＜IFU for US＞

Lacrosse NSE ALPHA Coronary Dilatation Catheter

1 Device Description

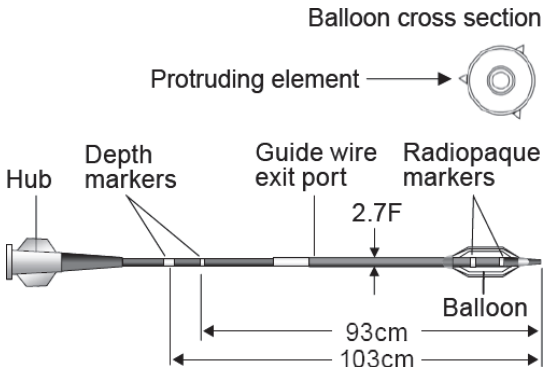
The product is a rapid exchange (RX) percutaneous transluminal coronary angioplasty (PTCA) balloon catheter. The balloon has nylon threads (protruding elements) that focus dilatation force during inflation. The three nylon threads are located at 120° intervals parallel to the shaft and bonded at the distal and proximal ends of the 13 mm long semi-compliant balloon. Inside the balloon, two radiopaque markers indicate the working length of the balloon to guide proper positioning in the target lesion.

The distal section of the 2.7 F catheter comprises a dual-lumen shaft; the outer lumen is for balloon dilatation, and the inner lumen allows for rapid exchange of 0.014” or smaller guide wires. A hydrophilic coating is applied to the catheter shaft and tapered distal tip. The proximal shaft contains catheter insertion depth markers at 93 cm and 103 cm, and the proximal hub enables balloon inflation and deflation using a standard balloon inflation device.

The device is available in balloon diameters ranging from 2.0 to 4.0 mm. The nominal inflation pressure is 6 atm and the rated burst pressure is 14 atm. The balloon compliance

chart is provided at the end of these Instructions for Use. The device is packaged sterile with a balloon protector and stylet that are removed prior to use.

<Product Diagram>



Recommended Inflation Pressure (NP: Nominal Pressure): 6 atm (6×10^2 kPa)
Maximum Inflation Pressure (RBP: Rated Burst Pressure): 14 atm (14×10^2 kPa)
Maximum Compatible Guide Wire Outer Diameter: 0.014inch (0.36mm)
Minimum Compatible Guiding Catheter ID: 6F

<Components>
Flush Device, Catheter Clip / 1unit each

2 Indications for Use

The Lacrosse NSE ALPHA™ Coronary Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of the coronary artery including both *de novo* and in-stent restenosis, for the purpose of improving myocardial perfusion.

3 Contraindications

3.1 Vasculature spasm without significant stenosis.
3.2 Lesions in left main trunk without protection from collateral blood flow, bypass or any other method.
3.3 Lesions located in bifurcation beyond stent struts.
3.4 Lesion located distal to a freshly implanted stent.
3.5 Lesions with stent damage such as fractures, cuts, cracks, bends, etc.

4 Warnings

4.1 The product is sterilized, is not re-usable and must not be resterilized. Resterilization and/or reuse could result in infection or degradation of product characteristics such as

balloon size, shaft strength or lubricity and could result in failure of the product during use.

4.2 Intravascular manipulation of the product should be carefully performed under fluoroscopy. Movement of the product distal tip or operation without confirming its location may result in damage to the product or the blood vessel.

4.3 Should any resistance to manipulation or abnormality in product tip movement and location occur during operation, immediately cease usage and confirm cause under fluoroscopy. Continued use may result in damage to the product or the blood vessel.

4.4 With the guide wire exit port of the product placed beyond the tip of a guiding catheter, care should be taken for eliminating any slack in the guide wire to the guide wire exit port when retracting the product into the guiding catheter. The product or the guide wire may become inoperable or incur damage.

4.5 To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate to the vessel just proximal or distal to the stenosis.

4.6 Carefully remove the product from the protective hoop and remove the stylet and the balloon protector from the product ensuring that no damage to the product is incurred. Damage to the balloon or the balloon lumen may cause balloon inflation/deflation failure or affect functionality.

4.7 When inserting and/or retrieving the product, use a gauze doused in heparinized saline to wipe the guide wire and remove any foreign particles from surface. Contaminant may cause damage to the product or the guide wire.

4.8 As the protruding elements are jointed at both the proximal and distal ends of the balloon, care should be taken when advancing a secondary device over the balloon or retrieving the product over a secondary device proximally located to the balloon in order to avoid entangling of the protruding elements with the secondary device. Such entangling may result in damage to the product and the secondary device.

4.9 Care should be taken when using the product on lesions with multiple stents implanted such as Y stenting, T stenting, culotte stenting and crush stenting (including bifurcated lesions). The protruding elements may potentially become entangled on the stent. Such condition may result in damage to the product.

4.10 Care should be given when using the product in distal sections of drug eluting stents. There are reports of extremely delayed coating of neointima with drug eluting stents.

4.11 The product should only be manipulated while fully deflated. Operating while inflated may cause damage to the product or the blood vessel.

4.12 The product should only be used in facilities capable of performing emergency coronary artery bypass grafting (CABG) as a provision against complications that may cause injury or serious complications that could prove to be life threatening.

4.13 Do not use any products comprising organic solvent, fat-based emulsions or oil to prevent damage to the product such as hub and protruding elements and/or hydrophilic

coating deterioration.

4.14 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.

4.15 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 a pressure gauge to prevent over-inflation of the balloon.

4.16 Use only an appropriate balloon inflation medium (e.g., 50:50 mixture of contrast medium and saline) to inflate the device. Do not use air or any gaseous medium to inflate the balloon. There is potential to cause complications associated with air embolization.

4.17 For in-stent restenosis (ISR) treatment, proceed with caution under fluoroscopy when inserting and withdrawing from the lesion.

5 Precautions

5.1 Precautions Prior To Use

5.1.1 This balloon is not intended for the post-delivery expansion of a stent.

5.1.2 Data from the EXPANSE-PTCA pivotal IDE clinical trial demonstrated that the Lacrosse NSE Alpha Coronary Dilatation Catheter failed to cross in 21 of 197 (10.7%) subjects. In most cases, these lesions were highly calcified and/or tortuous. Support guide catheter use is recommended when treating complex lesions. It may also be prudent to have additional accessory devices available in case the Lacrosse NSE Alpha Coronary Dilatation Catheter is unable to cross the lesion.

5.1.3 Refer to labeling, warnings, and precautions of all pharmaceuticals and medical devices used in relation to the target lesion and procedure.

5.1.4 The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

5.1.5 Do not use the product if the packaging or contents are damaged or contaminated. Especially take care not to damage protruding elements.

5.1.6 All product use should be undertaken in a sterile environment.

5.1.7 Sterile barrier system is a pouch. Only the contents in the pouch are provided aseptically.

5.1.8 One component of this device contains the following substance defined as Carcinogenicity 1B and Reproductive toxicity 1B in concentration above 0.1% weight by weight: Cobalt: CAS No. 7440-48-4. Current scientific evidence supports that exposure to cobalt containing alloys in medical devices does not

represent a hazard for carcinogenicity or reproductive toxicity.

5.2 Precautions During Use

5.2.1 Take care when using a guide wire or the flush device to ensure that any damage to the product does not occur.

5.2.2 To avoid coagulation of blood within the guide wire lumen, thereby affecting the operations of the product, be sure to adequately flush the lumen with heparinized solution and do not use the product for an extended period of time.

5.2.3 When the balloon cannot be concentrically inflated, take care that the balloon movement does not occur. Balloon movement during inflation may cause damage to the blood vessel.

5.2.4 The hemostatic valve should be closed in order to ensure that the balloon position is fixed during inflation. Balloon movement during inflation may cause damage to the blood vessel.

5.2.5 When closing the hemostatic valve, be sure not to impede the operation of the guide wire or the inflation/deflation line of the balloon.

5.2.6 Should the product incur kinking to the shaft, do not continue to use or attempt to repair. Fracture of the shaft may occur.

5.2.7 When placing a number of devices into the patient, operate the product and other devices carefully in order to prevent entanglement. If resistance is felt during procedure, confirm cause of resistance. Damage to the product or other devices may occur.

5.2.8 Check the product for abnormality such as damage, loosening of connected sections or leakage of inflation medium on a regular basis.

5.2.9 Once the balloon has been inflated, do not re-wrap the balloon by use of the balloon protector. Damage to the balloon may occur.

5.2.10 Administer appropriate anticoagulants and vasodilators during the procedure.

5.2.11 Do not rotate the product within a vasculature. Rotating may result in damage to the product or blood vessel.

5.2.12 Dispose the product as medical waste and take measures to prevent possible spread of infection.

6 Adverse Events

Possible adverse events associated with the use of this product include, but are not limited to, the following:

-Acute myocardial infarction

-Arrhythmia (including ventricular fibrillation, bradycardia, tachycardia)

-Arterial spasm

-Arteriovenous fistula

-Blood loss from puncture site
-Coronary artery dissection, perforation, rupture, or injury
-Death
-Hemorrhage or hematoma
-Hemorrhagic complications
-Hypo / Hypertension
-Infection
-Ischemia caused by long duration inflation
-Nausea or vomiting
-Palpitation
-Reaction (e.g., medicinal reaction or allergic reaction to contrast media)
-Restenosis following angioplasty
-Stroke, air embolization, distal embolization
-Thrombosis
-Total occlusion of the coronary artery or bypass graft
-Unstable angina

7 Materials Required

The following materials should be prepared for use:
-Guiding Catheter
-Guide Wire
-Hemostatic Valve
-Syringe
-Inflation Device
-3-way Stopcock

8 Instructions For Use

8.1 Preparation

8.1.1 Inspect and confirm each device for correct functionality.

8.1.2 Remove the product from the packaging (remaining in the protective hoop).

8.1.3 Flush the product with heparinized saline while retaining the product in the protective hoop. Ensure the product does not become contaminated by being ejected from the hoop during flushing process.

8.1.4 Carefully remove the product from the protective hoop.

8.1.5 Carefully remove the balloon protector and the stylet. Confirm that there is no damage to the product.

NOTE: Inflation and deflation of the balloon shall not be performed prior to use unlike the preparation for a conventional PTCA balloon catheter.

8.1.6 Using the flushing device or the flushing needle, remove air from the guide wire

lumen by flushing with heparinized saline through from the product tip (tip ofthe guide wire lumen).

8.1.7 Connect the stopcock to the product hub (balloon inflation port), and secure the stopcock lever in the “off” position for the channel to the balloon.

8.1.8 Prime an inflation device with appropriate amount of diluted contrast media (contrast : heparinized saline = 1:1). Connect it to the stopcock and flush the port of stopcock with contrast media.

8.1.9 Turn the stopcock lever to open the flow channel between the product and the inflation device, and with the inflation device tip facing downward, aspirate for 20-30 seconds.

8.1.10 With the inflation device tip facing downward, cease aspiration and confirm that the product lumen is devoid of air.

8.1.11 Repeat the above process until the product is completely devoid of residual air/bubbles.

8.1.12 Removing all residual air from the inflation device, again deflate the balloon and maintain the condition.

*Do not allow air or liquid to enter the balloon in order to preserve the balloon folding functionality and the protruding elements.

8.2 Insertion Of Product

8.2.1 Follow the package insert for each medical device and complete preparation of the devices prior to insertion of the product.

8.2.2 Cross the target lesion with the guide wire and confirm under fluoroscopy its entry into the distal vasculature.

8.2.3 With the balloon completely deflated, carefully insert the tail end of the guide wire into the distal tip of the product and advance the product to the target lesion.

Note: Additional guide support and/or predilatation may be necessary for the product to cross severely calcified and/or complex lesions.

8.3 Balloon Inflation

8.3.1 Confirm position of the balloon under fluoroscopy in relation to the target lesion and close the hemostatic valve, locking balloon into place.

8.3.2 Inflate the balloon to the nominal inflation pressure for appropriate length of time and deflate the balloon using the inflation device.

8.3.3 Perform multiple inflations as deemed necessary.

8.3.4 Upon completion of dilatation, ensure the balloon is completely deflated, return the product to within the guiding catheter and evaluate improvement to stenotic site via angiography.

8.3.5 Should adequate expansion not be achieved at this time, further improvement

may be attained by increasing inflation pressure or length of time (see compliance chart).

8.4 Removal Of Product

After complete deflation of the balloon, carefully remove the product while ensuring that the guide wire remains in location.

9 Storage Method, Shelf Life and Sterilization

9.1 Storage Method

9.1.1 Store the product in a room temperature location not exposed to high temperature and humidity or direct sunlight and take proper precautions to ensure the product does not contact water.

9.1.2 Avoid vibrations and impacts (including during transportation) and store on a level surface in a safe, stable environment.

9.1.3 Do not store near chemicals or in areas where the device may be exposed to chemical vapors.

9.2 Shelf Life

Use this product before the date of “Use By” shown on the package label.

9.3 Sterilization Method

The product package has been sterilized by exposure to Ethylene Oxide Gas (EtO) and is not intended to be re-sterilized.

10 Product Warranty Disclaimers and Limitation of Remedies

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11 References

The physician should consult current medical practice literature on balloon dilatation, such as that published by ACC/AHA.

12 OVERVIEW OF CLINICAL STUDY

A Study to Exhibit Percutaneous coronary Artery dilatation with Non-Slip Element balloon (EXPANSE-PTCA), ClinicalTrials.gov identifier: NCT 04985773

Study Design

A prospective, multi-center, single arm clinical study that followed subjects through hospital discharge.

Sites

The study was conducted at 10 investigational sites in the U.S.

Study Sample Size

200 subjects were enrolled, including the required minimum of 30 subjects with in-stent restenosis.

Subject Population

Patients with stenotic coronary artery disease.

Endpoints

Primary Endpoint

The primary endpoint for the study was device procedural success, defined as:

- Successful delivery, inflation, deflation, and withdrawal of the study balloon; and
- No evidence of device-related vessel perforation, flow limiting dissection (grade C or higher, per Clinical Events Committee (CEC) adjudication) or reduction in TIMI flow from baseline (per core laboratory assessment); and
- Final TIMI flow grade of 3 at the conclusion of the PCI procedure per core laboratory assessment.

Secondary Endpoints

The secondary endpoints of the study were:

1. Angiographic procedural success, defined as final diameter stenosis ≤50% in at least one of the NSE ALPHA attempted lesions following completion of the interventional procedure, including adjunctive stenting per core laboratory assessment.
2. MACE through hospital discharge per CEC adjudication. MACE is defined as a composite of:
    - All-cause death
    - Myocardial infarction (MI)
    - Clinically indicated target lesion revascularization (TLR)
3. Stent thrombosis within the target vessel(s) through hospital discharge using ARC-2 definitions for definite & probable, per CEC adjudication.
4. Clinically significant arrhythmia (defined as those requiring intervention) through hospital discharge, per CEC adjudication.
5. Occurrence of NSE ALPHA balloon rupture, per device deficiency eCRF.
6. Change in minimum lumen diameter (MLD) following use of the NSE ALPHA, measured by quantitative coronary angiography (QCA) per core laboratory assessment.

7. Device procedural success defined as for the primary endpoint, calculated and presented per target lesion.

A total of 200 subjects undergoing PCI of 220 lesions were enrolled in the study at 10 centers in the US. The median subject age was 69.5 years and 78.5% were male. Nearly half (42.5%) had undergone a prior coronary intervention and 24.0% had a prior myocardial infarction. (**Table 1**)

Table 1: Baseline Demographics & Medical History

Characteristic	Subjects (%) (N=200)
Baseline Demographics	
Age (years) (median/range)	69.5 (32.0 - 93.0)
Sex at birth	
Male	157 (78.5%)
Female	43 (21.5%)
Height (cm) (median/range)	175.0 (135.0 - 198.0)
Weight (kg) (median/range)	90.7 (50.0 – 147.0)
Race	
White	171 (85.5%)
Other	10 (5.0%)
Black or African American	8 (4.0%)
Subject chose not to disclose	7 (3.5%)
Asian	3 (1.5%)
American Indian or Alaska Native	1 (0.5%)
Ethnicity	
Not Hispanic or Latino	183 (91.5%)
Hispanic or Latino	7 (3.5%)
Subject chose not to disclose	10 (5.0%)
Medical History	
Prior coronary intervention(s)	85 (42.5%)
PCI	77 (38.5%)
CABG	18 (9.0%)
Prior myocardial infarction(s)	48 (24.0%)
Diabetes mellitus	
None	121 (60.5%)
Type I	3 (1.5%)
Type II	76 (38.0%)
Insulin required	30 (15.0%)
Dyslipidemia requiring treatment	183 (91.5%)
Hypertension requiring treatment	166 (83.0%)
Cigarette smoking	
Never	99 (49.5%)
Quit ≥ 6 months ago	80 (40.0%)
Current (w/in last 30 days)	20 (10.0%)
Quit > 1 month to < 6 months ago	1 (0.5%)
Chronic kidney disease	18 (9.0%)
Ejection fraction (%) (median/range)	55.0 (30.0 - 82.0)

Characteristic	Subjects (%) (N=200)
Acute coronary syndrome	20 (10.0%)
Cardiac status (at time of procedure)	
Chronic stable angina	89 (44.5%)
Ambiguous or abnormal symptoms with noninvasive functional study or FFR/iFR	65 (32.5%)
Unstable (accelerated) angina	31 (15.5%)
Stabilized acute coronary syndrome – stabilized patient 24-72 hours post STEMI	3 (1.5%)
Other	12 (6.0%)

The majority of subjects (89.0%) underwent attempted treatment of a single target lesion, and 13.5% underwent treatment of a non-target lesion. The predominant arterial access approach was radial (66.7%), and 92.3% of lesions were stented after use of the study device. (**Table 2**)

Table 2: Procedural Characteristics

Characteristic	Subjects (%) (N=200)
Number of target lesions treated	
1	178 (89.0%)
2	22 (11.0%)
Number of non-target lesions treated	
None	173 (86.5%)
1	27 (13.5%)
Total fluoroscopy time (minutes, median/range)	13.0 (3.0 - 71.0)
Radiation exposure (milligray, median/range)	1094.0 (18.0 - 5345.0)
	Target Lesions (N=222)
Access approach[1]	
Radial	148 (66.7%)
Femoral	75 (33.8%)
Other (ulnar)	1 (0.5%)
Reason NSE Alpha chosen	
Severe stenosis	104 (46.8%)
Calcified lesion	92 (41.4%)
Bulky lesion	42 (18.9%)
In-stent restenosis	31 (14.0%)
Long lesion	24 (10.8%)
Other	18 (8.1%)
Other balloon dilatation performed on target lesion before use of study balloon (and before other treatment, e.g., stent)[2,3]	98 (44.1%)
Other balloon used after study balloon (i.e., balloon and stenting; or balloon and no stenting)[2,4]	134 (60.4%)
Additional intervention on target lesion	
Stent	205 (92.3%)
Other balloon (after other treatment, e.g., stent)	135 (60.8%)
Other[5]	26 (11.7%)
Atherectomy	6 (2.7%)
Cutting balloon	1 (0.5%)

1. Some lesions had more than one access approach.
2. Categories are not mutually exclusive and will not sum to N=222 lesions.
3. Patient 390-006 is missing pre-dilatation data.
4. Balloon may be before or after stent.
5. Includes additional stent(s) (n=14), other non-study balloons (n=5), intravascular lithotripsy (n=5), brachytherapy (n=1) and brachytherapy and intravascular lithotripsy (n=1).

The left anterior descending artery was the most commonly treated vessel (48.6% of lesions). The median lesion length was 12.3 mm with a median reference vessel diameter of 2.9 mm. Most lesions were de novo (84.1%) and a majority (75%) had complex (B2 or C) lesion morphology. Severe calcification was seen in 55.0% of the lesions. (**Table 3**)

Table 3: Pre-procedure Target Lesion Characteristics and Morphology (Core Lab)

Characteristic	**n (%) (N = 220[1] Lesions)**
Vessel location[2]	
Left anterior descending	107 (48.6%)
Right coronary artery	65 (29.5%)
Left circumflex	47 (21.4%)
Left main	1 (0.5%)
Lesion location	
Proximal	75 (34.1%)
Mid	95 (43.2%)
Distal	42 (19.1%)
Ostial	8 (3.6%)
Lesion type	
De novo	185 (84.1%)
In-stent restenosis (ISR)	35 (15.9%)
ISR: stented length (mm) (median/range)	32.1 (9.7 - 114.9)
ISR: pattern	
IB	15 (42.9%)
IC	10 (28.6%)
ID	2 (5.7%)
II	6 (17.1%)
III	2 (5.7%)
Lesion morphology classification	
A	13 (5.9%)
B1	41 (18.6%)
B2	124 (56.4%)
C	41 (18.6%)
Unknown	1 (0.5%)
Eccentricity	
Concentric	162 (73.6%)
Eccentric	57 (25.9%)
Unknown	1 (0.5%)
Bend (degrees) (median/range)	18.0 (0.0 - 88.0)
Thrombus	1 (0.5%)
Tortuosity	
None	197 (89.5%)
Moderate	19 (8.6%)
Severe	3 (1.4%)

Characteristic	n (%) (N = 220[1] Lesions)
Unknown	1 (0.5%)
Ulcerated	1 (0.5%)
Calcification	
None/mild	37 (16.8%)
Moderate	56 (25.5%)
Severe	121 (55.0%)
Unknown	6 (2.7%)
Aneurysm present	0 (0.0%)
Ectasia present	7 (3.2%)
Side branch present	71 (32.3%)
Bifurcations, Medina type	
0,0,1	1 (0.5%)
0,1,0	39 (17.7%)
1,0,0	16 (7.3%)
1,0,1	1 (0.5%)
1,1,0	14 (6.4%)
RVD - user defined[3] (mm) (median/range)	2.9 (1.7 - 4.9)
Lesion length (mm) (median/range)	12.3 (4.2 - 45.9)
Focal ≤10 mm	70 (31.8%)
Long (>10 - 20 mm)	110 (50.0%)
Diffuse (>20 mm)	38 (17.3%)
Unknown	2 (0.9%)
MLD (mm) (median/range)	0.9 (0.0 - 2.3)
Diameter stenosis (%) (median/range)	67.6 (31.1 - 100.0)

[1] The number of lesions analyzed by the core lab (N = 220) differs from the number of lesions reported by the sites (N = 222) The sites reported two (2) target lesions in the same vessel for subjects 312-007 and 374-004 that the core lab measured as one contiguous lesion.

[2] CASS breakdowns by artery: right coronary artery, CASS 1-10; left main, CASS 11; left anterior descending, CASS 12-17 & 29; left circumflex,CASS 18-28.

[3] User defined is average of the proximal and distal reference vessel diameter.

A total of 228 Lacrosse NSE ALPHA devices were used to treat 220 lesions. The devices were inflated an average of 2 times per lesion with a median inflation pressure and inflation time of 10 atmospheres and 29.0 seconds, respectively.

The primary endpoint for the EXPANSE-PTCA study was device procedural success, defined as:

- Successful delivery, inflation, deflation, and withdrawal of the study balloon; and
- No evidence of device-related vessel perforation, flow limiting dissection (grade C or higher, per Clinical Events Committee (CEC) adjudication) or reduction in TIMI flow from baseline (per core laboratory assessment); and
- Final TIMI flow grade of 3 at the conclusion of the PCI procedure per core laboratory assessment.

The results for the primary endpoint are noted in Table 4.

Table 4: Summary of Primary Endpoint – Procedure Success (by Subject)

Characteristic	n (%) 90% CI (N=196)[1,5]
Met overall primary endpoint (procedure success)[2]	176 (89.8%) [85.5%, 93.1%]
Components of primary endpoint	
Successful delivery, inflation, deflation, and withdrawal of study balloon	176 (89.8%) [85.5%, 93.1%]
No evidence of device-related vessel perforation, device-related flow-limiting dissection, or reduction in TIMI flow from baseline[4]	195 (99.5%)[3] [97.6%, 100.0%]
Final TIMI flow grade of 3 at the conclusion of the PCI procedure[4]	195 (99.5%)[3] [97.6%, 100.0%]

[1] Four (4) subjects had no final TIMI assessed by either the core lab or the site so are not included in the assessment of primary endpoint. One of the four subjects was a "no-cross" subject.
[2] If a subject had greater than one target lesion, they needed to be a success in both lesions to be counted a study success.
[3] One subject had a reduction of TIMI flow and final TIMI II flow due to non-study device-related aortic dissection, with subsequent Q-wave myocardial infarction and periprocedural death.
[4] If final TIMI was not assessed by the core laboratory, due to missing imaging, site-reported data was used.
[5] Hypothesis testing for the primary endpoint was completed using a one-sided alpha level of 0.05. The 90% confidence interval is calculated using the Clopper-Pearson (Exact) method.

The study protocol defined a performance goal of 87.7% based on data from studies of comparable products. As shown in **Table 4,** the primary endpoint success rate (89.8%) was numerically higher than the performance goal (87.7%); however, the lower end of the 95% confidence interval was 85.5%, and therefore, the statistical objective was not metAll of the primary endpoint failures were due to failure of the technical component of the endpoint (successful delivery, inflation, deflation, and withdrawal of study balloon), specifically to inability to cross the study lesion. One subject also experienced reduction of TIMI flow and final TIMI II flow due to non-study device-related aortic dissection, with subsequent Q-wave myocardial infarction and periprocedural death.

A post-hoc lesion analysis was performed for "no-cross" cases. Based on the clinical review of the "no-cross" cases, a review of guide catheter extension usage was completed. The usage was analyzed to understand which lesions, at the discretion of the treating investigator, required additional guide catheter back up support for adequate delivery of devices. It was determined that additional guide catheter support may be needed for more complex procedures with severe lesion characteristics including calcification and tortuosity.

A guide catheter extension was involved in only 8.6% (17/197) of successfully crossed lesions and in 73.9% (17/23) of "no-cross" lesions. However, of these 17 "no-cross" lesions, the study device was not retried after placement of a guide catheter extension in 47.1% (8/17) of these lesions. (**Table 5**). Of the 21 no-cross subjects, lesions in 20 of the subjects were successfully crossed with an alternative device.

Table 5 Guide Catheter Extension Usage by Crossing Success (by Lesion)

Characteristic	Successful Crossing N=197 Lesions	"No-Cross" N=23[1] Lesions
Guide catheter extension used in procedure		
No	180 (91.4%)	6 (26.1%)

Yes	17 (8.6%)	17 (73.9%)
Was successful study device crossing achieved after placement of guide extension catheter?	**N = 17**	**N = 17**
Yes	13 (76.5%)	0 (0.0%)
No	0 (0.0%)	9 (52.9%)
NA – study device not retried after guide extension catheter placed	0 (0.0%)	8 (47.1%)
NA – study device crossed lesion prior to guide extension catheter use	4 (23.5%)	0 (0.0%)

[1] Two of the 21 "no-cross" subjects had 2 target lesions that were not crossed, resulting in n=23 "no-cross" lesions; in one lesion, the study device was tried but was unsuccessful in crossing, and in the other lesion, the study device was not tried after the initial "no-cross" of the first lesion.

Additional analysis of "no-cross" rates by lesion tortuosity and calcification was performed. Severely calcified lesions with any level of tortuosity had a 64.3% "no-cross rate" (9/14) compared to a 6.8% (14/206) "no-cross" rate in all other lesions. This analysis of core laboratory-assessed data showed that the presence of anatomical complexity was associated with no-cross occurrences. (**Table 6, Table 7**)

Table 6: "No-Cross" Rates by Tortuosity and Calcification (N=220 lesions)

		Tortuosity		
		None	**Moderate/Severe**	**Unknown**
Calcification	None/Mild	2.9% (1/35)	0.0% (0/2)	--
	Moderate	8.0% (4/50)	0.0% (0/6)	--
	Severe	8.4% (9/107)	64.3% (9/14)	--
	Unknown	0.0% (0/5)	--	0.0% (0/1)

Table 7: Lesion "No-Cross" Rates by Tortuosity/Calcification Subgroup

Subgroup	N	"No-Cross" Rate
Severely calcified and tortuous lesions	14	64.3% (9/14)
All other lesions	206	6.8% (14/206)

A summary of secondary endpoint data is provided in **Table 8.**

Table 8: Summary of Secondary Endpoints

Endpoint	N	n (%)
Angiographic procedural success (final diameter stenosis ≤50% in at least one of the NSE ALPHA attempted lesions following completion of the procedure[2]	197 subjects[1]	197 (100.0%)
Increase in MLD following use of NSE ALPHA[2]	158 lesions[4]	158 (100.0%)
Increase in MLD at the end of the procedure by target lesion[2, 3]	208 lesions[4]	208 (100.0%)
MACE through hospital discharge	200 subjects	1 (0.5%)
Death, all-cause	200 subjects	1 (0.5%)
Myocardial infarction	200 subjects	1 (0.5%)

Endpoint	N	n (%)
Clinically indicated target lesion revascularization	200 subjects	0 (0.0%)
Stent thrombosis through hospital discharge	200 subjects	0 (0.0%)
Clinically significant arrhythmia through hospital discharge	200 subjects	4 (2.0%)
Occurrence of NSE ALPHA rupture	200 subjects	1 (0.5%)
Device procedural success by target lesion	216 lesions[5]	193 (89.4%)

[1] Three subjects were missing final diameter stenosis (both core lab and site data).
[2] If final diameter stenosis or MLD was not assessed by the core laboratory, due to missing imaging, site-reported data was used.
[3] Additional analysis of MLD at the end of the procedure is included, due to the missing data at the post-study device time point.
[4] Reference available number of lesions as indicated in Table 18.
[5] Includes only those lesions in the subjects included in the primary endpoint analysis (N=196 subjects)

Angiographic procedural success was seen in 100.0% of subjects, and the overall decrease in diameter stenosis was 67.6% (pre-procedure) to 38.5% after study device use. Dilation with the study device was associated with improvement in median minimum lumen diameter from 0.9 mm to 1.7 mm after study device use. (**Table 9**)

Table 9: Minimum Lumen Diameter & Diameter Stenosis (by Lesion, per Core Lab)

Timepoint	Number of Lesions	Diameter Stenosis (%)	Minimum Lumen Diameter (mm)
Pre-procedure	219	67.6 (31.1 - 100.0)	0.9 (0.0 - 2.3)
Post-study device	158	38.5 (2.7 - 60.8)	1.7 (1.0 - 3.2)
Final	208	11.6 (2.1 - 25.5)	2.6 (1.7 - 4.1)
Values presented as median (min, max)			

Adverse Events

A summary of adverse events (AEs) is provided in **Table 10**. A total of 57 AEs were reported in 46 subjects. There were no unanticipated adverse device effects (UADEs). In total, 20 events in 17 subjects (8.5%) were serious, of which 14 events were procedure-related, 1 event was both device- and procedure-related, and 5 were not related.

Table 10: Summary of Adverse Events

Characteristic	Number of AEs	Subjects (%) with AE (N=200)
All AEs	57	46 (23.0%)
Unanticipated adverse device effects (UADE)	0	0 (0.0%)
Serious	20	17 (8.5%)
Procedure-related only	14	12 (6.0%)
Device-related only	0	0 (0.0%)
Device- and procedure-related	1	1 (0.5%)
Not procedure or device related	5	5 (2.5%)
Non-serious	37	32 (16.0%)
AEs by relationship to device		
Related	6	6 (3.0%)

Not related	51	40 (20.0%)
AEs by relationship to procedure		
Related	47	42 (21.0%)
Not related	10	10 (5.0%)
AEs by outcome		
Resolved	53	43 (21.5%)
Death	2[1]	1 (0.5%)
Resolved with sequelae	2	1 (0.5%)
Ongoing	0	0 (0.0%)
Ongoing at study completion	0	0 (0.0%)

[1] One subject had 2 adverse events that contributed to death outcome.

Device-Related AEs

Of the six AEs that were related to the study device, all were coronary arterial dissections. None of the device-related dissection AEs were flow-limiting. Five of the six dissections were non-serious and one dissection was adjudicated by the clinical events committee (CEC) as anatomically serious due to its proximal location, although it resulted in no short- or long-term clinical events. A summary of all AEs by diagnosis and seriousness (ordered by percent of total subjects with the event) is provided in **Table 11**.

Table 11: Adverse Events by Diagnosis & Seriousness

	Non-serious		Serious		Total	
Diagnosis	**No. of AEs**	**Number (%) of Subjects with AE (N=200)**	**No. of AEs**	**Number (%) of Subjects with AE (N=200)**	**No. of AEs**	**Number (%) of Subjects with AE (N=200)**
Total events[1]	**37**	**28 14.0%)**	**20**	**20 10.0%)**	**57**	**46 23.0%)**
Arterial dissection	17	17 8.5%)	4	4 2.0%)	21	21 10.5%)
Hematoma, access site, >5 cm	3	3 1.5%)	2	2 1.0%)	5	5 2.5%)
Blood loss from puncture site	2	2 1.0%)	2	2 1.0%)	4	4 2.0%)
Chest pain, non-cardiac	2	2 1.0%)	1	1 0.5%)	3	3 1.5%)
Hypotension	1	1 0.5%)	2	2 1.0%)	3	3 1.5%)
Arrhythmia, bradycardia	0	0 0.0%)	2	2 1.0%)	2	2 1.0%)
Arrhythmia, other	0	0 0.0%)	1	1 0.5%)	1	1 0.5%)
Arrhythmia, tachycardia	1	1 0.5%)	0	0 0.0%)	1	1 0.5%)
Arterial perforation	0	0 0.0%)	1	1 0.5%)	1	1 0.5%)
Hypertension	0	0 0.0%)	1	1 0.5%)	1	1 0.5%)
Myocardial infarction	0	0 0.0%)	1	1 0.5%)	1	1 0.5%)
Nausea or vomiting	1	1 0.5%)	0	0 0.0%)	1	1 0.5%)
Other, specify	10	9 4.5%)	3	3 1.5%)	13[2]	12 6.0%)

[1] Columns may not add to total as subjects may have experienced more than one event.
[2] Includes plaque shift (n=3), chest pain (n=2), groin pain (n=2), and 1 each of arterial occlusion, ecchymosis, hematemesis, shortness of breath, urinary retention, and vasovagal event.

Compliance Chart of NSE ALPHA

Inflation Pressure		Balloon Diameter (mm)							
atm	kPa	2.00mm	2.25mm	2.50mm	2.75mm	3.00mm	3.25mm	3.50mm	4.00mm
4	4x10²	1.87	2.14	2.32	2.51	2.69	3.02	3.16	3.58
5	5x10²	1.91	2.18	2.38	2.56	2.75	3.08	3.24	3.67
6	**6x10²**	**1.95**	**2.22**	**2.44**	**2.60**	**2.82**	**3.14**	**3.32**	**3.77**
7	7x10²	1.99	2.26	2.50	2.66	2.88	3.20	3.39	3.86
8	8x10²	2.03	2.30	2.55	2.70	2.94	3.25	3.46	3.94
9	9x10²	2.06	2.34	2.60	2.74	2.98	3.30	3.52	4.02
10	10x10²	2.09	2.38	2.64	2.78	3.03	3.33	3.55	4.07
11	11x10²	2.12	2.41	2.67	2.81	3.06	3.36	3.60	4.12
12	12x10²	2.16	2.44	2.70	2.84	3.10	3.38	3.64	4.15
13	13x10²	2.19	2.46	2.72	2.86	3.13	3.41	3.67	4.19
14	**14x10²**	**2.21**	**2.49**	**2.75**	**2.88**	**3.15**	**3.43**	**3.70**	**4.22**
15	15x10²	2.24	2.51	2.76	2.91	3.17	3.46	3.73	4.25
16	16x10²	2.27	2.53	2.79	2.93	3.20	3.48	3.76	4.28

Nominal Pressure Rated Burst Pressure (Do not exceed)

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Infraredx, Inc.
28 Crosby Drive, Suite 100
Bedford, MA 01730 USA

REF	Catalogue number		Contains hazardous substances
LOT	Batch code	UDI	Unique device identifier
	Use-by date	MD	Medical device
	Date of manufacture		Manufacturer
	Do not re-use	JP	Country of manufacture
STERILIZE	Do not resterilize	EC REP	Authorized representative in the European Community
	Consult instructions for use		Importer

STERILE EO	Sterilized using ethylene oxide		Distributor
	Keep dry	Ø	Balloon diameter
	Keep away from sunlight		Balloon length
Rx only	Caution : US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	CH REP	Authorised representative in Switzerland
	Do not use if package is damaged		Single sterile barrier system
			Single sterile barrier system with protective packaging outside

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