

URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: Merit Convenience Kits and Procedure Packs Containing BD Syringes and Needles (Concerning Intraocular Use)

Action Required: Read and Understand Notice

Merit Medical Systems, Inc. is notifying you of a Field Safety Corrective Action conducted by BD Medical which affects Merit Convenience Kits and Procedure Packs that contain BD's affected syringes and needles, see enclosed table of affected Merit Catalog Codes.

BD is advising of an added caution for their below products:

- BD 1ml Syringe Luer-Lok™ Tip
- BD Plastipak™ 1ml Luer
- BD Blunt Fill Needle with Filter 18G x 1 1/2 (1.2mm x 40mm) (5µm)
- BD Microlance™ 3 30G x 1/2" 0,3 x 13mm
- BD Microlance™ 3 30G x 1/2" 0,3 x 13mm

BD has identified through post-market surveillance reviews that a caution should be added to the Instructions for Use (IFU) for their impacted products. BD is providing the following caution and recommends it be applied when using the product.

Intraocular use is not validated by BD.

BD has become aware that when syringes and needles are used for intraocular injections, the potential exists for “floaters” in patients’ eyes which are believed to be due to silicone. (Note: Syringes and needles manufactured by BD have silicone applied to the inside of the barrels to provide lubrication for the plunger stopper, allowing it to move easily). The potential hazard is deposition of silicone oil (SO) droplets in the vitreous. The potential harm could be symptomatic “floaters” in the patient’s field of vision which, normally, are tolerable and resolve over a few months. However, if sufficiently bothersome, floaters may lead to a vitrectomy for their removal.

BD became aware of other potential risks associated with intraocular injections, such as endophthalmitis (inflammation of the interior of the eye), which may be associated with failure modes not previously identified by BD.

To reduce this risk of silicone floaters and inflammation or irritation that may occur, Healthcare Providers should only use the syringes and needles provided with ocular medications that are specifically designed and labelled for intravitreal injection.

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

Actions required of you:

1. Understand that identified Merit product does not need to be returned.
2. Ensure that applicable personnel within your organization are made aware of this notice regarding the intended use of BD syringes and/or needles within the Merit kit or pack.
3. If the Merit product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at 0031 – 43 3588233.

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

Enclosure(s)

Affected Merit Catalog Codes

AT-529	K12T-07186	K12T-09022	K12T-10525	OR-3253
AT-538	K12T-07491	K12T-09044	K12T-10593	OR-3270
AT-611	K12T-07796	K12T-09053	K12T-10600	OR-3338
AT-625	K12T-07803	K12T-09192	K12T-10615	OR-3343
AT-638	K12T-07918	K12T-09230	K12T-10616	OR-3345
K09T-12330	K12T-08044	K12T-09309	K12T-10623	OR-3346
K09T-13627	K12T-08216	K12T-09324	K12T-10641	OR-3347
K12T-02940	K12T-08232	K12T-09332	K12T-10703	OR-3375
K12T-03706	K12T-08267	K12T-09343	K12T-10718	OR-3387
K12T-04328	K12T-08351	K12T-09355	K12T-10781	OR-3647
K12T-04446	K12T-08570	K12T-09380	K12T-10783	OR-3675
K12T-04707	K12T-08639	K12T-09532	K12T-10786	OR-3715
K12T-04846	K12T-08640	K12T-09533	K12T-10798	OR-3731
K12T-05902	K12T-08641	K12T-09665	K12T-10977	OR-3771
K12T-06083	K12T-08677	K12T-09666	K12T-11021	OR-3772
K12T-06096	K12T-08729	K12T-09683	K12T-11120	OR-3773
K12T-06172	K12T-08745	K12T-09772	K12T-11139	OR-4049
K12T-06243	K12T-08782	K12T-09773	K12T-11170	OR-4056
K12T-06340	K12T-08788	K12T-09774	K12T-11188	OR-4057
K12T-06507	K12T-08860	K12T-09791	K12T-11257	OR-4105
K12T-06531	K12T-08874	K12T-09792	K12T-11401	OR-4107
K12T-06658	K12T-08932	K12T-10007	K12T-11409	OR-4118
K12T-06798	K12T-08933	K12T-10040	K12T-11594	OR-4185
K12T-06924	K12T-08934	K12T-10126	K22C-00038	
K12T-06982	K12T-08936	K12T-10200	OR-2805	
K12T-07051	K12T-08940	K12T-10423	OR-3200	
K12T-07104	K12T-08955	K12T-10510	OR-3244	