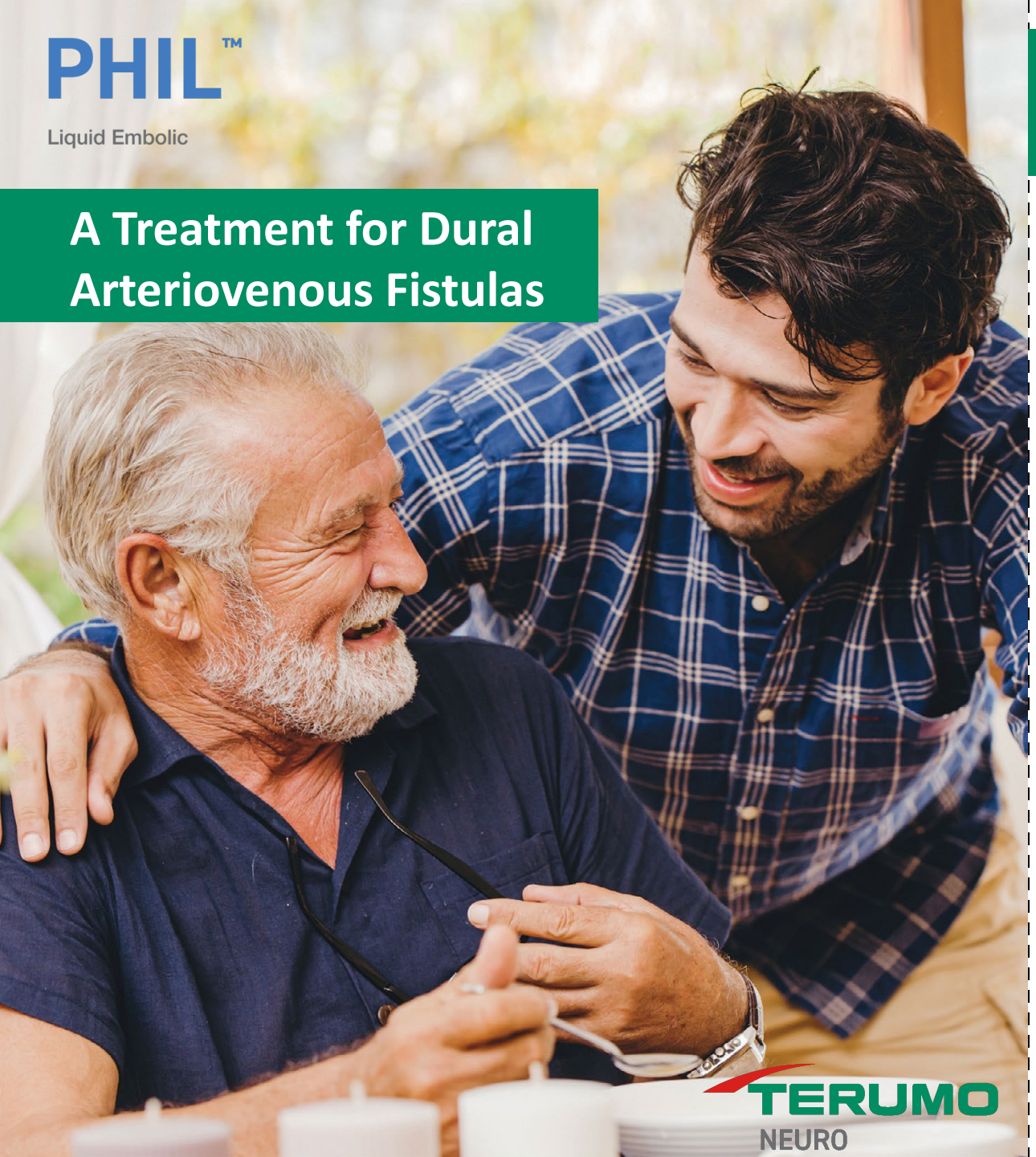
PHIL™

Liquid Embolic

A Treatment for Dural Arteriovenous Fistulas

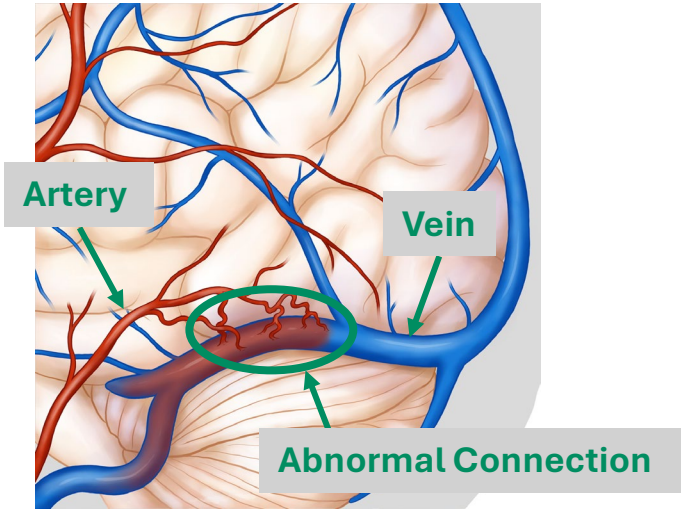


TERUMO NEURO

Understanding Dural Arteriovenous Fistulas (dAVF)

What is a dural arteriovenous fistula?

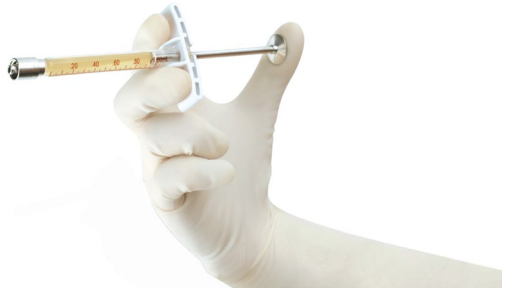
Dural arteriovenous fistulas (dAVF) are rare, abnormal connections between arteries and veins located in the protective layer surrounding the brain.



What are the clinical risks?

- Bleeding in the brain
- High blood pressure
- Ringing in the ears
- Cognitive or memory problems
- Headaches
- Seizures

What You Need to Know About PHIL™



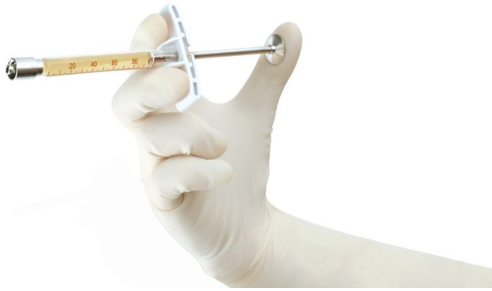
What is PHIL™?
PHIL™ Liquid Embolic is a special liquid used to block abnormal blood vessels. It's made of a soft material (a co-polymer) that is injected through very tiny tubes (catheters).

What condition does PHIL™ treat?
PHIL™ Liquid Embolic is used to treat dural arteriovenous fistulas (dAVF) by stopping the blood flow from the abnormal vessel.

The goal of the treatment is to stop the blood flow into the fistula to prevent rupture or rebleeding.

Other Treatment Options
- Observation (no treatment)
- Microsurgery
- Radiation therapy

What You Need to Know About PHIL™

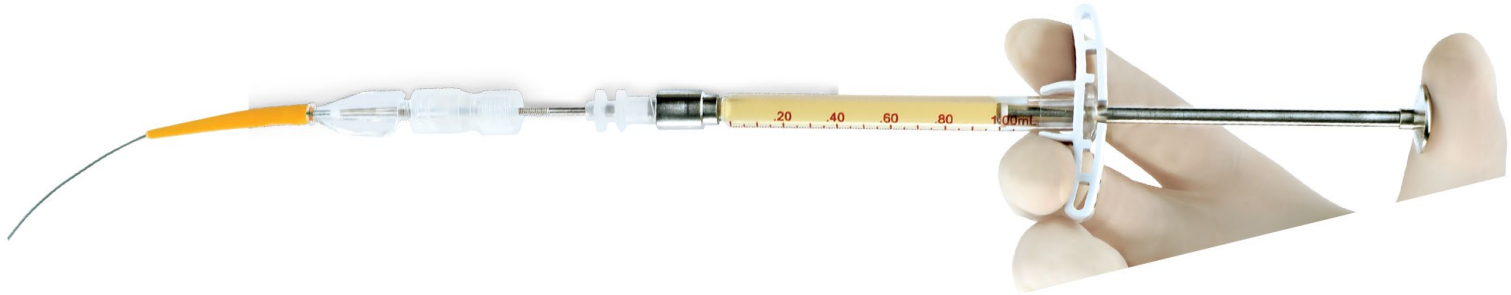


Why is PHIL™ a Humanitarian Use Device (HUD)?
This device treats rare conditions that affect fewer than 8,000 people each year in the United States.

What is a Humanitarian Device Exemption (HDE)?
The FDA granted PHIL™ Liquid Embolic Humanitarian Device Exemption (HDE) because it is intended for use in a small group of patients. An HDE allows a company to sell a device with less information on the effectiveness of the device due to the rarity of the disease.

Why did PHIL™ Receive FDA Approval?
The FDA approved this device because the device demonstrated safety and probable benefit, and there is no comparable FDA-approved device available for dAVF treatment.

PHIL™ Clinical Study Outcomes



Probable Benefit

Doctors were able to successfully block the target blood vessel in 96.7% of patients enrolled in the clinical study (60 out of 62 patients).

Safety

None (0%) of the study patients had a stroke on the treated side or died from a neurological cause within 30 days of the procedure. This means the treatment showed a very low risk of serious complications.

Adverse Events

Type of Adverse Event	Number of Patients
Device-related	
Nervous system disorders	1/62
Procedure-related	
Eye disorders	2/62
Injury, poisoning and procedural complications	10/62
Metabolism and nutrition disorders	1/62
Musculoskeletal and connective tissue disorders	1/62
Nervous system disorders	5/62
Respiratory, thoracic and mediastinal disorders	1/62

Benefits and Risks

Safety and probable benefit:

The FDA determined that the probable benefits of PHIL™ Liquid Embolic outweigh the risks. This decision is based on safety evidence and the assumption of a probable, but not proven, benefit.

What are the probable benefits?

- May reduce the risk of bleeding in the brain
- May improve blood flow to healthy brain tissue
- Can be used when other treatments (like microsurgery or radiosurgery) are not possible

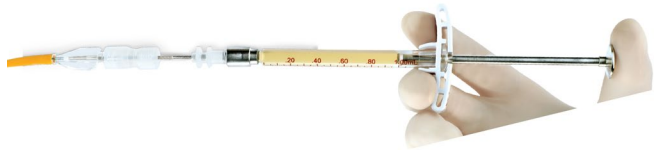
What are the possible risks?

- Bruising at puncture site
- Blood clot in a nearby blood vessel that was not intended to be treated
- Blockage of blood flow to the brain
- Bleeding inside the blood vessel
- Blood pressure changes causing bleeding in the brain
- Blockages or bleeding in the brain that may cause problems with brain function, stroke, or death
- Allergic reaction

Your doctor will explain which of these risks may apply to you.

For complete list of contraindications, warnings, precautions please refer to the Instructions for Use. You may obtain a copy from your treating physician or by contacting MicroVention, Inc. at +1 714 247 8000

What to Expect



Before the procedure:

- Your doctor will review your medical history and do imaging tests
- Your doctor may tell you to stop taking certain medications before your procedure
- You may need to stop eating or drinking for several hours beforehand

During the procedure:

- You will receive medication to help you relax or sleep
- The doctor will make a small incision in the leg or wrist, insert a small tube into a blood vessel, guide it to your brain, and deliver the device material

After the procedure:

- You may stay in the hospital overnight
- You may need follow up imaging
- Follow instructions from your doctor on which medications to take or stop taking

Call your doctor right away if you notice:

- Sudden severe headache
- Vision changes, weakness, or numbness
- Fever, chills, redness, or swelling at the site of injection

Questions? Talk to your doctor or contact MicroVention, Inc. at +1 714 247 8000 or www.terumoneuro.com

Humanitarian Device. Authorized by Federal law for use in the treatment of dural arteriovenous fistulas. The effectiveness of this device for this use has not been demonstrated.

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