TERUMO NEURO

REal-World Analyses of Stroke–Thrombus Occlusion Retrieval

RESTORE Study Final Results

STUDY OVERVIEW

The RESTORE study is a 710-patient broad eligibility registry intended to collect clinical evidence on the safety and effectiveness of Terumo Neuro devices, including SOFIA™ Flow Plus Catheter (6F), and the ERIC™ Retrieval Device, used as first line for mechanical thrombectomy (MT) treatment of acute ischemic stroke (AIS).

KEY HIGHLIGHTS

93%
recanalization rate mTICI ≥2b

17 min
revascularization time

0.6%
sICH within 24 hours

Summary of Results	
Final recanalization rates (mTICI ≥2b)	93.0%
Clot contact time (median)	13 minutes
Revascularization time (median)	17 minutes
sICH within 24 hours	0.6%
Emboli to new territory	0.4%

Indications for Use

The SOFIA™ Flow Plus Aspiration Catheter with the Gomco™ 405 Aspiration Pump and MicroVention™ Tubing Kit is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The SOFIA™ Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA™ Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA™ Catheter is not intended for use in coronary arteries.

The BOBBY™ Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

The ERIC Retrieval Device is indicated to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

For healthcare professional intended use only. Please refer to IFU for the full list of risks, contraindications, warnings, and precautions.

This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The SOFIA should only be used by physician who have received appropriate training for the device.

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