Boston Scientific

90741285-01

2012-01
< EN >

TruePath™

CTO Device

℞ ONLY

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

This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the device, as well as the carrier tube and pouch liner) are sterile. The external surface of the sterile barrier pouch, as well as the product carton, should not be considered sterile.

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risk of the procedure.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. **DO NOT REUSE, REPROCESS OR RESTERILIZE.** 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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The TruePath CTO Device is intended to assist the intraluminal placement of devices through a chronic total occlusion in native peripheral arteries prior to percutaneous intervention. The TruePath CTO Device creates a pathway through the occluded vessel via micro-dissection. The TruePath CTO Device consists of the TruePath CTO Device and an electronic Control Unit. The TruePath CTO Device is a sterile, disposable device that is intended for use during a single patient procedure and is used with the Control Unit, which is a sterile, disposable, battery-operated unit that controls TruePath CTO Device operation. The TruePath CTO Device is intended to be used in conjunction with commercially available 0.018 in (0.46 mm) guidewire compatible balloon catheters and micro-catheters with recommended usable lengths of ≤135 cm used for both support and exchange during the procedure.

The TruePath CTO Device consists of a 0.018 in Guidewire and a Motor Housing with Connector Cable. The TruePath CTO Device is 165 cm in working length and has a hydrophilic coating. The TruePath CTO Device has a shapeable Distal Tip. The distal 3 cm is radiopaque to facilitate visualization under fluoroscopy. The Motor Housing is located at the proximal end and is attached to the Guidewire. The Motor Housing can be detached permanently (once detached, it is not re-attachable),

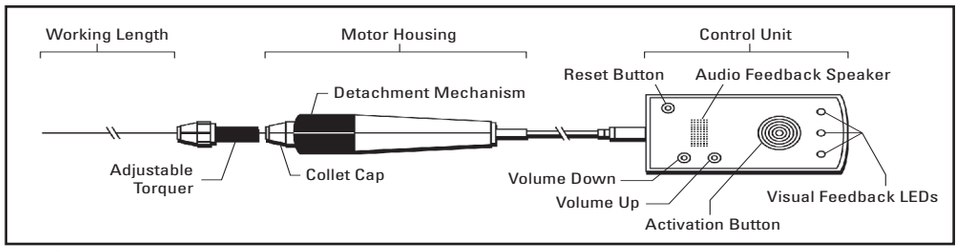

Figure 1.

which allows extending the TruePath CTO Device for catheter exchanges, while preserving the TruePath CTO Device position. The TruePath CTO Device has a pre-loaded torquer that can be adjusted along the working length. A flexible Driveshaft extends through the inner diameter of the Guidewire and connects the Active Tip to the Motor located in the Motor Housing. The Active Tip uses rotation to create a pathway through the occluded artery.

The Motor Housing of the TruePath CTO Device connects to the battery-operated Control Unit via the Connector Cable which allows the Control Unit battery power to operate the motor control electronic circuitry. An Activation Button on the Control Unit allows the user to activate the Motor and operate the Active Tip. The Control Unit houses auditory and LED systems that allow the user to receive both audio and visual feedback in device operation. The Control Unit meets Ingress Protection Rating of IP22. It has been tested for protection against dripping water, but is not waterproof.

Contents for (1) TruePath CTO Device

- One (1) TruePath CTO Device
- One (1) Tip Shaping Tool
- One (1) Control Unit

INTENDED USE/INDICATIONS FOR USE

The TruePath CTO Device is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions.

CONTRAINDICATIONS

The device is contraindicated for use in carotid arteries.

WARNINGS

The TruePath CTO Device Motor Housing can be permanently removed during a procedure, if the interventionalist wishes to utilize guidewire extension or exchange maneuvers. However, once the Motor Housing is detached the TruePath CTO Device will no longer be able to be activated, because the Motor Housing is not re-attachable.

PRECAUTIONS

- The TruePath CTO Device should only be used by physicians trained in percutaneous interventional techniques in a fully equipped catheterization laboratory.
- Do not use without completely reading and understanding the directions for use.
- Do not use after the last day of the month of the "Use By" date on the package label.
- Inspect the TruePath CTO Device for functionality and integrity prior to use to ensure that it is undamaged and suitable for the specific procedure.
- The TruePath CTO Device and Control Unit have been tested and found to comply with EMC limits for EN 60601-1-2. The equipment generates, uses, and can radiate radiofrequency (RF) signals and, if not used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. If this equipment does cause harmful interference with other devices (which can be determined by turning the equipment on and off) the user is encouraged to:
  - Reorient or relocate the receiving device
  - Increase the separation between equipment
  - Consult the manufacturer for further help.
- Advancement, manipulation, activation, and withdrawal of the TruePath CTO Device should always be performed under high quality fluoroscopic guidance.
- Ensure intraluminal position prior to advancement of the support catheter over the TruePath CTO Device.
- Use caution if resistance is encountered.
- If strong resistance is felt during device advancement and operation, determine the cause of the resistance before proceeding further. If the cause can not be determined, withdraw the TruePath CTO Device.
- If resistance is encountered, withdraw and activate the Active Tip and slowly move the device in and out in small movements to loosen and withdraw the device.
- If unusual audio and visual feedback is noted, retract and cease device activation, verify device position, and verify device operation prior to proceeding.
- If the TruePath CTO Device is removed from the patient during a procedure the Working Length must lay in a saline bath to ensure proper function.
- The TruePath CTO Device is not rated for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- The TruePath Control Unit contains electronics and a Lithium (Li-$Mn0_2$) battery. The TruePath Control Unit must be disposed of following local regulations and hospital procedures.

ADVERSE EVENTS

The risk and discomforts involved in treatment of chronic total occlusion include those associated with all peripheral vascular catheterization procedures. The following is a list of anticipated adverse events that may result from percutaneous transluminal peripheral intervention.

- Acute reclosure
- Allergic reaction
- Amputation
- Aneurysm
- Bleeding which may require transfusion or surgical intervention
- Death
- Dissection
- Distal embolization
- Excessive contrast loading, resulting in renal insufficiency or failure
- Excessive exposure to radiation
- Hematoma
- Hypertension/Hypotension
- Infection or fever
- Ischemic events

Boston Scientific (Master Brand DFU Template 8.2677in x 11.6929in A4, 90105918AL), eDFU, MB, TRUEPATH, CTO DEVICE, EN, 90741285-01A

- Perforation
- Peripheral artery bypass
- Pseudoaneurysm or fistula
- Repeat catheterization or angioplasty
- Restenosis
- Stroke/CVA
- Thrombosis

HOW SUPPLIED

Sterile:

This product is sterilized with ethylene oxide gas. It is intended for single use only. Do not resterilize. Non-pyrogenic.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage:

Store in a cool, dark, dry place.

Store product in outer carton.

Temperature limitation: -5°C to 38°C

Humidity limitation: 10% to 85%

Do not store devices where they are directly exposed to organic solvents or ionizing radiation.

DISPOSAL INSTRUCTIONS

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

EQUIPMENT REQUIRED

The use of the TruePath™ CTO Device should be performed in a specialized clinical setting equipped with a fluoroscopy unit, and its associated equipment, radiographic table, ACT measurements system, EKG recording system, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. When possible, the use of bi-plane imaging is recommended.

OPERATIONAL INSTRUCTIONS

Inspection Prior to Use

Check pouch for "Use By" date. Do not use the product after the "Use By" date. Carefully inspect the sterile package before opening. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package), contact your local Boston Scientific representative for return information. Do not use if any defects are noted.

Preparation

Step Action

1. Inspect the TruePath CTO Device package prior to opening. Do not use if package is opened or damaged.
2. Use sterile technique to carefully remove the tray from the pouch. Inspect the TruePath CTO Device and Control Unit to ensure that the device has no visible signs of damage.
3. Flush the TruePath CTO Device through the hub end of the packaging hoop with heparinized saline.
4. Remove the TruePath CTO Device and Control Unit from the tray.
5. Attach the Connector Cable from the TruePath CTO Device to the Control Unit. This turns on the Control Unit Power. The Activation Button will illuminate.
6. Turn the Control Unit Activation Button ON to verify the operation of the Active Tip. Verify that the first Visual Feedback LED is illuminated and an audio tone is noted. Press the Reset Button if the Visual Feedback LED is not illuminated and the audio tone is not noted. After pressing the Reset Button, press the Activation Button again and verify the first Visual Feedback LED is illuminated and an audio tone is noted. Adjust auditory feedback volume to the desired level using the "+" button to increase volume, and the "-" button to decrease volume. Turn the Control Unit Activation Button OFF. Do not use the device if the system is not operational.
7. Shape the TruePath CTO Device tip using the Shaping Tool if required. Align the Shaping Tool knob to its starting orientation as required. Insert the distal end of the Guidewire into Base of the Shaping Tool until the tip abuts the end of the Shaping Tool (as visualized in the Shaping Tool window). Rotate the Knob clockwise until locked (audible click).

Caution: Do not increase the tip angle beyond the limits of the Shaping Tool. Excessive tip angulation may adversely affect performance.

Caution: Do not shape the TruePath CTO Device more than one time. Multiple attempts to re-shape the tip may damage the TruePath CTO Device.

8. Introduce a compatible support catheter over the existing conventional guidewire that was used to reach the total occlusion.
9. Remove the conventional guidewire from the patient.
10. Introduce the TruePath CTO Device into support catheter.

Caution: Advancement, manipulation, activation, and withdrawal of the TruePath CTO Device should always be performed under high quality fluoroscopic guidance.

Caution: Perform multiple angiographic views to determine TruePath CTO Device position prior to advancement of the TruePath CTO Device.

11. Position the TruePath CTO Device within the support catheter at the target lesion. Use the adjustable torquer to position the TruePath CTO Device in the inactive mode, as needed.
12. Push the Activation Button to activate the Active Tip as needed and advance the TruePath CTO Device through the target lesion. For added support, ensure the tip does not extend more than 1 cm beyond the support catheter while advancing. The Reset Button can be pressed if the TruePath CTO Device does not activate or ceases to activate at any point during use. After pressing the Reset Button, the Activation Button can be pressed to resume activation.

Caution: Advance the TruePath CTO Device through the lesion in short steps without excessive force.

Caution: Keep the working length of the TruePath CTO device straight to prevent damage to the driveshaft.

Caution: The Control Unit has audio and visual feedback. Adjust auditory volume to the desired level. There are 3 LEDs and 3 audio tones. When the Active Tip encounters no resistance or minor resistance, 1 LED illuminates and the lowest of the 3 audible tones is heard. When the Active Tip encounters a larger resistance 2 LEDs illuminate and the middle of the 3 tones is heard. When the Active Tip encounters the highest resistance, 3 LEDs illuminate and the highest of the 3 tones is heard. Should this to occur, reduce the pressure being applied to the device to optimize penetration. Should the 3 LEDs illuminate and the highest of the 3 tones remain, slowly retract the device within the catheter before deactivating the system.

Caution: A change in auditory tone occurs as resistance is encountered when the TruePath CTO Device is advanced through the occlusion. If resistance is noted and the auditory tone does not significantly increase in tone or the number of lighted LEDs does not increase, remove the TruePath CTO Device and inspect for proper operation of the device.

13. Use the adjustable torquer to position the TruePath CTO Device as needed.

Caution: Active Tip operation can be stopped by turning off the Activation Button or detaching the TruePath CTO Device Connector Cable from the Control Unit.

Caution: If strong resistance is felt during device advancement and operation, determine the cause of the resistance before proceeding further. If the cause can not be determined, withdraw the TruePath CTO Device. If resistance is felt upon withdrawal, activate the Active Tip and slowly move the device in and out in small movements to loosen and withdraw the device.

Caution: Do not torque the TruePath CTO Device more that two 360° rotations in one direction. Excessive torquing in a single direction may damage the TruePath CTO Device.

14. Continue assessing progress under fluoroscopic guidance and reorient the TruePath CTO Device, as required.
15. Continue advancing the TruePath CTO Device, repeating steps 10 through 13, until a pathway through the occlusion is created.
16. Ensure that the TruePath CTO Device is free to move in the newly created passage through the occlusion.
17. Using fluoroscopy, verify the intraluminal positioning of the distal Device Tip.
18. Advance the support catheter over the TruePath CTO Device to enable an exchange with a conventional guidewire.
19. If the support catheter can not be advanced across the CTO, the TruePath CTO Device Motor Housing may be detached and extended with the TruePath Extension Wire[1]. The Motor Housing is detached by twisting the blue Detachment Mechanism located on the Motor Housing, loosening the Collet Cap, and removing the wire.
20. The support catheter can be removed and exchanged for another support catheter that may be able to cross the CTO over the TruePath CTO Device.

Warning: Once the Motor Housing is detached, the TruePath CTO Device will no longer be able to be activated, since the Motor Housing is not re-attachable.

21. When ready to replace the TruePath CTO Device with a conventional guidewire, proceed as follows: With the Active Tip inactive, carefully retract the TruePath CTO Device and introduce a conventional guidewire through the support catheter. Advance the guidewire through the pathway created by the TruePath CTO Device. Retract support catheter.
22. After confirming fluoroscopically that the entire CTO lesion has been crossed through the true lumen, proceed with the desired percutaneous intervention over the conventional guidewire of choice.

CLINICAL STUDY RESULTS

A prospective clinical study of 85 patients was conducted at 3 investigational sites to assess the safety and efficacy of the TruePath CTO Device in the treatment of infrainguinal target vessel occlusions classified angiographically as absolute (100% occlusion with no flow), where no antegrade filling beyond the occlusion was visible and following demonstration of resistance to crossing with conventional guidewire techniques.

Inclusion Criteria:

Documentation from a previous failed attempt OR a concurrent and reasonable attempt (at least 5 minutes) during this procedure is required to demonstrate resistance to conventional guidewire crossing; Patient must have objective evidence of lower extremity ischemia; Occluded artery must be the native infrainguinal arteries, Patient must have a totally occlusive lesion in the infrainguinal arteries defined as 100% narrowing of the artery, with no angiographically detectable antegrade blood flow, and the assessment that the lesion has been in existence for a minimum of 30 days, Evidence must exist that the target occlusion has been in existence for 30 days or greater (e.g., prior angiogram, Doppler, MRA, CT, date of onset of symptoms or date of previous peripheral bypass surgery involving target vessel), Patients target vessel occlusion length is <30 cm, Patients reference vessel diameter is >2.0 mm.

Exclusion Criteria:

Patient requires immediate treatment in more than one occluded vessel, in any combination of grafts or native vessels, within 30 days of the index procedure; Patient's target lesion CTO is located in any of the following vessels: Iliac, Profunda (deep femoral), Dorsalis Pedis, Carotid, Renal or Subclavian artery; Patient target vessel, proximal to the target lesion, reveals significant ectasia, dissection, aneurysm or thrombus; Patients target occlusion has a dissection that occurred within the last 60 days caused by a guidewire attempt; Patient has no collateral flow distal to the occlusion; Patient suffered a recent stroke (TIA or CVA) within the last 6 months; Patient suffered an MI within the last 6 months; Patient suffered a significant GI bleed within the last 6 months.

Primary Safety Endpoint:

Freedom from clinical perforation (any perforation requiring treatment) of the index lesion to 30 days.

[1] Sold separately.

Primary Clinical Efficacy Endpoint:

Advancement of the TruePath CTO Device into or through the CTO in native infrainguinal artery and subsequent achievement of distal vessel guidewire position with any conventional guidewire.

Primary Performance (Technical Success) Endpoint:

The ability of the TruePath CTO Device to facilitate crossing a CTO into the true distal lumen with the TruePath CTO Device and/or any conventional guidewire after use of the TruePath CTO Device.

Patient Demographics:

Characteristic	N = 85	95% CI **
Male	60 (70.6%)	59.7% - 80.0%
Female	25 (29.4%)	20.0% - 40.3%
Age (years)*	85, 70.3 (11.9), 72.0 (42-91)	67.8 - 72.9
Height (cm)*	83, 171.2 (7.7), 173.0 (152.0 - 185.0)	169.5 - 172.8
Weight (kg)*	84, 76.1 (13.9), 74.4 (47.0 - 115.0)	73.1 - 79.0
BMI*	83, 26.1 (4.7), 24.8 (18.0 - 39.1)	25.1 - 27.1
Medical History		
Neurological	6 (7.1%)	2.6% - 14.7%
Cardiovascular	71 (83.5%)	73.9% - 90.7%
Hypertension	63 (74.1%)	63.5% - 83.0%
Peripheral Vascular	83 (97.6%)	91.8% - 99.7%
Renal	19 (22.4%)	14.0% - 32.7%
Gastro-Intestinal	2 (2.4%)	0.3% - 8.2%
Hematologic	0 (0.0%)	--
Diabetes	27 (31.8%)	22.1% - 42.8%
Allergies	4 (4.7%)	1.3% - 11.6%
Smoking History		
Never	36 (42.4%)	31.7% - 53.6%
Current	28 (32.9%)	23.1% - 44.0%
Previous	21 (24.7%)	16.0% - 35.2%
Other Significant Illnesses***		
Yes	31 (36.5%)	26.3% - 47.6%
No	54 (63.5%)	52.4% - 73.7%
Peripheral Vascular History		
Claudication		
Yes	76 (89.4%)	80.8% - 95.0%
No	9 (10.6%)	5.0% - 19.2%
Rest Pain		
Yes	22 (25.9%)	17.0% - 36.5%
No	63 (74.1%)	63.5% - 83.0%
Ulceration		
Yes	14 (16.5%)	9.3% - 26.1%
No	71 (83.5%)	73.9% - 90.7%
Previous Amputation		
Yes	1 (1.2%)	0.03% - 6.4%
No	84 (98.8%)	93.6% - 100.0%
Previous PTA/Stent		
Yes	43 (50.6%)	39.5% - 61.6%
No	42 (49.4%)	38.4% - 60.5%
Previous Bypass		
Yes	4 (4.7%)	1.3% - 11.6%
No	81 (95.3%)	88.4% - 98.7%
Carotid Artery Disease		
Yes	8 (9.4%)	4.2% - 17.7%
No	77 (90.6%)	82.3% - 95.8%

** Shown as N, mean (SD), median (range)*

*** Confidence Interval (CI)*

****Other significant illnesses reported at baseline are as follows:*

- *COPD*
- *Sleeping disorder*
- *Biological Valve Heart/Ventricular Fibrillation*
- *Epilepsy*
- *Esophagitis*
- *Hypothyroidism*
- *Alcoholism*
- *Obesity*
- *Prostate cancer*
- *Prostatectomy*
- *Pneumothorax*
- *Nasal polyps*
- *Transurethral resection of bladder*
- *Sigmoid diverticulitis*
- *Gout*
- *Aortic valve replacement*
- *Right hemicolectomy (adeno carcinoma)*
- *Mitral valve insufficiency (mitral valve plasty)*
- *Hysterectomy*
- *Cardiac decompensation*
- *Cancer (right nephrectomy)*
- *Testicular Cancer*
- *Pancreatitis*
- *Kidney resection (partial)*
- *Brain tumor (benign)*
- *Obstructive Pulmonary Disease*
- *Chronic ischemic heart disease*
- *Varicose veins*
- *Vein occlusion of the right eye/glaucoma of the left eye*
- *Lung resection due to pneumonia*
- *Rupture of diaphragm*
- *Presbycusis*
- *Olfactorius Meningioma*
- *Sinus Cavernosus*
- *Hirsutisme*
- *Cholecestectomy*
- *Struma Nodosa*
- *Latent hyperthyreosis*
- *Amaurosis by glaucoma*

Boston Scientific (Master Brand DFUTemplate 8.2677in x 11.6929in A4, 90105918AL), eDFU, MB, TRUEPATH, CTO DEVICE, EN, 90741285-01A

Target Lesion and Vessel Characteristics:

Category	N = 85	95% CI
Leg Involved		
Right	51 (60.0%)	48.8% - 70.5%
Left	34 (40.0%)	29.5% - 51.2%
Target Vessel Involved		
SFA	61 (71.8%)	61.0% - 81.0%
Popliteal	6 (7.1%)	2.6% - 14.7%
Tibial	11 (12.9%)	6.6% - 22.0%
SFA and Popliteal	7 (8.2%)	3.4% - 16.2%
Target Lesion Location		
Proximal	15 (17.6%)	10.2% - 27.4%
Mid	22 (25.9%)	17.0% - 36.5%
Distal	15 (17.6%)	10.2% - 27.4%
Proximal, Mid	4 (4.7%)	1.3% - 11.6%
Mid, Distal	8 (9.4%)	4.2% - 17.7%
Proximal, Mid, Distal	21 (24.7%)	16.0% - 35.2%
Lesion Characteristics		
De Novo	47 (55.3%)	44.1% - 66.1%
Restenotic	5 (5.9%)	1.9% - 13.2%
Eccentric	0 (0.0%)	--
Concentric	4 (4.7%)	1.3% - 11.6%
De Novo, Restenotic	1 (1.2%)	0.03% - 6.4%
De Novo, Eccentric	5 (5.9%)	1.9% - 13.2%
De Novo, Concentric	18 (21.2%)	13.1% - 31.4%
Restenotic, Eccentric	2 (2.4%)	0.3% - 8.2%
Restenotic, Concentric	3 (3.5%)	0.7% - 10.0%
Target Lesion Stenosis = 100%		
Yes	85 (100%)	95.8% - 100.0%
No	0 (0.0%)	--
Target Lesion Age (months)		
≤6 months	70 (82.4%)	72.6% - 89.8%
7-11 months	1 (1.2%)	0.03% - 6.4%
≥12 months	14 (16.5%)	9.3% - 26.1%
Unknown	0 (0.0%)	--
Target Lesion Calcification		
None	5 (5.9%)	1.9% - 13.2%
Mild	12 (14.1%)	7.5% - 23.4%
Moderate	35 (41.2%)	30.6% - 52.4%
Severe	33 (38.8%)	28.4% - 50.0%
Thrombus Present		
Yes	6 (7.1%)	2.6% - 14.7%
No	79 (92.9%)	85.3% - 97.4%
Functional Occlusion		
Yes	85 (100%)	95.8% - 100.0%
No	0 (0.0%)	--
Tapered Stump		
Yes	68 (80.0%)	69.9% - 87.9%
No	17 (20.0%)	12.1% - 30.1%
Sidebranch at Point of Occlusion		
Yes	16 (18.8%)	11.2% - 28.8%
No	69 (81.2%)	71.2% - 88.8%
Lesion Description*		
Unknown	5 (5.9%)	1.9% - 13.2%
Discrete (<10 mm)	3 (3.5%)	0.7% - 10.0%
Tubular/Focal (≥10 mm and <20 mm)	0 (0.0%)	--
Diffuse (≥20 mm)	77 (90.6%)	82.3% - 95.8%
Occlusion Length (mm)		
<100 mm	33 (38.8%)	28.4% - 50.0%
101 - 200 mm	26 (30.6%)	21.0% - 41.5%
201 - 450 mm	26 (30.6%)	21.0% - 41.5%

Category	N = 85	95% CI
Reference Vessel Diameter (mm)*		
N	53	
Average	6.0	5.4 - 6.7
Standard Deviation	2.4	
Range	2.70 - 20.00	
Est. Vessel Diameter at Mid-Occlusion (mm)*		
N	52	
Average	5.4	5.1 - 5.7
Standard Deviation	1.1	
Range	2.70 - 7.80	
Vessel Tortuosity*		
Unknown	4 (4.7%)	1.3% - 11.6%
None/mild (<2 bends to reach target)	74 (87.1%)	78.0% - 93.4%
Moderate (2 bends >75° or 1 bend >90°)	5 (5.9%)	1.9% - 13.2%
Severe (2 bends >90°)	2 (2.4%)	0.29% - 8.2%
Vessel Angulation*		
Unknown	4 (4.7%)	1.3% - 11.6%
Non-angulated (<45°)	76 (89.4%)	80.8% - 95.0%
Moderate (≥45° and ≤90°)	5 (5.9%)	1.9% - 13.2%
Severe (>90°)	0 (0.0%)	--
Vessel Calcification*		
Unknown	3 (3.5%)	0.7% - 10.0%
None/Mild	60 (70.6%)	59.7% - 80.0%
Moderate	11 (12.9%)	6.6% - 22.0%
Severe	11 (12.9%)	6.6% - 22.0%

** Reported by the Independent Reviewer*

Study Results:

Primary Endpoints				
Category	**Definition**	**N = 85**	**95% CI (2-sided)**	**95% CI (1-sided)**
Safety	Freedom from clinical perforation at 30 day follow up	70‡		
	Yes	69 (98.6%)	92.3% - 99.96%	
	No	1 (1.4%)	0.04% - 7.7%	93.4%
	Freedom from clinical perforation at time of procedure			
	Yes	84 (98.8%)	93.6% - 99.97%	94.5%
	No (Cutting Balloon)	1 (1.2%)	0.03% - 6.4%	
Efficacy	Advancement of device through CTO and subsequent distal guidewire positioning			
	Yes	65 (76.5%)	66.0% - 85.0%	67.7%
	No	20 (23.5%)	15.0% - 34.0%	32.3%
Performance (Technical Success)	Facilitation of crossing CTO with any guidewire			
	Yes	68 (80.0%)	69.9% - 87.9%	71.5%
	No	17 (20.0%)	12.1% - 30.1%	28.5%
Secondary Endpoints				
Category	**Definition**	**N = 85**	**95% CI (2-sided)**	**95% CI (1-sided)**
Angiographic Perforation Classification*	Classification of extravasation of contrast during procedure			
	Perforation**			
	Unknown	4 (4.7%)	1.3% - 11.61%	10.4%
	No	61 (71.8%)	61.0% - 81.0%	62.6%
	Yes	20 (23.5%)	15.0% - 34.0%	32.3%
	Type 1 - wire exit	1 (1.2%)	--	--
	Type 2 - blush	5 (5.9%)	--	--
	Type 3 - staining	8 (9.4%)	--	--
	Type 4 - extravasations	6 (7.1%)	--	--
	Related to the TruePath™ CTO Device	*3 (3.6%)†*		
	Related to Other Devices	*3 (3.6%)*		
Procedure Success	Achievement of Technical Success plus stenosis of <50% and improved flow immediately post-procedure			
	Yes	60 (70.6%)	59.7% - 80.0%	61.40%
	No	25 (29.4%)	20.0% - 40.3%	38.60%
Clinical Success	Achievement of Procedure Success and freedom from limb loss and repeat revascularization from index through 30-days***			
	Yes	58 (68.2%)	57.2% - 77.9%	58.90%
	No	27 (31.8%)	22.1% - 42.8%	41.00%

‡85 patients – 15 withdrawals = 70 patients evaluable at 30 Days.

**Reported by the Independent Angiographic Reviewer*

***The Clinical Perforation is not included*

**** Although data for all 85 patients were not available at 30 days, 85 was used as the denominator to accurately account for the true Clinical Success in this patient population (Note: 15 patients [study withdrawals] that were not followed to 30 days were not clinical successes due to either the inability to cross the lesion and/or advance the interventional catheter/balloon)*

†1 of the 3 was reported as "Unable to Determine"

Definitions:

Technical Success: The ability of the TruePath CTO Device to facilitate crossing a CTO into the true distal lumen with the TruePath CTO Device and/or any conventional guide wire after use of the TruePath CTO Device.

Procedure Success: Achievement of Technical Success plus a residual stenosis of <50% and improved flow verified angiographically immediately post procedure.

Clinical Success: Achievement of Procedure Success and freedom from limb loss and repeat revascularization (bypass or PTA) from index hospitalization through the 30 day follow up.

Angiographic Perforation Classification and Rate: Tabulation of the formal classification (using the standard Type 1-4 classification) of any extravasation of contrast detected by the physician performing the procedure or the independent angio reviewer at any point during the procedure.

Clinical Perforation: Any perforation requiring treatment.

DEFINITIONS OF SYMBOLS USED

Speaker Volume

Power On/Off

Carefully read all instructions prior to use

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

EC REP **EU Authorized Representative**

Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

Boston Scientific (Master Brand DFU Template 8.2677in x 11.6929in A4, 90105918AL), eDFU, MB, TRUEPATH, CTO DEVICE, EN, 90741285-01A