iCast

covered stent system

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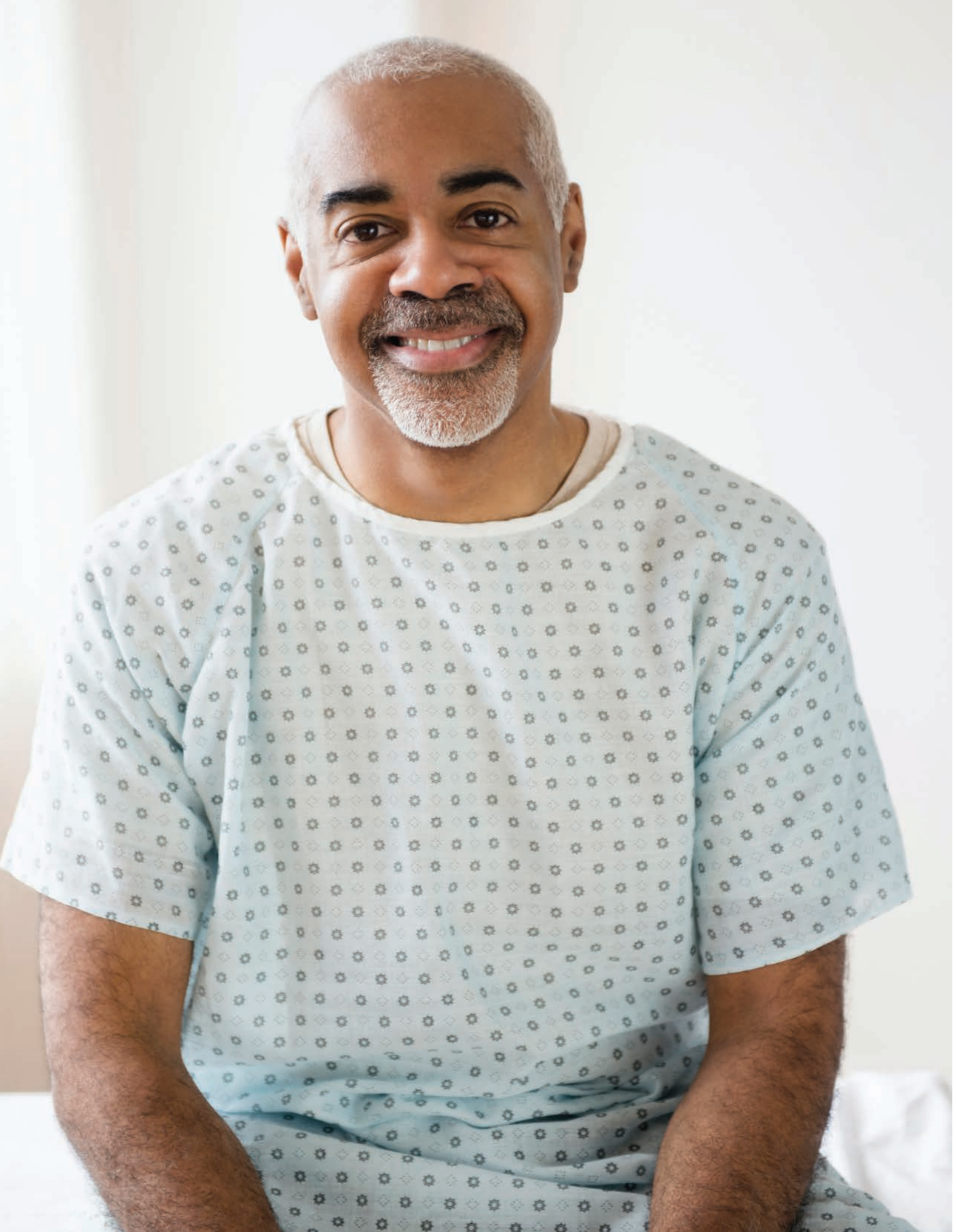

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More clinical data less restenosis.[1]

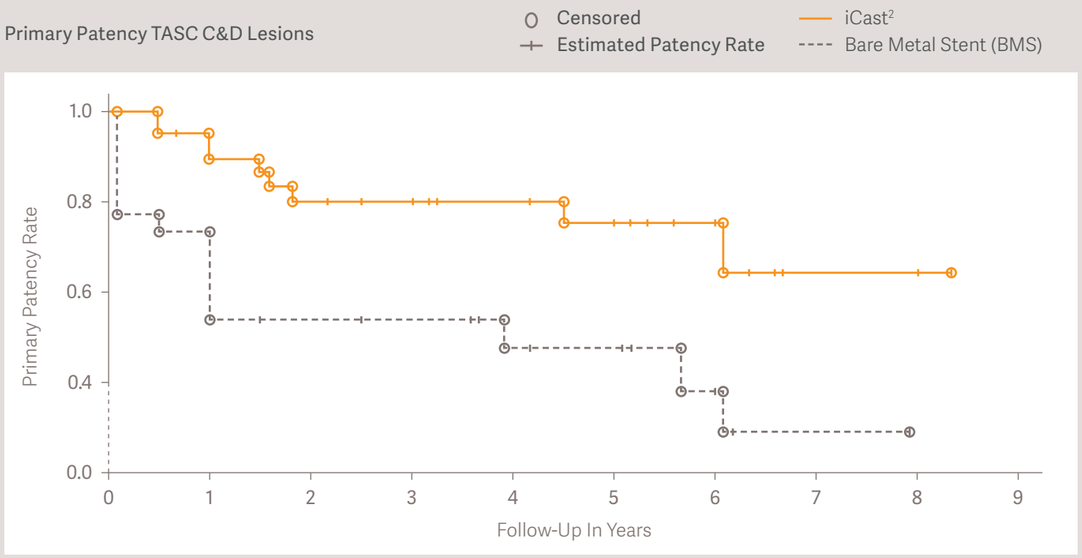
iCast covered stents have the first to market balloon expandable, fully encapsulated stent design that has served physicians with more than 850,000 units sold. Known for its precision and predictability — the versatile iCast covered stent has been meeting the needs of surgeons and patients for 20 years, and is the only durable solution backed by decades of real-world evidence.[1,2,3]

Optimized patient outcomes today, tomorrow and into the future[1,2,4,5,9]

- Published literature over the last 20 years supports safety and performance[1,4,5]
- Proven two-fold lower reintervention compared to bare metal stents at 5 years post-procedure[1]
- Full encapsulation with ePTFE minimizes neointimal hyperplasia formation[9]
- 316L stainless steel struts provide additional radial force — designed to support stent patency[2]

COBEST — 5-year results[1]

iCast vs. bare metal stent

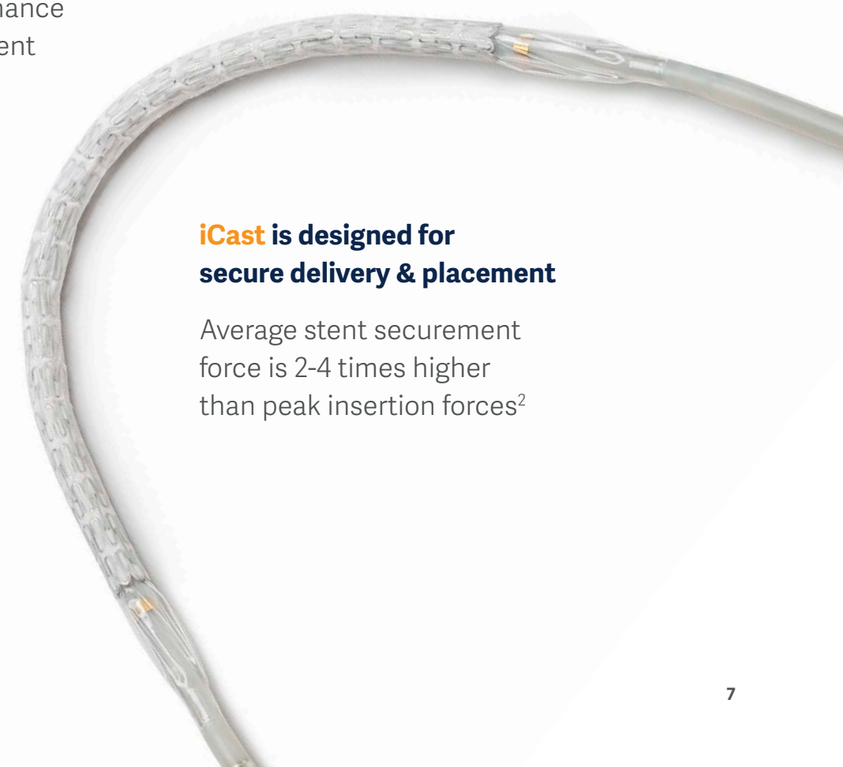


Significantly higher patency in complex TASC C&D lesions compared to bare metal stents at 5 years (p=0.003).

iCast is **the only** balloon-expandable covered stent to have **long-term, real-world follow-up,** including a reported 5-year primary patency rate of **74.7%.**[3]

The predictability and precision you need for covered stent placement[2,6,7]

- Low profile, reliable stent retention, and secure trackability facilitate stent implantation[2]
- 6 and 7 French compatible on all sizes[2]
- Predictable recoil and foreshortening promotes precise deployment[2]
- Full encapsulation with ePTFE helps mitigate the risks related to vessel perforation[6]
- Radiopaque markers enhance visibility during deployment and assist with accurate stent placement[2]
- Dog-bone inflation design is intended to reduce the chances of embolization[7]



iCast is designed for secure delivery & placement

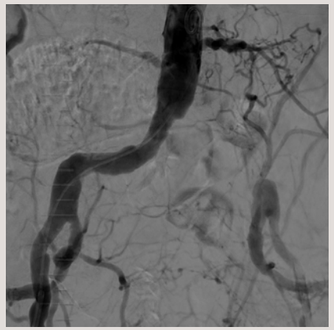
Average stent securement force is 2-4 times higher than peak insertion forces[2]

The versatility to adapt to different treatment needs, with flexibility to conform to the anatomy[2,8]

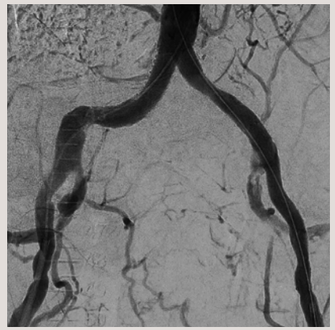
- Stent structure, cell design, and system provide versatility and flexibility in delivery and placement[2]
- Designed for pushability and trackability through tortuous anatomy with conformance to iliac arteries[2]
- Able to post-dilate and flare stent: conforming to the anatomy and customizing each patient's treatment[2,8]
- Smooth inner lumen offers ease of navigation during re-intervention[2]

Occlusive disease treatment with iCast covered stent system

Bilateral iliac artery occlusion

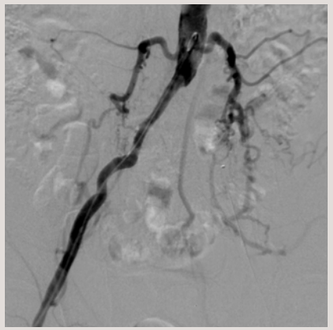


PRE-PROCEDURE

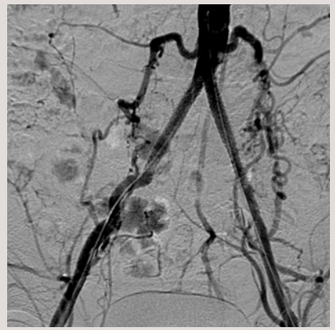


POST Restoration of the lumen diameter with iCast covered stent in RIA and overlapped iCast covered stents in LIA.

Bilateral common iliac artery occlusion

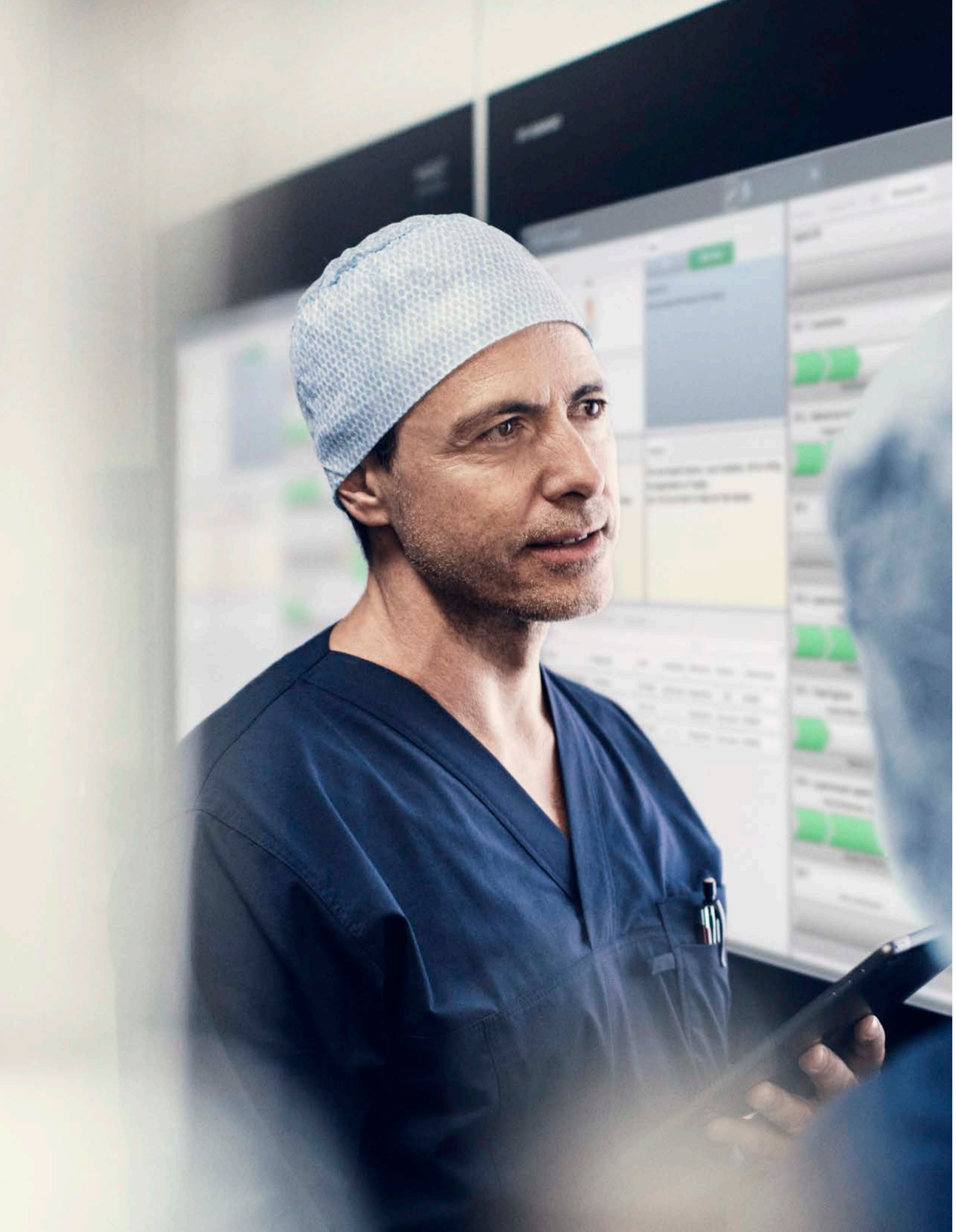


PRE-PROCEDURE



POST Restoration of the lumen diameter with iCast covered stents in RIA and LIA.

RIA - Right Iliac Artery, LIA - Left Iliac Artery



Ordering information

iCast covered stent system

5 - 10 mm Diameter, .035” guidewire

Stent Diameter/ Length	Cook GPN 80 cm Catheter Length	Cook RPN/Getinge Iliac Code 80 cm Catheter Length	Cook GPN 120 cm Catheter Length	Cook RPN/Getinge Iliac Code 120 cm Catheter Length	Foreshortened Length		Introducer Compatibility
					8 ATM Nominal Pressure	12 ATM Rated Burst Pressure	
5 x 16 mm	G60480	48516	G60497	42516	15.9 mm	15.6 mm	6 Fr
5 x 22 mm	G60481	48522	G60498	42522	21.3 mm	21.0 mm	6 Fr
5 x 38 mm	G60482	48538	G60499	42538	37.2 mm	37.7 mm	7 Fr
5 x 59 mm	G60483	48559	G60500	42559	58.6 mm	60.0 mm	7 Fr
6 x 16 mm	G60484	48616	G60501	42616	15.7 mm	15.1 mm	6 Fr
6 x 22 mm	G60485	48622	G60502	42622	20.8 mm	20.2 mm	6 Fr
6 x 38 mm	G60486	48638	G60503	42638	36.6 mm	37.0 mm	7 Fr
6 x 59 mm	G60487	48659	G60504	42659	57.8 mm	58.7 mm	7 Fr
7 x 16 mm	G60488	48716	G60505	42716	15.0 mm	14.2 mm	7 Fr
7 x 22 mm	G60489	48722	G60506	42722	20.1 mm	19.4 mm	7 Fr
7 x 38 mm	G60490	48738	G60507	42738	35.8 mm	35.7 mm	7 Fr
7 x 59 mm	G60491	48759	G60508	42759	57.1 mm	57.5 mm	7 Fr
8 x 38 mm	G60492	48838	G60509	42838	34.7 mm	34.7 mm	7 Fr
8 x 59 mm	G60493	48859	G60510	42859	56.0 mm	56.5 mm	7 Fr
9 x 38 mm	G60494	48938	G60511	42938	33.7 mm	32.7 mm	7 Fr
9 x 59 mm	G60495	48959	G60512	42959	54.6 mm	54.0 mm	7 Fr
10 x 38 mm	G60496	48038	G60513	42038	30.8 mm	30.9 mm	7 Fr

1. Mwipatayi, B.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. Journal of Vascular Surgery, 2016 (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. 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.

3. Mwipatayi, B.P., et al., A systematic review of covered balloon-expandable stents for treating aorto-iliac occlusive disease. *Journal of Vascular Surgery*, 2020.

4. Laird 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.

5. Sabri S, 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. Journal of Vascular and Interventional Radiology, 2010.

6. Feldman D. et al. "SCAI guidelines on device selection in Aorto-Iliac arterial interventions. ***Catheter Cardiovasc Interv***, 2020.

7. Grimme et al., Polytetrafluoroethylene Covered Stent Placement for Focal Occlusive Disease of the Infrarenal Aorta. ***Eur J Vasc Endovasc Surg***, 2014.

8. van der Riet et al., Three-Dimensional Geometric Analysis of Balloon-Expandable Covered Stents Improves Classification of Complications after Fenestrated Endovascular Aneurysm Repair. J of Clinical Medicine, 2022.

9. Rogers C, et al., Non-GLP study of biologic responses to uncoated and PTFE coated steel stents in rabbit iliac arteries. MIT iCast IH Study, 1997

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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