URGENT FIELD SAFETY NOTICE

Report Number: 2183787-02/07/2017-001-R

PLEASE READ THOROUGHLY

Greatbatch Medical – MobiCath™ Bi-Directional Guiding Sheath

Greatbatch Part number	Biosense Webster Model Number	Description
1000182-001	D140010	MobiCath™ Bi-Directional Guiding Sheath (Small Curve)
1000182-002	D140011	MobiCath™ Bi-Directional Guiding Sheath (Large Curve)

ALL LOT NUMBERS BELOW ARE AFFECTED FOR MODEL D140010

W3332609	W3338632	W3338635	W3348351	W3348350	W3338707	W3352503	W3359665	W3363850
W3370052	W3374700	W3374699	W3363851	W3379647	W3379650	W3384700	W3384701	W3390551
W3390549	W3397950	W3407815	W3397877	W3397879	W3407814	W3436355	W3436356	W3436351
W3436358	W3441735	W3446769	W3441737	W3446767	W3449392	W3451862	W3451863	W3455439
W3455438	W3459354	W3455440	W3462467	W3462470	W3470335	W3470336	W3483637	X3489776
W3493240	W3497507	W3501348	X3497121	X3497510	W3501349	X3501345	X3514814	X3501344
X3503248	X3507599	X3518116	X3565743	W3581648	X3581652	X3586059	X3592497	

ALL LOT NUMBERS BELOW ARE AFFECTED FOR MODEL D140011

W3330988	W3330990	W3338636	W3348352	W3351374	W3357184	W3361889	W3363852	W3374701
W3379653	W3384702	W3392891	W3436359	W3441739	W3449393	W3451865	W3462471	W3470337
W3479706	X3493675	W3494912	X3497511	X3501245	W3497509	X3501353	X3501350	W3501354
W3507597	X3507598	X3514815	W3542347	X3537038	X3565745			

NO OTHER GREATBATCH PRODUCTS ARE AFFECTED BY THIS RECALL

February 15, 2017

Dear Valued Customer,

The purpose of this communication letter is to inform you that Greatbatch Medical is voluntarily issuing a global Field Removal due to reports of unsealed pouches on specific lots of MobiCath™ Bi-Directional Guiding Sheath, Large Curve product (Catalogue Number: D140011) and Small Curve product (Catalogue Number D140010). Greatbatch Medical is the legal manufacturer of this product and Biosense Webster is the distributor.

REASON FOR THE FIELD SAFETY CORRECTIVE ACTION:

Greatbatch has received reports that one side of the pouch may not be sealed and as result, may cause the sterile barrier of the pouch to be compromised. We are requesting that you immediately segregate from your inventory all products with the lot numbers detailed on this field safety corrective action. Please return the products to *(location where product will be returned)* as detailed in the instructions.

RISK TO HEALTH:

Greatbatch has determined that when MobiCath™ Bi-Directional Guiding Sheath pouch is not sealed, the product may not be sterile. The use of a non-sterile product in surgery could potentially result in adverse health consequences, such as infection, which could lead to life threatening events and/or death.

Adverse events:	Greatbatch has received **no reports of deaths, illnesses, injuries, or other adverse effects associated with this issue.**

INSTRUCTIONS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS RECALL

1. Review this Urgent Recall
2. Examine your inventory and identify the **impacted lots** of MobiCath™ Bi-Directional Guiding Sheath that are in your possession, quarantine the devices immediately.
3. Complete the Acknowledgement Form indicating the quantity of devices to be returned and email it to *(location where product will be returned).*

The lot number on the product can be located:

Be aware the affected lots all start with the letter W or X and are followed by a 7 digit number.

4. You have concluded the actions to be taken in response to this field safety corrective action. We sincerely thank you for your assistance.

Available Assistance:
For questions related to this issue please contact your local Biosense Webster sales representative.

Other Information:
Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 and any relevant requirements to the local health authority in your country.

It is very important that you keep Biosense Webster informed of any complaints or adverse events associated with this device. Adverse events may be reported to your local Biosense Webster sales representative.

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure patient and customer satisfaction.

Sincerely,

Phyllis Piet-Hughes
Senior Manager Quality Compliance
Greatbatch, Inc.
2300 Berkshire Lane North
Plymouth, Minnesota 55441, USA

Enclosures:

1) Acknowledgement Form

Greatbatch Medical
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Minneapolis, MN 55441 USA

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35619 Braunfels
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