



URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: SCOUT® Guide and SCOUT CHECK® Handpiece

Action Required: Over-Label Devices

Merit Medical Systems, Inc. is voluntarily conducting a Field Safety Corrective Action (FSCA) of SCOUT® Guide and SCOUT CHECK® Handpiece devices due to required information missing from the label. Specifically, the European CE conformity mark and European Authorized Representative symbol and contact information are not on the label. This FSCA affects two (2) catalog codes, SG-01 (Guide) and CHKHP-01 (Handpiece), and is limited to only those units sold and distributed in Europe. This issue does not result in any additional risk to patient or user.

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 and quarantine them.
2. Ensure that applicable personnel within your organization are made aware of this field action.
3. If the product has been further distributed to other facilities or institutions, 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.
4. Please immediately over-label all affected devices in your facility (including product in consignment) according to the enclosed instructions.
5. Please fill out, scan, and email the completed CRF to Customer Service at **RESPONSE-EMEA@merit.com within 10 days**. All affected product shipped to you must be over-labelled and documented on the CRF, as instructed.









***Note:** The relevant National Competent Authorities will be notified of this Field Safety Corrective Action (FSCA).




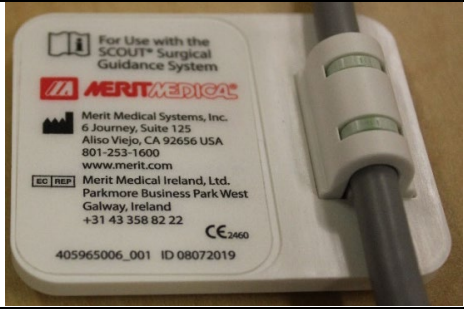


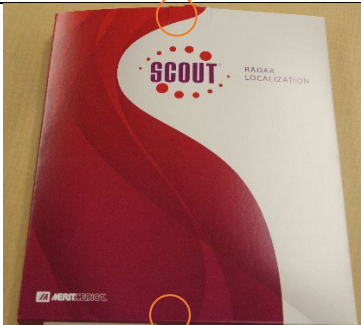
If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at **ukorders@merit.com or by phone at 0800 973115**.

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

Enclosure(s)

Over-labeling Merit Medical Systems, Inc. SCOUT Guide & CHECK Handpiece Guide Tag Label with CE Marked Label

Instructions	CHKHP-01	SG-01
1.Remove handpiece from case/zip lock bag.		
2. Turn the cable tag over to its back side.	<p>Front side:</p>  <p>Back side:</p> 	<p>Front side:</p>  <p>Back side:</p> 
3. Obtain labels provided by Merit Medical Systems, Inc. and identify the correct label for CHKHP-01 and SG-01.	<p>Existing Label:</p> 	<p>Existing Label:</p> 

	<p>New Label:</p>  <p>New P/N: 405965007 Used on: CHKHP-01/C</p>	<p>New Label:</p>  <p>New P/N 405965006 Used on SG-01/C</p>
<p>4. Align and place label provided on top existing label.</p>		
<p>5. Place handpiece/guide back into case/zip lock bag.</p>	 <p>Ensure that cable is wrapped tightly around tabs on backer card. Slide backer card with CHKHP-01/C attached into the zip lock bag. Close bag completely. Place the zip lock bag into the carton with the IFU.</p>	 <p>Place the guide into the case and wrap the cable neatly. Check that no part of the SG-01/C is protruding outside of the case. Close case and secure the lock.</p>
<p>6. For CHKHP-01/C if any tamper seal stickers were damaged or torn replace them with a new tamper seal over the existing tamper seal.</p>		<p>N/A</p>



Customer Response Form

Merit Medical Systems, Inc.

Merit Sales Rep: XXXXXXXXXXXX

Affected Product: SCOUT® Guide and SCOUT CHECK® Handpiece

Customer Name Ship to Address Customer Number	Customer Contact:
	Title:
	Phone Number:
	RMA #: XXXXX

Please provide status on the following:

Serial #	Part #	Qty Merit Shipped to You	Qty You Further Distributed	Qty You Over-Labeled

Please fill out and sign this Customer Response Form and scan and email the completed Customer Response Form to **Merit Customer Service at RESPONSE-EMEA@merit.com within 10 days.**

Merit may contact you regarding incomplete information. It is very important that you complete these steps in order to assist Merit in complying with applicable government regulations.

If you have further questions, please contact **Merit Customer Service at ukorders@merit.com or by phone at 0800 973115.**

I certify that I received and understood this notice. I certify that the above listed products have been over-labeled according to the notification instructions. Furthermore, if I have further distributed product listed on this form, I certify that a copy of this notice was provided to said consignee(s).

Signature of Customer Contact

Date