





FSCA-ref: 1721504-03/31/26-004R

URGENT FIELD SAFETY NOTICE (FSN)
SplashWire® Hydrophilic Steerable Guide Wire

1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p>The Merit SplashWire® Hydrophilic Steerable Guide Wire is a diagnostic guide wire. Components include a nitinol core wire, a polymer jacket with a hydrophilic coating. Configurations available in a standard and stiff body and with straight or angled tips.</p> <div style="text-align: center;">  <p>Merit Splash Hydrophilic Guide Wires</p> </div>
1.	<p>2. Commercial name(s)</p> <p>SplashWire® Hydrophilic Steerable Guide Wire</p>
1.	<p>3. Primary clinical purpose of device(s)*</p> <p>The Merit SplashWire® Hydrophilic Steerable Guide Wire is intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures.</p>
1.	<p>4. Device Model/Catalogue/part number(s)*</p> <p>See listed products in the table below in section 3.3.</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>An incomplete seal in the Merit SplashWire® Hydrophilic Steerable Guide Wire pouch. Use of the affected product may result in exposure to pathogens/pyrogens, which could lead to infection.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>Use of the affected product may result in exposure to pathogens/pyrogens, which could lead to infection.</p>
2.	<p>3. Probability of problem arising</p> <p>1 failure in every 7.45 units</p>
	<p>4. Predicted risk to patient/users</p>

2.	Use of the affected product may result in exposure to pathogens/pyrogens, which could lead to infection.
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3.	3. Type of Action to mitigate the risk*
3.	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p><u>Actions required of you:</u></p> <ol style="list-style-type: none"> Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility. A picture of the SplashWire® Hydrophilic Steerable Guide Wire® Hydrophilic Steerable Guide Wire is attached to help you identify the product. <div style="display: flex; justify-content: space-around; align-items: center;">    </div>

	<p>Please immediately discontinue the use of the affected lots of the SplashWire® Hydrophilic Steerable Guide Wire.</p> <ol style="list-style-type: none"> 3. Ensure that applicable personnel within your organization are made aware of this field action. 4. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities. 5. Please fill out, scan and email the completed Customer Response Form to Customer Service at RESPONSE-EMEA@merit.com within 10 business days. All affected product shipped to you must be accounted for on the CRF. 6. Please immediately return all affected lots in your possession to Merit, per the instructions in the attached CRF. 7. When requesting replacement for the SplashWire® Hydrophilic Steerable Guide Wire please utilize the table below for the replacement part number and contact RESPONSE-EMEA@merit.com along with the completed Customer Response Form <ol style="list-style-type: none"> a. Replacement of the affected product will be provided on a one-to-one basis. Replacement parts are subject to applicability to this recall and regional availability. <table border="1" data-bbox="792 1108 1138 1633" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="background-color: #c00000; color: white; text-align: center;">Replacement SplashWire® Hydrophilic Steerable Guide Wire Part Numbers</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">MSWSTDA3580</td></tr> <tr><td style="text-align: center;">MSWSTDA35150</td></tr> <tr><td style="text-align: center;">MSWSTDA35180</td></tr> <tr><td style="text-align: center;">MSWSTDA35260EX</td></tr> <tr><td style="text-align: center;">MSWSTDS35150</td></tr> <tr><td style="text-align: center;">MSWSTFA3580</td></tr> <tr><td style="text-align: center;">MSWSTFS35150</td></tr> <tr><td style="text-align: center;">MSWSTFA35260EX</td></tr> </tbody> </table>		Replacement SplashWire® Hydrophilic Steerable Guide Wire Part Numbers	MSWSTDA3580	MSWSTDA35150	MSWSTDA35180	MSWSTDA35260EX	MSWSTDS35150	MSWSTFA3580	MSWSTFS35150	MSWSTFA35260EX
Replacement SplashWire® Hydrophilic Steerable Guide Wire Part Numbers											
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MSWSTDA35150											
MSWSTDA35180											
MSWSTDA35260EX											
MSWSTDS35150											
MSWSTFA3580											
MSWSTFS35150											
MSWSTFA35260EX											
3.	2. By when should the action be completed?	Immediately									
3.	3. Is a customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes									

4. General Information*			
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">1. FSN Type*</td> <td style="width: 50%; text-align: center;">New</td> </tr> </table>	1. FSN Type*	New
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4.	2. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *		
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">3. List of attachments/appendices:</td> <td style="width: 50%;">https://www.merit.com/products/documents/product-notices/splashwirehydrophilicsteerableguidewire-recall/</td> </tr> </table>	3. List of attachments/appendices:	https://www.merit.com/products/documents/product-notices/splashwirehydrophilicsteerableguidewire-recall/
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Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organizations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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31-Mar -2026

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