Medtronic

Micro Therapeutics, Inc. d/b/a ev3
Neurovascular, a subsidiary of Medtronic.

Understanding Subacute and Chronic Subdural Hematoma (cSDH)

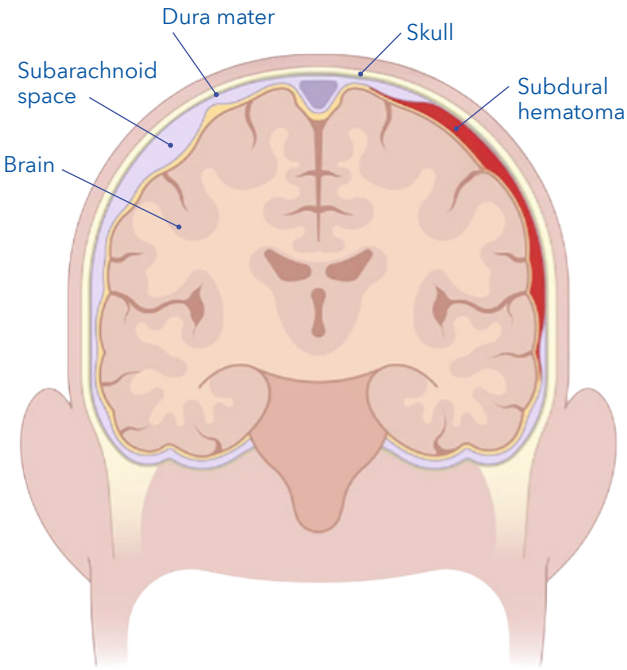
The Medtronic Onyx™ Liquid Embolic System (LES) can be used as an adjunct to surgery to treat symptomatic subacute or chronic subdural hematoma patients.

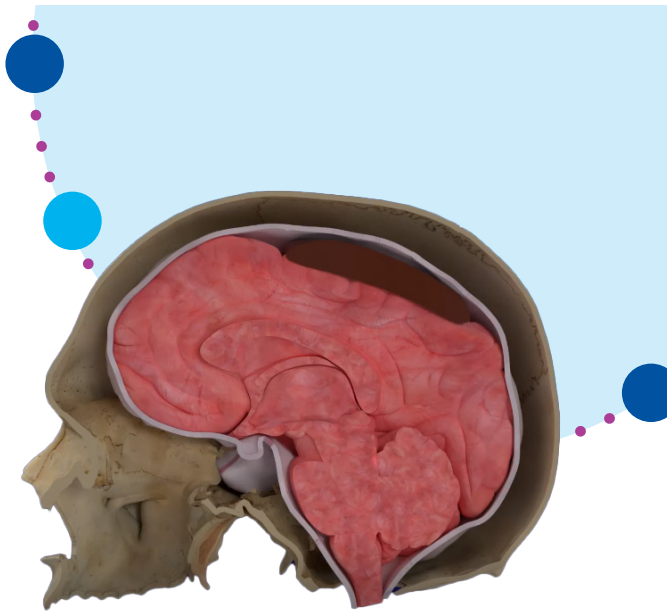
Talk to your doctor about your treatment options.

Subdural Hematoma

There are three types of subdural hematomas:

- **Acute:** less than 4 days; typically due to trauma or a tear in veins.
- **Subacute:** typically occurs 13-15 days post-trauma; transition phase from acute to subacute hematoma.
- **Chronic:** occurs 15+ days post-trauma; most common type of hematoma.





What is a chronic subdural hematoma (cSDH)?

A subdural hematoma is a collection of blood or blood clots between the external cover of the brain called the dura mater and the middle cover of the brain called the arachnoid mater. This is usually a result from some sort of trauma related event. Blood is supplied to this specific part of the brain via the Middle Meningeal Artery (MMA). The MMA is an artery that has multiple branches.

The most common subtype of subdural hematoma is chronic subdural hematoma (cSDH). Occurence is rising as the world's population ages. In patients aged 65 years and older, the occurrence rate is 58 out of 100,000 patients.[1]

cSDH is predicted to become the most common cranial neurosurgical condition among adults by 2030.[2,3]

If you have a subacute or chronic subdural hematoma, you may experience these symptoms:

- Headache
- Confusion
- Drowsiness
- Nausea
- Vomiting
- Slurred speech
- Loss of balance

Treatment options for cSDH

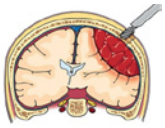
Monitoring

A cSDH can be monitored by your doctor, observing your individual hematoma symptoms.

Conventional surgery

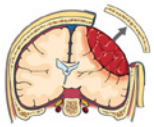
There are three types of surgical procedures for the treatment of cSDH. Each procedure carries its own risks and benefits. Your doctor will discuss these with you.

1 Burr hole irrigation



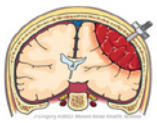
- Most common
- Burr hole(s) ~10mm diameter
- Flushed with saline
- Drain for 48 hours

2 Crainotomy



- Opening a bone flap of the skull (greater than 30mm)
- Flushing and removal of hematoma
- Replacing the bone flap

3 Twist drill trephination



- Small craniotomy using a hand drill
- Removal of the hematoma (like burr hole)
- Can be performed under local anesthesia

Embolization treatment + conventional surgery

Middle Meningeal Artery (MMA) Embolization using the Onyx™ 18, 34 Liquid Embolic System can be used in addition to surgery and is a minimally invasive treatment. MMA embolization can be done before or after surgery.

Talk to your doctor about your unique medical condition and the risks and benefits of any therapy.

What to expect before, during, and after the MMA embolization procedure

Before the MMA embolization procedure

Your doctor will review your medical history and recent brain scans with you. You may need routine lab tests to make sure it is safe to proceed. *Note: Your doctor may perform other tests before the surgical drainage of your hematoma.*

During the procedure

Your treatment team will determine whether you should have a mild sedative or general anesthesia for the MMA embolization procedure. You may be asked to not eat or drink for a few hours before the procedure. At the start of the procedure, your doctor will conduct imaging to see your blood vessels in real time using X-rays. The doctor will make a small puncture (cut) in the groin or in the wrist, and will insert a catheter (thin, flexible tube). This catheter will be guided up to the MMA. Contrast dye is injected through the catheter to help highlight the arteries. Throughout your procedure, your doctor will be viewing images of your head. These images help clearly locate the MMA and plan the safest path for treatment.

The doctor then injects Onyx™ 18 or 34 LES through the catheter into the main MMA and/or its branches. After a couple of minutes, the liquid solidifies with the intention to stop or reduce the blood flow to the cSDH. After the procedure, the catheter is removed and the small puncture site in the groin/wrist is closed. The procedure usually takes about 1 hour.

After the procedure

After the procedure, you will be monitored in the hospital. Your length of hospital stay will depend on several factors such as your age, other medical conditions, surgery type, and overall procedural outcomes for your surgery/MMA embolization. Before you leave the hospital, your doctor will explain what kinds of activities you can and cannot do, if you need to take any medications, and when you will need to see your doctor again. Follow-up imaging (like a CT scan of the head) will likely be scheduled over the next several weeks to check the progress of the hematoma. If you have concerns, discomfort, or changes in your health, be sure to let your doctor know right away.

If one part of the MMA is successfully blocked, treating that same spot again will not change how blood moves through it. However, the MMA has several parts, and your doctor may treat a different part later if needed.

If the Onyx™ LES device will remain implanted after the procedure, you will be given an MRI (Magnetic Resonance Imaging) card, which contains identifying information about the implanted device. Always carry your MRI card with you. Always tell your dentist and all doctors that you have an implanted device before you have any procedure. Contact your doctor if you notice any new or changing symptoms.

Potential benefits

- The Onyx™ LES embolization material is intended to stop or reduce blood flow in the MMA.
- Embolization of these blood vessels may help improve your symptoms, and reduce the recurrence of your subdural hematoma and the risk of repeated surgical interventions.

Potential Risks

The Onyx™ LES liquid could on rare occasions enter a wrong blood vessel and harden. This could lead to complications such as:

- Vision problems (caused by extra small arteries connections around the eye)
- Intracranial hemorrhage or hemorrhage in another vascular location (bleeding inside the skull or in another blood vessel).
- Ischemic events like TIA/stroke (a temporary or permanent loss of blood flow to the brain, which can cause a mini-stroke or stroke).

You may experience pain/soreness, a warm or burning feeling, headache, nausea, infection or other symptoms of illness or temporary discomfort during and after the procedure.

Other potential risks may include the following:

- Death
- Other complications at the puncture site such as:
  - Fistula (unusual connections between vessels)
  - Pseudo-aneurysm (small balloon-like bulges)
  - Pain
  - Inflammation (swelling)
  - Necrosis (death of tissue)
  - Granuloma (lumps of immune cells)
  - Pathological hand cold intolerance (feeling unusually cold in the hand)
  - The need for amputation (surgical removal of a limb)
  - Hematoma or hemorrhage (bleeding)
  - Hand dysfunction (trouble using the hand)
- Allergic reaction
- Arrhythmia (irregular heartbeat)

Potential Risks (continued)

- Heart Attack
- Catheter entrapment (stuck)
- Catheter rupture (breaking)
- Complications related to radiation exposure such as the below. These risks increase with longer or repeated procedures.
  - Alopecia (hair loss)
  - Burns ranging from skin reddening to ulcers
  - Cataracts
  - Delayed neoplasia (development of cancer later on).
- Other complications related to contrast dye, such as contrast neuropathy (kidney injury)
- Device migration and cast movement (movement of the Onyx™ LES device)
- Nerve damage or cranial nerve palsy (nerves that controls face, eyes, or other head functions stop working properly, causing weakness, numbness, or problems with movement)
- Neurological deficits/dysfunctions (complications of the brain and nervous system functioning)
- Pulmonary embolism (a blood clot traveling to the lungs and blocks blood flow)
- Seizures
- Thrombocytopenia (low blood platelet count)
- Thromboembolic events (blood clots forming or moving to other areas)
- Vascular complications (problems with blood vessels) such as:
  - Dissection (tearing of the inner layer of a vessel wall)
  - Perforation (a complete hole through all layers of the vessel)
  - Rupture (a complete burst/tear through all layers of the vessel)
  - Occlusion (blockages)
  - Vasospasm (narrowing)
  - Hypotension (low blood pressure)

Medtronic Clinical Data

Onyx™ LES was studied in the EMBOLISE trial. A total of 400 patients were included in the Surgery Cohort of the EMBOLISE trial. Of these, 197 patients were randomly assigned to the Test group (treated with surgery + MMA embolization with Onyx™ LES) and 203 patients were randomly assigned to the Control group (treated with surgery alone). Patients were examined at 14 days, 30 days, 90 days, and 180 days after the procedure.

The study showed that fewer patients in the Test group needed an additional surgical treatment (2nd surgery) compared to the Control group. Overall, the study results showed that the surgery + MMA embolization with Onyx™ LES procedure had an acceptable safety profile and was an effective treatment option for patients with cSDH. Treatment with Onyx™ LES in addition to surgery led to substantial clinical benefit with minimal additional harm/risk.

	Surgery + MMA embolization with Onyx™ LES Control	**Surgery Only Control** Test
Need for an additional surgical treatment *(2nd surgery)*	4 out of 100 patients	11 out of 100 patients
	4 out of 100 patients	12 out of 100 patients
Death from any cause	5 out of 100 patients	3 out of 100 patients
	7 out of 100 patients	4 out of 100 patients
Death from a neurological cause	5 out of 100 patients	2 out of 100 patients
	6 out of 100 patients	3 out of 100 patients
Stroke	2 out of 100 patients	2 out of 100 patients
	2 out of 100 patients	2 out of 100 patients
Embolization of the wrong vessel	No reported events*	Not applicable
	No reported events*	Not applicable
Movement of the Onyx™ LES device	No reported events*	Not applicable
	No reported events*	Not applicable

Within 90 days Within 180 days

* No events were reported, however, embolization of the wrong vessel or movement of the Onyx™ LES device remains a risk in an MMA embolization procedure.

For a complete list of events, refer to the device Instructions for Use.

Frequently asked questions

1 How did I develop a subdural hematoma?

As you age, brain tissue naturally shrinks, also known as atrophy. As the tissue shrinks, strain can be put on the blood vessels and even minor trauma can cause these blood vessels to tear.

2 How is a particular mode of treatment determined?

Your doctor will consider the risks and benefits associated with each treatment option and determine which one is right for your situation.

3 Will my subdural hematoma return?

The goal of blocking the middle meningeal artery (MMA) is to reduce the chance that the subdural hematoma will come back and to lower the need for additional surgeries.[4]

Talk to your doctor about your unique medical condition and the risks and benefits of this therapy.

1. El Rahal A, Beck J, Ahlborn P, et al. Incidence, therapy, and outcome in the management of chronic subdural hematoma in Switzerland: a populationbased multicenter cohort study. *Front Neurol*. 2023;14:1206996. Published 2023. Sep 14. doi:10.3389/fneur.2023.1206996
2. Balser D, Farooq S, Mehmood T, Reyes M, Samadani U. Actual and projected incidence rates for chronic subdural hematomas in United States Veterans Administration and civilian populations. *J Neurosurg.* 2015; 123: 1209-15.
3. Soleman J, Nocera F, Mariani L. The conservative and pharmacological management of chronic subdural haematoma. *Swiss Med Wkly.* 2017; 147:w14398.
4. Davies JM, Knopman J, Mokin M, et al. Adjunctive middlemeningeal artery embolization for subdural hematoma. *N EnglJ Med*. 2024;391:1890-900.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Indications For Use:
1. Onyx™ LES is indicated for Presurgical embolization of brain arteriovenous malformations (bAVMs).
2. Onyx™ LES is indicated for embolization of the middle meningeal artery (MMA) as an adjunct to surgery for the treatment of symptomatic subacute or chronic subdural hematoma (SDH).

Contraindications: The use of the Onyx™ LES is contraindicated when any of the following conditions exist:
- When optimal catheter placement is not possible.
- When provocative testing indicates intolerance to the occlusion procedure.
- When vasospasm stops blood flow.

Refer to the Instructions for Use for a full list of warnings, precautions, indications, and adverse events.

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