MINI TREK® RX
Coronary Dilatation Catheter

CAUTION

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DESCRIPTION

The MINI TREK RX Coronary Dilatation Catheters have an integrated shaft system and a balloon near the distal tip. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The second lumen, in the distal shaft, permits the use of a guide wire to facilitate advancement of the dilatation catheter to and through the stenosis to be dilated. The dilatation catheter is coated with HYDROCOAT® hydrophilic coating, which is activated when wet.

This device has several markers. The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure. The proximal shaft has proximal markers that aid in gauging dilatation catheter position relative to the guiding catheter tip (the marker located closest to the dilatation catheter adapter is for femoral guiding catheters and the other marker is for brachial guiding catheters).

The design of this dilatation catheter does not incorporate a lumen for distal dye injections and distal pressure measurements.

HOW SUPPLIED

Sterile – This device is sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.

This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and / or chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to contamination due to narrow gaps and/or spaces and diminished safety and / or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) MINI TREK RX Coronary Dilatation Catheter, one (1) primary flushing tool, one (1) protective sheath, one (1) dilatation catheter clip, and one (1) compliance card
Storage – Store in a dry, dark, cool place.

INDICATIONS

The MINI TREK RX Coronary Dilatation Catheter is indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion
- Balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction (MI)
- Balloon dilatation of a stent after implantation (balloon models 2.00 mm only)
- Balloon dilatation of de novo chronic total coronary occlusions (CTO)

Note: Post-deployment stent expansion testing was performed on the bench with the MULTI-LINK VISION® and MULTI-LINK ULTRA® stents. All stents should be deployed in accordance with the manufacturer’s indications and instructions for use.

CONTRAINDICATIONS

The MINI TREK RX Coronary Dilatation Catheters are not intended to be used to treat patients with:

- An unprotected left main coronary artery
- A coronary artery spasm in the absence of a significant stenosis

WARNINGS

This device is intended for one time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent overpressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Do not use or attempt to straighten a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead, prepare a new catheter.

Do not torque the catheter more than one (1) full turn.

Treatment of moderately or heavily calcified lesions is considered to be a moderate risk, with an expected success rate of 60 – 85%, and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment, and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

**PRECAUTIONS**

Note the “Use by” date specified on the package.

Inspect all product prior to use. Do not use if the package is open or damaged.

This device should be used only by physicians trained in angiography and PTCA, and / or percutaneous transluminal angioplasty (PTA).

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and to ensure that its size is suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

The design and construction of these catheters do not provide the user with distal pressure monitoring capability.

If the surface of the MINI TREK RX Coronary Dilatation Catheter becomes dry, wetting it with heparinized normal saline will reactivate the coating.

Do not reinsert the MINI TREK RX Coronary Dilatation Catheter into the coil dispenser after procedural use.

The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) have not been established.
ADVERSE EFFECTS

The EXPERT CTO Trial

The EXPERT CTO trial is a prospective, multicenter, single-arm study. A total of approximately 250 subjects with signs and/or symptoms considered typical of ischemic heart disease attributed to a CTO will be enrolled. Subjects receive elective, attempted CTO percutaneous revascularization. The primary objective of the EXPERT CTO clinical trial is to assess the safety and effectiveness of the XIENCE V® Everolimus Eluting Coronary Stent System, XIENCE nano® Everolimus Eluting Coronary Stent System, and the XIENCE PRIME® LL Everolimus Eluting Coronary Stent System for the treatment of chronic total coronary occlusions. Another key objective of this trial is to assess the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter in pre-dilatation of CTOs.

Assessment of the MINI TREK-related objective of the EXPERT CTO trial has been completed. Assessment of the MINI TREK-related objective was to be performed in at least the initial 60 subjects with successful guide wire crossing, identified as confirmation of the guide wire in the distal true lumen. However, evaluable data (including core laboratory ascertained angiography data immediately following pre-dilatation with the MINI TREK Coronary Dilatation Catheter) were not available in all initial 60 subjects. Therefore, a total analysis population of 88 subjects was reached that included 65 subjects with evaluable data for the MINI TREK-related primary analysis, and 23 subjects that did not have core laboratory ascertained angiography data immediately following pre-dilatation with the MINI TREK Coronary Dilatation Catheter.¹ In both the total analysis population (N=88) and the evaluable population (N=65), the MINI TREK Coronary Dilatation Catheter was used at first attempt for pre-dilatation of the CTO. Results are presented below for the total analysis population, as this set of results best represents the performance of the MINI TREK Coronary Dilatation Catheter in the entire intended CTO study population of the EXPERT CTO trial.

When analyzed using the Academic Research Consortium (ARC) definition for MI, in the total analysis population (N=88), there were nine subjects (10.23%) who experienced in-hospital ARC-defined major adverse cardiac events (MACE): this was comprised of nine subjects who had ARC-defined MI, one of whom also underwent clinically driven target lesion revascularization (TLR) by percutaneous coronary intervention (PCI) (1.14%).²

One (1.14%) definite subacute ST per ARC definition was reported for the total analysis population through hospital discharge. The same subject had non-Q-wave MI (NQMI) per ARC definition on day 2 and clinically indicated TLR on day 8.

¹ A total of 65 subjects with evaluable data were enrolled in the MINI TREK Coronary Dilatation Catheter cohort of the EXPERT CTO due to ongoing enrollment of the cohort that occurred in parallel with analyses to determine when at least 60 subjects with evaluable data had been enrolled.
² MACE and MI rates shown in Table 1 use the ARC definition for MI. If the WHO-based protocol definition for MI is used, the total analysis population in-hospital MACE rate is 2.27% (2/88), and the in-hospital MI rate is 1.14% (1/88).
### Table 1: In-Hospital Major Adverse Cardiac Events (MACE) and Stent Thrombosis (ST) per ARC Definitions

<table>
<thead>
<tr>
<th>In-Hospital Adjudicated Event</th>
<th>Total Analysis Population for Angioplasty Predilatation Endpoint (N=88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE (per ARC MI definition)</td>
<td>10.23% (9/88)</td>
</tr>
<tr>
<td>Death</td>
<td>0.00% (0/88)</td>
</tr>
<tr>
<td>MI</td>
<td>10.23% (9/88)</td>
</tr>
<tr>
<td>Clinically Driven TLR</td>
<td>1.14% (1/88)</td>
</tr>
<tr>
<td>All ST</td>
<td>1.14% (1/88)</td>
</tr>
<tr>
<td>Definite</td>
<td>1.14% (1/88)</td>
</tr>
<tr>
<td>Probable</td>
<td>0.00% (0/88)</td>
</tr>
<tr>
<td>Definite / Probable</td>
<td>1.14% (1/88)</td>
</tr>
<tr>
<td>Possible</td>
<td>0.00% (0/88)</td>
</tr>
<tr>
<td>Acute (&lt; 1 day)</td>
<td>0.00% (0/88)</td>
</tr>
<tr>
<td>Subacute (&gt; 1 to 30 days)</td>
<td>1.14% (1/88)</td>
</tr>
</tbody>
</table>
Possible adverse effects include, but are not limited to, the following:

- Acute myocardial infarction
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture, or injury
- Death
- Drug reactions, allergic reaction to contrast medium
- Embolism
- Hemorrhage or hematoma
- Hypo / hypertension
- Infection
- Restenosis of the dilated vessel
- Total occlusion of the coronary artery or bypass graft
- Unstable angina

PRIOR CLINICAL AND LABORATORY RESULTS

The GUSTO II DIRECT PTCA Substudy (GUSTO IIb)
To evaluate the safety and effectiveness of direct PTCA as a treatment for patients with ST-segment elevation acute myocardial infarction (AMI), Advanced Cardiovascular Systems (ACS) conducted a multicenter, prospective, randomized clinical trial using primarily ACS coronary dilatation catheters. The GUSTO II Direct PTCA Substudy (GUSTO IIb) evaluated the treatment of patients presenting within 12 hours of ST-segment elevation MI with direct PTCA or accelerated recombinant tissue plasminogen activator (t-PA). The primary hypothesis was that for patients with suspected AMI, with ST-segment elevation, direct PTCA would result in a lower rate of 30-day mortality, nonfatal reinfarction, and nonfatal disabling stroke when compared with thrombolytic therapy.

A total of 1138 patients were enrolled in this trial at 60 centers in 9 countries from North America, Europe, and Australia over a period of 17 months. Investigator-selection criteria included those physicians who had significant experience performing primary angioplasty for patients with AMIs, who fulfilled the 1993 ACC volume criteria of at least 50 to 75 cases of angioplasties per year. Investigational institutions were required to have performed at least 200 angioplasties per year and have a 24-hour on-call team with an established system for operating room back-up. Five hundred sixty-five patients were assigned to primary angioplasty and 573 to accelerated recombinant t-PA. At initial enrollment, the first 1012 patients were also randomized in a factorial design to intravenous heparin or intravenous hirudin as part of the GUSTO II trial. Thereafter, all patients received intravenous heparin. At enrollment, patients were given chewable aspirin (160 mg was recommended) followed by a daily dose of 80 to 325 mg. Patients received standard medical care post-assigned treatment. Other testing and adjunctive therapies were left up to the discretion of the physician.

Of the patients randomized to t-PA, 94.6% (542/573) received t-PA, 1.6% (9/573) received streptokinase, and 1.7% (10/573) had direct angioplasty. Eighty-two patients (14.4%) required emergency angiography and 60 (10.5%) required emergency PTCA. Two hundred seventy (47.3%) had elective angiography and 61 (10.7%) had elective PTCA. The in-hospital procedural characteristics for patients randomized to PTCA were 73.3% (374/510) of the infarct arteries occluded (Thrombolysis in Myocardial Infarction [TIMI] grade 0 or 1 flow) at initial
catheterization (core lab) and 79.2% (446/563) of patients received PTCA. Patency after angioplasty (TIMI grade 2 or 3 flow) was achieved in 93.1% (473/508) of patients (core lab). Twenty-two (4%) required emergency angiography and 19 (3.5%) required emergency PTCA. Nineteen (3.5%) had elective angiography and five (0.9%) had elective PTCA. The mean time from arrival at the hospital to treatment for patients randomized to accelerated t-PA was 1.2 ± 0.9 hours, and for the PTCA treatment group it was 2.2 ± 0.9 hours.

When comparing the treatment of patients with ST-segment elevation MI with direct PTCA to treatment with accelerated t-PA, PTCA resulted in a statistically significant lower 30-day composite endpoint rate of death, reinfarction, and nonfatal disabling stroke of 9.6% versus 13.7%, respectively (odds ratio = 0.67, p = 0.033). Additionally, the direct PTCA group had a statistically significant lower rate of recurrent ischemia at 30 days when compared to the t-PA group: 5.5% (29/526) versus 9.0% (48/532), respectively (odds ratio = 0.59, p = 0.03). The overall stroke rate for this study was 1.6% (18/1133). The stroke rate for patients treated with direct PTCA was 1.3% (7/562) versus 1.9% (11/571) for patients treated with t-PA (odds ratio = 0.64, p value = 0.36). The accelerated t-PA treatment group had a statistically significant higher rate of intracranial hemorrhagic strokes, when compared to PTCA: 1.5% (8/571) versus 0%, respectively (odds ratio = 0.06, p = 0.005). There was a statistically significant higher overall rate of bleeding in the PTCA group versus the t-PA group: 40.3% (227/563) versus 34.2% (195/571) (odds ratio = 1.30, p = 0.03). The rate of severe or life-threatening bleeding was equivalent in both treatment groups. Seventy percent (161/227) of bleeding complications in the PTCA treatment group were related to vascular access, and 62.9% (142/227) were mild in nature.

At 180 days, there was no statistical difference in the composite rate of death, reinfarction, and nonfatal disabling stroke for accelerated t-PA versus direct PTCA: 16.8% (87/517) versus 14.7% (75/509), respectively (odds ratio = 0.88, p = 0.36). The overall rate of re-admission to the hospital for chest pain, MI, stroke, and repeat cardiac procedures was similar between the two groups. At one year, there is no statistical difference in the rate of death for accelerated t-PA versus PTCA: 10.3% (52/507) versus 9.2% (46/500), respectively (odds ratio = 0.89, p = 0.57).

Direct PTCA with ACS coronary dilatation catheters is safe and effective in eligible patients presenting within 12 hours of ST-segment elevation MI, providing a reduced composite event rate at 30 days with an equivalent clinical outcome at 180 days and at one year compared with accelerated t-PA.

Direct angioplasty, when it can be accomplished on a prompt basis by experienced physicians at centers with catheterization laboratory availability, should be considered a primary treatment option for patients with AMI.

The EXPERT CTO Trial

The primary objective of the EXPERT CTO clinical trial is to assess the safety and effectiveness of the XIENCE V Everolimus Eluting Coronary Stent System, XIENCE nano Everolimus Eluting Coronary Stent System, and the XIENCE PRIME LL Everolimus Eluting Coronary Stent System for the treatment of chronic total coronary occlusions. Another key objective of this trial is to assess the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter in pre-dilatation of CTOs.
Assessment of the MINI TREK-related objective of the trial has been completed. Assessment of the MINI TREK-related objective was to be performed in at least the initial 60 subjects with successful guide wire crossing, identified as confirmation of the guide wire in the distal true lumen. However, evaluable data (including core laboratory ascertained angiography data immediately following pre-dilatation with the MINI TREK Coronary Dilatation Catheter) were not available in all 60 subjects, and therefore, a total of 98 patients were enrolled at 16 clinical sites from September 13, 2011 (the start of enrollment) to June 26, 2012 (which was the date when it was determined that at least 60 patients with “evaluable” data for full assessment of the angioplasty pre-dilatation related endpoint as defined per protocol had been enrolled). Of the 98 patients that were enrolled, 8 patients were excluded from the total analysis population for unsuccessful guide wire crossing and 2 patients were excluded for having no attempts to pre-dilate the target lesion with the MINI TREK. This resulted in a total of 88 patients comprising the total analysis population for the angioplasty pre-dilatation related analysis, with successful guide wire crossing (identified as confirmation of the guide wire in the distal true lumen), and in whom any attempt to cross the target lesion with the MINI TREK Coronary Dilatation Catheter was made. Of these 88 subjects, 65 subjects had evaluable data for the MINI TREK-related primary analysis, and 23 subjects that did not have core laboratory ascertained angiography data immediately following pre-dilatation with the MINI TREK Coronary Dilatation Catheter. In both the total analysis population (N=88) and the evaluable population (N=65), the MINI TREK Coronary Dilatation Catheter was used at first attempt for pre-dilatation of the CTO.

Abbott Vascular notes that assessment of the MINI TREK-related objective of the EXPERT CTO trial involved analysis of only the MINI TREK Coronary Dilatation Catheter cohort (subpopulation of the full EXPERT CTO study), for only data derived from the index procedure through the in-hospital visit.

Subjects with signs and / or symptoms considered typical of ischemic heart disease attributed to a CTO in a native coronary artery, who were suitable for a percutaneous revascularization, were included. Subjects with evidence of an AMI within 72 hours of the intended treatment were excluded. The target lesion was a de novo lesion with at least one target segment in a native coronary vessel meeting the definition of a CTO. Only one target lesion was allowed to be treated.

Primary Endpoint
The angioplasty pre-dilatation related primary endpoint was successful pre-dilatation of the CTO defined as follows: (1) successful delivery of the MINI TREK Coronary Dilatation Catheter to and across the target lesion; (2) successful inflation and deflation of the MINI TREK Coronary Dilatation Catheter; (3) absence (as determined by independent angiographic core laboratory assessment) of clinically significant vessel perforation, flow-limiting vessel dissection, reduction in TIMI from baseline, and clinically significant arrhythmias requiring medical treatment or device intervention following dilatation with MINI TREK and; (4) achievement of a final TIMI flow 3 for the target lesion at the conclusion of the index procedure (i.e., after stent implantation).

Baseline Subject Characteristics:
The 88 subjects in the total analysis population for the angioplasty pre-dilatation related endpoint had a mean (±SD) age of 61.52 (±10.37) years, and 76.1% (67/88) were men and 23.9% (21/88) were women. A total of 94.3% (83/88) of the subjects were dyslipidemic, 90.8%

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3 A total of 65 subjects with evaluable data were enrolled in the MINI TREK Coronary Dilatation Catheter cohort of the EXPERT CTO due to ongoing enrollment of the cohort that occurred in parallel with analyses to determine when at least 60 subjects with evaluable data had been enrolled.
(79/87) were hypertensive, and 39.8% (35/88) were diabetics with 31.4% (11/35) of the diabetic subjects requiring insulin. Cardiac history revealed prior MI in 31.0% (26/84) of the subjects and previous PCI in 45.5% (40/88). In addition, 32.2% (28/87) of the subjects had history of smoking within the last month prior to enrollment.

**Baseline Target Lesion Characteristics:**
A total of 88 target lesions were treated in 88 subjects in the total analysis population. Angiographic core lab data immediately post-MINI TREK pre-dilatation were available for 65 target lesions (evaluable population subset of the total analysis population), and angiographic core lab data at the end of the index procedure (i.e., after stent implantation) were available for all 88 target lesions in the total analysis population.

Of the target lesions treated in the total analysis population, 35.2% (31/88) were located in the LAD artery, 14.8% (13/88) were located in the LCX, and 50.0% (44/88) were located in the RCA. The mean (±SD) lesion length was 36.68 (±17.86) mm; one lesion (1.1%, [1/88]) was < 10 mm, 14.8% (13/88) of the lesions were 10 – 19.9 mm, and 84.1% (74/88) of them were ≥ 20 mm. The mean (±SD) occlusion length was 13.82 (±8.67) mm.

Assessment of the target lesions in the total analysis population at baseline revealed moderate calcification in 20.5% (18/88) and severe calcification in 14.8% (13/88) of the lesions, and 9.2% (8/87) were eccentric and 1.1% (1/88) had thrombus.

Assessment by the angiographic core laboratory for the total analysis population included mean (±SD) pre-procedure reference vessel diameter (RVD) of 2.59 (±0.45) mm, mean (±SD) pre-procedure MLD of 0.01 (±0.03) mm, and mean (±SD) pre-procedure percent diameter stenosis (DS) of 99.77% (±1.04). Pre-procedure TIMI flow of 0 was noted in 95.5% (84/88), and a pre-procedure TIMI flow of 1 was noted in 4.5% (4/88) of the lesions in the total analysis population.

**Pre-dilatation Balloon Use:**
In the evaluable population (N=65), in addition to the MINI TREK balloon (which was required at first attempt after guide wire crossing), a total of 66 non-study balloons were also used in the target lesions of 42 of the evaluable subjects. In the total analysis population (N=88), in addition to the MINI TREK balloon (which was required at first attempt after guide wire crossing), a total of 92 non-study balloons were used in the target lesions of 61 of the total analysis population.

<table>
<thead>
<tr>
<th>Table 2: EXPERT CTO Pre-dilatation Balloon Use</th>
<th>Total Analysis Population*</th>
<th>Angiographically Evaluable Subjects</th>
<th>Angiographically Unevaluable Subjects*</th>
</tr>
</thead>
<tbody>
<tr>
<td># of MINI TREK study catheters used for the initial dilatation</td>
<td>87</td>
<td>65</td>
<td>22</td>
</tr>
<tr>
<td># of MINI TREK study catheters used for additional (not initial) dilatation prior to stent implantation</td>
<td>38</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td># of non-study balloons used for additional (not initial) dilatation prior to stent implantation</td>
<td>92</td>
<td>66</td>
<td>26</td>
</tr>
</tbody>
</table>

* One patient had a study balloon with missing information for "Used as first attempt balloon."
Primary Endpoint Results:
The angioplasty pre-dilatation related primary endpoint was assessed in the 65 subjects with complete evaluable data for the MINI TREK-related primary analysis.

Importantly, although the 65 evaluable subjects comprise a subset of the 88 subjects in the total analysis population, there was high consistency between site-reported assessments and angiographic core lab assessments when both were available for direct comparison. Also, when analyses were performed for the total analysis population using site-reported data to impute for missing angiographic data, these analyses resulted in numerically similar primary endpoint results as the primary endpoint results for the evaluable population only. Based on the consistency of the results with all analyses performed, the missing angiographic data do not impact or bias the results.

The primary endpoint, successful pre-dilatation of the CTO, was achieved in 93.8% (61/65) of the 65 subjects in the evaluable population with a 95% confidence interval (CI) of [85.0%, 98.3%]. The individual criteria for successful pre-dilatation included:

1. Successful delivery of at least one MINI TREK balloon to and across the target lesion in 96.9% (63/65) of the evaluable population
2. Successful inflation and deflation with at least one MINI TREK balloon in 100.0% (63/63) of the evaluable population
3. Absence of clinically significant vessel perforation, flow-limiting vessel dissection, reduction in TIMI from baseline, or clinically significant arrhythmias requiring medical treatment or device intervention following the dilatation with the MINI TREK balloon in 96.9% (63/65) of the evaluable population
4. Final TIMI 3 flow at the conclusion of the index procedure (i.e., after stent implantation) in 100.0% (65/65) of the evaluable population.

When assessed among the total analysis subjects (N=88) imputing site-reported data for missing angiographic data, the primary endpoint of successful pre-dilatation of the CTO was achieved in 93.2% (82/88) of the evaluable subjects with a 95% CI of [85.7%, 97.5%].

The denominator includes only subjects in whom inflation and deflation of the MINI TREK was attempted (i.e., subjects with successful delivery of the MINI TREK across the target lesion). A subject was considered successful for this component if at least one MINI TREK dilatation catheter was successfully inflated and deflated per the clinical site.
### Table 3: Primary Endpoint Results – Evaluable Population

<table>
<thead>
<tr>
<th>Event</th>
<th>Success</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioplasty pre-dilatation related endpoint</td>
<td>93.8%</td>
<td>(61/65) [85.0%, 98.3%]</td>
</tr>
<tr>
<td>Successful delivery of MINI TREK Coronary Dilatation Catheter to and across target lesion</td>
<td>96.9%</td>
<td>(63/65) [89.3%, 99.6%]</td>
</tr>
<tr>
<td>Successful inflation and deflation with MINI TREK Coronary Dilatation Catheter</td>
<td>100.0%</td>
<td>(63/63) [94.3%, 100.0%]</td>
</tr>
<tr>
<td>Absence of clinically significant vessel perforation, flow-limiting vessel dissection, reduction in TIMI flow from baseline, or clinically significant arrhythmias requiring medical treatment or device intervention following dilatation with MINI TREK</td>
<td>96.9%</td>
<td>(63/65) [89.3%, 99.6%]</td>
</tr>
<tr>
<td>Achievement of final TIMI flow 3 for the target lesion at the conclusion of the index procedure</td>
<td>100.0%</td>
<td>(65/65) [94.5%, 100.0%]</td>
</tr>
</tbody>
</table>

1 Data source: site-reported. A subject was considered successful for this component if at least one MINI TREK dilatation catheter was successfully delivered to and across the target lesion per the clinical site.

2 Data source: site-reported. The denominator includes only subjects in whom inflation and deflation of the MINI TREK was attempted (i.e., subjects with successful delivery of the MINI TREK across the target lesion). A subject was considered successful for this component if at least one MINI TREK dilatation catheter was successfully inflated and deflated per the clinical site.

3 Data source: angiographic core laboratory for vessel perforation, flow limiting vessel dissection, and reduction in TIMI from baseline; site-reported for clinically significant arrhythmia.

4 Data source: angiographic core laboratory.

### Secondary Endpoint Results:

Device Success, defined as attainment of < 50% residual stenosis of the target lesion using the assigned study device, was achieved in 100.0% (88/88) of the lesions in the total analysis population.

Procedure Success, defined as device success and absence of in-hospital MACE (per the protocol definition), was achieved in 97.7% (86/88) of the total analysis population. In the total analysis population (N=88), the mean (±SD) procedural time was 77.13 (±40.17) minutes. The mean (±SD) contrast volume used during the procedure was 251.27 (±113.14) mL, and the mean (±SD) fluoroscopy duration was 32.88 (±21.05) minutes.

Procedural success evaluated according to crossing technique included success in:
- 98.7% (77/78) of the total analysis population using Anterograde Only crossing technique
- 100% (4/4) of the total analysis population using Retrograde Only crossing technique
- 66.7% (2/3) of the total analysis population using combined Anterograde and Retrograde crossing techniques
- 100% (3/3) of the total analysis population using multiple crossing techniques
- Other crossing methods than listed above were not used

No clinically significant perforations occurred in the total analysis population. When analyzed using the ARC definition for MI, in the total analysis population there were nine subjects.
(10.23%) who experienced in-hospital ARC-defined MACE: this was comprised of nine subjects who had ARC-defined MI, one of whom also underwent clinically driven TLR (1.14%).6

Immediately following pre-dilatation of the target lesion with the MINI TREK balloon, the evaluable population (N=65) had a mean MLD (±SD) of 0.44 (±0.37) mm with a mean (±SD) change in MLD of 0.39 (±0.35) mm. In addition, 21.5% (14/65) of the lesions had a TIMI flow of 0, 20.0% (13/65) of the lesions had a TIMI flow of 1, 6.2% (4/65) of the lesions had a TIMI flow of 2, and 52.3% (34/65) of the lesions had a TIMI flow of 3 following pre-dilatation. The mean (±SD) change in TIMI flow was 1.72 (±1.28). Assessment of these parameters for the entire total analysis population could not be performed, since angiography immediately following MINI TREK pre-dilatation was not available for angiographic core lab assessment for the remaining subjects in the total analysis population.

Conclusions:
One of the main objectives of the EXPERT CTO trial was to assess the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter in pre-dilatation of CTOs. In the total analysis population, with site-reported data where angiography core laboratory data immediately following MINI TREK pre-dilatation were not available, the primary endpoint of successful pre-dilatation of the CTO was achieved in 93.2% (82/88) of the subjects with a 95% CI of [85.7%, 97.5%]. These success rates compare favorably with historical averages for this complex lesion class [4, 6-7], and are in accordance with the recent trend towards significantly higher success rates among experienced operators utilizing advanced device technology and procedural techniques [8-10]. These favorable outcome data demonstrate the MINI TREK to be both effective and safe in pre-dilatation of CTOs.

The effectiveness profile of the MINI TREK is further supported by the increase in TIMI flow and MLD observed immediately following pre-dilatation with the MINI TREK as well as at the conclusion of the procedure.

The low rates of procedural complications associated with the use of the MINI TREK, including low in-hospital TLR rates, further support the safety profile of the MINI TREK Coronary Dilatation Catheter.

The data emerging from the EXPERT CTO study compare favorably to the published rates of procedural success and in-hospital complications for the recanalization of CTOs, a notoriously difficult lesion class. These data support the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter for the treatment of CTOs.

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6 When analyzed using the WHO-based protocol MI definition, in the total analysis population (N=88), 2.27% (2/88) of the subjects experienced in-hospital MACE, with 1.14% (1/88) experiencing clinically indicated TLR, 1.14% (1/88) experiencing MI, and no in-hospital death.
MATERIALS REQUIRED

Single Use, Sterile Items (Do not resterilize or reuse.)

- Sterile heparinized normal saline
- Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery
- Hemostatic valve(s)
- 60% contrast medium diluted 1:1 with normal saline
- 20 cc luer lock syringe (optional)
- Appropriately sized guide wire (diameter not to exceed the maximum guide wire for the dilatation catheter; see product label)
- Guide wire introducer
- Guide wire torque device
- Inflation device

PREPARATION FOR USE

Prior to use examine all equipment carefully for defects. Examine the dilatation catheter for bends, kinks, or other damage. Do not use any defective equipment.

Prepare equipment to be used following the manufacturer’s instructions or standard procedure.

Complete the following steps to prepare the MINI TREK RX Coronary Dilatation Catheter for use:

1. Remove the protective mandrel from the flushing sheath.

2. Flush the MINI TREK RX Coronary Dilatation Catheter:
   a) Attach a syringe filled with heparinized normal saline to the flushing hub, which is attached to the protective balloon sheath, and inject heparinized saline into the lumen, or
   b) Attach a syringe filled with heparinized normal saline to the flushing tool, insert the flushing tool into the distal end of the catheter, and inject heparinized normal saline into the lumen. Follow this procedure for subsequent flushing. Flush solution should be seen coming out of the guide wire exit notch located approximately 25 cm proximal to the balloon.

3. Slide the protective sheath off the balloon.

   Note: Submerge the balloon in sterile heparinized normal saline during balloon preparation to activate the coating.

4. Prepare an inflation device with the recommended contrast medium according to the manufacturer’s instructions.

5. Evacuate air from the balloon segment using the following procedure:
   a) Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.
b) After attaching the syringe or inflation device to the balloon inflation lumen, orient the dilatation catheter with the distal tip and the balloon pointing in a downward vertical position.

c) Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.

d) Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.

e) Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.

f) Slowly release the device pressure to neutral.

g) Disconnect the 20 cc syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.

CAUTION: All air must be removed from the balloon and displaced with contrast prior to inserting into the body (repeat steps 5a through 5g, if necessary); otherwise, complications may occur.

INSTRUCTIONS FOR USE

1. Insert a guide wire through the hemostatic valve following the manufacturer's instructions. Advance the guide wire carefully into and through the guiding catheter. When complete, withdraw the guide wire introducer, if used.

2. Attach a torque device to the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

3. Backload the distal tip of the dilatation catheter onto the guide wire ensuring that the guide wire exits the notch located approximately 25 cm proximal to the balloon.

   Note: When backloading the dilatation catheter onto the guide wire, the dilatation catheter should be supported. In advancing the dilatation catheter into the guiding catheter, one's hand should support the dilatation catheter and firmly grasp the proximal shaft. Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the dilatation catheter.

4. Advance the dilatation catheter over the guide wire until it approaches the hemostatic valve. Open the hemostatic valve. Insert the dilatation catheter while maintaining guide wire position and tighten the hemostatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.

   a) Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting the movement of the dilatation catheter. This will allow continuous recording of proximal coronary artery pressure.
Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the dilatation catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.

b) Advance the dilatation catheter until the appropriate proximal marker aligns with the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.

5. Balloon should be of appropriate size for the vessel. Larger balloons will have larger crossing profiles (up to 0.048" / 1.22 mm) and smaller balloons will have smaller profiles. Advance the dilatation catheter over the guide wire and into the stenosis or stent. Inflate the balloon to a very low pressure (1 atm, 1 bar or 15 psi) to confirm that the balloon is correctly positioned.

Note: When using the dual wire technique, a DUOSTAT® (or equivalent) dual hemostatic valve should be used and care taken when introducing, torquing, and removing one or both wires to avoid entanglement. Guide wires should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdrawn from the patient before removing additional equipment.

6. Inflate the balloon (not to exceed 10 total inflations in a stent or 20 total inflations without a stent) to perform PTCA or postimplant dilatation of a stent per standard procedure. Maintain negative pressure on the balloon between inflations.

7. Deflate the balloon by applying negative pressure to the inflation device. Larger and longer balloons will take more time (up to 30 seconds) to deflate than smaller and shorter balloons. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

Note: After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile, heparinized normal saline and stored. Prior to reinsertion, the balloon should be submerged in sterile, heparinized normal saline to reactivate the coating.

Note: If resistance is felt during removal of either the balloon catheter from the guide wire or the guide wire from the balloon catheter, the balloon catheter and guide wire should be removed together as a unit and set aside. Neither balloon catheter nor the guide wire should be re-used for additional attempts to dilate the artery, either separately or in combination.

8. Coil the dilatation catheter using the clip as follows:

a) The dilatation catheter may be coiled once using the clip provided in the package. See the following diagram for proper dilatation catheter coiling and clip placement.

b) Care should be taken not to kink or bend the shaft upon placement or removal of the clip. Only the proximal shaft should be secured with the dilatation catheter clip; it is not intended for the distal end of the dilatation catheter.
EXCHANGE PROCEDURE TECHNIQUE

The MINI TREK RX Coronary Dilatation Catheters have been specifically designed for rapid, single-operator balloon exchanges. To perform a dilatation catheter exchange:

1. Loosen the hemostatic valve.

2. Hold the guide wire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.

3. Maintain guide wire position in the coronary artery by holding the wire stationary, and begin pulling the dilatation catheter out of the guiding catheter while monitoring the wire position under fluoroscopy.

4. Withdraw the deflated dilatation catheter until the notch in the guide wire lumen is reached (marker indicates notch). Carefully inch the flexible, distal portion of the dilatation catheter out of the rotating hemostatic valve while maintaining the guide wire’s position across the lesion.

5. Slide the distal tip of the dilatation catheter out of the hemostatic valve, and tighten onto the guide wire to hold it securely in place. Completely remove the dilatation catheter from the guide wire.

6. Prepare the next dilatation catheter to be used, as previously described in the Preparation for Use section.

7. Backload another dilatation catheter onto the guide wire as previously described under the Instructions for Use section, step 3, and continue the procedure accordingly.

REFERENCES
The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by the American College of Cardiology and the American Heart Association.

PATENTS AND TRADEMARKS

This product and / or its use may be covered by one or more of the following United States Patents: 5,480,383; 5,496,275; 5,525,388; 5,533,968; 5,554,121; 6,013,069; 6,059,748; 6,139,525; 6,165,152; 6,179,810; 6,200,325; 6,206,852; 6,217,547; 6,221,425; 6,224,803; 6,238,376; 6,251,094; 6,368,301; 6,488,688; 6,572,813; 6,579,484; 6,589,207; 6,835,059; 6,923,822; 6,964,750; 7,273,487; 7,322,959; 7,549,975; 7,662,130; 7,828,766; 7,833,597; 7,862,541. Other U.S. patents pending. Foreign patents issued and pending.

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**Graphical Symbols for Medical Device Labeling**

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