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

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

DEVICE DESCRIPTION
The Scoreflex NC Scoring PTCA Catheter is designed for easy guidewire exchange and available with balloon diameters of 1.75, 2.0, 2.25, 2.5, 2.75, 3.0, 3.5 and 4.0mm, balloon lengths of 10, 15 and 20mm and a catheter working length of 140cm. The balloon is made of a minimally complaint material with a rated burst pressure of 20 atmospheres. The proximal shaft of the catheter is composed of a female luer connector bonded to a PTFE coated stainless steel hypotube and the scoring wire is laser welded to the distal end of the hypotube. The proximal shaft joins with a smooth transition to the distal shaft (composed of an outer nylon tube with the balloon/tip tube and scoring wire welded at the distal tip). The cutting section of the scoring wire is outside of the balloon. Two radiopaque platinum/iridium marker bands are located on the scoring wire and aligned with the balloon shoulders to ensure accurate positioning of the balloon. The tip lumen is compatible with a standard 0.014-inch (0.36mm) guidewire. The guidewire enters the catheter tip and advances coaxially out the Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard-length guidewire. Two marked sections, 5mm in length, are located on the proximal shaft indicating the catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements. The catheter is lubricated with hydrophilic coating on the tip and the distal outer body surface; the tip lumen and the balloon are lubricated with silicone coating

HOW SUPPLIED
Sterile. Sterilized with ethylene oxide gas. Non-pyrogenic. For single use only. Do not resterilize.
Contents: One (1) Scoreflex NC Scoring PTCA Catheter; one (1) re-wrap tool (sheath + stylet); one (1) securement clip.
Storage: Store in a dry, dark, cool place. Do not use if the package is opened or damaged.

INDICATIONS
The Scoreflex NC Scoring PTCA Catheter is indicated for:

Balloon dilatation of a de novo stenotic portion of a coronary artery and in-stent restenosis in coronary arteries in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion

CONTRAINDICATIONS
The use of the Scoreflex NC Scoring PTCA Catheter is contraindicated in the following patient types:
- Patients with an unprotected left main coronary artery.
- Patients with coronary artery spasm in the absence of a significant stenosis.

WARNINGS
When using this type of device, the following warnings should be observed:
- This device is intended for single use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of cross-contamination.
- This balloon is not intended for the expansion or delivery of a stent.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- 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. Applying excessive force to the catheter can result in tip or catheter breakage, catheter kink, or balloon separation.

- Do not twist the catheter shaft in excess of 180 degrees when the tip is constrained.
- Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Do not re-straighten a kinked hypotube; straightening a kinked metal shaft may result in breakage of the shaft.
- 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.

PRECAUTIONS

- Use the catheter prior to the "Use By" date specified on the package.
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician.
- Never advance the Scoreflex NC Scoring PTCA Catheter without the guidewire extending from the tip.
- Do not use oil-based contrast medium, organic solvents, or alcohols; there is a possibility of catheter leak, damage, or lubrication loss.
- The balloon deflation time has been established as 15 seconds based on *in vitro* bench testing results.
- Do not reinsert the PTCA catheter into the coil dispenser after procedural use.
- Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.

ADVERSE EFFECTS

Adverse effects due to the use of this product include, but are not limited to, the following:

- Death
- Acute myocardial infarction
- Total occlusion of the coronary artery
- Coronary vessel dissection, perforation, rupture, or injury
- Acute vessel closure
- Restenosis of the dilated vessel
- Unstable angina
- Stroke, air embolism and embolization of fragmentation of thrombotic or atherosclerotic material
- Arrhythmias, including ventricular fibrillation
- Hypertension
- Hypotension
- Coronary artery spasm
- Hemorrhage or hematoma
- Arteriovenous fistula
- Drug reactions, allergic reaction to contrast medium
- Infection
- Need for blood transfusion

OVERVIEW OF CLINICAL STUDY

Scoreflex NC - Scoring PTCA Catheter Clinical Study [ClinicalTrials.gov identifier: NCT03763747]

Objective and Purpose:

The primary objective was to assess the acute safety and device procedural success of the Scoreflex NC Scoring PTCA Catheter in its intended use for the dilatation of coronary artery stenosis (>70% diameter stenosis).

Study Design:

Scoreflex NC Scoring PTCA Catheter Study is a prospective, open label, multi-center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Scoreflex NC Scoring PTCA Catheter in subjects with stenotic coronary arteries during percutaneous coronary intervention.

Two hundred (200) subjects were treated at twelve (12) US investigational sites with the Scoreflex NC Scoring PTCA catheter to dilate coronary arteries during their index procedure. All subjects were screened according to the protocol inclusion and exclusion criteria and were followed through hospital discharge.

The primary endpoint was Device Procedural Success consisting of a composite of:

- Successful delivery, inflation, deflation, and withdrawal of the study balloon.
- No evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline related to the study balloon.
- Final TIMI flow grade of 3 at the conclusion of the PCI procedure.

The secondary peri-procedure related endpoints of study device effectiveness included the individual components of the primary endpoint, the occurrence of Scoreflex NC study balloon rupture, along with the angiographic core lab determined improvement in the Minimum Lumen Diameter (MLD) following dilation of the lesion with the study balloon, and a final diameter stenosis <50% in at least one of the Scoreflex NC attempted lesions following completion of the interventional procedure including adjunctive stenting.

The secondary in-hospital clinical safety and efficacy endpoints reported through hospital discharge included: in-hospital Major Adverse Cardiac Events (MACE), defined as a composite of; all death (cardiac and non-cardiac), Myocardial Infarction (MI) and clinically indicated Target Lesion Revascularization (TLR). Also reported are the individual components of the MACE composite endpoint, along with in-hospital Stent Thrombosis (ST) within the target vessel, or clinically significant arrhythmias (requiring intervention). Both MI and ST were determined by the Academic Research Consortium (ARC) classification criteria.

Demographics

A total of two hundred (200) subjects were treated in accordance with the protocol at twelve (12) U.S. investigational sites. All subjects were screened according to the protocol inclusion and exclusion criteria and were followed through hospital discharge. The analyses were performed on the intent-to-treat (ITT) population and were descriptive.

Table 1, Baseline Patient Demographics – ITT Population

Variables	**Patients (N=200)**
Age (Years)	
Mean (SD)	67.3 (8.98)
Median	68
Min, Max	40, 89
Gender	
Female	46/200 (23.0%)
Male	154/200 (77.0%)
Race	
Asian	2/200 (1.0%)
Black or African American	18/200 (9.0%)
White or Caucasian	178/200 (89.0%)
Other	2/200 (0.5%)
BMI (kg/m^2)	
Mean (SD)	31.3 (5.81)
Median	30
Min, Max	20, 52
Left Ventricular Ejection Fraction	
30-40%	28/200 (14.0%)
>40%	170/200 (85.0%)
Not Done	2/200 (1.0%)
Current Cardiac Status	
Asymptomatic	18/200 (9.0%)
Silent Ischemia	8/200 (4.0%)
Stable angina	116/200 (58.0%)
Unstable angina	57/200 (28.5%)
NSTEMI	0 (0.0%)
STEMI	1/200 (0.5%)
Unknown	0 (0.0%)
Heart failure NYHA class III or IV	4/200 (2.0%)
History of the following	
Diabetes mellitus	88/200 (44.0%)
Prior PCI	106/200 (53.0%)
CABG	26/200 (13.0%)
MI	61/200 (30.5%)
Diagnosis of Heart Failure	18/200 (9.0%)
Hypertension (requiring treatment)	182/200 (91.0%)
Hypercholesterolemia (requiring treatment)	181/200 (90.5%)
Multivessel disease	26/200 (13.0%)
Cigarette smoking (within 30 days)	37/200 (18.5%)

[1] Age is defined as (Enrollment Date – Birth Date + 1)/365.25
[2] BMI is defined as weight (in kg)/$height^2$ (in meter)
SD: Standard Deviation

Of the two hundred (200) subjects treated, the investigator specified reasons for selecting the Scoreflex NC Scoring PTCA Catheter follows: pre-dilatation 63.5%, resistant or calcified lesions 8.5%, in-stent restenosis 9.5%, chronic total occlusion 2.5%, and general use of a non-compliant balloon 16%.

Table 2, Reason for Using the Scoreflex NC

Reason for selecting the Scoreflex NC	**Patients (N=200)**
Predilatation	127 (63.5%)
Resistant or calcified lesions	17 (8.5%)
Fibrotic lesion	0 (0.0%)
In-stent restenosis	19 (9.5%)
Chronic Total Occlusion (CTO)	5 (2.5%)
Or general use of non-compliant balloon	32 (16.0%)

Baseline Lesion Characteristics

Table 3, Baseline Angiographic Characteristics

Parameters	**Lesions - 221 (%)**
Number of lesions treated per patient	
1 lesion	179/200 (89.5%)
2 lesions	21/200 (10.5%)
Lesion Length, mm (mean ± SD; min, max)	18.37±12.93; 3.45, 83.75
Reference vessel diameter, mm (mean ± SD; min, max)	2.62±0.45; 1.58, 3.95
Minimal luminal diameter, mm (mean ± SD; min, max)	0.84±0.40; 0.00, 2.10
Vessel Location	
LAD	97/221 (43.9%)
LCx	55/221 (24.9%)
RCA	68/221 (30.8%)
N/A	1/221 (0.5%)
Lesion Location	
Ostial	7/221 (3.2%)
Proximal	98/221 (44.3%)
Middle	93/221 (42.1%)
Distal	23/221 (10.4%)
Bifurcation	
Present	83/221 (37.6%)
Absent	137/221 (62.0%)
N/A	1/221 (0.5%)
Calcification, Any	
Moderate	29/221 (13.1%)
Severe	52/221 (23.5%)
None/Mild	123/221 (55.7%)
N/A	17/221 (7.7%)
Pre-TIMI	
0	6/221 (2.7%)
1	5/221 (2.3%)
2	6/221 (2.7%)
3	204/221 (92.3%)

Parameters	Lesions - 221 (%)
Total Occlusion	
Yes	11/221 (5.0%)
No	210/221 (95.0%)

SD: Standard Deviation

Primary Endpoint:

As shown below in Table 4, Device Procedural Success was site reported as achieved in 187/200 (93.5%) of the subjects, defined as successful delivery, inflation, deflation, and withdrawal of all the study balloons, an absence of device-related vessel injury, and a final TIMI flow grade of 3 at the conclusion of the PCI procedure.

Table 4, Primary Endpoint Summary – ITT Population

Primary Endpoint	**Scoreflex NC Scoring PTCA Catheter** Subjects (n=200)	Two sided 95% CI Lower Bound using Normal Approximation	Two sided 95% CI Upper Bound using Normal Approximation
Device Procedural Success	187/200 (93.5%)	90.1 %	96.9 %
Success of delivery, inflation/deflation, and withdrawal	191/200 (95.5%)	92.6%	98.4%
Absence of vessel perforation, flow limiting dissection (grade C or higher), or reduction in TIMI flow from baseline related to the study balloon.	196/200 (98.0%)	96.1%	99.9%
Final TIMI flow grade of 3 at the conclusion of the PCI procedure.	198/200 (99.0%)	97.6%	100.0%

Of the nine (9) occurrences where the study balloon was not successfully used,

- seven (7) instances where the study balloon could not cross into the lesion, this included
  - four (4) cases where the operator was able to cross with another device to treat the lesion,
  - one (1) case where the operator downsized to a smaller sized study device and was able to successfully cross to treat the lesion,
  - one (1) case where the target lesion was a chronic total occlusion (CTO) that could not be crossed by any device and was left untreated,
  - one (1) case where the study device could not exit the guiding catheter, was removed from the patient and returned to the Sponsor for assessment.
- one (1) instance where the balloon could not be inflated.
- one (1) instance where the study balloon ruptured on the second inflation of the device.

Table 5, Summary of Unsuccessful Uses

Listing of nine (9) instances where the study balloon was not successfully used	**Scoreflex NC Scoring PTCA Catheter** Subjects (n=200)
Physician was able to cross with another device to treat the lesion	4/200 (1.0%)
Physician down-sized to a smaller sized study device and was able to successfully cross to treat the lesion	1/200 (0.5%)
The target lesion was a chronic total occlusion (CTO) that could not be crossed by any device and was left untreated	1/200 (0.5%)
Study device could not exit the guiding catheter, was removed from the patient and returned to the Sponsor for assessment.	1/200 (0.5%)
Study balloon could not be inflated	1/200 (0.5%)
Study balloon burst during first inflation	1/200 (0.5%)

The freedom from device-related injury, defined as no evidence of vessel perforation; flow limiting dissection; or reduction in TIMI Flow from baseline as related to the use of the Scoreflex NC Scoring PTCA balloon, was achieved in 196/200 subjects (98.0%). Of the four occurrences of device related injury, there was one (1) case of a vessel perforation caused by the manipulation of the steerable guidewire, one (1) case of flow-limiting dissection associated with the use of the study device, and finally in two (2) cases the angiographic core laboratory determined that a reduction in TIMI flow from baseline was observed after the attempted use of the study device. In each of these cases there were no reports of adverse events or site reported MACE events. There were no unanticipated adverse device effects in the reported data, no reportable events from the enrolling sites and there were zero (0) deaths during the conduct of this study.

TIMI grade flow of 3 at the completion of the PCI procedure, was achieved in 198/200 (99.0%) of the subjects, as evaluated by the angiographic core laboratory. In one (1) subject who presented with a CTO previously presented, the physician could not treat the lesion by any modality including with the Scoreflex NC Scoring PTCA study device, where the subject did not achieve a TIMI grade flow of 3 at the conclusion of the overall PCI procedure. In another case, the Scoreflex NC Scoring PTCA study device was successfully used, however the final TIMI flow at the completion of the procedure was of graded at 2, therefore not meeting the criteria TIMI grade flow of 3 for this endpoint.

Secondary Endpoints

The secondary peri-procedural endpoints of the Scoreflex NC Scoring PTCA catheter study device effectiveness are summarized in Table 6a below.

Table 6a, Study Device Effectiveness Outcomes

Secondary Endpoint	**Site Reported or Angiographic Central Core Lab Reported (QCA)**	**Overall Population (n=200 subjects)**	Two sided 95% CI Lower Bound using Normal Approximation	Two sided 95% CI Upper Bound using Normal Approximation
Peri-procedural endpoints of study device effectiveness				
Successful balloon delivery to the target lesion	Site Reported	193/200 (96.5%)	94.0%	99.0%

Successful inflation at the target lesion	Site Reported	192/200 (96.0%)	93.3%	98.7%
Successful deflation	Site Reported	193/200 (96.5%)	94.0%	99.0%
Successful withdrawal of the study balloon	Site Reported	199/200 (99.5%)	98.5%	100.0%
Absence of vessel perforation	Site Reported	199/200 (99.5%)	98.5%	100.0%
Absence of flow limiting dissection (Grade C or higher)	Site reported	199/200 (99.5%)	98.5%	100.0%
No reduction in TIMI flow from baseline related to the study balloon*	Core Lab Reported	178/180 (98.9%)	97.4%	100.0%
Final TIMI flow grade of 3 at the conclusion of the PCI procedure	Core Lab Reported	198/200 (99.0%)	97.6%	100.0%
Absence of balloon rupture of the study balloon	Site Reported	198/200 (99.0%)	97.6%	100.0%
Improvement in Minimum Lumen Diameter (measured by QCA) post-use of study device**	Core Lab Reported	161/177 (91.0%)	85.7%	94.7%
Final Diameter Stenosis <=50% at least one of Scoreflex NC study device attempted lesions***	Core Lab Reported	197/200 (98.5%)	96.8%	100.0%

*The TIMI flow after study balloon dilation was not analyzable in 20 patients by the Angiographic Core Lab. Therefore, reduction in TIMI flow from baseline related to the study balloon could only be analyzed in 180 patients.

**The Improvement in MLD after use of the study balloon as measured by QCA was not analyzable in 23 patients by the Angiographic Core Lab. Therefore, this value could only be analyzed in 177 patients.

*** The percent diameter stenosis was computed by comparing the minimal lumen diameter (MLD)at the stenosis with the corresponding reference diameter (RM) with the formula, [[1-(minimum lumen diameter/reference diameter)]*100]. MLD and RM are the average of MLD and RM at two projections, respectively as provided by the angiographic core laboratory.

The breakdown of the Scoreflex NC Scoring PTCA catheter periprocedural performance has been explained in the discussion of the primary endpoint. In addition, a single (1) case of vessel perforation was caused by manipulation of the steerable guidewire and unrelated to the study device. The occurrence of study balloon rupture was reported in two (2) cases: one case where the balloon rupture occurred during the first inflation and prevented successful treatment of the lesion with the Scoreflex NC Scoring PTCA catheter and another case where the balloon burst during the second inflation after the lesion had been treated successfully with the Scoreflex NC Scoring PTCA Catheter. In both occurrences the lesion was successfully treated with the Scoreflex NC Scoring PTCA catheter or another device and there were no dissections or adverse events related to these two incidents or the use of the study device.

The attainment of a final diameter stenosis <50% in at least one study device treated lesion following completion of the interventional procedure, as determined by the angiographic core laboratory, was achieved in 197/200 subjects (98.5%). In one (1) subject discussed previously whom presented with a CTO which the physician could not treat the lesion by any modality including with the Scoreflex NC Scoring PTCA study device, and the procedural angiographic efficacy was not achieved. In one (1) subject who also failed the primary endpoint previously presented above where the physician could not reach the lesion, the physician obtained 64% residual stenosis without adjunctive stenting. The third subject resultant in-segment stenosis was 51% with adjunctive stenting. Adjunctive stenting was not a protocol requirement for inclusion into this study, and there were a total of fifteen (15) subjects treated without the use of adjunctive stenting.

The independent Clinical Events Committee (CEC) positively adjudicated the occurrence of ten (10) major adverse cardiac events (MACE) reported in nine (9) subjects as detailed in Table 6b below.

Table 6b, In-hospital Clinical Safety and Efficacy Outcomes

Secondary Endpoint	CEC Adjudication (per protocol)	CEC Adjudication & Subjects without post-procedure enzyme testing*
In-hospital clinical safety and efficacy		
In-hospital MACE (composite of all death, target vessel MI or clinically indicated TLR)	9/200 (4.5%)	14/200 (7.0%)
All Death (cardiac & non-cardiac)	0/200 (0.0%)	0/200 (0.0%)
Myocardial Infarction	8/200+ (4.0%)	13/200 (6.5%)
Clinically indicated TLR	1/200 (0.5%)	1/200 (0.5%)
In-hospital stent thrombosis (ST) within the target vessel	0/200 (0.0%)	0/200 (0.0%)
Clinically significant arrhythmias requiring intervention	1/200 (0.5%)	1/200 (0.5%)

+Eight (8) cases of asymptomatic peri-procedural MIs detected by cardiac enzyme rises
*Worst case calculations for MI and MACE that includes the five (5) patients with missing enzyme data post procedure and assumes elevated enzymes in these patients.

There were eight (8) incidents of asymptomatic peri-procedural MIs as detected by post-procedure elevations in cardiac enzyme levels which did not require treatment (4.0%), one (1) case with a target lesion revascularization (0.5%), and there were no reports (0) of death in the study. There was one (1) report of a clinically significant arrhythmia requiring intervention (0.5%) and there were no incidents of stent thrombosis.
Investigational sites were instructed to record any observed device deficiencies in the eCRF and report to the Sponsor. Study sites were also instructed to report any AE results from a device deficiency or other device issue as related to the use of the Scoreflex NC study device. There were no UADEs or AEs as a result of the site-reported device deficiencies and no device related complications occurred before discharge in any of the 200 patients. Table 7 below is a summary of the reported device deficiencies

Table7, Summary of Site Reported Deficiencies

Device Deficiency Noted	Qty of devices (N)	Resulted in an AE (Y/N)	Returned to Sponsor for Evaluation	Resulted in a MACE event (Y/N)
Unable to cross Lesion	N=8	No (N=8)	N=7	No (N=8)
GW trapped within distal Tip of Balloon, removed intact	N=2	No (N=2)	N=1	No (N=2)
Balloon burst	N=1	No (N=1)	N=1	No (N=1)
Balloon did not inflate	N=1	No (N=1)	N=0	No (N=1)
Balloon inflated to 16 atm for 30 seconds, 16 atm for 20 seconds. Balloon burst during second inflation and was removed	N=1	No (N=1)	N=0	No (N=1)

Device Deficiency Noted	Qty of devices (N)	Resulted in an AE (Y/N)	Returned to Sponsor for Evaluation	Resulted in a MACE event (Y/N)
Balloon slipped off lesion	N=1	No (N=1)	N=1	No (N=1)
Balloon tip bent on itself when removed	N=1	No (N=1)	N=1	No (N=1)
Unable to exit guide with Balloon	N=1	No (N=1)	N=1	No (N=1)

The major and minor protocol deviations are summarized in Table 8 below. There were nineteen (19) major protocol deviations reported for eighteen (18) subjects.

Table 8, Protocol Deviations

Major deviations	**N=19**
Informed Consent Procedure	0
Pre-procedure Laboratory testing not conducted per protocol	7
Treatment of a target lesion prior to the treatment on a non-target lesion	5
The need to treat more than 2 lesions after the procedure commenced	3
Non-target lesion located in same artery as target lesion.	1
Target lesion located in saphenous vein graft	1
Ejection Fraction value was not known prior to procedure	2
Minor deviations	**N=87**
Scoreflex NC device used on more than one lesion	6
CBC not collected	18
ECG not conducted post procedure	11
Report of at least one laboratory not conducted	34
Report of at least one laboratory collected out of window	16
Medication review not conducted within protocol specified time period	2

Device Procedural Success

The Device Procedural Success of the Scoreflex NC Scoring PTCA catheter by the investigator specified indication for use in the study is given below in Table 9.

Table 9. Device Procedural Success by Investigator Specified Indication for Use of Scoreflex NC

	Subjects	**Device Procedural Success**	**Successful use of Study Balloon**	**Absence of Device-Related Injury**	**Final TIMI flow grade of 3**
Overall	200	187/200 (93.5%)	191/200 (95.5%)	196/200 (98.0%)	198/200 (99.0%)
Pre-dilatation	127	120/127 (94.5%)	121/127 (95.3%)	125/127 (98.4%)	126/127 (99.2%)
Resistant or Calcified Lesions	17	16/17 (94.1%)	16/17 (94.1%)	17/17 (100%)	17/17 (100%)
In-Stent Restenosis	19	19/19 (100%)	19/19 (100%)	19/19 (100%)	19/19 (100%)
Chronic Total Occlusions	5	3/5 (60%)	5/5 (100%)	4/5 (80%)	4/5 (80%)
General Use of NC Balloon	32	29/32 (90.6%)	30/32 (93.8%)	31/32 (96.9%)	32/32 (100%)

Conclusion

The results of the Scoreflex NC - Scoring PTCA Catheter Clinical Study support the acute safety and device success of the Scoreflex NC - Scoring PTCA Catheter and its intended use as a dilatation catheter in the stenotic portion of a coronary artery stenosis (≥70% diameter stenosis).

MATERIALS REQUIRED

- Arterial Sheath
- Guiding catheter of appropriate size, tip shape, and length
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- Sterile heparinized normal saline
- 20 cc luer-lock syringe
- Inflation device with manometer
- Appropriately sized guidewire with maximum diameter of 0.014”
- Guidewire introducer
- Guidewire torque device

PREPARATION FOR USE

Prior to use, examine all equipment carefully for defects. Examine the PTCA catheter for bends, kinks, or other damage. Do not use any defective equipment. Prepare equipment to be used following manufacturer’s instructions or standard procedure. Complete the following steps to prepare the PTCA catheter for use:

1. Slide the protective sheath off the balloon.
2. Submerge the catheter tip/guidewire lumen in heparinized normal saline.
3. Prepare an inflation device with the recommended contrast medium according to the manufacturer’s instructions.
4. 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 catheter hub (balloon inflation lumen), orient the PTCA 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 PTCA catheter.
d. Disconnect the syringe or inflation device from the catheter hub.
e. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the catheter hub. Maintain negative pressure on the balloon until air no longer returns to the device.
f. Slowly release the device pressure to neutral.

5. Disconnect the 20-cc syringe (if used) and connect the inflation device to the catheter hub (balloon inflation lumen) 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, otherwise complications may occur.**

INSTRUCTIONS FOR USE

1. Insert a guidewire through the hemostatic valve following the manufacturer's instructions.
2. Advance the guidewire carefully into and through the guiding catheter. Withdraw the guidewire introducer, if used.
3. Attach a torque device to the guidewire, if desired. Under fluoroscopy, proceed with accepted PTCA techniques to advance the guidewire to and across the lesion.
4. Backload the distal tip of the PTCA catheter onto the guidewire ensuring that guidewire exits the catheter at the notch located distal to the balloon. **Note: When backloading the catheter onto the guidewire, the catheter should be supported, ensuring that the guidewire does not wrap around the balloon.**
5. Advance the PTCA catheter over the guidewire until it approaches the hemostatic valve.
6. Open the hemostatic valve. Insert the PTCA catheter while maintaining guidewire position and tighten the hemostatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.
7. Tighten the hemostatic valve to create a seal around the PTCA catheter without inhibiting movement of the PTCA 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 PTCA catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guidewire movement.**
8. Advance the PTCA catheter until the appropriate shaft marker aligns with the hemostatic valve hub. This indicates that the PTCA catheter tip has reached the guiding catheter tip.
9. Advance the PTCA catheter over the guidewire and into the stenosis. Continue under fluoroscopy and use the radiopaque marker band(s) to position the usable (dilating) section of the balloon within the stenosis.
10. Continue the procedure using accepted coronary angioplasty technique to dilate the stenosis. **Note: Do not exceed the rated burst pressure printed on the package label. Maintain negative pressure on the balloon between inflations.**
11. Withdraw the deflated PTCA catheter and guidewire into the guiding catheter. Using a technique of choice, remove the PTCA catheter, guidewire, and guiding catheter from the vasculature. Discard the PTCA catheter, guidewire, and guiding catheter.

EXCHANGE PROCEDURE TECHNIQUE

The PTCA catheter has been specifically designed for rapid, single operator balloon exchanges. To perform a dilatation catheter exchange:

1. Loosen the hemostatic valve.
2. Hold the guidewire and hemostatic valve in one hand, while grasping the catheter shaft in the other hand.
3. Maintain guidewire position in the coronary artery by holding the wire stationary and begin pulling the PTCA catheter out of the guiding catheter while monitoring the wire position under fluoroscopy.

4. Withdraw the deflated PTCA catheter until the guidewire lumen is reached. Carefully pull back the flexible, distal portion of the PTCA catheter out of the rotating hemostatic valve while maintaining the guidewire position across the lesion. **Note: If resistance is felt, remove PTCA catheter, guidewire, and guiding catheter together from the vasculature.**
5. Slide the distal tip of the PTCA catheter out of the hemostatic valve and tighten valve onto the guidewire to hold it securely in place.
6. Prepare the next PTCA catheter to be used, as previously described in the Preparation For Use section.
7. Backload another PTCA catheter onto the guidewire as previously described under the Instructions For Use Section and continue the procedure accordingly.

REFERENCES

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

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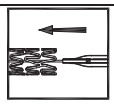
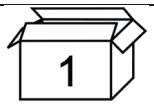
EXPLANATION OF SYMBOLS

Description	Symbol
Catalog Number	
Lot Number	
Balloon Diameter	
Balloon Length	
Sterilized Using Ethylene Oxide	
Use By	
Do Not Re-use	
Caution	
Do Not Resterilize	
Recommended Guiding Catheter	
Recommended for In-Stent Restenosis	
Contents (numeral represents quantity of units inside)	
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