[Contact Name]

[Department/Title]
[Hospital Name]
[Address Line 1]
[Town/City]
[Postal Code]
[Country]

[Date]

Reference: FA2018-12

URGENT FIELD SAFETY NOTICE

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

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 surveillance process, 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 confirmed through testing that the removal of the beading can result in small tears in the graft material when the removal technique noted in the IFU is not followed. This has resulted in a failure rate of 0.25% globally.

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-

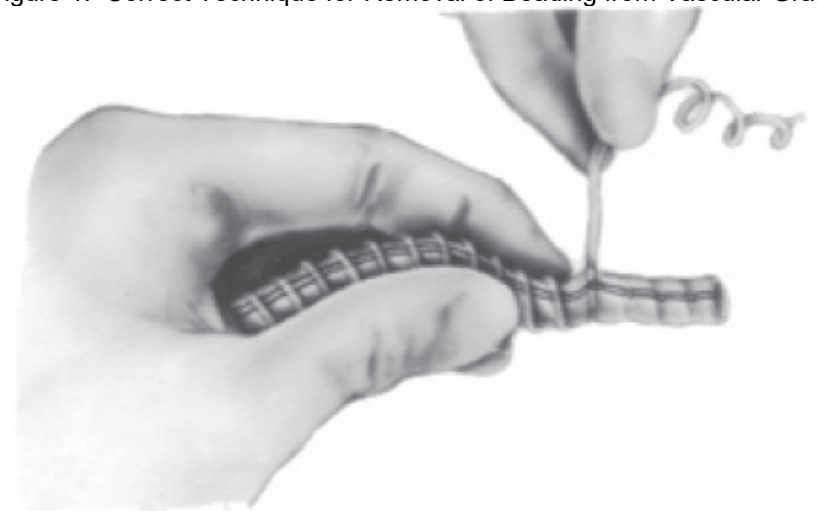
optimal anastamosis. This is more likely to be present at the time the vascular graft is being placed and therefore noticed intraoperatively.

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.

Correct Technique for Removal of Beading from Vascular Graft

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



Instructions for your facility:

1. Pass this Field Safety Notice to all personnel involved with the use of the Bard ePTFE Small Beading Vascular Grafts.
2. Ensure that the contents of this Field Safety Notice are understood by the associated personnel.
3. If you have further distributed this product then please identify the organisation and notify them at once of this notification. You may include a copy of this letter in your notification.
4. Please complete the attached Reply Effectiveness Check Form and return to the contact listed in the form

Note: Although the return of product is not required by this FSN, it is extremely important that we receive your completed Reply Effectiveness Check Form as soon as possible.

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. As part of this action, we require that you follow the instructions detailed above.

Should you have any questions or require assistance in this matter, please contact your local sales specialist or local Bard Customer Service Representative. The local sales specialist or local Bard Customer Service Representative will also be able to help with any request to return product. The determination for returning the product should be based on whether the health care provider believes the risk of using the grafts in its inventory outweighs the health benefit of use provided to the patient.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologise for any inconvenience that may result from this action.

Sincerely,

Attachment 1 – Affected Product Codes
Attachment 2 – Reply Effectiveness Check Form

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	7 - 4 mm x 70 cm
	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

Product Description	Product Code	Dimensions
	F7007TWS	7 mm x 70 cm
	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

REFERENCE: FA2018-12

REPLY EFFECTIVENESS CHECK FORM

Bard ePTFE Small Beading Vascular Grafts

By completing the below information you confirm that the Field Safety Corrective Action Reference Number 2018-12 has been received by your Healthcare Facility or Organisation, that it has been read and understood and the requested actions have been completed.

Please PRINT Your Contact Information and fill form out completely	
Name	
Title	
Name of Account / Hospital	
Contact Phone Number	
Signed	
Date	

Please return completed form to:
[Local Contact Name]
[Local Contact Title]
[Bard® XYZ (Insert IBC Name / Address / Country]
[Tel: (Local Tel #)] [Fax: (Local Fax #)] [Email: (name@crbard.com)