Instructions for use

iCast
covered stent system

GETINGE

Instructions for use

Description

The iCast covered stent system is a balloon-expandable stent, made of 316L stainless steel encapsulated with expanded PTFE (ePTFE). The delivery system comprises an over-the-wire (OTW) catheter with a non-compliant balloon. The device is available in diameters of 5 mm to 10 mm and crimped lengths of 16 mm, 22 mm, 38 mm, and 59 mm depending on diameter.

Figure 1. iCast Balloon Expandable Covered Stent

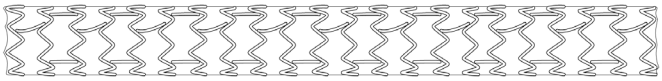
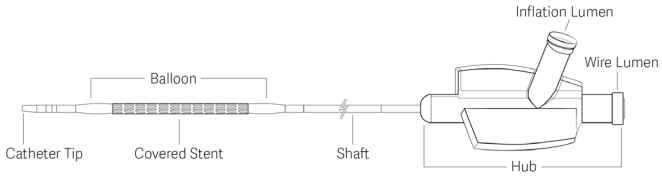


Figure 2. iCast Delivery System



The OTW delivery catheter has a wire lumen that is used for flushing and guidewire introduction. The delivery system is compatible with a 0.035" guidewire and has a usable length of 80 cm or 120 cm. The secondary or inflation lumens are used for inflation/deflation of the attached balloon to deploy the endoprosthesis. To facilitate accurate device placement, two radiopaque bands are attached to the catheter shaft marking the ends of the crimped device and dilatation length of the balloon.

The device is provided sterile for one procedure only. Do not resterilize or reuse. Do not use the iCast covered stent if the sterile package is compromised or the iCast covered stent is damaged. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Indications for Use

The iCast covered stent system is indicated for use in improving luminal diameter in patients with symptomatic atherosclerotic disease of the native common and/or external iliac arteries up to 110 mm in length, with a reference vessel diameter of 5 mm to 10 mm.

The iCast covered stent system is also indicated for use as a bridging stent between a branch vessel and an endovascular graft. This is limited to endovascular grafts that are approved for use with the iCast covered stent as a bridging stent, for treatment of patients with aneurysmal disease.

Intended Use

The iCast covered stent system is intended to restore and improve the patency of the iliac arteries when endovascular therapy is required.

The iCast covered stent system is also intended for use as a bridging stent between a branch vessel and an endovascular graft to preserve flow to branch vessels. Note that this is limited to an endovascular graft that specifically identifies the iCast covered stent as a bridging stent option.

Intended User and Intended Patient Population

The primary intended users of the iCast covered stent system are vascular surgeons, interventional cardiologists or interventional radiologists who have been trained in performing operative procedures, aseptic techniques and the preservation of the patient's homeostatic state. Appropriate analgesia and anesthetic preparation of the patient must be ensured as well. Proper hemostatic technique can be expected.

The iCast covered stent system is intended for use in adult patients.

Contraindications

The iCast covered stent system is contraindicated for use in:

1. Vessels that are not possible to access with standard placement techniques.
2. Patients with uncorrected bleeding disorders or history of coagulation disorders.
3. Patients who cannot receive anticoagulation and/or antiplatelet therapy.
4. Heavily calcified lesions resistant to Percutaneous Transluminal Angioplasty (PTA), resulting in the inability to ensure passage of the endovascular system or fully expand the stent.
5. Lesions in or adjacent to collateral vessels which, in clinician's opinion, are critical to maintain the perfusion.
6. Lesions in locations subject to external compression.
7. Aneurysms adjacent to site of stent implantation in case of occlusive disease treatment.
8. Untreated stenosis distal to site of stent implantation.
9. Patients who have a known active infection at the site of implant.
10. Patients with known allergy or hypersensitivity to 316L stainless steel (in particular nickel) or ePTFE.

Expected Clinical Benefits

- Stents restore patency (i.e. blood flow) to the vessel.
- Stents serve as a component of a system to preserve flow to target tissue while excluding an aneurysm.
- The ePTFE cover is intended to limit neo-intimal hyperplasia and endoleak.

Warnings

General Warnings

- Only physicians trained in interventional techniques should use this device. Follow these instructions, which provide technical guidance specific to this device. Failure to follow these instructions, such as using the device differently than intended or indicated, may result in unforeseen risks to the patient. The effectiveness of the device may also be limited based upon anatomical or physiologic limitations.
- The device is provided sterile for one procedure only. Do not resterilize or reuse. Reuse, reprocessing or resterilization may compromise the device integrity and/or lead to failure, which may result in patient injury, illness or death.
- Use the stent system on or before the 'Use By' date specified on the package.

Pre-Procedure Warnings

- Use device in a sterile environment and ensure patient is appropriately anesthetized prior to procedure.
- Prescribe appropriate anticoagulation and/or antiplatelet therapy. Special consideration should be given to patients who have a history of coagulation disorders, contraindications to anticoagulation or antiplatelet therapy, or contraindications to medications necessary for the procedure.
- The 316L stainless steel stent may cause susceptibility artifacts in MRI scans due to distortion of the magnetic field. Incorrect settings or conditions may cause harm. (See MRI Safety Information, page 10).

Procedural Warnings

- Do not use device if storage temperature is outside of the specified range (15 °C – 25 °C).
- Use proper hemostatic technique during procedure. Failure to do so may result in bleeding.
- Establish and maintain guidewire access to target vessel before advancing device. Do not force passage or withdrawal of the guidewire or delivery system if resistance is encountered. This may result in stent dislodgement, damage to the delivery system, or separation of the balloon or catheter hub from the delivery catheter. Refer to the "Troubleshooting" section for details (page 9).
- Inspect packaging and device(s) prior to use. Do not use the iCast covered stent if the box or sterile package is opened or damaged, or if the iCast covered stent is damaged.

- Follow aseptic technique when removing device from sterile barrier system and presenting to the sterile field.
- Do not use air or gaseous medium to inflate the balloon. Significant amounts of air in the balloon may cause uneven expansion of the stent, difficulty in deployment of the stent, or balloon rupture.
- Do not expose this device to organic solvents (such as alcohol), ionizing radiation or ultraviolet light.
- The device should be used as a system. Do not cut the stent or delivery system or remove the covered stent from the balloon. The stent is not intended for use with other dilation catheters for initial deployment. The delivery system should not be used in conjunction with other stents. Do not remove, reposition or hand crimp the stent. Do not handle or in any way disrupt the placement of the stent on the balloon.
- The delivery system is not designed for use with power injection systems.
- Clinical experience with the stent has shown that Arrow International ArrowFlex® Polyurethane Sheath should not be used.
- If using a 10 mm device with a Cook introducer sheath, it is recommended to size up to an 8 French sheath to minimize potential for resistance.
- When using the iCast covered stent system with an accessory or adjunct device, refer to and follow the associated manufacturer's instructions.
- Prior to deployment, check for vessel exclusion to avoid unintended jailing (blocking) of any side branches. Stenting across a side branch will compromise flow and impact future diagnostic or therapeutic procedures.

Selection and Sizing Warnings

- To ensure patency, special care should be taken to ensure the appropriately sized stent for the procedure is selected; considering individual lesion, aneurysm, and vessel characteristics. Native vessel dimensions must be accurately measured, not estimated. Oversizing or use of higher than recommended inflation pressures may cause dissection. Undersizing may cause inadequate lesion coverage leading to edge stent restenosis or inadequate wall apposition leading to stent dislodgement, migration, thromboembolic complications or vessel occlusion.

Stent Deployment Warnings

- Do not expand the stent if it is not properly positioned at the intended site. Prior to and following stent inflation, utilize fluoroscopy to verify that the stent has been properly positioned, without shifting or damage, ensuring that there is adequate lesion/aneurysm coverage and that unintended vessel exclusion has not occurred.
- Do not exceed rated burst pressure. Balloon pressures are indicated on the product label and should be monitored during inflation. To ensure full stent expansion, inflate to at least the nominal pressure. Inflation pressures higher than recommended may cause dissection.
- Do not post-dilate the iCast covered stent greater than the recommended post-dilation diameter (see Table 1, page 6). Post-dilation greater than the recommended diameter may result in the fracture of the stent, which may cause restenosis or vessel damage. Vessel damage may cause serious injury or death.
- When multiple stents are required to cover the lesion, place the first stent in the distal segment of the lesion followed by placement of the proximal stent(s). When overlapping stents, maintain a minimum of 10 mm overlap. To minimize the risk of corrosion, it is recommended to only overlap the iCast covered stent with devices constructed of stainless steel and/or nitinol.
- Recrossing a partially or fully expanded stent with adjunct devices must be performed with caution to prevent stent and balloon damage.
- Long-term outcomes following repeat dilation of previously placed (endothelialized) stents are unknown.
- If removal of an unexpanded or partially expanded stent is necessary, do not pull it back through the introducer sheath. Do not attempt to reposition a fully or partially expanded stent once balloon inflation or deployment has been initiated. Do not attempt to withdraw or reposition the catheter without completely deflating the balloon. Ensure appropriate withdrawal technique is used. If procedural issues are encountered such as deployment failure, stent dislodgement or migration, catheter leak, inability to deflate balloon or to withdraw the balloon catheter, balloon separation or embolization, refer to the "Troubleshooting" section for details (page 9).

⚠ Precautions

⚠ Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Always consult the product label or Table 2 (page 7) to ensure a compatible sheath is selected for use.

Ensure proper removal and disposal. Failure to properly remove and dispose of the device could result in exposure to infectious pathogens.

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, ePTFE, 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
- Endoleak
- 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

Any adverse outcomes potentially associated with the device must be reported within 10 working days to Atrium Medical Corporation, a subsidiary of Getinge AB at +1 (603) 880-1433 and directly to your country's medical device regulatory authority.

Directions for Use

General Procedure

These instructions for use are specific to the deployment of the iCast covered stent system. For adjunct devices used with the iCast covered stent system, refer to and follow the associated manufacturer's instructions for sizing, access and deployment steps, removal instructions, and MRI information.

1. Patient preparation should be the same as for any angioplasty procedure.
2. Standard techniques for placement of a sheath and guidewire should be employed when using this device.
3. Perform diagnostic angiography to confirm site of implantation and major branch vessels.
4. Evaluate and mark the target vessel.

Note: Standard PTA techniques should be used if predilation is necessary.

Sizing

1. The iCast covered stent will foreshorten during deployment. Refer to the stent sizing table (Table 1, page 6) listed below and on the product label for the stent length dimensions of the deployed stent.
2. While treating occlusive disease, measure the length of the lesion to determine the length of the stent required. It is recommended to have the stent extend at least 5 mm proximal and distal to the lesion after expansion when possible. While treating aneurysmal disease, using the iCast covered stent as a bridging stent, ensure a minimum of 10 mm overlap with the distal vasculature, or longer, if recommended by the adjunct device manufacturer IFU.
   If overlapping stents are required, select stent lengths that also allow for a minimum of 10 mm overlap.
3. Measure the inner diameter of the vessel to determine the appropriate diameter stent. The iCast covered stent is labeled as the outer diameter. Refer to the stent sizing table (Table 1, page 6) listed below and on the product label for the stent OD dimensions of the deployed stent.
4. Based on the size of the iCast covered stent system identified on the product label, select compatibly sized accessories per Table 2 (page 7).

Table 1: 5-10mm Stent Sizing and Post-Dilation

Balloon Diameter (mm)	Stent Length (mm)	Post Nominal Pressure 8ATM (811kPa)		Post Rated Burst Pressure 12ATM (1216kPa)		Max Post-Dilated Stent Diameter	
		OD[1] (mm)	Length[1] (mm)	OD[1] (mm)	Length[1] (mm)	OD[1] (mm)	Length[1] (mm)
5	16	4.9	15.9	5.2	15.6	7.3	14.2
5	22	4.9	21.3	5.2	21.0	7.3	19.4
5	38	5.1	37.2	5.3	37.7	9.8	32.7
5	59	5.0	58.6	5.3	60.0	9.8	54.0
6	16	5.7	15.7	6.2	15.1	7.3	14.2
6	22	5.8	20.8	6.2	20.2	7.3	19.4
6	38	6.0	36.6	6.3	37.0	10.0	30.8
6	59	6.0	57.8	6.3	58.7	10.0	53.3
7	16	6.9	15.0	7.3	14.2	7.3	14.2
7	22	6.9	20.1	7.3	19.4	7.3	19.4
7	38	6.9	35.8	7.3	35.7	10.1	30.8
7	59	7.0	57.1	7.3	57.5	10.1	53.3
8	38	8.1	34.7	8.5	34.7	10.2	30.8
8	59	8.0	56.0	8.4	56.5	10.2	53.3
9	38	8.9	33.7	9.3	32.7	10.4	30.9
9	59	8.9	54.6	9.3	54.0	10.4	52.5
10	38	10.0	30.8	10.4	30.9	10.6	30.9

[1] Provided as general guidance based on averages observed during in vitro testing

Table 2: Accessory Device Selection -Sheath and Guidewire

The delivery system is available in 80cm or 120cm lengths

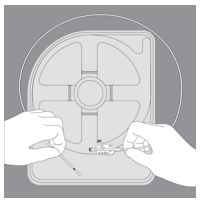
Stent Labeled Diameter (mm)	Crimped Stent Length (mm)	Introducer Sheath Size (Fr)[1]	Guidewire Diameter (inches)
5	16, 22	6	0.035
5	38, 59	7	0.035
6	16, 22	6	0.035
6	38, 59	7	0.035
7	16, 22, 38, 59	7	0.035
8	38, 59	7	0.035
9	38, 59	7	0.035
10	38	7[2]	0.035

[1] Do not use with Arrow International ArrowFlex® Polyurethane Sheath.
[2] If using a 10mm device with a Cook introducer sheath, it is recommended to use an 8 French sheath to minimize potential for resistance.

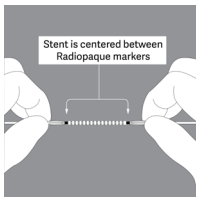
Preparation

The iCast covered stent system packaging consists of an outer shelf box (made of paperboard), sealed pouch, and an inner tray. Each inner tray contains one stent. The contents within the sealed pouch (i.e. the inner tray) are considered sterile.

1. Inspect both the box and the pouch for signs of damage and confirm that product expiration date has not been exceeded. Confirm that the shelf box label matches the pouch label.
2. Ensure device tracking labels located on the pouch are provided for hospital and patient record keeping. Utilize one label from the pouch and adhere to the Patient Implant Card in accordance with section "Instructions for Completing the Patient Implant Card" (page 11). Utilize two labels from the pouch and adhere to the Implant Tracking Card in accordance with section "Instructions for Completing the Implant Tracking Card" (page 11).
3. Upon confirming that the correct device has been selected, transfer the inner tray to the sterile field using standard aseptic technique.
4. Carefully remove the device from the inner tray and inspect for damage. Ensure the device does not come in contact with any non-sterile surfaces or instruments to avoid contamination. Minimize handling to prevent potential transfer of foreign material.

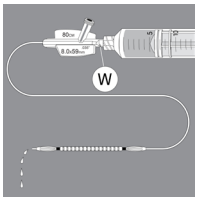


5. Visually inspect the stent to ensure it is centered within the RO markers which are viewable through the folded balloon.



6. Prefill a syringe with sterile saline.

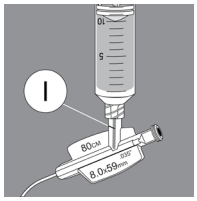
7. Attach the prefilled syringe to the guidewire lumen port as shown (labeled with letter "W" on the catheter hub) and flush the guidewire lumen until the fluid exits the guidewire lumen at the distal tip of the device.



Note: Preparation may be performed using a syringe or inflation device equipped with a manometer. Steps 8-12 demonstrate preparation using a syringe. Instructions for use of an inflation device are not provided within these steps. If using an inflation device, refer to the respective manufacturer's documentation.

IMPORTANT: For preparation steps 8-14, do not apply positive pressure (i.e. do not press the plunger) to the balloon as it can loosen the stent.

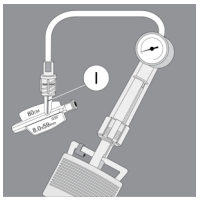
8. Draw approximately 10 cc of diluted contrast media into a 20 cc syringe. Attach to the inflation lumen port of the catheter hub (labeled with the letter "I").



9. With the syringe vertical, distal tip pointing down, draw back on the syringe to apply negative pressure to the catheter; and hold for 30 seconds.

10. Release the pressure to neutral by gently letting go of the syringe plunger (keeping syringe in an upright position) to allow contrast to fill the delivery catheter inflation lumens.

11. Repeat steps 9 and 10 at least 3 times until all of the air in the delivery system is expelled. Steps 9 & 10 remove the air from the inflation lumens and balloon, to allow diluted contrast media to fill the inflation lumens to provide more uniform inflation of the balloon during stent deployment.
12. Remove the syringe from the inflation lumen port.
13. Draw 10 cc of diluted contrast media into a 20 cc inflation device equipped with a manometer. Follow the inflation device instructions. Expel all of the air from the inflation device.
14. Attach the prefilled inflation device to the inflation lumen of the catheter hub (labeled with the letter "I" on the catheter hub), ensuring no air bubbles remain at the catheter connection.



15. After the inflation device is connected, confirm the covered stent is between the RO markers. This visual inspection verifies all preparation steps did not create positive pressure (which could cause inadequate stent deployment) and the stent remains securely positioned within the RO markers prior to patient use.

Deployment

1. Visually inspect the stent for adherence to the balloon and centered placement in relation to the RO markers on the balloon.
2. Advance the device over a (0.035") guidewire and through the sheath to the target location under direct fluoroscopic visualization.
3. Utilize fluoroscopy to verify the stent has not shifted or been damaged during positioning. Do not expand the stent if it is not properly positioned.
4. Steadily inflate the balloon to the nominal deployment pressure as stated on the product label (See Table 1, page 6).
5. Maintain the inflation pressure for a minimum of 30 seconds at nominal pressure but not greater than burst pressure for full stent expansion (See Table 1, page 6).
6. Deflate balloon by pulling vacuum on the inflation device to its maximum volume and allow sufficient time for full deflation.

Note: Deflation times may vary based on balloon size, catheter length, and inflation media used. Deflation may take longer with larger devices and higher concentrations of contrast.

IMPORTANT: Visually verify full deflation of the balloon via fluoroscopy before proceeding to step 7 for withdrawal of the delivery system.

⚠ **CAUTION:** Do not force withdrawal of the delivery system if resistance is encountered. Forcing withdrawal may result in damage to the delivery system, including separation of the balloon or catheter hub from the delivery catheter. If unable to fully deflate the balloon or resistance is encountered, remove the delivery system and introducer sheath as one unit.

Note: It is recommended that the guidewire remain across the lesion until the procedure is completed.

7. While maintaining guidewire position and negative pressure on the inflation device, slowly withdraw the delivery catheter.
8. Confirm optimal stent apposition, vessel patency and satisfactory flow using standard angiographic procedures.

Post-Dilation

If necessary, the stent can be post-dilated using standard angioplasty techniques. Maximum iCast covered stent post dilation sizes are listed in Table 1 (page 6).

Troubleshooting

The following actions are recommended in the instance of stent delivery or deployment failures. Clinical judgement should be followed.

	Hazardous Situation	Recommended Action
1	Covered stent system will not pass through the sheath	Verify sheath and covered stent system compatibility, refer to Table 2 (page 7). Visualize sheath using fluoroscopy to ensure there are no kinks. If kinked, remove sheath and covered stent system together. Do not reuse the same covered stent system.
2	Stent loosened or dislodged from the balloon while inside the sheath	Remove the sheath and covered stent system together, leaving the guidewire in place, if possible. If the stent remains on the shaft of the catheter, the balloon may be slightly inflated in order to keep the stent on the catheter during sheath and covered stent system removal. Do not reuse the same covered stent system.
3	Stent is unexpanded or partially expanded and requires removal prior to deployment	Align the proximal end of the stent with the distal tip of the introducer sheath, leaving the guidewire in place. Remove both the covered stent system and introducer sheath as one unit. After removal, do not reuse the same covered stent system. Do not attempt to pull an expanded or partially expanded stent back into the introducer sheath, as dislodgement of the stent from the balloon may occur. Do not reuse the same covered stent system.
4	Loose or dislodged stent on the catheter shaft beyond the end of the introducer sheath	If feasible, deploy stent in a safe location. If not feasible or unsuccessful, see #5

	Hazardous Situation	Recommended Action
5	Dislodged stent on the guidewire beyond the catheter	If feasible, advance an appropriately sized percutaneous transluminal angioplasty (PTA) balloon within the stent. Deploy in a safe location. If unsuccessful, consider crushing the stent by advancing a PTA balloon over a second guidewire. Inflate balloon to crush stent against vessel wall, then deploy a second stent to cover crushed stent. Do not reuse the same covered stent system. If not feasible or unsuccessful, see #6 for removal
6	Unexpanded or partially expanded stent migrates or embolizes beyond the guidewire	Use a loop snare (or similar device) to pull or push stent into a favorable location where it can be deployed safely or retrieved. If unable to retrieve the stent percutaneously, an open surgical procedure may be needed. Do not reuse the same covered stent system.
7	Balloon inflation will only partially expand the stent	Partially deploy the stent (if leak is suspected, attempt high-pressure balloon inflation with saline solution). Advance the sheath to pin the stent so that it is not withdrawn with the balloon. Rotate and remove the balloon catheter. Advance an appropriately sized percutaneous transluminal angioplasty (PTA) balloon to complete deployment. If a new PTA balloon is unable to be advanced into the stent, attempt to snare the stent and remove percutaneously. If unable to retrieve the stent percutaneously, an open surgical procedure may be needed.
8	Difficult or unable to withdraw balloon	Do not force withdrawal. Visually verify the balloon is deflated under fluoroscopy. If the catheter can be withdrawn to the point of the sheath, align the proximal end of the balloon with the distal tip of the introducer sheath, leaving the guidewire in place. Remove both the catheter and introducer sheath as one unit. If unable to reach the sheath, see #9
9	Delivery system component separation (i.e. balloon and catheter separation, distal tip and catheter separation)	Use standard percutaneous techniques for retrieval, such as the use of a loop snare. If unable to retrieve the components percutaneously, an open surgical procedure may be needed.

MRI Safety Information

Under the following conditions, a patient with an iCast covered stent can be safely scanned immediately after implantation.

Note: When using iCast as a component of a system for aneurysmal treatment, refer to the MRI conditions in the adjunct stent-graft device instructions for use. The scanning conditions that are most restrictive between the device labels should be used.

Non-clinical testing of single and overlapped stents has demonstrated that the iCast covered stent is MR Conditional.

Static Magnetic Field Strength (Bo)	1.5 or 3.0 T	
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)	
RF Polarization	Circularly Polarized (CP)	
RF Transmit Coil Type	There are no Transmit Coil restrictions	
RF Operating Mode	Normal Operating Mode	
Maximum SAR	**Whole Body:** 2.0 W/kg	**Head:** 3.2 W/kg
Calorimetry measured values, whole body averaged SAR	**1.5 T:** 2.17 W/kg	**3.0 T:** 1.76 W/kg
Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence of back-to-back series/scan without breaks).	
MR Image Artifact	The presence of the iCast covered stent may produce an image artifact. Larger imaging artifact has been observed when using a gradient echo sequence. Some manipulation of scan parameters may be needed to compensate for the artifact.	

Effects of heating in MRI environment for stents with fractured struts are not known.

Post-Implantation Instructions

Patients should be educated by their physician on appropriate post-procedure care prior to discharge, including counseling on required medication following endovascular therapy, and any potentially adverse environments that could affect the implant.

Complete the information fields on the Patient Implant Card in accordance with section "Instructions for Completing the Patient Implant Card" (page 11) and give the implant card to the patient.

Instruct patients to show their Patient Implant Card to medical personnel and inform them about their stent(s) prior to undergoing an MRI.

Sterilization

The iCast covered stent systems are provided sterile and are intended for single use only. The devices are sterilized via ethylene oxide (EO) gas sterilization methods. The devices are not intended for re-sterilization.

Storage Conditions

The iCast covered stent systems should be stored in a clean dry place, not in direct sunlight and not subject to excessive heat.

Storage Temperature: 15 °C – 25 °C (59 °F – 77 °F)

Disposal of Waste Material

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Ensure proper removal and disposal. Failure to properly remove and dispose of the device could result in exposure to infectious pathogens.

Device Lifetime

The iCast covered stent is intended for use as a permanent implant.

Note: The intended product lifetime is currently supported with at least 15 years on the market with low complaint rates and 8 years of clinical data. The anticipated product lifetime is longer based upon the use of well-characterized and well-established materials (316L stainless steel and ePTFE). Further clinical data will be collected through Post-Market Surveillance to support and further define product lifetime.

Electronic IFU is available at eIFU.getinge.com.

Instructions for Completing the Patient Implant Card

Complete the following information in the Patient Implant Card:

1. Patient Surname, First Name, Date of Birth.
2. Physician Name, Hospital Name, Hospital Address, Country.
3. Record the date of implantation, stent size, and implant location for up to 3 stents per card.
4. For each device implanted, remove one tracking label from the pouch or outer box and adhere it to the implant card in one of the the designated spaces marked "Adhere Tracking Label Here".

Instructions for Completing the Implant Tracking Card

Follow directions provided on the Implant Tracking Card. Note that if more than two stents are implanted, additional tracking cards are required.

Complete the following information in the top portion of the Implant Tracking Card; detach and mail to Getinge:

1. Implant Location for each stent implanted, Date Used.
2. Patient Name, Address, Telephone Number, Social Security Number.
3. Physician, Hospital Name, Address, Telephone Number, Follow up Physician, Hospital Name, Address, Telephone Number.
4. Hospital Name, Address, Date Used, Physician, Implant Location.

5. For each device implanted, remove one tracking label from the pouch or outer box and adhere it to the tracking card in one of the two designated spaces marked “Adhere Tracking Labels Here”.

Complete the following information in the bottom portion of the Implant Tracking Card, as required for hospital records:

1. Hospital Name, Address, Date Used, Physician.
2. Implant Location.
3. For each device implanted, remove one tracking label from the pouch or outer box and adhere it to the tracking card.
4. Tracking labels should be adhered to the single designated space marked “Adhere Tracking Labels Here”.

Summary of iCARUS Clinical Study

The iCARUS (iCast covered stent Atrium Registry Ultrasound Study) study was a prospective, multicenter, non-randomized, single-arm study performed to evaluate the safety and effectiveness of the iCast covered stent in the treatment of patients with symptomatic claudication or rest pain and angiographic confirmation of de novo or restenotic lesions in the common and/or external iliac artery[1]. Patients were treated between October 18, 2007 and October 27, 2010. Data was collected through 31 October 2013 and included 165 subjects enrolled from 25 investigational sites. The primary endpoint of the iCARUS study was a composite endpoint defined as the occurrence of death within 30 days, target site revascularization (TSR) within 9 months, or restenosis at 9 months post-procedure. The determination of restenosis was made by direct evaluation of the iliac arteries using duplex ultrasound (or angiography done in lieu of ultrasound). Key secondary endpoints included in Major Adverse Vascular Event (MAVE) at each time point through 12 months and Major Adverse Event (MAE) rate at 30 days; device success, acute procedural success, clinical success at each time point through 36 months; patency at each time point through 36 months; and a composite rate of 30-day death, 9-month TSR, and 9-month restenosis in subjects without total occlusions of the iliac.

Patient Population

Patients were required to be at least 18 years of age with lifestyle limiting claudication or rest pain (Rutherford-Becker scale 2-4), and with presence of de novo and/or restenotic lesions in the common and/or external iliac artery. Single or multiple target lesions (ipsilateral and/or bilateral), with ≥50% stenosis by visual estimate which would be crossed with a guide wire and dilated, were allowed. Eligible target lesions were between 5 and 12 mm in diameter and <110 mm in length; with evidence of patent profunda or superficial femoral artery (SFA) in the target limb(s). Treatment of non-target lesions in the SFA, meeting certain criteria, was permissible following successful treatment of the target lesion.

To participate in the study, patients were required to give informed written consent, be willing to adhere to the required follow-up visits and testing through month 36 and the required medication regimen following the procedure.

The 165 subjects were enrolled at 24 US sites and 1 German site. Of the 165 subjects enrolled, 13 subjects had inclusion/exclusion violations and were not included in the Intent to Treat (ITT) population.

Subject demographics, medical history and risk factors are summarized in Table 3. The demographics of the study population were typical for this type of study performed in the United States. The iCARUS population was predominantly male (61.8%) with a history of smoking (91.4%), hypertension (84.9%) and hypercholesterolemia (85.5%).

Table 3 Subjects Demographics, Medical History and Risk Factors – ITT Population

Characteristics	Subjects (N=152)
Age*	**Years**
Mean ± SD	65.2 ± 10.0
Median	66.4
Range (Min, Max)	42.2, 86.3
Sex	**% (m/n)**
Male	61.8 (94/152)
Female	38.2 (58/152)
Race	**% (m/n)**
American Indian or Alaska Native	0 (0/152)
Asian	0 (0/152)
Black or African American	5.3 (8/152)
Native Hawaiian or Other Pacific Islander	0 (0/152)
White	93.4 (142/152)
Other	1.3 (2/152)
Ethnicity	**% (m/n)**
Hispanic or Latino	2.0 (3/152)
Not Hispanic or Latino	98.0 (149/152)
Medical History and Risk Factors	**% (m/n)**
Previous Peripheral Artery Revascularization/Surgery	16.7 (25/150)
Coronary Artery Disease	51.0 (77/151)
Previous Myocardial Infarction	23.2 (35/151)
Previous Percutaneous Coronary Revascularization	25.8 (39/151)
Coronary Artery Bypass Graft Surgery	22.5 (34/151)
Cerebrovascular Accident	7.2 (11/152)
Previous Amputation	1.3 (2/152)
Transient Ischemic Attack (TIA)	4.6 (7/151)
Diabetes Mellitus	36.8 (56/152)
Hypertension	84.9 (129/152)
Hypercholesterolemia	85.5 (130/152)
Renal Insufficiency	12.5 (19/152)
Cigarette Smoking Status	**% (m/n)**
Current Smoker	50.3 (76/151)
Former Smoker	41.1 (62/151)
Non-Smoker	8.6 (13/151)

ITT = Intent to Treat, SD = standard deviation
m = number of subjects in category
n = number of subjects with sufficient data for analysis
*The safety and effectiveness of the iCast covered stent in pediatric populations was not studied in the iCARUS trial. As Peripheral Arterial Disease (PAD) is not typically found in the pediatric population, with the exception of rare homozygous lipid disorders, there is no plan to treat atherosclerotic disease of the common and/or external iliac arteries in this population.

Tables 4 and 5 summarize pre- and post-procedure lesion characteristics as assessed by the angiographic core laboratory. Two hundred twenty-three (223) lesions were treated in 206 limbs in 152 subjects. The majority of lesions had severe calcification (60.1%) pre-procedure. Among the 223 evaluable baseline lesions, mean reference vessel diameter (RVD) was 8.3±2.1 mm, mean percent stenosis was 69.3±16.7% and mean minimum lumen diameter (MLD) was 2.6±1.5 mm.

Table 4 Angiographic Morphology Data – ITT Population

Lesion Characteristics	Lesions (N=223) %(m/n)
Pre-Procedure Assessment	
Eccentric	49.3 (110/223)
Ulceration	28.7 (64/223)
Totally Occluded Calcification	12.1 (27/223)
None/Mild	12.6 (28/223)
Moderate	27.4 (61/223)
Severe	60.1 (134/223)
Thrombus	
None	99.6 (222/223)
Possible Thrombus	0.4 (1/223)
Post-Procedure Assessment Dissection Grade	
None	91.0 (202/222)
A	0.0 (0/222)
B	5.0 (11/222)
C	3.6 (8/222)
D	0.5 (1/222)
E	0.0 (0/222)
F	0.0 (0/222)

ITT = Intent to Treat
m = number of lesions in category
n = number of lesions with sufficient data for analysis

Table 5 Angiographic Quantitative Analysis – ITT Population

Lesion Characteristics	Lesions (N=223)
Lesion Length	**mm**
Mean ± SD (n) Median Range (Min, Max)	25.4 ± 16.8 (223) 20.4 0.0, 90.0
Pre-Procedure Assessment	
Reference Vessel Diameter	**mm**
Mean ± SD (n) Median Range (Min, Max)	8.3 ± 2.1 (223) 8.1 4.1, 16.7
Percent Stenosis (Most severe)	**%**
Mean ± SD (n) Median Range (Min, Max)	69.3 ± 16.7 (223) 66.2 26.7, 100.0
Minimum Lumen Diameter	**mm**
Mean ± SD (n) Median Range (Min, Max)	2.6 ± 1.5 (223) 2.7 0.0, 7.9
Post-Procedure Assessments: In stent	
Reference Vessel Diameter	**mm**
Mean ± SD (n) Median Range (Min, Max)	8.4 ± 2.1 (222) 8.1 4.1, 17.0
Percent Stenosis (Most severe)	**%**
Mean ± SD (n) Median Range (Min, Max)	11.8 ± 9.9 (222) 12.4 -21.2, 40.8
Minimum Lumen Diameter	**mm**
Mean ± SD (n) Median Range (Min, Max)	7.3 ± 1.7 (222) 7.1 3.7, 13.1

ITT = Intent to Treat
SD = standard deviation
n = number of lesions with sufficient data for analysis

Methods

Prior to implantation, standard diagnostic angiography was performed to confirm angiographic criteria for the study were met. Lesion length and native vessel diameter were measured in order to select the appropriate length and diameter of the stent(s). Subjects were considered enrolled once the investigational device was entered into the body.

Standard procedures for percutaneous interventional procedures were followed. Pre- and post-dilation of the lesions were performed at the discretion of the investigator. Concomitant antiplatelet/anti-thrombin and anti-coagulant therapy was administered per routine practice. After the procedure, subjects were prescribed up to 325 mg of daily aspirin and 75 mg of clopidogrel for 6 months. Ticlopidine could be substituted for subjects with sensitivity to clopidogrel.

After hospital discharge, patients were required to return to the study center for clinical assessments on Day 30 (± 7 days), 6 months (± 14 days), 9 months (± 14 days), 12 months (± 30 days), and annually thereafter through 36 months (± 30 days). Assessments including, but not limited to ECG (30 day only), Rutherford Becker score, ankle-brachial index (ABI), health status assessment, and duplex scans were performed.

Additionally, an angiogram was performed as needed to confirm restenosis and assess the safety and effectiveness of the iCast covered stent.

Results

The primary composite endpoint rate, based on available cases in the ITT population, was 8.1% (10/123), with an exact one-sided upper 95% CI of 13.4% (p=0.005). This was below the protocol-specified performance goal of 16.57% and the study stent is considered to have met the performance goal (Table 6).

Table 6 Primary Composite Endpoint – ITT Population

Endpoint	ITT population (N=152)	Exact one-sided upper 95% CI limit	Assessment of Primary Endpoint Rate < 16.57%
Primary composite endpoint to 9 months (Available cases)	8.1% (10/123)	13.4%	p=0.005
Death to 30 days	0.0% (0/151)		
TSR within 9 months	2.9% (4/139)		
Restenosis at 9 months	4.9% (6/123)		

ITT = Intent to Treat
TSR = Target site revascularization
CI = Confidence Interval

Key secondary endpoints included Major Adverse Vascular Events (MAVE) and Major Adverse Events (MAE) as adjudicated by the independent Clinical Events Committee, device success, acute procedural success (with and without pressure gradient), clinical success, patency (primary, primary-assisted, and secondary), and a composite rate consisting of 30-day death, 9-month TSR, and 9-month restenosis in subjects without iliac total occlusions. MAVE was defined as a composite rate of myocardial infarction at 30 days, stent thrombosis, clinically apparent distal embolization, defined as causing end-organ damage, arterial rupture, acute limb ischemia, target limb amputation or a procedure related bleeding event requiring transfusion. MAVEs are summarized through 12 months post-procedure (Table 7). MAE was defined as a composite rate of MAVE, any death, or stroke up to 30 days post-procedure.

Device success was defined as the successful delivery and deployment of the study stent and intact retrieval of the delivery system.

Acute procedural success was defined as device success with <30% residual stenosis immediately after stent placement, mean trans-stenotic pressure gradient <5 mm Hg, and without occurrence of in-hospital MAVE.

Early clinical success was defined as improvement of the Rutherford-Becker clinical criteria by ≥ 1 category, and assessed between baseline and the 1 month follow-up visit.

Late clinical success was defined as a maintained improvement in ABI, assessed as either (1) Normalized (>0.90) or (2) An increase of 0.1 from the baseline level and not decreased by >0.15 from the maximum result (observed post-procedure). This endpoint was to be assessed during follow-up at the 6, 9, 12, 24, and 36 month visits.

Patency was assessed at each follow up time point, categorized as:

- Primary patency, defined as continuous flow without revascularization, bypass, or target limb amputation.
- Primary assisted patency, defined as continuous flow assisted when the target vessel has restenosed at any time post-procedure.
- Secondary patency, defined as re-establishment of flow to distal arteries after occlusion has occurred at the target vessel.

In the ITT population, 4.6% (7/151) of subjects experienced at least one (1) MAVE to 30 days and 6.9% (10/144) of subjects experienced at least one (1) MAVE to 6 months. The most common MAVE events were procedure-related bleeding events that required transfusion. This type of event occurred among 4 of 151 (2.6%) ITT subjects to 30 days, and among 7 of 144 (4.9%) subjects to 6 months. There were no additional subjects experiencing MAVE events beyond 6 months post-procedure, for a total MAVE rate of 7.1% (10/140) at 9 months and 7.2% (10/139) at 1 year.

Eight (8) of 151 (5.3%) subjects experienced a MAE to 30 days (seven (7) subjects experienced a MAVE and one (1) subject experienced a stroke). There were no deaths in the ITT population reported to 30 days.

Acute procedural success was achieved in 92.7% (140/151) of subjects. In the eleven (11) subjects that did not achieve acute procedural success, seven (7) subjects experienced an in-hospital MAVE; three (3) subjects had residual stenosis >30%; and two (2) subjects were documented as device non-success. Note that the eleven (11) subjects include one (1) subject that experienced both device non-success as well as residual stenosis >30%. One (1) additional subject was missing angiography and was not assessed for acute procedural success, though the subject achieved device success and had no in-hospital MAVE.

Primary patency was achieved in 100.0% of the ITT subjects at 1 month, 99.3% of the subjects at 6 months and 96.4% of the subjects at 9 months. Primary patency was 93.5% at 12 months, 87.6% at 24 months and 84.7% at 36 months. Primary-assisted patency was achieved in all (100.0%) of subjects at 1, 6, 9 and 12 months, in 99.2% of subjects at 24 months, and 99.1% of subjects at 36 months. Secondary patency was achieved in all (100%) subjects at all time-points through 36 months post-procedure (Table 7). Device, procedural and clinical success results are listed in Table 7.

The composite rate of 30-day death 9-month TSR, and 9-month restenosis in subjects without total occlusions of the iliac was 5% (5/100).

Table 7 Device, Procedural and Clinical Success – ITT Population

Endpoint	Subjects (N=152) % (m/n)	95% CI
Major Adverse Vascular Events		
to 30 days	4.6 (7/151)	[1.9%, 9.3%]
to 6 months	6.9 (10/144)	[3.4%, 12.4%]
to 9 months	7.1 (10/140)	[3.5%, 12.7%]
to 12 months	7.2 (10/139)	[3.5%, 12.8%]
Major Adverse Events		
to 30 days	5.3 (8/151)	[2.3%, 10.2%]
Device Success	98.7 (150/152)	[95.3%, 99.8%]
Acute Procedural Success	78.2 (111/142)	[70.5%, 84.7%]
Acute Procedural Success (without Pressure Gradient)	92.7 (140/151)	[87.3%, 96.3%]
Early Clinical Success	88.7 (133/150)	[82.5%, 93.3%]
Late Clinical Success		
6 months	63.5 (80/126)	[54.4%, 71.9%]
9 months	76.6 (98/128)	[68.3%, 83.6%]
12 months	67.2 (86/128)	[58.3%, 75.2%]
24 months	70.8 (80/113)	[61.5%, 79.0%]
36 months	72.4 (76/105)	[62.8%, 80.7%]
Patency at 1 month		
Primary	100.0 (151/151)	[97.6%, 100.0%]
Primary Assisted	100.0 (151/151)	[97.6%, 100.0%]
Secondary	100.0 (151/151)	[97.6%, 100.0%]
Patency at 6 months		
Primary	99.3 (143/144)	[96.2%, 100.0%]
Primary Assisted	100.0 (144/144)	[97.5%, 100.0%]
Secondary	100.0 (144/144)	[97.5%, 100.0%]
Patency at 9 months		
Primary	96.4 (134/139)	[91.8%, 98.8%]
Primary Assisted	100.0 (139/139)	[97.4%, 100.0%]
Secondary	100.0 (139/139)	[97.4%, 100.0%]
Patency at 12 months		
Primary	93.5 (129/138)	[88.0%, 97.0%]
Primary Assisted	100.0 (138/138)	[97.4%, 100.0%]
Secondary	100.0 (138/138)	[97.4%, 100.0%]
Patency at 24 months		
Primary	87.6 (113/129)	[80.6%, 92.7%]
Primary Assisted	99.2 (128/129)	[95.8%, 100.0%]
Secondary	100.0 (129/129)	[97.2%, 100.0%]
Patency at 36 months		
Primary	84.7 (100/118)	[77.0%, 90.7%]
Primary Assisted	99.1 (114/115)	[95.3%, 100.0%]
Secondary	100.0 (115/115)	[96.8%, 100.0%]

m= number of subjects in the category
n = number of subjects with sufficient data for analysis

Safety Results

A total of 44 of 165 (26.7%) enrolled subjects experienced Serious Adverse Events (SAEs) to 9 months. The most frequent SAEs were in the vascular disorders MedDRA System Organ Class (SOC) (14/165) and the cardiac SOC (13/165). A total of 86 of 165 (52.1%) enrolled subjects experienced SAEs to 36 months. The most frequent SAEs were in the vascular disorders SOC (30/165) and the cardiac SOC (33/165).

There were 14 deaths total reported in the study (six (6) deaths reported prior to 9 months). None of the deaths were deemed to be related to the study procedure or the study device. There were no Unanticipated Adverse Device Effects (UADEs) reported in the study. SAEs that occurred throughout the study for all enrolled subjects are listed in Table 8. Results were similar in the ITT population.

Table 8 Summary of Serious Adverse Events – All Enrolled Subjects (N=165)

System Organ Class (SOC)/Preferred Term	Subjects n(%) with events to 9 months	Subjects n(%) with events to 36 months
Any SAE	44 (26.7%)	86 (52.1%)
Blood and Lymphatic System Disorders (Anaemia, Haemorrhagic anaemia)	2 (1.2%)	3 (1.8%)
Cardiac Disorders (Acute coronary syndrome*, Acute myocardial infarction, Angina pectoris, Angina unstable, Atrial fibrillation, Atrial flutter*, Atrioventricular block, Cardiac arrest*, Cardiac failure, Cardiac failure congestive, Cardio-respiratory arrest, Coronary artery disease, Coronary artery occlusion*, Myocardial infarction, Stress cardiomyopathy*, Ventricular tachycardia)	13 (7.9%)	33 (20.0%)
Ear and Labyrinth Disorders (Vertigo*)	0	1 (0.6%)
Gastrointestinal Disorders (abdominal pain*, Colitis*, Gastritis*, Gastrointestinal haemorrhage, Intestinal obstruction*, Intestinal perforation, Nausea*, Pancreatitis*, Pancreatitis acute*, Peritonitis*, Rectal haemorrhage*, Small intestine obstruction*, Upper gastrointestinal haemorrhage, Vomiting*)	5 (3.0%)	13 (7.9%)
General Disorders and Administration Site Conditions (Asthenia, Catheter site hematoma, Chest pain, Impaired healing*, Non-cardiac chest pain*)	6 (3.6%)	10 (6.1%)
Hepatobiliary Disorders (Cholecystitis*, Hepatic steatosis*)	0	2 (1.2%)
Immune System Disorders (Anaphylactic reaction)	1 (0.6%)	2 (1.2%)
Infections and Infestations (Abdominal abscess, Bronchitis*, Bronchitis bacterial*, Cellulitis*, Gastroenteritis viral*, Groin abscess*, Influenza*, Pneumonia, Pneumonia staphylococcal*, Post procedural sepsis*, Sepsis, Urosepsis*)	6 (3.6%)	18 (10.9%)
Injury, Poisoning, and Procedural Complications (Abdominal wound dehiscence*, Anaemia postoperative*, Aortic injury*, Arterial injury, Device dislocation*, Femur fracture, In-stent arterial restenosis, Incisional hernia*, Postoperative ileus*, Spinal fracture*, Stent occlusion*, Subdural haematoma, Tendon injury*, Traumatic brain injury*, Urostomy complication*, Vascular graft occlusion*)	5 (3.0%)	19 (11.5%)
Metabolism and Nutrition Disorders (Acidosis*, Fluid overload*, Hyperkalaemia*, Hypoglycaemia, Hyponatraemia, Obesity*)	2 (1.2%)	6 (3.6%)
Musculoskeletal and Connective Tissue Disorders (Arthralgia*, Arthritis, Fistula*, Muscular weakness*, Osteoarthritis, Rhabdomyolysis*)	2 (1.2%)	7 (4.2%)
Neoplasm Benign, Malignant, and Unspecified (cysts and polyps) (Bronchial carcinoma*, Colon cancer, Colon cancer recurrent*, Hepatic neoplasm malignant*, Lung cancer metastatic, Lung neoplasm malignant, Lymphoma*, Metastases to liver, Prostate cancer*, Transitional cell carcinoma*)	3 (1.8%)	9 (5.5%)
Nervous System Disorders (Brain mass*, Carotid artery stenosis, Cerebrovascular accident, Encephalopathy, Polyneuropathy*, Subarachnoid haemorrhage, Syncope, Syncope vasovagal*, Transient ischaemic attack)	7 (4.2%)	14 (8.5%)
Psychiatric Disorders (Depression)	1 (0.6%)	1 (0.6%)
Renal and Urinary Disorders (Calculus ureteric*, Renal artery occlusion*, Renal artery stenosis*, Renal disorder*, Renal failure*, Renal failure acute, Renal failure chronic, Renal mass*)	2 (1.2%)	13 (7.9%)
Reproductive System and Breast Disorders (Galactorrhoea*)	0	1 (0.6%)
Respiratory, Thoracic, and Mediastinal (Acute respiratory failure*, Chronic obstructive Pulmonary disease*, Dyspnoea*, Epistaxis, Pleural effusion*, Pneumonia aspiration, Pneumothorax*, Pulmonary embolism*, Pulmonary mass*, Pulmonary edema, Respiratory failure*)	2 (1.2%)	10 (6.1%)
Skin and Subcutaneous Tissue Disorders (Psoriasis*, Skin ulcer*)	0	2 (1.2%)
Vascular Disorders (Aortic stenosis*, Arterial restenosis, Arterial thrombosis limb, Femoral arterial stenosis, Femoral artery occlusion, Haemorrhage*, Hypotension, Iliac artery stenosis, Intermittent claudication, Orthostatic hypotension, Peripheral artery aneurysm*, Peripheral arterial occlusive disease, Peripheral ischaemia*, Peripheral vascular disorder*, Subclavian artery stenosis, Vascular pseudoaneurysm)	14 (8.5%)	30 (18.2%)

SOC = System Organ Class
SAE = Serious Adverse Event
*Preferred Term applies to events to 36 months only
n = number of subjects in category

Conclusion

This prospective, multi-center, single-arm clinical trial (iCARUS) has demonstrated that the iCast covered stent is safe and effective for its intended use as a treatment for iliac artery disease in the indicated population.

This clinical trial compared the safety and effectiveness of the iCast covered stent to a predetermined performance goal.

The composite safety and effectiveness endpoint was defined as the occurrence of death within 30 days, target site revascularization (TSR) within 9 months, or restenosis at 9 months post-procedure (as determined by DUS). The primary composite endpoint rate was 8.1% (10/123), with an exact one-sided upper 95% CI of 13.4% as compared to the performance goal of 16.57% (p=0.005). As this is significantly below the performance goal of 16.57%, the trial met its primary composite endpoint. There were no deaths within 30 days, the rate of TSR within 9 months was 2.9% and the restenosis rate at 9 months was 4.9%. Although no formal performance metric was designated for other secondary safety and effectiveness endpoints, analysis of key pre-specified endpoints is consistent with a low rate of MAVE and MAE, and a high rate of early and late clinical and angiographic success with use of the iCast covered stent.

The benefits of stenting with the iCast covered stent were maintained in the majority of subjects during long-term follow-up. At 36 months, primary patency was present in 84.7% of subjects, primary-assisted patency was present in 99.1%, and 100% of subjects in the ITT population had secondary patency. Similarly, late clinical success was present in 72.4% of subjects at this time-point. These data are consistent with comparable long-term effectiveness data available for other approved iliac stents and support the safety and effectiveness of the iCast covered stent when used for revascularization of iliac artery lesions. These results were consistent with clinical results from the COBEST study[2,3]. Altogether, these data support the safety and effectiveness of the iCast covered stent when used for revascularization of iliac lesions in the studied patient population.

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Symbols Used On Product Labels

Keep away from sunlight Keep dry Do not resterilize Do not re-use Non-pyrogenic MR Conditional

Caution Use-by date Manufacturer Do not use if package is damaged DIM Dimensions

STERILE EO Sterilized using ethylene oxide REF Catalogue number SN Serial number QTY Box quantity

Consult instructions for use UDI Unique device identifier Country of manufacture Temperature limit

Single sterile barrier system with protective packaging Inside

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