	POLICIES & PROCEDURES Number: **7311-60-014** Title: **Re-Use of Single Use Medical Devices**
Authorization [ ] Board of Directors [X] Senior Leadership Team [ ] Vice President	Source: Materials Management/SPD Cross Index: Date Reaffirmed: Date Revised: Date Effective: November 1, 2004 Scope: SHR/SPH

1. POLICY

1.1 The re-use of single use critical medical devices will not be permitted.

1.2 The re-use of single use semi-critical and non-critical medical devices will be permitted under certain conditions and in accordance with the procedure outlined below.

2. PURPOSE

2.1 To ensure safety of patients and staff.

2.2 To utilize SHR's resources appropriately.

3. PROCEDURE

3.1 Definitions

3.1.1 Categorization of equipment/supplies based on the potential risk of infection involved in their use according to guidelines recommended by the Association of Practitioners in Infection Control (APIC) 1996.

Critical Medical Devices – Critical medical devices are those objects that enter sterile tissue or the vascular system. Medical devices assigned to the critical category present a high risk of infection if the item is contaminated with any microorganisms, including bacterial spores. Thus these medical devices must be sterile. This category includes but is not limited to surgical instruments, cardiac and urinary catheters, implants and needles.

Semi-Critical Medical Devices – Semi-critical medical devices are those objects which came in contact with mucous membranes or with skin that is not intact. These medical devices must be free of all microorganisms, with the exception of bacterial spores. Intact mucous membranes are generally resistant to infection by common spore forming bacteria but are susceptible to other organisms, such as tubercle bacilli and viruses. Respiratory therapy, anaesthesia equipment and endoscopes are included in this category.

Non-Critical Medical Devices – These medical devices come in contact with intact skin but not with mucous membranes. Intact skin acts as an effective barrier to most microorganisms, and sterility is not critical. Examples of non-critical medical devices include bedpans, blood pressure cuffs, crutches, and patient furniture.

3.1.2 Sterile Processing Categories

Re-sterilization – sterilization of an unopened sterile single use medical device.

Reprocessing – the re-packaging and sterilization/disinfection of a single use medical device whose packaging is not intact but is unused.

Re-use – the cleaning, re-packaging and sterilization of a single use medical device, which has been used and/or soiled. Re-use may be for the same or another patient.

3.2 The end-user submits a written request for re-sterilization, reprocessing or re-use of a single use device to the chairperson of the SHR Re-use Advisory Committee. A completed proposal form must accompany the request.

3.3 The SHR Re-use Advisory Committee reviews the requests or identifies areas that requires further investigation.

3.4 The Committee uses an established review process, which includes consideration of:

- the categorization of the device
- the safety and efficacy of re-sterilization or reprocessing
- the likelihood the device will work properly after re-sterilization or reprocessing
- the cost effectiveness of re-sterilization or reprocessing for re-use
- the ability of the organization to measure any of these considerations through objective, quantifiable means

- the manufacturers' willingness to collaborate in the re-use program by providing pertinent information e.g. product specifications, sterilization parameters

3.5 The Committee will approve or reject requests for re-use. This decision will be forwarded in writing to the applicant.

3.6 End-users may appeal the Committee's decision within 30 days to the Director of Materials Management and the Director of Risk Management. Their decision will be final.

3.7 The Re-use Advisory Committee will maintain a list of items authorized for re-use. No person, by virtue of this policy, may re-use items not contained on the list of approved devices.

References

1. APIC Infection Control and Applied Epidemiology principles and Practice 1996
2. The Re-use of Single Use Medical Devices. Guidelines for Healthcare Facilities. Canadian Health Care Association 1996
3. Spaulding EH Chemical Disinfection of Medical and Surgical Materials. In: Block SSEd.
   Disinfection, Sterilization and Preservation. Philadelphia: Lea & Febiger 1968: S17-31