
Urgent Field Safety Notice

Bullfrog® Micro-Infusion Device (BF101x Device Family)
BF101x Recall 080717-01 FSN
Device Modification: Changes to product Instructions For Use

Date: 7 August 2017

Attention: Bullfrog® Micro-Infusion Device Clinical Sites

Details on affected devices:
This Notice is specifically related to the BF101x Device Family. The table below denotes each part number, lot number, quantity and country to where these units were distributed.

Part #	Lot #	Qty	Country
BF101S	1680334	1	**GERMANY**
BF101S	1701945	3	**AUSTRIA**
BF101S	1701945	5	**GERMANY**
BF101S	1701945	2	**SWITZERLAND**
BF101S	1742158	2	**GERMANY**
BF101M	1705104	4	**AUSTRIA**
BF101M	1705104	5	**GERMANY**
BF101M	1753030	2	**SWITZERLAND**

Description of the problem:
This Field Safety Notice is being initiated due to a missing CE mark and incorrect revision of the Instructions for Use (IFU). The deficiencies are related to violations of the MDD 93/42/EEC regulations only. There is no patient risk associated with these deficiencies.

Advise on action to be taken by the user:
Please examine your inventory to determine what product is subject to this recall notice. In addition, if you may have further distributed this product, please identify those recipients and notify them at once of this product recall notice. Your notification to those recipients may be enhanced by including a copy of this recall notification letter.

You do not need to return any devices to Mercator as part of this recall. Rather, prior to use of these devices, please review the enclosed, corrected Instructions For Use (IFU). Please discard the IFU currently packaged with each device, and replace them with the enclosed, corrected IFU.

In addition, please complete and return the enclosed response form with the devices as soon as possible.

Contact reference person:
Steve Tivey
Mercator MedSystems, Inc.
1900 Powell Street, Suite 800
Emeryville, CA 94608
st@mercatormed.com
510-564-7763

Your assistance is appreciated and necessary to complete this action.

Please note that the appropriate Competent Authorities have been made aware of this action.