

SAMPLE PHYSICIAN DICTATION FOR TRANSCAROTID ARTERY REVASCULARIZATION (TCAR)

DATE OF OPERATION: [report date of operation here; MM/DD/YYYY]

PREOPERATIVE DIAGNOSES: [list preoperative diagnoses here. Examples may include the following]

- Right internal carotid artery stenosis
- Intermittent transient ischemic attacks

OPERATION PERFORMED: Right/Left internal carotid artery TCAR (Transcarotid artery revascularization) with the ENROUTE® Transcarotid Neuroprotection and Stent System

SURGEON: [report physician name]

ANESTHESIA: General or local anesthesia

COMPLICATIONS: [report complications, if any]

BLOOD LOSS: [characterize blood loss]

PROCEDURE FINDINGS: [describe procedure findings. Examples of findings may include the following]

1. Moderately calcified, nearly occlusive, ulcerative plaque in proximal right internal carotid artery.
2. Excellent temporary flow reversal established by the ENROUTE® Transcarotid Neuroprotection system prior to lesion engagement.
3. Placement of the ENROUTE® Transcarotid stent to cover the length of the lesion in the right internal carotid artery.
4. The patient awoke from anesthesia neurologically intact.

DESCRIPTION OF PROCEDURE: [describe procedure here; an example description follows]

The patient was brought to the operating room, where support lines were placed and general anesthesia was secured. The right neck and left groin were prepped and the patient was sterilely draped. A transverse 2-4 cm incision was made between the sternal and clavicular heads of the sternocleidomastoid muscle, below the omohyoid. Following longitudinal division of the carotid sheath the jugular vein was partially dissected and retracted medially. Once 3 cm of common carotid artery (CCA) were isolated, umbilical tape was placed around the proximal 1/3 of the CCA under direct vision. A 5.0 polypropylene suture was pre-placed in the anterior wall of the CCA, in a "U stitch" configuration, close to the clavicle to facilitate hemostasis upon removal of the arterial sheath at completion of the TCAR procedure.

The contralateral (left) common femoral vein (CFV) was accessed under ultrasound guidance, using standard Seldinger and micropuncture access technique. Permanent recorded image(s) was/were saved in the patient's medical record. The Venous Return Sheath was advanced into the CFV over the 0.035" wire provided. Blood was aspirated from the flow line followed by flushing of the Venous Sheath with heparinized saline. The Venous Sheath was secured to the patient's skin with suture to maintain optimal position in the vessel.

Heparin was given to obtain a therapeutic activated clotting time >250 seconds prior to arterial access. A 4-French non-stiffened ENHANCE® Transcarotid / Peripheral Access set was used, puncturing the artery with the 21G needle through the pre-placed "U" stitch while holding gentle traction on the umbilical tape to stabilize and centralize the CCA within the incision. Careful attention was paid to the change in CCA shape when using the umbilical tape to control or lift the artery. The micropuncture wire was then advanced 3-4 cm into the CCA and, the 21G needle was removed. The micropuncture sheath was advanced 2-3 cm into the CCA and the wire and dilator were removed. Pulsatile backflow indicated correct positioning. The provided 0.035" J-tipped guidewire was inserted as close as possible to the bifurcation without engaging the lesion. After micropuncture sheath removal, the Transcarotid Arterial Sheath was advanced to the 2.5cm marker and the 0.035" wire and dilator were then removed. Arterial Sheath position was assessed under fluoroscopy in two projections to ensure that the sheath tip was oriented coaxially in the CCA. The Arterial Sheath was sutured to the patient with gentle forward tension. Blood was slowly aspirated followed by flushing with heparinized saline. No ingress of air bubbles through the passive hemostatic valve was observed. The stopcocks were closed. Traction applied to the CCA previously to facilitate access was gently released.

The Flow Controller was connected to the Transcarotid Arterial Sheath, prepared by passively allowing a column of arterial blood to fill the line and connected to the Venous Return Sheath. CCA inflow was occluded proximal to the arteriotomy with a vascular clamp to achieve active flow reversal. To confirm flow reversal, a saline bolus was delivered into the venous flow line on both "High" and "Low" flow settings of the Flow Controller. Angiograms were performed with slow injections of a small amount of contrast filling just past the lesion to minimize antegrade transmission of micro-bubbles.

Prior to lesion manipulation, heart rate (70bpm) and systolic BP (140-160mmHg) were managed upwards to optimize flow reversal and procedural neuroprotection. The lesion was crossed with an 0.014" ENROUTE® guidewire and pre-dilation of the lesion was performed with a 5mm x 20mm rapid exchange 0.014" compatible balloon catheter to 8 atmospheres for 10 seconds. Stenting was performed with an 9mm x 40mm ENROUTE® Transcarotid stent, sized appropriately to the right CCA. AP and lateral angiograms (gentle contrast injections) were performed to confirm stent placement and arterial wall stent apposition.

At TCAR case completion, antegrade flow was restored by releasing the clamp on the CCA then closing the NPS stopcocks to the flow lines. The Transcarotid Arterial Sheath was removed and the pre-closure suture was tied. Heparin reversal was employed and a drain was placed.

The Venous Return Sheath was removed and hemostasis was achieved with brief manual compression.

The patient tolerated the procedure well and was extubated on the table. The patient was moving all four extremities to command prior to transfer to the recovery room.