

**UNIVERSITY OF WASHINGTON MEDICAL CENTER
NEW IMPLANT & INVESTIGATIONAL DEVICE REQUEST**

Background: The purpose of this new formal process for devices (implantable and investigational non-implantable) is to assure compliance with billing regulations. Improper billing can lead to organizational as well as individual liability. Financial reimbursement may be hindered if the process is not followed. This would include not only the device, but also the physician's fees and entire inpatient and outpatient services.

New Process: All UWMC physicians desiring to bring in a device (implantable and investigational non-implantable) that is not currently in inventory must first obtain authorization from the Implant & Investigational Device Committee. Investigational Implant Packet Review is managed through Lisa Westlund-Compliance Officer. 11/2009

Financial reimbursement to the vendor will occur only if the implant has been formally approved by the Committee. For surgical implants, the purchase order requisition must also be submitted by the Implant Room within the O.R. for the vendor to receive reimbursement. All Surgical Services implants are ordered by the implant room pending IIDC approval and implant planning document from MD sent one week in advance of procedure.

Complete the information and save a copy to file. Send the completed form to Cathy Robertson and service line RN3, Surgical Services OR Business Manager/Finance, Box 356118 or FAX to 206-598-4419. Phone: 206-598-6538.

Financial Interests Disclosure

This disclosure is intended to ensure that potential financial conflicts of interest involving devices are recognized, disclosed, and managed. For purposes of this form, "Financial Interests" means any direct or indirect beneficial interest in the company manufacturing or selling the device or in the device itself. It includes the requesting physician but also the requesting physician's spouse and children.

Financial Interests (within the past 5 years, currently or expected) **Yes** **No**

Salary or other monetary recognition for services? (e.g. consulting fees, honoraria, travel and accommodations) If yes, disclose amount and extent.

Equity interests? (e.g. stocks, stock options, or other ownership interests)

Intellectual property rights? (e.g. patents, copyrights, and/or royalties

from those rights)

If yes to any of the above Amount:

Other financial interests that could benefit or be perceived to benefit from the acquisition of the device?

Is the acquisition of the device expected to lead to financial benefit or perceived benefit to the University of Washington or any component of the University of Washington?

Medicare Billing Eligibility & Device Classification

Under current Medicare rules, no bill may be submitted for any "services related to the use of" a "Category A" device. Medicare guidelines specify that a bill may be submitted for services related to use of a "Category B" device, but only if specific information has been previously submitted to Medicare and if Medicare has provided a billing authorization code. UWMC will forward the information to Medicare and will work with the agency to expedite receipt of the billing authorization code. **(This form gathers this required information.)** Other insurers may also adopt these guidelines. The FDA will have informed the manufacturer of the device's categorization; the manufacturer should have passed this information on to the Principal Investigator.

PLEASE PRINT ALL RESPONSES:

Attending Physician:

Department/Division:

E-mail Address: Phone: Pager:

Generic Name of Implant:

Brand Name/Manufacturer:

Vendor Name if known:

Intended Clinical Use:

Placement Frequency:

Date of Earliest Desired Use:

How is this device similar to and/or different from other comparable products on the market ? (e.g. similarity to 1st generation device that this evolved from?)

What devices, if any will this replace that is currently in inventory?

Do you want to bring in the device for a trial period or to immediately add to inventory?

For implants where contracts are currently in place a sole source justification will need to be made and further financial analysis are pending prior to implant committee review.

Are you willing to champion this device with your colleagues who use similar clinically equivalent implants?

1) For all devices, **attach a copy of the FDA Letter** (obtain from the manufacturer) concerning this device's classification. This will state whether the device:

- a) Has FDA pre-market approval for commercial marketing
- b) Has a FDA declaration of substantial equivalence (a 510 (k) clearance)
- c) Is a Class I, II, or III
- d) Is subject to an FDA-approved Investigational Device Exemption (IDE) and identifies the actual IDE number
- e) Is Category A or Category B

2) Is this device being used for the indication approved by the FDA? yes no

Explanation:

3) Is this a device that is custom-made for the use by a particular physician or patient?

yes no Explanation:

If the device is in a Clinical Trial, proceed to the next set of questions: [The application goes to Lisa Westlund for investigational devices with a copy to cathyl@.](#) All approvals will be made outside the implant committee.

4) What is the Human Subjects Approval Number: Approval Date:

5) Who is the Principal Investigator?

6) **Attach a description** of all actions taken to conform to any applicable FDA special controls (*FDA letter will state the need to conform to any special controls. Examples are performance standards and post-market surveillance. Please define what controls you have put in place.*)

7) **Attach an explanation** of the protocol for obtaining informed consent. (*Refer to and attach section III D #6 of the Human Subjects Application.*)

8) **Attach a copy of the Final Informed Consent** form as approved by the Human Subjects Review Committee.

Physician Signature: Date:

Please also forward copies to Cathy Robertson of any of the following: device adverse events; sponsor safety reports; substantive changes in approved Consent forms and manufacturer letters changing the device FDA categorization.

For Committee Use Only: Date Received by Manager, O.R. Support Services:	
Date Received by Committee Members:	
Dates of any Committee Meetings regarding this implant:	
Dates of any Appeal meetings regarding this implant:	
Final Committee Decision:	Approved Not Approved
Date of Final Decision:	
Comments:	
UWMC Billing Code:	
Date Billing Information sent to Blue Cross:	By Whom?
Date Blue Cross Authorized billing:	(for Category B devices only) Blue Cross Letter Attached? Yes No