

FRED®

Flow Re-Direction Endoluminal Device

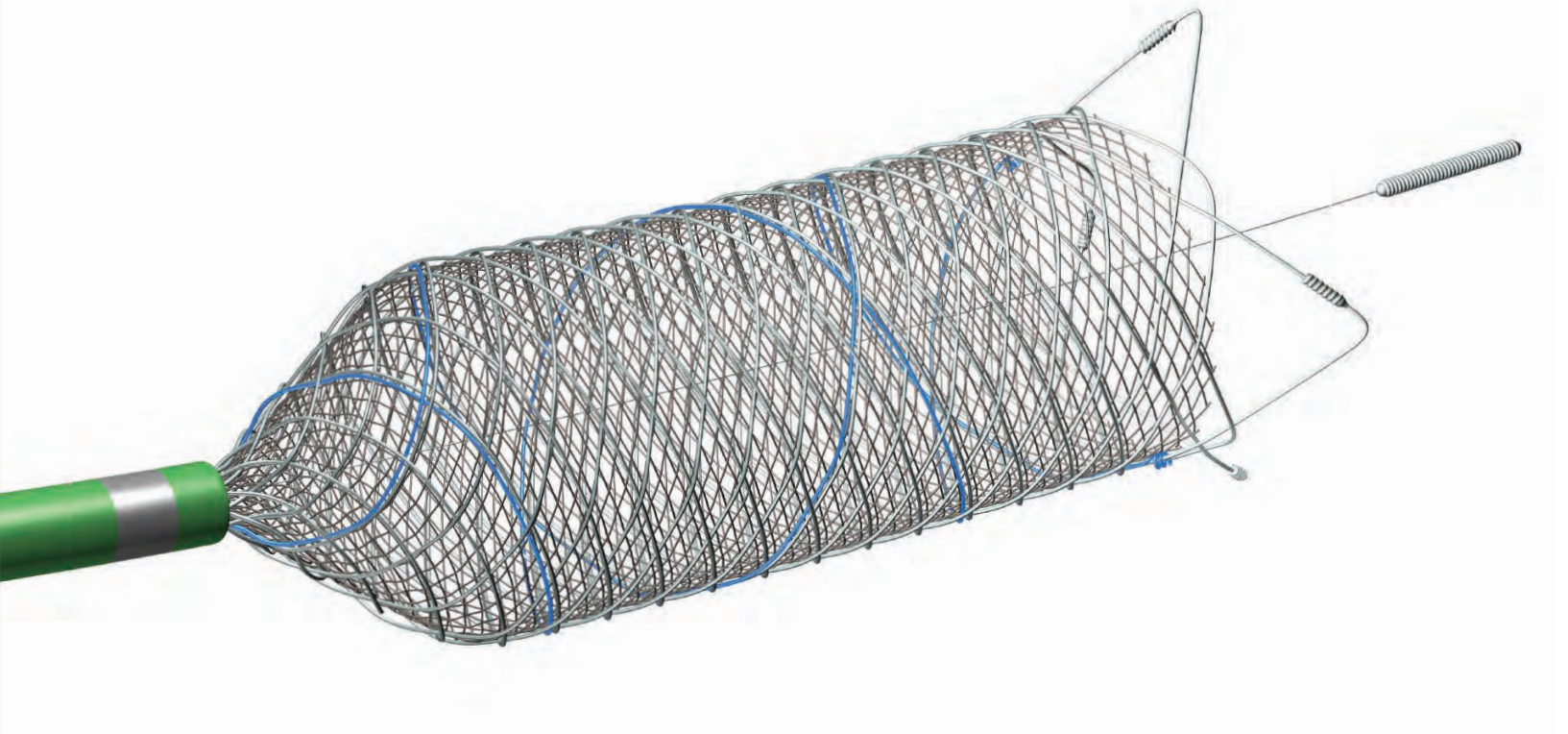
Optimized for
Performance and
Ease of Use. Designed
with Titanium Oxide Surface

31. Stentas remodeliuojantis srovę

MicroVention provides **FRED[®]**, a unique flow diverter stent comprised of two integrated Nitinol braided inner and outer stent layers

FRED[®]

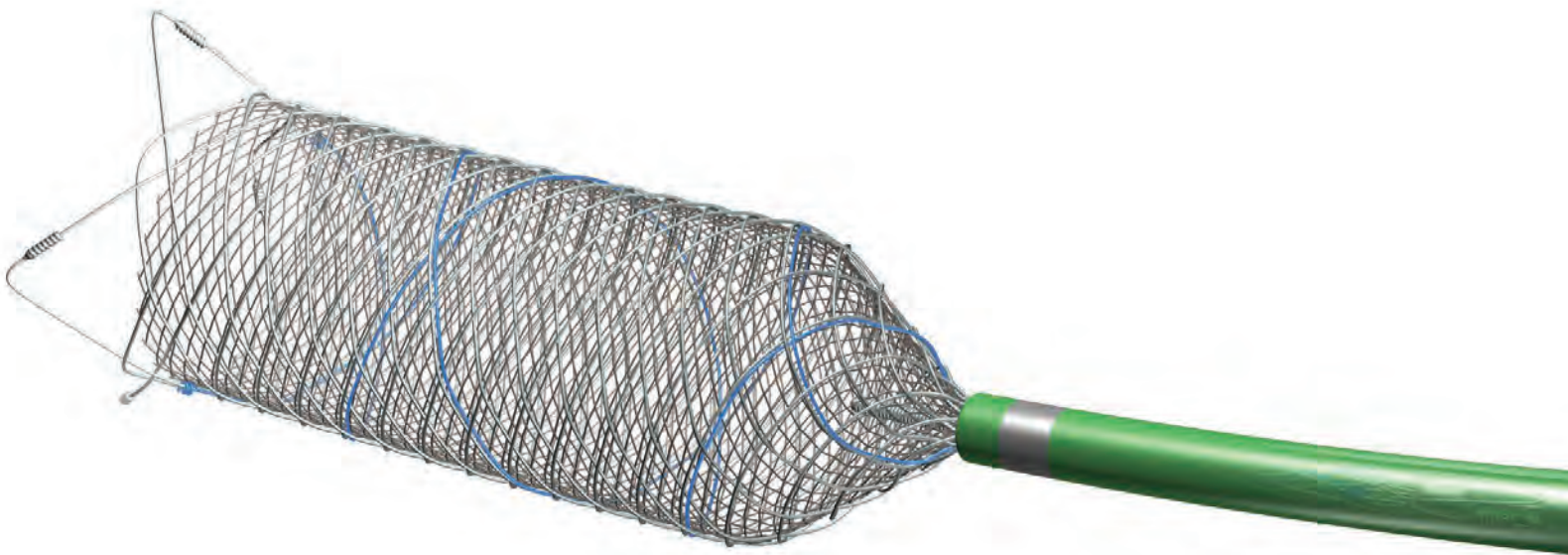
Flow Re-Direction Endoluminal Device



DELIVERED THROUGH:
Headway[®] 27
Microcatheter

31. Stentas remodeliuojantis srovę

The FRED device has key design characteristics that create an environment for flow diversion, vessel wall apposition and a scaffold for neointimal growth **for long term aneurysm occlusion**^{1,2}



DELIVERED THROUGH:
Headway[®]
Microcatheter **21**

31. Stentas remodeliuojantis srovę



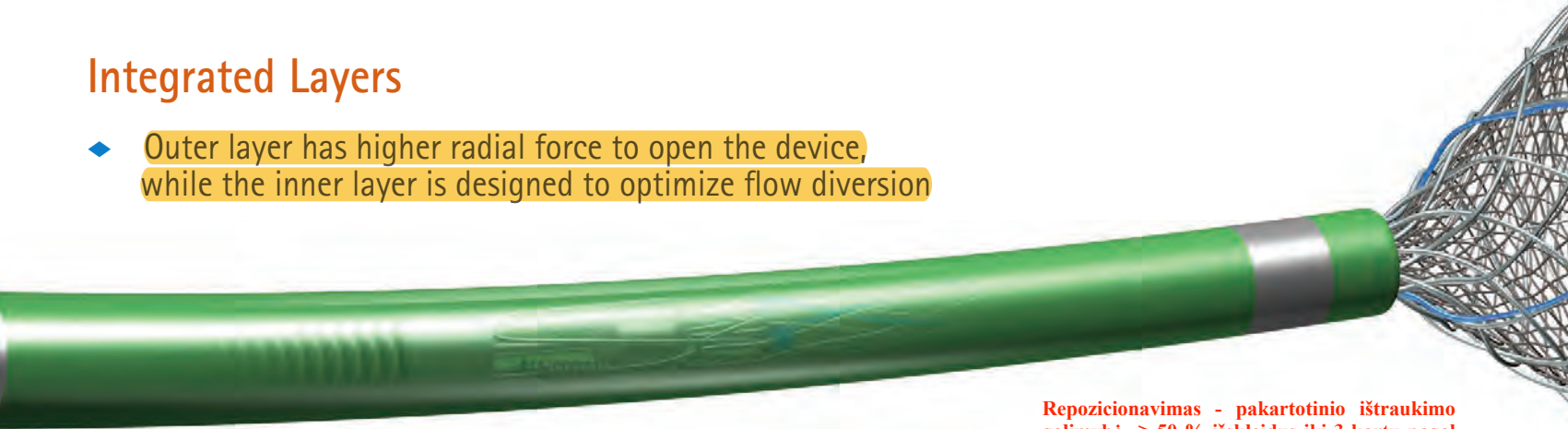
Struktūra - dv sluoksnis stentas, sudarytas iš vienos nitinolinės vielos su 16 išorinių ir 36 arba 48 vidinių persipynusių vijų (iš viso 54 arba 66), sienelės vidinio paviršiaus efektyvus metalo dangos tankis 28% - 44%

Flow Re-Direction Endoluminal Device

Designed for Performance

Integrated Layers

- ◆ Outer layer has higher radial force to open the device, while the inner layer is designed to optimize flow diversion



Repozicionavimas - pakartotinio ištraukimo galimybė $\geq 50\%$ išskleidus iki 3 kartų pagal vartojimo instrukcijos rekomendacijas

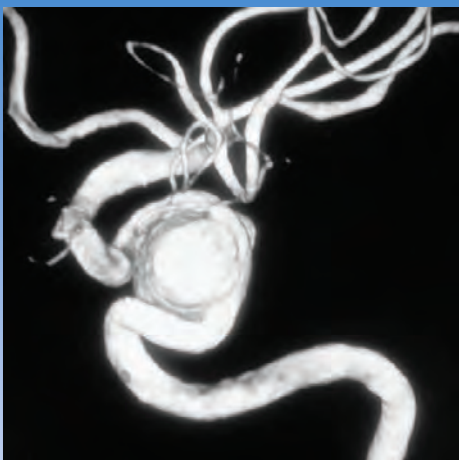
Designed with Titanium Oxide Surface

- ◆ Produced with electropolishing passivation for smoothness and corrosion resistance

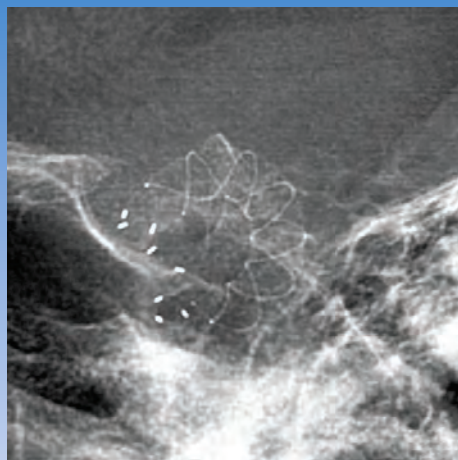
Designed for Ease of Use

- ◆ Smooth delivery through Headway® microcatheters
- ◆ The device can be recaptured up to 50% of deployment. This can be done up to three times
- ◆ Clear radiopacity on stent body and flared ends

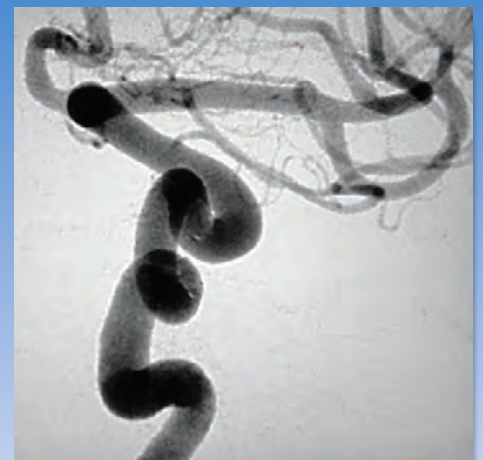
Tortuous Left Internal Carotid Giant Sidewall Aneurysm, FRED® device, size 4518 – Courtesy of Dr. Alejandro Ceciliano, Hospital Austral, Argentina



PLANNING 3D

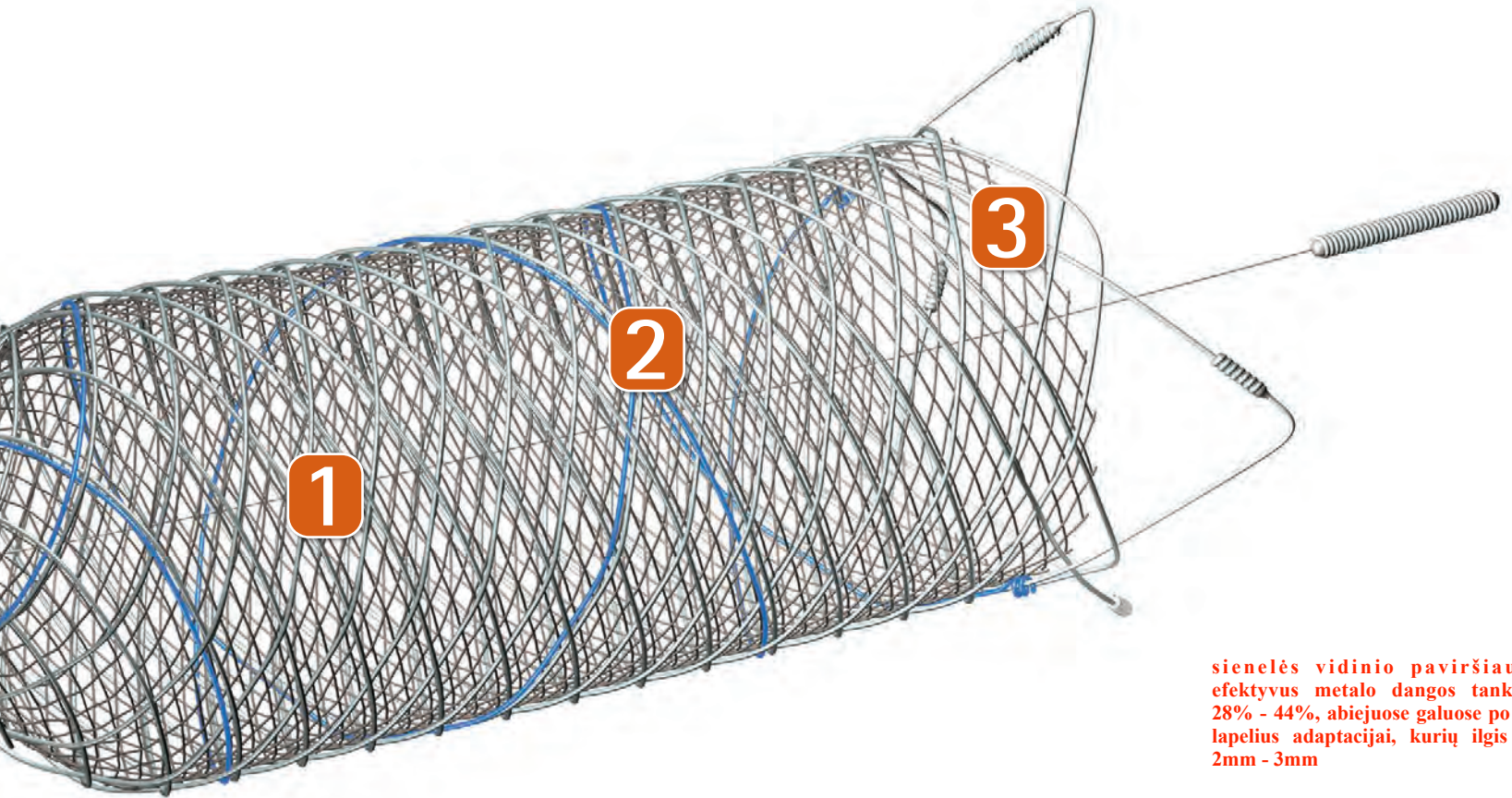


POST-DEPLOYMENT



7 MONTH FOLLOW-UP

31. Stentas remodeliuojantis srovę



sienelės vidinio paviršiaus efektyvus metalo dangos tankis 28% - 44%, abiejuose galuose po 4 lapelius adaptacijai, kurių ilgis - 2mm - 3mm

1. Flow Diversion:

Effective Metal Surface Area %

*FRED® device inner layer provides an average of 37% effective metal surface area**

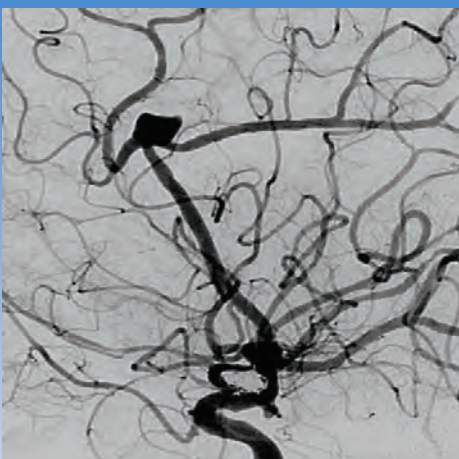
2. Radiopacity:

Tantalum helical strands *throughout device and flared ends allow visible tracking and confirms successful deployment*

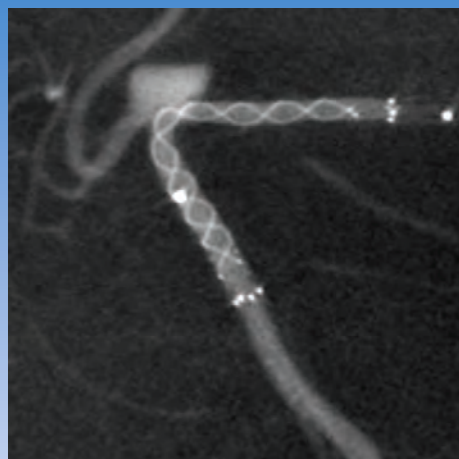
3. Device Opening:

High Radial Force *due to integrated nitinol design*

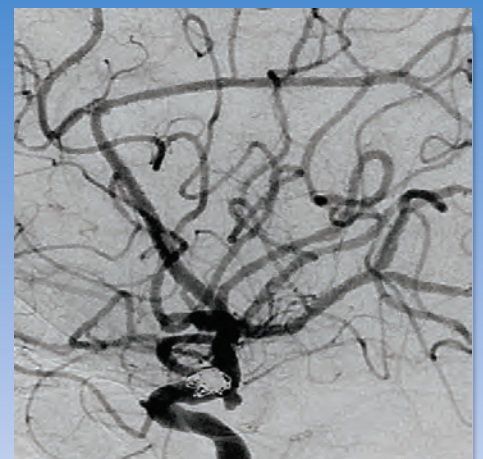
Right Pericallosal Aneurysm, FRED® Jr. device, size 2526 – Courtesy of Dr. Saruhan Cekirge, Koru Hospital, Turkey



PRE-DEPLOYMENT



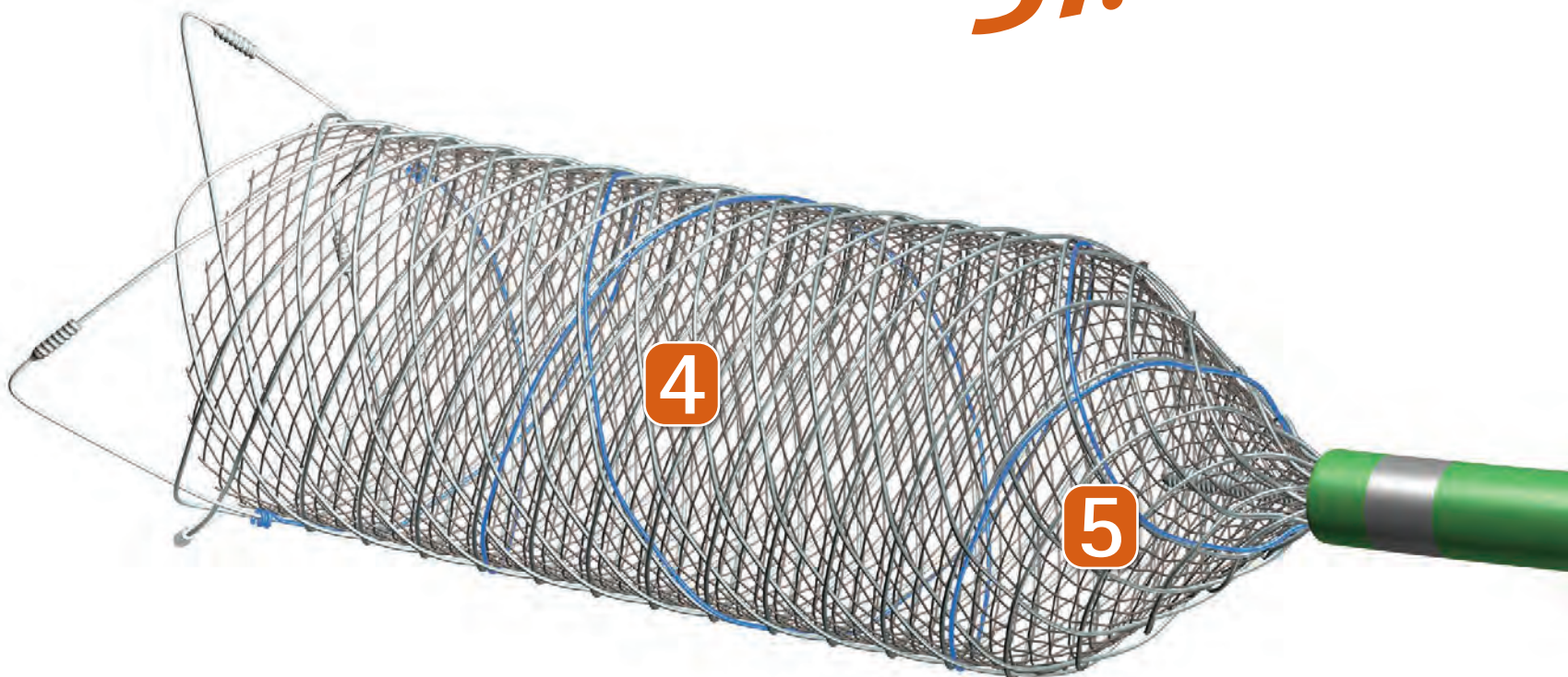
POST-DEPLOYMENT



6 MONTH FOLLOW-UP

31. Stentas remodeliuojantis srovę

sienelės vidinio paviršiaus
efektyvus metalo dangos tankis
28% - 44%, abiejuose galuose po 4
lapelius adaptacijai, kurių ilgis -
2mm - 3mm



4. Flow Diversion:

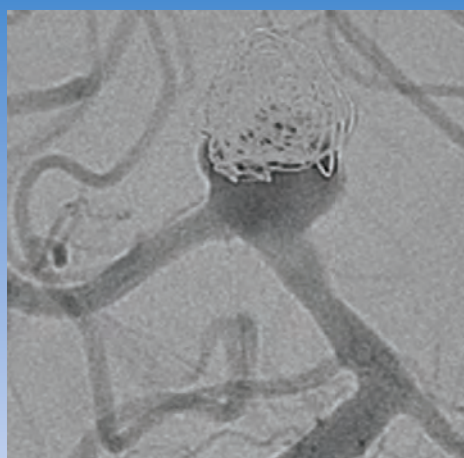
Effective Metal Surface Area %

*FRED[®] Jr. device inner layer provides an average
of 30% effective metal surface area**

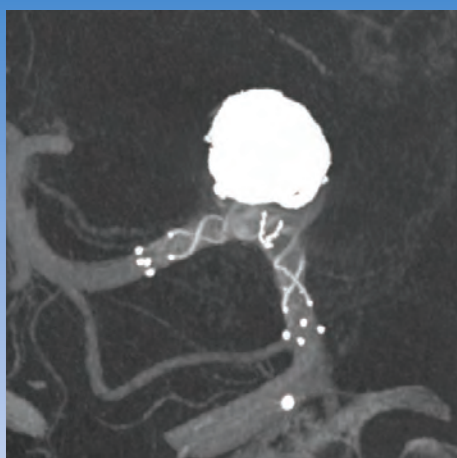
5. Shorter Tip:

*Designed with a shorter delivery wire
for smaller vessels*

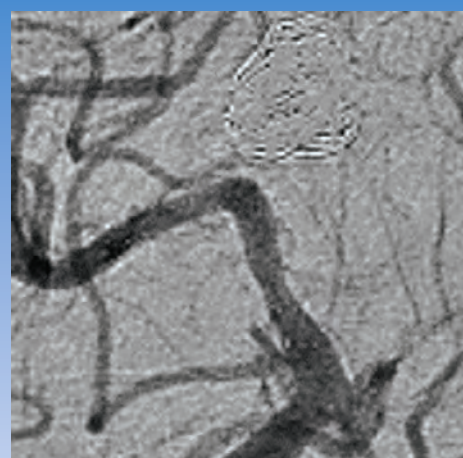
Partially Thrombosed P1-P2 aneurysm (Previously coiled), FRED[®] Jr. device, size 3021 – Courtesy of Dr. Pedro Lylyk, ENERI, Argentina



PRE-DEPLOYMENT



POST-DEPLOYMENT



3 MONTH FOLLOW-UP

31. Stentas remodeliuojantis srovę

Headway[®] **21** 156cm
Microcatheter

Headway[®] **27** 156cm
Microcatheter

NOW WITH **Duo!** TECHNOLOGY

Hybrid braid/coil construction, to improve the stent delivery experience

Stento suderinamumas - stentai iki 3 mm suderinami su visų modelių mikrokategorijomis, kurių vidinis skersmuo ID 0,021" ir stentai nuo 3,5 mm suderinami su visų modelių mikrokategorijomis, ID 0,027"



A. PTFE Liner:

Lubricious, durable inner liner for smooth stent delivery

B. Soft Distal Shaft:

Smooth and atraumatic tracking

C. Lubricious Hydrophilic Coating:

Reduced friction during navigation in tortuous anatomy and during lengthy procedures

D. Hybrid Braid And Coil Design:

Coil reinforcement provides lumen integrity, bending flexibility and excellent shape retention. Proximal variable braid reinforcement provides support and torque control. Hybrid design provides 1:1 push/pull control for trackability

E. Stretch Resistant Shaft:

For stability and prevention of catheter body twisting

Duo Technology Hybrid Braid/Coil Design

FEATURES	BENEFITS
<ul style="list-style-type: none">◆ Proximal column strength for stability and torqueability◆ 156cm working length with distal flexible transitions◆ Resistance to kinking and ovalization◆ Resistance to stretching◆ Resistance to twisting	<ul style="list-style-type: none">◆ Facilitate access to the lesion◆ Smooth device trackability◆ Controlled device delivery

Duo!
TECHNOLOGY

The FRED® and FRED® Jr. systems are CE Marked. The FRED Jr. system is not approved in the United States.
The FRED system is limited by United States law to investigational use only.

References:

- ¹ M.A. Möhlenbruch, C. Herweh, L. Jestaedt, S. Stampfl. The FRED Flow-Diverter Stent for Intracranial Aneurysms: Clinical Study to Assess Safety and Efficacy. AJNR. February 26, 2015 as 10.3174/ajnr.A4251 <http://dx.doi.org/10.3174/ajnr.A4251>
- ² Naci Kocer, M.D., Civan Islak, M.D., Osman Kizilkilic, M.D., Flow Re-direction Endoluminal Device in treatment of cerebral aneurysms: initial experience with short-term follow-up results. J Neurosurg. March 14, 2014; DOI: 10.3171/2014.1.JNS131442
- * Stent inner layer effective metal surface area calculated by measuring stents having the same diameter target vessel.

FRED System and FRED Jr. System Product Indications:

The system is intended for endovascular embolization of intracranial neurovascular aneurysms.
The FRED and FRED Jr. system may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

Contraindications:

Use of the FRED system or FRED Jr. system is contraindicated under these circumstances:

- Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs are contraindicated
- Patients with known hypersensitivity to nickel-titanium
- Patients in whom angiography demonstrated inappropriate anatomy that does not permit passage or deployment of the FRED or FRED Jr. system

Headway Microcatheter Indications:

The Headway Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.



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