BRONSON	Affix Patient Label
	Patient Name: Date of Birth:

This information is given to you so that you can make an informed decision about this treatment.

Reason and Purpose of the Surgery

This device is used to treat aneurysms in the brain. An aneurysm is a bulge or ballooning in the wall of an artery.

The Food and Drug Administration (FDA) approved this stent as a Humanitarian Use Device (HUD). A HUD is used where there is no other device available for treatment.
The Neuroform Microdelivery Stent System is designed to help stop the rupture of the aneurysm. The stent system will be placed under general anesthesia.

The stent is a small wire mesh tube. Small metal coils are passed through the stent into the aneurysm. The coils block blood from going to the aneurysm. This may help to keep the aneurysm from rupturing.

Benefits of this surgery:
You might receive the following benefit. Your doctor cannot promise you will receive any benefit. Only you can decide if the benefit is worth the risk.

- Placing a stent in the vessel may make it easier for your doctor to treat your aneurysm with coils.

General Risks of Surgery:

- Small areas of the lungs may collapse. This would increase the risk of infection. They may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. 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 may occur.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases death may occur. The anesthesiologist will discuss this with you.

Risks of Surgery:
No proAcedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor can't expect.

Risks of this Surgery:

- A mass of clotted blood or a hematoma, which may need surgery.
- Pain that may require medications.
- Infection at the access site that may be painful and need antibiotics.
- The aneurysm may rupture. This could result in stroke or death.
- Blood clots, air bubbles, or broken pieces of plaque that travel through the blood vessels. This could result in a stroke.
- Bleeding in the brain that may cause stroke.
- Less blood flow to the leg on the side of the groin puncture. This may cause pain.
- Less movement of the leg that may need surgery.
- Bleeding after the procedure that may require IV fluids or a blood transfusion.
- The stent could be blocked which may cause bleeding or stroke.

- The stent could move which may cause bleeding or stroke.
- Blood will not clot which may require blood products.
- Kidneys will not function and you may require hemodialysis.
- Death may occur.

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.

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 specific to you:

_____

_____

Alternative Treatments:
- Do nothing. You can decide not to have the procedure.
- There are no other stents for treatment.

If you choose not to have this treatment:
- The aneurysm may rupture.

General Information:
- During this procedure, the doctor may need to perform more or different procedures than I agreed to.
- During this procedure the doctor may need to do more testing 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.

This facility may release my medical record to:
- FDA (Food and Drug Administration)
- OHRP (Office for Human Research Protections) or
- OCR (Office of Civil Rights)

Medical Implants/Explants
I agree to the release of my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me, if needed.

BRONSON	Affix Patient Label
	Patient Name: Date of Birth:

My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.

I have been given the Neuroform Stent Information booklet and have had time to read it. My questions about the booklet have been answered. Patient Initials:_____ Time:_____

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. I have had my questions answered.
- I received a copy of the patient booklet on this stent. I have reviewed the information. My questions have been answered.
- I want to have this procedure: **Neuroform Microdelivery Stent**
- I understand that other doctors, including medical residents, will help with surgery. 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 surgery. IF so, please obtain consent for blood/product.

Patient Signature_____ Date:_____ Time:_____
Relationship: □Patient □Closest relative (relationship)_____ □Guardian

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.
Interpreter's signature:_____ 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: _____ (patient signature**)**

Validated/Witness:_____Date:_____Time:_____