

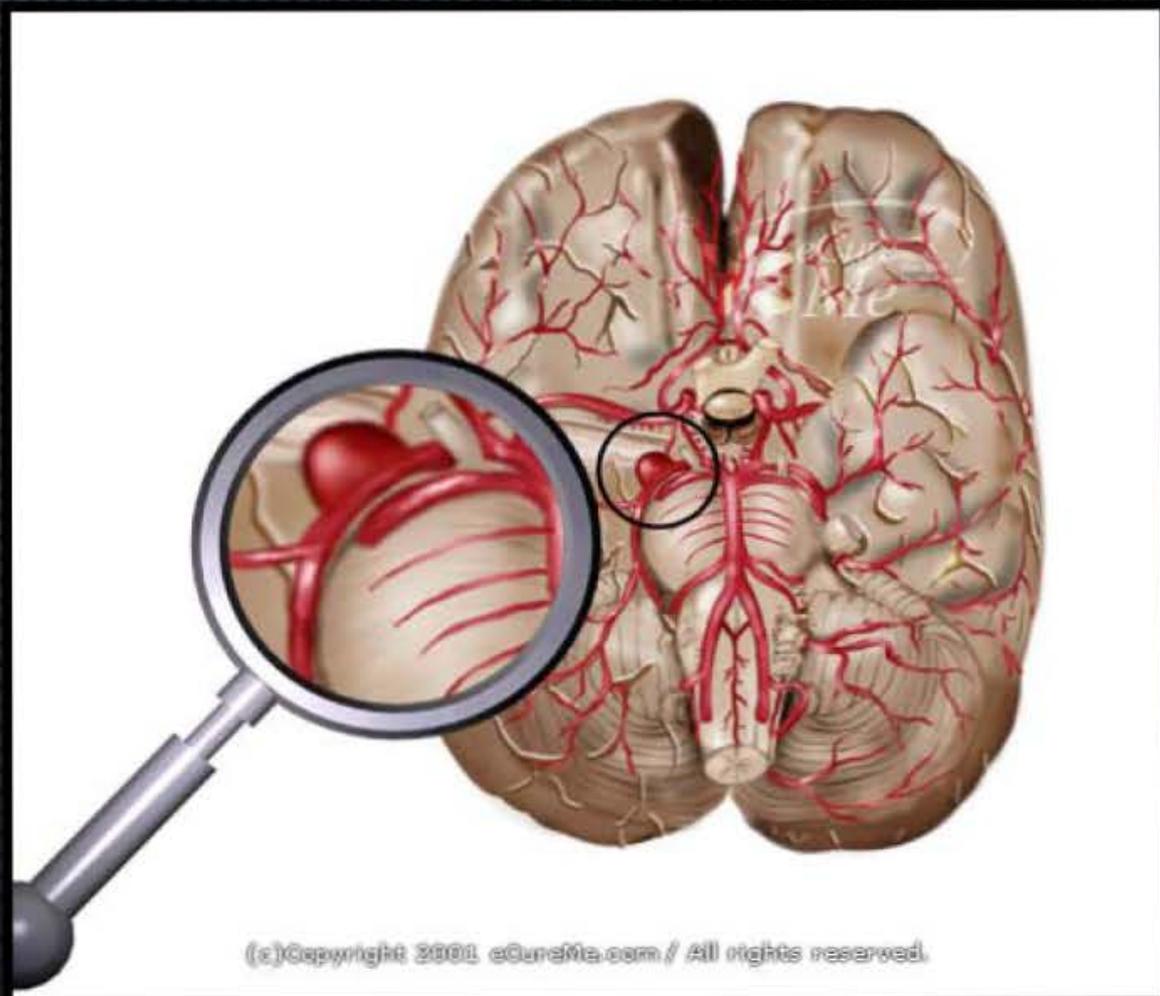
Jill Frebershauser, NMT

Neurological Devices Panel For
The Medical Devices Advisory
Committee

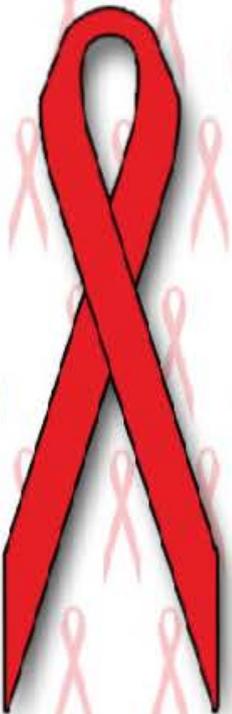
HILTON WASHINGTON DC, NORTH. SALONS A-D BALLROOM

MARCH 1, 2018

I AM A SURVIVOR. HERE IS PART OF MY STORY.



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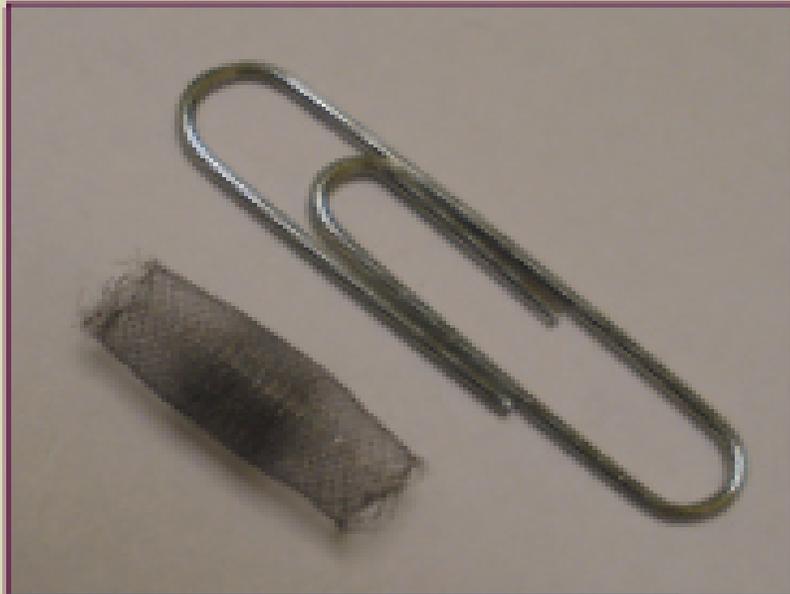
Stroke Awareness

Do YOU know the signs?

- Sudden numbness or weakness - especially to only one side of the body
- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden dizziness, trouble walking, loss of balance or coordination
- Sudden severe headache with no known cause

If you, or someone you love, experiences ANY of these symptoms
Call 911 immediately and tell the dispatcher it is a suspected stroke!
Response time is critical! Time lost is brain lost!

PIPELINE EMBOLIZATION DEVICE - AN INNOVATIVE TOOL SIMILAR TO A STENT AND IS USED IN THE TREATMENT OF LARGE NECKED INTRACRANIAL BRAIN ANEURYSMS.



This small PED device can collapse giant aneurysms

It is composed of platinum ,tungsten, cobalt ,chromium and nickel alloys making it MRI compatible.

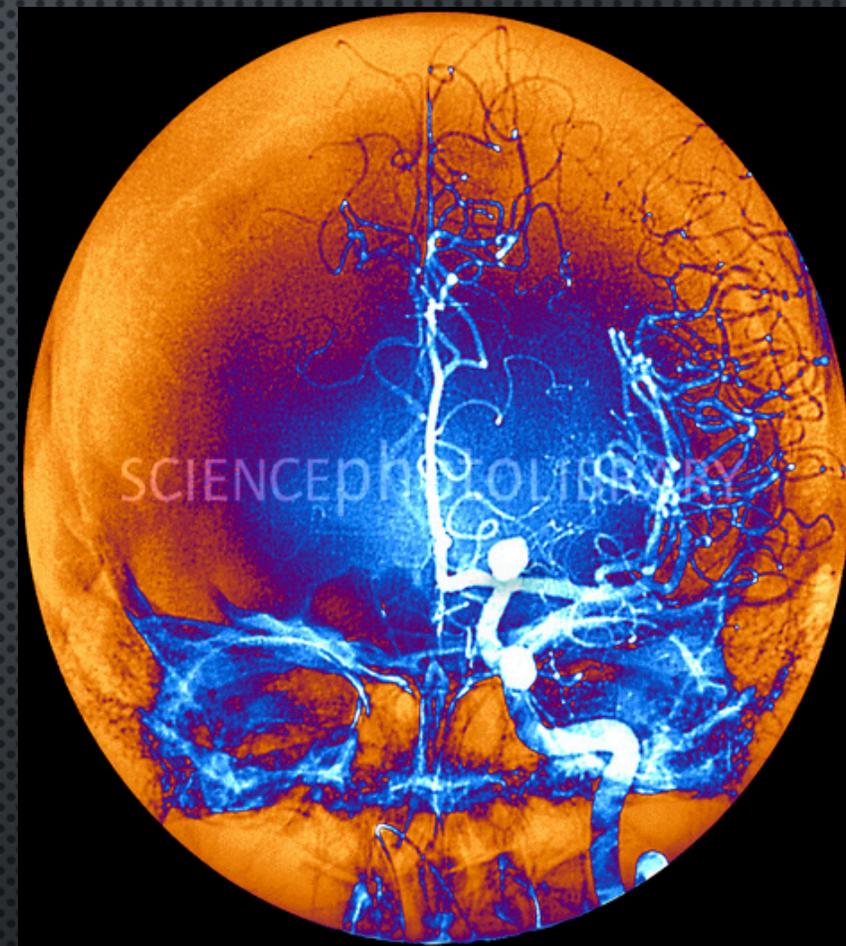
Device PIPELINE EMBOLIZATION DEVICE
Classification Name Intracranial Aneurysm Flow Diverter
Generic Name Intracranial Aneurysm Flow Diverter
Applicant
MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR
9775 Toledo Way
Irvine, CA 92618

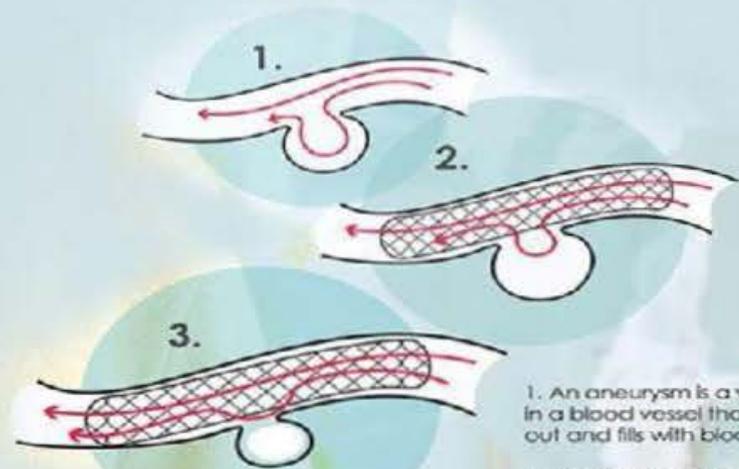
PMA Number P100018
Date Received 05/18/2010
Decision Date 04/06/2011

AN ANGIOGRAM OF LEFT ICA ANEURYSM.

A vascular image of
fireworks similar to my
experience.

ABSOLUTELY BREATHTAKING.



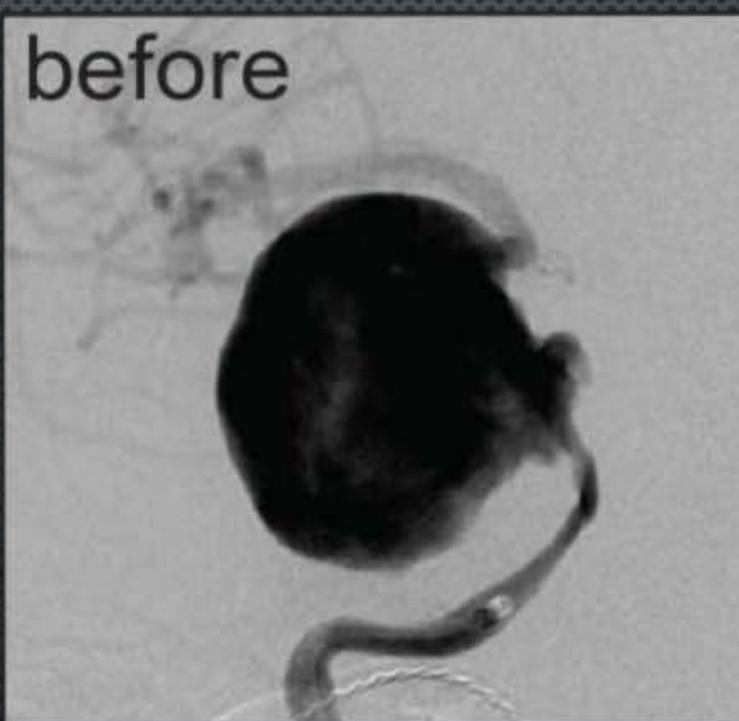


1. An aneurysm is a weak spot in a blood vessel that balloons out and fills with blood.

2. The Pipeline Embolization Device prevents blood flow into the aneurysm, allowing the blood vessel to heal.

3. Over time, the aneurysm will shrink on its own.

before



after



PED

ALSO CALLED A FLOW DIVERSION METHOD IN
A SHORT AMOUNT OF TIME COMPLETE
ABSORPTION CAN BE ACHIEVED.

AFTER CARE ISSUES/PATIENTS

- The average person may not have any knowledge of the area that their aneurysm is located.
- What is normal for them?
- What kind of healing can they expect?
- What will their quality of life be like?

AFTER SURGERY CAN BE JUST AS CONFUSING AS BEFORE, A PATIENT CAN BENEFIT FROM A FULL UNDERSTANDING ABOUT WHAT HAS HAPPENED.

THE THREE FACTORS RESPONSIBLE FOR MY RECOVERY

- The innovation of biomedical companies
- The patient care of the doctors and nurses who continually educate themselves to grow with technological advances.
- The FDA for being an institution dedicated to providing safe devices and medicines to patients in need.

There is a human element to my recovery. I used meditation, nutrition, exercise and my knowledge of muscle therapies as an alternative resource for my recovery. Alternative medicine should only be used in conjunction with modern health care.

FROM THE BOTTOM OF MY
HEART.

