

**U.S. URGENT MEDICAL DEVICE RECALL NOTICE**

**Name of Affected Products:** Merit SplashWire® Hydrophilic Steerable Guide Wire

**Action Required: Return Product to Merit Medical**

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Merit Medical Systems, Inc. is voluntarily conducting a recall of the Merit SplashWire® Hydrophilic Steerable Guide Wire due to a packaging defect. Specifically, there may be an incomplete seal in the Merit SplashWire® Hydrophilic Steerable Guide Wire pouch. This issue affects lots and part numbers identified in the table below. Merit has not received any reports of patient harm or injury relating to this issue. According to Merit’s evaluation of health hazard(s), use of the affected product may result in exposure to pathogens/pyrogens, which could lead to infection. Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lots and return the affected product to Merit Medical.

**Affected Lot Table:**

<b>Product description</b>	<b>Catalog Code</b>	<b>Lot Number</b>
<b>SplashWire® Hydrophilic Steerable Guide Wire™.Guide Wire..0.035" (0.89 mm).150 cm (59").Angled Tip.Standard....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTDA35150</b>	K3410951
		K3420005
		K3420006
		K3420007
		K3420106
<b>SplashWire™.Guide Wire..0.035" (0.89 mm).150 cm (59").Straight Tip.Stiff....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTDS35150</b>	K3420082
		K3420101
<b>SplashWire® Hydrophilic Steerable Guide Wire™.Guide Wire..0.035" (0.89 mm).150 cm (59").Straight Tip.Standard....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTFS35150</b>	K3399729
<b>SplashWire™.Guide Wire..0.035" (0.89 mm).180 cm (71").Angled Tip.Standard....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTDA35180</b>	K3405121
		K3405126
		K3405127
		K3405128
		K3405129
		K3405130

		K3410953
		K3420010
<b>SplashWire™.Guide Wire..0.035" (0.89 mm).260 cm (102").Angled Tip.Standard Exchange....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTDA35260EX</b>	K3405122
		K3410937
		K3410958
<b>SplashWire™.Guide Wire..0.035" (0.89 mm).260 cm (102").Angled Tip.Stiff Exchange....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTFA35260EX</b>	K3405261
<b>SplashWire™.Guide Wire..0.035" (0.89 mm).80 cm (31.5").Angled Tip.Standard....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTDA3580</b>	K3405257
<b>SplashWire™.Guide Wire..0.035" (0.89 mm).80 cm (31.5").Angled Tip.Stiff....3 cm.Fixed Core.Plastic Jacket.Hydrophilic Coated...Sterile.</b>	<b>MSWSTFA3580</b>	K3420079

**Actions required of you:**

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
2. A picture of the SplashWire® Hydrophilic Steerable Guide Wire® Hydrophilic Steerable Guide Wire is attached to help you identify the product.



Please immediately discontinue the use of the affected lots of the SplashWire® Hydrophilic Steerable Guide Wire.

3. Ensure that applicable personnel within your organization are made aware of this recall.
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@merit.com](mailto:RESPONSE@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@merit.com](mailto:RESPONSE@merit.com), along with the completed Customer Response Form
  - 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.

Replacement SplashWire® Hydrophilic Steerable Guide Wire Part Numbers
MSWSTDA3580
MSWSTDA35150
MSWSTDA35180
MSWSTDA35260EX
MSWSTDS35150
MSWSTFA3580
MSWSTFS35150
MSWSTFA35260EX

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), by regular mail, or by fax.

If you have any questions concerning this communication, please don’t hesitate to contact your Merit Sales Representative or Merit Customer Service via email at [RESPONSE@merit.com](mailto:RESPONSE@merit.com) or via phone at +1 800 356 3748 | Hours: 6 am to 6 pm MST | Mon-Fri.

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this recall may cause.

Enclosure(s)