

Bard Singapore Pte Ltd
1 Harbourfront Avenue, #04-11/13
Keppel Bay Tower, Singapore 098632
Tel: (65) 6250 5988
Fax: (65) 6337 3588
GST Reg No. 19-9901639-R



ATTENTION: RISK MANAGER/MATERIALS MANAGER
URGENT MEDICAL DEVICE NOTIFICATION

ePTFE Small Beading Vascular Graft Products
DISTAFLO [®] Bypass Graft
DISTAFLO [®] Mini Cuff Bypass Graft
DYNAFLO [®] Bypass Graft
IMPRA [®] ePTFE Vascular Graft
IMPRA [®] CARBOFLO [®] ePTFE Vascular Graft

2 October 2018

Dear Valued Customer,

This letter is to provide information to you about the ePTFE Small Beading Vascular Graft products distributed by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of Becton, Dickinson and Company. Specific product codes are affected as outlined in Attachment 1. Our records show that your facility has purchased one or more of the affected product codes.

All other product codes not listed in Attachment 1 are not affected by this medical device notification.

Reason for Notification:

Through our post-market trending we have identified a potential concern with the use of the ePTFE Small Beading Vascular Graft products produced by BPV. As noted in our Instructions For Use (IFU), the removal of the beading material is a critical step in the preparation of the graft for use. We have identified that in up to 0.25% of the cases, the removal of this beading can result in small tears in the graft material when the removal technique noted in the IFU is not followed.

The cause of the tear in the material is not related to the overall strength of the graft material, as that remains unchanged and continues to perform as it has historically. We have observed some variability in the strength of the beading adherence to the surface of the graft. This variability presents no concerns when following the beading removal technique noted in the IFU. However, not following the technique described can result in small graft tears at the interface of the beading and the graft.

Clinical Risk Statement:

In the event that the graft were to tear from not following the proper beading removal technique, the immediate or long-term health consequence that may result involve the potential for bleeding due to sub-optimal anastomosis. This is more likely to be present at the time the vascular graft is being placed and therefore noticed intraoperatively.

During preparation of the vascular graft, the user may remove and trim off enough beading to cut the graft to the appropriate length. This process allows the user to be aware of any graft tears caused by removal of the beading prior to use; therefore, any defect or tear will likely be noticed at the time of preparation or procedure. Any bleeding will likely be seen during the procedure, as common practice is to assure a proper placement of the graft includes a viable seal.

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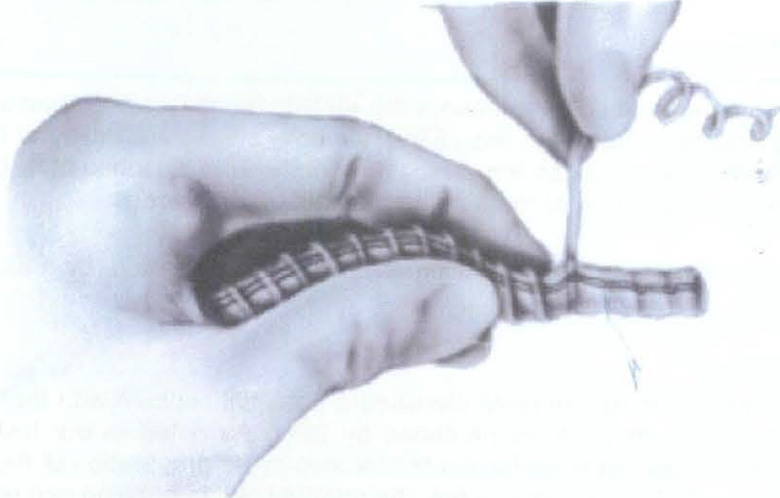


Instructions to Customer:

Please review the proper beading removal technique as outlined below and in the IFU. Failure to follow this technique may result in a tear in the graft upon removal of the beading. After successfully removing the beading from the graft, please thoroughly inspect the graft for tears or damage prior to use.

When removing the external spiral support (beading) of the vascular graft, the beading must be removed slowly and at a 90° angle to the graft, as shown in Figure 1. Rapid unwinding and/or removal at less than a 90° angle may result in graft damage. Do not use surgical blades or sharp, pointed instruments to remove the beading as this may damage the graft wall. If damage occurs, that segment of the graft should not be used. Refer to "Anastomotic Preparation" within the IFU, for further instructions.


Figure 1: Correct Technique for Removal of Beading from Vascular Graft



Complete and email Complaints.Singapore@crbard.com the accompanying **Acknowledgement Receipt Form** to acknowledge receipt and understanding of this letter (Attachment 2).

No further action is necessary. However, if the unit does not meet your needs, please contact your Bard representative to return the product and place a new order. We sincerely regret any inconvenience this may cause you and your facility. If you have any questions, please do not hesitate to contact your Bard representative.

Sincerely,


Melvin Tay
Business Director
BD Interventional SEA

CC: Chairman Medical Board and relevant Head of Departments

Attachment 1 – Affected Product Codes
Attachment 2 - Acknowledgement Receipt Form

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Attachment 1 – List of Affected Product Codes

Product Description	Product Code	Dimensions
DISTAFLO® Bypass Graft, Flex Small Beading With Standard Cuff	DF5006SC	6 mm x 50 cm
	DF5007SC	7 mm x 50 cm
	DF5008SC	8 mm x 50 cm
	DF6006SC	6 mm x 60 cm
	DF6007SC	7 mm x 60 cm
	DF6008SC	8 mm x 60 cm
	DF7006SC	6 mm x 70 cm
	DF7007SC	7 mm x 70 cm
	DF7008SC	8 mm x 70 cm
	DF8006SC	6 mm x 80 cm
	DF8007SC	7 mm x 80 cm
	DF8008SC	8 mm x 80 cm
DISTAFLO® Bypass Graft, Flex Small Beading With Small Cuff	DFM5006SC	6 mm x 50 cm
	DFM6006SC	6 mm x 60 cm
	DFM7006SC	6 mm x 70 cm
	DFM8006SC	6 mm x 80 cm
DISTAFLO® Mini Cuff Bypass Graft, Flex Small Beading With Mini Cuff	DFX6006SC	6 mm x 60 cm
	DFX7006SC	6 mm x 70 cm
	DFX8006SC	6 mm x 80 cm
	DFX9006SC	6 mm x 90 cm
DYNAFLO® Bypass Graft, Flex Small Beading	DNF5007SC	7 mm x 50 cm
	DNF5008SC	8 mm x 50 cm
	DNF6007SC	7 mm x 60 cm
	DNF6008SC	8 mm x 60 cm
	DNF7007SC	7 mm x 70 cm
	DNF7008SC	8 mm x 70 cm
	DNF8007SC	7 mm x 80 cm
	DNF8008SC	8 mm x 80 cm
IMPRA® ePTFE Vascular Graft, Flex Small Beading	F2006S	6 mm x 20 cm
	F4008S	8 mm x 40 cm
	F5008S	8 mm x 50 cm
	F7006S	6 mm x 70 cm
	F7008S	8 mm x 70 cm
	F8006S	6 mm x 80 cm
	F8008S	8 mm x 80 cm
	IMPRA® ePTFE Vascular Graft, Flex Tapered Small Beading	F70T74S
F70T85S		8 - 5 mm x 70 cm
IMPRA® ePTFE Vascular Graft, Flex Thinwall Small Beading	F1006TWS	6 mm x 10 cm
	F5006TWS	6 mm x 50 cm
	F5008TWS	8 mm x 50 cm
	F6006TWS	6 mm x 60 cm
	F7006TWS	6 mm x 70 cm
	F7007TWS	7 mm x 70 cm

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Product Description	Product Code	Dimensions
	F7008TWS	8 mm x 70 cm
	F8006TWS	6 mm x 80 cm
	F8007TWS	7 mm x 80 cm
	F8008TWS	8 mm x 80 cm
IMPRA® ePTFE Vascular Graft, Flex Thinwall Tapered Small Beading	F70T74TWS	7 - 4 mm x 70 cm
IMPRA® CARBOFLO® ePTFE Vascular Graft, Flex Small Beading	F5006SC	6 mm x 50 cm
	F7006SC	6 mm x 70 cm
	F7008SC	8 mm x 70 cm
	F8006SC	6 mm x 80 cm
	F8008SC	8 mm x 80 cm
IMPRA® CARBOFLO® ePTFE Vascular Graft, Flex Thinwall Small Beading	F3006TWSC	6 mm x 30 cm
	F3008TWSC	8 mm x 30 cm
	F5006TWSC	6 mm x 50 cm
	F5008TWSC	8 mm x 50 cm
	F6006TWSC	6 mm x 60 cm
	F7005TWSC	5 mm x 70 cm
	F7006TWSC	6 mm x 70 cm
	F7007TWSC	7 mm x 70 cm
	F7008TWSC	8 mm x 70 cm
	F8006TWSC	6 mm x 80 cm
	F8007TWSC	7 mm x 80 cm
	F8008TWSC	8 mm x 80 cm
IMPRA® CARBOFLO® ePTFE Vascular Graft, Flex Thinwall Tapered Small Beading	F70T74TSC	7 - 4 mm x 70 cm
	F70T85TSC	8 - 5 mm x 70 cm
	F80T74TSC	7 - 4 mm x 80 cm

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Attachment 2 – Acknowledgement Receipt Form

ePTFE Small Beading Vascular Graft Products
DISTAFLO [®] Bypass Graft DISTAFLO [®] Mini Cuff Bypass Graft DYNAFLO [®] Bypass Graft IMPRA [®] ePTFE Vascular Graft IMPRA [®] CARBOFLO [®] ePTFE Vascular Graft

Please complete this form by **as soon as possible** and email a scanned copy to Complaints.Singapore@crbard.com or return to a Bard Representative

1. By signing below, you are acknowledging receipt and understanding of the attached letter.

I, _____ have read and understand the instructions provided in this letter.
Print Name

Signature

Date

2. Please PRINT CLEARLY your Complete Contact Information:

Name: _____ Title: _____

Phone: _____ Email: _____

Facility Name: _____

Address _____

Email a scanned copy to Complaints.Singapore@crbard.com