

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

Background: The primary purpose of this 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.

Effective Date: 8/1/97 for surgical devices. All other devices, 6/98.

New Process: All UWMC physicians desiring to bring in a device (implantable and/or investigational non-implantable) that is not currently in inventory must first obtain authorization from the Implant & Investigational Device Committee.

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 or UWMC Materials Management. for the vendor to receive reimbursement.

Forward this completed request to Bill Anton, O.R. Business Director, Box 356118 or FAX to 000-0000, e-mail _____, Phone: 000-0000

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 surgeon but also the requesting surgeon's spouse and children.

<u>Financial Interests (within the past 5 years, currently or expected)</u>	<u>Yes</u>	<u>No</u>
Salary or other monetary recognition for services? (e.g. consulting fees, honoraria, travel and accommodations)	_____	_____
Equity interests? (e.g. stocks, stock options, or other ownership interests)	_____	_____
Intellectual property rights? (e.g. patents, copyrights, and/or royalties from those rights)	_____	_____
Other financial interests that could benefit or be perceived to benefit from the acquisition of the device?	_____	_____

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: _____

Intended Clinical Use: _____

Placement Frequency: _____

Date of Earliest Desired Use: _____

How is this device unique from other comparable products on the market ? _____

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

Trial period or to immediately add to inventory? _____

Please provide the following information for ALL Devices:

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:

- 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 the OR Business Director 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