LVIS® Intraluminal Stent Device:
Separates itself from other stents used in treatments for aneurysm with recent PMA FDA approval

What is an aneurysm?

A brain aneurysm is a bulging, weak area in the wall of an artery that supplies blood to the brain. Treating these weak points is critically important to protecting the patient. There are two states of aneurysms, **unruptured** and **ruptured**.

Unruptured Aneurysms

- Usually discovered incidentally through imaging devices such as MRI/MRA, prior to rupturing[1]
- Don't always cause symptoms[1]
- If left untreated, some unruptured aneurysms have the risk of rupturing[1]

Ruptured Aneurysms

- Causes bleeding in the brain, also known as subarachnoid hemorrhage (SAH)[2]
- SAH can cause brain damage, coma or/and death[2]
- Survivors may have more serious deficits as well as a much longer recovery time[2]

1. Unruptured Brain Aneurysms. BAFound.org. https://www.bafound.org/about-brain-aneurysms/types-of-brain-aneurysms/unruptured-brain-aneurysms/. 2. Subarachnoid Hemorrhaging. BAFound.org. https://www.bafound.org/about-brain-aneurysms/types-of-brain-aneurysms/subarachnoid-hemorrhage/.

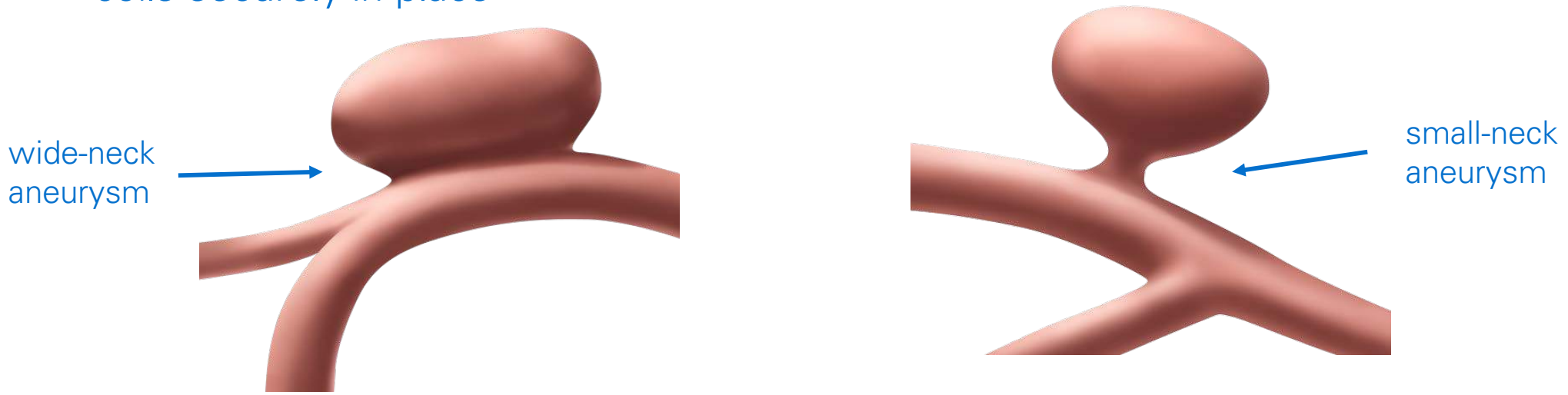
A problem for millions of Americans

- An estimated 6 million people in the United States have an unruptured brain aneurysm, or 1 in 50 people[1]
- Most aneurysms are small, about 1/8 inch to nearly one inch, and an estimated 50 to 80 percent of all aneurysms do not rupture during the course of a person's lifetime[1]
- About 30,000 people in the United States suffer a brain aneurysm rupture per year[1]
  - A is a brain aneurysm ruptures every 18 minutes[1]

1. Brain Aneurysms Statistics and Facts. BAFound.org. https://www.bafound.org/about-brain-aneurysms/brain-aneurysm-basics/brain-aneurysm-statistics-and-facts/.

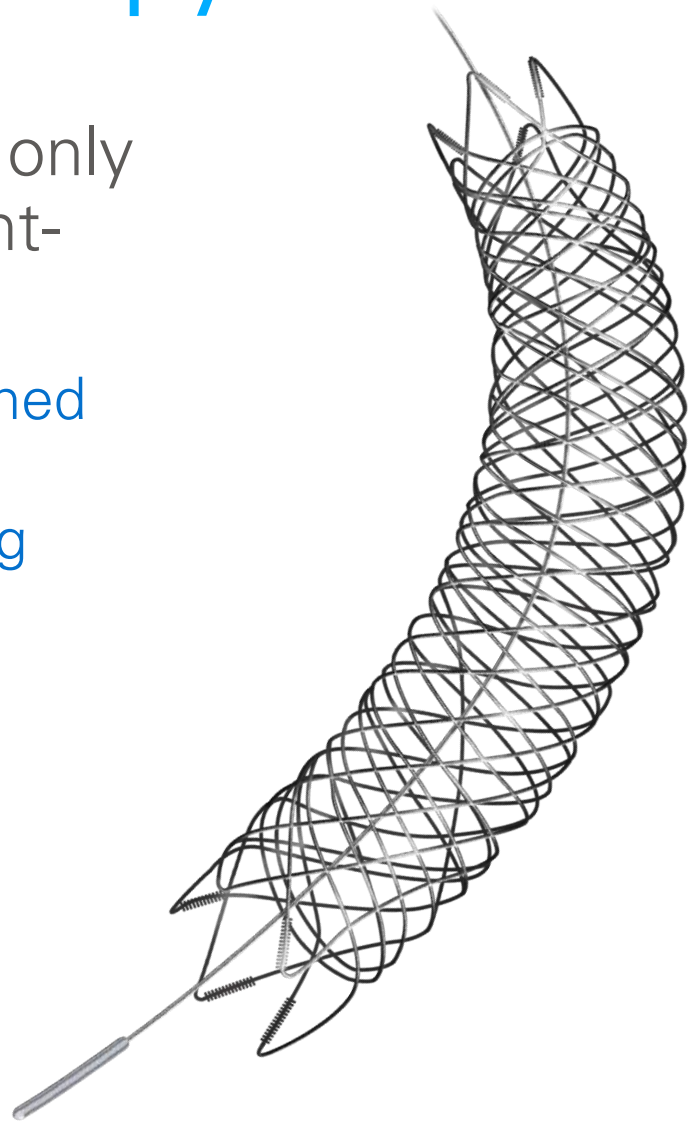
A new option for aneurysm therapy

- The FDA has granted Premarket Approval (PMA) for the LVIS® and LVIS® Jr. stents for stent-assisted coil embolization of wide-necked saccular intracranial aneurysms
  - Wide-necked aneurysms are particularly difficult to manage as the larger opening means coils are more apt to exit the aneurysm, thus necessitating the use of a stent to keep coils securely in place



A new option for aneurysm therapy

- The LVIS® and LVIS® Jr. stents are the first and only stents with Premarket Approval (PMA) for stent-assisted coil embolization
  - The approval was based upon scientific evidence gained through a clinical trial assessing the safety and effectiveness of LVIS® and LVIS® Jr. devices in treating patients with stent-assisted coil embolization
  - No other stent designed for stent-assisted coil embolization has conducted a clinical trial proving its safety and effectiveness for stent-assisted coil embolization



Why PMA approval is so significant

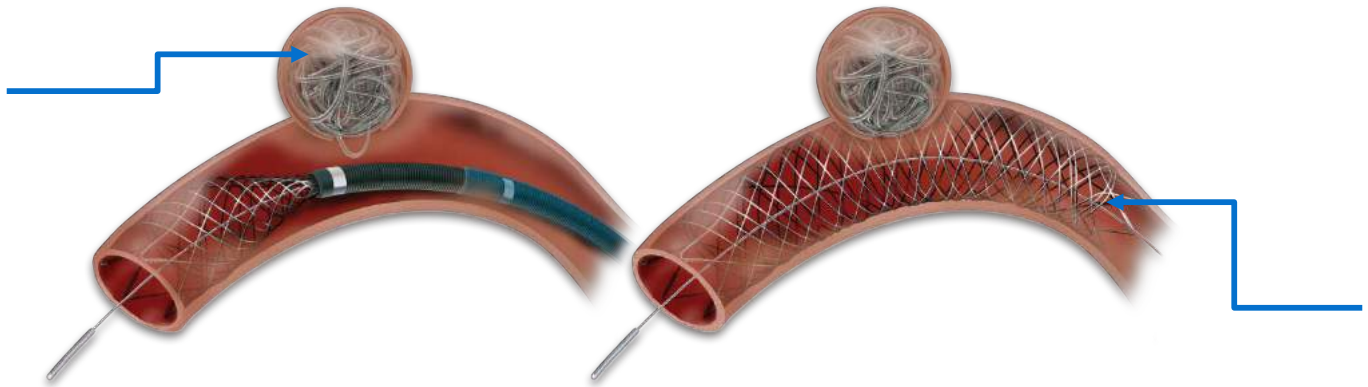
- PMA is the most stringent type of device marketing application required by FDA
  - A PMA approval requires that there is scientific evidence that the device is both **safe** and **effective** for its intended use. A humanitarian device exemption (HDE) confirms the probable benefits of the device, but is exempt from the effectiveness data requirements of a PMA.
- For PMA approval, MicroVention conducted a rigorous clinical trial that proved to the agency that there was sufficient valid scientific evidence demonstrating that LVIS® and LVIS® Jr. stents are not just safe, but effective for their intended use(s)
  - 153 patients were enrolled in the LVIS PMA study. Other stents that have a HDE approval enrolled approximately 30 patients in their respective HDE studies.
  - Use of the LVIS device has been shown to directly benefit patients, with a low retreatment rate of 4.3% at 12-month imaging follow-up[1].

1. Data from LVIS Device Instructions for Use IFU100003A

How stent embolization with LVIS® and LVIS® Jr. devices works

- Stent-assisted coil embolization involves permanently placing a stent in the blood vessel adjacent to the aneurysm to provide a scaffolding of support that keeps the coils within the aneurysm sac

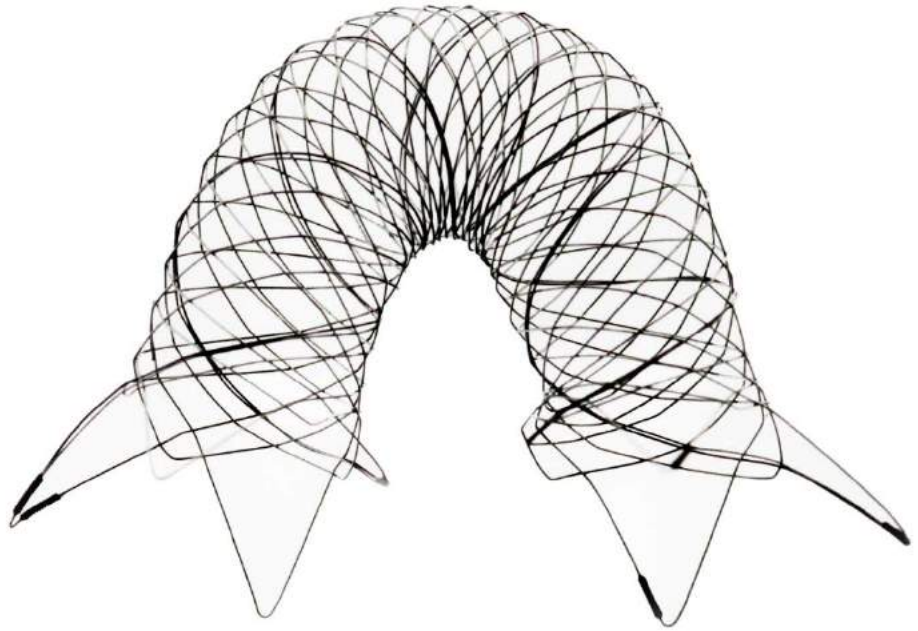
Coil embolization uses soft coils to fill an aneurysm in such a way that the coil mass disrupts blood flow to protect the aneurysm from rupture



Stent-assisted coil embolization places a stent in the blood vessel adjacent to the aneurysm to provide a scaffolding or support to keep the coils within the aneurysm sac

Unique design attributes of LVIS® and LVIS® Jr. stents

- Unlike other stents designed for stent-assisted coil embolization of intracranial aneurysms that are laser cut, LVIS® and LVIS® Jr. stents utilize proprietary braided stent design
- A single nickel-titanium alloy (nitinol) wire is braided into the shape of the stent and provides:
  - High metal coverage
    - Keeps coils in the aneurysm
    - Works well in wide-necked aneurysms
    - Works well with small finishing coils
  - Better conformity to the vessel wall[1]
    - Ensures the stent remains in place, more easily accommodating the curvatures of the vasculature
    - Minimizes risk of narrowing or blockage of blood vessel (stenosis)



1. Nicholas K Cheung,et al. "Long-term follow-up of aneurysms treated electively with woven stent-assisted coiling" J NeuroIntervent Surg 2017;0:1–6. doi:10.1136/neurintsurg-2017-013402
Ebrahimi et al. "Stent Conformity in Curved Vascular Models with Simulated Aneurysm Necks Using Flat-Panel CT: An In Vitro Study" AJNR Am J Neuroradiol 28:823–29 May 2007

"With their low-profile and consistent visibility, LVIS® and LVIS® Jr. stents expand the treatment options for patients with challenging, wide-necked aneurysms. The pivotal trial shows that these stents are safe and effective for patients with aneurysms that may be challenging to treat with other devices."

Dr. David Fiorella

Professor of Neurological Surgery and Radiology,

Director of Neurointerventional Radiology,

Co-Director of Stony Brook University Cerebrovascular and Stroke Center

MicroVention

Founded in 1997, MicroVention develops and markets medical devices that enable or significantly improve treatment of cerebrovascular diseases. In 2006, Terumo Corporation, a major worldwide medical device company headquartered in Tokyo, Japan, acquired MicroVention into their family of Companies. Terumo's acquisition of MicroVention allowed both Companies to leverage their unique, proprietary technologies toward an increased focus on treating cerebrovascular diseases.

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The LVIS® and LVIS® Jr. devices are indicated for use with neurovascular embolization coils in patients ≥ 18 years of age for the treatment of wide-neck (neck width ≥ 4 mm or dome to neck ratio < 2) saccular intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 4.5 mm.

RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician.
This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The LVIS® and LVIS® Jr. Devices should only be used by physicians who have received appropriate training for the device.

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Refer to Instructions for Use, contraindications and warnings for additional information.