



**IRB#:** \_\_\_\_\_

**Humanitarian Use Device (HUD) CONSENT FORM**

Physician Name: \_\_\_\_\_ Dept: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

E Mail: \_\_\_\_\_

Name of device: \_\_\_\_\_

Your consent is requested to use the above-named product in:

- Your care
- The care of your child
- The care of someone for whom you are the legal representative.

Patient at the following facility (NYUMC or its affiliates):

- The NYU Hospitals Center (Tisch Hospital; the Rusk Institute of Rehabilitation Medicine);
- Bellevue Hospital Center;
- Hospital for Joint Diseases Orthopedic Institute;
- NYU College of Dentistry;
- The New York Campus of the Veteran’s Affairs New York Harbor Healthcare System.

1 of 4                      Subject’s Initials: \_\_\_\_\_ Date: \_\_\_\_\_

**(IRB Official Use Only)**

*This Consent Document is approved for use by the New York University’s Institutional Review Board (IRB).  
Only the IRB-stamped approved form may be used.*

Approved: From: \_\_\_\_\_ To: \_\_\_\_\_

The study expiration date applies for this form



This product has been approved by the Food and Drug Administration as a Humanitarian Use Device for the treatment of **[insert indication]**. The safety of this device has not been evaluated or demonstrated through research testing. The use of this device is not for research/testing evaluation purposes. If you agree to the use of this product, this is what we will do: explain in detail what will be done during the implantation of this device and after. Include any return visits after surgery.

A humanitarian use device (HUD) is defined by the Federal Food, Drug and Cosmetic Act as a device intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

You are being asked to give your consent for use of an HUD by your physician because you have **(condition)** and you have not improved with available treatments. Your participation is voluntary. The (device/product) use will be under the direction of \_\_\_\_\_, in the department of \_\_\_\_\_. There may be other physicians and professional staff persons who may assist (him/her) in the use of this (device/product)

This is not a research study.

**Purpose**

Description of the purpose, use and indications for the device

**Description of Procedures**

Description of the procedures involved in the use of the device

**Costs:**

You or your insurance company **will/will not[choose one or the other]** be charged or held responsible for the costs of your care. Your individual insurance or government health insurance program may not cover certain services, items or procedures. You may want to discuss this with your insurance carrier in advance. You will be responsible for any co-payments and/or deductibles for services rendered"

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**Risks:**

Potential risks are: [This information should be described according to frequency and anticipation of each type of risk. Those most likely to expect should be identified as such and listed first. Those least likely to be expected should be identified as such as listed next. Risks include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience, or breach of confidentiality.]

There may be other significant or even life-threatening risks that we do not know about.

***Risks to Pregnant Women***

Describe risks, precautions.

**Benefits:**

The possible benefits are:

**Alternatives:**

If you do not consent to the use of this product, the alternatives are:

This device use is regulated by the Food and Drug Administration (FDA) and other regulatory agencies, the sponsor of the study and NYUSM staff working under the direction of the IRB may inspect records identifying you as having received this device for your condition.: The facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The medical record is maintained by your treating physician or hospital, as applicable, and will be subject to New York State and federal laws and regulations concerning confidentiality of medical records. In addition, if you are a Bellevue Hospital Center patient, this form and your study information will be available to Bellevue Hospital administration and their auditors.

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Subject's Initials: \_\_\_\_\_ Date: \_\_\_\_\_

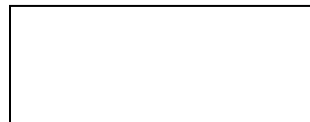
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This Hospital and any government agency or sponsor providing the drug will not provide special services, free care, or compensation for any injuries resulting from the use of this device. Treatment for such injuries will be provided under the same financial arrangements as those under which treatment is usually provided.

If you have any questions about the device, please contact Dr. \_\_\_\_\_ at \_\_\_\_\_.

If you consent to this treatment and later believe that you have suffered any injury as a result of this emergency care, you may contact Dr. \_\_\_\_\_ at \_\_\_\_\_.

If you have a complaint that has not been resolved or you have questions regarding your rights regarding the use of this device in your medical care, please contact the NYU Langone Medical Center Institutional Review Board at 212-263-4110. They can review the matter with you, identify other resources that may be available to you, and provide information as to how to proceed.

This device use will not be claimed as research and you will not be considered a research subject. Any data regarding your treatment will not be included in any report of a research activity.

I have read the above explanations and have received answers to any questions I have about treatment with this product. I consent voluntarily to the use of this device.

\_\_\_\_\_  
Print Name of Participant  
or Legal Representative\*

\_\_\_\_\_/\_\_\_\_\_  
Signature of Participant / Date  
or Legal Representative\*

\_\_\_\_\_  
Print Name of Person  
Obtaining Consent

\_\_\_\_\_/\_\_\_\_\_  
Signature of Person / Date  
Obtaining Consent

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