

**MEDICAL DEVICE NOTIFICATION AND
LIABILITY**

2005 GENERAL SESSION

STATE OF UTAH

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LONG TITLE

General Description:

This bill requires a reprocessor of a critical single-use medical device to assume the liability associated with the original manufacturing and the reprocessing of the critical single-use medical device.

Highlighted Provisions:

This bill:

- ▶ amends the Judicial Code to establish that a reprocessor of a critical single-use medical device assumes all liability related to the original manufacturing and reprocessing of the critical single-use medical device.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

ENACTS:

78-11-28, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **78-11-28** is enacted to read:

78-11-28. Liability of reprocessor of single-use medical devices.

(1) For purposes of this section:

(a) "Critical single-use medical device" means a medical device that:

(i) is marked as a single-use device by the original manufacturer; and

(ii) is intended to directly contact normally sterile tissue or body spaces during use, or is physically connected to a device intended to contact normally sterile tissue or body spaces during use.

(b) "Original manufacturer" means any person or entity who designs, manufactures, fabricates, assembles, or processes a critical single-use medical device which is new and has not been used in a previous medical procedure.

(c) "Reprocessor" includes a person or entity who performs the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development of a reprocessed critical single-use medical device.

(d) "Reconditioned or reprocessed critical single-use medical device" means a critical single use medical device that:

(i) has previously been used on a patient and has been subject to additional processing and manufacturing for the purpose of additional use on a different patient;

(ii) includes a device that meets the definition under Subsection (1)(a), but has been labeled by the reprocessor as "recycled," "refurbished," or "reused"; and

(iii) does not include a disposable or critical single-use medical device that has been opened but not used on an individual.

(2) A reprocessor who reconditions or reprocesses a critical single-use medical device assumes the liability:

(a) of the original manufacturer of the critical single-use medical device; and

(b) for the safety and effectiveness of the reconditioned or reprocessed critical single-use

medical device.