

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**

5th 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

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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,

A handwritten signature in blue ink, appearing to read "Paul Sharp".

Paul Sharp
Director of Quality
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Enclosure

1. Product Listing
2. Acknowledgement Form