Medtronic

Urgent Field Safety Notice

Bellco MICROPLAS plasmafilters

Recall

February 2020

Medtronic reference: FA904

Dear Valued Customer,

The purpose of this letter is to advise you that Bellco, now a part of Medtronic, is voluntarily recalling specific production lots of the MICROPLAS plasmafilters.

Issue Description:
This voluntary recall is being conducted due to the potential for the unintended use of the MICROPLAS plasmafilter.
In March 2018, Medtronic (Bellco) initiated an Urgent Field Safety Notice following two customer reports where a Bellco MICROPLAS plasmafilter was inadvertently used instead of a hemofilter during continuous renal replacement therapy. In one of these incidents, the use of an incorrect device resulted in patient death.
Based on our investigations, there was no device malfunction. Both the incidents resulted from a user error where a plasmafilter was inadvertently used for treatment rather than the intended hemofilter. At the time of the reported complaints the product contained a warning placard. (Refer to Figures 1 and 2 below).

Figure 1: MICROPLAS Plasmafilter with warning label

Figure 2: Closeup of warning label

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 on acutely ill patients in the intensive care setting.
A hemofilter is used for hemofiltration. Through convection, larger molecular weight toxins are removed from the blood by passing the blood through extracorporeal filters. 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.

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

Figure 3: MICROPLAS plasmafilter

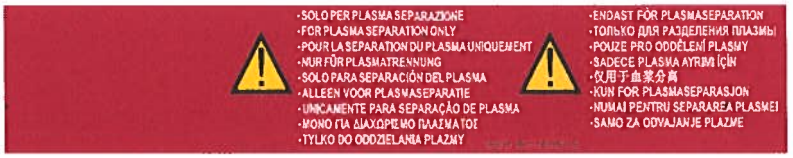

Figure 4: Closeup of additional warning label

In November 2018, we subsequently implemented an additional label to the device (refer to Figures 3 and 4) to further warn the user that the MICROPLAS plasmafilter is intended "For Plasma Separation Only."

After implementation of the additional warning label, another incident occurred where a MICROPLAS plasmafilter was inadvertently used instead of a hemofilter. This occurred with a MICROPLAS plasmafilter that was shipped prior to implementation of the additional warning label. As such, this voluntary recall affects only products that do not have the label shown in Figure 3. The affected item codes and lots are listed in Attachment A.

Required Actions:

1. Please immediately quarantine and discontinue use of the affected lots listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and lots must be returned.
3. If you have distributed the MICROPLAS plasmafilters listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Return Verification Form **even if you do not have inventory.**

	Customer with inventory	**Customer with zero inventory**	**Where to send the completed form**
Purchased **directly** from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative or Customer Service.

Sincerely,

Brendan Fayne

Brendan Fayne
Program Manager
Medtronic

Enclosure:

- Attachment A: Affected Codes and Lots
- Attachment B: Bellco MICROPLAS plasmafilter label

Attachment A: Affected Codes and Lots

Item Code	Item Description	Affected Lots			
IBP4102	MICROPLAS MPS 05	1501210014	1512000074	1704000019	1804000184
		1501210015	1601000199	1705000058	1806000078
		1503250101	1602000079	1705000081	1806000213
		1503250102	1603000342	1705000130	1809000112
		1503250103	1605000059	1706000113	1810000081
		1504300101	1607000162	1707000259	1810000118
		1504300102	1607000187	1707000471	
		1506170008	1608000140	1709000020	
		1506170009	1609000212	1709000021	
		1506170010	1609000292	1709000022	
		1506260017	1610000232	1710000026	
		1506260018	1610000391	1710000027	
		1509040139	1611000411	1710000212	
		1509040140	1701000190	1710000418	
		1510000072	1702000030	1803000464	
IBP4103	MICROPLAS MPS 07	1502230141	1704000106	1810000364	
		1504300103	1704000270		
		1510000014	1707000258		
		1603000358	1708000043		
		1608000217	1712000179		
		1609000340	1712000212		
		1611000265	1801000176		
		1701000004	1802000095		
		1701000230	1803000104		
		1702000031	1805000371		
IBP4104	MICROPLAS MPS 03	1501210018	1707000257		
		1502230142	1707000365		
		1601000204	1712000009		
		1602000216	1801000139		
		1608000036	1802000290		
		1608000139	1805000166		
		1609000416	1809000307		
		1702000075			
		1704000107			

Attachment B: Bellco MICROPLAS plasmafilter label