Trusted. Reliable. Proven.

Advanta V12 balloon expandable covered stent

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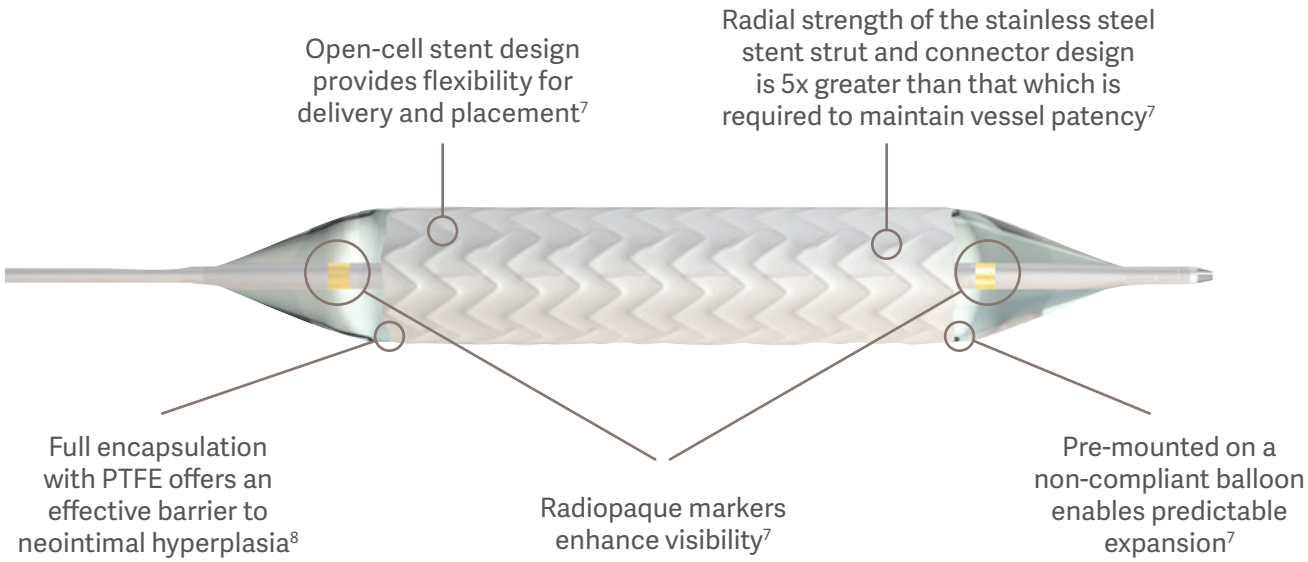
Trusted Design

For more than 15 years, the Advanta V12 balloon expandable covered stent has been trusted by physicians for its proven and reliable outcomes.[1–6]

- **Over 500,000 lives touched**
- **Strong clinical evidence** with over 500 publications[7]
- **5-year data demonstrating superior patency** over bare metal stents[5]



- **Conformable, deliverable, flexible** — Designed to track through tortuous arteries and flex to accommodate the iliac and renal anatomy

- **Low profile** —
  - 6Fr & 7Fr compatibility offers versatility and efficient delivery in complex endovascular procedures
  - 9Fr compatibility for large diameter stents offers more options for percutaneous interventions

- **Ability to post-dilate** — Allows a customized solution to various anatomy*

*Post dilation should always be performed following the guidelines within the Advanta V12 balloon expandable covered stent IFU.

Reliable Outcomes

The Advanta V12 stent has been shown to consistently improve patient outcomes by restoring iliac and renal patency, reducing restenosis and re-intervention rates, improving ABIs and sustaining symptom relief.[5,6,9,10]

iCARUS: Single-Arm IDE Study with 3-Year Follow-Up

- Real-world patient population with multiple lesions and bilateral disease
- Study showed sustained clinical benefit with freedom from target lesion revascularization (TLR) up to 3 years[9]

Freedom from TLR

Proven Performance

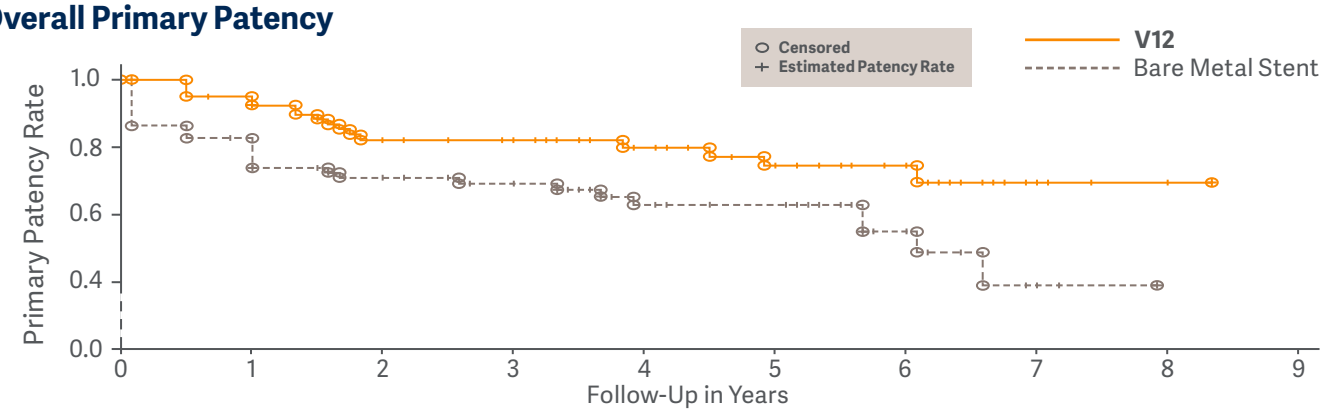
As the only covered stent with randomized, controlled data up to 8 years, the Advanta V12 stent demonstrates superior patency vs. bare metal stents, year after year, even in the most challenging TASC C and D lesions.

COBEST – Randomized Multicenter Study

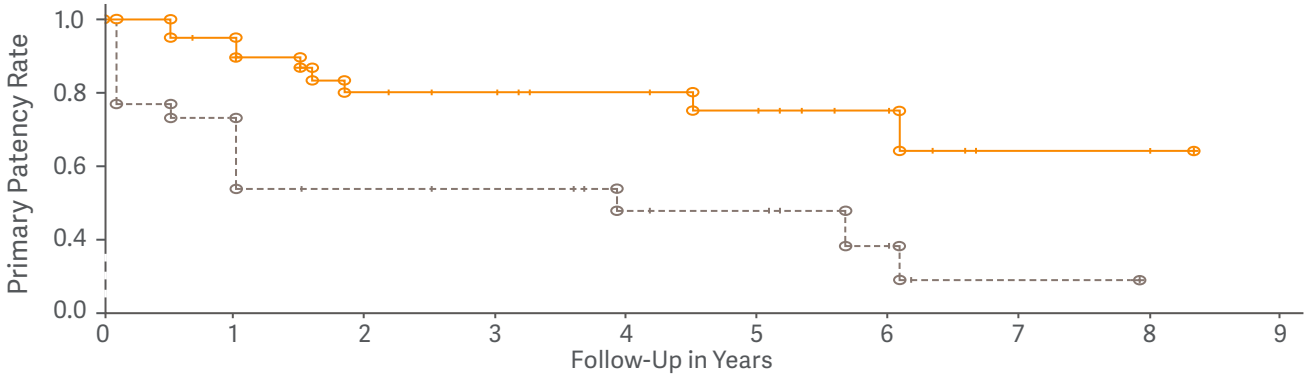
Advanta V12 vs. Bare Metal Stents

- Two-fold lower incidence of re-intervention (p=.02)
- Significantly higher patency rates at 5 years (74.7% vs. 62.9%; p=.01)†
- Significantly higher patency in subgroup analysis of TASC C/D lesions (p=.003)[5]

Overall Primary Patency



Primary Patency TASC C/D Lesions



†Patency evaluated at 18, 24, 48 and 60 months (Advanta V12: 95.1%, 82.1%, 79.9%, 74.7% vs. BMS: 73.9%, 70.9%, 63%, 62.9%)

Ordering Information

Advanta V12 balloon expandable covered stent

5 - 10 mm Diameter, .035" guidewire

Stent Diameter/Length	Order Number 80 cm Catheter Length	Order Number 120 cm Catheter Length	Foreshortened Length		Introducer Compatibility
			8 ATM Nominal Pressure	12 ATM Rated Burst Pressure	
5 x 16 mm	85340	85350	15.9 mm	15.6 mm	6 Fr
5 x 22 mm	85341	85351	21.3 mm	21.0 mm	6 Fr
5 x 32 mm	85388	85394	32.3 mm	32.3 mm	7 Fr
5 x 38 mm	85320	85330	37.2 mm	37.7 mm	7 Fr
5 x 59 mm	85321	85331	58.6 mm	60.0 mm	7 Fr
6 x 16 mm	85342	85352	15.7 mm	15.1 mm	6 Fr
6 x 22 mm	85343	85353	20.8 mm	20.2 mm	6 Fr
6 x 32 mm	85389	85395	31.7 mm	31.5 mm	7 Fr
6 x 38 mm	85322	85332	36.6 mm	37.0 mm	7 Fr
6 x 59 mm	85323	85333	57.8 mm	58.7 mm	7 Fr
7 x 16 mm	85344	85354	15.0 mm	14.2 mm	7 Fr
7 x 22 mm	85345	85355	20.1 mm	19.4 mm	7 Fr
7 x 32 mm	85390	85396	31.3 mm	31.2 mm	7 Fr
7 x 38 mm	85324	85334	35.8 mm	35.7 mm	7 Fr
7 x 59 mm	85325	85335	57.1 mm	57.5 mm	7 Fr
8 x 32 mm	85391	85397	30.0 mm	29.6 mm	7 Fr
8 x 38 mm	85326	85336	34.7 mm	34.7 mm	7 Fr
8 x 59 mm	85327	85337	56.0 mm	56.5 mm	7 Fr
9 x 32 mm	85392	85398	28.7 mm	29.2 mm	7 Fr
9 x 38 mm	85328	85338	33.7 mm	32.7 mm	7 Fr
9 x 59 mm	85329	85339	54.6 mm	54.0 mm	7 Fr
10 x 38 mm	85360	85364	30.8 mm	30.9 mm	7 Fr
10 x 59 mm	85361	85365	53.3 mm	52.5 mm	7 Fr

12 mm Large Diameter, .035" guidewire **New Size Available**

Stent Diameter/Length	Order Number 80 cm Catheter Length	Order Number 120 cm Catheter Length	Foreshortened Length		Introducer Compatibility
			8 ATM Nominal Pressure	10 ATM Rated Burst Pressure	
12 x 29 mm	85370	85379	25.6 mm	25.3 mm	9 Fr
12 x 41 mm	85371	85380	37.6 mm	37.1 mm	9 Fr
12 x 61 mm	85372	85381	58.2 mm	57.6 mm	9 Fr

[1] Mwipatayi BP, Thomas S, Wong J, et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease (COBEST). *J Vasc Surg*. 2011; 54(6):1561-1570.

[2] Cerezo M, Tinto G. Long term results (7 years) of the use of a new peripheral covered stent. *Endovasc Techniques*. 2008; Vol XI (1). Jan-Apr; 2371-2379.

[3] Bosiers M, Iyer V, Deloose K, Verbist J, Peeters P. Flemish experience using the Advanta v12 stent-graft for the treatment of iliac artery occlusive disease. *J Cardiovasc Surg (Torino)*. 2007; 48(1):7-12.

[4] Chang R, Goodney P, Baek J, Nolan B, Rzucidlo E, Powell R. Long-term results of combined common femoral endarterectomy and iliac stenting/stent grafting for occlusive disease. *J Vasc Surg*. 2008.48(2).

[5] Mwipatayi BP, Sharma S, Daneshmand A, et al. Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease. *J Vasc Surg*. 2016. Jul; 64(1):83-94.

[6] Harris W, Lesar C, Sprouse L, et al. Covered stents convey improved performance over bare metal stents for artherosclerotic renal artery stenosis. *J Vasc Surg*. May Suppl. 2013.

[7] Data on file at Getinge.

[8] Rogers C, Edelman EA. Non-GLP study of biologic responses to uncoated and PTFE coated steel stents in rabbit iliac arteries. *MIT iCAST IH Study*, July 16, 1997.

[9] Laird J, et al. iCAST Balloon-Expandable Covered Stent for Iliac Artery Lesions: 3-Year Results from Laird J, et al. iCAST Balloon-Expandable Covered Stent for Iliac Artery Lesions: 3-Year Results from the iCARUS Multicenter Study.Journal of Vascular and Interventional Radiology, 2019 Jun;30(6):822-829.

[10] Sabri S, Choudhri A, Orgera G, et al. Outcomes of covered kissing stent placement compared with bare metal stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation. *J Vasc Int Radiol*. 2010 Jul;21(7):995-1003.

All information presented in this brochure is either referenced by the above publications or is on file at Getinge.

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The Advanta V12 balloon expandable covered stent is CE marked and TGA approved for restoring and improving the patency of iliac and renal arteries. Renal approval is for 5-7 mm diameter arteries. Advanta V12 has Canadian Health Ministry license for restoring the patency of iliac lesions. The Advanta V12 stent is not available in the U.S.

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