Clinical Process Instruction Manual

Tissue Recovery Materials Qualification Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) is committed to ensuring that it maintains appropriate supplies required for recovery of tissues. Accordingly, TGLN uses the process described in this procedure for approval of materials and solutions used in recovery and packaging. These are reagents and supplies which could affect the safety and come into direct contact with tissues. Surgical recovery supplies are approved based on the *Materials and Solutions Qualification List* that is reviewed annually. Eye recovery supplies are approved by the Eye Bank of Canada (EBC) in accordance with their requirements.

Process:

1. Materials and solutions to be used for recovery and packaging are selected and approved for use by the Recovery Manager – Tissue or designate.

2. Once approved, the Recovery Manager - Tissue or designate notifies the Quality Department with all relevant information to add the materials and/or solutions to the *Recovery Materials Qualification List*. See Exhibit 1.

3. Materials and solutions are generally used in accordance with their manufacturer's intended use. If TGLN's use differs from the manufacturer's intended use, this is documented on the *Recovery Materials Qualification List*.

4. For the supplies which do not affect the safety or come into direct contact with the tissues, a formal, rigorous documentation is not required.

5. The Recovery Manager - Tissue or designate will notify the Quality Department when items on the *Recovery Materials Qualification List* change. If an approved item becomes inactive for some reason (e.g., manufacturing issues, recall, etc.) this will be updated in the Notes column on the list. If an item loses its approval, it will be removed from the list.

6. Annually or when deemed necessary, the Recovery Manager - Tissue or designate(s) will review the currency of the items listed on the *Recovery Materials Qualification List.*

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Recovery Materials Qualification List	CSF-9-73	Quality Assurance Department	Quality Assurance Department	16 years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. K1.300.
- *Organ Recovery Materials Qualification Process Instruction, CPI-9-424.*

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Exhibit 1: Recovery Materials Qualification List

CSF-9-73

Recovery Materials Qualification List: Intended Use & Storage Requirements

Product	Manufacturer	Manufacturer Product #	Supplier	Supplier Product #	Website or Contact Name, Phone #, Email	Source of Intended Use/Storage Requirements	Manufacturer's/ Supplier's Intended Use	Storage Requirements	Initials (individual who verified information received)	Other Requirements if not already specified (if required)	Notes	Revision Date

June 19, 2017