TRUFILL™ n-BCA Liquid Embolic System for Middle Meningeal Artery Embolization

Patient Information

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Glossary

Embolization – A medical procedure that stops blood from flowing to a specific blood vessel. A doctor sends tiny material through a thin tube (catheter) to plug the vessel.
Hematoma – A collection of blood that has leaked out of a blood vessel and pooled in the body. A subdural hematoma is like a deep bruise inside the head.
Liquid Embolic – A liquid that doctors inject into a blood vessel. Once inside, it changes into a solid plug that blocks blood flow.
n-BCA – Short for n-butyl cyanoacrylate – the chemical name for a type of liquid embolic that is used to block blood vessels.
Middle Meningeal Artery - A major artery that supplies blood to the dura, the outer covering of the brain. Doctors often call it the MMA for short.
Subdural – The space just under the dura, which is the tough outer covering of the brain. This is where a subdural hematoma pools.

Subdural Hematomas – What are they?

Subdural hematomas (SDHs) occur when small blood vessels leak between your brain and the outermost covering of your brain. The leaking blood forms a mass called a hematoma that presses on the brain tissue. This can cause many symptoms, such as headache, seizures, loss of memory, or confusion. If the hematoma develops slowly or keeps coming back, small blood vessels fed by the middle meningeal artery (MMA) – an artery that supplies the outermost covering of the brain – can cause the blood collection to grow or persist. Some SDHs can occur fast, showing symptoms very quickly (within 72 hours) and requiring surgery right away. Some SDHs may develop more slowly with symptoms that may not appear for weeks or months. Sometimes, SDHs cause few or no symptoms and are small enough that they do not need treatment.

What are your treatment options?

For small, symptom-free SDHs, doctors may just monitor you with scans and checkups. Some symptoms can be treated with medication while watching the hematoma. For large or dangerous hematomas, surgeons can drain the blood and relieve the pressure by making one or more holes in the skull. Discuss your treatment options with your doctor to decide what is best for you.

Middle Meningeal Artery Embolization with Surgery

In some cases, a SDH will come back again even after surgery. Doctors can use a medical device called a liquid embolic device, which is a liquid designed to be injected into the MMA where it will harden in the vessel to block the blood flow through the artery. Studies have shown that this procedure, when done in addition to surgery, can stop more blood from collecting and lower the chances of the SDH returning. One product used for this is called TRUFILL n-BCA, a type of liquid embolic material.

TRUFILL n-BCA Liquid Embolic System Device Description

The TRUFILL n-BCA Liquid Embolic System is a medical device used by doctors to block or decrease blood flow to treat SDH.

Device Materials

TRUFILL n-BCA Liquid Embolic System is made up of three parts:

- n-BCA: A liquid that hardens in the MMA to reduce blood flow. Contains: n-Butyl Cyanoacrylate (n-BCA) 99.0% n-Butyl Cyanoacetate; Sulfur Dioxide; Butylated Hydroxyanisole

Your doctor will mix it with: Ethiodized Oil: Used to control the n-BCA hardening rate. Contains: Ethyl esters of iodized fatty acids of poppy seed oil.

Your doctor may also mix it with:

- Tantalum Powder: A finely ground, dark gray metal. This allows the device to be seen on X-ray. Contains: Tantalum

Your doctor will use a thin flexible hollow tube (catheter) to inject the TRUFILL n-BCA mixture into the MMA where it will harden to block blood flow.

Tell your doctor before surgery about any allergies you have to cyanoacrylates, ethiodized oil or iodine.

What to expect before, during, and after the procedure

Before your procedure, expect the doctor to visit you, explain exactly what will be done, and answer any questions you have.

On the day of the procedure, depending on the hospital practice, you will either be put under general anesthesia or given local anesthesia. After that, your doctor will make a small incision in your leg or wrist and guide the catheter through the incision and through your arteries until it reaches your brain. When the catheter reaches the MMA, your doctor will inject through the catheter, a small amount of the TRUFILL n-BCA Liquid Embolic that she or he mixed. The TRUFILL n-BCA will go through the catheter and into your artery to block the blood flow in the vessel. The TRUFILL n-BCA Liquid Embolic will change from

liquid to solid and stay in place in the blood vessel in your brain. Your doctor will then remove the catheter and close the incision in your leg or wrist.

After the procedure, you will go to a hospital room where medical staff will monitor you. You will need to remain flat in bed for several hours. Your doctor will limit your activities for the next few days and will tell you when you can return to normal activities. Your doctor may give you instructions on changes to medications. It is important that you follow your doctor's instructions for taking medications.

Potential Risks

All neurological procedures have risks. Many of the risks with TRUFILL n-BCA Liquid Embolic System are the same as with many neurological procedures.

Potential risks associated with embolization procedures can occur at any time during or after the procedure. These include, but are not limited to:

- Allergic or hypersensitivity reaction to x-ray dye, medications used during the procedure or the materials used in TRUFILL n-BCA
- Bleeding, bruising, pain or damage to the blood vessel in your leg or wrist where the doctor inserts the catheter into your body
- Bleeding inside the head or in other parts of your body
- Blockage of blood vessel due to an air bubble or blood clots Blockage of the small hollow tube (catheter) used to inject TRUFILL n-BCA, which may lead to prolonged surgery time and may prevent injection of TRUFILL n-BCA
- Catheter glued/stuck inside vessel
- Changes in the condition of your brain (including brain swelling), nerves, and/or brain messages to your body, which could permanently affect your behavior, function and/or sensation
- Damage to brain tissues or heart due to restriction in blood supply
- Death
- Early polymerization (meaning, the liquid embolic hardens before it should)
- Blocked catheter preventing injection of the TRUFILL n-BCA
- Headache
- Heart attack (myocardial infarction)
- Infection/inflammation
- Kidney failure
- Late polymerization (meaning, the liquid embolic hardens later than expected)
- Nausea or vomiting

- Passage of TRUFILL n-BCA into unintended vessels next to the target treatment area which may cause blindness, facial pain, burning, and/or itching, facial weakness, deafness, or stroke.
- Pooling of blood outside the blood vessels
- Seizure
- Stroke (bleeding or a clot in the blood vessels of the brain that interrupts normal blood flow, causing death of brain cells)
- Sudden narrowing or spasm of a blood vessel (vasospasm)
- Tear or injury to a blood vessel
- Worsening or increase in size of the SDH causing symptoms or requiring reoperation following the initial treatment
- Risks from x-ray imaging including hair loss, burns, cataracts, and delayed cancer

Potential Benefits

Studies have shown that embolization of the MMA when done with surgery, will stop the bleeding, reducing the chance of further brain surgery.

Clinical trial information

A study called the MEMBRANE study demonstrated that TRUFILL n-BCA is safe and effective when used in addition to surgery to treat SDH to lower the chance of problems that may need additional surgery. The study included a total of 376 patients with SDH. About half of the patients had their MMA blocked using the TRUFILL n-BCA in addition to surgery or medicine to treat the SDH. The other half of patients only received surgery or medicine (without TRUFILL n-BCA). The study showed that the TRUFILL n-BCA, when used with surgery, reduced the possibility of patients requiring additional surgical procedures due to the SDH coming back in comparison to the control patients who did not receive TRUFILL n-BCA. The study also showed that the device and procedure are reasonably safe. The table below shows common complications that patients who had surgery with or without TRUFILL n-BCA embolization in the study experienced.

	TRUFILL n-BCA + Surgery	Surgery alone
Need for additional	2 out of 100 patients	6 out of 100 patients

surgical procedure		
Death	1 out of 100 patients	9 out of 100 patients
Death from neurological cause	1 out of 100 patients	3 out of 100 patients
New onset of Seizure	7 out of 100 patients	4 out of 100 patients
Stroke	1 out of 100 patients	2 out of 100 patients
Myocardial infarction	2 out of 100 patients	2 out of 100 patients
Thromboembolic complications	2 out of 100 patients	1 out of 100 patients
Note: This table is based on the number of subjects that received their assigned treatment without any crossover. Note: Death from neurological cause, new onset of seizure, stroke, myocardial infarction, and thromboembolic complications were adjudicated by the Clinical Events Committee (CEC).		