More clinical data less restenosis.[1]

74.7% primary patency at 5 years[1]

iCast

covered stent system

- First to market balloon expandable covered stent
- 6 Fr and 7 Fr compatible on all sizes
- Backed by years of real-world evidence in challenging iliac lesions[2]
- Significantly higher patency rates at 5 years compared to bare metal stents (BMS)[1] (74.7% iCast vs. 62.9% BMS; *p*=.01).

1. Mwipatayi BP, 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;64(1):83-94.e1. doi:10.1016/j.jvs.2016.02.064 | Mwipatayi BP, et al. showed less restenosis when comparing Advanta V12 covered stent to bare metal stent in TASC C and D through 5 years.
2. Mwipatayi BP, et al. A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease. *J Vasc Surg*. 2020;72(4):1473-1486. e2. doi:10.1016/j.jvs.2020.01.084.
3. Both Advanta V12 and iCast covered stent systems are manufactured by Atrium Medical Corporation and are identical products. Advanta V12 is available outside of the United States. iCast is available only in the United States. Both products are the same physical stent and delivery system under different brands. Duration of use, number of units, and publications are combined Advanta V12 and iCast records. Data on file.

See reverse side for data

iCast® Covered Stent System

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

POTENTIAL HAZARDS AND ADVERSE EVENTS: The following anticipated adverse events (AEs) have been identified as possible complications of endovascular stent implantation in iliac arteries: • Acute myocardial infarction • Allergic reaction to stainless steel, PTFE, drugs or contrast agent • Angina/coronary ischemia • Arrhythmia • Arterial aneurysm • Arterial rupture • Arteriovenous fistula • Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention • Death • Detachment, dislodgement, and/or implantation of a component of the system • Emboli (air, tissue, or thrombotic emboli) • Emergency surgery to correct vascular complications • Hematoma/hemorrhage • Hypotension/hypertension • Infection, local or systemic • Intimal injury/dissection/perforation • Pain at catheter insertion site or limb • Pseudoaneurysm formation • Pulmonary embolism • Renal insufficiency or failure • Restenosis of the stented artery/occlusion • Short-term hemodynamic deterioration • Stent malposition/stent migration • Stent strut fracture • Stent thrombosis/occlusion • Stroke • Target limb loss (amputation of toe, foot and/or leg) • Tissue necrosis • Vascular thrombosis • Vessel spasm • Worsening claudication/rest pain

See Instructions for Use for full product information.

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COBEST[1] 5-year data

Covered versus Balloon Expandable Stent Trial

Introduction:
The COBEST trial was the first multicenter prospective randomized controlled trial to investigate the patency of iCast[3] balloon expandable covered stents (CS) versus bare metal stents (BMS) in the treatment of aorto-iliac arterial occlusive disease. The clinical trial demonstrated that iCast CS outperformed BMS in maintaining patency for the TASC C and D lesions at 18 months. Long-term data from this same patient population was analyzed retrospectively to determine if the initial patency advantage of iCast CS over BMS was sustained at the five-year follow-up.

Methods:
In this retrospective post hoc analysis, long-term data from 77 (119 target vessels) of the initial 125 patients were assessed at 60 months for the primary and secondary endpoints, with particular attention paid to the outcomes stratified according to TASC lesion severity.

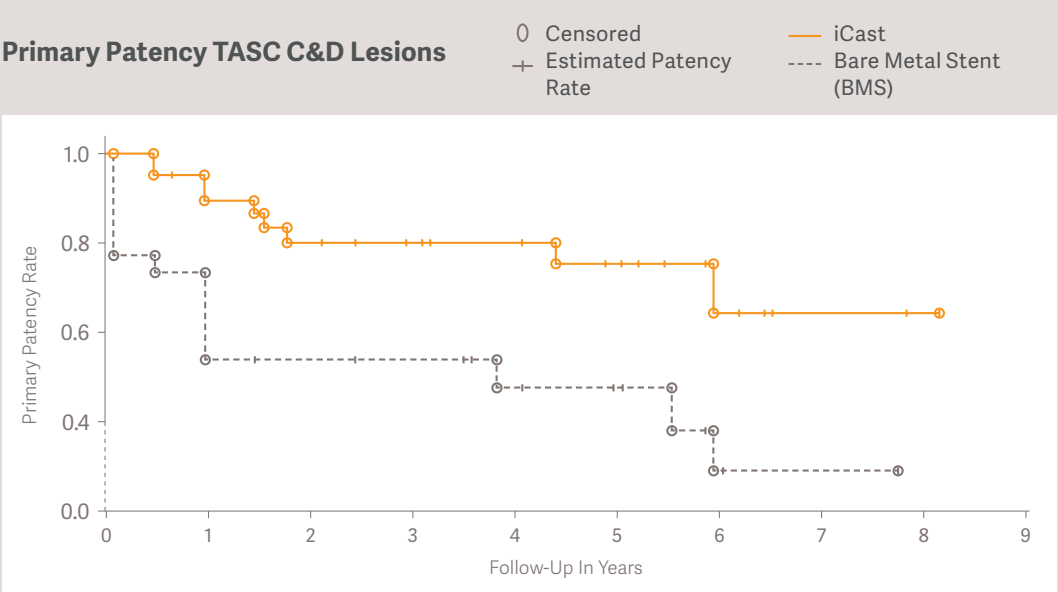
Primary endpoint:
The primary study endpoint was the rate of primary patency. Primary patency was defined as an uninterrupted patency (i.e. absence of stenosis (>50%) or occlusion of the treated segment). Patency was assessed using post-operative vascular imaging.

Results:
Primary endpoint:
- At 5 years, iCast CS had a higher primary patency rate compared to bare metal stents (CS – 74.7% vs. BMS – 62.9% p=0.01).

Subgroup analysis:
- In particular, for TASC C & D lesions, covered stents showed a statistically significant patency benefit vs. bare metal stents (see figure below).

Other outcomes:
- At 5 years, there was a twofold higher incidence of target lesion revascularization (TLR) in the BMS group compared with the CS group.

Primary Patency TASC C&D Lesions



Significantly higher patency in complex TASC C&D lesions compared to bare metal stents at 5 years (p=0.003).

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