



The Canadian Orthopaedic Association *L'Association Canadienne d'Orthopédie*



Canadian Orthopaedic Association Position Statement on the:

Reuse of Single-Use Medical Devices

According to Health Canada, the reuse of single-use medical devices may be hazardous to patient safety. The Canadian Orthopaedic Association strongly endorses the Health Canada recommendations that in order to minimize the risks to patients:

1. Health care facilities and health care providers should not reprocess single-use devices (SUDs) unless the facility has established quality systems for reprocessing that include:
 - a. A reuse committee to establish policies and ensure adherence to approved procedures;
 - b. Written procedures for each type of device that is reprocessed;
 - c. Validation of cleanliness, sterility and function of the reprocessed devices;
 - d. Continual monitoring of reprocessing procedures to ensure their quality.
2. Health care facilities that wish to have their SUDs reprocessed by a third-party reprocessor should ensure that the reprocessor's facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety and functionality of the reprocessed devices.

In the interest of patient safety, the COA further recommends that there be no reprocessing of critical single-use medical devices ("critical" as defined by ASTM 2000). Furthermore, all reprocessors in Canada should need to provide evidence to Health Canada demonstrating that a reprocessed single-use device is both safe and effective. The level of regulation of reprocessed single-use devices must be equivalent to that of the original manufacturer of the device and we ask Health Canada to take the appropriate legislative action on this important issue.

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