BARD® ePTFE

Peripheral Vascular Grafts

The Evidence Is Clear in Peripheral Bypass

BARD | PERIPHERAL VASCULAR

The evidence is clear in Peripheral Bypass

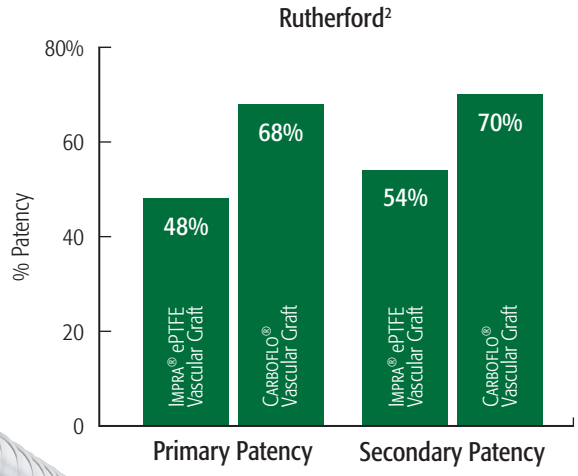
For more than 35 years, Bard has been your source for ePTFE grafts and improved clinical performance supported by evidence you can trust.

CARBOFLO®

Vascular Grafts

- **Designed to Reduce Early Graft Failure Due to Thrombosis**
- **Cost Effective Alternative to Pharmacological Grafts[1]**
- **Proven Clinical Outcomes in Below-Knee Popliteal & Distal Bypass[2]**

12-Month Cumulative Patency



BARD® IMPRA®

ePTFE Vascular Grafts

- **Proven Patency when Compared to Wrapped Grafts[3-6]**
- **Designed for Fewer Interventions**
- **Promotes Better Tissue Incorporation**

FOR IMPROVED CLINICAL PERFORMANCE YOUR CHOICE IS CLEAR

BARD® ePTFE
Peripheral Vascular Grafts

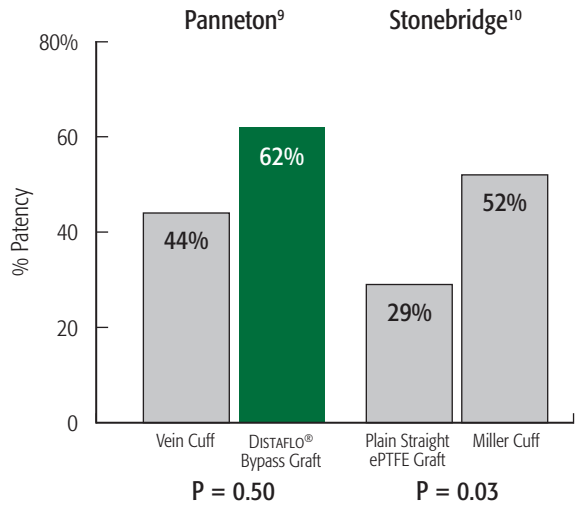
DYNAFLO®
Bypass Graft

- **Designed for Above-Knee and Extra-Anatomic Bypass Applications**
- **Unique Cuff Geometry for Higher Flow Velocities[7,8]**

DISTAFLO®
Bypass Graft

- **Designed for Below-Knee and Distal-Tibia Applications**
- **Unique Cuff Geometries for Small Target Vessels and Low Flow Rates**
- **Proven Patency and Limb Salvage Equal to Vein Cuffs at 24 Months[9]**

24 Months Cumulative Primary Patency



Hemodynamic Cuffs

DYNAFLO® Cuff

DISTAFLO® Regular Cuff

DISTAFLO® Small Cuff

DISTAFLO® Mini-Cuff

References

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2. Rutherford RB, *Vascular Surg.* Sixth Edition: Section VIII; Chapter 49, XUE, L. & Greisler, H. Prosthetic Grafts; Page 729.
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5. Epstein DA, Marshall JS, DiLiberti JH, et al. Randomized clinical trial comparing Gore-Tex and IMPRA expanded PTFE grafts. In: Henry ML, ed. *Vascular Access for Hemodialysis VI*. Chicago, IL: Precept Press; 1999:423-430.
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7. Harris P, How T. Haemodynamics of cuffed arterial anastomoses. *Critical Ischemia*. 1999;9(No. 1):20-26.
8. Fisher RK, How TV, Toonder IM, et al. Harnessing haemodynamic forces for the suppression of anastomotic intimal hyperplasia: the rationale for precuffed grafts. *Eur J Vasc Endovasc Surg*. 2001;21:520-528.
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BARD® ePTFE
Peripheral Vascular Grafts

Peripheral Vascular Grafts

IMPRA® Vascular Grafts
available in:

Straight
Large Diameter
Tapered
Straight Thinwall
IMPRA® Flex
Flex Small Beading
Flex Tapered
Flex Tapered Small Beading
Flex Large Diameter
Flex Thinwall
Flex Thinwall Small Beading
Flex Thinwall Tapered Small Beading

CARBOFLO® Vascular Grafts
available in:

Straight
Straight Thinwall
Flex Small Beading
Flex Thinwall Small Beading
Tapered
Tapered Thinwall
Flex Thinwall Tapered Small Beading

DISTAFLO® Bypass Grafts
for below-knee and distal-tibia applications available in:

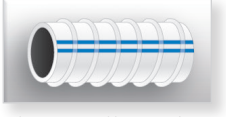
Flex Small Beading with Standard Cuff
Flex Small Beading with Small Cuff
Flex Small Beading with Mini Cuff

DYNAFLO® Bypass Grafts
for above-knee and extra-anatomic applications available in:

Flex Small Beading

Tapered

Designed to reduce the risk of steal syndrome



Flex Small Beading

Designed to strengthen critical areas and prevent kinking

IMPRA® and CARBOFLO® Vascular Grafts

Indications for Use: IMPRA® ePTFE Vascular Grafts are indicated for use as vascular prostheses. Straight, Tapered, Short Tapered, Stepped, and CENTERFLEX™ graft configurations are intended for use as subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of peripheral arterial blood vessels. Tapered, Short Tapered, and Stepped configurations may help minimize the risk of steal syndrome and high cardiac output. CENTERFLEX™ graft configurations have a non-removable external spiral support (beading) and can be used where resistance to compression or kinking is desired. IMPRA® Flex graft configurations are intended for bypass or reconstruction of peripheral arterial blood vessels and have removable spiral support (beading) over the entire graft. These grafts can be used where resistance to compression or kink is desired. Insufficient clinical data are available on which to base any conclusions regarding the use of Thinwall grafts in blood access or to support the use of IMPRA® ePTFE Vascular Grafts for applications involving; pulmonary arteries, cerebral arteries, coronary arteries, brachiocephalic trunk, cardiac vein, pulmonary veins, or the inferior or superior vena cava.

Contraindications: None known.

Warnings: 1) All IMPRA® ePTFE Vascular Grafts are supplied sterile and non-pyrogenic unless the package is open or damaged. IMPRA® ePTFE Vascular Grafts are sterilized by ethylene oxide. Each graft is intended for single patient use only. DO NOT RESTERILIZE. **2)** Do not use after expiration date printed on the label. **3)** Anastomotic or graft disruption has been associated with Axillofemoral, Femoral Femoral, or Axillobifemoral bypass procedures if implanted improperly. Refer to Specific Operative Procedures (Extra-Anatomic Bypass Procedures) for further instructions. Thinwall and IMPRA® Flex Thinwall grafts are NOT recommended for these types of bypass procedures. **4)** For Extra-Anatomic procedures, (e.g., Axillofemoral, Femoral Femoral, or Axillobifemoral Bypass) the patient should be cautioned that sudden, extreme or strenuous movements should be totally avoided for a period of at least six to eight weeks to allow for proper stabilization of the graft. Routine activities such as raising the arms above the shoulders, reaching out in front, extended reaching, throwing, pulling, striding or twisting should be avoided. **5)** IMPRA® ePTFE grafts do not stretch (are non-elastic) in the longitudinal direction. The correct graft length for each procedure must be determined by considering the patient's body weight, posture, and the range of motions across the anatomical area of graft implantation. Failure to cut the grafts to an appropriate length may result in anastomotic or graft disruption, leading to excessive bleeding, and loss of limb or limb function, and/or death. **6)** Aggressive and/or excessive graft manipulation when tunneling, or placement within a too tight or too small tunnel, may lead to separation of the spiral beading and/or graft breakage. **7)** When embolectomy or balloon angioplasty catheters are used within the lumen of the graft, the inflated balloon size must match the inner diameter of the graft. Over-inflation of the balloon or use of an inappropriately sized balloon may dilate or damage the graft. **8)** Do not remove the external spiral support (beading) from any CENTERFLEX™ graft. Attempts to remove the beading may damage the graft wall. If damage occurs, discard the graft. **9)** Do not cannulate IMPRA® Flex grafts with external support over the full length of the graft or the externally supported portion of CENTERFLEX™ grafts. Cannulation at these sites may lead to beading embolization and/or pseudoaneurysm formation. **10)** Avoid repeated or excessive clamping at the same location on the graft. If clamping is necessary, use only atraumatic or appropriate vascular smooth jawed clamps to avoid damage to the graft wall. **11)** Exposure to solutions (e.g., alcohol, oil, aqueous solutions, etc.) may result in loss of the graft's hydrophobic properties. Loss of the hydrophobic barrier may result in graft wall leakage. Preclotting of this graft is unnecessary. **12)** Avoid excessive graft manipulation after exposure to blood or body fluids. Do not forcibly inject any solution through the lumen of the graft, or fill the graft with fluid prior to pulling it through the tunnel as loss of the graft's hydrophobic properties may occur. Loss of the hydrophobic barrier may result in graft wall leakage.
13) Do NOT expose IMPRA® ePTFE grafts to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures producing highly toxic decomposition products. **14)** After use, the product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state and federal laws and regulations. **15)** During tunneling create a tunnel that closely approximates the outer diameter of the graft. A tunnel that is too loose may result in delayed healing and may also lead to perigraft seroma formation.

Precautions: 1) Only physicians qualified in vascular surgery techniques should use this prosthesis. The healthcare provider is responsible for all appropriate postoperative care instructions to the patient. **2)** The healthcare provider must observe aseptic technique during implantation and postoperatively. **3)** When removing the external spiral support (beading) of IMPRA® Flex grafts, the beading must be removed slowly and at a 90° angle to the graft. 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. **Note:** Do not remove spiral support beading from CENTERFLEX™ grafts. **4)** When suturing, avoid excessive tension on the suture line, inappropriate suture spacing and bites, and gaps between the graft and host vessel. Failure to follow correct suturing techniques may result in suture hole elongation, suture pull-out, anastomotic bleeding and/or disruption. Refer to "Suturing" for further instructions. **5)** To minimize fluid collection around the graft in Extra-Anatomic bypass procedures or in peripheral reconstructive procedures, the lymphatics should be carefully ligated and sealed, especially in the groin area. **6)** Consider intraoperative and postoperative patient anticoagulation therapy for each patient as appropriate.

Adverse Reactions: Potential complications which may occur with any surgical procedure involving a vascular prosthesis include, but are not limited to: disruption or tearing of the suture line, graft, and/or host vessel • suture hole bleeding • graft redundancy • thrombosis, embolic events, occlusion or stenosis • ultrafiltration • seroma formation • swelling of the implanted limb • formation of hematoma or pseudoaneurysm • infection • aneurysm/dilation • blood leakage • hemorrhage • steal syndrome • and/or skin erosion.

DISTAFLO® Bypass Grafts

Indications for Use: DISTAFLO® Bypass Grafts are intended for bypass or reconstruction of peripheral arterial blood vessels.

Contraindications: None known.

Warnings: 1) All DISTAFLO® Bypass Grafts are supplied sterile and non-pyrogenic unless the package is opened or damaged. DISTAFLO® Bypass Grafts are sterilized by ethylene oxide. **2)** Do not use after expiration date printed on the label. **3)** This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. **4)** Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. **5)** Anastomotic or graft disruption has been associated with Axillofemoral, Femoral Femoral, or Axillobifemoral bypass procedures if implanted improperly. Refer to Specific Operative Procedures (Extra-Anatomic Bypass Procedures) for further instructions. **6)** For Extra Anatomic procedures (e.g. Axillofemoral, Femoral Femoral, or Axillobifemoral bypass), the patient should be cautioned that sudden, extreme or strenuous movements should be totally avoided for a period of at least six to eight weeks to allow for proper stabilization of the graft. Routine activities such as raising the arms above the shoulders, reaching out in front, extended reaching, throwing, pulling, striding or twisting should be avoided.
7) DISTAFLO® Bypass Grafts do not stretch (are non-elastic) in the longitudinal direction. The correct graft length for each procedure must be determined by considering the patient's body weight, posture, and the range of motions across the anatomical area of graft implantation. Failure to cut the graft to an appropriate length may result in anastomotic or graft disruption, leading to excessive bleeding, and loss of limb or limb function, and/or death. **8)** Aggressive and/or excessive graft manipulation when tunneling, or placement within a too tight or too small tunnel, may lead to separation of the spiral beading and/or graft breakage. The distal anastomosis should be made after tunneling or suture disruption can occur. DO NOT pass the cuff portion (distal end) of the DISTAFLO® Bypass Grafts through a tunneler sheath or the tissue tunnel, as this could lead to separation of the spiral beading and/or graft breakage. **9)** When embolectomy or balloon angioplasty catheters are used within the lumen of the graft, the inflated balloon size must match the inner diameter of the graft. Over-inflation of the balloon or use of an inappropriately sized balloon may dilate or damage the graft. **10)** Avoid repeated or excessive clamping at the same location on the graft. If clamping is necessary, use only atraumatic or appropriate vascular smooth jawed clamps to avoid damage to the graft wall. Do not clamp the cuffed portion of the graft.
11) Exposure to solutions (e.g., alcohol, oil, aqueous solutions, etc.) may result in loss of the graft's hydrophobic properties. Loss of the hydrophobic barrier may result in graft wall leakage. Preclotting of this graft is unnecessary. **12)** Avoid excessive graft manipulation after exposure to blood or body fluids. Do not forcibly inject any solution through the lumen of the graft, or fill the graft with fluid prior to pulling it through the tunnel as loss of the graft's hydrophobic properties may occur. Loss of the hydrophobic barrier may result in graft wall leakage. **13)** Do NOT expose DISTAFLO® Bypass Grafts to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures, producing highly toxic decomposition products. **14)** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations. **15)** During tunneling, create a tunnel that closely approximates the outer diameter of the graft. A tunnel that is too loose may result in delayed healing and may also lead to perigraft seroma formation.

Precautions: 1) Only physicians qualified in vascular surgery techniques should use this prosthesis. The healthcare provider is responsible for all appropriate postoperative care instructions to the patient. **2)** The healthcare provider must observe aseptic technique during implantation and postoperatively. **3)** When removing the external spiral support (beading) of the DISTAFLO® graft, the beading must be removed slowly and at a 90° angle to the graft. 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" for further instructions. **4)** DISTAFLO® grafts have been developed for and are especially suitable for below the knee and infrapopliteal bypass and are not recommended for Extra-Anatomic Bypass Applications. **5)** When suturing, avoid excessive tension on the suture line, inappropriate suture spacing and bites, and gaps between the graft and host vessel. Failure to follow correct suturing techniques may result in suture hole elongation, suture pull-out, anastomotic bleeding and/or disruption. Refer to "Suturing" for further instructions. **6)** To minimize fluid collection around the graft in Extra-Anatomic bypass procedures or in peripheral reconstruction procedures, the lymphatics should be carefully ligated and sealed, especially in the groin area. **7)** Consider intraoperative and postoperative patient anticoagulation therapy for each patient as appropriate.

Adverse Reactions: Potential complications which may occur with any surgical procedure involving a vascular prosthesis include, but are not limited to: Disruption or tearing of the suture line, graft, and/or host vessel • suture hole bleeding • graft redundancy • thrombosis • embolic events • occlusion or stenosis • ultrafiltration • seroma formation • swelling of the implanted limb • formation of hematomas or pseudoaneurysm • infection • skin erosion • aneurysm/dilation • blood leakage • and hemorrhage.

DYNAFLO® Bypass Grafts

Indications for Use: DYNAFLO® Bypass Grafts, with or without Flex beading, are intended for bypass or reconstruction of peripheral arterial blood vessels.

Contraindications: None known.

Warnings: 1) All DYNAFLO® Bypass Grafts are supplied sterile and non-pyrogenic unless the package is opened or damaged. DYNAFLO® Bypass Grafts are sterilized by ethylene oxide. Each graft is intended for single patient use only. DO NOT RESTERILIZE. **2)** Do not use after expiration date printed on the label. **3)** Anastomotic or graft disruption has been associated with Axillofemoral, Femoral Femoral, or Axillobifemoral bypass procedures if implanted improperly. Refer to Specific Operative Procedures (Extra-Anatomic Bypass Procedures) for further instructions. **4)** For Extra Anatomic procedures (e.g. Axillofemoral, Femoral Femoral, or Axillobifemoral bypass), the patient should be cautioned that sudden, extreme or strenuous movements should be totally avoided for a period of at least six to eight weeks to allow for proper stabilization of the graft. Routine activities such as raising the arms above the shoulders, reaching out in front, extended reaching, throwing, pulling, striding or twisting should be avoided. **5)** DYNAFLO® Bypass Grafts do not stretch (are non-elastic) in the longitudinal direction. The correct graft length for each procedure must be determined by considering the patient's body weight, posture, and the range of motions across the anatomical area of graft implantation. Failure to cut the graft to an appropriate length may result in anastomotic or graft disruption, leading to excessive bleeding, and loss of limb or limb function, and/or death. **6)** Aggressive and/or excessive graft manipulation when tunneling, or placement within a too tight or too small tunnel, may lead to separation of the spiral beading and/or graft breakage. The distal anastomosis should be made after tunneling or suture disruption can occur. DO NOT pass the cuff portion (distal end) of the DYNAFLO® Bypass Graft through a tunneler sheath or the tissue tunnel, as this could lead to separation of the spiral beading and/or graft breakage. **7)** When embolectomy or balloon angioplasty catheters are used within the lumen of the graft, the inflated balloon size must match the inner diameter of the graft. Over-inflation of the balloon or use of an inappropriately sized balloon may dilate or damage the graft. **8)** Avoid repeated or excessive clamping at the same location on the graft. If clamping is necessary, use only atraumatic or appropriate vascular smooth jawed clamps to avoid damage to the graft wall. Do not clamp the cuffed portion of the graft. **9)** Exposure to solutions (e.g., alcohol, oil, aqueous solutions, etc.) may result in loss of the graft's hydrophobic properties. Loss of the hydrophobic barrier may result in graft wall leakage. Preclotting of this graft is unnecessary. **10)** Avoid excessive graft manipulation after exposure to blood or body fluids. Do not forcibly inject any solution through the lumen of the graft, or fill the graft with fluid prior to pulling it through the tunnel as loss of the graft's hydrophobic properties may occur. Loss of the hydrophobic barrier may result in graft wall leakage. **11)** Do NOT expose DYNAFLO® Bypass Grafts to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures, producing highly toxic decomposition products. **12)** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations. **13)** During tunneling create a tunnel that closely approximates the outer diameter of the graft. A tunnel that is too loose may result in delayed healing and may also lead to perigraft seroma formation.

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Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

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