



## **URGENT: Blowfish Transbronchial Micro-Infusion Device RECALL**

August 3<sup>rd</sup>, 2017

Dr. John Faul  
Connolly Hospital  
Mill Rd, Abbotstown  
Dublin 15, Ireland D15 X40D

Dear Dr. Faul,

This is to inform you of a product recall involving:

**Blowfish Transbronchial Micro-Infusion Device, Catalog Code BH201M, Lot # 00493**

This recall has been initiated due to a missing CE mark and an incorrect revision of the Instructions For Use (IFU). The deficiencies are related to violations of the MDD regulations only. The patient risk associated with these deficiencies is delayed treatment due to inventory confusion.

We shipped **5 devices** to you on **6/26/17**.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify those recipients and notify them at once of this product recall. Your notification to those recipients may be enhanced by including a copy of this recall notification letter.

Please do not use these devices. These devices must be returned to Mercator MedSystems as soon as possible. Returned goods authorization, RGA080317-01, has been issued for this product return. Please mark the external shipping box with "RGA080317-01" and use the prepaid FedEx return label provided.

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

Your assistance is appreciated and necessary to complete this Product Recall.

If you have any questions, call Steven Tivey, VP – Operations & Quality, at 510-564-7763.

A handwritten signature in blue ink, appearing to read 'S. Tivey', is written over the printed name and title of the sender.

Steven E Tivey  
VP – Operations & Quality  
Phone: 510-564-7763



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**Blowfish Transbronchial Micro-Infusion Device, Catalog Code BH201M, Lot # 00493**

**5 devices shipped on 6/26/17.**

Did you receive these devices:  Yes  No

How many of these devices have been used prior to receipt of RECALL notice? \_\_\_\_\_.

Have you reviewed the attached RECALL notice:  Yes  No

**Please return this completed form along with the devices to:**

**Steven Tivey  
c/o Mercator MedSystems, Inc,  
1900 Powell St, Suite 800  
Emeryville, CA 94608**

## Monica Barrett

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**From:** Kevin Griego  
**Sent:** Thursday, August 3, 2017 5:19 PM  
**To:** doctorfaul@gmail.com  
**Cc:** Kirk Seward; Steven Tivey; Monica Barrett; Trent Reutiman  
**Subject:** Product Recall  
**Attachments:** Product Recall.pdf

Hello Dr. Faul,

I have attached a notice for a product recall for five Blowfish Catheters, Lot 00493. Can you please read the notice, fill out the second page, and return to Mercator? I have also sent a hard copy of this notice along with RGA 080317-01 to return the devices to Mercator. A prepaid FedEx label and shipping documents to return the devices are enclosed in the FedEx shipment that was sent to you today. If you have any questions, please feel free to reach out.

Thank you,

Kevin Griego  
Business Operations Manager

Mercator MedSystems  
1900 Powell Street | Suite 800 | Emeryville, CA 94608  
Office: 510.488.6402 | Mobile: 510.856.7170 | Fax: 510.614.4560  
Customer Support: +1.800.805.3764  
[www.mercatormed.com](http://www.mercatormed.com)



Invoice:	Date : 03Aug17	Shipping :	37.75	
Customer :	Weight : 0.5 LBS	Special :	1.04	
Phone : (510)856-7170	COD :	Handling :	0.00	
Dept :	DV :	0.00	Total :	38.79

Svcs: INTL PRIORITY  
TRCK: 7206 0806 3106

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Invoice:	Date : 03Aug17	Shipping :	37.75
Customer :	Weight : 0.1 LBS	Special :	1.04
Phone : (510)856-7170	COD :	Handling :	0.00
Dept :	DV :	0.00 Total :	38.79

Svcs: INTL PRIORITY  
TRCK: 7206 0806 3091