Medtronic

URGENT FIELD SAFETY NOTICE

MICROPLAS plasmafilters

March, 2018

Medtronic Reference: FA807

Attention: Risk Management Director, Safety Officer, OR and ICU Materials Management, ICU Medical Directors

Dear Valued Customer:

The purpose of this letter is to advise you that Bellco, now a part of Medtronic, is issuing a Field Safety Corrective Action (FSCA) for its

MICROPLAS plasmafilters

Medtronic is issuing this FSCA following two customer reports where a MICROPLAS plasmafilter was inadvertently used instead of a hemofilter during continuous renal replacement therapy. In one of these incidents, the use of the incorrect device resulted in patient death.

Based on our investigations, there was no device malfunction. Both incidents resulted from a user error where a MICROPLAS plasmalfilter was inadvertently used for treatment rather than the intended hemofilter. While the MICROPLAS plasmafilter has been commercially available for over 15 years, only three such events have occurred, two being reported in the last 6 months.

This FSCA is in relation to all plasmafilters listed in **Table 1** below.

Table 1

Product Code	Product Description
IBP4102	MICROPLAS MPS 05
IBP4103	MICROPLAS MPS 07
IBP4104	MICROPLAS MPS 03

Medtronic is requesting that users be observant of the differences between a plasmafilter and a hemofilter.

A plasmafilter is used for the extracorporeal separation of plasma from whole blood when disease mediators that are acutely toxic are present. Plasma filtration for the purposes of toxin removal followed by a return of replacement solution is a procedure performed in the intensive care setting in acutely ill patients.

A hemofilter is used for hemofiltration. Through convection, larger molecular weight toxins are removed from the blood by passing the blood through extracorporeal filters, commonly in acute settings. Inadvertent use of a plasmafilter instead of a hemofilter during renal replacement therapy could lead to significant hemodynamic compromise which could be fatal in the acutely ill patient.

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The MICROPLAS plasmafilters are individually packaged in sterile pouches that are individually boxed and placed in a larger shipping container (**Figure 1**).

Figure 1: Packaging configuration for MICROPLAS plasmafilter

Commercially available hemofilters are packaged in single sterile pouches, as shown in **Figure 2.**

Figure 2: Commercially available hemofilters

As depicted in **Figure 3**, MICROPLAS plasmafilters are packaged with a cardboard sleeve indicating that the device is "For Plasma Separation only". This warning is attached to both ends of the plasmafilter and it is designed to alert the user and be discarded prior to use.

Figure 3: Cardboard warning on Bellco MICROPLAS plasmafilter

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Please highlight these packaging differences and the warning statement with your staff, as appropriate, and refer to the device manual for detailed information regarding the instructions for use, warnings, and precautions.

If you have further distributed the MICROPLAS plasmafilter, please promptly forward the information from this letter to those recipients. This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request that you contact Medtronic if you experienced quality problems or adverse events.

Medtronic is committed to providing you with the most up-to-date and relevant information with respect to the use of our products. If you have any questions, please contact your Medtronic/Bellco Representative.

Sincerely,

Insert Local BU signature

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FIELD SAFETY CORRECTIVE ACTION

MICROPLAS plasmafilter

Acknowledgement and Receipt Form – Response is required

Customers must complete the form even if you do not have inventory.

Please complete this form in its entirety.

Date:	**Account Name:**
Name of person completing this form:	**Primary Account Number, if known:**
Title:	**Account Address:**
Direct phone number:	**City, Country and Postal Code:**
Email:	

I have read and acknowledge receipt of the Field Safety Notice regarding the MICROPLAS plasmafilter dated March, 2018, by signing below.

I also agree to further distribute and communicate this information within my facility and, if applicable, any recipient that received MICROPLAS plasmafilters from my facility.

Name : (print)	Signature:	Date:

If you have any questions regarding this Field Safety Notice, please contact your Bello/Medtronic Sales Representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT (Page 3) TO:
XXXXXX@medtronic.com or fax to +XX XXXX XXXX