has an atraumatic tip and a hub/strain relief combination for kink resistance (at the hub), device connectivity, and device handling.

Product issue Stryker Neurovascular has observed that Guider devices from Lot 27339850 appear to have the incorrect tip curve shape. The impacted products were distributed with an MPXF tip curve shape instead of the 40XF tip curve shape for the Guider/40XF/8FR/90CM guide catheter. See images below.

URGENT:
MEDICAL DEVICE VOLUNTARY Recall
Recall Number: RA2022-3037482

Non-conforming unit (MPXF Curve)	Conforming Unit (40XF Curve)
	

Potential hazard

As our customer, you have not received a device with the labeled tip curve shape. However, the non-conforming tip curve shape is easily identifiable upon product inspection/preparation. There have been no reported patient harms.

Potential risks

Potential Risk: Patients previously treated with the impacted devices**:** None

For potential patients: If the incorrect tip curve shape is used, the most serious anticipated outcome would be that the guide catheter may not navigate to the desired anatomy location and would be exchanged for another device. However, the tip curve shape is easily identifiable upon product inspection/preparation; therefore, the most serious and most common anticipated health consequence that could occur is procedural delay while the device is swapped for another with the correct tip curve shape prior to use on the patient. Device exchange can be performed with no significant delay, and within the expected duration of the procedure.

stryker

URGENT:
MEDICAL DEVICE VOLUNTARY Recall
Recall Number: RA2022-3037482

Required Actions

1. Immediately check your internal inventory for affected devices.
2. Segregate the affected units in a secure location for return to Stryker.
3. Circulate this Recall-Removal notice internally to all interested/affected parties.
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. Inform Stryker if any of the subject devices have been distributed to other organizations. If yes, provide contact details so that Stryker can inform the recipients appropriately.
6. Please inform Stryker of any adverse events concerning the use of the subject devices.
7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
8. Return the completed form to your local Stryker Contact.
9. Product Return Information will be provided to you by your designated Sales Representative.

We request that you respond to this notice within 10 calendar days from the date of receipt. The target date for completion of this action is 31 December 2022 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action by the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

Bhavana Kurian
Manager, Quality

stryker

Business Reply Form

Recall Number: RA2022- 3037482

Account number:
Account name:
Account Address:

Product: Guider Softip™ XF Guide Catheter

Catalog number	Universal Device Identifier (UDI) Number	Product description	Lot Impacted
H965100440	(01)08714729202486(17)240518(10)27339850	Guider/40XF/8FR/90CM	27339850

Please check your inventory and fill out the table below

Catalog Number	Lot Number	Qty to be returned*	Qty Used	Qty not located
H965100440	27339850			

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Please return this signed and dated form to **your local Stryker representative.**

Note: Your signature indicates that you have received and understand the enclosed notification.

_____ _____
Printed name Title

_____ _____
Contact phone number Signature Date

_____ _____
Email address Phone Number

If you have loaned or sold any of the units listed, please, forward a copy of this notice to the new users and advise Stryker of their new location.