

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Carotid Stent System

Device Trade Name: XACT™ Carotid Stent System

Device Procode: NIM

Applicant's Name and Address: Abbott Medical
3200 Lakeside Drive
Santa Clara, CA 95054

Date of Panel Recommendation: None

Date of FDA Notice of Approval: TBA

The original PMA P040038 was approved on September 6, 2005 and is indicated for use in conjunction with the Abbott Vascular Devices embolic protection system for the improvement of the lumen diameter of carotid arteries in patients considered at high risk for adverse events from carotid endarterectomy who require percutaneous carotid angioplasty and stenting for occlusive artery disease and meet the criteria outlined below:

- Patients with carotid artery stenosis $\geq 50\%$ for symptomatic patients by ultrasound or angiography or $\geq 80\%$ for asymptomatic patients by ultrasound or angiography) located between the origin of the common carotid artery and the intracranial segment of the internal carotid artery AND
- Patients must have a reference vessel diameter ranging between 4.8 mm and 9.1 mm at the target lesion.

The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indication for use with other compatible embolic protection devices and a transcarotid approach.

II. INDICATIONS FOR USE

The XACT™ Carotid Stent System (XACT), used in conjunction with compatible Embolic Protection Systems and via appropriate access approach, such as transfemoral and transcarotid approach, is indicated for the improvement of the lumen diameter of carotid arteries in patients considered at high risk for adverse events from carotid endarterectomy who require percutaneous carotid angioplasty and stenting for occlusive artery disease and meet the criteria outlined below:

- Patients with carotid artery stenosis ($\geq 50\%$ for symptomatic patients by ultrasound or angiography or $\geq 80\%$ for asymptomatic patients by ultrasound or

angiography) located between the origin of the common carotid artery and the intracranial segment of the internal carotid artery AND

- Patients must have a reference vessel diameter ranging between 4.8 mm and 9.1 mm at the target lesion.

III. **CONTRAINDICATIONS**

Contraindications associated with angioplasty must be considered when using the XACT Carotid Stent System. These include, but are not limited to:

- Patients in whom anticoagulant and / or antiplatelet therapy is contraindicated.
- Patients with a known allergy or hypersensitivity to stent materials (nickel-titanium alloy) or contrast medium, who cannot be adequately premedicated.
- Patients with uncorrected bleeding disorders.
- Patients in whom carotid bifurcation is less than 5 cm above the clavicle (ENROUTE Transcarotid NPS only)

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the XACT Carotid Stent System device labeling.

V. **DEVICE DESCRIPTION**

The XACT Carotid Stent System is comprised of a delivery system and a self-expanding stent. The delivery system is a rapid exchange (RX) system designed to deliver the self-expanding stent to the carotid vasculature.

Stent

The self-expanding stent is cut from a Nitinol tube into a flexible tubular prosthesis. Upon deployment of the stent into the carotid vasculature via the delivery system, the stent should appose the vessel wall and apply an outward pressure to establish patency. The XACT stent is available in tapered and straight configurations (Figures 1 and 2), with diameters ranging from 6 mm to 10 mm. Stent lengths range from 20 mm to 40 mm. Refer to Table 1 below for the XACT Carotid Stent System size matrix.

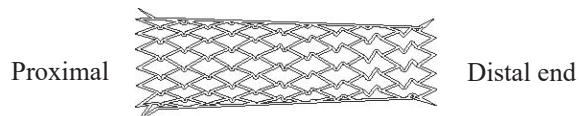


Figure 1: Tapered Stent

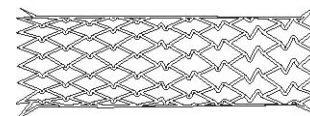


Figure 2: Straight Stent

Table 1: XACT Carotid Stent System Size Matrix

XACT Carotid Stent System				
Stent Outside Diameter	Proximal Outside Diameter	Distal Outside Diameter	Stent Length	Stent Configuration
7mm	7mm	7mm	20mm	Straight
8mm	8mm	8mm	20mm	Straight
9mm	9mm	9mm	20mm	Straight
10mm	10mm	10mm	20mm	Straight
7mm	7mm	7mm	30mm	Straight
8mm	8mm	8mm	30mm	Straight
9mm	9mm	9mm	30mm	Straight
10mm	10mm	10mm	30mm	Straight
8mm	8mm	6mm	30mm	Tapered
9mm	9mm	7mm	30mm	Tapered
10mm	10mm	8mm	30mm	Tapered
8mm	8mm	6mm	40mm	Tapered
9mm	9mm	7mm	40mm	Tapered
10mm	10mm	8mm	40mm	Tapered

Delivery System

The delivery system has an outer diameter (OD) of 5.7 Fr. It is compatible with an 8 Fr guiding catheter or a 6 Fr sheath - with a 0.088" inner diameter or greater. The delivery system has a working length of 136 cm. See Figure 3 for a graphical depiction of the XACT Stent System. The delivery system is comprised of a tip (5), distal outer sheath (3), catheter shaft (9), and stabilizer (11). The distal outer sheath houses the crimped XACT stent (7). At the proximal end of the distal outer sheath is the guide wire exit port (10). The proximal portion of the shaft and stabilizer connects the delivery system to the handle (1). The stabilizer (11) works with the hemostatic valve on the guiding catheter / sheath to help improve stent placement accuracy during deployment.

The inner system assembly consists of a tip (5) installed over a 0.014" guide wire compatible guide wire lumen (4). The guide wire lumen (4) is flushed via the tip (5) using the flushing tip. For more detailed instructions on device flushing, see the section entitled Delivery System Preparation in this document. The crimped XACT stent is constrained between the guide wire lumen (4) and the distal outer sheath (3). Radiopaque marker bands on the delivery system are located at the proximal (8) and distal (6) ends of the stent. Prior to deployment, these radiopaque markers are used as guides to position the stent.

Deployment of the XACT stent is achieved by grasping the handle (1) and rotating the deployment actuator (2) in a clockwise direction. See section 8.7, entitled Stent Deployment, for detailed instructions on deploying the stent.

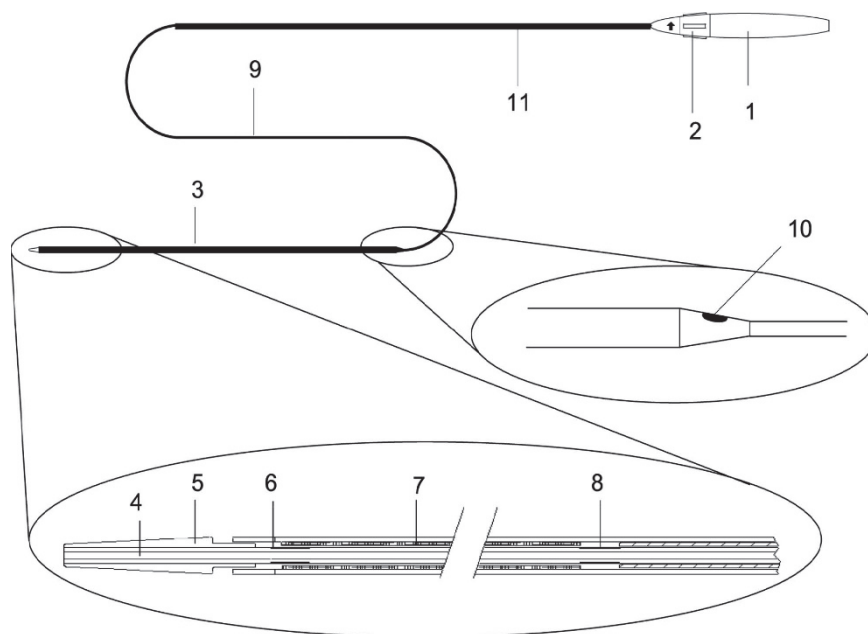


Figure 3: XACT RX Carotid Stent System

1	Handle	7	Xact Stent
2	Deployment Actuator	8	Radiopaque Proximal Marker
3	Distal Outer Sheath	9	Catheter Shaft
4	Guidewire Lumen	10	Guide Wire Exit Port
5	Tip	11	Stabilizer
6	Radiopaque Distal Marker		

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are other alternatives for the treatment of carotid artery disease. These include medical therapy, surgical revascularization (carotid endarterectomy (CEA) to remove plaque), or endovascular revascularization through carotid artery stenting. Medical therapy can also include modification of lifestyle risk factors for stroke, such as cigarette smoking and alcohol use. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The XACT Carotid Stent System has been commercially available in the United States since November 2005. It is also available for sale in over 50 countries outside of the

United States including the European Union, Middle East, Asia Pacific, Latin America and Africa. These countries are:

ALBANIA	COSTA RICA	IRELAND	NETHERLANDS	SERBIA
ARGENTINA	CYPRUS	ISRAEL	NORTHERN IRELAND	SINGAPORE
AUSTRALIA	CZECH REPUBLIC	ITALY	NORWAY	SLOVAKIA
AUSTRIA	DOMINICAN REPUBLIC	JORDAN	PALESTINE	SLOVENIA
BAHRAIN	FRANCE	KAZAKHSTAN	PANAMA	SOUTH AFRICA
BELARUS	GEORGIA	LATVIA	PERU	SPAIN
BELGIUM	GERMANY	LEBANON	POLAND	SWEDEN
BRAZIL	GREECE	LIBYA	PORTUGAL	SWITZERLAND
BULGARIA	HUNGARY	LITHUANIA	PUERTO RICO	TAIWAN
CANADA	INDIA	MACEDONIA	REPUBLIC OF ARMENIA	TURKEY
CHILE	INDONESIA	MALAYSIA	ROMANIA	UNITED ARAB EMIRATES
CHINA	IRAN	MALTA	RUSSIAN FEDERATION	UNITED KINGDOM
COLOMBIA	IRAQ	MEXICO	SAUDI ARABIA	VIETNAM

The XACT Carotid Stent System has not been withdrawn from marketing in any country for any reason related to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS ON THE DEVICE ON HEALTH

As reported in the literature, the following adverse events are potentially associated with carotid stents and embolic protection systems:

- Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, stent materials (nitinol, nickel, titanium), and drug reactions to anticoagulation, or antiplatelet drugs
- Vascular access complications which may require transfusion or vessel repair, including:
 - Catheter site reactions
 - Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage)
 - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, and laceration
 - Embolism (air, tissue, plaque, thrombotic material or device)
 - Thrombophlebitis
- Target artery complications which may require additional intervention, including:
 - Total occlusion or abrupt closure

- Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture
- Embolism (air, tissue, plaque, thrombotic material or device)
- Artery, stent, or filter thrombosis / occlusion thrombosis
- Stenosis or restenosis
- Vessel spasm or recoil
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
- Cardiac ischemic conditions (including myocardial ischemia, myocardial infarction, and unstable or stable angina pectoris)
- Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA)
- System organ failure:
 - Cardio-respiratory arrest
 - Cardiac failure
 - Cardiopulmonary failure (including pulmonary edema)
 - Renal failure / insufficiency
 - Shock
- Bleeding
- Blood cell disorders, including Heparin-induced thrombocytopenia (HIT) and other coagulopathy
- Hypotension / hypertension
- Peripheral nerve injury
- Other ischemic conditions / infarct
- Infection – local and systemic (including post-procedural)
- Nausea and vomiting
- Chest pain
- Dyspnea
- Edema / cerebral edema and fluid overload
- Fever
- Pain, including headache
- Hyperperfusion syndrome
- Other neurologic and systemic complications
 - Seizure
- Cerebral hemorrhage
- Death
- Device-related complications which may require additional intervention, including:
 - Detachment and / or implantation of a component of the system
 - Stent / filter entanglement / damage
 - Stent malposition
 - Stent migration / embolization
- Emergent or urgent endarterectomy surgery (CEA)

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

A summary of previously reported preclinical studies can be found in the SSED for the original PMA. These previously collected data sufficiently represent the performance of the device for the new indications for use, therefore no new verification testing was conducted. Simulated use design validation was performed to evaluate the compatibility, functionality (delivery, deployment, and retraction to the intended deployment location), and acceptability of the user interface under conditions simulating physiologic and anatomic conditions of the carotid stenting procedure when the XACT is used in conjunction with the ENROUTE Transcarotid Neuroprotection System (ENROUTE NPS). Table 2 contains a summary of the simulated use testing.

Table 2. XACT Simulated Use Test Description, Acceptance Criteria and Results

Test Description	Acceptance Criteria	Results
Ability to deliver the device to the intended deployment location	The user can deliver the device to the intended location	Pass
Ability to deploy the device at the intended location	The user can deploy the device at the intended location	Pass
Ability to remove the device delivery system post deployment	The user can remove the device delivery system post deployment	Pass
Compatibility with the ENROUTE sheath	The user determines that the device was compatible with the ENROUTE sheath during delivery and removal	Pass
User expected functionality	The user experiences the expected functionality of the device during device transit thru the ENROUTE sheath	Pass
Accuracy of deployment was characterized by identifying the target deployment location and measuring the post deployment location relative to the target location using a pre-defined coordinate system. Femoral access was compared to transcarotid artery revascularization (TCAR) access	For characterization only	The absolute difference in deployment accuracy between the two groups, normalized by stent length, was approximately 1%

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant utilized real-world data (RWD) housed in the CREST-2 Registry (C2R) to conduct analyses presented to support the transcarotid approach using the ENROUTE NPS system. The analyses establish real-world evidence (RWE) to provide reasonable assurance of the safety and effectiveness of the XACT Stent System in high surgical risk patients during transcarotid artery revascularization (TCAR) procedures. Reasonable assurance of safety and effectiveness was demonstrated through an analysis of patient-level data from the carotid artery stenting (CAS) and carotid endarterectomy (CEA) registry of the C2R.

The C2R was approved by NINDS-NIH in September 2014 and initiated on September 17, 2014 to credential interventionalists and obtain more data on carotid artery revascularization in patients with high surgical risk in the US. There are 103 sites participating in the C2R. A summary of the clinical data is presented below.

A. Study Design

The XACT / ENROUTE Transcarotid Neuroprotection System (ENROUTE NPS) data analysis project was a retrospective analysis of data from the C2R with patient-level data for XACT / ENROUTE NPS cases. The objective was to assess the safety and performance of the XACT stent with the transcarotid artery revascularization (TCAR) approach with flow reversal procedure using the ENROUTE NPS, in treatment of patients with symptomatic or asymptomatic carotid artery disease in the C2R. There were no pre-specified endpoints in the C2R. The study leadership collected a monthly report from sites on the following adverse events based on the study protocol: stroke or TIA; myocardial infarction; death, bleeding.

1. Clinical Inclusion and Exclusion Criteria

Patients in C2R were required to meet one or more of the inclusion criteria and have none of the exclusion criteria listed below. The analyses included any subject treated with the XACT stent in conjunction with the ENROUTE NPS. The assessment of surgical risk for CEA was determined based on anatomic and/or physiologic criteria. High anatomic risk for CEA was defined as having one or more of the following factors: prior ipsilateral CEA, contralateral ICA occlusion, laryngeal nerve palsy, lesion above C2, lesion below clavicle, prior neck radiation, stoma in neck, prior radical neck surgery, cervical immobility, or tandem ICA stenosis > 70%. High physiologic risk for CEA was defined as having one or more of the following factors: age ≥ 75 years, CHF class 3 A – 4, LVEF < 30%, severe angina, coronary artery disease in ≥ 2 vessels, myocardial infarction < 6 weeks prior to procedure, severe pulmonary disease, chronic kidney disease (creatinine > 2.5 mg/dL), need heart surgery, or need major surgery. Patients who had one or more high anatomic risk factors and/or high physiologic risk factors were considered as high surgical risk for CEA. Patients who did not have any high anatomic risk factors or high physiological risk factors were considered as standard surgical risk for CEA.

Enrollment in the registry was limited to patients who met the following inclusion criteria:

Asymptomatic patients

Age ≥ 18 and ≤ 80 and any one of the following:

1. $\geq 70\%$ stenosis, standard surgical risk for CEA
2. $\geq 70\%$ stenosis, high anatomic risk for CEA
3. $\geq 70\%$ stenosis, high physiologic risk for CEA

Symptomatic patients

Symptomatic patients are defined by the following characteristics: Ipsilateral carotid Transient Ischemic Attack (TIA), with neurologic symptoms persisting less than 24 hours; Ipsilateral non-disabling stroke: Modified Rankin Scale (mRS) ≤ 3 ; and Ipsilateral transient monocular blindness: amaurosis fugax. [Source: current Medicare NCD for CAS]

Age ≥ 18 and ≤ 80 and any one of the following:

1. $\geq 50\%$ stenosis, standard surgical risk for CEA
2. 50% to 69% stenosis, high anatomic risk for CEA
3. 50% to 69% stenosis, high physiologic risk
4. $\geq 70\%$ stenosis, high anatomic and / or physiologic risk for CEA
5. $\geq 70\%$ stenosis, post-CEA and –CAS - currently covered by Medicare, but sites are strongly encouraged to voluntarily include these patients in C2R
6. $\geq 70\%$ stenosis, post-irradiation - currently covered by Medicare, but sites are strongly encouraged to voluntarily include these patients in C2R

Patients were excluded from the registry study if they met any of the following exclusion criteria:

1. NYHA Class IV CHF
2. COPD on chronic continuous oxygen therapy
3. Severe (Childs Class D) liver failure
4. Cancer with metastatic spread and / or undergoing active chemotherapeutic treatment
5. Any dementia considered greater than “mild”

2. Follow-up Schedule

This project was a retrospective analysis of data from the C2R. The data collection included the following time points: at baseline, during or immediately post-procedure, at hospital discharge, and at 30 days post procedure.

3. Clinical Endpoints

There was no primary endpoint or formal hypothesis testing. Patient baseline characteristics, lesion and vessel characteristics, procedural outcomes and clinical safety outcomes (i.e. stroke, death or myocardial infarction for the in-hospital period and through 30 days post-procedure) were assessed using descriptive statistics. Outcomes were analyzed on an as-treated basis with no pre-defined patient censoring.

B. Accountability of PMA Cohort

From study start of September 17, 2014 through cutoff date of November 18, 2022, C2R study personnel reported that a total of 39 subjects at 9 investigational sites had been treated with the XACT stent system by TCAR approach using the ENROUTE NPS. No subjects were excluded, withdrawn or censored by C2R study personnel or by Abbott.

The analysis population was comprised of the complete XACT / ENROUTE NPS patient cohort in the C2R study as of the cutoff date.

C. Study Population Demographics and Baseline Parameters

The demographics of the analysis population are typical for a carotid artery stenting (CAS) study performed in the US. The baseline patient characteristics for the XACT / ENROUTE NPS patients are summarized in Table 3. For symptomatic carotid artery disease patients (N = 22), asymptomatic carotid artery disease patients (N = 17) and the overall population (N = 39), median age was 73.5 years, 70.0 years and 72.0 years, respectively. Female gender was 63.6%, 64.7% and 64.1%, respectively. There was a high prevalence of baseline hypertension (95.2%, 87.5% and 91.9%, respectively) and high surgical risk for carotid endarterectomy (CEA) (90.9%, 82.4% and 87.2%, respectively). The incidence of patients with prior CEA or CAS procedures was 22.7%, 52.9% and 35.9%, respectively.

Table 3: Patient Baseline Characteristics (Per-Subject Analysis)

Characteristic	Symptomatic (N=22)	Asymptomatic (N=17)	Overall (N=39)
Age (years)			
Mean $\pm$ SD (n)	73.6 $\pm$ 11.6 (22)	71.8 $\pm$ 7.0 (17)	72.8 $\pm$ 9.8 (39)
Median (Q1, Q3)	73.5 (63.0, 85.0)	70.0 (66.0, 78.0)	72.0 (64.0, 83.0)
Range (min, max)	(54, 90)	(61, 84)	(54, 90)
Sex			
Female	63.6% (14/22)	64.7% (11/17)	64.1% (25/39)
Baseline Diabetes	18.2% (4/22)	11.8% (2/17)	15.4% (6/39)
Baseline Hypertension	95.2% (20/21)	87.5% (14/16)	91.9% (34/37)
Baseline CAD	27.3% (6/22)	23.5% (4/17)	25.6% (10/39)
Smoking History			
Never	18.2% (4/22)	5.9% (1/17)	12.8% (5/39)
Prior	45.5% (10/22)	41.2% (7/17)	43.6% (17/39)
Current	36.4% (8/22)	52.9% (9/17)	43.6% (17/39)
Prior CEA/CAS /	22.7% (5/22)	52.9% (9/17)	35.9% (14/39)
High risk for CEA	90.9% (20/22)	82.4% (14/17)	87.2% (34/39)

The baseline anatomical characteristics of symptomatic patients, asymptomatic patients and the overall population of the XACT / ENROUTE NPS analysis are summarized in Table 4 on a per-lesion basis. Right side lesions comprised 34.8%, 35.0% and 34.9%, respectively, and internal carotid artery (ICA) lesion location was 56.5%, 55.0% and 55.8%, respectively. Operator assessed lesion stenosis was 85.7%, 83.8% and 84.7%, respectively, and operator assessed lesion length was 29.0 mm, 17.9 mm and 24.1 mm, respectively.

Table 4: Patient Anatomical Characteristics (Per-Lesion Analysis)

Characteristic	Symptomatic (N=22) (L=23)	Asymptomatic (N=17) (L=20)	Overall (N=39) (L=43)
Lesion Side			
Right	34.8% (8/23)	35.0% (7/20)	34.9% (15/43)
Lesion Location¹			
Bifurcation	34.8% (8/23)	35.0% (7/20)	34.9% (15/43)
CCA	8.7% (2/23)	15.0% (3/20)	11.6% (5/43)
ICA	56.5% (13/23)	55.0% (11/20)	55.8% (24/43)
Lesion Stenosis (%)			
Mean $\pm$ SD (I)	85.7 $\pm$ 10.6 (18)	83.8 $\pm$ 11.6 (17)	84.7 $\pm$ 11.0 (35)
Median (Q1, Q3)	87.5 (76.0, 95.0)	85.0 (80.0, 90.0)	85.0 (80.0, 91.0)
Range (min, max)	(70, 99)	(50, 99)	(50, 99)
Lesion Length (mm)			
Mean $\pm$ SD (I)	29.0 $\pm$ 16.3 (15)	17.9 $\pm$ 6.7 (12)	24.1 $\pm$ 13.9 (27)
Median (Q1, Q3)	30.0 (15.0, 35.0)	17.5 (11.5, 23.5)	20.0 (15.0, 30.0)
Range (min, max)	(10, 70)	(10, 30)	(10, 70)

¹ There can be more than one location within one lesion.

D. Safety and Effectiveness Results

1. Safety Results

The clinical safety outcomes of symptomatic patients, asymptomatic patients and the overall population of the XACT / ENROUTE NPS analysis are summarized in Table 5 for the in-hospital period and through 30 days post-procedure. In the overall population there were a total of 4 stroke, death or myocardial infarction events occurring in 3 patients over the 30-day follow-up period. Through 30 days in the overall population, the stroke or death rate was 5.1% (2/39) and the stroke, death or myocardial infarction rate was 7.7% (3/39). Of these subjects, one subject had a myocardial infarction before hospital discharge; one subject had a myocardial infarction and stroke, both occurring before hospital discharge; one subject died 13 days after procedure during a long hospitalization. No safety events occurred after hospital discharge.

Table 5: Safety Outcomes (Per-Subject Analysis)

Characteristic	Symptomatic (N=22)	Asymptomatic (N=17)	Overall (N=39)
In-Hospital			
Stroke, Death or Myocardial Infarction	9.1% (2/22)	5.9% (1/17)	7.7% (3/39)
Stroke or Death	9.1% (2/22)	0.0% (0/17)	5.1% (2/39)
Stroke	4.5% (1/22)	0.0% (0/17)	2.6% (1/39)
Death	4.5% (1/22)	0.0% (0/17)	2.6% (1/39)

Characteristic	Symptomatic (N=22)	Asymptomatic (N=17)	Overall (N=39)
Myocardial Infarction	4.5% (1/22)	5.9% (1/17)	5.1% (2/39)
0-30 Days			
Stroke, Death or Myocardial Infarction	9.1% (2/22)	5.9% (1/17)	7.7% (3/39)
Stroke or Death	9.1% (2/22)	0.0% (0/17)	5.1% (2/39)
Stroke	4.5% (1/22)	0.0% (0/17)	2.6% (1/39)
Death	4.5% (1/22)	0.0% (0/17)	2.6% (1/39)
Myocardial Infarction	4.5% (1/22)	5.9% (1/17)	5.1% (2/39)

The observed incidences of stroke, MI, and/or death adverse events are not unexpected for this patient population, considering that the majority (87.2% = 34/39) of the patients treated with the XACT stent and ENROUTE Neuroprotection System were “high risk” for carotid endarterectomy, prior CEA or CAS procedures had been performed in 35.9% (14/39) of subjects, subjects median age was 72.0 years, and that TCAR patients frequently have clinical and/or anatomic features that would have made them poor candidates for carotid artery stenting using traditional access routes.

2. Effectiveness Results

The procedural outcomes of symptomatic patients, asymptomatic patients, and the overall population of the XACT / ENROUTE NPS analysis are summarized in Table 6. Number of stents used per patient was 1.3 ± 0.5 , 1.2 ± 0.4 and 1.3 ± 0.4 , respectively, and total stent length was 41.3 ± 14.7 mm, 38.4 ± 10.4 mm and 40.0 ± 12.9 mm, respectively. Flow reversal time mediated through the ENROUTE NPS Flow Controller was 14.69 ± 6.74 min, 18.42 ± 17.55 min and 16.55 ± 12.82 min, respectively. The total procedure time (72.9 ± 25.3 min, 113.2 ± 62.5 min and 89.0 ± 47.5 min, respectively) and contrast volume (75.2 ± 60.4 mL, 119.6 ± 83.8 mL and 95.5 ± 74.4 mL, respectively) were higher for asymptomatic patients, but fluoroscopy time (7.8 ± 3.9 min, 8.2 ± 3.0 min and 8.0 ± 3.5 min, respectively) did not show differences across patient symptom status. Technical success, defined as ability to access the common carotid artery (CCA), cross the lesion and deploy the stent as intended, was 100%. There were no reports of procedural complications involving failure to remove the delivery system or the ENROUTE NPS from the patient anatomy.

Table 6: Procedural Outcomes

Characteristic	Symptomatic (N=22) (L=23)	Asymptomatic (N=17) (L=20)	Overall (N=39) (L=43)
Per-Subject Analysis			
Number of Stents Used			
Mean $\pm$ SD (n)	1.3 ± 0.5 (22)	1.2 ± 0.4 (17)	1.3 ± 0.4 (39)
Median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)
Range (min, max)	(1, 2)	(1, 2)	(1, 2)
Maximum Stent Diameter (mm)			
Mean $\pm$ SD (n)	7.4 ± 1.2 (22)	7.2 ± 1.2 (17)	7.3 ± 1.2 (39)

Characteristic	Symptomatic (N=22) (L=23)	Asymptomatic (N=17) (L=20)	Overall (N=39) (L=43)
Median (Q1, Q3)	7.0 (6.0, 8.0)	7.0 (6.0, 8.0)	7.0 (6.0, 8.0)
Range (min, max)	(6, 10)	(6, 10)	(6, 10)
Total Stent Length (mm)			
Mean $\pm$ SD (n)	41.3 $\pm$ 14.7 (22)	38.4 $\pm$ 10.4 (17)	40.0 $\pm$ 12.9 (39)
Median (Q1, Q3)	35.0 (30.0, 50.0)	40.0 (30.0, 40.0)	40.0 (30.0, 40.0)
Range (min, max)	(30, 70)	(20, 62)	(20, 70)
Flow Reversal Time (min)			
Mean $\pm$ SD (n)	14.69 $\pm$ 6.74 (6)	18.42 $\pm$ 17.55 (6)	16.55 $\pm$ 12.82 (12)
Median (Q1, Q3)	13.06 (12.00, 18.00)	11.75 (10.00, 19.00)	13.00 (10.25, 18.50)
Range (min, max)	(6.00, 26.00)	(5.00, 53.00)	(5.00, 53.00)
Total Procedure Time (min)			
Mean $\pm$ SD (n)	72.9 $\pm$ 25.3 (18)	113.2 $\pm$ 62.5 (12)	89.0 $\pm$ 47.5 (30)
Median (Q1, Q3)	68.0 (54.0, 89.0)	88.5 (79.0, 120.0)	81.0 (61.0, 99.0)
Range (min, max)	(37, 119)	(51, 258)	(37, 258)
Contrast Volume (mL)			
Mean $\pm$ SD (n)	75.2 $\pm$ 60.4 (19)	119.6 $\pm$ 83.8 (16)	95.5 $\pm$ 74.4 (35)
Median (Q1, Q3)	60.0 (26.0, 140.0)	125.0 (41.0, 150.0)	75.0 (30.0, 150.0)
Range (min, max)	(1, 200)	(15, 320)	(1, 320)
Fluoroscopy Time (min)			
Mean $\pm$ SD (n)	7.84 $\pm$ 3.89 (16)	8.21 $\pm$ 2.99 (10)	7.98 $\pm$ 3.51 (26)
Median (Q1, Q3)	7.85 (5.10, 8.70)	7.25 (5.70, 10.20)	7.65 (5.40, 9.10)
Range (min, max)	(3.9, 20.5)	(5.0, 13.7)	(3.9, 20.5)
Technical Success	100.0% (22/22)	100.0% (17/17)	100.0% (39/39)
Per-Lesion Analysis			
Maximum Stent Diameter (mm)¹			
Mean $\pm$ SD (I)	7.3 $\pm$ 1.2 (23)	7.1 $\pm$ 1.2 (18)	7.2 $\pm$ 1.2 (41)
Median (Q1, Q3)	7.0 (6.0, 8.0)	7.0 (6.0, 8.0)	7.0 (6.0, 8.0)
Range (min, max)	(6, 10)	(6, 10)	(6, 10)
Total Stent Length (mm)¹			
Mean $\pm$ SD (I)	39.5 $\pm$ 13.3 (23)	36.2 $\pm$ 9.0 (18)	38.0 $\pm$ 11.6 (41)
Median (Q1, Q3)	30.0 (30.0, 40.0)	40.0 (30.0, 40.0)	40.0 (30.0, 40.0)
Range (min, max)	(30, 70)	(20, 60)	(20, 70)

¹ Length and diameter data only available for 41/43 lesions.

Data collection rates were high for baseline patient and anatomical characteristics, but were somewhat lower for procedural outcomes, particularly for flow reversal time (12 out of 39 patients). The maximum observed flow reversal time was 53 minutes in a patient who had 2 lesions treated and who experienced a myocardial infarction during the in-hospital period. The next highest flow reversal times observed were 26 minutes, 19 minutes and 18 minutes, where there were no reported clinical safety events.

3. Subgroup analysis

There were no pre-specified subgroup analyses in the XACT / ENROUTE NPS analysis population. The number of symptomatic (N=22) and asymptomatic (N=17)

patients were similar; thus, on a post-hoc basis the presentation of study population baseline characteristics, safety outcomes and procedural outcomes in Tables 3 – 6 were stratified by symptomatic status. No other post-hoc subgroup analyses were performed.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The XACT / ENROUTE NPS project was a retrospective analysis of data from the C2R which is not an Abbott-sponsored study. The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FOR PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusion

The risks and performance of the device are based on non-clinical studies as well as analyses of registry data to support PMA approval as described above. Simulated use testing demonstrated the compatibility of the XACT Stent System and the ENROUTE NPS for their intended use. The non-clinical engineering testing conducted on the stent and delivery system demonstrated that the performance characteristics met the product specifications.

In the analysis of C2R, a patient cohort of 39 subjects (22 symptomatic and 17 asymptomatic) were treated with the XACT stent using the TCAR procedure with the ENROUTE NPS from February 2015 to May 2022. The patients were predominantly high risk for CEA and hypertensive, and in contrast to most published studies of carotid stenting, the patient population was predominantly female.

There were no technical issues encountered with use of the XACT stent in conjunction with ENROUTE NPS. Flow reversal time and procedure time were in line for real-world

experience reported in the literature with a broad mix of physician experience and patient complexity. The findings from this experience are representative of a carotid artery disease population, and do not suggest any concerns with safety and performance associated with use of the XACT stent with the ENROUTE NPS. The number of observed clinical events was low and as expected for this population. Long-term safety and effectiveness of the stent were leveraged from clinical data to support the original PMA.

B. Benefit-Risk Determination

The probable benefits and risks of the device are based on data collected in the XACT / ENROUTE NPS analysis in the C2R to support PMA supplement approval as described above, as well as experience from the clinical literature. The probable risks of the device are inherent in percutaneous carotid artery stenting and include higher risk of periprocedural minor stroke and higher risk of restenosis compared to CEA.

A benefit of using the XACT stent with ENROUTE NPS with the TCAR approach is that it offers an alternative option for physicians performing carotid stent procedures that does not involve navigating through severely atherosclerotic aortic arches, thus decreasing risks associated with dislodging aortic plaques during endovascular aortic arch navigation.

1. Patient Perspective

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that for the treatment of patients at high risk for adverse events from CEA who require carotid revascularization via a transcarotid approach, the probable benefits outweigh the probable risks.

C. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. An analysis of the CREST-2 Registry demonstrated compatibility of the XACT with the ENROUTE NPS to treat patients who are at high risk for adverse events from surgery and require a transcarotid approach. These data, in combination with previous clinical data on the XACT and the ENROUTE NPS, have established the safety and effectiveness of the XACT Carotid Stent System for this supplemental premarket approval application.

XIII. CDRH DECISION

CDRH issued an approval order on [approval date].

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.