stryker® Neurovascular

TransForm™

OCCLUSION BALLOON CATHETER

Take Control. Elevate Performance.

The first .014in Stryker Neurovascular guidewire-compatible, single lumen occlusion balloon catheter featuring Synchro® Guidewire Technology with optimal visibility, superior navigability and exceptional stability.

TransForm Compliant
Occlusion Balloon Catheter

Catalog Number	Balloon Nominal Diameter	Balloon Nominal Length
M003**ERC0310**0	3mm	10mm
M003**ERC0315**0	3mm	15mm
M003**ERC0410**0	4mm	10mm
M003**ERC0415**0	4mm	15mm
M003**ERC0420**0	4mm	20mm
M003**ERC0430**0	4mm	30mm
M003**ERC0510**0	5mm	10mm
M003**ERC0515**0	5mm	15mm
M003**ERC0520**0	5mm	20mm
M003**ERC0530**0	5mm	30mm

TransForm Super Compliant
Occlusion Balloon Catheter

Catalog Number	Balloon Nominal Diameter	Balloon Nominal Length
M003**ESC0305**0	3mm	5mm
M003**ESC0407**0	4mm	7mm
M003**ESC0410**0	4mm	10mm
M003**ESC0707**0	7mm	7mm
M003**ESC0710**0	7mm	10mm
M003**ESC0715**0	7mm	15mm

TransForm™ Occlusion Balloon Catheter

See package insert for complete indications, contraindications, warnings and instructions for use.

INDICATIONS FOR USE

The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neurovasculature to temporarily stop or control blood flow, to treat vasospasm, and for balloon assisted embolization of aneurysms.

CONTRAINDICATIONS

None known.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the use of balloon catheters or with the endovascular procedures include, but are not limited to: access site complications, allergic reaction, aneurysm perforation, aneurysm rupture, death, embolism (air, foreign body, plaque, thrombus), hematoma, hemorrhage, infection, ischemia, neurological deficits, pseudoaneurysm, stroke, transient ischemic attack, vasospasm, vessel dissection, vessel occlusion, vessel perforation, vessel rupture, vessel thrombosis. Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS/PRECAUTIONS

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- The TransForm Occlusion Balloon Catheter is designed specifically for use with a Stryker Neurovascular 0.014 in (0.36mm) guidewire. Compatibility with other guidewires has not been established.
- To facilitate balloon catheter handling, the proximal portion of the balloon catheter does not have a hydrophilic surface. Greater resistance may be encountered when this section of the balloon catheter is advanced into the Rotating Hemostatic Valve (RHV).
- Exercise care in handling the balloon catheter during a procedure to reduce the possibility of accidental breakage, bending, or kinking.
- To control introduction, movement, positioning, and removal of the balloon catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- The TransForm™ Occlusion Balloon Catheter has not been tested in coronary vessels.
- The TransForm Occlusion Balloon Catheter is not intended for angioplasty treatment of intracranial atherosclerotic disease.
- Use prior to the “Use By” date shown on the package label. Aging beyond use by date may result in material degradation resulting in adverse performance of the product.
- Use caution while removing contents from packaging. Rapid removal or jerking from the package may cause catheter damage.
- Do not reinsert the balloon catheter into the dispenser coil. Reinserting the balloon catheter into the dispenser coil may cause kinking or damage to the balloon catheter. Once the balloon catheter has been hydrated, do not allow to dry.

WARNINGS

- Contents supplied STERILE, using an ethylene oxide (EO) process. Non-Pyrogenic. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.
- The compatibility of the TransForm Occlusion Balloon Catheter has not been evaluated with polyvinyl alcohol (PVA) particles or n-butyl cyanoacrylate (n-BCA)
- 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 device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- These devices should only be used by physicians who have received appropriate training in neurointerventional surgery, interventional neuroradiology, or interventional radiology.
- Use only with appropriate inflation media (of saline and contrast mixture). Do not use oil-based contrast agents such as Lipiodol® or Ethiodol®. Use of these contrast agents can damage the balloon.
- The balloon catheter is not intended to be used as an infusion catheter, for embolectomy or subselective angiography. The balloon may inadvertently inflate if used for these types of procedures.
- Presence of implanted devices such as clips and stents, and anatomical structures or irregularities such as bone fragments or calcifications, may damage the balloon or prevent entry/removal.
- Do not steam shape the catheter tip, as heat may damage the balloon material.
- The balloon should never be inflated or deflated with a pressure-based inflation device.
- Carefully inspect the balloon catheter prior to use. If product is damaged do not use and contact your Stryker Neurovascular representative. Use of a damaged catheter may cause serious injury.
- Verify device size, configuration, and patient conditions are suitable for the specific procedure.
- Prior to introducing the balloon catheter system into the vasculature purge the system carefully to avoid accidental introduction of air into the balloon catheter system. Failure to do so may release trapped air during device use and cause neurological deficit. Do not perform initial balloon flush within the vasculature.
- Never advance or withdraw the balloon catheter system against resistance. Movement of device against resistance could dislodge a clot, perforate a vessel wall, or damage the device. If resistance is felt when advancing or removing the balloon catheter from the guide catheter, carefully remove them as a unit to prevent damage to the blood vessel, guide catheter or the device.
- Do no inflate the balloon beyond the diameter of the vessel being treated or beyond the maximum allowed inflation volume. Excessive inflation volume may result in a ruptured balloon or damage to the vessel. Do not move the balloon catheter while the balloon is inflated.
- Withdrawing the guidewire into the balloon catheter past the distal tip (e.g., in-vivo guidewire exchange, flushing the balloon, etc.) is not recommended due to the risk of blood entry into the balloon. Blood in the balloon may result in risk of serious injury due to poor balloon visualization and the potential of flushing embolic clots. If the guidewire is withdrawn into the balloon catheter past the distal tip, withdraw the entire balloon catheter system. Prior to reintroduction, prepare the balloon catheter system per the directions in the Prepare Occlusion Balloon Catheter steps.

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