HAWAII HEALTH SYSTEMS CORPORATION "Touching Lives Everyday"	Department: Legal	Policy No.: **EOC 0003**
		Revision No.: N/A
Policies and Procedures	Issued by: Alice Hall, VP & General Counsel	Effective Date: May 1, 2001
Subject: ***Single Use Devices***	Approved by: Thomas M. Driskill, Jr., President & CEO	Supersedes Policy: N/A
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I. PURPOSE: The U.S. Food and Drug Administration (FDA) has adopted a regulatory program that imposes upon hospitals and third-party reprocessors the same requirements as those imposed upon the original manufacturer (OEM). These regulations are aimed at guaranteeing that the reprocessed device meets the same sterility and efficacy standards that applied to the device at the time of the original release of the product. This policy:

A. Defines guidelines for the safe and efficacious processing and reuse of devices designated by the manufacturer as single use.

B. Defines HHSC expectations of third party reprocessors.

C. Requires compliance with all applicable laws and regulations governing the reprocessing and reuse of single-use devices (SUDs).

II. POLICY: To protect the health of the public by basing the practice of reusing single-use devices (SUDs) on good science, through compliance with all applicable laws and U.S. Food and Drug Administration rules and regulations governing the reuse and reprocessing of SUDs.

III. PROCEDURE:

A. With the exception of opened-but-unused devices, HHSC facilities shall not reprocess any SUDs internally. An opened-but-unused device is a single-use, disposable device whose sterility has been breached or compromised because its sterile package was opened, but which has not been used on a patient and has not been in contact with blood or bodily fluids.

B. All HHSC facilities shall use only those third party reprocessors with which HHSC has contracted. No HHSC facility shall contract independently with any third party reprocessors.

C. HHSC shall only contract with third party reprocessors that demonstrate to the satisfaction of HHSC that:

1. They are in full compliance with the FDA final guidance on the practice of reprocessing and reusing SUDs, and with any and all applicable requirements of the Food, Drug, and Cosmetic Act; and

2. Will provide full indemnification and warranty on reprocessed products.

D. The hospital will be responsible to the third party reprocessor for the following:

1. Provide manufacturers' information as necessary for labeling and handling.

2. Confine SUDs for reprocessing to the appropriate containers, package them responsibly, making sure to protect the item as well as handlers of the items from injury.