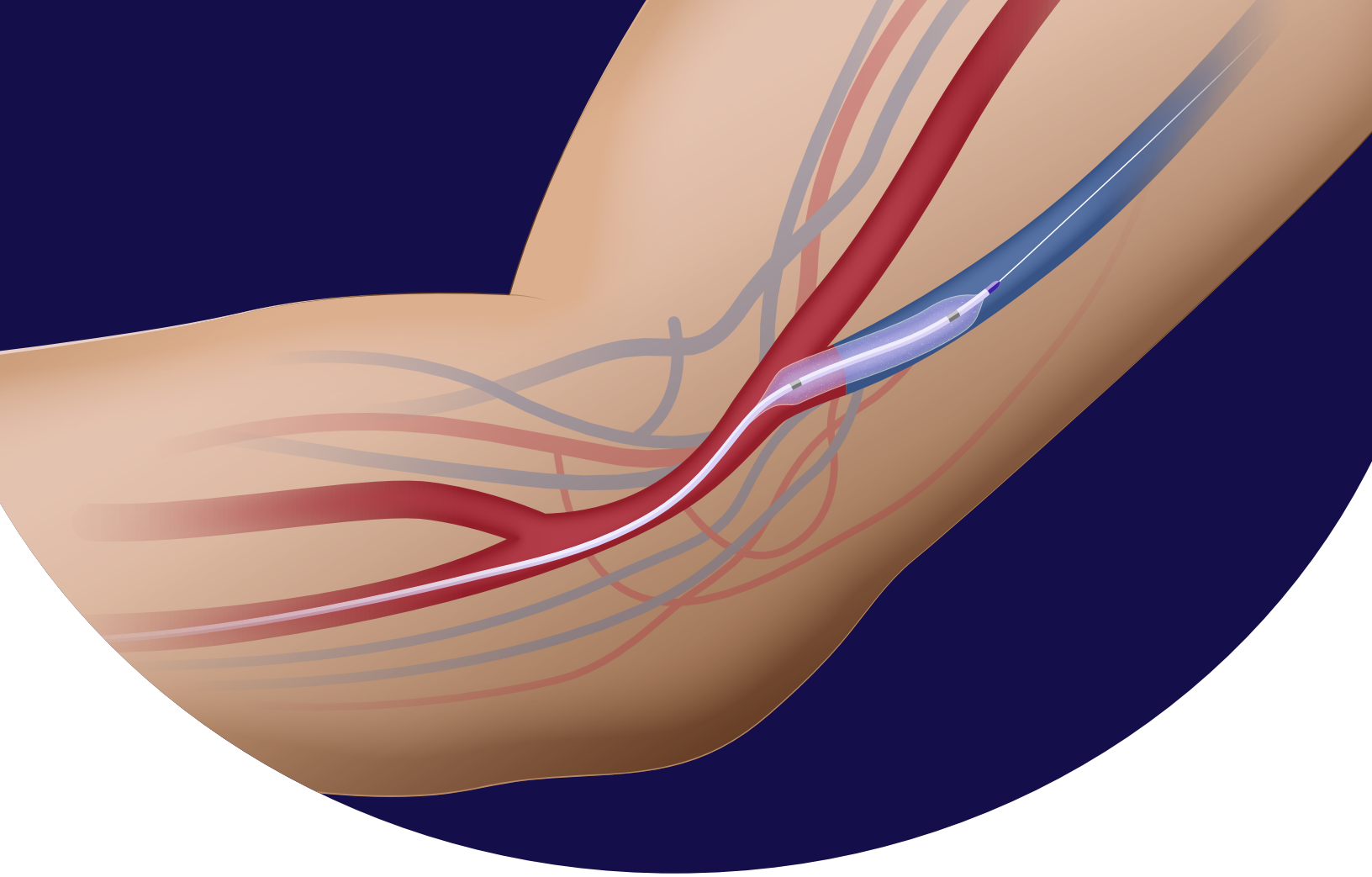


Medtronic

IN.PACT™ AV Drug-Coated Balloon (DCB)

Get ahead of AV fistula restenosis[1]

The proactive approach for AV fistula maintenance in end-stage kidney disease (ESKD) patients

Fewer interventions, more of what matters

Patients with end-stage kidney disease (ESKD) may need frequent AV fistula interventions to maintain proper flow for dialysis.

This can be hard on patients and their families. It's one more hardship for people who are already profoundly impacted by disease.

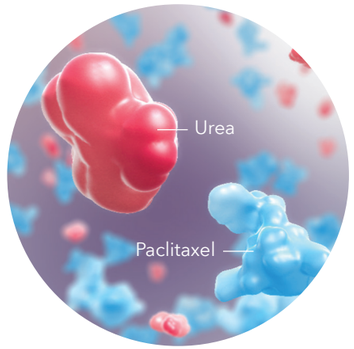
The IN.PACT AV DCB can help.

Unlike traditional percutaneous transluminal angioplasty (PTA), the IN.PACT AV DCB treats the cause – not just the symptoms of fistula stenosis – enabling you to get ahead of restenosis and go longer between interventions.[1]

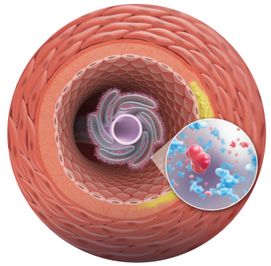
As a result, patients may need 56% fewer maintenance interventions than with PTA.[1]

That's a good thing for your patients – and those who love them.

Treat restenosis proactively



Science behind the outcomes



Efficient delivery

A proprietary combination of paclitaxel drug and urea excipient allows rapid transfer of an antiproliferative drug to the vessel wall to inhibit neointimal hyperplasia (NIH), the primary cause of AV fistula stenosis.[2]

Sustained duration

Reservoirs of paclitaxel can be sustained in the vessel wall for up to 180 days, delivering unparalleled clinical results.[1-3]

Extended effect

Uniquely combining an appropriate dosage for an appropriate amount of time,[2] the IN.PACT AV DCB can reduce the need for reinterventions and catheter-based dialysis and the related risks of infection and all-cause mortality.[1]

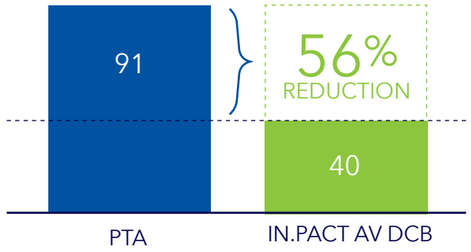
Risks may include: pain, hemorrhage; arterial or venous aneurysm/thrombosis, dissection, infection, perforation or rupture; loss of permanent access; and death.

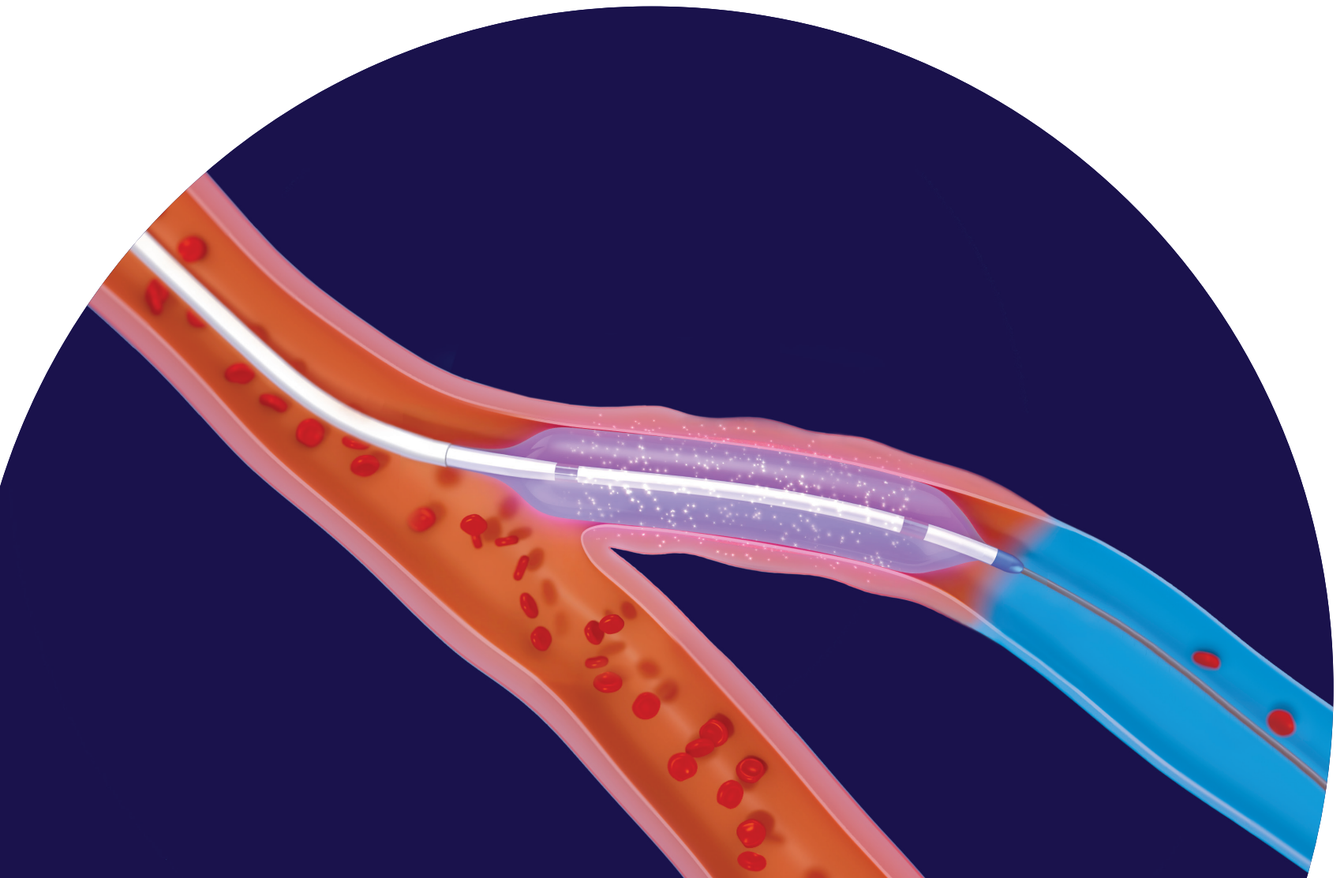
Leave a clear path for the dialysis lifeline

The IN.PACT AV DCB demonstrates 56% fewer reinterventions than PTA to maintain target lesion primary patency.[1] It slows the progression of restenosis and minimizes the potential post-treatment limitations of stents.

In the largest randomized global DCB study published on AV fistula patients, the IN.PACT AV DCB reduced the need for reinterventions by more than half.[1]

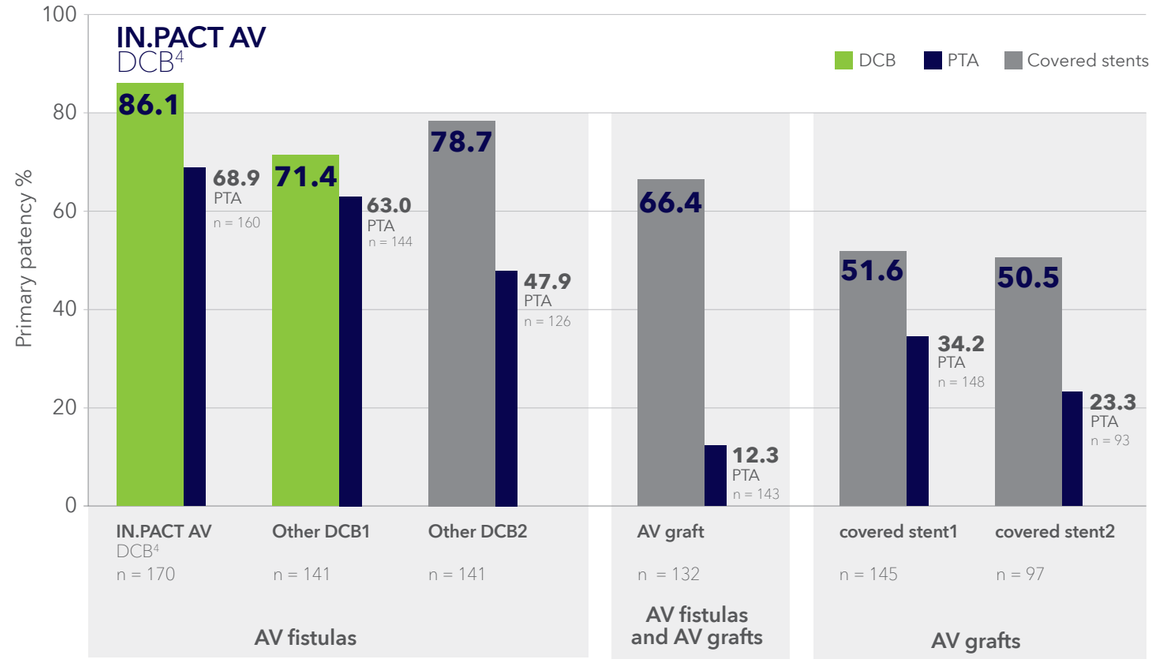
Number of reinterventions required to maintain target lesion primary patency[1]





Only device to achieve > 80% primary patency† through six months in AVF trial

AV access maintenance trials – target lesion primary patency‡



‡Primary patency rates are defined differently; results are from different studies and may vary in a head-to-head comparison; charts are for illustration purposes only.

Risks may include: pain, hemorrhage; arterial or venous aneurysm/thrombosis, dissection, infection, perforation or rupture; loss of permanent access; allergic/immunologic reaction; and death.

†In an AV fistula IDE randomized controlled trial.

First and only DCB with superior, sustained results at 36 months[10,11]

Compared to PTA, the IN.PACT AV drug-coated balloon is the first and only DCB to show both superior and sustained results at 36 months in treating AV fistula lesions.

Risks may include: pain, hemorrhage; arterial or venous aneurysm/ thrombosis, dissection, infection, perforation or rupture; loss of permanent access; allergic/immunologic reaction; and death.

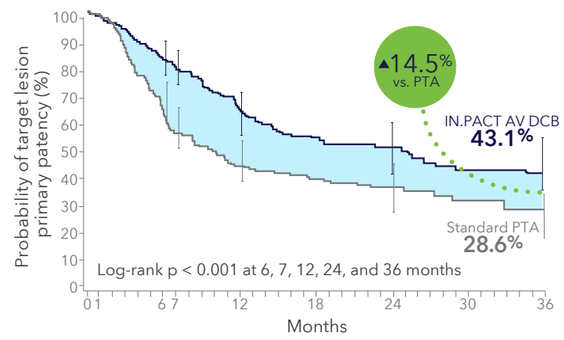
Sustained effectiveness

The highest reported primary patency of any DCB at 36 months

Results from separate trials comparing drug-coated balloons to standard PTA for AV fistula maintenance.

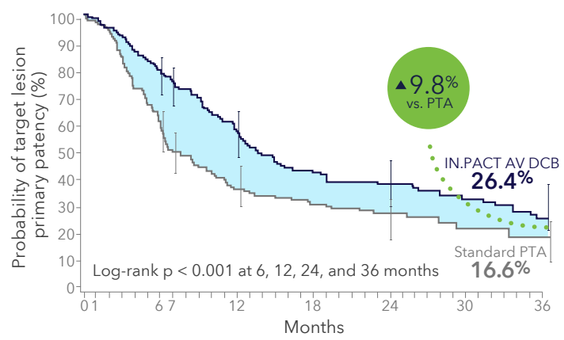
Target lesion primary patency at 36 months[§]

IN.PACT AV DCB[ϙ10]



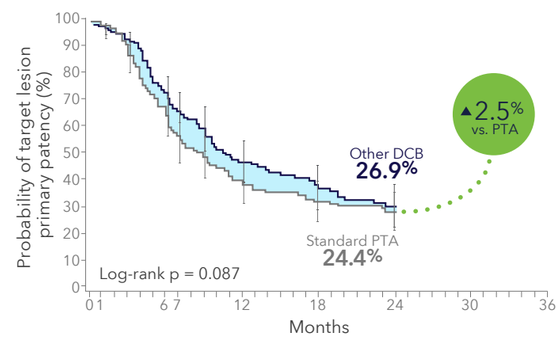
Access circuit primary patency at 36 months[§]

IN.PACT AV DCB[††1]



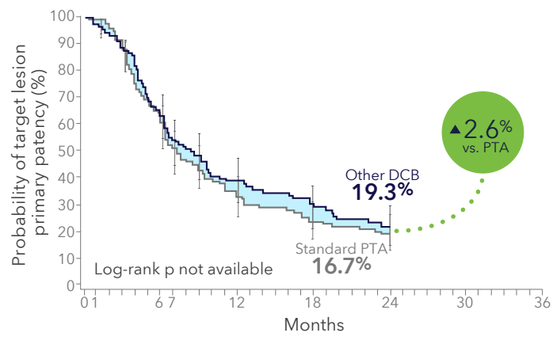
Target lesion primary patency at 36 months[§]

Other DCB[‡‡3]



Access circuit primary patency at 36 months[§]

Other DCB[§§3,11]



[§]Primary patency rates are defined differently; results are from different studies and may vary in a head-to-head comparison; charts are for illustration purposes only.

[ϙ]IN.PACT AV Access Trial: Target Lesion Primary Patency Rate was defined as freedom from clinically driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured through 36 months (1,080 days) post-procedure.
[††]IN.PACT AV Access Trial: Access Circuit Primary Patency was defined as freedom from reintervention in the access circuit or access circuit thrombosis measured through 36 months (1,080 days) post-procedure.
[‡‡]Lutonix AV Clinical Trial: Target Lesion Primary Patency was defined as freedom from clinically driven reintervention of the target lesion or access thrombosis measured through 24 months.
[§§]Lutonix AV Clinical Trial: Access Circuit Primary Patency was defined as freedom from access circuit revascularization or access circuit thrombosis measured through 24 months.

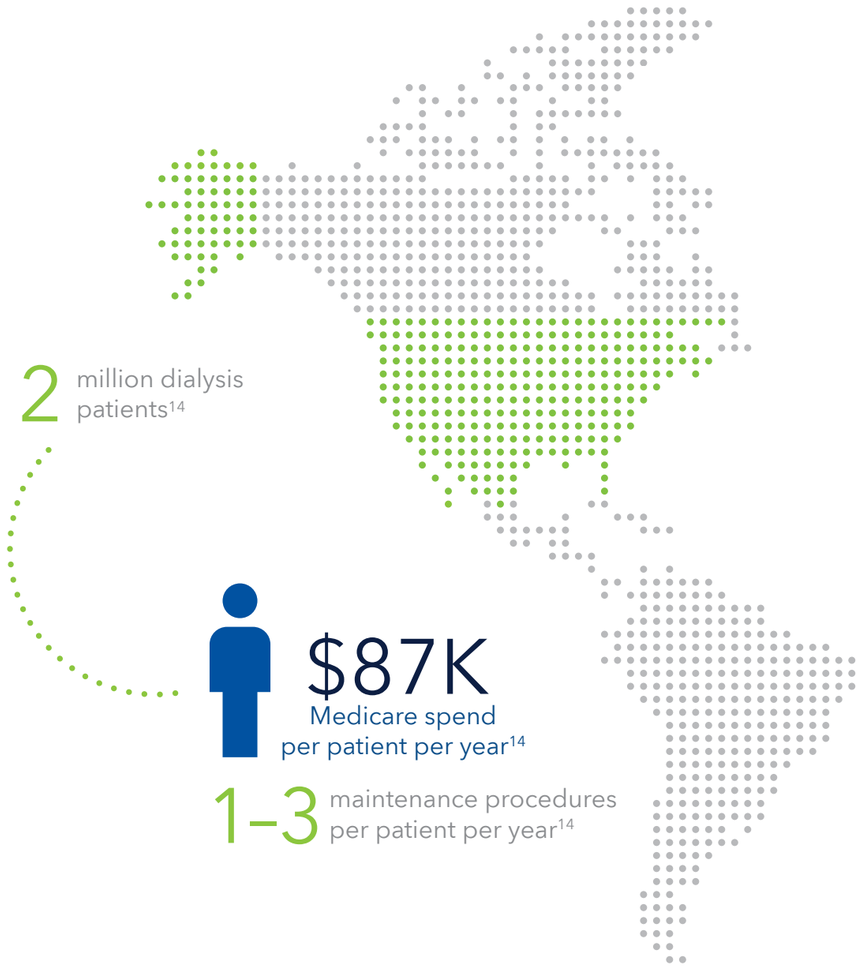
Make an impact, with bottom-line benefits

The IN.PACT AV DCB may enable dramatically fewer AV fistula reinterventions, which could keep patients out of the hospital longer.[12] It can make a real impact – clinically, financially,[13] and emotionally.

Clinical unmet need

End-stage kidney disease and AV access maintenance

AV fistulas fail often and traditional treatment options may not be enough. ESKD patients represent a significant cost to the healthcare system.



2 million dialysis patients[14]

$87K
Medicare spend per patient per year[14]

1–3 maintenance procedures per patient per year[14]

Economic burden of end-stage renal disease

Hemodialysis patients are complex

$11.4B
spent on acute inpatient care related to ESKD patient populations[13]

1.64
hospital admissions per year[12]

Over **6x** general Medicare rate[14]

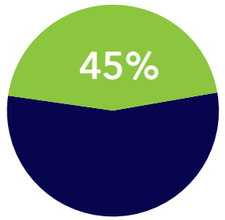
35%
30-day readmission rate[15]

2x general Medicare rate[12]

Fewer reinterventions – lower cost of care

Minimizing hospitalizations could present less risk to patients and payers and lower the cost of care for hospitals.

Why fewer reinterventions matters



Of the top 10 ESKD dialysis inpatient care codes, 45% include vascular procedures, sepsis, and infections.[13]

84,000 ESKD patients on dialysis contract hospital-related infections annually.[13]

There is an opportunity to improve the difference in costs between a successfully working AV fistula and a failing fistula.[13]

$5B total direct expenditures associated with AV vascular care in the United States[13]

$14.8K
savings per patient per year[13]

$7.9K
annualized cost of working AVF used for dialysis[13]

$22.7K
annualized cost of AVF maintenance[13]

Redefine consistent patient outcomes

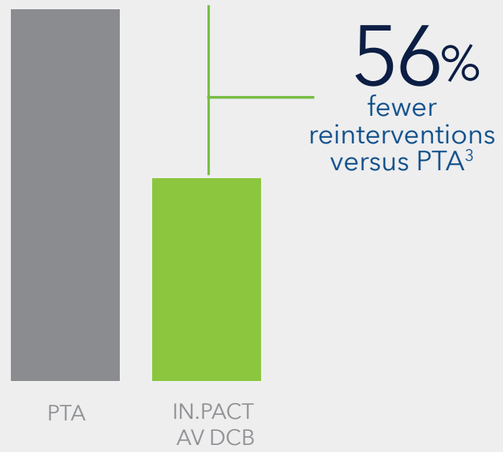
IN.PACT AV DCB had 56% fewer reinterventions required to maintain target lesion primary patency at 210 days versus PTA.[12]

Fewer reinterventions can mean less interruption in patient dialysis care, potentially easing the burden on patients.[12]

Patient satisfaction[12]

Quality of care[12]

Therapy effectiveness[12]



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[5] Dolmatch B. Presented at CIRSE 2020.
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[9] Flair™* Endovascular Stent Graft Instructions for Use.
[10] Holden A. The IN.PACT AV Access Study: Results through 36 Months. Presented at Charing Cross 2022.
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[12] Lookstein RA, Haruguchi H, Ouriel K, et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. N Engl J Med. 2020;383(8):733-742.
[13] Thamer M, Lee TC, Wasse H, et al. Medicare Costs Associated With Arteriovenous Fistulas Among US Hemodialysis Patients. *Am J Kidney Dis*. 2018;72(1):10-18.
[14] 2019 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2019. United States Renal Data System. Available at: https://www.usrds.org/annual-data-report/. Accessed November 3, 2022.

This material is for Healthcare Professionals in countries with applicable health authority product registrations.

Important: Always refer to the Instructions For Use (IFU) packaged with the product/e-IFU for complete instructions, indications, contraindications, warnings, and precautions.

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