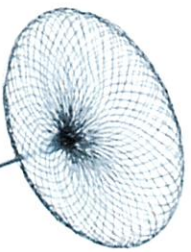


KATALOGAS Nr. 2

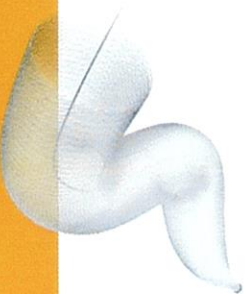
stryker

Neurovascular interventions

Product catalogue



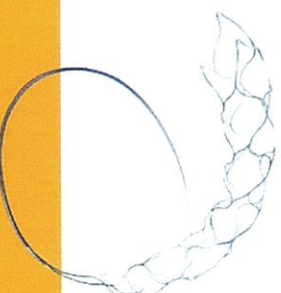
Contour
Neurovascular
System™



Surpass Evolve
Flow Diverter™



Target
Detachable Coils™



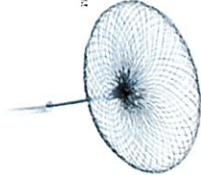
Trevor NXT
ProVue Retriever™



AXS Vectra
Aspiration Catheters™

Contour

Neurovascular System™



Access devices

Detachable coils

Intrasaccular embolization devices

Hemorrhagic devices

Contour Neurovascular System

Negstent Coil Assisted Flow Diverters

Ischemic devices

Trenza Embolization Devices

Accessories

Flow diverters

Intracranial aneurysmal disease devices

Adjunctive devices

Contour Neurovascular System



Product number	Product description	Implant diameter
CNS21005-15	CONTOUR 021 5MM - CE	5mm
CNS21007-15	CONTOUR 021 7MM - CE	7mm
CNS21009-15	CONTOUR 021 9MM - CE	9mm
CNS011-15	CONTOUR 027 11MM - CE	11mm
CNS014-15	CONTOUR 027 14MM - CE	14mm

Accessories



Access devices

Detachable coils

Intrasaccular embolization devices

Hemorrhagic devices

Accessories

InZone Detachment System

e-moji Detachment System

Ischemic devices

Flow diverters

Adjunctive devices

Intracranial aneurysmal disease devices

InZone Detachment System

Product number	Product description	Designed for use with
M00345100950	InZone Detachment System	Target Detachable Coil Trenza Embolization Device

e-moji Detachment System

Product number	Product description	Designed for use with
ED2-CS2	e-moji SI CS2 Detachment System - CE	Contour Neurovascular System Nexstent Coil Assisted Flow Diverter
CAB701-01	Cerus 01 Cable Set	



Balloon Guide Catheters



Access devices

Guidewires

Microcatheters

Guide catheters

Distal access catheters

Delivery assist catheters

Long sheaths

Balloon guide catheters

FlowGate² Balloon Guide Catheters

Merci Balloon Guide Catheters

FlowGate² Balloon Guide Catheters



Product number	Product description	ID	OD	Length
90485	FlowGate ² BGC 8F×85cm	0.084in (2.1mm/6.4F)	8F (2.7mm)	85cm
90495	FlowGate ² BGC 8F×95cm	0.084in (2.1mm/6.4F)	8F (2.7mm)	95cm

Merci Balloon Guide Catheters

Product number	Product description	ID	OD	Length
90073	Merci Balloon Guide Catheter 8F×95cm	0.078in (1.9mm)	8F (2.7mm)	95cm
90074	Merci Balloon Guide Catheter 9F×95cm	0.085in (2.1mm)	9F (3.0mm)	95cm
90076	Merci Balloon Guide Catheter 8F×80cm	0.078in (1.9mm)	8F (2.7mm)	80cm
90077	Merci Balloon Guide Catheter 9F×80cm	0.085in (2.1mm)	9F (3.0mm)	80cm

Haemorrhagic devices

Ischemic devices

Interventional atherosclerotic devices

FlowGate™ BALLOON GUIDE CATHETER

ReadyPack Accessories

Simplify prep and use when time is critical

Guide Assist Catheter (Dilator)
Facilitates delivery of the balloon guide catheter



Luer Activated Flow Valve
Engineered to maintain balloon inflation and simplify balloon prep



Peel Away Sheath

Designed to protect the balloon and the distal tip of the balloon guide catheter when inserting the catheter through the insertion sheath



RHV & Tuohy Borst With Sideport

Can be used interchangeably to accommodate desired catheter working length

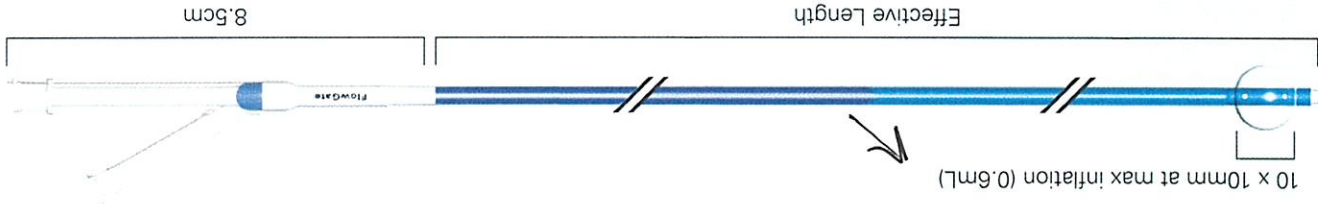


Extension Tubing

Facilitates aspiration with a 60mL syringe



FlowGate Balloon Guide Catheter Specifications



Reference Number	Description	Outer Diameter	Inner Diameter	Effective Length
90254	8F x 85cm FlowGate BGC	8F	0.084in	85cm
90253	8F x 95cm FlowGate BGC	8F	0.084in	95cm



FlowGate Balloon Guide Catheter



FlowGate™ and Merc® Balloon Guide Catheters

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

INDICATIONS FOR USE

FlowGate™ Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular 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.

COMPLICATIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to, the following: infection, hematoma, distal embolization, vessel thrombosis, dissection, false aneurysm formation, acute occlusion, clot formation, hemorrhage at the puncture site, intracranial hemorrhage, arterial rupture, stroke and death.

COMPATIBILITY

Introducer sheath French size must be greater than or equal to balloon guide catheter French size.

WARNINGS

- Contents supplied STERILE, using an ethylene oxide (EO) process. Nonpyrogenic.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance or torque catheter against resistance without careful assessment of cause of resistance using fluoroscopy. If causes cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- To reduce risk of complications due to slow balloon deflation, adhere to the following recommendations:
 - Use peel-away sheath to advance catheter in to introduce sheath over balloon.
 - Use peel-away sheath to introduce catheter in to introduce sheath. Minimize pushing forces on shaft during advancement. These forces can cause wrinkles in shaft that can slow balloon deflation.
 - Do not use device if shaft is damaged during use.
- To reduce risk of complications due to air emboli, remove air from balloon according to Recommended Procedure.
- Withdrawn balloon through introducer sheath may damage balloon. Do not use catheter again after withdrawing balloon through introducer sheath.
- To avoid balloon leakage, do not allow balloon to contact calcified or stenosed arteries and do not allow balloon to move during inflation.
- Do not use a device that has been damaged. Use of damaged devices may result in complications.
- Do not exceed maximum recommended balloon inflation volume. Excess inflation volume may rupture balloon.
- For thorough-lumen, do not exceed 2068 kPa (300 psi) maximum recommended inflation pressure. Excess pressure may result in catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.

PRECAUTIONS

- Prescription only – device restricted to use by or on order of a physician.
- Store in a cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to solvents.
- Use device in conjunction with fluoroscopic visualization and proper anti-coagulation agents.
- Torquing guide catheter while kinked may cause damage that could result in separation of catheter shaft.
- If a device lodged in guide catheter, or if guide catheter becomes severely kinked, withdraw entire system (guide catheter, guidewire and catheter sheath introducer).
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through guide catheter lumen.

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Stryker Neurovascular
47900 BaySide Parkway
Fremont, CA 94538

Concentric Medical
301 East Evelyn Avenue
Mountain View, CA 94041

PRECAUTIONS

- Administer anti-coagulation and anti-platelet medications per standard institutional guidelines.
- Prescription only – device restricted to use by or on order of a physician.
- If Retrieval is difficult to withdraw from the vessel, do not torque Retrieval. Advance Microcatheter distally, gently pull Retrieval back into Microcatheter, and remove Retrieval and Microcatheter as a unit. If undue resistance is met when withdrawing the Retrieval into the Microcatheter, consider extending the Retrieval using the Abbott Vascular DOC guidewire extension (REF 22260) so that the Microcatheter can be exchanged for a larger diameter catheter such as a D4C® catheter. Gently withdraw the Retrieval into the larger diameter catheter.
- Administer anti-coagulation and anti-platelet medications per standard institutional guidelines.

PRECAUTIONS

- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.
- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to solvents.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate microcatheter with saline for 2 minutes minimum before use. Once hydrated, do not allow it to dry.
- To maintain hydrophilic coating lubricity, provide continuous flow of appropriate solution between microcatheter and guide catheter.
- Hemostatic side-arm adapters may be used to provide seal around guidewire and microcatheter.

Catheter	Pressure
MAC t4 (REF 90043)	MAC t4 (REF 90043)
MAC t8 (REF 90044)	MAC t8 (REF 90044)
Trevo 18 MC (REF 90047)	2070 kPa (300 psi)
Trevo Pro 18 MC (REF 90738)	1034 kPa (150 psi)

- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Do not exceed maximum recommended inflation pressure. Excess pressure may result in catheter rupture or tip severance.

WARNINGS

Refer to product label for device dimensions. Refer to labeling provided with other medical technologies to determine compatibility.

COMPATIBILITY

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to the following: infection, hematoma at the puncture site, vessel perforation, emboli, hemorrhage, ischemia, vasospasm, neurological deficits including stroke, death.

COMPLICATIONS

The Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary, and neurovascular during diagnostic and/or therapeutic procedures.

INDICATIONS FOR USE

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

Microcatheter

- Do not attach a torque device to the shaped proximal end of DOC® Microcatheter and Retrieval or guidewire.
- Compatible Retrieval. Damage may occur, preventing ability to attach DOC® Guide Wire Extension.

COMPLICATIONS

The Trevo® Retrieval is intended to restore blood flow in the neurovascularity by removing thrombus in patients experiencing ischemic stroke within 6 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.

INDICATIONS FOR USE

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

Trevo® Retrieval

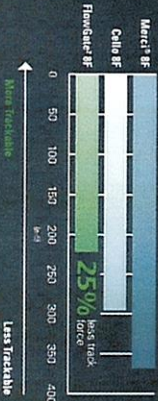
FlowGate²TM
BALLOON GUIDE CATHETER

DESIGNED FOR SUCCESS

Proximal Flow Control —————
With a 10mm compliant balloon

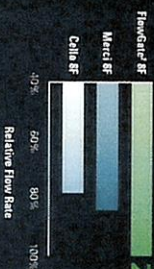
**Superior Trackability for Rapid
Neurovascular Access**
With a balance of proximal support
and distal flexibility

Max Force Needed to Track the ICA (g)



Best test results may not be indicative of clinical performance. Data are on file at Stryker Neurovascular and will be made available upon request.

High Flow Rates



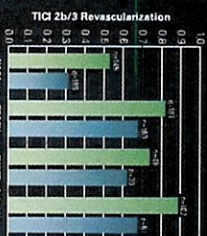
Optimized for Maximum
Clot Capture



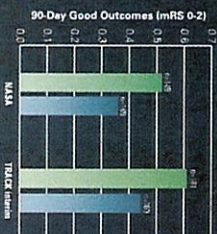
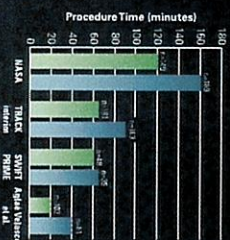
Improved stability
With stainless steel double braid and five transition zones for proximal support and distal flexibility

FLOW CONTROL FOR SUCCESS

Study results correlate AIS procedure efficacy with use of flow control



Faster Procedure Time

[illegible]

Success accelerated.

Take Control. Capture More.

FlowGate™
BALLOON GUIDE CATHETER



stryker®
Neurovascular

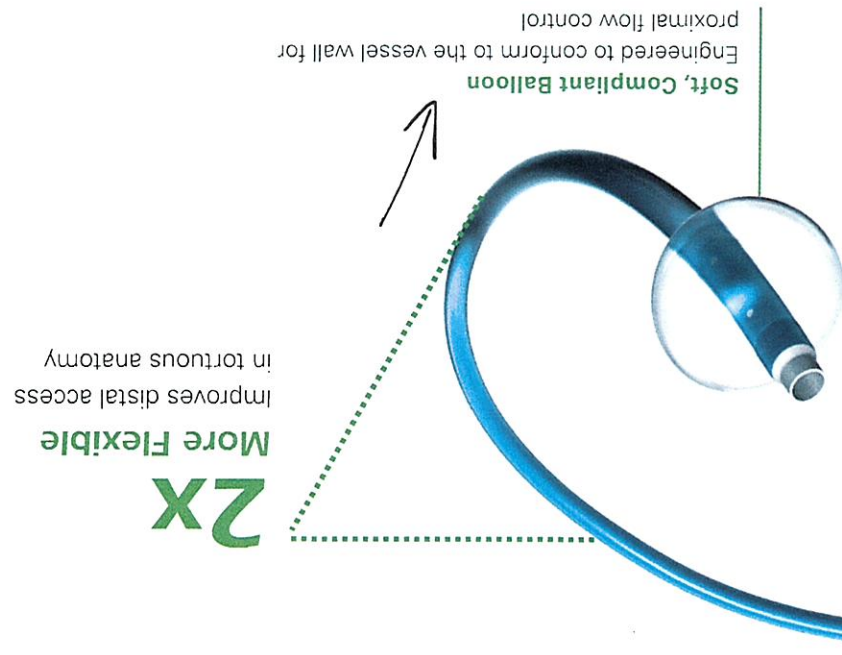
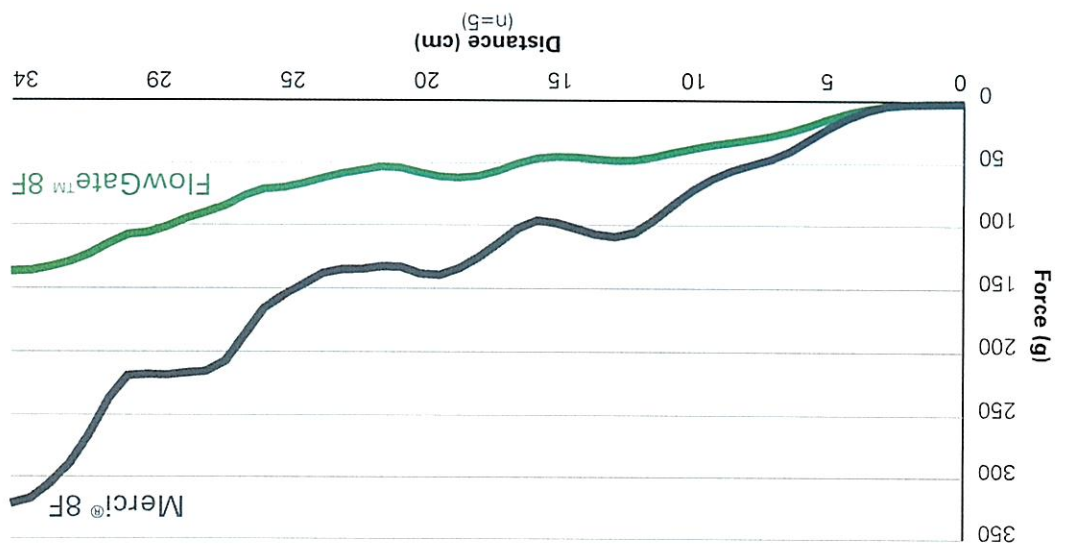
Take Control. Capture More.

Large .084in ID
for Maximum Clot Capture



Easy Access

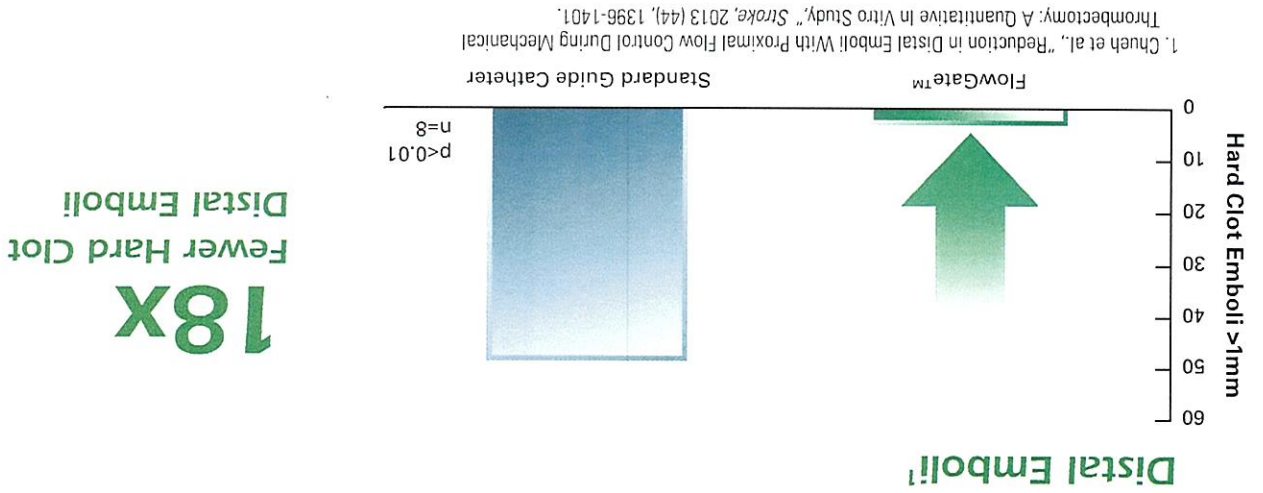
Trackability



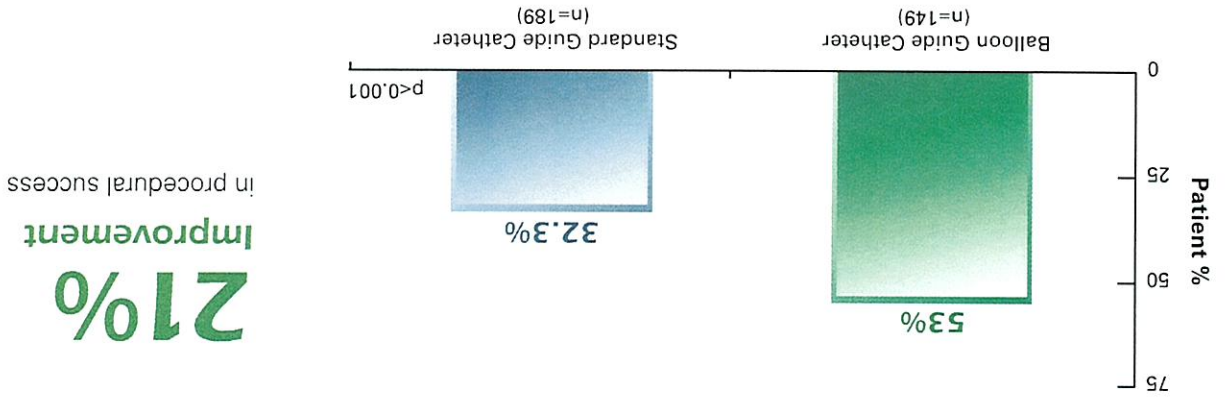
1.5X
More Stable
Greater support for
advancement and retrieval

Bench test results may not necessarily be indicative of clinical performance. Testing completed by Stryker Neurovascular. Data on file and available upon request.

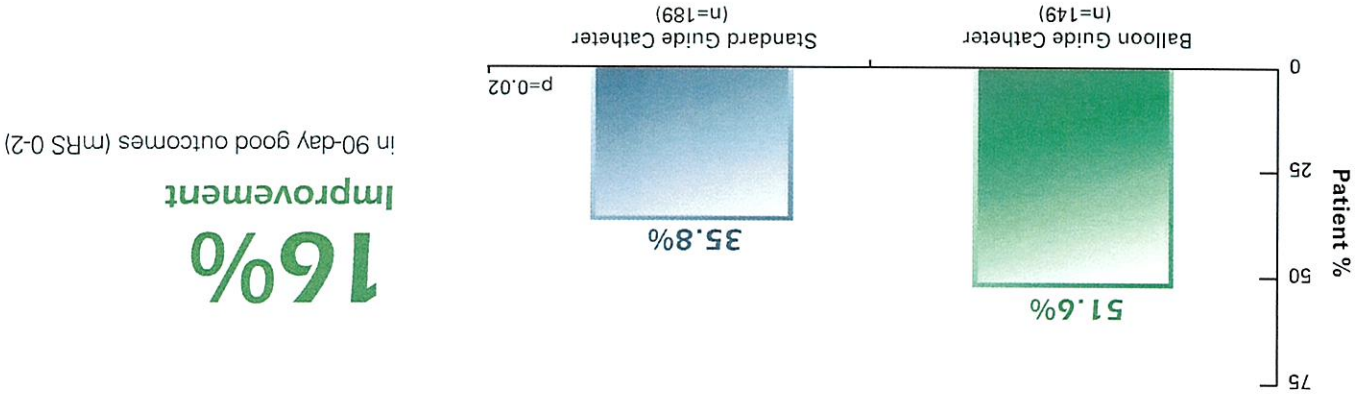
Control Flow for Better Outcomes.



Better TICl 3 Revascularization²



Independent Predictor of Good Clinical Outcomes²

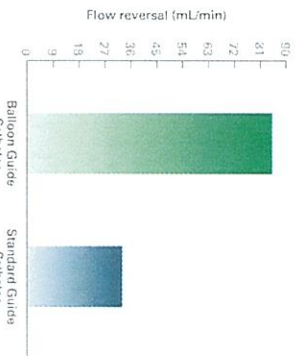


² Balloon guide catheter improves recanalization, procedure time, and clinical outcomes with Solitaire in acute stroke: analysis of the NASA Registry. T Nguyen et al. *J Neurointerventional Surg* 2013(5) A2-A3 2013.

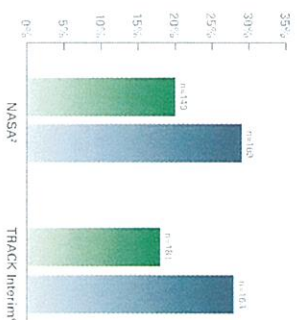
Higher MCA flow reversal

Less rescue therapy

"When the ICA flow was blocked by the balloon catheter, applying aspiration resulted in higher flow reversal in the MCA as compared to aspiration through the standard guide catheter." – Chuen et al.



Patients treated with a balloon guide catheter required less rescue therapy.



Studies

UMASS¹

Description: In vitro analysis designed to evaluate the impact of proximal flow control on distal flow during aspiration thrombectomy in a distal anterior artery occlusion. Evaluated three independent variables: clot type, device (Merci Retriever®, Solitaire FR and Trevo® Retriever) and use of a balloon guide catheter (BGC) on the size and number of distal emboli generated during thrombectomy.

Conclusion: The risk of distal embolization was significantly reduced with the use of the balloon guide catheter.

NASA²

Description: Designed to evaluate the role of the BGC and recanalization success in a sub-study of the TRACK Intermittent study. Patients with Acute Stroke Registry (NASAR). A total of 438 patients were included in this analysis. 44% of patients (n=194) had placement of a BGC with Solitaire, leaving 189 patients who were treated with Solitaire but without a BGC.

Conclusion: Use of a balloon guide catheter with the Solitaire Stent retriever in acute ischemic stroke results in superior recanalization results, faster procedure time, decreased need for rescue therapy and improved clinical outcome.

SWIFT PRIME³

Description: Patients from the Solitaire arm of SWIFT PRIME were selected to evaluate the impact of BGC on distal flow during aspiration thrombectomy. Subanalysis of the Solitaire arm. A total of 87 patients were treated with mechanical thrombectomy using Solitaire. 48 patients with a BGC and 39 patients without a BGC.

Conclusion: BGC use demonstrated significantly lower infarct size and higher reperfusion rates at 27h. Overall procedure times were shorter for BGC group.

TRACK

Description: Investigator initiated post-market, retrospective registry on the use of BGC in patients with acute ischemic stroke. Patients were analyzed in anterior circulation patients with onset to groin puncture within 8 hours and NIHSS 8 or greater. BGC use reported in 181 patients compared to 163 patients who were treated without BGC.

Conclusion: BGC showed better clinical and angiographic outcomes in TRACK Registry with less distal embolization consistent with current literature.

Velasco, et al.

Description: Multi-center retrospective study to evaluate the effectiveness of proximal flow control in AIS, performed by using a BGC or non-BGC catheter. 183 patients with MCA or carotid terminus occlusions evaluated. 102 patients treated with a stent retriever with a BGC and 81 patients with a stent retriever without a BGC.

Conclusion: The effectiveness of mechanical thrombectomy with stent retrievers in AIS in the anterior circulation in terms of angiographic results and procedure duration was improved when performed in combination with a BGC.

STRATIS

Description: Subanalysis of the STRATIS study. BGC use during outcomes in 3 groups. BGC use during outcomes in 3 groups. BGC use during outcomes in 3 groups. BGC use during outcomes in 3 groups. BGC use during outcomes in 3 groups.

Conclusion: Despite having a similar successful approach in STRATIS demonstrated higher rate of good clinical outcome at 90 days compared to CCG and DLBC.

Compelling benefits observed with proximal flow control

Efficient and timely recanalization is critical in endovascular stroke therapy. Many factors, including the presence of distal emboli and time to recanalization, serve as potential predictive markers for neurological outcomes and mortality. Studies suggest temporary proximal flow arrest, along with aspiration during clot retrieval may reduce the number of thrombectomy attempts, procedure time, and the risk of distal embolization.¹

Proximal flow control correlates with:	TRACK early results¹ n=334	SWIFT PRIME³ n=84	NASA² n=338	Velasco, et al.⁵ n=183	UMASS¹ n=8	STRATIS⁶ n=380
Better angiographic results (recanalization/perfusion TICI 2b-3)	✓	✓	✓	✓	✓	✓
Higher rate of first pass success	✓	✓	✓	✓	✓	✓
Shorter procedure time	✓	✓	✓	✓	✓	✓
Better clinical outcomes (90 days mRS 0-2)	✓	✓	✓	✓	✓	✓
Less distal emboli	✓	✓	✓	✓	✓	✓
Lower infarct size and volume	✓	✓	✓	✓	✓	✓
Better flow reversal	✓	✓	✓	✓	✓	✓
Less rescue therapy	✓	✓	✓	✓	✓	✓

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Concentric Medical
301 East Evelyn Avenue
Mountain View, CA 94041

Stryker Neurovascular
47900 Bayview Parkway
Fremont, CA 94538

STRATIS
Sponsor Address
Stryker Australia Pty Ltd
8 Herbert Street
St Leonards, NSW 2065
Australia

DATE OF RELEASE: JUL 2017
EX_EN_GL

¹ Reduction of Distal Emboli With Proximal Flow Control During Mechanical Thrombectomy. Creager, Jui-Yu, et al. Stroke 44(10) May 2013.

² NASA. Analysis of the NASA Registry. T. Nguyen, et al. J Neurointerv Surg 2015B; A2-A3 2013.

³ V. Pereira et al. J Neurointerv Surg 2015; (Suppl 1) A1-114.

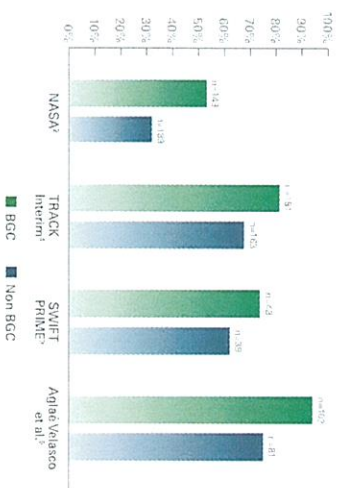
⁴ Osama O. Zaidat. TRACK. LINC 2015.

⁵ Agnieszka Velasco, et al. Radiology 2016.

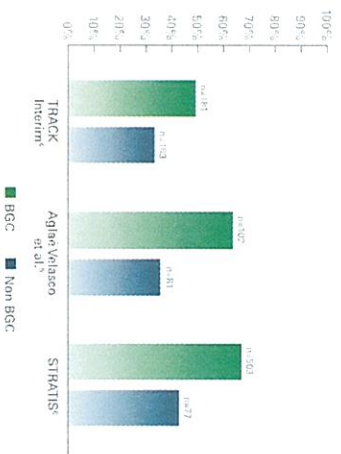
⁶ STRATIS Registry Sub-analysis. JSC. Feb. 22, 2017.

Better procedural outcomes

Higher TICI 2b/3 revascularization



Higher first pass success



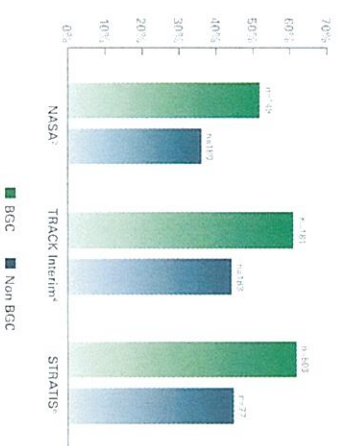
Improved clinical outcomes

Consistent results across trials

In the NASA, TRACK and STRATIS trials, the number of patients needed to treat (NNT) with BGC to generate a positive clinical outcome in mRS 0 to 2 at 90 days was 6, 7, 4, 6

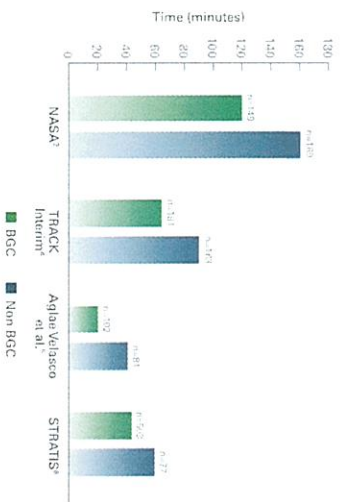


90 days good outcomes



Reduced procedure time

Minutes saved in procedure time

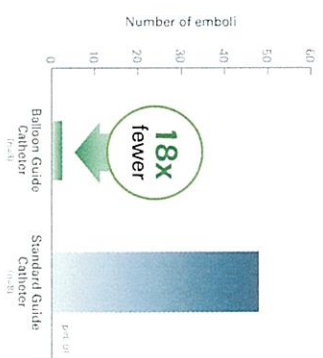


¹ Total procedure time. From puncture to revascularization time.

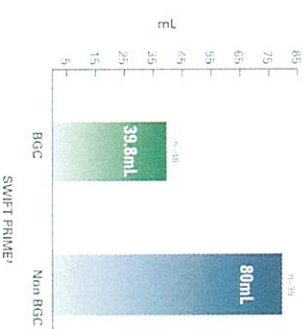
Decreased distal emboli and infarct size

Flow control during thrombectomy may reduce large fragments of hard clot by 18 times.

Fewer distal emboli



Infarct size mL



² NASA. Analysis of the NASA Registry. T. Nguyen, et al. J Neurointerv Surg 2013(6):A2-A3 2013.

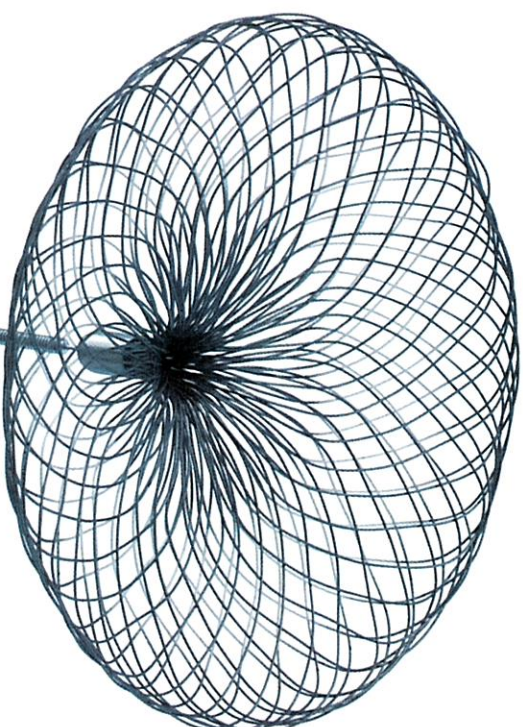
³ V Pereira et al., J Neurointerv Surg 2015;7(Suppl 1):A1-114.

⁴ Osama O. Zaidat, TRACK, JINCC 2015.

⁵ Aglae Velasco, et al., Radiology, 2016.

⁶ STRATIS Registry Sub-Analysis, JSC, Feb. 22, 2017.

Physician inservice guide




Contour
Neurovascular System™

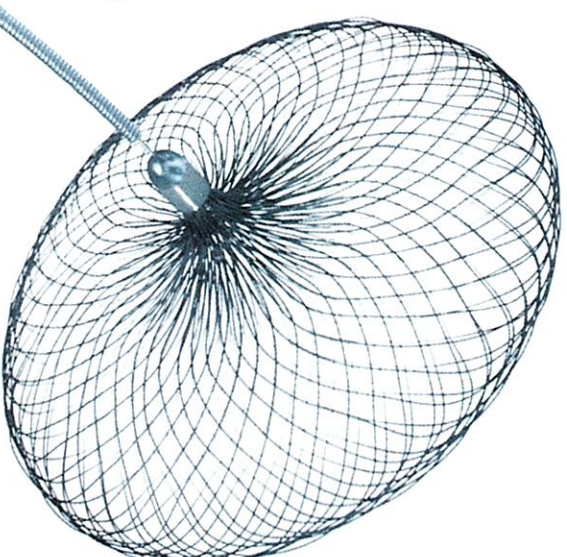


**Product
overview****Technical
specifications****Sizing****Deployment tips
& techniques****Value added
resources****Case highlights
& clinical data****1.0 Product overview****Size. Place. Done.**

By treating the entire aneurysm at the neck – away from the vulnerable dome – the Contour Neurovascular System makes treatment easy and quick.

Just size it, place it, and you're done.

- **Size simplified** 
 - Treat 2.0-10.5mm aneurysms with only 5 sizes
- **Place in a broad range of aneurysms**
 - No distal marker
 - Focused treatment at the neck
- **Done with one**
 - Effectively treat aneurysms with flow diversion and flow disruption at the neck
 - Unique stabilizing design intended to anchor the device
 - Supports endothelial growth at the neck



Product
overview

Technical
specifications

Sizing

Deployment tips
& techniques

Value added
resources

Case highlights
& clinical data



1.1 Product overview

Size: simplified

 Click here for more sizing tips and techniques.

Aneurysms can be complex. **Sizing should be simple.**

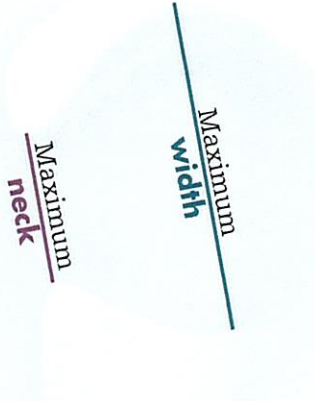
Due to the Contour Neurovascular System's unique design, **with just 5 sizes** and two measurements, you can treat aneurysm diameters from 2.0 to 10.5mm.



Product code	Microcatheter	Device diameter (mm)	Maximum aneurysm width* (mm)	Maximum aneurysm neck (mm)
CNS21005-15	0.021"	5.0	2.0 – 3.5	2.0 – 3.0
CNS21007-15	0.021"	7.0	3.0 – 5.5	3.0 – 5.0
CNS21009-15	0.021"	9.0	5.0 – 7.5	4.0 – 6.0
CNS011-15	0.027"	11.0	7.0 – 8.5	5.0 – 8.0
CNS014-15	0.027"	14.0	8.0 – 10.5	7.0 – 10.0

*Maximum width is equivalent to equatorial diameter

stryker



2.0 Technical specifications

System overview

Click here for device specifications.

Product
overview

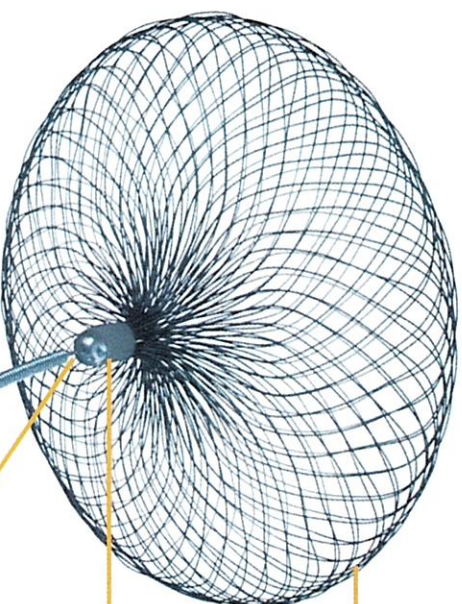
Technical
specifications

Sizing

Deployment tips
& techniques

Value added
resources

Case highlights
& clinical data



Implant

Drawn-filled tubing (DFT) wires (nitinol + platinum)
0.0009" – 0.0010" wire OD
128-144 wires

Implant marker

Platinum-iridium
0.019" – 0.025" OD
0.024" length

Detachment point

Electrolytic detachment zone
~0.008" length
0.0027" diameter

Delivery wire

Stainless-steel
185cm length

Click here for wire details.

Introducer sheath

Teflon



**Product
overview**

**Technical
specifications**

Sizing

**Deployment tips
& techniques**

**Value added
resources**

**Case highlights
& clinical data**

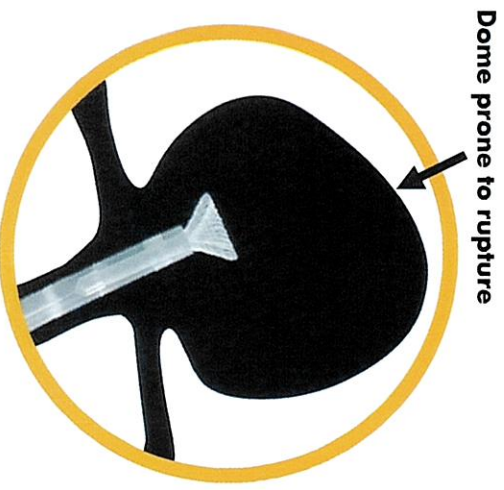


1.2 Product overview

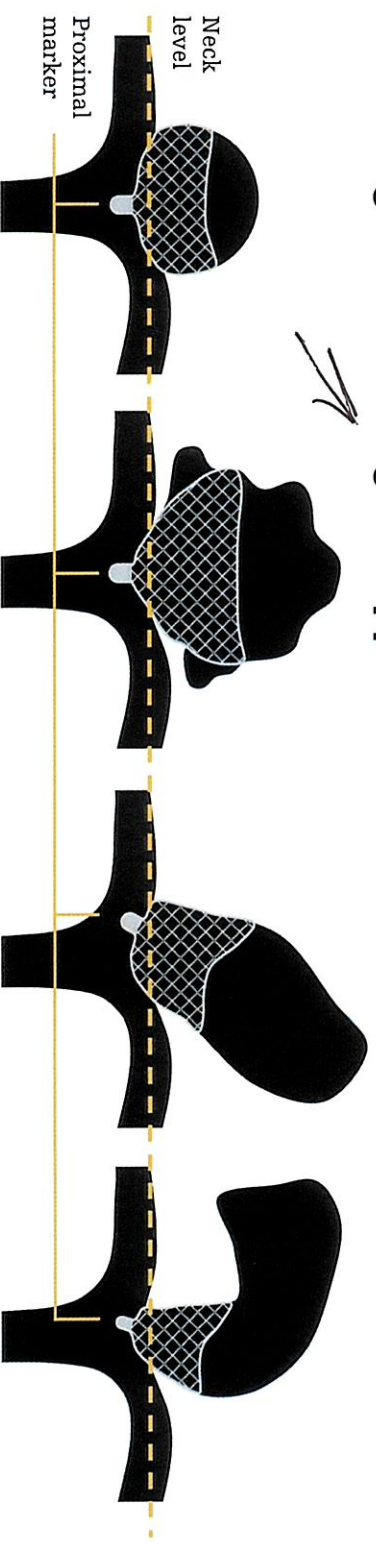
Place: treat a broad range of aneurysms

The Contour Neurovascular System is designed to be placed in the lower part of the aneurysm, **reducing contact with the vulnerable dome.**

Upon unsheathing, the braid is designed to flower, offering an atraumatic distal end.



The Contour Neurovascular System focuses treatment at the neck – unlocking a broad range of applications.



The proximal marker should be below the level of the neck

Product
overview

Technical
specifications

Sizing

Deployment tips
& techniques

Value added
resources

Case highlights
& clinical data



3.0 Sizing

Sizing fundamentals

- 1 Measure the **maximum width** of the aneurysm
- 2 Measure the **maximum neck** diameter
- 3 Select from the correct size based on the table below:

For Stability
(more important)

Product code	Microcatheter	Device diameter (mm)	Maximum aneurysm width* (mm)	Maximum aneurysm neck (mm)
CNS21005-15	0.021"	5.0	2.0 – 3.5	2.0 – 3.0
CNS21007-15	0.021"	7.0	3.0 – 5.5	3.0 – 5.0
CNS21009-15	0.021"	9.0	5.0 – 7.5	4.0 – 6.0
CNS011-15	0.027"	11.0	7.0 – 8.5	5.0 – 8.0
CNS014-15	0.027"	14.0	8.0 – 10.5	7.0 – 10.0

*Maximum width is equivalent to equatorial diameter

For Seal

Maximum
width

Maximum
neck