



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Craniotomy for Cranioplasty

This information is given to you so that you can make an informed decision about having a **craniotomy for cranioplasty**.

Reason and Purpose of this Procedure:

A craniotomy is an operation where an opening is made in the skull, or cranium. The goal of a craniotomy for cranioplasty, is to:

- Replace the bone plate.
- Place a new synthetic bone plate.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Recreate the shape and protection of the skull.
- Your doctor can discuss further benefits with you. This will depend on your diagnosis

General Risks of Procedures:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVT or deep vein thromboses. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke.
- Bleeding may occur. If excessive you may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks of this Procedure:

- **Brain injury.** This procedure could cause injury to the surrounding brain.
- **Death.** Death may occur during or soon after surgery.
- **Failure of the procedure.** Your condition may not improve.
- **Functional loss.** You may have problems chewing after surgery. You may have problems with strength, sensation, speech and language, memory, hearing or vision after surgery.
- **Hemorrhage.** Some bleeding in the brain and around the area of the cranioplasty following surgery is common and expected. Too much bleeding may require additional surgery.
- **Hydrocephalus.** The normal flow of spinal fluid around the brain may change. This may need more treatment, including surgery or placement of a drain
- **Increased pain.** Pain or other symptoms may get worse after this procedure. You may have a headache for up to a month after surgery and occasionally for a longer period of time
- **Infection.** Infection may occur in the wound, either near the surface or deep within the tissues. This could include the bone. You may need antibiotics or further treatment.
- **Neurologic decline.** You may have weakness, numbness, and speech and memory problems after surgery. This could be from hemorrhage (bleeding) or cerebral edema (buildup of fluid that results in swelling and pressure on the brain).

- **Seizure activity.** You may develop seizures.
- **Spinal fluid leakage.** A spinal fluid leakage may cause a spinal headache or need more surgery.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation. Smoking has also been shown to slow down or stop the bone fusion.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Diabetes or Immune System Compromise:

The risk of infection, slow wound healing and slow bone healing are increased in:

- Diabetes
- Chemotherapy or radiation therapy
- AIDS
- Steroid use

Risks Specific to You:

Alternative Treatments:

Other choices:

- Wear a helmet.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- You may choose the alternative treatments listed above.
- Your neurological function may decrease.

General Information

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.



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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
 - I understand its contents.
 - I have had time to speak with the doctor. My questions have been answered.
 - I want to have this procedure: **Craniotomy for Cranioplasty** _____
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- I understand that my doctor may ask a partner to do the procedure.
 - I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian/POA Healthcare

Interpreter’s Statement: I have interpreted the doctor’s explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter’s Signature: _____ ID #: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____

(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____