<Original English Text>

URGENT FIELD SAFETY NOTICE (FSN)

Date

ATTENTION: Hospital Administrator/Interventional Radiology Lab Manager/Risk Manager

Dear Sir or Madame,

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of 1mL Medallion® syringes due to a supplier manufacturing defect with the syringe plunger tip. Prior to use and during prep, when fluid is drawn into the syringe, air may enter the barrel and/or fluid may leak out the back of the barrel. Merit has identified the affected lots and catalog numbers as detailed in the table below. Merit has received no reports of patient harm or injury as a result of this issue. Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lots and return them to Merit. If you have further distributed any of the affected lots, immediately initiate a product recall in accordance with your company's established policies for customers to whom you have shipped affected product.

Catalog Numbers	Lot Numbers
701989001	B617173
K01-07427	H1082598
K01-05197P	H1082648 H1082649
MSS011-YP	H1082809
K01-07946P	H1085511
MSS011	H1085645 H1092907
MSS011-LB	H1085649 H1097018
MSS011-R	H1085658
MSS011-Y	H1085659
MSS011P	H1085735
MSS011-LBP	H1089234
MSS011-DG	H1089419
K08-02926AP	H1090184
K01-07742P	H1101188
K10-05457P	H1101443

Our records indicate that you have received affected lots.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form are within your facility, quarantine them, and discontinue use.
2. Ensure that all personnel to whom the devices were distributed are made aware of this field action.
3. Please fill out, scan and email the attached Customer Response Form to response@merit.com.
4. Please return all affected lots in your possession to Merit, per the instructions found in the Customer Response Form.

Note: If the affected 1 mL syringe is used, the failure would be identified by the medical professional prior to use because air would be drawn in and/or fluid would leak from the back of the syringe. The impact to the patient would be a delay in the procedure while the affected syringe is replaced.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Michelle Savelkoul at +31 43 3588247 (Ext. 9007) or msavelkoul@merit.com.

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

Kind Regards,

Enclosure