TERUMO

Roadsaver™

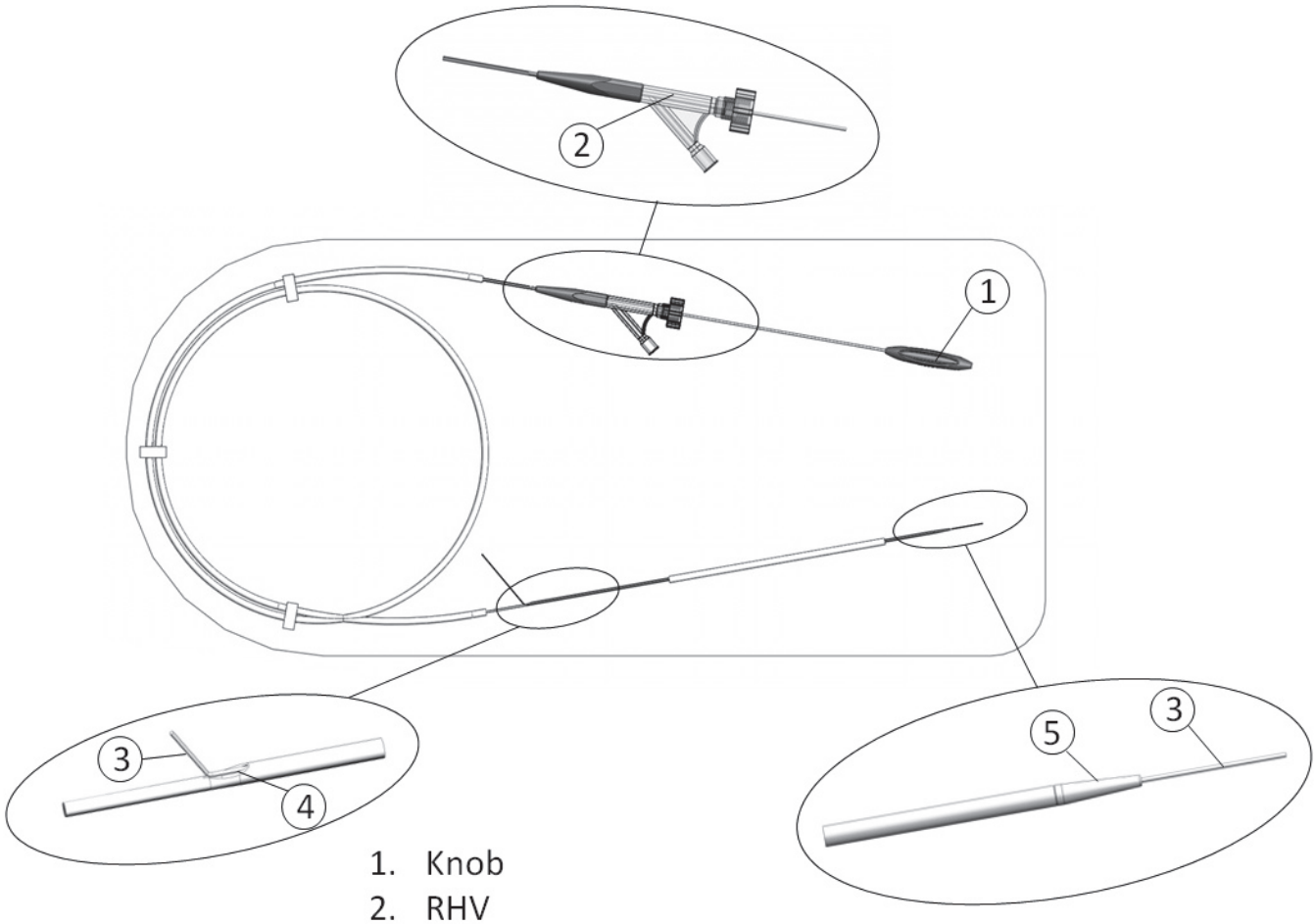
INSTRUCTIONS FOR USE

Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician

A. DEVICE DESCRIPTION

The Roadsaver™ Carotid Stent System consists of two basic components: a self-expanding stent (see Figure 2) and a 5 French Rapid Exchange (RX) delivery catheter (See Figure 1). The Stent component is a dual-layer braided closed cell design (See Figure 2). The stent outer layer is a woven closed cell structure with flared ends. The stent inner layer is a braided closed cell structure with micromesh sized pores. Both the outer and inner stents are composed of a nickel titanium (Nitinol) material. The stent is designed to expand to a pre-determined diameter when deployed by the delivery catheter. Upon exiting the delivery catheter at the target lesion, the implant expands to the vessel lumen diameter. The Roadsaver system is to be used with the Nanoparasol™ Embolic Protection System (EPS). The delivery system is 143 cm length.

Figure 1.
Roadsaver System Set-up



1. Knob
2. RHV
3. Guidewire Lumen Mandrel
4. Proximal RX Port
5. Distal Tip

Figure 2.
Roadsaver Stent (Unconstrained)

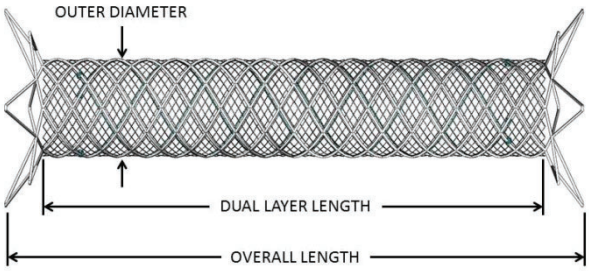
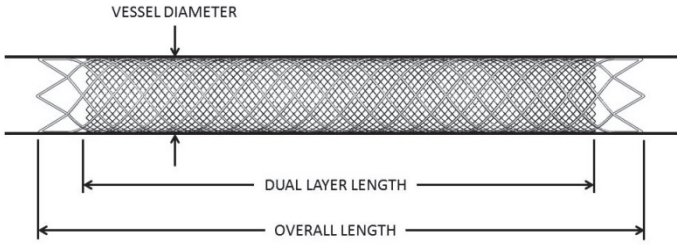


Figure 3.
Roadsaver Stent (Implanted/Constrained)



The Roadsaver stent is provided in multiple lengths and diameters. Table 1 lists the available stent diameters and lengths.

During deployment, the Roadsaver stent foreshortens (decreases in length between catheter-loaded condition and deployed condition) by approximately 6-28% depending on the diameter and length of the stent.

Table 1: Roadsaver Carotid Stent System Models and Dimensions

Catalog Number	Stent Implant Unconstrained Dimensions		Vessel Diameter Range (mm)	% Foreshortening*
	Outer Diameter (mm)	Overall / Dual Layer Length (mm)		
RDS-0520-143RX	5	25 / 20	3.5-4	6.33-10.15
RDS-0530-143RX	5	37 / 30	3.5-4	9.88-14.08
RDS-0540-143RX	5	47 / 40	3.5-4	9.50-13.38
RDS-0616-143RX	6	22 / 16	4-5	9.94-15.59
RDS-0625-143RX	6	33 / 25	4-5	10.31-17.66
RDS-0630-143RX	6	40 / 30	4-5	8.27-15.95
RDS-0718-143RX	7	25 / 18	5-6	12.57-18.69
RDS-0725-143RX	7	35 / 25	5-6	13.31-21.03
RDS-0730-143RX	7	40 / 30	5-6	13.85-22.11
RDS-0820-143RX	8	25 / 20	6-7	16.21-22.49
RDS-0825-143RX	8	35 / 25	6-7	17.23-25.05
RDS-0830-143RX	8	40 / 30	6-7	17.05-25.44
RDS-0840-143RX	8	47 / 40	6-7	18.44-27.29
RDS-0920-143RX	9	33 / 20	7-8	16.47-23.64
RDS-0930-143RX	9	40 /30	7-8	17.58-26.70
RDS-1020-143RX	10	35 / 20	8-9	20.26-26.07
RDS-1030-143RX	10	43 / 30	8-9	21.21-27.89

* Foreshortening defined as percent change in length from loaded to deployed length over the loaded length.

B. INDICATIONS FOR USE

The Roadsaver Carotid Stent System, when used in conjunction with the Nanoparasol™ Embolic Protection System (EPS), is indicated for the treatment of carotid artery stenosis in patients with elevated risk for adverse events following carotid endarterectomy and meet the criteria outlined below:

1. Patients who have either de novo atherosclerotic or post endarterectomy restenotic lesion(s) in the internal carotid arteries or at the carotid bifurcation with ≥50% stenosis if symptomatic or ≥80% stenosis if asymptomatic (both defined by angiography),

AND

2. Patients having a vessel with reference diameters between 3.5 mm and 9.0 mm at the target lesion.

C. CONTRAINDICATIONS

The Roadsaver Carotid Stent System is contraindicated for use in:

- Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs are contraindicated
- Patients with known hypersensitivity to nickel-titanium
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system, or stent system
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery
- Carotid vessel with <25mm gap between the target location of the distal end of the stent and the proximal end of the distal protection device.

D. WARNINGS

Visually inspect all the sterile barrier systems, that are labeled as sterile, immediately prior to use. Do not use if breaches in sterile barrier system integrity are evident, such as pouch is damaged, open.

The Roadsaver stent should be implanted in vessels with the referenced diameters according to the product label.

Should unusual resistance be felt at any time during access or removal, the sheath introducer/guide catheter and Roadsaver system should be removed as a single unit. Applying excessive force during delivery or retrieval of the Roadsaver system can potentially result in loss or damage to the device and delivery components.

When using the Nanoparasol™ Embolic Protection System (EPS), allow for and maintain adequate distance between the filter (no less than 2.5 cm), the stent delivery system or deployed stent to avoid potential entanglement.

Do not reposition the Roadsaver system without fully retrieving the device. The Roadsaver stent MUST be retrieved into the delivery system and redeployed at the desired target location or removed completely from the patient.

Do not attempt to reposition the Roadsaver implant after detachment.

The use of a guiding sheath or guiding catheter with a fixed hemostasis valve may cause the distal tip of the delivery catheter to detach at the hemostasis valve upon removal if the valve is not adequately opened.

When multiple stents are required, stent materials should be of similar composition.

Multiple stents should not be used in an overlapped configuration.

Persons allergic to nickel titanium (Nitinol) may suffer an allergic reaction to this implant.

It is not recommended that the stent be used in patients with the following additional characteristics:

- Patients with poor renal function and in the opinion of physician may be at risk for a reaction to contrast medium
- Pregnant patients
- Patients with perforated vessels evidence by extravasation of contrast medium.
- The presence of extensive atherosclerotic disease involving the aortic arch and proximal common carotid artery that would preclude the safe introduction of a guiding catheter, sheath or EPS.

E. PRECAUTIONS

Only physicians trained and familiar with carotid stent placement and the associated complications, side effects and hazards should use this device.

The stent should not be sized to the vessel beyond the reference vessel diameter range listed on the product label.

The flexible design of the Roadsaver stent may result in variation in the deployed stent length (**see Table 1**).

Carefully inspect the sterile package and the Roadsaver system device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the package is opened or damaged.

See the product label for shelf life. Do not use the Roadsaver system beyond the labeled use by date.

Carefully remove the guide wire lumen mandrel (see Figure 1 for Proximal Rx port location) and fully flush the guide wire lumen. Do not use the delivery system if flush is not observed exiting at the stent Rx delivery system port locations (proximal and distal).

Exercise caution when crossing the deployed/detached Roadsaver system with the Nanoparasol™ Embolic Protection System (EPS), catheters or balloon catheters to avoid disrupting the device geometry and device placement.

The Roadsaver system is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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

Store in a cool and dry place.

F. POTENTIAL COMPLICATIONS

Possible complications include but are not limited to the following:

- Arrhythmia
- Aneurysm and pseudoaneurysm formation
- Abrupt vessel closure
- Allergic reactions (including to antiplatelet agents, contrast medium or stent materials)
- Arteriovenous fistula
- Bleeding from anticoagulation/antiplatelet medication
- Bradycardia and hypotension
- Carotid artery spasm
- Angina/Coronary ischemia
- Cerebral Edema
- Cerebral Hemorrhage
- Congestive Heart failure
- Death
- Disseminated intravascular coagulation
- Emboli (air, tissue, plaque, thrombus, device or other)
- Emergency artery bypass graft surgery
- Hematoma
- Hemorrhagic or embolic stroke/transient ischemic attach (TIA)
- Hyperperfusion Syndrome
- Infection and/or pain at insertion site/Sepsis
- Intimal tear/dissection
- Myocardial Infarction (MI)
- New or worse encephalopathy

- Pain
- Renal failure/insufficiency
- Respiratory arrest
- Restenosis of stented segment
- Stent misplacement
- Seizure
- Severe Unilateral Headache
- Tissue necrosis
- Total occlusion of carotid artery
- Vessel injury/dissection/perforation/rupture/trauma
- Vessel occlusion or thrombosis
- Vessel spasm or recoil

G. SYMBOLS

	Batch code		Non-pyrogenic
	Medical device		Unique device identifier
	Sterilized using ethylene oxide		For prescription use only
	Use-by date		Manufacturer
	Keep away from sunlight		Consult instructions for use
	Keep dry		Do not use if package is damaged
	Single sterile barrier		Contents
	Country and Date of Manufacture		Catalog number
	MR Conditional		Caution
	Do not re-sterilize		Do not reuse

H. MRI Safety Information

MRI Safety Information
A patient implanted with the Roadsaver Carotid Stent may safely be scanned under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Roadsaver Carotid Stent System
Static Magnetic Field Strength (B_0)	1.5T and 3T, Only
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2-W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	15 minutes of continuous scanning followed by 15 minutes of cooling
Image Artifacts	Extends approximately 5-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system

I. CLINICIAN USE INFORMATION

Materials

The Roadsaver Carotid Stent System does not contain latex or PVC materials. The following parts are required to use the Roadsaver System:

Accessories for performing a procedure but NOT supplied should be selected based on the physician's experience and preferences:

- Appropriate Guiding sheath or catheter with a minimum internal diameter (I.D.) of .074 in. (1.9 mm).
- Nanoparasol™ Embolic Protection System (EPS) compatible with the Roadsaver System
- Saline solution/heparin-saline solution continuous flush set
- 5 cc syringe for flushing the Roadsaver System
- Contrast solution
- Rotating Hemostatic Valve (RHV)
- Pressurized sterile Infusion solutions – IV stand
- Arterial access device, sterile needle, guide wire

J. PACKAGING AND STORAGE

The Roadsaver System is placed inside a protective packaged which includes a tray, sterile sealed pouch and unit carton. The Roadsaver System will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place. Keep dry and away from sunlight. See the product label for the device's shelf life. Do not use the device beyond the labeled shelf life.

K. SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled use by date.

L. PREPARATION FOR USE

Device and Delivery System Selection

Appropriate selection of the Roadsaver Carotid Stent System is important for patient safety. In order to choose the optimal Roadsaver stent size for any given lesion, examine pre-treatment angiograms for correct and accurate vessel measurements. Reference the Product Specification chart for the Roadsaver Carotid Stent System or see the device box label. The stent diameter should be slightly (1-2 mm) larger than the diameter of the reference vessel to obtain secure placement. Choose the unconstrained diameter and dual layer stent length as indicated on the outer box label to correspond with the implanted dual layer length, at a minimum, as long as the target lesion.

M. DIRECTIONS FOR USE

Delivery System Preparation

Note: You can prepare and flush the delivery system within the packaging tray or you can remove it and flush the delivery system outside the packaging.

1. Remove the pouched tray enclosing the Roadsaver System from the carton.

2. Inspect the pouch for any signs of damage to the sterile barrier.

Warning: If it is suspected that the sterile barrier seal has been opened or compromised, do not use the carotid delivery system and return it to the manufacturer.

The delivery system should be flushed using a 5-ml syringe.

1. Peel open the pouch, remove the tray with delivery system from the pouch and inspect the delivery system for any signs of damage.

2. Remove the guidewire lumen mandrel from the proximal Rx port and flush the delivery system (See Figure 1 for Proximal Rx Port location).

3. Attach a 5-ml syringe filled with sterile heparinized saline solution to the RHV luer and flush the delivery system (See Figure 1 for RHV). Apply positive pressure until the saline weeps or comes out in drops from the valve seal of the RHV. Close the seal of the RHV, continue to apply positive pressure until the saline weeps or comes out in drops from the proximal RX port (See Figure 1). Pinch the proximal RX port and continue to apply positive pressure until the saline weeps or comes out in drops from the distal RX port or distal tip of the delivery catheter.

4. Carefully remove the delivery system from the tray and remove the catheter from the tubing within the tray without kinking the catheter.

Pre-procedure

The use of the Nanoparasol™ Embolic Protection System (EPS) is required. Refer to the instructions for use for the Nanoparasol™ Embolic Protection System (EPS) for use with the Roadsaver carotid stent system. Gain vascular access according to standard angiographic practice and perform a diagnostic angiogram to determine the appropriate stent diameter and length for the target lesion. Refer to the Product Specification chart for the Roadsaver Carotid Stent System or see the device box label for choosing the stent size.

Introduction of the Stent Delivery System

Refer to the outer box label for choosing the proper guide sheath or guiding catheter for use with the Roadsaver Carotid Stent System.

Access the treatment site using the appropriate accessory equipment and insert the Nanoparasol™ Embolic Protection System (EPS) usable as a guidewire.

Warning: Always use the Nanoparasol™ Embolic Protection System (EPS) when advancing or withdrawing the delivery system. If necessary perform a pre-dilatation at the lesion target site using a standard PTA technique using the recommended guide sheath or guiding catheter on the outer box label. The Nanoparasol™ device should be advanced past the target lesion site. Then the delivery system should be advanced over the Nanoparasol™ wire to the lesion site using fluoroscopy.

Warning: If necessary perform a pre-dilatation using a standard PTA procedure and then introduce the system through the sheath or guiding catheter.

Caution: Do not advance the delivery system against significant resistance. The cause of the resistance should be determined by fluoroscopy and remedial action taken. Withdraw the system and use a new one.

Slack Removal

Ensure that the delivery system catheter outside the patient remains flat and straight.

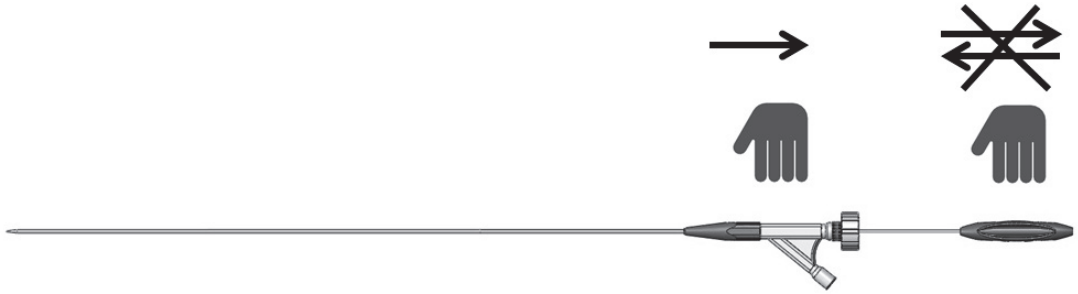
Warning: Slack in the delivery system catheter either outside or within the patient may result in misplacement of the stent beyond the lesion.

Stent Deployment

Note: The Roadsaver stent should be sized to the vessel according to the reference vessel diameter range listed on the product label. The Roadsaver stent foreshortens as it expands to the diameter of the native vessel. The stent foreshortening should be taken into account when sizing and deploying the Roadsaver Carotid Stent System. If the Roadsaver stent positioning is not satisfactory across the target lesion, the stent may be recaptured and repositioned if it is not fully deployed. The implant may be recaptured up to 50% of its deployment from the catheter delivery system (**See Figure 5 and 6**). Recapturing of stent can be accomplished by removing the slack in the delivery catheter shaft and then maintaining the inner catheter (handle) position and advancing or pushing forward the outer catheter. After recapturing the stent into the delivery system then you can redeploy the stent across the lesion, taking into consideration the foreshortening of the stent.

Ensure the RHV is open. The stent is deployed by outer catheter retraction. Deployment is complete by maintaining inner catheter position (holding handle) while retracting the outer catheter and allowing the stent to expand **(See Figure 4**).

Figure 4.



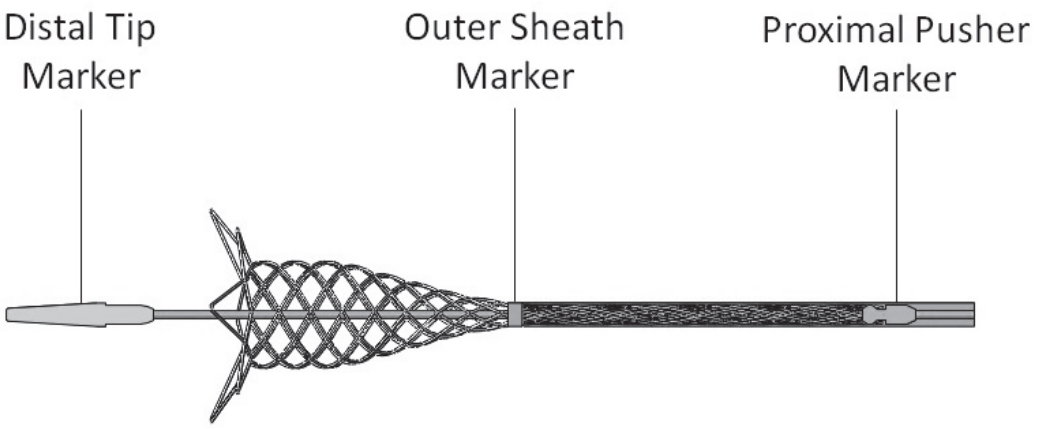
Stent Deployment

Figure 5.

Stent Retraction

Figure 6.

Stent Recapture: Approximately 50% Deployment



Withdrawing Stent Delivery System

After the stent has been completely deployed, using fluoroscopy, withdraw the delivery system carefully, leaving the EPS in place. Perform standard post-procedural angiography.

Post-deployment Stent Dilatation

If the stent is not completely expanded within the length of the lesion, post-dilation with the balloon catheter inside the stent may be done with standard PTA technique. The inflated nominal diameter of the PTA balloon used for post-dilation should be approximately the same as the diameter of the referenced native vessel.

Post Stent Placement

Upon final angiography confirming a satisfactory result, the Nanoparasol™ EPS should be removed along with the guide sheath or guiding catheter. Refer to the Instructions for use for the Nanoparasol™ EPS when removing the device. Hemostasis of the puncture site should be established.

N. SUMMARY OF PRIMARY CLINICAL STUDY

A clinical study was performed to establish a reasonable assurance of safety and effectiveness of the Roadsaver Carotid Stent System used in conjunction with the Nanoparasol Embolic Protection System for the treatment of carotid artery stenosis in patients at increased risk for adverse events from carotid endarterectomy.

1. Design

Patients were treated between April 21, 2016, and February 19, 2020. The database reflected data collected through February 24, 2021 and included the first 256 enrolled patients through the 12-month milestone. There were 30 investigational sites.

The study, titled "CONFIDENCE Trial - Carotid Stent Trial to Evaluate the Safety and Efficacy of the Roadsaver Stent Used in Conjunction with the Nanoparasol Embolic Protection System for Patients at Increased Risk for Adverse Events from Carotid Endarterectomy," was an open-label, multicenter, prospective, single-arm study with follow-up at hospital discharge, 30 days, 180 days and 12 months post-procedure. Two hundred and fifty-six (256) patients were enrolled in 30 investigational sites in the US.

The safety and effectiveness of the Roadsaver Stent used in conjunction with the Nanoparasol Embolic Protection System in the CONFIDENCE study was evaluated with the primary endpoint of Clinical Events Committee (CEC)-adjudicated Major Adverse Event (MAE) rate, which consisted of death, stroke, or myocardial infarction (MI) events within 30 days of the index procedure plus ipsilateral stroke 31–365 days post-procedure. The performance goal (PG) rate was set at 13.9%, derived from a comparable subset of patients from other recent randomized trials[1-3]. That is, if the upper limit of the 95% CI for the event (failure) was <13.9%, the null hypothesis was rejected, and the study endpoint was considered to be met.

This study included an independent CEC, Data Safety and Monitoring Board (DSMB), angiographic imaging core laboratory ("core lab"), and study monitors who confirmed neurological assessments, adverse events, imaging data, and study data with source documentation.

2. Inclusion and Exclusion Criteria

Enrollment in the pivotal clinical study was limited to patients who met the following inclusion criteria.

- **General Inclusion Criteria**
  Patients were eligible for inclusion in the study if they met **all** the following inclusion criteria:

  1. Patient was between ≥21 and ≤80 years of age.
  2. Patient was willing and capable of complying with all study protocol requirements, including specified follow-up period and could be contacted by telephone.
  3. Patient or LAR provided written informed consent before enrollment in study.
  4. Patient was diagnosed with carotid artery stenosis and considered a high perioperative risk for carotid endarterectomy (CEA).
  5. Patient was either:
     a. Symptomatic with carotid stenosis ≥50% as determined by angiography using North American Symptomatic Carotid Endarterectomy Trial (NASCET) methodology. Symptomatic was defined as amaurosis fugax ipsilateral to the carotid lesion; TIA or non-disabling stroke within 180 days of the procedure within the hemisphere supplied by the target vessel; or
     b. Asymptomatic with carotid stenosis ≥80% as determined by angiography using NASCET methodology.
  6. Patient had a target lesion located at the carotid bifurcation and/or proximal internal carotid artery (ICA).
  7. Patient had a single, de novo or restenotic (post CEA) target lesion or severe tandem lesions close enough to be covered by a single Roadsaver stent.
  8. Patient had a vessel with reference diameters 3.5–9.0 mm at the target lesion and met the criteria for device use per Instructions for Use.

- **High-risk Inclusion Criteria**
  For inclusion in the study, a patient had to qualify in ≥1 anatomic and/or ≥1 comorbid high-risk condition per below:

  Anatomic high-risk conditions

  1. Patient had a target lesion at or above the second vertebral body (level of jaw) or below the clavicle.
  2. Patient had an inability to extend the head due to cervical arthritis or other cervical disorders.
  3. Patient was status/post radiation therapy to the neck.
  4. Patient had a previous head and neck surgery in the region of the carotid artery.
  5. Patient had spinal immobility of the neck.
  6. Patient had the presence of a tracheostomy stoma.
  7. Patient had laryngeal palsy or laryngectomy.
  8. Patient had a hostile neck or surgically inaccessible lesion.
  9. Patient had severe tandem lesions.

  Comorbid high-risk conditions

  1. Patient was ≥70 years of age (maximum 80 years at the time of enrollment.
  2. Patient had New York Heart Association (NYHA) Class III or IV congestive heart failure (CHF) with left ventricular ejection fraction LVEF ≤35%.
  3. Patient had chronic obstructive pulmonary disease (COPD) with forced expiratory volume FEV ≤30%.
  4. Patient had unstable angina.
  5. Patient had a recent MI (≥30 days before stenting procedure).
  6. Patient had coronary artery disease with ≥2 vessels with ≥70% stenosis.
  7. Patient had planned coronary artery bypass grafting (CABG) or valve replacement surgery 31–60 days after the carotid artery stenting (CAS) procedure.
  8. Patient required peripheral vascular surgery or abdominal aortic aneurysm repair between 31–60 days after the CAS procedure.
  9. Patient had contralateral laryngeal nerve paralysis.
  10. Patient had restenosis after a previous CEA.
  11. Patient had contralateral occlusion in the ICA as the only comorbid high-risk condition.

- **General Exclusion Criteria**
  Patients were excluded from the study for any of the following reasons:

  1. Patient had life expectancy of <1 year.
  2. Patient was experiencing (or had experienced) an evolving, acute, or recent disabling stroke in the last 30 days.
  3. Patient had anticipated or potential sources of emboli (e.g, known previously symptomatic patent foramen ovale (PFO), mechanical heart valve, or deep vein thrombosis (DVT) treated within 6 months) that were not adequately treated with antithrombotics for ≥2 weeks with documented coagulation parameters in the target therapeutic range.
  4. Patient had atrial fibrillation.
  5. Patient had an acute MI within 60 days prior to the index procedure.
  6. Patient had or planned to have any major surgical procedure (i.e., intra-abdominal or intrathoracic surgery or any surgery/interventional procedure involving cardiac or vascular system) within 30 days of the index procedure.
  7. Patient had a history of major ipsilateral stroke.
  8. Patient had >60% carotid stenosis contralateral to the target lesion requiring treatment before completion of the study-required 12-month follow-up.
  9. Patient had a mRS score >2 or had another neurological deficit not due to stroke that may confound the neurological patient assessments.
  10. Patient had chronic renal insufficiency (serum creatinine ≥2.5 mg/dL) or had a history of severe hepatic impairment, malignant hypertension, and/or was morbidly obese.
  11. Patient had platelet count <100,000/µL.
  12. Patient had known sensitivity to heparin or previous incidence of heparin-induced Thrombocytopenia (HIT) type II.
  13. Patient had contraindication to standard-of-care study medications, including antiplatelet therapy.
  14. Patient had known sensitivity to contrast media that could not be controlled adequately with pre-medication.
  15. Patient had known bleeding diathesis or hypercoagulable state or refuses blood transfusions.

16. Patient had intracranial pathology that, in the opinion of the Investigator, made the patient inappropriate for study participation (e.g, brain tumor, arteriovenous malformation [AVM], cerebral aneurysm, cerebral vascular disease [microangiopathy or large vessel], etc.) or would confound neurological evaluation.
17. Patient had intracranial hemorrhage within the last 90 days.
18. Patient was enrolled in another investigational study protocol and had not completed its primary endpoint or that may have confounded the current study endpoints. Patients who were involved in the long-term surveillance of a clinical study were eligible.
19. Patient suffered from confusion or dementia or was unable or unwilling to cooperate with the study requirements and/or follow-up procedures.
20. Patient had a known, unresolved history of drug use or alcohol dependency.
21. Patient had an active infection.
22. Patient had renal failure and/or was on dialysis.
23. Patient had documented uncontrolled diabetes.
24. Patient was pregnant.

- **Angiographic Exclusion Criteria**
  A patient was not eligible for enrollment if s/he met any of the following angiographic exclusion criteria:

1. Patient had a total occlusion of the target carotid arteries (i.e., CCA, ICA).
2. Patient had a previously placed stent in the ipsilateral carotid artery.
3. Patient had severe lesion calcification or vascular tortuosity that precluded the safe introduction of the sheath, guiding catheter, embolic protection system, or stent.
4. Patient had a mobile filling defect or thrombus in target vessel.
5. Patient had occlusion or presence of “string sign” of the target vessel.
6. Patient had carotid (intracranial) stenosis located distal to target stenosis that was more severe than the target stenosis.
7. Patient had known mobile plaque or thrombus in the aortic arch.
8. Patient had a type III aortic arch.
9. Patient in whom femoral access was not possible.
10. Patient had intracranial AVMs in the territory of the target carotid artery.
11. Patient had an aneurysm in the territory of the target carotid artery that required treatment within 12 months.
12. Patient’s ipsilateral carotid artery had ≥2 90-degree bends in the target landing zone.

3. Follow-up Schedule

All patients were scheduled to return for follow-up examinations post-procedure/prior to discharge and at 30 days (±7 days), 6 months (±28 days), 12 months (±56 days), 24 months (±56 days) and 36 months (±56 days). Assessments were performed and data was collected from patients at the preoperative, surgical, and postoperative visits. The key timepoints are also shown below in Table 2.

Table 2: Study Timeline

Visit (Window)	Pre-Procedure Visits			Post- Procedure Visits (with visit window periods)						
	Screening <45 days	Pre-Procedure Within 24hrs	At Enrollment	Before Hospital Discharge	30 days (±7 days)	6 months (±28 days)	12 months (±56 days)	24 & 36 months (±56 days)	Early Withdrawal	Unscheduled Visit
Informed consent	X									
Demographic Evaluation	X									
mRS	X*									
NIHSS		XR		XR	X‡	X‡	X‡	X‡	X‡	X‡
CT or MRI	X**R									
Head/Neck/Chest CTA or MRA	X****									
Carotid Duplex Ultrasound	X***R				XR	XR	XR	XR	X	X‡
Carotid/Cerebral Angiography			XR			X‡‡	X‡‡	X‡‡	X‡‡	X‡‡
Index Procedure			XR							
12-lead ECG	X*R			XR	XR					X‡
P2Y12 Reaction Units (PRU) Assessment		X ϕ		X ϕ						
Cardiac Enzymes (CK-MB)		X‡		X‡	X‡					X‡
Antiplatelet Therapy		XR		XR	XR	XR	XR	XR	X	X
Concomitant Medications	XR	XR		XR	XR	XR	XR	XR	X	X
Adverse Events				XR	XR	XR	XR	XR	X	X

NOTES:	
*	May be obtained at either screening or pre-procedure visit
**	Required for symptomatic patients only within 180 days before screening visit
***	Obtained within the 180 days preceding the screening visit
****	Standard of Care for symptomatic cases
‡	If clinically indicated; NIHSS score will be collected 7 days post-stroke or before discharge.
‡‡	Performed if carotid follow-up intervention is required. Pre- and post-procedure scans will be submitted to the Core Lab.
R	Standard of Care
ϕ	Required if only done per site's standard of care.
NIH Stroke Scale	Neurological assessments should be done by a physician or research personnel certified in the administration of NIHSS
Standard of Care	For the purposes of this study protocol, 12-lead ECG at 30 days, carotid duplex ultrasound, and an Intra-procedure CK-MB are considered standard of care

4. Clinical Endpoints

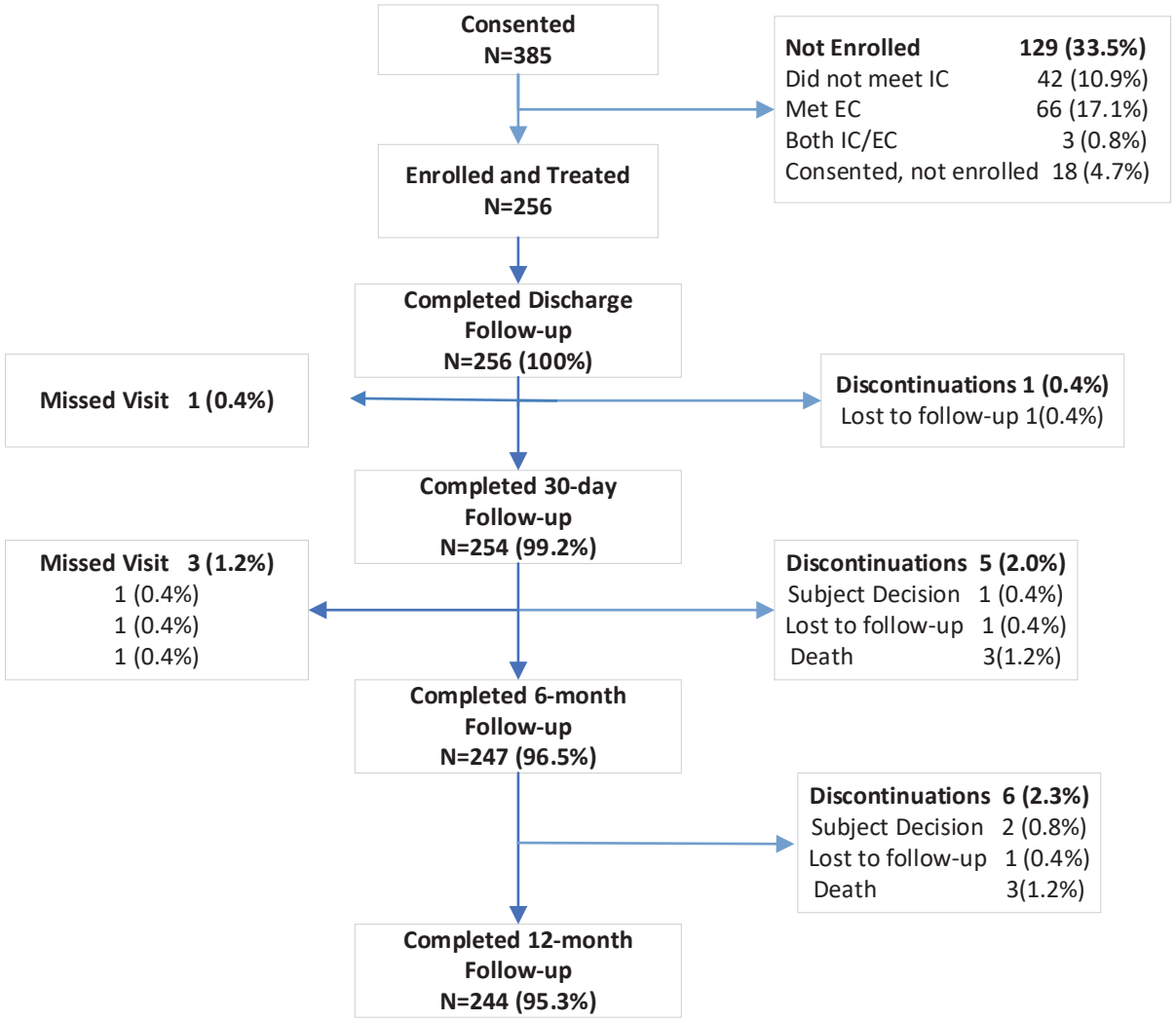
The primary endpoint to establish a reasonable assurance of the safety and effectiveness of the device is a Major Adverse Event (MAE) composite endpoint consisting of death, stroke, or myocardial infarction (MI) within 30 days of the index procedure plus ipsilateral stroke within 12 months. MI was defined as a creatine kinase-MB level that was 2× the upper limit of normal (ULN) according to the center's laboratory, in addition to either chest pain or symptoms consistent with ischemia or electrocardiographic evidence of ischemia, including new ST segment depression or elevation of >1 mm in ≥2 contiguous leads.

Secondary Endpoints:

1. Procedure Success: Successful Roadsaver implantation, <50% residual angiographic stenosis as determined by the angiography Core Laboratory by visual North American Symptomatic Carotid Endarterectomy Trial (NASCET) assessment immediately post procedure at the target lesion, and no in-hospital (pre-discharge) MAE (stroke, MI, or death).
2. Stent Technical Success: Successful Roadsaver deployment in the planned targeted treatment location with a residual diameter stenosis <50% immediately after post-dilatation as determined by the angiography Core Laboratory and successful removal of the delivery system.
3. EPD Technical Success: EPD successfully delivered and deployed beyond the target lesion and successfully retrieved after completion of the stent placement.
4. Target Lesion Revascularization (TLR): any clinically driven revascularization procedure of the original treatment site associated with narrowing of >80% within 12 months post- procedure, including angioplasty, stenting, endarterectomy, or thrombolysis, performed to open or increase the luminal diameter inside or ≤5 mm of the previously treated lesion.
5. In-stent Restenosis (ISR): Patients with >70% residual stenosis were determined by ultrasound (peak systolic velocity (PSV) >300 cm/s and/or ICA/CCA PSV ratio >4.0) in stented lesion at the 30-day and 12-month follow-ups.
6. Major stroke within 30 days
7. Minor stroke within 30 days
8. TIA within 30 days
9. Neurologic death (days 31–365)

5. Subject Accountability Flowchart

At the time of database lock, of 256 patients enrolled in the study, 95.3% (244 patients) were available for analysis at the 12-month follow-up assessment. A summary of subject disposition is presented in **Figure 7** below.



Note: The number of patients who discontinued or missed a visit will not add up to the total number of patients that completed each visit because patients who missed a visit were not excluded from further analysis. They may have completed subsequent visits.

Figure 7: Summary of subject disposition

6. Demographics

The baseline demographic characteristics for the intent to treat (ITT) population in the pivotal clinical study are summarized in Table 3. In the ITT population, the mean (SD) age was 69.6 (6.8) years, and the majority of the subjects were men (65.2% [n=167]). 91% [n=233] of subjects were white, 4.7% of subjects identified themselves as Hispanic or Latino; 4.3% (n=11) identified themselves as Black or African American. In the ITT population, mean (SD) height was 67.0 (4.0) inches, mean (SD) weight was 185.5 (43.1) pounds, and mean (SD) body mass index (BMI) was 28.8 (5.5) kg/m^2. Overall, these demographic characteristics are consistent with a typical cohort of subjects with carotid artery stenosis at high operative risk for CEA.

Table 3: Demographics and Baseline Characteristics (ITT Population)

Characteristic	ITT (N=256)
Age (years)	
Mean (SD)	69.6 (6.8)
Median (min, max)	71.0 (46.0, 80.0)
Gender, n (%)	
Male	167 (65.2%)
Female	89 (34.8%)
Ethnicity, n (%)	
Not Hispanic or Latino	244 (95.3%)
Hispanic or Latino	12 (4.7%)
Race, n (%)	
White	233 (91.0%)
Black or African American	11 (4.3%)
Other	6 (2.3%)
Asian	5 (2.0%)
American Indian or Alaska Native	1 (0.4%)
Height (inches)	
Mean (SD)	67.0 (4.0)
Weight (pounds)	
Mean (SD)	185.5 (43.1)
Body Mass Index (kg/m^2)	
Mean (SD)	28.8 (5.5)

As presented in Table 4, among all enrolled subjects, 23.8% (61/256) were symptomatic (i.e., amaurosis fugax ipsilateral to the carotid lesion, TIA or non-disabling stroke within 180 days of the procedure within the cerebral hemisphere supplied by the target vessel), and 76.2% (195/256) were asymptomatic. Among all enrolled subjects, 40.2% of subjects (103/256) had ≥1 anatomic high-risk conditions; 84.4% of subjects (216/256 had ≥1 comorbid high-risk conditions.

Table 4: Summary of Symptomatic/Asymptomatic Subjects and Subjects with High-risk Conditions (ITT Population)

Characteristic	N=256 n (%)
Symptomatic Asymptomatic	61 (23.8%) 195 (76.2%)
Subjects with ≥1 anatomic high-risk conditions Subjects with ≥1 clinical comorbid high-risk conditions	103 (40.2%) 216 (84.4%)

The target lesion characteristics and extent of stenosis are presented in Table 5. There was a total of 132 (51.6%) lesions in the right carotid artery. The mean (SD) percent stenosis was 82.4% (7.76).

Table 5: Target Lesion Characteristics & Extent of Stenosis – Site-reported Angiography (ITT Population)

Parameters and Statistics	ITT (N=256) n (%)
Location of target lesion	
Right carotid artery	132 (51.6%)
Left carotid artery	124 (48.4%)
Minimum lumen diameter	
Mean (SD)	1.0 (0.9)
Median (min, max)	0.55 (0, 3)
(95% CI)	(0.9, 1.1)
Percent Stenosis	
Mean (SD)	82.4 (7.76)
Median (min, max)	81.0 (50, 99)
(95% CI)	(81.5, 83.4)

The results for the pre-procedure target lesion morphology performed by the Core Angiography Laboratory are summarized in Table 6. Overall, the target lesion location was contiguous for the majority of subjects (85.3% [215/252]). The mean (SD) distance of the lesion from the ostium was 7.2 (8.0) mm; the median length (range) was 21.3 (5.0–40.0) mm. ICA calcification was severe in 23.4% of subjects (59/252).

Table 6: Target Lesion Morphology – Core Laboratory Angiography (ITT Population)

Parameters and Statistics	ITT (N=252) n (%)
Lesion Location	
Both	1 (0.4%)
Contiguous	215 (85.3%)
Remote	36 (14.3%)
Distance (mm) from ostium	
Mean (SD)	7.2 (8.0)
Median (min, max)	5.0 (0.0, 32.0)
(95% CI)	(6.2, 8.2)
Length (mm)	
Mean (SD)	20.9 (8.2)
Median (min, max)	21.3 (5.0, 40.0)
(95% CI)	(19.8, 21.9)
Eccentricity, concentric / eccentric	
Concentric	220 (87.3%)
Eccentric	32 (12.7%)
ICA calcification	
Moderate	39 (15.5%)
None/Mild	154 (61.1%)
Severe	59 (23.4%)

O. CLINICAL STUDIES – SAFETY AND EFFECTIVENESS

1. Patient Analysis Population

The primary analysis was conducted on the Intent-To-Treat (ITT) population, which includes 256 subjects that were enrolled and treated with the device. The Complete Case (CC) population includes all ITT subjects completing the 12-month follow-up evaluation. 15 ITT subjects were considered to have missing data for the following reasons: death after 30 days (6); missed visit (3); lost to follow-up (3); subjects' decision to discontinue (3). FDA considers the CC population to be most relevant, since the method of multiple imputations used for outcomes of 15 subjects with missing data in the ITT population differed from the method that was prespecified.

2. Primary Endpoint Results

The primary endpoint was MAE, a composite measure of death, stroke, or MI within 30 days of the index procedure plus ipsilateral stroke 31–365 days after the procedure. In the study, 15 patients (5.9% [95% exact binomial CI: 3.32, 9.48]; p=0.0002 experienced a MAE. The upper limit of the 95% exact binomial CI was 9.48%, which was below the PG of 13.9%. Because the upper limit of the CI was less than the PG, the null hypothesis (H0) is rejected, and the alternative hypothesis is accepted (H1). Thus, the primary endpoint of the study was met.

Table 7: CEC-adjudicated MAE Rate

	ITT Population§ N=256	**CC Population N=244**
Subjects who had an MAE*, n (%)	15 (5.9%)‡	15 (6.1%)‡
95% exact binomial CI	(3.32, 9.48)	(3.48, 9.94)
p-value†	0.0002	0.0005
Subjects who died within 30 days of the index procedure	1 (0.4%)	1 (0.4%)
Subjects who had a stroke within 30 days of the index procedure	7 (2.7%)	7 (2.9%)
Subjects who had an MI within 30 days of the index procedure	1 (0.4%)	1 (0.4%)
Subjects who had an ipsilateral stroke 31-365 days post-index procedure	7 (2.7%)	7 (2.9%)

*MAE is defined as death, stroke, or MI within 30 days of the procedure plus ipsilateral stroke 31-365 days post-index procedure.
§ Presented in this table for the ITT population is data based on recorded data, without imputation, and assuming no events for patients who discontinued.
‡ Two MAE events occurred in one subject
† Probability value derived from the 2-sided binomial test vs. an a priori Performance Goal of 13.9%.

3. Secondary Endpoint Results (Performance Analysis)

Secondary endpoints include technical success, procedure success, embolic protection device technical success, target lesion revascularization within 12 months of follow-up, and in-stent restenosis at 30-day and 12-month follow-up.

As shown in Table 8, Technical Success was achieved in 96.9% (248/256) of subjects; 8 subjects did not achieve residual stenosis diameter <50%. In all ITT subjects, the Roadsaver device was successfully deployed, and the delivery

system was successfully retrieved. Procedure Success was achieved in 94.9% (243/256) of subjects; 8 subjects did not achieve residual stenosis diameter <50%. Four subjects (1.6%) had a stroke pre-discharge, and 1 subject (0.4%) had a MI pre- discharge. There were no pre-discharge deaths. Embolic Protection Device Technical Success was achieved in 98.8% (253/256) of subjects. Nine subjects (3.5%) required 10 TLRs within 12 months of the index procedure. ISR was reported in 5 subjects (2.0%) at the 30-day follow-up and 14 subjects (5.5%) at the 12-month follow-up.

Table 8: Performance Analysis

Endpoint	ITT Population N=256 n (%)	CC Population N=244 n (%)
Technical Success[a]	248 (96.9%)	236 (96.7%)
Successful deployment	256 (100.0%)	244 (100%)
Residual diameter stenosis <50%[b]	248 (96.9%)	236 (94.7%)
Successful removal of delivery system	256 (100.0%)	244 (100%)
Procedure Success[c]	243 (94.9%)	231 (94.7%)
Successful Roadsaver implantation	256 (100.0%)	244 (100%)
Residual angiographic stenosis <50%[d]	248 (96.9%)	236 (96.7%)
No in-hospital (pre-discharge) MAE (stroke, MI, or death)	251 (98.0%)	239 (98.0)
Stroke	4 (1.6%)	4 (1.6%)
MI	1 (0.4%)	1 (0.4%)
Death	0	0
Embolic Protection Technical Success[e]	253 (98.8%)	241 (98.8%)
Target Lesion Revascularization[f]	9 (3.5%)	9 (3.7%)
In-stent Restenosis[g] at 30-day follow-up	5 (2.0%)	5 (2.0%)
In-stent Restenosis at 12-month follow-up	14 (5.5%)	14 (5.7%)

[a]Successful deployment of Roadsaver in targeted treatment location with a residual diameter stenosis <50% immediately after post-dilatation as determined by the angiography Core Laboratory and with successful removal of delivery system.

[b]Determined by the Core Angiography Laboratory immediately after post-dilatation.

[c]Successful Roadsaver implantation, <50% residual angiographic stenosis as determined by the angiography Core Laboratory by visual NASCET assessment immediately post procedure at the target lesion and no in-hospital (pre-discharge) MAE (stroke, MI or death)

[d]Determined by Angiography Core Laboratory by visual NASCET assessment immediately after the procedure.

[e]Successful delivery and deployment beyond the target lesion and successful retrieval after completion of the stent placement.

[f]TLR was defined as any clinically driven revascularization procedure of the original treatment site associated with narrowing >80% within 12 months post-procedure, including angioplasty, stenting, endarterectomy, or thrombolysis, performed to open or increase the luminal diameter ≤5 mm of the previously treated lesion.

[g]In-stent Restenosis included subjects with >70% residual stenosis determined by ultrasound (PSV >300 cm/s and/or ICA/CCA PSV ratio >4.0) within the stented lesion.

4. **Adverse Events**

Adverse Events (AEs) were defined as any unfavorable and unintended sign (including laboratory findings), symptom or disease that occurred to a patient and resulted in a change in normal baseline health while enrolled in this clinical investigation. Serious Adverse Events (SAE) were defined as an AE that led to a patient death or serious deterioration in the health of the patient that resulted in:

- a life-threatening illness or injury; or
- a permanent impairment of a body structure or a body function; or
- in-patient or prolonged hospitalization; or
- medical or surgical intervention to prevent permanent impairment to a body structure or a body function; or
- fetal distress, fetal death, or a congenital abnormality or birth defect

Table 9 presents possibly, probably, or definitely device- or procedure-related adverse events occurring at a rate of >1% that were observed through 12 months in the Roadsaver pivotal clinical study for the ITT population. Table 10 presents possibly, probably, or definitely device- or procedure-related serious adverse events occurring at a rate of >1%. No unanticipated adverse device effects (UADE) occurred during this trial.

Table 9: Site Reported Device and Procedure-related Adverse Events (Within 1 Year, ITT Population)

Preferred Term **Relationship**	**N=256** **n (%)**
Possibly, probably, or definitely Roadsaver related AEs	
Carotid Artery Restenosis	8 (3.1%)
Carotid Artery Stenosis	4 (1.6%)
Cerebral Vasoconstriction	5 (2.0%)
Cerebrovascular Accident	4 (1.6%)
Possibly, probably, or definitely Nanoparasol related AEs	
Cerebral Vasoconstriction	8 (3.1%)
Vascular Disorders	4 (1.6%)
Vasospasm	3 (1.2%)
Possibly, probably, or definitely procedure related AEs	
Bradycardia	8 (3.1%)
Urinary Tract Infection	3 (1.2%)
Incision Site Hemorrhage	3 (1.2%)
Procedural Headache	5 (2.0%)
Cerebral Vasoconstriction	9 (3.5%)
Transient Ischemic Attack	3 (1.2%)
Hypotension	26 (10.2%)

Table 10: Site Reported Device and Procedure-related Serious Adverse Events (Within 1 Year, ITT Population)

System Organ Class **Preferred Term and Relationship**	**N=256** **n (%)**
Possibly, probably, or definitely Roadsaver related SAEs	
Nervous System Disorders	11 (4.3%)
Carotid Artery Occlusion	1 (0.4%)
Carotid Artery Restenosis	5 (2.0%)
Carotid Artery Stenosis	3 (1.2%)
Cerebrovascular Accident	4 (1.6%)
Possibly, probably, or definitely procedure related SAEs	
Hypotension	9 (3.5%)

5. **Subgroup Analyses**

Subgroup analyses were conducted by gender, race, ethnicity, age, symptomatic status and anatomic risk factors using the proportion of patients who experience the primary endpoint with 2-sided 95% exact binomial confidence intervals. Although the study was not specifically powered to detect such differences, the results suggest that the proportion of patients who experienced the primary endpoint is similar between subgroups defined for gender, ethnicity, age, symptomatic status and anatomic risk factors. Please note that the subgroup analysis for race suggested a slightly higher likelihood of an event among the Black/African American population. However, there is a limited sample size for this race subgroup (n=11); therefore, it is difficult to draw any conclusions from this data. The subgroup analyses results are listed in Table 11 below.

Table 11. Proportion of Patients Who Experienced the Primary Endpoint (Major Adverse Event) Stratified by Sub-Group

Sub-Group Parameter	Sub-Group Category	Number of Patients	Patients Who Experienced the Event of Interest, Number (%)	Lower Bound of the 2-Sided 95% Exact Binomial Confidence Interval*	Upper Bound of the 2-Sided 95% Exact Binomial Confidence Interval*
Gender	Female	89	4 (4.5%)	1.24	11.11
	Male	167	11 (6.6%)	3.33	11.48
Race	American Indian or Alaska Native	1	0	0.00	97.5
	Asian	5	0	0.00	52.18
	Black / African American	11	4 (36.4%)	10.93	69.21
	Other (3 Hispanic, 1 Unspecified, 2 Multiracial	6	0	0.00	45.93
	White	233	11 (4.7%)	2.38	8.29
Ethnicity	Hispanic / Latino	12	1 (8.3%)	0.21	38.48
	Not Hispanic / Latino	244	14 (5.7%)	3.17	9.44
Age	<60 Years of Age	27	1 (3.7%)	0.09	18.97
	60 to <70 Years of Age	79	2 (2.5%)	0.31	8.85
	70 to <=80 Years of Age	150	12 (8.0%)	4.20	13.56
Symptomatic Classification	Asymptomatic	195	9 (4.6%)	2.13	8.58
	Symptomatic	61	6 (9.8%)	3.70	20.19
Anatomic Risk Factors	No	153	8 (5.2%)	2.28	10.04
	Yes	103	7 (6.8%)	2.78	13.50

Note: Population: Restricted to the Clinical Sites With a Minimum of 8 Patients
* Based on the Percentage of Patients Who Experienced the Event of Interest

A poolability assessment of the primary endpoint was performed across 8 sites enrolling ≥ 8 patients. Data was determined poolable (p = 0.7969, Fisher's exact test) after excluding a single site (site 36) which reported 5 MAEs among 16 patients enrolled in comparison to 5 MAEs among 164 total patients enrolled across the other 7 high-enrolling sites. Because site 36 reported a cluster of MAEs while all other high-enrolling sites-maintained MAE rates below the expected performance goal, enrollment was suspended at this site upon recommendation of the study DSMB and it was excluded from the poolability assessment as an outlier.

P. CONCLUSION

The clinical study results support the reasonable assurance of safety and effectiveness of Roadsaver Carotid Stent System when used in accordance with the indications for use. The benefits of the device outweigh probable risks when considering the clinically significant results of the pivotal data conducted in the intended population under its proposed condition of use.

Q. HOW SUPPLIED

Sterile: This device is sterilized using Ethylene Oxide. Non-pyrogenic
Contents: One (1) Roadsaver system
Storage: Store product in a dry, cool place.

R. References

1. Abbott Vascular Devices. Xact® Rapid Exchange Carotid Stent System 5.7Fr (1.9mm): Instructions for Use. Galway, Ireland: Abbott Laboratories; 2005.
2. Gray WA, Hopkins LN, Yadav S, et al. Protected carotid stenting in high-surgical-risk patients: the ARCHeR results. J Vasc Surg 2006; 44: 258-68.
3. Iyer SS, White CJ, Hopkins LN, et al. Carotid artery revascularization in high-surgical-risk patients using the Carotid WALLSTENT and FilterWire EX/EZ: 1-year outcomes in the BEACH Pivotal Group. J Am Coll Cardiol 2008; 51: 427-34.

WARRANTY DISCLAIMER

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

Prices, specifications, and model availability are subject to change without notice.

TERUMO

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Roadsaver™

INSTRUCTIONS FOR USE

Rx Only: Federal (USA) law restricts this device to sale by or on the order

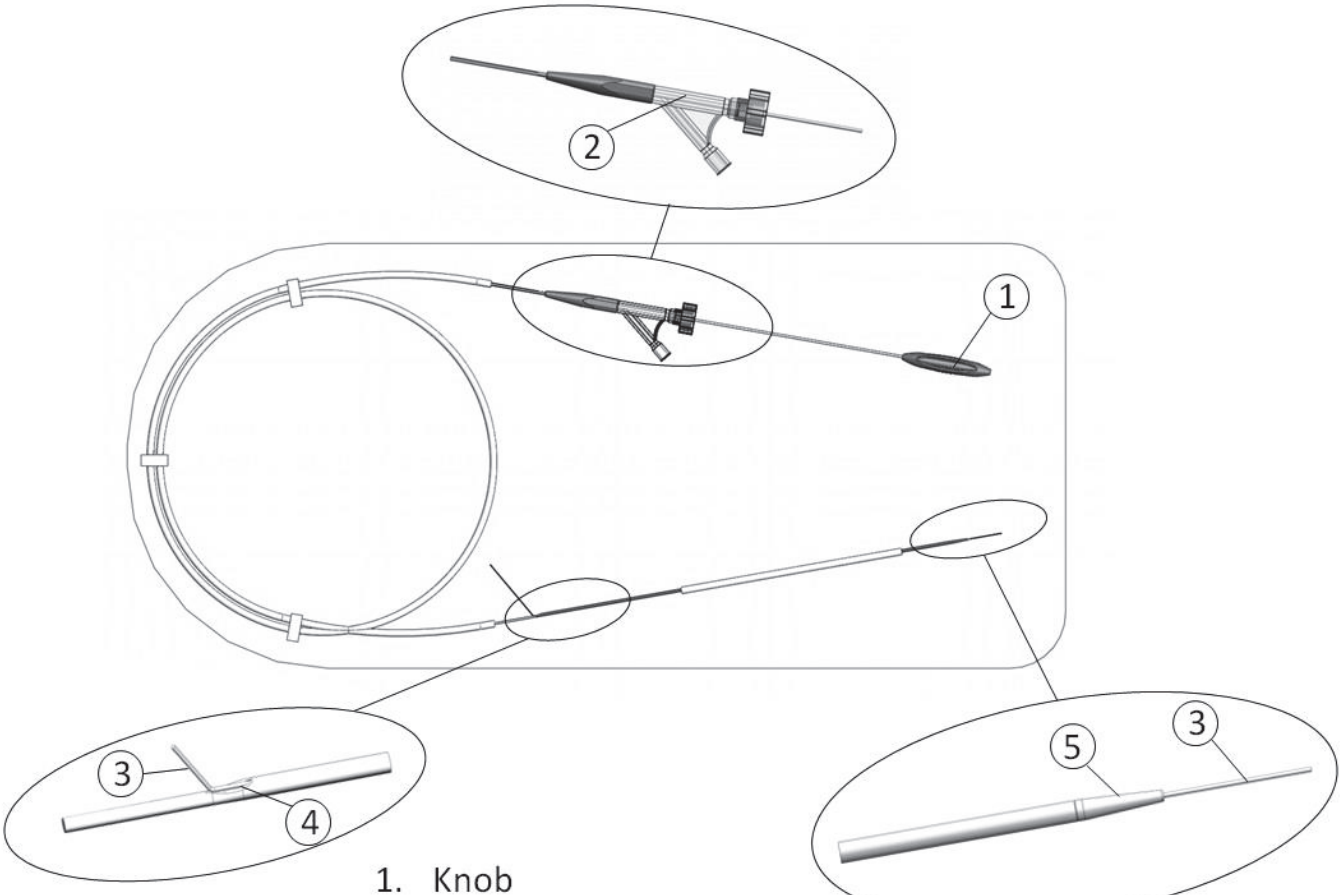
TERUMO

IFU100208 Rev. X2 Revised 2022-07

A. DEVICE DESCRIPTION

The Roadsaver™ Carotid Stent system consists of two basic components: a self expanding stent (see Figure 2) and a 5 French Rapid Exchange (RX) delivery catheter (See Figure 1). The Stent component is a dual-layer braided closed cell design (See Figure 2). The stent outer layer is a woven closed cell structure with flared ends. The stent inner layer is a braided closed cell structure with micromesh sized pores. Both the outer and inner stents are composed of a nickel titanium (Nitinol) material. The stent is designed to expand to a pre-determined diameter when deployed by the delivery catheter. Upon exiting the delivery catheter at the target lesion, the implant expands to the vessel lumen diameter. The Roadsaver system is to be used with the Nanoparasol™ Embolic Protection System (EPS). The delivery system is 143 cm length.

Figure 1.
Roadsaver System Set-up



1. Knob
2. RHV
3. Guidewire Lumen Mandrel
4. Proximal RX Port
5. Distal Tip

Figure 2.
Roadsaver Stent (Unconstrained)

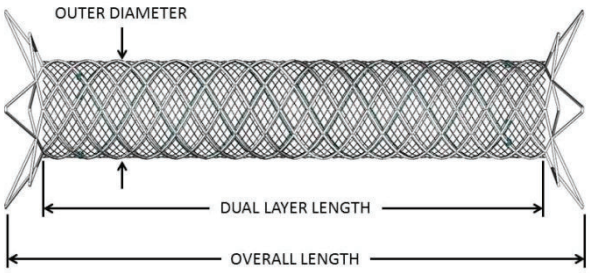
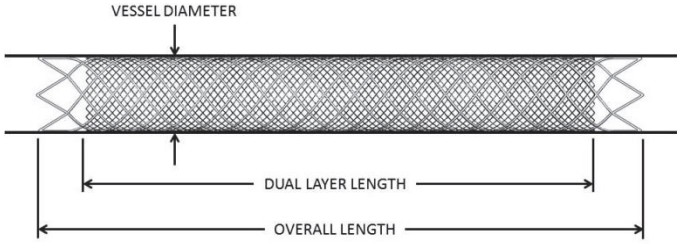


Figure 3.
Roadsaver Stent (Implanted/Constrained)



B. INDICATIONS FOR USE

The Roadsaver Carotid Stent System, when used in conjunction with the Nanoparasol embolic protection system, is indicated for the treatment of carotid artery stenosis in patients with elevated risk for adverse events following carotid endarterectomy and meet the criteria outlined below:

1. Patients who have either de novo atherosclerotic or post endarterectomy restenotic lesion(s) in the internal carotid arteries or at the carotid bifurcation with ≥50% stenosis if symptomatic or ≥80% stenosis if asymptomatic (both defined by angiography),

AND

2. Patients having a vessel with reference diameters between 3.5 mm and 9.0 mm at the target lesion.

C. CONTRAINDICATIONS

The Roadsaver Carotid Stent System is contraindicated for use in:

- Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs are contraindicated
- Patients with known hypersensitivity to nickel-titanium
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide wire, guide catheter, introducer sheath, an embolic protection device, delivery catheter, or retrieval catheter
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery
- Carotid vessel with <25mm gap between the target location of the distal end of the stent and the proximal end of the distal protection device.

D. WARNINGS

Visually inspect all the sterile barrier systems, that are labeled as sterile, immediately prior to use. Do not use if breaches in sterile barrier system integrity are evident, such as pouch is damaged, open.

The Roadsaver stent should be implanted in vessels with the referenced diameters according to the product label.

Should unusual resistance be felt at any time during access or removal, the sheath introducer/guide catheter and Roadsaver system should be removed as a single unit. Applying excessive force during delivery or retrieval of the Roadsaver system can potentially result in loss or damage to the device and delivery components.

When using the Nanoparasol embolic protection system, allow for and maintain adequate distance between the filter (no less than 2.5 cm), the stent delivery system or deployed stent to avoid potential entanglement.

Do not reposition the Roadsaver system without fully retrieving the device. The Roadsaver stent MUST be retrieved into the delivery system and redeployed at the desired target location or removed completely from the patient.

Do not attempt to reposition the Roadsaver implant after detachment.

The use of a guiding sheath or guiding catheter with a fixed hemostasis valve may cause the distal tip of the delivery catheter to detach at the hemostasis valve upon removal if the valve is not adequately opened.

When multiple stents are required, stent materials should be of similar composition.

Multiple stents should not be used in an overlapped configuration.

Persons allergic to nickel titanium (Nitinol) may suffer an allergic reaction to this implant.

It is not recommended that the stent be used in patients with the following additional characteristics:

- Patients with poor renal function and in the opinion of physician may be at risk for a reaction to contrast medium
- Pregnant patients
- Patients with perforated vessels evidence by extravasation of contrast medium.
- The presence of extensive atherosclerotic disease involving the aortic arch and proximal common carotid artery that would preclude the safe introduction of a guiding catheter, sheath or EPS

E. PRECAUTIONS

Only physicians trained and familiar with carotid stent placement and the associated complications, side effects and hazards should use this device.

The stent should not be sized to the vessel beyond the reference vessel diameter range listed on the product label.

Carefully inspect the sterile package and the Roadsaver system device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the package is opened or damaged.

See the product label for shelf life. Do not use the Roadsaver system beyond the labeled use by date.

Carefully remove the guide wire lumen mandrel (see Figure 1 for Proximal Rx port location) and fully flush the guide wire lumen. Do not use the delivery system if flush is not observed exiting at the stent Rx delivery system port locations (proximal and distal).

Exercise caution when crossing the deployed/detached Roadsaver system with the Nanoparasol embolic protection system, catheters or balloon catheters to avoid disrupting the device geometry and device placement.

The Roadsaver system is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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

Store in a cool and dry place.

F. POTENTIAL COMPLICATIONS

Possible complications include but are not limited to the following:

- Arrhythmia
- Aneurysm and pseudoaneurysm formation
- Abrupt vessel closure
- Allergic reactions (including to antiplatelet agents, contrast medium or stent materials)
- Arteriovenous fistula
- Bleeding from anticoagulation/antiplatelet medication
- Bradycardia and hypotension
- Carotid artery spasm
- Angina/Coronary ischemia
- Cerebral Edema
- Cerebral Hemorrhage
- Congestive Heart failure
- Death
- Disseminated intravascular coagulation
- Emboli (air, tissue, plaque, thrombus, device or other)
- Emergency artery bypass graft surgery
- Hematoma
- Hemorrhagic or embolic stroke/TIA
- Hyperperfusion Syndrome
- Infection and/or pain at insertion site/Sepsis
- Intimal tear/dissection
- Myocardial Infarction (MI)
- New or worse encephalopathy
- Pain
- Renal failure/insufficiency
- Respiratory arrest
- Restenosis of stented segment
- Stent misplacement
- Seizure
- Severe Unilateral Headache
- Tissue necrosis
- Total occlusion of carotid artery
- Vessel injury/dissection/perforation/rupture/trauma
- Vessel occlusion or thrombosis
- Vessel spasm or recoil

G. SYMBOLS

	Caution
	Lot Number
	Catalog Number
	Contents
	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Manufacturer
	MR Conditional
	Non-pyrogenic
	Consult Instructions for Use
	For Prescription Use Only
	Do Not Use if Package is Damaged

H. MRI Safety Information

MRI Safety Information
A patient implanted with the Roadsaver Stent may safely be scanned under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Roadsaver Stent
Static Magnetic Field Strength (B_0)	1.5T and 3T, Only
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2-W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	15 minutes of continuous scanning followed by 15 minutes of cooling
Image Artifacts	Extends approximately 5-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system

I. CLINICIAN USE INFORMATION

Materials

The following parts are required to use the Roadsaver system:

Accessories for performing a procedure but NOT supplied should be selected based on the physician's experience and preferences:

- Appropriate Guiding sheath or catheter with a minimum internal diameter (I.D.) of .074 in. (1.9 mm).
- Nanoparasol embolic protection system compatible with the Roadsaver System
- Saline solution/heparin-saline solution continuous flush set
- 5 cc syringe for flushing the Roadsaver System
- Contrast solution
- Rotating Hemostatic Valve (RHV)
- Pressurized sterile Infusion solutions – IV stand
- Femoral artery access device, sterile needle, guide wire
- The Roadsaver system does not contain latex or PVC materials.

J. PACKAGING AND STORAGE

The Roadsaver System is placed inside a protective packaged which includes a tray, sterile sealed pouch and unit carton. The Roadsaver System will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

K. SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled use by date.

L. PREPARATION FOR USE

Device and Delivery System Selection

Appropriate selection of the Roadsaver Carotid Stent System is important for patient safety. In order to choose the optimal Roadsaver stent size for any given lesion, examine pre-treatment angiograms for correct and accurate vessel measurements. Reference the Product Specification chart for the Roadsaver Carotid Stent System or see the device box label. The stent diameter should be slightly (1-2 mm) larger than the diameter of the reference vessel to obtain secure placement. Choose the unconstrained diameter and dual layer stent length as indicated on the outer box label to correspond with the implanted dual layer length, at a minimum, as long as the target lesion.

M. DIRECTIONS FOR USE

Delivery System Preparation

Note: You can prepare and flush the delivery system within the packaging tray or you can remove it and flush the delivery system outside the packaging.

1. Remove the pouched tray enclosing the Roadsaver System from the carton.

2. Inspect the pouch for any signs of damage to the sterile barrier.

Warning: If it is suspected that the sterile barrier seal has been opened or compromised, do not use the carotid delivery system and return it to the manufacturer.

The delivery system should be flushed using a 5-ml syringe.

1. Peel open the pouch, remove the tray with delivery system from the pouch and inspect the delivery system for any signs of damage.

2. Remove the guidewire lumen mandrel from the proximal Rx port and flush the delivery system (See Figure 1 for Proximal Rx Port location).

3. Attach a 5-ml syringe filled with sterile heparinized saline solution to the RHV luer and flush the delivery system (See Figure 1 for RHV). Apply positive pressure until the saline weeps or comes out in drops from the valve seal of the RHV. Close the seal of the RHV, continue to apply positive pressure until the saline weeps or comes out in drops from the proximal RX port (See Figure 1). Pinch the proximal RX port and continue to apply positive pressure until the saline weeps or comes out in drops from the distal RX port or distal tip of the delivery catheter.

4. Carefully remove the delivery system from the tray and remove the catheter from the tubing within the tray without kinking the catheter.

Pre-procedure

The use of the Nanoparasol embolic protection system is required. Refer to the instructions for use for the Nanoparasol embolic protection system for use with the Roadsaver carotid stent system. Gain vascular access according to standard angiographic practice and perform a diagnostic angiogram to determine the appropriate stent diameter and length for the target lesion. Refer to the Product Specification chart for the Roadsaver Carotid Stent System or see the device box label for choosing the stent size.

Introduction of the Stent Delivery System

Refer to the outer box label for choosing the proper guide sheath or guiding catheter for use with the Roadsaver Carotid Stent System.

Access the treatment site using the appropriate accessory equipment and insert the Nanoparasol embolic protection system usable as a guidewire

Warning: Always use the Nanoparasol when advancing or withdrawing the delivery system. If necessary perform a pre-dilatation at the lesion target site using a standard PTA technique using the recommended guide sheath or guiding catheter on the outer box label. The Nanoparasol embolic protection device should be advanced past the target lesion site. Then the delivery system should be advanced over the Nanoparasol wire to the lesion site using fluoroscopy.

Warning: If necessary perform a pre-dilatation using a standard PTA procedure and then introduce the system through the sheath or guiding catheter.

Caution: Do not advance the delivery system against significant resistance. The cause of the resistance should be determined by fluoroscopy and remedial action taken. Withdraw the system and use a new one.

Slack Removal

Ensure that the delivery system catheter outside the patient remains flat and straight.

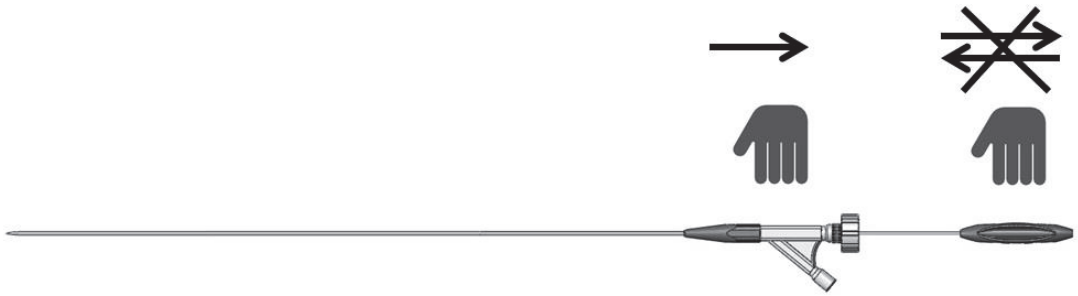
Warning: Slack in the delivery system catheter either outside or within the patient may result in misplacement of the stent beyond the lesion.

Stent Deployment

Note: The Roadsaver stent should be sized to the vessel according to the reference vessel diameter range listed on the product label. The Roadsaver stent foreshortens as it expands to the diameter of the native vessel. The stent foreshortening should be taken into account when sizing and deploying the Roadsaver Carotid Stent System. If the Roadsaver stent positioning is not satisfactory across the target lesion, the stent may be recaptured and repositioned if it is not fully deployed. The implant may be recaptured up to 50% of its deployment from the catheter delivery system (**See Figure 5 and 6**). Recapturing of stent can be accomplished by removing the slack in the delivery catheter shaft and then maintaining the inner catheter (handle) position and advancing or pushing forward the outer catheter. After recapturing the stent into the delivery system then you can redeploy the stent across the lesion, taking into consideration the foreshortening of the stent.

Ensure the RHV is open. The stent is deployed by outer catheter retraction. Deployment is complete by maintaining inner catheter position (holding handle) while retracting the outer catheter and allowing the stent to expand **(See Figure 4**).

Figure 4.



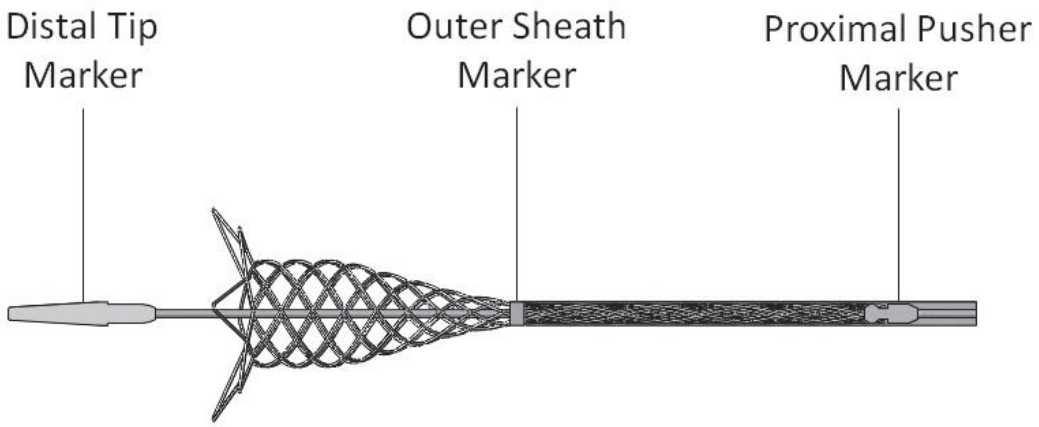
Stent Deployment

Figure 5.

Stent Retraction

Figure 6.

Stent Recapture: Approximately 50% Deployment



Withdrawing Stent Delivery System

After the stent has been completely deployed, using fluoroscopy, withdraw the delivery system carefully, leaving the EPS in place. Perform standard post-procedural angiography.

Post-deployment Stent Dilatation

If the stent is not completely expanded within the length of the lesion, post-dilation with the balloon catheter inside the stent may be done with standard PTA technique. The inflated nominal diameter of the PTA balloon used for post-dilation should be approximately the same as the diameter of the referenced native vessel.

Post Stent Placement

Upon final angiography confirming a satisfactory result, the Nanoparasol EPS should be removed along with the guide sheath or guiding catheter. Refer to the Instructions for use for the Nanoparasol EPS when removing the device. Hemostasis of the puncture site should be established.

N. CLINICAL STUDIES – SAFETY AND EFFECTIVENESS

1. Design

The study, titled "*CONFIDENCE Trial - Carotid Stent Trial to Evaluate the Safety and Efficacy of the Roadsaver™ Stent Used in Conjunction with the Nanoparasol Embolic Protection System for Patients at Increased Risk for Adverse Events from Carotid Endarterectomy*," was an open-label, multicenter, prospective, single-arm study with follow-up at hospital discharge, 30 days, 180 days and 12 months post procedure. Two hundred and fifty-six (256) subjects were enrolled in 30 investigational sites in the US.

The primary endpoint was the Major Adverse Event (MAE) composite endpoint consisting of death, stroke, or myocardial infarction (MI) within 30 days of the index procedure plus ipsilateral stroke within 12 months.

2. Inclusion and Exclusion Criteria

Enrollment in the Roadsaver pivotal clinical study was limited to patients who met the following inclusion criteria.

- **General Inclusion Criteria**
  Patients were eligible for inclusion in the study if they met **all** the following inclusion criteria:

  1. Patient was between ≥21 and ≤80 years of age.
  2. Patient was willing and capable of complying with all study protocol requirements, including specified follow-up period and could be contacted by telephone.
  3. Patient or LAR provided written informed consent before enrollment in study.
  4. Patient was diagnosed with carotid artery stenosis and considered a high perioperative risk for carotid endarterectomy (CEA).
  5. Patient was either:
     a. Symptomatic with carotid stenosis ≥50% as determined by angiography using North American Symptomatic Carotid Endarterectomy Trial (NASCET) methodology. Symptomatic was defined as amaurosis fugax ipsilateral to the carotid lesion; TIA or non-disabling stroke within 180 days of the procedure within the hemisphere supplied by the target vessel; or
     b. Asymptomatic with carotid stenosis ≥80% as determined by angiography using NASCET methodology.
  6. Patient had a target lesion located at the carotid bifurcation and/or proximal internal carotid artery (ICA).
  7. Patient had a single, de novo or restenotic (post CEA) target lesion or severe tandem lesions close enough to be covered by a single Roadsaver stent.
  8. Patient had a vessel with reference diameters 3.5–9.0 mm at the target lesion and met the criteria for device use per Instructions for Use.

- **High-risk Inclusion Criteria**
  For inclusion in the study, a patient had to qualify in ≥1 anatomic and/or ≥1 comorbid high-risk condition per below:

  Anatomic high-risk conditions

  1. Patient had a target lesion at or above the second vertebral body (level of jaw) or below the clavicle.
  2. Patient had an inability to extend the head due to cervical arthritis or other cervical disorders.
  3. Patient was status/post radiation therapy to the neck.
  4. Patient had a previous head and neck surgery in the region of the carotid artery.
  5. Patient had spinal immobility of the neck.
  6. Patient had the presence of a tracheostomy stoma.
  7. Patient had laryngeal palsy or laryngectomy.
  8. Patient had a hostile neck or surgically inaccessible lesion.
  9. Patient had severe tandem lesions.

Comorbid high-risk conditions

1. Patient was ≥70 years of age (maximum 80 years) at the time of enrollment.
2. Patient had New York Heart Association (NYHA) Class III or IV congestive heart failure (CHF) with left ventricular ejection fraction (LVEF) ≤35%.
3. Patient had chronic obstructive pulmonary disease (COPD) with forced expiratory volume (FEV) ≤30%.
4. Patient had unstable angina.
5. Patient had a recent MI (≥30 days before stenting procedure).
6. Patient had coronary artery disease with ≥2 vessels with ≥70% stenosis.
7. Patient had planned coronary artery bypass grafting (CABG) or valve replacement surgery 31–60 days after the carotid artery stenting (CAS) procedure.
8. Patient required peripheral vascular surgery or abdominal aortic aneurysm repair between 31–60 days after the CAS procedure.
9. Patient had contralateral laryngeal nerve paralysis.
10. Patient had restenosis after a previous CEA.
11. Patient had contralateral occlusion in the ICA as the only comorbid high-risk condition.

- **General Exclusion Criteria**
  Patients were excluded from the study for any of the following reasons:

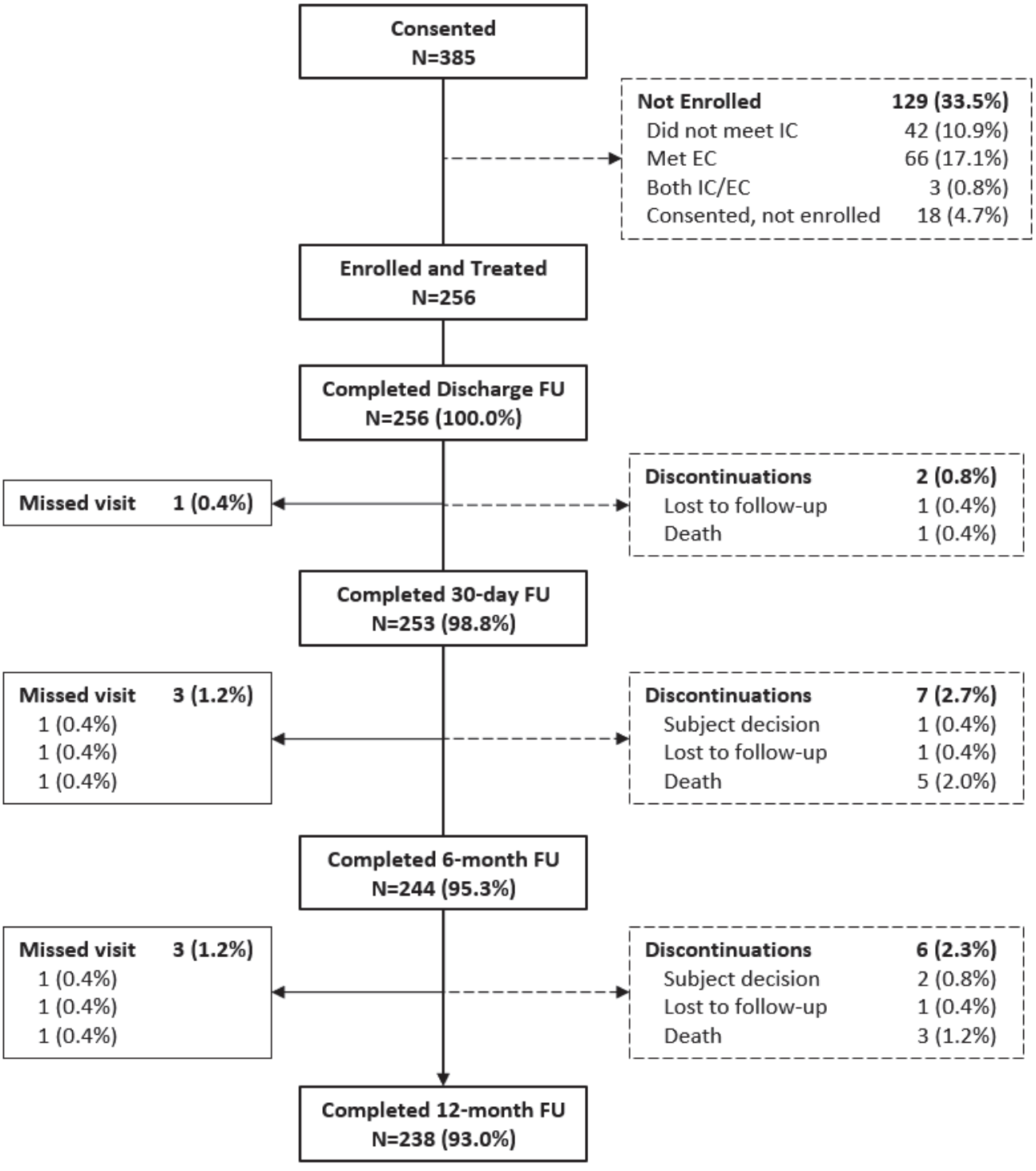
1. Patient had life expectancy of <1 year.
2. Patient was experiencing (or had experienced) an evolving, acute, or recent disabling stroke in the last 30 days.
3. Patient had anticipated or potential sources of emboli (eg, known previously symptomatic patent foramen ovale (PFO), mechanical heart valve, or deep vein thrombosis (DVT) treated within 6 months) that were not adequately treated with antithrombotics for ≥2 weeks with documented coagulation parameters in the target therapeutic range.
4. Patient had atrial fibrillation.
5. Patient had an acute MI within 60 days prior to the index procedure.
6. Patient had or planned to have any major surgical procedure (ie, intra-abdominal or intrathoracic surgery or any surgery/interventional procedure involving cardiac or vascular system) within 30 days of the index procedure.
7. Patient had a history of major ipsilateral stroke.
8. Patient had >60% carotid stenosis contralateral to the target lesion requiring treatment before completion of the study-required 12-month follow-up.
9. Patient had a mRS score >2 or had another neurological deficit not due to stroke that may confound the neurological patient assessments.
10. Patient had chronic renal insufficiency (serum creatinine ≥2.5 mg/dL) or had a history of severe hepatic impairment, malignant hypertension, and/or was morbidly obese.
11. Patient had platelet count <100,000/µL.
12. Patient had known sensitivity to heparin or previous incidence of heparin-induced Thrombocytopenia (HIT) type II.
13. Patient had contraindication to standard-of-care study medications, including antiplatelet therapy.
14. Patient had known sensitivity to contrast media that could not be controlled adequately with pre-medication.
15. Patient had known bleeding diathesis or hypercoagulable state or refuses blood transfusions.
16. Patient had intracranial pathology that, in the opinion of the Investigator, made the patient inappropriate for study participation (eg, brain tumor, arteriovenous malformation [AVM], cerebral aneurysm, cerebral vascular disease [microangiopathy or large vessel], etc.) or would confound neurological evaluation.
17. Patient had intracranial hemorrhage within the last 90 days.
18. Patient was enrolled in another investigational study protocol and had not completed its primary endpoint or that may have confounded the current study endpoints. Patients who were involved in the long-term surveillance of a clinical study were eligible.
19. Patient suffered from confusion or dementia or was unable or unwilling to cooperate with the study requirements and/or follow-up procedures.
20. Patient had a known, unresolved history of drug use or alcohol dependency.
21. Patient had an active infection.

22. Patient had renal failure and/or was on dialysis.
23. Patient had documented uncontrolled diabetes.
24. Patient was pregnant.

- **Angiographic Exclusion Criteria**
  A patient was not eligible for enrollment if s/he met any of the following angiographic exclusion criteria:

  1. Patient had a total occlusion of the target carotid arteries (ie, CCA, ICA).
  2. Patient had a previously placed stent in the ipsilateral carotid artery.
  3. Patient had severe lesion calcification or vascular tortuosity that precluded the safe introduction of the sheath, guiding catheter, embolic protection system, or stent.
  4. Patient had a mobile filling defect or thrombus in target vessel.
  5. Patient had occlusion or presence of “string sign” of the target vessel.
  6. Patient had carotid (intracranial) stenosis located distal to target stenosis that was more severe than the target stenosis.
  7. Patient had known mobile plaque or thrombus in the aortic arch.
  8. Patient had a type III aortic arch.
  9. Patient in whom femoral access was not possible.
  10. Patient had intracranial AVMs in the territory of the target carotid artery.
  11. Patient had an aneurysm in the territory of the target carotid artery that required treatment within 12 months.
  12. Patient’s ipsilateral carotid artery had ≥2 90-degree bends in the target landing zone.

3. Subject Accountability Flowchart



Note: the numbers of patients who discontinued or missed a visit will not add up to the total number of patients that completed each visit because patients who missed a visit were not excluded from further analysis. They may have completed subsequent visits.

4. Demographics

The baseline demographic characteristics for the intent to treat (ITT) population in the pivotal clinical study are summarized in Table 7. In the ITT population, the mean (SD) age was 69.6 (6.8) years, and the majority of the subjects were men (65.2% [n=167]). 95.3% [n=244] of subjects were not of Hispanic or Latino; 4.7% of subjects identified themselves as Hispanic or Latino. 91% [n=233] of subjects were white; 4.3% (n=11) identified themselves as Black or African American. In the ITT population, mean (SD) height was 67.0 (4.0) inches, mean (SD) weight was 185.5 (43.1) pounds, and mean (SD) body mass index (BMI) was 28.8 (5.5) kg/m2. Overall, these demographic characteristics are consistent with a typical cohort of subjects with carotid artery stenosis at high operative risk for CEA.

Table 1: Demographics and Baseline Characteristics (ITT Population)

Characteristic	ITT (N=256)
Age (years)	
Mean (SD)	69.6 (6.8)
Median (min, max)	71.0 (46.0, 80.0)
Gender, n (%)	
Male	167 (65.2%)
Female	89 (34.8%)
Ethnicity, n (%)	
Not Hispanic or Latino	244 (95.3%)
Hispanic or Latino	12 (4.7%)
Race, n (%)	
White	233 (91.0%)
Black or African American	11 (4.3%)
Other	6 (2.3%)
Asian	5 (2.0%)
American Indian or Alaska Native	1 (0.4%)
Height (inches)	
Mean (SD)	67.0 (4.0)
Weight (pounds)	
Mean (SD)	185.5 (43.1)
Body Mass Index (kg/m^2)	
Mean (SD)	28.8 (5.5)

As presented in Table 2, among all enrolled subjects, 23.8% (61/256) were symptomatic (ie, amaurosis fugax ipsilateral to the carotid lesion, TIA or non-disabling stroke within 180 days of the procedure within the cerebral hemisphere supplied by the target vessel), and 76.2% (195/256) were asymptomatic. Among all enrolled subjects, 40.2% of subjects (103/256) had ≥1 anatomic high-risk conditions; 84.4% of subjects (216/256) had ≥1 comorbid high-risk conditions.

Table 2: Summary of Symptomatic/Asymptomatic Subjects and Subjects with High-risk Conditions (ITT Population)

Characteristic	N=256 n (%)
Symptomatic Asymptomatic	61 (23.8%) 195 (76.2%)
Subjects with ≥1 anatomic high-risk conditions Subjects with ≥1 clinical comorbid high-risk conditions	103 (40.2%) 216 (84.4%)

The target lesion characteristics and extent of stenosis is presented in Table 3. There was a total of 132 (51.6%) lesions in the right carotid artery and the mean (SD) percent stenosis was 82.4% (7.76).

Table 3: Target Lesion Characteristics & Extent of Stenosis – Site-reported Angiography (ITT Population)

Parameters and Statistics	ITT (N=256) n (%)
Location of target lesion	
Right carotid artery	132 (51.6%)
Left carotid artery	124 (48.4%)
Minimum lumen diameter	
Mean (SD)	1.0 (0.9)
Median (min, max)	0.55 (0, 3)
(95% CI)	(0.9, 1.1)
Percent Stenosis	
Mean (SD)	82.4 (7.76)
Median (min, max)	81.0 (50, 99)
(95% CI)	(81.5, 83.4)

The results for the pre-procedure target lesion morphology performed by the Core Angiography Laboratory are summarized in Table 4. Overall, the target lesion location was contiguous for the majority of subjects (85.3% [215/252]). The mean (SD) distance of the lesion from the ostium was 20.9 (8.2) mm; the median (range) was 21.3 (5.0–40.0) mm. ICA calcification was severe in 23.4% of subjects (59/252).

Table 4: Target Lesion Morphology – Core Laboratory Angiography (ITT Population)

Parameters and Statistics	ITT (N=252) n (%)
Distance (mm) from ostium	
Mean (SD)	7.2 (8.0)
Median (min, max)	5.0 (0.0, 32.0)
(95% CI)	(6.2, 8.2)
Length (mm)	
Mean (SD)	20.9 (8.2)
Median (min, max)	21.3 (5.0, 40.0)
(95% CI)	(19.8, 21.9)
Eccentricity, concentric / eccentric	
Concentric	220 (87.3%)
Eccentric	32 (12.7%)
ICA calcification	
Moderate	39 (15.5%)
None/Mild	154 (61.1%)
Severe	59 (23.4%)

O. CLINICAL STUDIES – SAFETY AND EFFECTIVENESS

1. Patient Analysis Population

The ITT population includes 256 subjects that had the Roadsaver delivery device inserted and the Roadsaver device implanted.

2. Primary Endpoint Results

The primary endpoint was MAE, a composite measure of death, stroke, or MI within 30 days of the index procedure plus ipsilateral stroke 31–365 days after the procedure In the ITT population, 15 patients (5.9% [95% exact binomial CI: 3.89, 10.69]; p=0.0014) experienced a MAE. In the ITT analysis using multiple imputations for subjects who discontinued prematurely, the MAE rate was 6.2% (16/256) (Table 5). The upper limit of the 95% exact binomial CI was 9.22%, which was below the PG of 13.9%. Because the upper limit of the CI was less than the PG, the null hypothesis (H_0) is rejected, and the alternative hypothesis is accepted (H_1). Thus, the primary endpoint of the study was met.

Table 5: CEC-adjudicated MAE Rate with Multiple Imputations for Subjects Who Discontinued Prematurely (ITT Population)

Endpoint	N=256
Subjects who had an MAE*, n (%)	16 (6.2%)‡
95% exact binomial CI	(3.17, 9.22)§
p-value†	0.0004
Subjects who died within 30 days of the index procedure	1 (0.4%)
Subjects who had a stroke within 30 days of the index procedure	7 (2.7%)
Subjects who had an MI within 30 days of the index procedure	1 (0.4%)
Subjects who had an ipsilateral stroke 31-365 days post-index procedure	7 (2.7%)

*MAE is defined as death, stroke, or MI within 30 days of the procedure plus ipsilateral stroke 31-365 days post-index procedure.
†Probability value derived from the 2-sided binomial test vs. an a priori Performance Goal of 13.9%.
‡Based on the estimated value, the count was rounded up to derive the probability value.
§CI was derived from the multiple imputation procedure.
Subjects may have more than one failed safety component. One subject with stroke expired within 30 days of the index procedure.

3. Secondary Endpoint Results (Performance Analysis)

Secondary endpoints include technical success, procedure success, embolic protection device technical success, target lesion revascularization within 12 months of follow-up, and in-stent restenosis at 30-day and 12-month follow-up.

As shown in Table 6, technical Success was achieved in 96.9% (248/256) of subjects; 8 subjects did not achieve residual stenosis diameter <50%. In all ITT subjects, the Roadsaver device was successfully deployed, and the delivery system was successfully retrieved. Procedure Success was achieved in 94.9% (243/256) of subjects; 8 subjects did not achieve residual stenosis diameter <50%. Four subjects (1.6%) had a stroke pre-discharge, and 1 subject (0.4%) had a MI pre-discharge. There were no pre-discharge deaths. Embolic Protection Device Technical Success was achieved in 98.8% (253/256) of subjects. Nine subjects (3.5%) required 10 TLRs within 12 months of the index procedure. ISR was reported in 5 subjects (2.0%) at the 30-day follow-up and 14 subjects (5.5%) at the 12-month follow-up.

Table 6: Performance Analysis (ITT Population)

Endpoint	N=256 n (%)
Technical Success[a]	248 (96.9%)
Successful deployment	256 (100.0%)
Residual diameter stenosis <50%[b]	248 (96.9%)
Successful removal of delivery system	256 (100.0%)
Procedure Success[c]	243 (94.9%)
Successful Roadsaver implantation	256 (100.0%)
Residual angiographic stenosis <50%[d]	248 (96.9%)
No in-hospital (pre-discharge) MAE (stroke, MI, or death)	251 (98.0%)
Stroke	4 (1.6%)
MI	1 (0.4%)
Death	0
Embolic Protection Technical Success[e]	253 (98.8%)
Target Lesion Revascularization[f]	9 (3.5%)
In-stent Restenosis[g] at 30-day follow-up	5 (2.0%)
In-stent Restenosis at 12-month follow-up	14 (5.5%)

[a]Successful deployment of Roadsaver in targeted treatment location with a residual diameter stenosis <50% immediately after post-dilatation as determined by the angiography Core Laboratory and with successful removal of delivery system.
[b]Determined by the Core Angiography Laboratory immediately after post-dilatation.
[c]Successful Roadsaver implantation, <50% residual angiographic stenosis as determined by the angiography Core Laboratory by visual NASCET assessment immediately post procedure at the target lesion and no in-hospital (pre-discharge) MAE (stroke, MI or death)
[d]Determined by Angiography Core Laboratory by visual NASCET assessment immediately after the procedure.
[e]Successful delivery and deployment beyond the target lesion and successful retrieval after completion of the stent placement.
[f]TLR was defined as any clinically driven revascularization procedure of the original treatment site associated with narrowing >80% within 12 months post-procedure, including angioplasty, stenting, endarterectomy, or thrombolysis, performed to open or increase the luminal diameter ≤5 mm of the previously treated lesion.
[g]In-stent Restenosis included subjects with >70% residual stenosis determined by ultrasound (PSV >300 cm/s and/or ICA/CCA PSV ratio >4.0) within the stented lesion.

P. CONCLUSION

The clinical study results support the reasonable assurance of safety and effectiveness of Roadsaver Carotid Stent System when used in accordance with the indications for use. The benefits of the device outweigh probable risks when considering the clinically significant results of the pivotal data conducted in the intended population under its proposed condition of use.

Q. HOW SUPPLIED

Sterile: This device is sterilized using Ethylene Oxide. Non-pyrogenic
Contents: One (1) Roadsaver system
Storage: Store product in a dry, cool place.

IFU100208X2

WARRANTY DISCLAIMER

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

Prices, specifications, and model availability are subject to change without notice.

TERUMO

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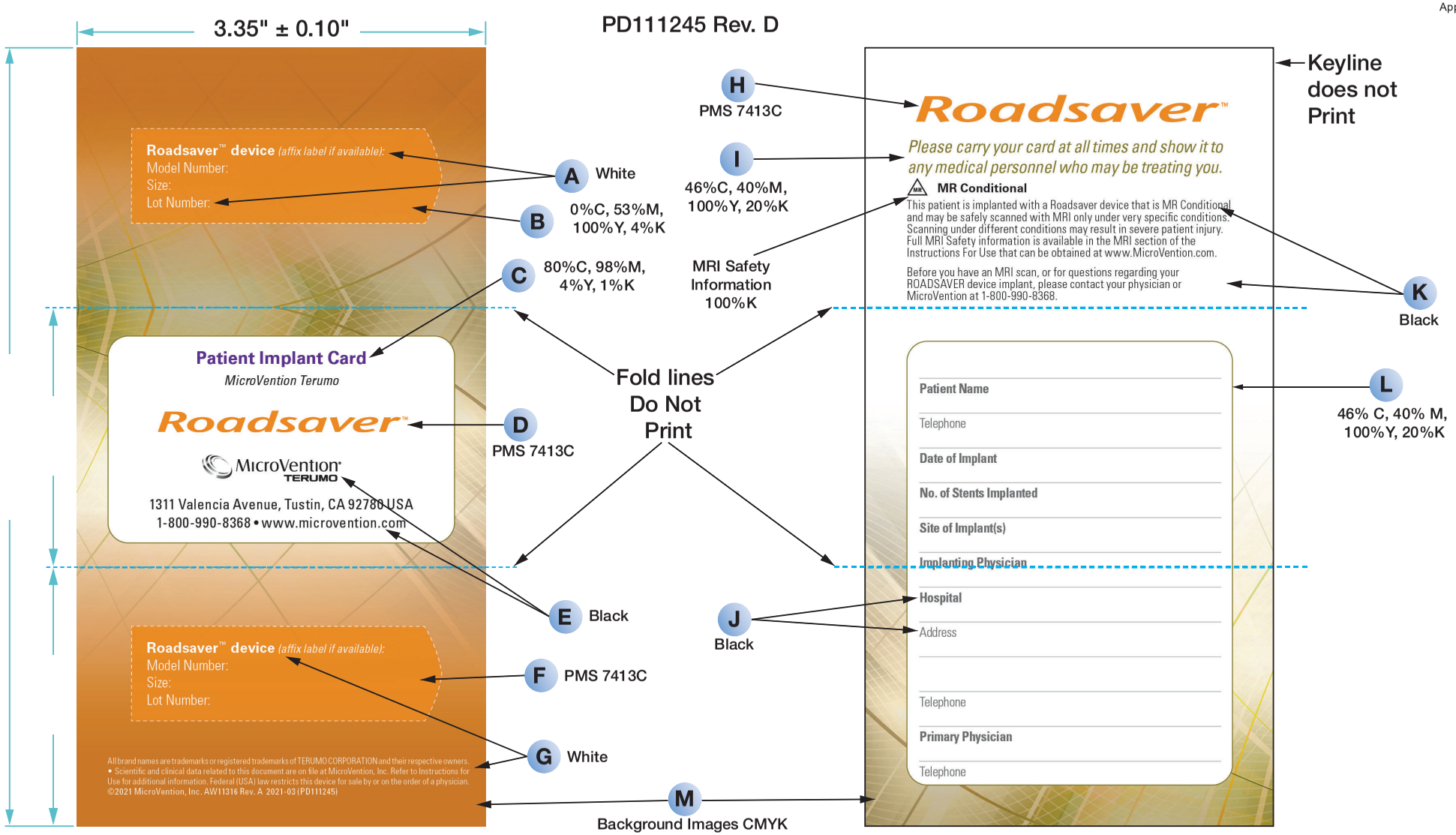

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