URGENT FIELD SAFETY NOTICE (FSN)
Bridge™ Prep Kit

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Merit Medical 0.035" InQwire® Amplatz guidewires are supplied in the Bridge Prep Kit. Per the Bridge Prep Kit IFU: Merit InQwire Amplatz guide wires are fabricated from high quality stainless steel with PTFE coating. Amplatz wires have increased stiffness which provides added strength and stability. Guide wires are packaged in a plastic hoop fitted with a luer hub. This packaging facilitates compliance with the manufacturer recommended guidelines that the guide wire be flushed with saline or heparinized saline prior to use. Guide wires are supplied sterile and non-pyrogenic.
1.	2. Commercial name(s)
	Philips Bridge Balloon Prep Kit
1.	3. Primary clinical purpose of device(s)*
	Merit InQwire Amplatz guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.
1.	4. Device Model/Catalogue/part number(s)*
	Merit Medical Kit Numbers: K12-09098B, K12-09098C, Philips REF 591-001.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Merit recently became aware of a potential device interaction issue associated with the use of the Bridge™ Prep Kit (Manufactured by Merit and distributed by Philips) with the Philips Bridge™ Occlusion Balloon catheter (Manufactured by Philips). Specifically, in some cases, the Philips catheters may experience resistance when being advanced over the 0.035" InQwire® Amplatz guidewire supplied in the Bridge™ Prep Kit (model IQA502P). Risk to Health: In situations requiring emergency hemorrhage control, if not detected prior to the procedure start, the inability to advance the Philips Balloons over the Merit guidewire to the intended site could delay hemorrhage control and may result in serious patient harm, including death. This communication provides interim risk mitigation instructions for continued safe use. No changes are being made to the Merit product labeling or Instructions for Use. Merit Medical has made the decision to discontinue the Bridge™ Prep Kit from the market. This impacts unexpired lots of the Bridge™ Prep Kit from Merit Medical Kit Numbers: K12-09098B and K12-09098C; and Philips REF 591-001.
2.	2. Hazard giving rise to the FSCA*
	The Philips catheters may experience resistance when being advanced over the 0.035" InQwire® Amplatz guidewire supplied in the Bridge™ Prep Kit (model IQA502P).

2.	3. Probability of problem arising
	This defect has a failure rate of 18 parts per million (PPM).
2.	4. Predicted risk to patient/users
	In situations requiring emergency hemorrhage control, if not detected prior to the procedure start, the inability to advance the Philips Balloons over the Merit guidewire to the intended site could delay hemorrhage control and may result in serious patient harm, including death.

3.	**3. Type of Action to mitigate the risk***
1. 3.	**4. Action To Be Taken by the User***
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☐ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
	☒ Other ☐ None
	Actions required of you: 1. Ensure that applicable personnel within your organization are made aware of this notice. 2. Please immediately determine if any of the devices identified in section 1.4. have been distributed. 3. If the product has been further distributed to other facilities, institutions, or manufacturers, please immediately communicate the following to your customers: For continued safe use of the Philips Bridge™ Occlusion Balloon, as outlined in the “Prophylactic Directions for Use” in the IFU, the following actions

	should be taken prior to the beginning of any procedure to confirm proper interaction between devices: i. After placement of the guidewire, advance the Balloon over the guidewire. This will confirm that the Balloon can freely be advanced over the entire length of the guidewire without resistance, thereby confirming that the guidewire is compatible with the Balloon. ii. Should resistance be felt during this step, the guidewire should be replaced with an alternate 0.035" stiff/super stiff wire, and Step i should be repeated prior to the beginning of the procedure. 4. Please circulate this information to all users of the Philips Bridge™ Prep Kit device, so that they are aware of the issue.		
3.	1. By when should the action be completed?	Immediately	
3.	2. Is customer Reply Required? * 3. (If yes, form attached specifying deadline for return)		Yes. Refer to Philips' Response Form

	4. General Information*	
4.	1. FSN Type*	New
4.	2. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	3. List of attachments/appendices:	Not applicable.

	Transmission of this Field Safety Notice
	This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations 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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.