



University of Washington Medical Center

New Service/Device Information Worksheet

(Vendor Response on Service/Device Review)

Service / Device to be reviewed:

Date Submitted:

Vendor response instructions: The UWMC New Service / Device Information Worksheet (NS/DIW) is used to introduce a new service/device into the UWMC system. UWMC is a member of VHA-Novation; in addition we do our own local contracting for service/products not covered within these agreements or are low volume use products. Please respond by accurately completing all information. The shaded blocks allow you to include as much information as necessary. All request considered need a UWMC manager or physician sponsor. Worksheets will be reviewed only if all information is completed.

Please return the completed NS/DIW via e-mail to the UWMC Manager/RN3 sponsor with a copy sent to cathy1@u.washington.edu and/or marburyK@u.washington.edu . The Vendor Instruction Sheet is for your reference.

INTERNAL USE ONLY

Date Completed NS/DIW Received:

PESC/IIDC Support / Liaison:

Date Approved:

Date sent to Business Finance Manager:

Date sent to Business Operations

Date sent to Purchasing:

Requestor:



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NEW SERVICE / DEVICE INFORMATION WORKSHEET CRITERIA

University of Washington Medical Center (UWMC) uses three criteria when reviewing any new service or device. If your service or device meets all or one of these criteria, the service or device will be reviewed; the criteria are:

1. If the device is designed for patient care, the device must be clinically effective / beneficial-producing a superior outcome better than current device demonstrated by proven clinical trials. If not for patient care, the product must have documented quality standards.
2. There must be a compelling reason (i.e. substantiated Clinician preferences) for UWMC to either add/change the service/device or to begin using the new service/device you are introducing.
3. The device must be cost competitive.

The following information must be completed when introducing new services or products: UWMC (including Roosevelt campus) and Harborview (HMC) are an IDN and share pricing information;

VENDOR INFORMATION

Product/Device Description:

Manufacturer:

Representative Name:

Telephone Number:

Pager:

E-mail:

UWMC Campuses: Main Campus Surgery Pavilion Roosevelt

Novation Contact? Yes No Contract ID Number:

WA State Contract? Yes No Contract ID Number:



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BUSINESS RELATIONSHIP DISCLOSURE

Do you, or the company that you represent, currently have or seek to initiate any business or financial relationship with any individual employee or physician with staff privileges at UWMC (including Grants; Research)? Please verify your response to this query with the appropriate personnel in the company corporate office.

YES NO

If YES, please describe the relationship:

Vendor warrants and represents that Vendor and its employees and agents are not suspended or debarred from participation in any Federal or State governmental program.

YES NO

If NO, please explain:

UTILIZATION ASSESSMENT

1. Define the purpose/function of the service/device.

Response:

2. Is this an introduction of a new device? Yes No

If yes, what opportunity/value does this service/device offer UWMC, clinical care providers and/or the patient?

Response:

3. Is this a replacement of an existing device? Yes No

If yes, please explain what device will be replaced. Please give the product name, manufacturer, catalog number, and the UWMC PMM number.

Response:

4. If the device fails to gain favorable status at the end of an evaluation period; can the remainder of the product be returned to the company for a full refund? Yes No

If the answer is yes, will there be a stocking fee for the returned product?

Yes No



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5. What department/clinical area will use the service/device by campus?

Please be specific; i.e., cardiology, oncology, adult, pediatrics, neonatal, etc.
Response:

7. Does this device require a Material Safety Data Sheet (MSDS)

Yes No

If yes, please provide a copy of the MSDS.

8. Can this device be reprocessed? Yes No

9. If not, are there special considerations regarding the disposal of this device? Please explain. Response:

10. Will this device be used in conjunction with a new service/procedure?

Yes No

If yes, please explain:

11. Is there any other equipment and/or accessories involved with the use of this product? Yes No

If yes, please explain and include an itemized list including the cost and catalog numbers of the accessories/equipment.

12. Is this device used as a "kit"? Yes No

If yes, you must list all components, including device name, catalog number, and cost of each component included in the kit. Itemize all kits, even if they cannot be purchased individually.

13. Is this device considered reusable equipment? Yes No

14. If yes, how many sterilization pans are required to use for this system and how much does each pan weigh?

15. Is this device considered a bulk supply where utilization would not be easily tracked to a specific patient? Yes No

16. Can this device be purchased through a distributor? Yes No



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SURGICAL / PROCEDURAL DEVICES

1. Does the device have a FDA investigational device exemption (IDE)?
Yes No

If yes, what is the reimbursement category?

2. Has the device ever been granted a humanitarian device exemption from the FDA? Yes No
3. Is the device FDA approved? Yes No

If yes, what is the FDA approval number? (You must **provide** a scanned copy of the FDA approval document as an attachment)

4. Does this device require device tracking per the FDA "Medical Device Tracking Act? Yes No
5. Is this device intended for implantation, transplantation, infusion, or transfer into human recipients (including investigational products) by any and all means including but not limited to surgical? Yes No

A. Does this implant contain any **human cells**, tissues, cellular and/or tissue based products of natural origin, or any and all bioengineering process? (Some examples of HCT/P's include skin, tendons, bone, heart valves, corneas, hematopoietic stem cells, manipulated autologous chondrocytes, and epithelial cells on a synthetic matrix, genetically modified human/animal tissue, semen or other reproductive tissue). Be specific in your response.

B. Does this implant contain any **animal cells**, tissues, cellular and/or tissue based products of natural origin or any and all bioengineering processes? Please identify the species of origin and the bioengineering processes (if applicable). Be specific.

C. Was this device derived from another tissue processing facility other than the one you represent? If yes, identify:

D. Do you have the ability to trace, locate, quarantine and recall materials, consumables and product found at any stage not to meet quality requirements essential to patient safety?



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- E. As a distributor for this device, do you operate a quality assurance program to include risk assessment and management?
- F. Please include a copy of the testing techniques, method of procurement, staff competencies, processing environment, reagent and equipment used, packaging materials, labels and process intermediates.
- G. How will this device arrive (FedEx; UPS..ect)?
- H. Does the container or shipping crate contain cold packs, dry ice or liquid nitrogen?
- I. At what temperature is required for safe storage of this product facility?
- J. What is the temperature of this device during shipment and how is it monitored during shipment?
- K. Is the transportation of this device time sensitive? Be specific.
- L. Do you use and or transport with the aid of thermal indicators?
If so, what is the time/temperature range of these indicators?
- M. Does this device need to be refrigerated or frozen upon arrival?
- N. Is the shipping container tested and approved by the FDA and/or AATB?
- O. Please attach a copy of the recommendations for temperature and storage.
- P. Does this devise require rinsing, or special handling prior to implant?
- Q. Attach a copy of the clinical handling instructions/preparations prior to implantation.
- R. If product is not sterilized, please attach the protocol for sterilization.



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- S. Is it possible this product may have been shipped to another facility and returned? If so, how many times are allowed for handling before eventual discard? How is this indicated on the product?

If you answered yes to any of the above questions, please include copies of your AATB certification (current), and both federal and state licenses.

6. Is this device considered a "surgical" device? Yes No
7. Is this device a sterile supply? (UB92 272) Yes No
8. Is the device a ostomic/prosthetic/orthotic device? (UB92 274)
Yes No
9. Is the device a pacemaker or AICD? (UB92 275) Yes No
10. Is the device an IOL? (UB92 276) Yes No
11. Is the device intended to remain implanted in the patient for an extended period of time? (UB92 278) Yes No
12. Are additional components required when this device is used?
Yes No
- If yes, please list all device required including device name, catalog number and cost of each item.
13. Is this device used in Inpatient Surgery (Greater than 23-Hour stay)?
Yes No
14. Is this device used in Outpatient Surgery (Less than 23-Hour stay)?
Yes No
15. Does this device utilize anesthesia gas, medical gas contrast media or irrigation solution used under a physician's order as part of the treatment?
Yes No

EDUCATION

1. What educational tools and methods will be used for training; e.g. posters, in-service, videos, etc.?
Response:



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- 2. If requested, please provide a sample of the educational material that would be used; e.g. posters, fliers, videos, photos, etc.
- 3. Please give an estimate of the length of time required to educate a single care provider in the use of your device. Is there education material provided?

Response:

- 4. If your device is evaluated in a clinical setting, will you provide a sufficient amount of product to conduct a reasonable clinical pilot at a reduced cost to UWMC? Yes No UWMC cannot accept free devices except through authorized clinical investigations.
- 5. In the event your device is selected for evaluation in a clinical setting, will you provide evaluation sheets? Yes No

If yes, please provide a sample evaluation sheet.

- 6. If your device is accepted for use by UWMC, will you provide the necessary amount of product required to complete education in all clinical areas at reduced cost to UWMC? Yes No
- 7. Please provide, if available, any outcome data from clinical trials that supports a positive impact on patient safety, provider safety, provider satisfaction, or improved patient outcomes.
- 8. If the service/device requires a company representative to be present to operate equipment or to provide assistance to the physicians, please provide a copy of the representative's credentials, certificate, or license.
- 9. Please provide a copy of the device packaging.
- 10. Please attach the names and phone numbers of two (2) clinical references;

i.e. RNs or MDs users of this device willing to discuss its application or use and benefits.

Please check with your company reimbursement specialist and supply the following information to the hospital the proposed coding information:

HCPSC CPT Codes:
C-Code:
ICD-9 Procedure Code/s:

Supply:
Procedure:
ICD-9 Diagnosis Code/s:



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SERVICE / PRODUCT REVIEW**

INFORMATION SERVICE / DEVICE	CURRENT SERVICE / DEVICE (To be completed by Internal UWMC Purchasing)	REQUESTED SERVICE / DEVICE (To be completed by Vendor)
Description		
PMM Number		N/A
Manufacturer Name		
Manufacturer Catalog Number: <i>Please list <u>all</u> catalog numbers, provide a complete, detailed description of each item (the block will expand and attach excel document)</i>		
Source/Distributor		
Packaging		
Annual Usage (Per Item)		
Per Item Cost		
Total Annual Cost		
Is this device latex free?		
Is this device patient chargeable?		
Can this device be consigned?		
Does this device have an expiration date? If yes, give time period.		



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FINANCE / HEALTH PLANS CONTRACTING

**Internal Use Only-Finance / Health Plans Contracting FOR OVER \$100,000
IMPACT**

Supply Charge:

Procedure Charge:

Inpatient:

Outpatient:

Reimbursement:

Inpatient:

Medicare:

Medicaid:

Regence:

Premera:

First Choice:

Aetna:

Outpatient:

Medicare:

Medicaid:

Regence:

Premera:

First Choice:

Aetna:

Date returned completed section to the Business Manager:

This section of the NS/DIW was completed by



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SERVICE / DEVICE EVALUATION DATA AND TRACKING

Internal Use Only- Business Manager and/or Business Operations Manager

BUSINESS MANAGER FINANCE and/or BUSINESS OPERATIONS MANAGER:

Date of IIDC /PESC Committee evaluation approval:

Evaluation start date:

Evaluation end date:

Campuses: UWMC Main Surgery Pavilion Roosevelt

Number of times product can be used:

Is this service / product patient chargeable? Yes No

If required, date NS/DIW sent to Revenue Specialist:



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CONTRACTS / PURCHASING REPORT

Internal Use Only - Contracts / Purchasing:

CONTRACTS:

Date NS/DIW received:

Contract: Yes No

Length of Contract:

Contract Provisions:

- A. Shipping Allowances
- B. Replacement Items
- C. Expirations
- D. Other

This section of the NS/DIW was completed by:

Date NSPVIW sent to Purchasing:

PURCHASING/FINANCE:

Is this service / product patient chargeable? Yes No

Date completed NS/DIW sent to Revenue Specialist, Distribution and clinical contacts:

This section of the NS/DIW was completed by: