Vancouver CoastalHealth

Application for Variance from VCH Reprocessing Standards

[e.g., variance from Manufacturer's Instructions for Use (MIFU)]

Preamble:

Medical Devices used in Vancouver Coastal Health Facilities must comply with BC Ministry of Health, CSA and VCH Best Practice Guidelines for Patient Safety and Infection Control, when reprocessed between patients.

One such standard is that VCH is required to follow the Manufacturer's Instructions for Use (MIFU). MIFU are the validated reprocessing, cleaning, disinfection, and sterilization procedures for the device, and are the basis on which the device was approved for sale in compliance with regulatory requirements.

If you are proposing to reprocess a device other than according to MIFU - or at variance from any other VCH, CSA or Ministry of Health standard - please submit an Application for Variance from VCH Reprocessing Standards (this form).

You are required to provide supporting evidence regarding the benefits (efficiency, cost, etc.) and risks (patient safety, workload, device integrity, etc.).

In your application, please consider the following:

1. Determine whether or not the manufacturer has alternate MIFU that would meet current reprocessing practices within the VCH facility you propose to use this item.
2. Check with other facilities concerning their use and reprocessing of the device (what is industry practice?).
3. Check for published evaluations of the safety and integrity of the device using various reprocessing approaches

Documentation to support the Application for Variance:

Attach or paste into this document:

1. An explanation in simple language which can be understood by a layperson of the proposed variance from standards you are suggesting.
2. Include details of the proposed procedure to reprocess this device between patient uses; including photographs or diagrams of any disassembly and reassembly necessary. (Does it need to be taken apart for cleaning and reprocessing?)

3. What is the rationale for this variance from the MIFU or any other VCH, CSA or Ministry of Health standard?
4. Industry practice – What is the practice at our peer organizations concerning this device?
5. Reprocessing may cause deterioration of the device overtime. By what process will the safety, integrity and functionality of the device be monitored?

Please include a list of references, articles or website links to support your application.

If you have questions please email reprocessing@vch.ca

The process:

Please complete the application on the next two pages and submit those pages to: reprocessing@vch.ca

The committee will review the application. You may be asked to attend with the device to explain or discuss your submission with them. At this time the application may be approved; approved in principle (more information may be necessary before a decision can be made) or the application may be declined.

Application for Variance from VCH Reprocessing Standards

[e.g., variance from Manufacturers Instructions for Use (IFU)]

Name: _____Date: _____

Department: _____

Position: _____

E-mail: _____

Phone number: _____

Device information:

Name of device: _____

Classification: Critical Semi-critical Non-critical

Use / application of device: _____

*Attach a copy of manufacturers' instructions for use

1. Reason for proposed Variance:

2. Proposed procedure to clean, disinfect or sterilize this device between patient uses; including photographs or diagrams of any disassembly and reassembly necessary. (Attach separate sheet if necessary.)

3. What is the rationale for this variance from the IFU or any other VCH, CSA or Ministry of Health standard?

4. Industry practice – What is the practice at our peer organizations concerning this device?

5. By what process will the safety, integrity and functionality of the device be monitored?

6. Submit completed application to reprocessing@vch.ca