

## ADDITIONAL INFORMATION

Commercial name of the affected product: **Bead Block™ (Embollic Bead)**

FSCA-identifier: **PR #16295**

Type of action: **Advice given by Manufacturer regarding the use of the device**

19<sup>th</sup> March, 2015

Dear Healthcare Provider:

Following on from the communication of the enclosed Field Safety Notice, please note that we now require you to conduct the following additional actions requested by Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM):

- Please send all unused affected market units detailed in the original enclosed Field Safety Notice to Terumo Europe (contact details listed below). These affected units will be over-labelled by Terumo Europe and returned to your facility.
- Please acknowledge receipt of this notification by completing the attached Acknowledgement Form and returning via email as a scanned copy. Terumo Europe contact information is listed below. Returning the completed Acknowledgement Form promptly will ensure that you do not receive repeat notices.

Product Name	Product Code
Bead Block™ (100-300 µm)	EB2S103
Bead Block™ (300-500 µm)	EB2S305

### TERUMO EUROPE

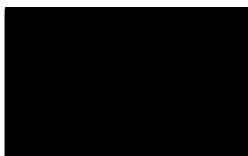
Researchpark Haasrode 1520  
Interleuvenlaan 40  
3001 Leuven,  
Belgium

E-mail: [REDACTED]@terumo-europe.com



Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Yours sincerely,



Director of Quality  
Biocompatibles UK Ltd., a BTG International group company  
Chapman House  
Farnham Business Park  
Weydon Lane  
Farnham  
Surrey GU9 8QL  
United Kingdom  
Tel: +44 (0)12527 [REDACTED]

Enclosure:

1. Field Safety Notice
2. Acknowledgement Form - BfArM

## URGENT FIELD SAFETY NOTICE

Commercial name of the affected product: **Bead Block™ (Embollic Bead)**

FSCA-identifier: **PR #16295**

Type of action: **Advice given by Manufacturer regarding the use of the device**

5<sup>th</sup> February, 2015

Dear Healthcare Provider:

Biocompatibles UK Ltd. (the Manufacturer), is sending this communication to inform you of contradictory labelling used for certain sizes of medical device, Bead Block™ (Embollic Bead). This notification is not due to increases in complaints or adverse events associated with Bead Block™. Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.

Product Name	Product Code
Bead Block™ (100-300 µm)	EB2S103
Bead Block™ (300-500 µm)	EB2S305

### Issue

Through an internal review, the Manufacturer has become aware that while the Bead Block™ instructions for use (IFU) state; "When using Bead Block for uterine fibroid embolization (UFE), do not use beads smaller than 500 microns.", the cartons containing Bead Block™ sizes 100-300 µm (EB2S103) and 300-500 µm (EB2S305) state; "Indication: Embolisation of **uterine fibroids (UFE)**, hypervascular tumours and arteriovenous malformations (AVMs)". The carton for the stated sizes of Bead Block™ is incorrectly labelled with indication for UFE. **The IFU correctly states not to use beads smaller than 500 microns for UFE.**

The Manufacturer has undertaken a medical review of the potential impact of the above stated misalignment between the carton and IFU for the affected sizes of Bead Block™. This medical review has indicated that the overall risk to patients is remote. The Manufacturer is, however, issuing this notification as a precautionary measure in the event Healthcare Practitioners were to follow the UFE indication on the carton for the affected sizes without referring to the product IFU. If such an event were to occur, there is a potential risk of infarction of non-targeted tissue.

### Affected Product Details

Alongside the table noted above, please refer to the attached "Product Listing" for details of affected distributors, LOT numbers and product expiration dates.

### Healthcare Provider Instructions

Please keep a copy of this notification with affected units of Bead Block™ and ensure you refer to the product IFU before use





If you are a distributor, wholesaler or if you have provided the affected units of Bead Block™ to any other department/facility, please transfer this notice to applicable person(s) on whom this action has an impact.

Please acknowledge receipt of this notification by completing the attached Acknowledgement Form and returning via email as a scanned copy. BTG Customer Service contact information is listed below. Returning the completed Acknowledgement Form promptly will ensure that you do not receive repeat notices.

**Product Correction** The Manufacturer is correcting the applicable carton for Bead Block™ sizes 100-300 µm (EB2S103) and 300-500 µm (EB2S305) to remove indication for UFE. The Manufacturer will re-commence release of the affected sizes following this correction.

**Contact Information** Please contact the BTG Customer Service person listed below with regards to any questions or clarifications concerning this communication.

**BTG Customer Service**

Michelle Goodhand  
Biocompatibles UK Ltd., a BTG International group company  
Chapman House  
Farnham Business Park  
Weydon Lane  
Farnham  
Surrey GU9 8QL UK  
United Kingdom  
Tel: +44 1252 732 674  
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Email: michelle.goodhand@btgplc.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Yours sincerely,

  
Director of Quality  
Biocompatibles UK Ltd., a BTG International group company  
Chapman House  
Farnham Business Park  
Weydon Lane  
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Surrey GU9 8QL  
United Kingdom  
Tel: +44 (0)12527 

Enclosure

1. Product Listing
2. Acknowledgement Form



## Acknowledgement Form (FSCA-identifier: PR #16295)

I, the undersigned, confirm that I have received the enclosed "Additional Information" document and taken appropriate action in line with the instructions contained within the notice.

Number of affected units in inventory	
Number of affected units sent to Terumo Europe for over-labelling	

Company	
Name	
Title	
Signature	
Date	