

Advanta V12

Balloon Expandable Covered Stents

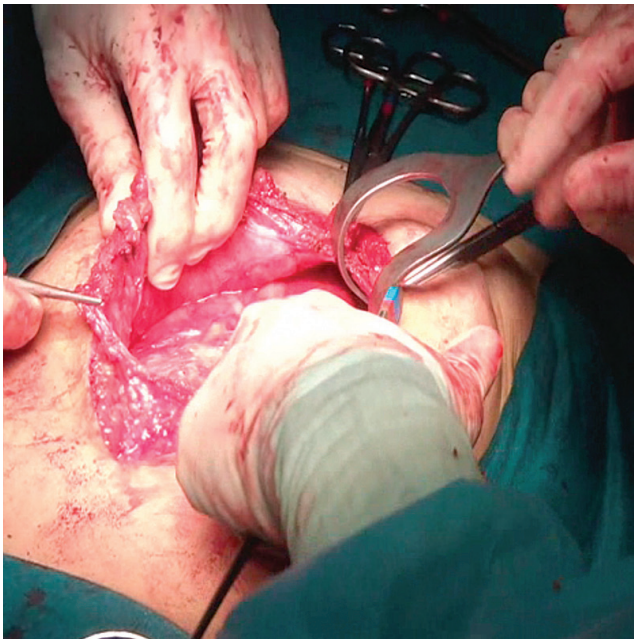
This document is intended to provide information to an international audience outside of the US. Advanta V12 covered stent is not approved or available in the US.

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Improving Patient Outcomes

with an endovascular approach

What is your preferred treatment strategy for peripheral arterial disease?



Open surgery



Endovascular therapy

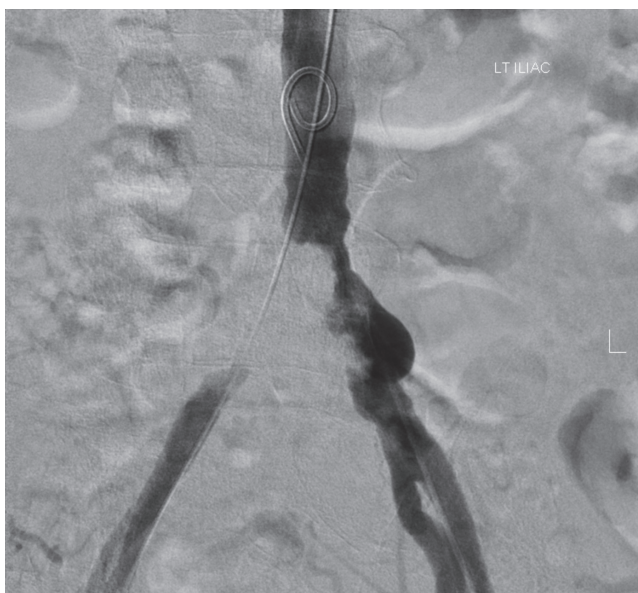
Aortoiliac outcomes

	Open Surgery	Endovascular Therapy
In hospital complication rate	25% ³	16% ³
Average mortality rate	3.7% ⁴	1.9% ⁴
Average hospital stay	7 days +/-2 ⁵	1 day +/-0.3 ⁵

Iliac stenting outcomes

	Open Surgery	Bare Metal Stent	BX Covered Stents	P Value
Primary Patency	86% (5 year) ⁶	53% (5 year) ⁷	87% (5 year) ⁷	P<.01
ABI		.85 (12 month) ⁸	.94 (12 month) ⁸	P<.014

What would be your approach? Open or endo?



Total occlusion of right common iliac artery



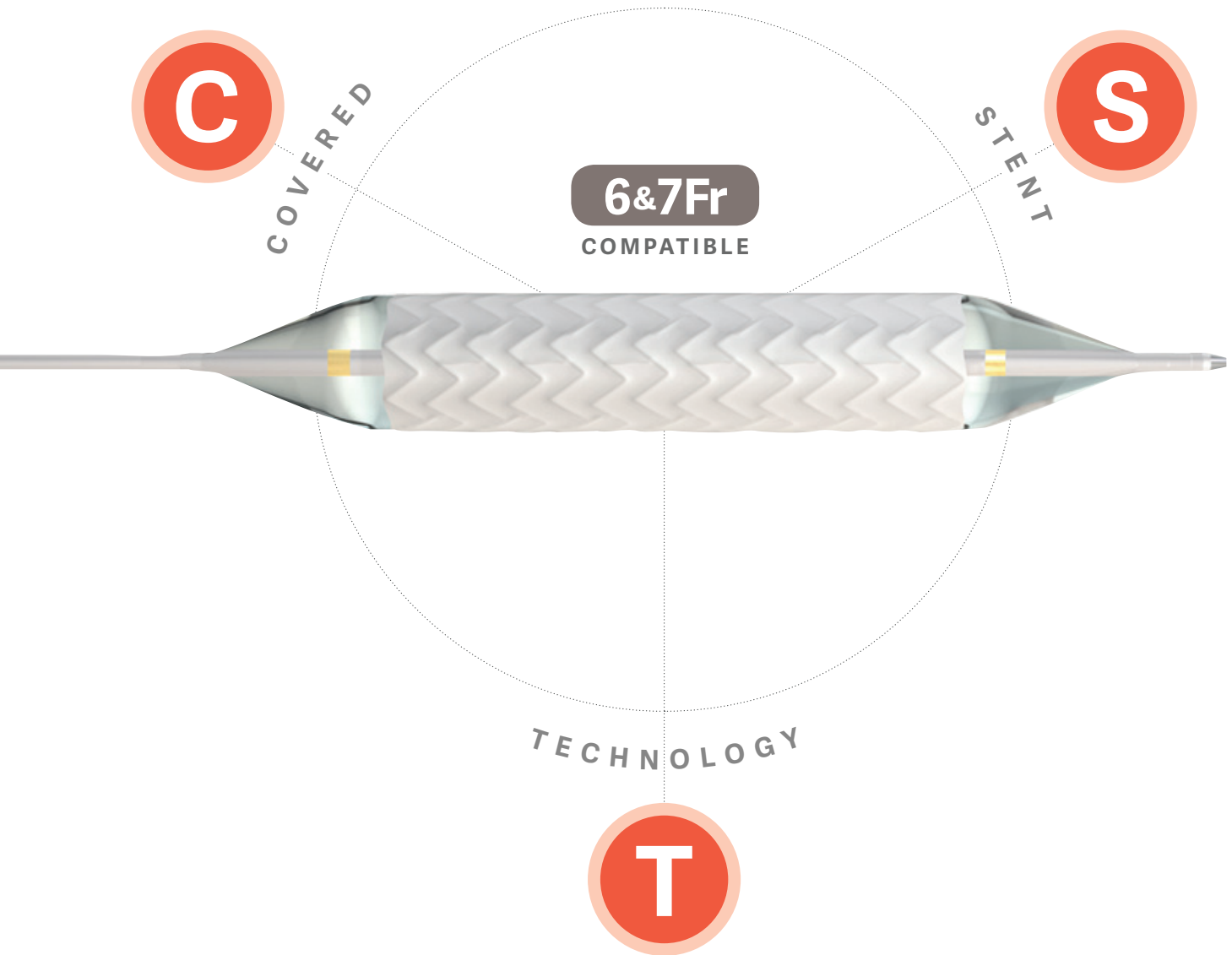
Bare metal stent restenosis



Severe stenosis of left renal artery

To get the best
clinical outcome
with an endovascular
approach, how will you
treat your patient?

The market leading balloon expandable covered stent.



Experience

- Commercially available since 2003
- Over 200 clinical publications

Clinical Success

- Significantly reduces neointimal hyperplasia⁹
- Superior patency advantage over bare metal stents long term¹
- Dramatically lower TVR rates compared to bare metal stents¹

Features

- 316L Stainless steel
- Flexible, open cell design
- Low profile
- Encapsulated in one piece of PTFE
- Pre-mounted on a PET balloon catheter (non-compliant)
- Customizable (ability to post-dilate)*

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

Customize Advanta V12 covered stents to help you achieve the best clinical outcome for your patients.

Maximum recommended post-dilation (mm)*

Labeled Diameter	Max. Recommended Post-Dilation (mm)				
	Device Length				
	16 mm	22 mm	32 mm	38 mm	59 mm
5	7.3	7.3	9.3	9.8	9.8
6	7.3	7.3	9.3	10.0	10.0
7	7.3	7.3	9.3	10.1	10.1
8	-	-	9.3	10.2	10.2
9	-	-	9.3	10.4	10.4
10	-	-	-	10.6	10.6



*Guidelines per product IFU
Images are a pictorial demonstration and not actual product applications.

One stent, multiple treatment options.

Primary Renal Stenosis



Pre



Post

Primary Iliac Stenosis



Pre

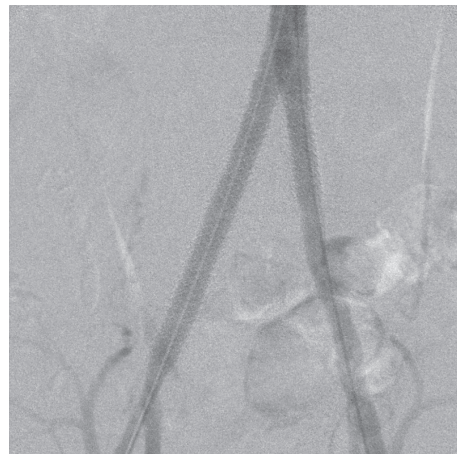


Post

Bare Metal In-Stent Stenosis



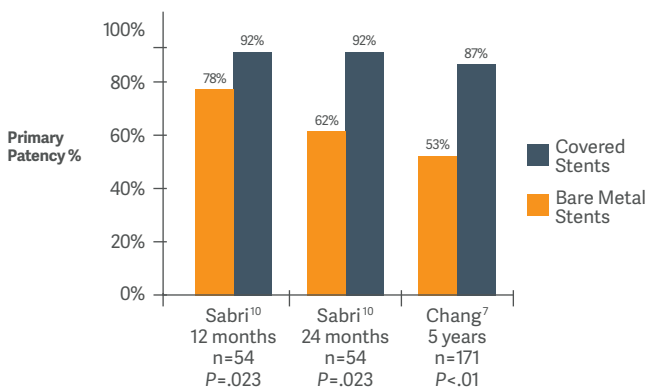
Pre



Post

Proven clinical success

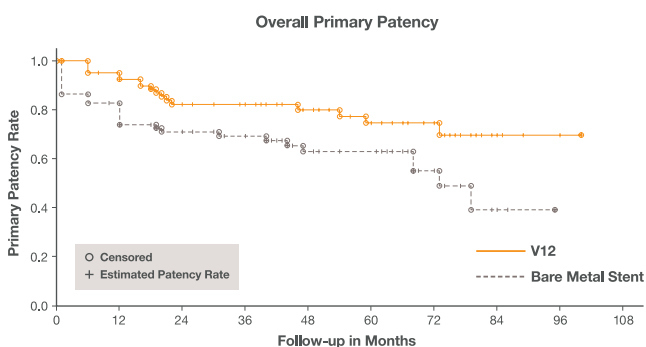
Primary patency outcome for the treatment of aortoiliac occlusive disease



Significantly less TLR with covered stents as compared to bare metal stents at 5 years, $P=.021$

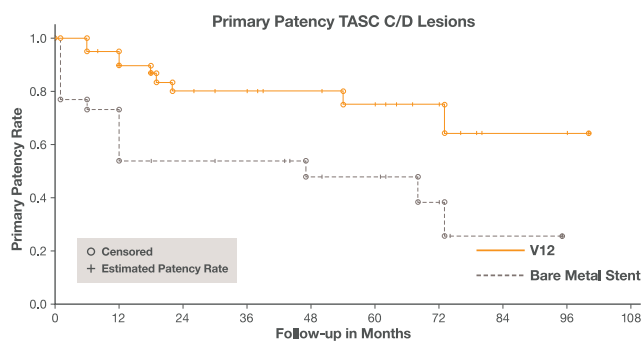
COBEST: Randomized, multicenter, controlled trial¹

Advanta V12 Covered Stents vs. Bare Metal Stents for Aortoiliac Occlusive Disease



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Covered Stent (n. at risk)	83	74	52	47	35	28	17	5	2
Standard Error (%)	-	2.95	4.54	4.54	4.93	5.84	5.84	7.27	7.27
BMS (n. at risk)	85	66	46	40	28	23	10	3	1
Standard Error (%)	-	4.89	5.13	5.27	5.94	5.94	7.36	11.2	11.2

Kaplan-Meier curve of overall primary patency rates of both stent groups. The overall patency rate was 74.7% in the covered stent (CS) group vs 62.9% in the bare-metal stent (BMS) group at 60 months of follow-up (log-rank test, $P=.01$). n at risk, Number of stents at risk of severe restenosis.



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Covered Stent (n. at risk)	40	36	24	21	18	15	8	3	2
Standard Error (%)	-	4.87	6.90	6.90	6.98	8.08	8.08	12.1	12.1
BMS (n. at risk)	24	19	13	12	9	8	4	2	1
Standard Error (%)	-	9.78	9.78	9.78	10.4	10.4	11.9	13.1	13.1

Kaplan-Meier curve of primary patency for TASC C/D lesion. The Kaplan-Meier survival estimates showed a statistically significant benefit when a covered stent (CS) was used in TASC C and D lesions compared with a bare-metal stent (BMS; HR, 3.302; 95% CI, 54.253-75.753; $P=.003$) in terms of the primary patency.

Ordering Information

Advanta V12 OTW 5-10 mm Covered Stent, .035" Guidewire



Stent Diameter/Length	80 cm Catheter Length	120 cm Catheter Length	Introducer
5 x 16 mm	85340	85350	6 FR
5 x 22 mm	85341	85351	6 FR
5 x 32 mm	85388	85394	7 FR
5 x 38 mm	85320	85330	7 FR
5 x 59 mm	85321	85331	7 FR
6 x 16 mm	85342	85352	6 FR
6 x 22 mm	85343	85353	6 FR
6 x 32 mm	85389	85395	7 FR
6 x 38 mm	85322	85332	7 FR
6 x 59 mm	85323	85333	7 FR
7 x 16 mm	85344	85354	7 FR
7 x 22 mm	85345	85355	7 FR
7 x 32 mm	85390	85396	7 FR
7 x 38 mm	85324	85334	7 FR
7 x 59 mm	85325	85335	7 FR
8 x 32 mm	85391	85397	7 FR
8 x 38 mm	85326	85336	7 FR
8 x 59 mm	85327	85337	7 FR
9 x 32 mm	85392	85398	7 FR
9 x 38 mm	85328	85338	7 FR
9 x 59 mm	85329	85339	7 FR
10 x 38 mm	85360	85364	7 FR
10 x 59 mm	85361	85365	7 FR

1. Mwipatayi P 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. *JVS* 2016.
2. Harris et al. Covered stents convey improved performance over bare metal stents for atherosclerotic renal artery stenosis. *JVS* May 2013.
3. Indes et al. Endovascular procedures for aorto-iliac occlusive disease are associated with superior short-term clinical and economic outcomes compared with open surgery in the inpatient population. *JVS* 2010; 52: 1173-1179.
4. Upchurch GR et al. Diffusion of new technology in health care: the case of aorto-iliac occlusive disease. *Surgery* 2004;136:812-8.
5. Sachwani et al. Results of iliac stenting and aorto femoral grafting for iliac artery occlusions. *JVS* 2013;57:1030-7.
6. Timaran et al. Iliac artery stenting versus surgical reconstruction for TASC type B and type C iliac lesions. *JVS* 2003; Aug;38(2):272-278.
7. Chang et al. Long-term results of combined common femoral endarterectomy and iliac stenting/stent grafting for occlusive disease. *JVS* 2008;48:362-367.
8. Mwipatayi P et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease (COBEST). *JVS*, December, 2011.
9. 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.
10. Sabri 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. *JVIR* 2010; 21:995-1003.

Advanta V12 covered stent is CE approved for restoring the patency of iliac and renal arteries. Renal approval is for 5-7mm sizes.
Advanta V12 is not available in the U.S.



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