TransForm Registry:[1] Trial design and results[2]

Primary objective

- Collect real-world data on safety and performance of the TransForm® Occlusion Balloon Catheter when used in neurointerventional procedures.

Methods & procedure

- The **first prospective, international, multi-center registry trial** of balloon-assisted coiling (BAC) for intracranial aneurysms.
- TransForm Occlusion Balloon Catheter was used in **81 patients for 86 balloon procedures**, including: BAC (74%), safety precaution (9%), test occlusion (6%), other (11%).

Conclusions

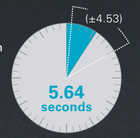
- Based on the registry results, physicians determined that the use of TransForm Occlusion Balloon Catheter in BAC procedures was successful and proved beneficial for patients with intracranial aneurysms.[3]
- TransForm Occlusion Balloon Catheter has improved performance over other commercially available balloon catheters[4] due to:
  - Shorter inflation and deflation times
  - The ability to use an 0.014in guidewire

Balloon performance features

Fast.

Average inflation time*

Average deflation time*



Easy.

Visibility

1.76**

Ability to reach the target site

1.59**

5 4 3 2 1

Poor Excellent

Stable.

Stability during inflation

1.56**

Stability during deflation

1.57**

5 4 3 2 1

Poor Excellent

Please ask your Stryker representative for more information regarding the TransForm Registry.

1. TransForm Registry was sponsored by Stryker.
2. Taqi, Asif M. et al. A Prospective Multi-Center Trial of TransForm Occlusion Balloon Catheter: Trial Design and Results. Society of NeuroInterventional Surgery, July 2015.
3. Raymond class I achieved in 69.44% 2) Thrombus formation in 4.8% 3) Vessel rupture/perforation in 1.2% but unrelated to TransForm Occlusion Balloon Catheter.
4. Quadri, Syed A. et al. "Early Experience with the TransForm™ Occlusion Balloon Catheter: A Single-Center Study." Interventional Neurology 3.3-4 (2015): 174 -183. PMC. Web.

*Contrast ratio used: 70-30 (36%), 50-50 (30%), 100-0 (28%). Average contrast ratio used is 72.07%.
**Averages based on physician score on a 1 – 5 scale, where 1 = Excellent and 5 = Poor.

TransForm® Compliant Occlusion Balloon Catheter

Greater neck coverage, ideal for sidewall aneurysms

Catalog number	Balloon nominal diameter	Balloon nominal length
M003**SRC0310**0	3mm	10mm
M003**SRC0315**0	3mm	15mm
M003**SRC0410**0	4mm	10mm
M003**SRC0415**0	4mm	15mm
M003**SRC0420**0	4mm	20mm
M003**SRC0430**0	4mm	30mm
M003**SRC0510**0	5mm	10mm
M003**SRC0515**0	5mm	15mm
M003**SRC0520**0	5mm	20mm
M003**SRC0530**0	5mm	30mm

TransForm® Super Compliant Occlusion Balloon Catheter

Greater conformability for complex anatomy, such as bifurcations

Catalog number	Balloon nominal diameter	Balloon nominal length
M003**SSC0305**0	3mm	5mm
M003**SSC0407**0	4mm	7mm
M003**SSC0410**0	4mm	10mm
M003**SSC0707**0	7mm	7mm
M003**SSC0710**0	7mm	10mm
M003**SSC0715**0	7mm	15mm

Effective length: 150cm
Max catheter shaft OD: 2.8F/0.95mm
Min guide catheter ID: 0.053in/1.35mm
Recommended guidewire OD: Stryker 0.014in/0.36mm
DMSO compatible

TransForm® Occlusion Balloon Catheter

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

INTENDED USE/INDICATIONS FOR USE

The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial 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.

WARNINGS

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.
- 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 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 solution mixture). Do not use oil-based contrast agents such as Lipiodol® or Ethiodol®. Use of these contrast agents can damage the balloon.
- The compatibility of the TransForm Occlusion Balloon Catheter has not been evaluated with polyvinyl alcohol (PVA) particles or n-butyl cyanoacrylate (n-BCA).
- 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 deficits. Do not perform initial balloon flush while in 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 not inflate the balloon beyond the diameter of the vessel being treated or beyond the maximum allowed inflation volume (see tables 2-4). 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.

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 (0.36 mm) 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.

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Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

strykerneurovascular.com

Date of Release: MAR/2017

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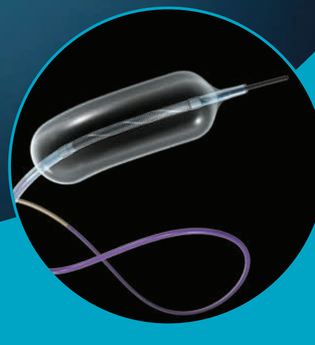
stryker

Effortless performance.



TransForm®

OCCLUSION BALLOON CATHETER

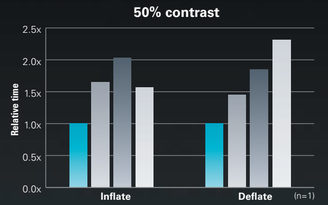
TransForm®
OCCLUSION BALLOON CATHETER

0.014in guidewire compatibility
Supports navigation and stability

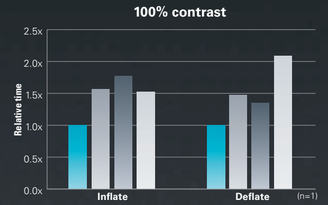
Fast

Inflation and deflation lead to quicker wall apposition, minimized jumping, and shorter procedure times

Faster inflation and deflation times*



55%
faster using 50/50 contrast mixture**



61%
faster using 100% contrast**

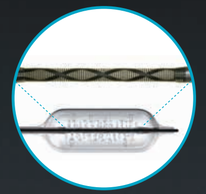
TransForm HyperGlide Ascent Scepter

4x10mm Compliant Balloon Catheters. Bench test results. n=1. Bench test results may not necessarily be indicative of clinical performance. Testing performed by Stryker. Data are on file at Stryker and will be made available upon request.

*Competitive balloon inflation/deflation times are indexed off the inflation/deflation time of TransForm Occlusion Balloon Catheter.

**Than the average of the three competitive balloons.

Micromachined hypotube
Provides rapid and uniform inflation



Easy

To use from start to finish, in multiple intracranial vasculatures*

① **Prep** | Ready to use in just a few simple steps.

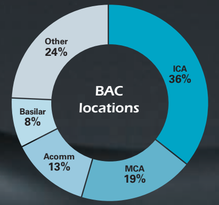
② **Navigate** | Uses a supportive 0.014in guidewire.

③ ***Visualize*** | Two-thirds of physicians from the registry inflated with **70% to 100% contrast.**

Compatible with 100% contrast
Facilitates optimal visibility

Treats a range of aneurysm locations

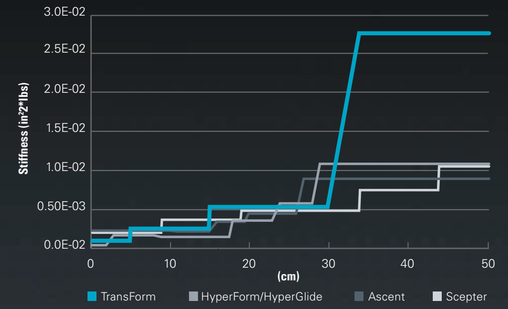
*In the TransForm Registry, TransForm Occlusion Balloon Catheter was used to treat aneurysms in the following locations:



Stable

System for support, ease of access, and trackability

Optimized catheter support profile
Balances proximal stability and distal navigability



2x
more supportive

4x10 Compliant Balloon Catheter. Chart indicates catheter length from proximal balloon bond.

Effortless performance.