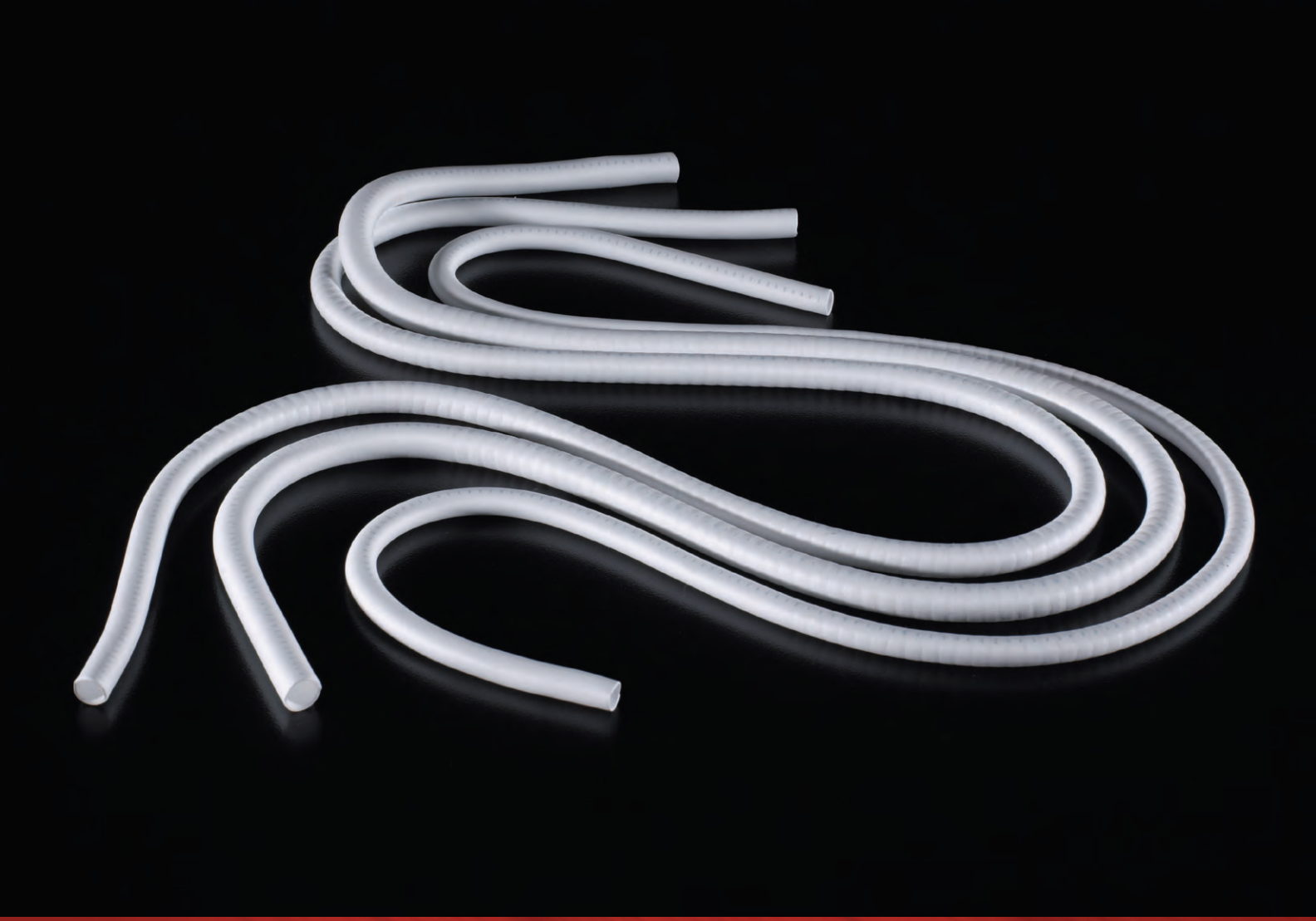
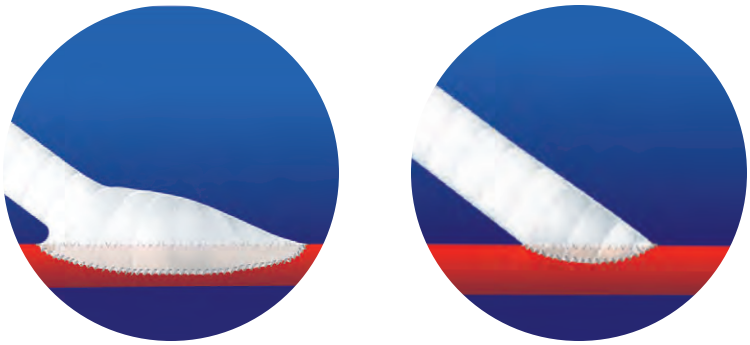


Bypass Hemodynamics
Pre-Cuffed Graft FAQs



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Bard DISTAFLO® – Bypass Graft Frequently Asked Questions

What is the DISTAFLO® Bypass Graft?

The DISTAFLO® Bypass Graft is an ePTFE graft with an enlarged **hooded shape (cuff)** at one end. It is marketed as a graft to be used in **below-knee bypasses**.

What is the rationale for the hooded shape (cuff)?

The hooded shape is meant to produce blood flow patterns at the anastomosis that differ from the flow patterns produced by a conventional graft. The hooded shape was **designed to reproduce the flow patterns that occur within vein cuffs**.[1] Because of this hooded shape, the graft is considered "pre-cuffed," and therefore eliminates the need to create a vein cuff.

What is a vein cuff, and does it produce better clinical outcomes?

When creating a distal bypass anastomosis, the surgeon may utilize a technique in which a small piece of **autogenous vein is sewn into a collar shape** and interposed between the ePTFE graft and the artery. Some clinical studies have shown **improved primary patency** when this technique is used.[2] On the other hand, some studies have found that **clinical outcomes are no better than plain ePTFE**.[3,4,5]

If a vein cuff improves results, how?

Animal studies have shown that the benefit of vein cuffs is **due to the biological material, rather than the shape**. The native biological vein material provides a better mechanical compliance match and **serves as a biological buffer between the native artery and the synthetic graft material**.[6,7]

What is the relationship between hemodynamics and bypass graft failure?

When a vascular graft is sewn into an artery in an end-to-side configuration, the flow conditions that the artery experiences at the anastomosis can be significantly altered compared to the normal physiological condition. **Animal studies have correlated the locations of the intimal hyperplasia with the locations of poor blood flow conditions**.[8] These are locations where changes in flow cause changes in shear stress at the artery wall, or where a high-velocity impact occurs against the artery wall. Occlusion of an artery or graft due to intimal hyperplasia is a significant cause of graft failure.

Do conventional end-to-side bypasses always have poor hemodynamics?

No. Recent studies have shown that a variety of geometric factors can influence the hemodynamics at an anastomosis, and **a conventional end-to-side bypass can produce relatively good hemodynamics**.[9,10]

What is the "vortex" found in the DISTAFLO® Bypass Graft anastomosis?

A number of benchtop flow studies have identified the presence of a persistent vortex flow within the DISTAFLO® Bypass Graft anastomosis geometry, similar to that found in the vein cuff geometry.[1] The vortex is an area in the flow where the **fluid moves in a circular motion**.

Haven't there been studies that showed the hemodynamic benefit of the vortex?

Early studies used flow visualization techniques to display the structure of the vortex flow. These studies discussed the idea that the flow velocity and shear stress would be increased to "normal" levels, and therefore would eliminate areas of poor flow seen in conventional end-to-side anastomoses.[1] These **early studies did not actually measure flow velocity or shear stress, so they did not provide quantitative data to support this idea**.

Does the DISTAFLO® Bypass Graft improve hemodynamics by producing higher flow velocity and shear stress?

Recent studies have used sophisticated flow velocity measurement techniques to reveal additional information about the vortex flow within the pre-cuffed anastomosis. 3-D velocity measurements compared flow in the DISTAFLO® Bypass Graft anastomosis versus flow in a conventional graft anastomosis. The vortex in the DISTAFLO® Bypass Graft was found to consist of **low-velocity recirculating flow**.[9,10] This finding provides evidence against the idea that the vortex increases the flow velocity and shear stress throughout the cardiac cycle. This result is in agreement with computer models that predict **no hemodynamic benefit for the pre-cuffed geometry**.[11,12,13]

What are potential clinical implications of areas of low-velocity recirculating flow?

Areas of slow recirculation **may be more susceptible to thrombus formation**. While the relationship between hemodynamics and clinical outcome has not been established, one clinical study reported finding large thrombus formation in the hood of the DISTAFLO® Bypass Graft.[14]

Even if the hemodynamics are not improved, doesn't the DISTAFLO® Bypass Graft hood provide a larger area that will take longer to occlude from intimal hyperplasia?

While the graft itself may have a larger area at the anastomosis, **the artery diameter is unchanged**. Intimal hyperplasia may occur in the artery, just distal to the toe.

A larger diameter graft should provide higher flow volume, so wouldn't the increased cross-sectional area at the cuff increase the flow?

This is true for a larger diameter graft because the cross-sectional area is large at the inflow and along the entire length. In contrast, with the cuff, the sudden cross-sectional expansion at the end of a graft **reduces the flow velocity due to the flow diffuser effect**.

Does the DISTAFLO® Bypass Graft save operating time?

While the DISTAFLO® Bypass Graft may save time over creating a cuff from autologous vein, it **does not save time over implanting a conventional ePTFE graft**. As noted above, evidence suggests that a conventional ePTFE graft may be used without a vein cuff, for equivalent clinical outcomes.

Is a specific graft design required for the below-knee bypass location?

Currently available bypass grafts with a **specific design for below-knee application have not proven their clinical superiority to conventional ePTFE bypass grafts**, which can be used in both above-knee and below-knee locations.

Is there clinical evidence that the DISTAFLO® Bypass Graft improves results?

Current evidence is limited. In four of the five studies performed to date (*see Table 1*), DISTAFLO® Bypass Graft was compared against vein-cuffed ePTFE grafts. The clinical results for DISTAFLO® Bypass Graft in these studies were statistically equivalent to those for vein-cuffed ePTFE. Based on these results and the presumption that vein-cuffed ePTFE has better performance than plain ePTFE, the DISTAFLO® Bypass Graft has been assumed to be superior to plain ePTFE. However, vein-cuffed ePTFE has not been proven to be superior to plain ePTFE,[5] and therefore it cannot be assumed that the DISTAFLO® Bypass Graft is superior to plain ePTFE. Results from a survey of recent literature, summarized in Table 2, provide evidence that **one- and two-year primary patencies for below-knee bypass of DISTAFLO® Bypass Graft are no better than those of ePTFE without a cuff or patch**.

Table 1

Number of Bypasses	Primary Patency One Year	Two Years	Three Years	Study
50*	39%			Fisher RK, *et al*., 2003[15]
35	51%			Alcocer F, *et al*., 2004[16]
47	52%	44%		Panneton JM, *et al*., 2004[17]
40	71%	57%	57%	Oderich GS, *et al*., 2005[18]
52	65%			Gulkarov I, *et al*., 2008[19]

* Includes above-knee bypasses

Table 2

Average Primary Patency for Below-knee Bypasses[a]	ePTFE Pre-cuffed Graft[b]	ePTFE Standard End-to-Side (no vein cuffs or patches)[c]	Vein Bypass[c]
One-year	60% (N = 174)	63% (N = 549)	81% (N = 9570)
Two-year	50% (N = 87)	50% (N = 301)	72% (N = 5062)

N = total number of bypasses

[a] Weighted average

[b] Includes studies of below-knee popliteal and distal bypasses only. Through July 2010.Data of analysis on file.

[c] Data based on analysis of current literature: Several Medline searches were performed to identify publications pertaining to ePTFE synthetic vascular graft and vein infragenicular bypasses. Search criteria included (1) articles published from January 2000 to September 2005, (2) key words used were below-knee, polytetrafluoroethylene, prosthetic, bypass, patency, (3) articles in English language, (4) N equal or greater than 30 bypasses, (5) clinical publications, (6) reviews, case reports or meta-analysis articles were excluded, (7) articles containing the key word AV access (including synonyms) were excluded, (8) majority tibial bypasses. Articles that did not meet the above criteria were deemed ineligible for this analysis. Data of analysis on file.

Bard DYNAFLO® Bypass Graft Frequently Asked Questions

What is the DYNAFLO® Bypass Graft?

The DYNAFLO® Bypass Graft is an ePTFE graft with an enlarged **hooded shape (cuff)** at one end. It is marketed as a graft to be used in **above-knee bypasses**. The DYNAFLO® Bypass Graft is similiar to the DISTAFLO Bypass Graft and is meant to improve clinical results by improving the hemodynamics at the graft anastomosis.

Do vein cuffs improve hemodynamics and clinical outcomes in above-knee bypasses?

The use of vein cuff in the above-knee indication has not been found to improve the clinical performance of ePTFE grafts.[2]

Is there clinical evidence that the DYNAFLO® Bypass Graft improves clinical results for above-knee bypass?

Rückert *et al.*[20] reported two-year cumulative primary patency of 72% in a prospective non-randomized trial of 135 DYNAFLO® implants. Because there was no control group for comparison, it is unclear whether these results represent any significant improvement over standard ePTFE grafts. For purposes of comparison, Rückert *et al.*[20] cite reports in the literature for above-knee standard ePTFE grafts ranging between 50% and 77% cumulative primary patency at two years.

Bard IMPRA® CARBOFLO® – Bypass Graft Frequently Asked Questions

What is the carbon lining for?

The carbon lining is meant to reduce platelet adhesion and the risk of thrombosis.

Is there clinical evidence that the CARBOFLO® Bypass Graft improves clinical results for below-knee bypass?

Clinical studies have found **no difference in clinical outcome** (patency, limb salvage) between carbon-lined and plain ePTFE grafts.[21,22]

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