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℞ Only

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

The InspireMD CGuard® Prime TransCarotid Stent System delivers a self-expanding stent to the carotid arteries via the transcarotid artery revascularization (TCAR) approach using a rapid exchange (Rx) delivery system.
The stent is constructed of a nickel-titanium alloy (Nitinol) and covered by a permanent protective micromesh (MicroNet™). It is preloaded into the Rx delivery system, which is positioned at the target lesion. Retraction of the protective sheath allows the stent to expand. The stent and micromesh remain implanted as permanent vessel scaffolding. Upon deployment, the stent exerts an outward radial force on the arterial wall to establish lumen patency. Available stent sizes are shown in **Table 1.**

TABLE 1: CGUARD PRIME CAROTID STENT SIZE MATRIX

Reference Vessel Diameter (mm)	Length (mm)		
	Diameter (mm)	30	40
6.4 – 7.3	8.0	CNS0830	CNS0840
7.2 – 8.1	9.0	CNS0930	CNS0940
8.0 – 9.0	10.0	CNS1030	CNS1040

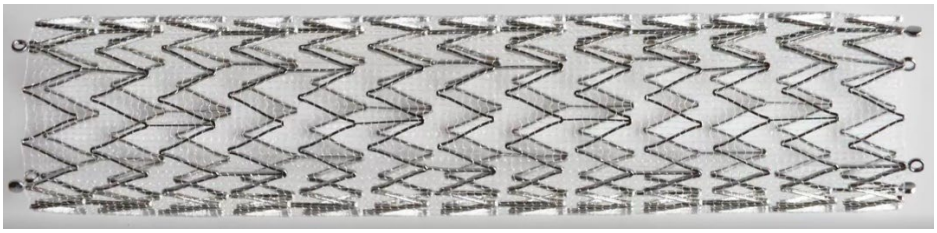


FIGURE 1: CGUARD PRIME CAROTID STENT

The CGuard Prime TransCarotid Stent System Rx delivery system deploys using a two-step process: a pre-release (step 1), and stent deployment (step 2). This delivery system is suitable for all sizes of the CGuard Prime Carotid Stent. It is comprised of an outer shaft and an inner assembly. A pictorial representation of the delivery system is presented in **Figure 2**.

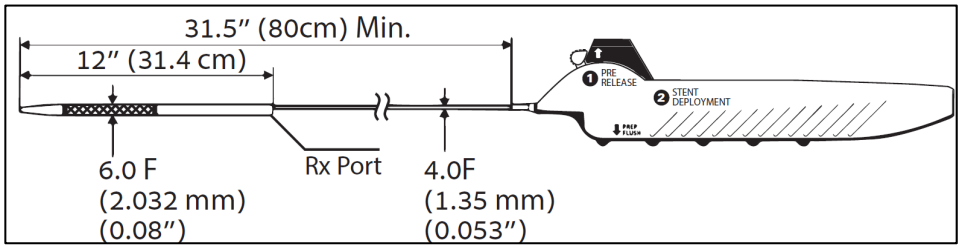


FIGURE 2: RX DELIVERY SYSTEM OF 80CM WORKING LENGTH

The following accessories are compatible with the CGuard Prime TransCarotid Stent System:

- 0.014” (0.36 mm) guide wire.

HOW SUPPLIED

- The device is supplied sterile, non-pyrogenic and is sterilized by ethylene oxide gas.
- Do not use after the “Use By” (expiration date printed on the label).
- The CGuard Prime TransCarotid Stent System is designed for single use only; do not reuse the device.
- Reuse may cause device failure or procedural complications, including device damage, compromised biocompatibility, and contamination, leading to patient harm.

STORAGE & HANDLING

- Store in ambient conditions.
- Handle and dispose of the device and packaging in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.

INDICATIONS FOR USE

The CGuard Prime TransCarotid Stent System, when used in conjunction with an embolic protection system specified in the labeling, is indicated for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below:

- Patients with neurological symptoms and ≥ 50% stenosis of the common or internal carotid artery by angiogram, or patients without neurological symptoms and ≥ 80% stenosis of the common or internal carotid artery by angiogram.
- Patients having a vessel with reference diameters between 6.4mm and 9.0mm at the target lesion.
- A carotid bifurcation location that is at least 5 cm above the clavicle, verified through duplex Doppler ultrasound, computer tomography (CT) angiography, or magnetic resonance (MR) angiography.

COMPATIBLE EMBOLIC PROTECTION SYSTEMS

ENROUTE™ Transcarotid Neuroprotection System.

CONTRAINDICATIONS

The CGuard Prime TransCarotid Stent System is contraindicated for use in:

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.
- Patients with whom a transcarotid neuro protection system cannot be effectively placed.
- Patients with known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.

WARNINGS

- Only physicians familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with transcarotid stent placement should use this device. Preparation of patients receiving the CGuard Prime Carotid Stent should include initiation of an appropriate dosage of oral antiplatelet medication prior to and following the procedure. Effective anticoagulation therapy should be maintained throughout the procedure and continued into the postoperative period as deemed appropriate by the treating physician.
- Manufacturers' instructions for use should be consulted for all interventional devices used in conjunction with the CGuard Prime TransCarotid Stent System for their use, contraindications, warnings and precautions.
- Placement of a stent across a bifurcation may preclude future diagnostic or therapeutic procedures.
- As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture.
- The safety and efficacy of the CGuard Prime TransCarotid Stent System has not been demonstrated with systems other than the compatible embolic protection systems listed.
- The safety and effectiveness of concurrent treatment of lesions in patients with bilateral carotid artery disease have not been established.
- The CGuard Prime Carotid Stent has not been evaluated for overlapping stent placement. Ensure that the selected stent is sufficiently long for total lesion coverage.
- Do not use contrast material while performing flush preparation to the CGuard Prime TransCarotid Stent System.
- Perform all device exchanges slowly in order to prevent air from being introduced to the system or trauma to the artery.
- Pre-dilating the lesion without neuroprotection may increase the risk of an adverse outcome. Implanting a stent or post-dilatation may lead to distal and / or proximal dissection and may cause acute vessel closure, requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents).
- The stent systems may cause thrombus migration from the implant site along the arterial lumen and may produce distal embolization.
- In the event of thrombosis of the expanded stent, thrombectomy or thrombolysis should be considered, and surgical removal of the stent may be required.
- In the event of complications such as infection, pseudo-aneurysm, or fistulation, surgical stent removal may be required.
- The delivery system is not designed for use with power injection. The use of power injection may adversely affect device performance.
- Before contrast injection, aspirate any air in the guiding catheter.
- Flush the guiding catheter with saline every time after injecting contrast media.
- Ensure optimal positioning of the stent prior to deployment. Position correction might be performed after the pre-deployment step. Once deployment is initiated, the stent cannot be repositioned or recaptured. Stent retrieval methods such as snares and/or forceps may result in additional trauma to the carotid vessel or the vascular access site. Complications may result in vessel dissection, bleeding, hematoma, pseudoaneurysm, stroke, or death.
- Continuously observe the CGuard Prime Carotid Stent System under fluoroscopy during stent deployment.
- DO NOT use the device if the seal or package is torn or broken.
- DO NOT use the product if the ethylene oxide (EO) sterilization indicator on the inner pouch is yellow-brown.
- DO NOT re-use. DO NOT re-sterilize, as this can compromise device performance and may increase the risk of cross-contamination due to inappropriate reprocessing.

PRECAUTIONS

CAUTION: Venous access should be available during carotid stenting to manage possible bradycardia and/or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker if needed.

- Embolic protection of the target vessel is mandatory for all CGuard Prime TransCarotid Stent System procedures using a compatible embolic protection system. The compatible embolic protection system shall be used in accordance with the applicable Instructions for Use.
- Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.
- The stent and the delivery system are designed to perform as an integrated system and to be used only as designed.
- Do not expose the delivery system to organic solvents, as structural integrity and/ or device function may be impaired.

POTENTIAL ADVERSE EVENTS

Based on the literature and clinical and commercial experience with carotid stents and embolic protection systems, the following list includes possible adverse events associated with these devices:

- Abrupt vessel closure
- Allergic reaction (contrast medium; drug; stent or filter material)
- Amaurosis fugax
- Aneurysm or pseudoaneurysm in the vessel or at the vascular access site
- Angina/coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial and/or ventricular tachycardia, atrial and/or ventricular fibrillation)
- Asystole or Bradycardia
- Arteriovenous fistula
- Bleeding complications from anticoagulants or antiplatelet medication
- Cardiac tamponade
- Cardiogenic shock
- Carotid artery spasm
- Cerebral edema
- Cerebral hemorrhage
- Cerebral ischemia
- Congestive heart failure (CHF)
- Death
- Detachment and/or implantation of a component of the system
- Dissection of blood vessel
- Emboli (air, tissue, plaque, thrombotic material, stent)
- Emergency artery bypass graft surgery
- Emergent or urgent carotid endarterectomy
- Emergent surgery to remove stent.
- Hematoma at the vascular access site, with or without surgical repair
- Hemorrhagic event, with or without transfusion
- Hyperperfusion syndrome
- Hypotension/hypertension
- Infection, local or systemic, including bacteremia or septicemia
- Ischemia/ infarction of tissue organ
- Myocardial infarction
- New or worse encephalopathy
- Pain
- Pain at the catheter insertion site
- Pericardial effusion
- Pulmonary edema
- Renal failure/insufficiency
- Respiratory failure
- Restenosis of the stented segment
- Seizure
- Severe unilateral headache
- Stent collapse or fracture
- Stent malposition/migration
- Stent thrombosis or occlusion
- Stroke / Cerebrovascular accident (CVA)
- Transient ischemic attack (TIA)
- Tissue necrosis
- Total occlusion of the carotid artery
- Vascular thrombosis/occlusion at the access site, treatment site, or remote site
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil

MAGNETIC RESONANCE (MR) ENVIRONMENT

Magnetic Resonance Imaging (MRI) Safety Information  MR Conditional	
A patient implanted with a CGuard Prime Carotid Stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Parameter	*Condition of Use/Information*
Static Magnetic Field Strength (B_o)	1.5T or 3.0T
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
Radiofrequency (RF) Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
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 and Wait Time	Scan for 60 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series)
MR Image Artifact	The presence of the CGuard Prime Carotid Stent may produce an image artifact that can extend approximately 15 mm from the implant.

STENT SIZE DETERMINATION

Stent sizing is important for successful stenting. Depending on the stent size, a stent shall provide a minimum of 0.5mm -1mm over-size between the stent and vessel. This is recommended in order to achieve optimum sizing and stent expansion of the self-expanding stent (see **Table 2** for reference).

- The stent will expand to accommodate the varying sizes of the internal carotid artery, bifurcation, and common carotid artery. Thus, the stent sizing should be determined usually by the common carotid artery diameter. For example, select a 8.0 mm stent to treat a 6.4 – 7.3 mm diameter vessel. Select a 9.0 mm stent to treat a 7.2 – 8.1 mm diameter vessel.
- The mean percentage of foreshortening for all stent sizes is **less than 10%** (see **Table 2**).
  The optimal length size is the shortest stent length consistent with total lesion coverage plus the safety margins.

WARNING

- The CGuard Prime TransCarotid Stent System is contraindicated for use with lesions in the ostium of the common carotid and aorta.
- Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration.
- The CGuard Prime Carotid Stent has not been evaluated for overlapping stent placement. Ensure that the selected stent is sufficiently long for total lesion coverage.

TABLE 2: STENT FORESHORTENING DATA

Reference Vessel diameter [mm]	Stent Labeled diameter [mm]	Average Foreshortening [%]	Unconstrained stent diameter [mm] (After deployment)
6.4 -7.3	8	2.6	>7.6
7.2- 8.1	9	1.9	>8.4
8.0-9.0	10	2.3	>9.3

DIRECTIONS FOR USE

A **PRE-PROCEDURE**

Patient preparation and sterile precautions should be the same as for any trans carotid stent procedure. The placement of the carotid stent in a stenotic or obstructed carotid artery must be done in a procedure room with angiography capabilities. Angiography should be performed to map out the extent of the lesion and the collateral flow. Access vessels must be sufficiently patent to proceed with further intervention.

CAUTION: Do not use if the package is damaged, unintentionally opened, or exposed to environmental conditions outside of those specified on the label before use.

B INSPECTIONS PRIOR TO USE

- Inspect the CGuard Prime TransCarotid Stent System protective packaging (pouch). Ensure that the pouch is sealed and in an undamaged/non-deformed state.
  CAUTION: Do not use the system if the protective packaging is found to be damaged.
- The operating assistant (non-sterile assistant) should open the protective packaging, and the sterile operator should take the system tray out of the protective packaging (pouch).
- All the following steps described below should be performed by the physician (a sterile operator);
- Carefully remove the CGuard Prime TransCarotid Stent System from the hoop and out of its tray. Lay the device flat. Take care not to kink the shaft of the Rx delivery catheter system.
- Inspect the delivery system handle for any damage (see **Figure 3**).
- Inspect the Rx delivery system distal shaft and tip to verify that it has not been damaged during shipment.
- Ensure that the stent is fully covered by the delivery system shaft.

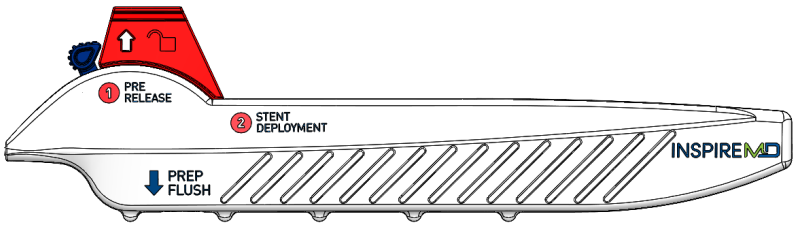


FIGURE 3: DELIVERY SYSTEM HANDLE

CAUTION: The Rx delivery system has an internal shaft. Take care to avoid unnecessary handling, which may kink or damage the delivery system. Keep the Rx delivery system as straight as possible and the delivery handle stationary during deployment. Do not use the device if it is kinked.

CAUTION: Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is especially important during delivery system removal from packaging, placement over the distal embolic protection device wire, and advancement through a hemostatic valve and guiding catheter hub.

CAUTION: The stent on the Rx delivery system is intended to perform as a system. Do not remove the stent from the delivery system, as removal may damage the stent. If removed, the stent cannot be placed back on the Rx delivery system.

C DELIVERY SYSTEM PREPARATION

- For device flushing, connect a 3 mL or 5 mL luer lock syringe to the "PREP FLUSH" port (see **Figure 4**) filled with heparinized saline solution (DO NOT USE CONTRAST), maintain positive pressure until saline fluid drops are observed exiting the CGuard Prime TransCarotid Stent System at the distal end. This process may take up to 30 seconds. Ensure saline is observed at the distal end as well as at the Rx guide wire port.
- At the end of the flushing process, remove the syringe.
- The system is flushed.
- Keep the device straight and flat to avoid kinking the shaft.
- Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is most important during catheter removal from packaging, placement over the guidewire, and advancement through the hemostasis valve and guiding catheter or vascular sheath.
- Do not attempt to deploy the stent from its delivery system while the system is not located in the target lesion. If deployed, the stent cannot be retrieved back into the delivery system, and the stent may become damaged.

CAUTION: Make sure to flush the system with at least 2 mL of saline.
CAUTION: Ensure correct flushing is performed in order to remove all air from the delivery system and eliminate the chance of friction within the sheath.
CAUTION: Ensure that CGuard Prime TransCarotid Stent System is fully flushed with heparinized saline prior to use. Do not use the CGuard Prime TransCarotid Stent System if flushing is not visible exiting at the distal end of the catheter.
CAUTION: Do not use contrast material while flushing.

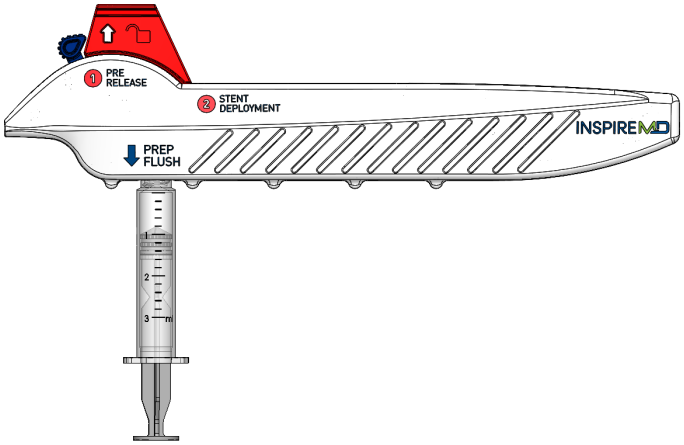


FIGURE 4: EXAMPLE OF 3 ML LUER LOCK SYRINGE CONNECTED TO THE CGUARD PRIME TRANSCAROTID STENT SYSTEM FOR FLUSHING

D LESION PREPARATION

- Maintain the patient's Activated Clotting Time (ACT) at > 250 seconds throughout system usage.

  WARNING: Administer a heparin dose sufficient to maintain an ACT of > 250 seconds to prevent thrombus formation on the devices.
  CAUTION: Venous access should be available during carotid stenting to manage bradycardia and/or hypotension by a pacemaker placement or pharmaceutical intervention if needed.
  CAUTION: The CGuard Prime TransCarotid Stent System must be used with a vascular sheath to maintain adequate support of the 0.014" (0.36 mm) guidewire throughout the procedure.
  CAUTION: The system is not compatible with guidewires larger than 0.014" wire (0.36 mm).
  CAUTION: Ensure that there is a tight seal between the CGuard Prime TransCarotid Stent System and the arterial sheath valve during aspiration. Failure to do so could result in air entering the arterial sheath.
  CAUTION: When the catheter is in the body, it should be manipulated only under fluoroscopy. Radiographic equipment that provides high-quality images is needed.
  WARNING: Perform all catheter exchanges slowly in order to prevent air embolism or trauma to the artery.

- It is mandatory to use a compatible embolic protection system.
- If required, pre-dilate the lesion with an appropriate-size balloon dilatation catheter to a minimum of 3.0 mm after the distal protection device is in place beyond the lesion.
  Note: If no pre-dilatation balloon is utilized, there must be a minimum luminal opening of 3.0 mm to enable retrieval of the tip of the CGuard Prime TransCarotid Stent System delivery system.

E PROCEDURE

- If lesion pre-dilatation has been performed, remove the balloon catheter and load the delivery system onto the 0.014" (0.36 mm) guide wire.

  CAUTION: The delivery system is not designed for use with a power injector. Use of a power injector may adversely affect device performance.

- Keep the device flat to avoid kinking the shaft.
- Insert the Rx delivery system through the hemostatic valve adapter. Ensure that the hemostatic valve of the guiding sheath/ guiding catheter is open to allow freedom of movement of the delivery system outer sheath during deployment.

  CAUTION: If resistance is encountered during the Rx delivery system introduction, the system should be withdrawn and a new system used.

- Advance the stent and the Rx delivery system forward under fluoroscopic guidance to the lesion site.

  CAUTION: Avoid any tension in the Rx delivery system prior to deployment.

F STENT DEPLOYMENT

- The deployment mechanism contains two steps:
  Step 1 – Pre-deployment – in this step, the stent is advanced toward the distal end of the catheter sheath
  Step 2 – Deployment – in this step, the catheter is retracted, and the stent is deployed.

  CAUTION: Ensure that the hemostatic valve of the guiding sheath/guiding catheter is open before the pre-deployment step and during deployment to allow the delivery system outer sheath to move freely.

- Catheter positioning at target lesion:
- Ensure optimal positioning of the stent prior to deployment. Once deployment is initiated, the stent cannot be repositioned or recaptured. Stent retrieval methods (use of additional wires, snares, and/or forceps) may result in additional trauma to the carotid vasculature and/or vascular access site. Complications may include death, stroke, bleeding, hematoma, or pseudoaneurysm.

- Confirm the stent position angiographically prior to deployment. Adjust position, if necessary, after the pre-deployment step.

Step 1 – Stent Pre-deployment

- When the target location is achieved, squeeze the safety tab with your fingers to release the tab and remove the safety tab. Discard the tab. See Figure 5 and **Figure 6** below for a visual demonstration of the start and end positions of the safety tab removal step.



FIGURE 5: SAFETY TAB REMOVAL START POSITION



FIGURE 6: SAFETY TAB REMOVAL END POSITION

Note: Ensure that the Rx delivery system is straight and not coiled. Keep the Rx delivery system stationary during deployment. Do not restrain the main shaft of the Rx delivery catheter during deployment. It must be free to move.

- The system is ready for stent deployment.

- Carefully retract the lever along the top arc. This is the pre-deployment step. See **Figure 7** below for a visual demonstration of the pre-deployment step.

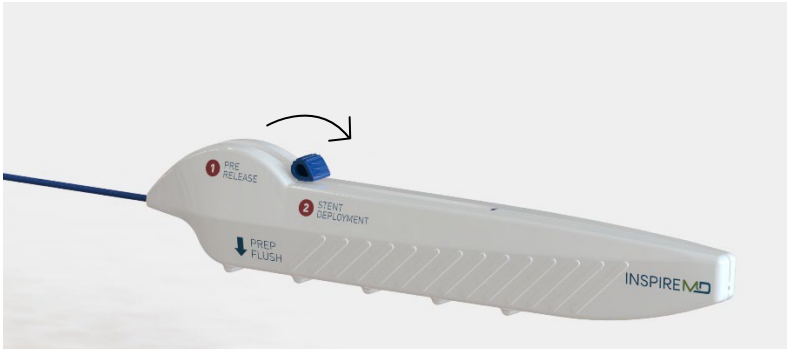


FIGURE 7: PRE-DEPLOY END POSITION

- Following pre-deployment, check stent positioning and if required, immediately perform a location adjustment. The system lever is now locked in place and ready for Step 2- stent deployment.

CAUTION: The stent location cannot be adjusted once Step 2- stent deployment has begun.

Step 2 – Stent Deployment

- Carefully retract the lever along the top plane of the handle until the lever reaches the end of its stroke. This is the stent deployment step. See **Figure 8** and **Figure 9** below for a visual demonstration of the start and end positions of the stent deployment step.

Note: Before the beginning of the deployment step, ensure that the previous step, pre-deployment, was completed. i.e., the blue lever is located on the lowest point of the arc, ready to be pulled back along the straight plane.

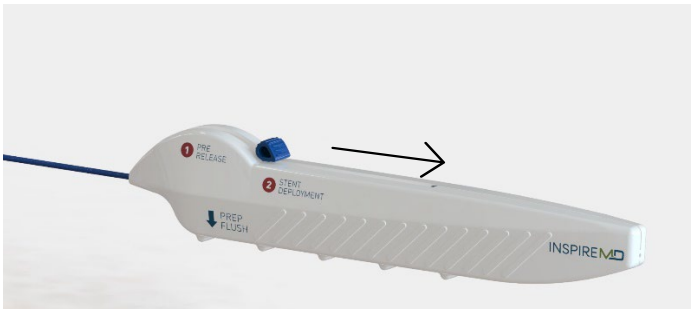


FIGURE 8: STENT DEPLOY START POSITION

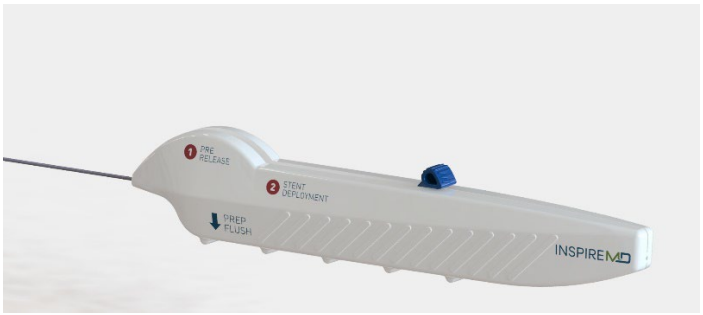


FIGURE 9: STENT DEPLOY END POSITION

Note: If significant resistance is encountered during lever retraction for deployment and before stent release is initiated, stop this action and remove the system. Once stent deployment is initiated, the stent cannot be recovered back to the sheath.

CAUTION: Once stent placement has been initiated, do not attempt to pull a partially expanded stent back through the guiding catheter or vascular sheath, as dislodgement of the stent from the Rx delivery system may occur.

CAUTION: In the event of partial deployment of the stent as the result of the inability to fully deploy the stent, remove the entire Rx delivery system from the patient by pulling it gently backward. This may result in damage to the vessel wall and may require surgical intervention.

CAUTION: Do not return the deployment lever back to its home position once the deployment step has begun or completed.

- Under fluoroscopy, confirm that the stent has been deployed at the target lesion.

G POST-STENT DEPLOYMENT

- After stent deployment, carefully withdraw the white distal tip of the Rx delivery system through the stent. Then, carefully withdraw the delivery system out of the patient's body.

  CAUTION: Ensure that the Rx delivery system is entirely removed from the patient. Once the Rx delivery system is out of the patient, you should be able to remove it from the guiding wire entirely.

- If additional stent-to-wall apposition is desired or to facilitate the use of other interventional devices, the stent can be post-dilated with a balloon dilatation catheter. Do not expand the stent beyond its unconstrained maximum diameter, as stated on the label and in **Table 2**. Post-dilate as needed in accordance with the compliance chart accompanying the selected balloon catheter.

  CAUTION: Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.

  WARNING: Overstretching of the artery may result in artery rupture and life-threatening bleeding.

- Following stent placement, an angiogram should be performed to document the stent's final result and vessel

patency.

- Upon completion of the angiogram, the neuroprotection system should be removed in accordance with the instructions for use with that device.

- Patients should be put on an appropriate regimen of anticoagulants/antiplatelets.

H PATIENT INFORMATION

A patient implant card, which contains identifying information about the implanted device, is included in the device package. After the device is implanted, complete the patient implant card and provide it to the patient before they are discharged.

Healthcare providers should communicate the following instructions to their patients:

- Always carry their implant card with them.
- Always inform any healthcare personnel that they have an implanted device before any procedure.

I INFORMATION ON THE MATERIALS TO WHICH PATIENTS CAN BE EXPOSED

The implant, is a self- expanding stent constructed of a nickel titanium alloy (Nitinol) and is covered by a permanent protective micromesh made of polyethylene terephthalate (PET). The delivery system, which the patient is exposed for short time is constructed of Stainless steel, Pebax, Polyimide, Polyethylene terephthalate (PET), Polyolefin & Polytetrefluoroethylene (PTFE).

J WARRANTY/LIABILITY

The product and each component of its system have been designed, manufactured, tested and packaged with all reasonable care. The warnings contained in InspireMD instructions for use are expressly considered as an integral part of this provision. InspireMD warrants the product until the expiration date indicated on it or its packaging. The warranty is valid provided that the use of the product was consistent with the instructions for use. InspireMD disclaims any warranty of merchantability or fitness for a particular purpose of the product. InspireMD is not liable for any direct, indirect, incidental or consequential damages caused by the product. Except in the case of fraud or grave fault on the part of InspireMD, compensation of any damage to the buyer will not, in any event, be greater than the invoice price of the disputed products. The guarantee contained in this provision incorporates and substitutes the legal guarantees for defects and compliance, and excludes any other possible liability of InspireMD, however originating, from its product supplied.

These limitations of liability and warranty are not intended to contravene any mandatory provisions of applicable law. If any clause of the disclaimer is considered by a competent court to be invalid or to be in conflict with applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects InspireMD legitimate interest in limiting its liability or warranty. No person has any authority to bind InspireMD to any warranty or liability regarding the product.

K REPORTING OF ADVERSE EVENTS AND SERIOUS INCIDENT

Contact the Customer Service Center with any feedback via the website https://www.inspiremd.com or email complaints@inspiremd.com & ussupport@inspiremd.com or call 1-786-425-3292.
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SUMMARY OF PRIMARY CLINICAL STUDY

A clinical study (CGUARDIANS II) was performed to establish a reasonable assurance of safety and effectiveness of the CGuard Prime TransCarotid Stent System for the treatment of carotid artery stenosis in human subjects at elevated risk for adverse events following carotid endarterectomy (CEA).

A Study Design

Patients were treated between December 6, 2024 and April 22, 2026.. The database reflected data collected through April 28, 2026 and included 52 patients (50 pivotal and 2 roll-in patients) at 11 investigational sites.

The study was a multicenter, single-arm, prospective clinical investigation to evaluate the safety and effectiveness of the CGuard Prime TransCarotid Stent System used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System in patients undergoing carotid artery stenting via the Transcarotid Artery Revascularization (TCAR) approach.

The primary procedural endpoints were acute device success and technical success. Acute device success was defined as successful insertion of the delivery system, successful deployment of the CGuard Prime Stent, and successful retraction of the delivery system during a TCAR procedure when used in conjunction with the ENROUTE Transcarotid Neuroprotection System. Technical success was defined as the proportion of patients with at least one CGuard Prime Carotid Stent successfully delivered and deployed with final residual diameter stenosis <30% following final post-balloon dilation (if performed).

Secondary endpoints evaluated 30-day clinical outcomes, including hierarchical death, stroke, or myocardial infarction (DSMI), hierarchical death or stroke, and individual rates of death, stroke (major and minor), and myocardial infarction. Secondary endpoints also evaluated stent thrombosis or occlusion within 30 days and through 1 year, device-related serious adverse events within 30 days and through 1 year, and ipsilateral stroke between 31-365 days post index procedure.

Analysis populations included Intent-to-Treat (ITT), Per-Protocol (PP), and Roll-In (RI). The ITT analysis population includes all enrolled subjects who provided informed consent, met all eligibility criteria, were approved by the screening committee and in whom the CGuard Prime TransCarotid Stent System was advanced beyond the arterial sheath. The PP population was the primary analysis population and consisted of a subset of the ITT population who were implanted with the CGuard Prime Carotid Stent at the target lesion, had no major procedural protocol deviations, and had follow-up data available.. Roll-In patients were analyzed separately.

All endpoints were analyzed descriptively. Results were summarized using counts and percentages. No formal hypothesis testing was performed.

The Data Safety Monitoring Board (DSMB) reviewed all study safety data on a regular basis and advised on the continuing safety, validity and scientific merit of the study. Serious Adverse Events were adjudicated by an independent Clinical Events Committee (CEC). All vascular imaging required for the study was evaluated and analyzed by an independent core lab.

i. Clinical Inclusion and Exclusion

Enrollment in the C-GUARDIANS II study was limited to patients who met the following inclusion criteria:

1. Patient is ≥ 18 years and ≤ 82 years of age.

2. Patient is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit requirements.

3. Patient is diagnosed with carotid artery disease treatable with a Carotid Artery Stent via a Transcarotid Artery Revascularization approach and is either symptomatic or asymptomatic, defined as:

   Symptomatic carotid stenosis ≥ 50%. Symptomatic is defined as amaurosis fugax, transient ischemia attack (TIA) or stroke within the last 6 months ipsilateral to the side of the stenosis, Or Asymptomatic carotid stenosis ≥ 80%

4. High Risk condition for CEA: at least one, as shown below:

   Comorbid conditions:
   - Age ≥ 70 (maximum 82 years)
   - Canadian Cardiovascular Society (CCS) angina class 3-4 or unstable angina
   - Congestive Heart Failure (CHF), New York Heart Association (NYHA) class III-IV
   - Left ventricular ejection fraction (LVEF) ≤ 35%
   - Myocardial infarction (MI) ≥ 72 hours and < 6 weeks pre-procedure
   - Multi-vessel coronary artery disease (CAD) (≥ 2 vessels >70% stenosis) and history of angina
   - Chronic Obstructive Pulmonary Disease (COPD) with forced expiration volume in 1 second (FEV1)<50
   - Permanent contralateral cranial nerve injury/paralysis
   - Restenosis from previous carotid endarterectomy (CEA)
   - Planned coronary artery bypass grafting (CABG) or valve replacement surgery

between 31-60 days after carotid artery stenting (CAS)
- Abdominal aortic aneurysm surgical repair or Endovascular repair is planned between 31 to 60 days after CAS.

Anatomic conditions:
- Occlusion of the contralateral common carotid artery (CCA) or internal carotid artery (ICA).
- Prior radiation treatment to the neck or a radical neck dissection.
- Severe bilateral ICA stenosis requiring treatment.
- Target lesion at or above the level of the jaw (C2) or below the clavicle.
- Severe tandem lesions
- Inability to extend the neck due to cervical disorders.
- Laryngeal palsy or laryngectomy.
- Prior head and neck surgery in the region of the carotid artery.
- Tracheostomy or tracheostoma.
- Spinal immobility of the neck.
- Hostile neck or surgically inaccessible lesion.

5. Target vessel and lesion meet all requirements for the CGuard Prime Carotid Stent:
- Target lesion location at the carotid bifurcation and/or proximal internal carotid artery (ICA) 2. The diameter at the stent landing zone is between 4.8 mm and 9.0 mm.
- The target lesion length is ≤ 36 mm and can be covered by a single CGuard Prime Carotid Stent.
- Patient must have a 5 cm long disease-free segment of the common carotid artery (CCA) measured from the clavicle to the carotid bifurcation, with a minimum vessel diameter of 6 mm suitable for vascular access, sheath insertion, and vessel clamping.

Patients were <u>not</u> permitted to enroll in the CGUARDIANS II study if they met any of the following exclusion criteria:

1. Patient had or will have an interventional procedure or surgery of the carotid, coronary or peripheral arteries within 30 days before or after the index carotid procedure.
2. Patient had or will have open heart surgery or valvular intervention (percutaneous or surgical), or any major operation, within 30 days before or after the index carotid procedure.
3. Vascular anatomy that would preclude safe sheath insertion or deliverability of stent
4. Patient had a previously placed stent in the ipsilateral ICA or CCA.
5. Total occlusion or presence of a “string sign” of the ipsilateral ICA or CCA.
6. Presence of a filling defect of the target lesion.
7. Tandem lesions with ≥ 50% or ≥ 80% diameter stenosis for symptomatic or asymptomatic patients, respectively, which cannot be covered by a single CGuard Prime™ stent.
8. Patient has a stenosis of the innominate artery or proximal CCA requiring revascularization
9. Patient has an open neck stoma.
10. Patient has a history of bleeding diatheses or coagulopathy.
11. Patient has hypercoagulable state.
12. Patient has an alternative source of cerebral embolus, including but not limited to:
    a) Chronic atrial fibrillation.
    b) Episode(s) of paroxysmal atrial fibrillation within the past 6 months or history of paroxysmal atrial fibrillation requiring chronic anticoagulation.
    c) Knowledge of cardiac sources of embolus (e.g. left ventricular aneurysm, intracardiac filling defect, cardiomyopathy, aortic or mitral prosthetic heart valve, calcific aortic stenosis, endocarditis, mitral stenosis, atrial septal defect, atrial septal aneurysm, or left atrial myxoma).
    d) Recently (<60 days) implanted heart valve (either surgically or endovascularly) as a known source of emboli as confirmed on echocardiogram,
    e) Abnormal angiographic findings: ipsilateral intracranial or extracranial arterial stenosis (as determined by angiography, computed tomography angiography (CTA), or magnetic resonance angiography (MRA) 6 months prior to index procedure) greater in severity than the lesion to be treated; cerebral aneurysm > 5mm; arteriovenous malformation (AVM)of the cerebral vasculature, or other abnormal angiographic findings.
13. Patient has a known sensitivity or allergy to nickel or titanium.
14. Patient has a sensitivity to contrast media that cannot be adequately pre-treated.
15. Patient has a sensitivity to both forms of protocol-acceptable anticoagulation strategies (i.e., both heparin AND Bivalirudin)
16. Patient has a sensitivity to an antiplatelet agent AND all protocol acceptable alternative antiplatelet options
17. Patient has a known intolerance to statins.
18. Patient has a life expectancy of less than 3 years from the date of enrollment as determined by the Wallaert Life Expectancy Scale
19. Patient has malignancy, primary or recurrent, and does not have independent assessment of life expectancy performed by the treating oncologist or an appropriate specialist other than the physician performing TCAR.
20. Patient has an evolving stroke or intracranial hemorrhage, or a history of previous intracranial

hemorrhage or brain surgery within the past 12 months.

21. Patient had a recent stroke (≤ 7 days) placing him/her at risk of a hemorrhagic conversion during the index procedure.
22. Patient has a history of a major stroke with a neurologic deficit (National Institute of Health Stroke Scale (NIHSS) of ≥ 15 or modified Rankin Scale (mRS) ≥3).
23. Patient had a TIA or amaurosis fugax or stroke within 48 hours of the index procedure.
24. Female patient who is pregnant or lactating or is planning to become pregnant.
25. Dementia or other neurologic condition that is likely to confound the neurologic assessment.
26. Clinical condition that, in the opinion of the investigator, makes endovascular therapy impossible or hazardous.
27. Patient has been previously enrolled in this clinical trial.
28. Patient is likely to be non-compliant with protocol-required follow up or medication in the opinion of the investigator.
29. Patient is currently participating in another clinical trial that has not completed its primary endpoint assessment or that may confound this study results.

ii. Follow-up Schedule

All patients were scheduled to return for follow-up examination at 30 days (**±** 7 days), and 1 year (± 30 days) postoperatively, as shown in **Table 3** below. Adverse events and complications were recorded at all visits.

To determine subject eligibility, a screening committee reviewed imaging data, along with patient medical history, for assessment of inclusion criteria, and approval prior to the study procedure.

The screening committee was comprised of an interdisciplinary team of study investigators with pertinent knowledge in carotid stenting. Prior to a subject being enrolled in the study, the investigational site received confirmation from the screening committee that the subject was eligible to be enrolled.

TABLE 3: SCHEDULE OF EVENTS

Test/Assessment	Screening	Baseline	Index Procedure	Discharge or 96 hours post-procedure	30 Day (±7D) (9)	1-Year (± 30D)	Unscheduled Visit	Early Withdrawal
Study Visit No.	**1**	**2**	**3**	**4**	**5**	**6**	--	--
Study Consent	X							
Medical History (incl. Wallert Scale)	X							
Concomitant Medications	X	X	X	X	X	X	X (7)	X (8)
Targeted Physical Exam	X (1)			X	X	X	X (7)	X (8)
Cranial nerve palsy assessment			X	X	X	X		
NIH Stroke Scale (2)		X		X	X	X	X (7)	X (8)
Modified Rankin Scale (mRS)	X (1)			X	X	X	X (7)	X (8)
Carotid Duplex Ultrasound	X (3)				X	X	X (7)	X (8)
CTA, MRA, or catheter angiography	X (4)		X					
12-lead electrocardiogram (ECG)	X (1)			X				
Complete Blood Count	X (1)			X				
Coagulation Panel international normalized ratio (INR) for patients on Vitamin K Antagonist (VKA) therapy	X (1)			X	X	X	X (7)	X (8)
Chemistry Panel (blood urea nitrogen (BUN), Creatinine)	X (1)							
Cardiac Biomarkers (troponins or creatine kinase-myocardial band (CK-MB))		X		X (5)				
Pregnancy Test (only for females of child-bearing potential) (6)		X						
Adverse Events	X	X	X	X	X	X	X	X

(1) May be obtained at either Screening or Baseline visit.
(2) Neurological assessment must be performed by a physician or other study team personnel certified in administration of NIHSS.

(3) Bilateral carotid duplex ultrasound is required within 180 days of the procedure. The pre-procedure ultrasound was NOT sent to the core lab.
(4) CTA, MRA or catheter angiography (visualization of vasculature from arch origin to Circle of Willis) is required within 180 days prior to the procedure.
(5) Routine collection for all patients at approximately the following post-index procedure intervals: 12-24 hours, 36-48 hours, 72 hours or at discharge. Thereafter, if cardiac biomarkers remain elevated, collected daily until values showed a decline.
(6) Urine or serum pregnancy test was acceptable.
(7) To be performed as clinically indicated.
(8) Test/assessments to be performed to the extent possible.
(9) If the CGuard Prime TransCarotid Stent System entered the vasculature and was unsuccessful, a telephone follow-up visit was required at 30 days (±7 days).

iii. Study Endpoints

Primary Endpoint

The two primary procedural endpoints were as follows:

Acute device success: Successful insertion of the delivery system, successful deployment of the CGuard Prime Carotid Stent, and successful retraction of the delivery system when used in conjunction with the FDA cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.

Technical success: Technical Success Rate is defined as the number of patients with at least one CGuard Prime Carotid Stent successfully delivered and deployed with final residual diameter stenosis < 30% following final post-balloon dilatation (if performed) divided by the total number of patients where CGuard Prime TransCarotid Stent System device deployment was attempted when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.

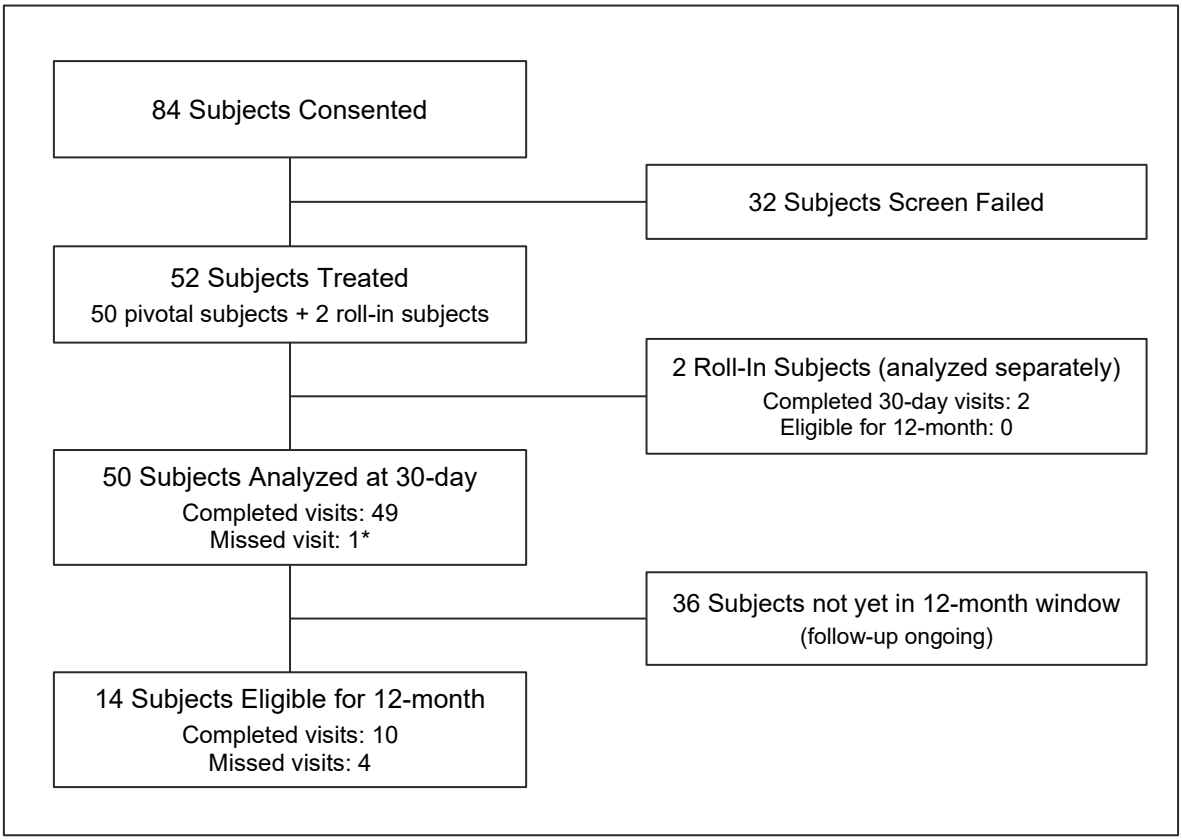
Secondary Endpoints included the following:

- Hierarchical Death, Stroke or Myocardial Infarction (DSMI) within 30 days of the procedure
- Hierarchical Death or Stroke rate within 30 days of the procedure
- Rate of death within 30 days of the procedure
- Rate of all strokes within 30 days of the procedure
- Rate of major stroke within 30 days of the procedure
- Rate of minor stroke within 30 days of the procedure
- Rate of MI within 30 days of the procedure
- Rate of stent thrombosis or occlusion within 30 days of the index procedure
- Rate of stent thrombosis or occlusion through 1-year of the index procedure
- All device-related serious adverse events within 30 days of the procedure
- All device-related serious adverse events through 1-year of the procedure
- Rate of ipsilateral strokes between 31 and 365-day post index procedure
- Procedural success: defined as number of patients who meet Acute Device Success for the CGuard Prime TransCarotid Stent System without experiencing death, stroke or MI through 30-day post-procedure when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.
- Treatment Success Rate: defined as the number of patients who meet CGuard Prime TransCarotid Stent System Technical Success without experiencing death, stroke, or MI through 30-day post-procedure, divided by the total number of patients where CGuard Prime TransCarotid Stent System device deployment was attempted when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.

B Subject Accountability

A summary of subject disposition per ITT analysis is presented in Figure **10.**

FIGURE 10 - SUBJECT DISPOSITION



*One subject completed the 30-day carotid duplex ultrasound but did not complete all other protocol-required 30-day assessments; the subject was retained in the 30-day analysis.

C Study Population Demographics and Baseline Parameters

i. Study demographics

The demographics of the study population are typical for a carotid artery stenting study performed in the US.

Table 4 presents demographic and lifestyle factors, race/ethnicity, baseline neurologic scales, and symptomatology, characterizing the 50 subjects in the PP population. The mean age was 69.7 ± 6.6 years (median 70.0 years; range 54–82), and 62.0% of subjects were male. Cardiovascular risk factors were common, including a history of smoking in 72.0% of subjects and current alcohol use in 26.0%. Baseline neurologic status was favorable, with 91.5% of subjects scoring 0 on the NIH Stroke Scale and 89.3% scoring 0 on the modified Rankin Scale. The majority of subjects (76.0%) were asymptomatic, defined as having no history of ipsilateral symptoms (stroke, TIA, or amaurosis fugax) within 180 days prior to the index procedure.

TABLE 4: SUBJECT DEMOGRAPHICS

Demographics (by patient)	PP N=50* n, (n/N%)
Age(years)	
N	50
Mean ± SD	69.7 ± 6.59
Median [IQR]	70.0 [64.0, 74.0]
(Range)	(54, 82)
Gender, n(%)	50
Male	31 (62.0%)
Female	19 (38.0%)
Race, n(%)	50
American Indian or Alaska Native	1 (2.0%)
Asian	1 (2.0%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)
Black or African American	3 (6.0%)
White	42 (84.0%)
Unknown or not reported	3 (6.0%)

Demographics (by patient)	PP N=50* n, (n/N%)
Ethnicity, n(%)	50
Hispanic or Latino	3 (6.0%)
Not Hispanic or Latino	41 (82.0%)
Unknown or Not Reported	6 (12.0%)
Current Alcohol Use (Yes), n(%)	13 (26.0%)
Smoking History (Yes), n(%)	36 (72.0%)
Years Smoked	
N	33
Mean ± SD	29.7 ± 15.41
Median [IQR]	30.0 [20.0, 44.0]
(Range)	(0, 56)
Total Packs Year	
N	31
Mean ± SD	30.0 ± 19.46
Median [IQR]	25.0 [14.0, 44.0]
(Range)	(4, 90)
NIH Stroke Scale Total Score	47
0	43 (91.5%)
1	2 (4.3%)
2	1 (2.1%)
3	0 (0.0%)
4	1 (2.1%)
Modified Rankin Scale (mRS Score)	28
0	25 (89.3%)
1	3 (10.7%)
2	0 (0.0%)
Symptomatic/Asymptomatic, n(%)	50
Asymptomatic	38 (76.0%)
Symptomatic	12 (24.0%)
* Percentages are calculated using the number of patients (N) with available data for that category. N=50 unless otherwise noted.	

ii. Subject Medical History

Table 5 enumerates cardiovascular, neurologic, pulmonary, metabolic, and other relevant comorbidities at baseline to contextualize patient risk. Hypertension was the most common condition, reported in 94.0% of subjects, followed by hypercholesterolemia/dyslipidemia in 86.0%, and diabetes mellitus in 44.0%. Coronary artery disease was also present in 44.0%, with 16% having a prior percutaneous coronary intervention (PCI) and 20.0% a history of myocardial infarction. Cerebrovascular history was also significant: 30.0% of subjects had a previous stroke, and 12.0% had experienced a transient ischemic attack. Additional relevant comorbidities included chronic obstructive pulmonary disease COPD (14.0%), chronic renal impairment (14.0%), peripheral vascular disease (14.0%), and cancer (20.0%).

TABLE 5: SUBJECT MEDICAL HISTORY

Medical History (by patient)	PP (N=50)
Alzheimer Disease, n (%)	1 (2.0%)
Diabetes Mellitus, n (%)	22 (44.0%)
Non-Alzheimer Dementia, n(%)	1 (2.0%)
Depression, n (%)	10 (20.0%)
Angina, n (%)	7 (14.0%)
Cardiac Arrythmia, n (%)	1 (2.0%)
Atrial Fibrillation, n (%)	0 (0.0%)
Congestive Heart Failure, n (%)	3 (6.0%)
Coagulopathy, n (%)	0 (0.0%)
COPD, n (%)	7 (14.0%)
FEV1 <50, n (%)	0 (0.0%)
Congenital Heart Disease, n (%)	0 (0.0%)
Coronary Artery Disease, n (%)	22 (44.0%)
Previous PCI, n (%)	8 (16.0%)
Previous Carotid Intervention, n (%)	6 (12.0%)
GI/GU Bleeding, n (%)	1 (2.0%)
Chronic Renal Impairment, n (%)	7 (14.0%)
Hypercholesterolemia/Dyslipidemia, n (%)	43 (86.0%)
Hypertension, n (%)	47 (94.0%)
Hypotension, n (%)	1 (2.0%)

Medical History (by patient)	PP (N=50)
Peripheral Vascular Disease, n (%)	7 (14.0%)
Myocardial Infarction, n (%)	10 (20.0%)
Transient Ischemic Attack, n (%)	6 (12.0%)
Stroke, n (%)	15 (30.0%)
Amaurosis Fugax, n (%)	1 (2.0%)
Cancer, n (%)	10 (20.0%)
Heart Conduction Troubles, n (%)	0 (0.0%)
Other Medical History, n (%)	25 (50.0%)

iii. Procedure Characteristics

Table 6 captures the procedural parameters (procedure time, pre/post-dilatation details, anticoagulation, ACT measurement) and immediate angiographic results (e.g., dissections). The mean procedure duration was 90.5 ± 39.43 minutes. All subjects (100%) had successful advancement, deployment, and retrieval of the CGuard Prime TransCarotid Stent System. Pre-dilatation was performed in all 50 subjects.

Post-dilatation was performed in 84.0% of cases, including the subject who did not meet the criterion for technical success (final residual diameter stenosis of 31%).

Protamine was administered in 93.9% of subjects, and ACT was measured in 98.0% of procedures. All procedures included radiation, contrast, and anticoagulation.

TABLE 6: SITE REPORTED PROCEDURAL CHARACTERISTICS

Procedural Parameters	PP (N=50)
Procedure time(mins)	
N	50
Mean ± SD	90.5 ± 39.43
Median [IQR]	80.0 [64.0, 108.0]
(Range)	(41, 207)
CGuard Prime TransCarotid Stent System advanced beyond the arterial sheath, n (n/N%)	50 (100.0%)
CGuard Prime TransCarotid Stent System Stent Deployed, n (n/N%)	50 (100.0%)
CGuard Prime TransCarotid Stent System Delivery System Retrieved, n (n/N%)	50 (100.0%)
Second stent used, n (n/N%)	1 (2.0%)*
Radiation used, n (n/N%)	50 (100.0%)
Contrast used, n (n/N%)	49 (100.0%)**
Anticoagulation medication used, n (n/N%)	50 (100.0%)
ACT measured, n (n/N%)	49 (98.0%)
Protamine used, n (n/N%)	46 (93.9%)
Pre-dilatation performed, n (n/N%)	50 (100.0%)
Dissection after Pre-dilatation, n (n/N%)	0 (0.0%)
Post-dilatation performed, n (n/N%)	42 (84.0%)
Dissection after Post-dilatation, n (n/N%)	0 (0.0%)
* In one subject, a second stent was placed for complete lesion coverage ** One value for the contrast used was missing; therefore, percentages were calculated based on non-missing values	

Table 7 summarizes lesion type, location, morphology, calcification, reference diameters, and pre/post-stenosis (site-assessed), as well as vessel tortuosity and arch type. The treated lesions were predominantly de novo, reported in 98.0% of subjects, with only 1 case (2.0%) of re-stenotic CEA. Lesion location was mainly within the internal carotid artery (ICA) (78.0%), while 22.0% involved the carotid bifurcation. Morphologically, lesions were primarily eccentric (67.3%), with ulceration present in 20.4% and thrombus noted in 10.2% of cases. Vessel tortuosity was mostly mild (58.0%) or absent (22.0%).

Table 7: LESION CHARACTERISTICS (SITE REPORTED)

Target Lesion Parameters	PP (N=50)
Target Lesion, n(%)	
De novo	49 (98.0%)
Re-stenotic CEA	1 (2.0%)
Target Lesion (Location), n(%)	
ICA	39 (78.0%)
Bifurcation	11 (22.0%)
Target Lesion Characteristics*	
Eccentric	33 (67.3%)
Concentric	11 (22.4%)
Ulceration	10 (20.4%)
Thrombus present in lesion	5 (10.2%)
None	0 (0.0%)
Target Lesion Assessed by, n(%)	
Quantitative Angiography	45 (90.0%)
Other	5 (10.0%)
Vessel Tortuosity, n(%)	
None	11 (22.0%)
Mild	29 (58.0%)
Moderate	7 (14.0%)
Severe	3 (6.0%)
Stent Diameter at Narrowest point (mm)	
Mean ± SD	4.9 ± 0.99
Median [IQR]	4.9 [4.5, 5.1]
(Range)	(3, 10)
Arch Type, n(%)**	48
Type I	23 (47.9%)
Type II	15 (31.3%)
Type III	5 (10.4%)
Bovine	5 (10.4%)
* Not mutually exclusive ** Two subjects had multiple Arch Type values recorded in the electronic data capture (EDC) system and were excluded from the Arch Type summary.	

Table 8 provides core-lab quantitative angiography for lesion length, lumen diameters, calcification, and pre/post-intervention stenosis to support performance outcomes. Core laboratory analysis confirmed the angiographic severity and morphology of the treated lesions prior to intervention. Mean lesion length was approximately 12 mm, with a minimum lumen diameter of 1.6 mm and reference lumen diameter of 4.2 mm. Moderate or severe calcification was present in 89.6% of lesions. Mean pre-procedure diameter stenosis was 84.5 ± 12.0%. Following treatment, residual diameter stenosis was reduced to 5.3 ± 8.3%, with a post-procedure minimum lumen diameter of 4.4 mm

TABLE 6: LESION CHARACTERISTICS (CORE LAB REPORTED*)

Parameter	PP (N=50)**
Pre-intervention	
Lesion Length (mm), N	49
Mean ± SD	12.1 ± 5.5
Median [IQR]	11.0 [8.0, 15.0]
Range	(3.9, 29.0)
Minimum Lumen Diameter (mm), N	49
Mean ± SD	1.6 ± 0.7
Median [IQR]	1.5 [1.0, 1.9]
Range	(0.2, 4.1)
Reference Lumen Diameter (mm), N	49
Mean ± SD	4.2 ± 0.8
Median [IQR]	4.1 [3.7, 4.8]
Range	(2.9, 6.0)
Calcification, N	48
None/Mild	5 (10.4%)
Moderate	21 (43.8%)

Severe	22 (45.8%)
Average Percent Diameter Stenosis (%), N	45
Mean ± SD	84.5 ± 12.0
Median [IQR]	88.0 [81.0, 91.0]
Range	(40.0, 99.0)
CCA Reference Lumen Diameter (mm), N	49
Mean ± SD	6.9 ± 1.4
Median [IQR]	6.6 [5.9, 8.1]
Range	(3.9, 9.8)
Post-Intervention	
Minimum Lumen Diameter (mm), N	48
Mean ± SD	4.3 ± 0.9
Median [IQR]	4.2 [3.7, 5.0]
Range	(2.8, 6.4)
Average Percent Diameter Stenosis (%), N	46
Mean ± SD	5.3 ± 8.3
Median [IQR]	0.0 [0.0, 9.0]
Range	(0.0, 31.0)
* Measurements represent the core laboratory assessment from the angiographic projection providing the optimal visualization of the target lesion. When multiple projections were available, the view demonstrating the most severe lesion characteristics was utilized for summary reporting. ** N varies as noted for each parameter and results are presented based on data available.	

D Safety and Effectiveness Results

i. Primary Endpoint Results

Table 9 reports acute device and technical success. Acute Device Success was achieved in all 50 subjects (100.0%). Technical Success was achieved in 49 of 50 subjects (98.0%). One subject did not meet the criterion for Technical Success because the core laboratory reported final residual diameter stenosis was 31% and therefore did not meet the definition of Technical Success (final residual diameter stenosis < 30%).

TABLE 7: PRIMARY PROCEDURAL ENDPOINTS

Endpoint	Subjects n/N (%)
Acute Device Success	50/50 (100.00%)
Technical Success	49/50 (98.00%)

ii. Secondary Endpoint Results

Secondary endpoint results were descriptive in nature without any formal statistical hypotheses testing.

Across all secondary clinical endpoints evaluated at 30 days, no subjects experienced an event. Death, stroke, myocardial infarction, and stent thrombosis within 30 days following the procedure were all 0/50 (0%).

Secondary procedural endpoints mirrored the primary results. Procedural Success was achieved in 50/50 subjects (100.0%). Treatment Success, defined using core-laboratory or investigator-reported residual stenosis when core-laboratory data were missing, was achieved in 49/50 subjects (98.0%). Further details are presented in Table 10.

TABLE 10: SECONDARY PROCEDURAL ENDPOINTS

	PP (N=50)
Endpoint	Subjects n (%)
Procedural Success	50/50 (100.00%)
Treatment Success	49/50 (98.00%)

Follow-up to the 1-year timepoint continues and secondary endpoints evaluated at 1-year will be assessed in the continued follow-up post-approval study.

iii. Adverse Events

An Adverse Event (AE) was defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. (ISO 14155:2020)

A Serious Adverse Event (SAE) was defined as Adverse Event that led to any of the following:

1. Death
2. Serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:
    a. a life-threatening illness or injury
    b. a permanent impairment of a body structure or a body function, including chronic disease, or
    c. the prolongation of an existing hospitalization, or
    d. Resulted in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or a body function, fetal distress, fetal death, a congenital abnormality, or birth defect including physical or mental impairment (ISO 14155:2020).

A planned hospitalization for a pre-existing condition was not considered a SAE. An Adverse Device Effect (ADE) was defined as an Adverse Event related to use of an investigational medical device as defined by ISO 14155:2020 and adjudicated by the CEC.

Table 11 provides 0–30 days AE incidence, including procedure- and device-relatedness and seriousness, with subject counts and total events. Across the ITT population (N=50), 22 subjects (44.0%) experienced 33 adverse events during the first 30 days of the study. Two device-related adverse events were reported in two subjects (4.0%). Procedure-related adverse events were reported in 15 subjects (30.0%), representing 21 events.

TABLE 11: SUMMARY OF ALL AEs

	ITT (N=50)	
	0-30 Days	
Adverse Event Category	**Subjects n/N (%)**	**Number of Events**
All Adverse Events	22/50 (44.0%)	33
Device Related	2/50 (4.0%)	2
Procedure Related	15/50 (30.0%)	21
Serious Adverse Events	6/50 (12.0%)	9
Device Related	2/50 (4.0%)	2
Procedure Related	5/50 (10.0%)	6
Non-Serious Adverse Events	18/50 (36.0%)	24
Device Related	0/50 (0.0%)	0
Procedure Related	12/50 (24.0%)	15
Note: Two adverse events have a missing onset date and are not included in the table.		

Serious adverse events were reported in 6 subjects (12.0%), totaling 9 events. Two Serious adverse events were device-related, and no serious adverse events resulted in death. Serious adverse events are summarized by System Organ Class and Preferred Term in **Table 12.**

TABLE 12: SERIOUS ADVERSE EVENT SUMMARY

	ITT (N=50)		PP (N=50)	
Serious Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Infections and infestations	2 (4.0%)	4	2 (4.0%)	4
Bacteremia	1 (2.0%)	1	1 (2.0%)	1
Clostridium difficile colitis	1 (2.0%)	1	1 (2.0%)	1
Gastroenteritis	1 (2.0%)	1	1 (2.0%)	1
Pyelonephritis acute	1 (2.0%)	1	1 (2.0%)	1
Injury, poisoning and procedural complications	1 (2.0%)	1	1 (2.0%)	1
Vascular access site swelling	1 (2.0%)	1	1 (2.0%)	1
Investigations	1 (2.0%)	1	1 (2.0%)	1
Hemoglobin decreased	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	3 (6.0%)	3	3 (6.0%)	3
Hypotension	2 (4.0%)	2	2 (4.0%)	2

	ITT (N=50)		PP (N=50)	
Serious Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Hypertensive urgency	1 (2.0%)	1	1 (2.0%)	1

[1]Subjects may have more than one event and will be counted once in each category for which they had an event.

Note: Adverse Events are classified by Medical Dictionary for Regulatory Activities(MedDRA) System Organ Class(SOC) and Preferred Term.(PT)

Non-serious AEs were reported in 18 subjects (36.0%), totaling 24 events. The most represented SOC categories included vascular disorders (8.0%), musculoskeletal/connective tissue disorders (6.0%), respiratory disorders (4.0%), infections (4.0%), nervous system disorders (4.0%) and skin and subcutaneous tissue disorders (4.0%). No non-serious AEs were attributed to the study device. Further details are presented in the following **Table 13**.

Following the data-cut off on April 20, 2026, a potential additional adverse event was discovered through a monitoring visit, which had not been previously reported. A subject with extensive cardiovascular disease and prior left hemispheric strokes underwent the index procedure, remained neurologically stable, and was discharged 5 days later to an inpatient rehabilitation facility due to persistent functional deficits and high fall risk related to pre-existing conditions. The event was not deemed to be related by the device or procedure by the site. The event did not meet the criteria for CEC adjudication.

TABLE 13: NON-SERIOUS ADVERSE EVENT SUMMARY

	ITT (N=50)		PP (N=50)	
Non-Serious Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Blood and lymphatic system disorders	1 (2.0%)	1	1 (2.0%)	1
Normocytic anemia	1 (2.0%)	1	1 (2.0%)	1
Cardiac disorders	1 (2.0%)	1	1 (2.0%)	1
Bradycardia	1 (2.0%)	1	1 (2.0%)	1
Endocrine disorders	1 (2.0%)	1	1 (2.0%)	1
Diabetic neuropathy	1 (2.0%)	1	1 (2.0%)	1
Eye disorders	1 (2.0%)	1	1 (2.0%)	1
Visual impairment	1 (2.0%)	1	1 (2.0%)	1
Gastrointestinal disorders	1 (2.0%)	1	1 (2.0%)	1
Gastroesophageal reflux disease	1 (2.0%)	1	1 (2.0%)	1
Infections and infestations	2 (4.0%)	2	2 (4.0%)	2
Upper respiratory tract infection	2 (4.0%)	2	2 (4.0%)	2
Injury, poisoning and procedural complications	2 (4.0%)	2	2 (4.0%)	2
Urinary retention postoperative	1 (2.0%)	1	1 (2.0%)	1
Vascular access site swelling	1 (2.0%)	1	1 (2.0%)	1
Musculoskeletal and connective tissue disorders	3 (6.0%)	3	3 (6.0%)	3
Back pain	2 (4.0%)	2	2 (4.0%)	2
Arthralgia	1 (2.0%)	1	1 (2.0%)	1
Nervous system disorders	2 (4.0%)	2	2 (4.0%)	2
Essential tremor	1 (2.0%)	1	1 (2.0%)	1
Vertigo positional	1 (2.0%)	1	1 (2.0%)	1
Psychiatric disorders	1 (2.0%)	1	1 (2.0%)	1
Anxiety	1 (2.0%)	1	1 (2.0%)	1
Renal and urinary disorders	1 (2.0%)	1	1 (2.0%)	1
Urinary retention	1 (2.0%)	1	1 (2.0%)	1
Reproductive system and breast disorders	1 (2.0%)	1	1 (2.0%)	1
Benign prostatic hyperplasia	1 (2.0%)	1	1 (2.0%)	1
Respiratory, thoracic and mediastinal disorders	2 (4.0%)	2	2 (4.0%)	2
Dyspnea	1 (2.0%)	1	1 (2.0%)	1
Epistaxis	1 (2.0%)	1	1 (2.0%)	1
Skin and subcutaneous tissue disorders	2 (4.0%)	2	2 (4.0%)	2
Rash	2 (4.0%)	2	2 (4.0%)	2
Surgical and medical procedures	1 (2.0%)	1	1 (2.0%)	1

	ITT (N=50)		PP (N=50)	
Non-Serious Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Incisional drainage	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	4 (8.0%)	4	4 (8.0%)	4
Hypotension	2 (4.0%)	2	2 (4.0%)	2
Hematoma	1 (2.0%)	1	1 (2.0%)	1
Hypertension	1 (2.0%)	1	1 (2.0%)	1
[1]Subjects may have more than one event and will be counted once in each category for which they had an event. Note: Adverse Events are classified by MedDRA SOC and Preferred Term.				

Device Related Adverse Events occurred in two subjects (4.0%), with two events of hypotension reported. These events were classified as serious and resolved with appropriate medical management within 1 and 2 days, respectively.

Table 14 details Device Related Adverse Events and **Table 17** details Serious Device Related Adverse Events, with subject and event counts.

TABLE 14: DEVICE RELATED ADVERSE EVENTS

	ITT (N=50)		PP (N=50)	
All Device Related Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Vascular disorders	2 (4.0%)	2	2 (4.0%)	2
Hypotension	2 (4.0%)	2	2 (4.0%)	2
[1]Subjects may have more than one event and will be counted once in each category for which they had an event. Note: Adverse Events are classified by MedDRA SOC and Preferred Term.				

TABLE 15: SERIOUS DEVICE RELATED ADVERSE EVENTS

	ITT (N=50)		PP (N=50)	
All Device Related Serious Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Vascular disorders	2 (4.0%)	2	2 (4.0%)	2
Hypotension	2 (4.0%)	2	2 (4.0%)	2
[1]Subjects may have more than one event and will be counted once in each category for which they had an event. Note: Adverse Events are classified by MedDRA SOC and Preferred Term.				

Procedure-related events occurred in 15 subjects (30%), with 21 events reported. These included vascular access site swelling (4.0%), urinary retention (2.0%), visual impairment (2.0%), and transient respiratory (4.0%) or musculoskeletal symptoms (2.0%). No single event type occurred at a concerning frequency. **Table 1**6 below, details procedure-related AEs by SOC/PT with subject and event counts.

TABLE 16: PROCEDURE RELATED ADVERSE EVENTS

	ITT (N=50)		PP (N=50)	
Procedure Related Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Blood and lymphatic system disorders	1 (2.0%)	1	1 (2.0%)	1
Normocytic anemia	1 (2.0%)	1	1 (2.0%)	1
Cardiac disorders	1 (2.0%)	1	1 (2.0%)	1
Bradycardia	1 (2.0%)	1	1 (2.0%)	1
Eye disorders	1 (2.0%)	1	1 (2.0%)	1
Visual impairment	1 (2.0%)	1	1 (2.0%)	1
Infections and infestations	1 (2.0%)	1	1 (2.0%)	1
Clostridium difficile colitis	1 (2.0%)	1	1 (2.0%)	1
Injury, poisoning and procedural complications	3 (6.0%)	3	3 (6.0%)	3
Vascular access site swelling	2 (4.0%)	2	2 (4.0%)	2
Urinary retention postoperative	1 (2.0%)	1	1 (2.0%)	1
Investigations	1 (2.0%)	1	1 (2.0%)	1
Haemoglobin decreased	1 (2.0%)	1	1 (2.0%)	1

	ITT (N=50)		PP (N=50)	
Procedure Related Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Musculoskeletal and connective tissue disorders	1 (2.0%)	1	1 (2.0%)	1
Arthralgia	1 (2.0%)	1	1 (2.0%)	1
Renal and urinary disorders	1 (2.0%)	1	1 (2.0%)	1
Urinary retention	1 (2.0%)	1	1 (2.0%)	1
Reproductive system and breast disorders	1 (2.0%)	1	1 (2.0%)	1
Benign prostatic hyperplasia	1 (2.0%)	1	1 (2.0%)	1
Respiratory, thoracic and mediastinal disorders	2 (4.0%)	2	2 (4.0%)	2
Dyspnea	1 (2.0%)	1	1 (2.0%)	1
Epistaxis[2]	1 (2.0%)	1	1 (2.0%)	1
Skin and subcutaneous tissue disorders	2 (4.0%)	2	2 (4.0%)	2
Rash	2 (4.0%)	2	2 (4.0%)	2
Surgical and medical procedures	1 (2.0%)	1	1 (2.0%)	1
Incisional drainage	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	6 (12.0%)	6	6 (12.0%)	6
Hypotension	4 (8.0%)	4	4 (8.0%)	4
Hypertension	1 (2.0%)	1	1 (2.0%)	1
Hypertensive urgency	1 (2.0%)	1	1 (2.0%)	1

[1]Subjects may have more than one event and will be counted once in each category for which they had an event.

[2]The onset date for Adverse Event No. 3 in Subject CGII-04-001 was missing; therefore, this adverse event was not included in the total count (see **Table 15**, Overall Adverse Event Summary) but is reported here for completeness.

Note: Adverse Events are classified by MedDRA SOC and Preferred Term

Serious procedure-related events were rare, occurring in 5 subjects (10.0%), with 6 total events, as detailed in **Table 17**, below. All events were non-fatal, resolved with appropriate medical management, and occurred exclusively in the early post-procedure period. Importantly, no serious procedure-related strokes or myocardial infarctions were reported.

TABLE 17: SERIOUS PROCEDURE RELATED ADVERSE EVENTS

	ITT (N=50)		PP (N=50)	
Procedure Related Serious Adverse Events	**Subjects[1] n(%)**	**Events N**	**Subjects[1] n(%)**	**Events N**
Infections and infestations	1 (2.0%)	1	1 (2.0%)	1
Clostridium difficile colitis	1 (2.0%)	1	1 (2.0%)	1
Injury, poisoning and procedural complications	1 (2.0%)	1	1 (2.0%)	1
Vascular access site swelling	1 (2.0%)	1	1 (2.0%)	1
Investigations	1 (2.0%)	1	1 (2.0%)	1
Hemoglobin decreased	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	3 (6.0%)	3	3 (6.0%)	3
Hypotension	2 (4.0%)	2	2 (4.0%)	2
Hypertensive urgency	1 (2.0%)	1	1 (2.0%)	1

[1]Subjects may have more than one event and will be counted once in each category for which they had an event.

Note: Adverse Events are classified by MedDRA SOC and Preferred Term

Secondary safety endpoints were consistent with the primary safety results. Two Serious Device-Related Adverse Events occurred within 30 days of the procedure in two subjects (4.0%;). Both events were hypotension; one was assessed by the investigator as probably related and one as possibly related to the device. Both events resolved with appropriate medical management within 1 and 2 days, respectively.

TABLE 18: SERIOUS DEVICE RELATED ADVERSE EVENTS WITHIN 30 DAYS OF PROCEDURE

	PP (N=50)	
Endpoint	**Number of Events**	**Number of Subjects n (%)**
Serious Adverse Device Effect (SADE) within 30 days of procedure	2	2 (4.00%)
Causally Related	0	0 (0%)

Probably Related	1	1 (2.00%)
Possibly Related	1	1 (2.00%)
Type of SADE		
Vascular disorders	2	2 (4.0%)
Hypotension	2	2 (4.0%)

iv. Subgroup Analyses

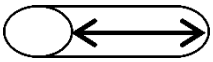
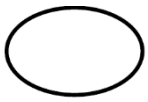
Table 19 reports subgroup analyses of Acute Device Success and Technical Success by symptomatic status and age (< 71 years and ≥ 71 years), respectively.

Acute Device Success was achieved in all 38 asymptomatic subjects (100.0%) and all 12 symptomatic subjects (100.0%), while Technical Success was achieved in 37 of 38 asymptomatic subjects (97.37%) and in all symptomatic subjects (100.0%). In the age subgroup analysis, Acute Device Success was achieved in all 26 subjects aged <71 years (100.0%) and in all 24 subjects aged ≥71 years (100.0%). Technical Success was achieved in all subjects aged <71 years (100.0%) and in 23 of 24 subjects aged ≥71 years (95.83%).

TABLE 19: PRIMARY PROCEDURAL ENDPOINTS – SUBGROUP ANALYSES

Subgroup		**Endpoint, n/N (%)**	
		Acute Device Success	**Technical Success**
Symptomatic Status	Asymptomatic	38/38 (100.00%)	37/38 (97.37%)
	Symptomatic	12/12 (100.00%)	12/12 (100.00%)
Age	Age <71 years	26/26 (100%)	26/26 (100%)
	Age ≥71 years	24/24 (100%)	23/24 (95.83%)

SYMBOL DEFINITIONS

	CAUTION		USE BY DATE
	KEEP AWAY FROM SUNLIGHT		STERILIZED WITH ETHYLENE OXIDE GAS
	CATALOG NUMBER		DO NOT REUSE
	KEEP DRY		DO NOT RESTERILIZE
	SERIAL NUMBER		DO NOT USE IF PACKAGE IS DAMAGED
	TEMPERATURE LIMITATION		CONSULT INSTRUCTIONS FOR USE
	MR conditional		STENT LENGTH
	MANUFACTURER		COUNTRY OF MANUFACTURE
	SINGLE STERILE BARRIER SYSTEM		SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
	UNIQUE DEVICE IDENTIFIER		MEDICAL DEVICE
	INNER DIAMETER		OUTER DIAMETER
	MODEL NUMBER		PACKAGING UNIT
	**CAUTION:** FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN		



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