1.0 Purpose

1.1 The purpose of this document is to list the mechanical performance specifications (Design Input) and general specifications of the disposable set for the Celution™ Clinical Cell Concentration Device.

1.1.1 Intended Use - The Clinical Regenerative Cell Hardware Device is a device that can be used to process human blood/ saline and adipose tissue mixture. Processing of adipose tissue will include washing and concentrate the available progenitor cells, in preparation for re-infusion.

1.1.2 Intended User - The intended user of the device is a medical practitioner who specialties in surgical procedures

1.1.3 Intended Environment of Use - The intended Environment of Use of the device is a hospital and/or plastic surgery surgical suite.

2.0 Scope

2.1 This document applies to the Celution™ Clinical Cell Concentration Device. The collection system of the disposable-set is a modification of the Stem Source collection canister (1550008).

3.0 Acronyms & Definitions

3.1 Acronyms

3.1.1 FDA – Food and Drug Administration (United States Government)

3.1.2 PLA – Process Lipoaspriate (Tissue Sample)

3.2 Definitions

3.2.1 Adipocyte: A connective tissue cell specialized for the synthesis and storage of fat. Such cells are bloated with globules of triglycerides, the nucleus being displaced to one side and the cytoplasm seen as a thin line around the fat droplet.

3.2.2 Adipose Tissue: Adipose tissue is an anatomical term for loose connective tissue composed of adipocytes. Its main role is to store energy in the form of fat, although it also cushions and insulates the body.

3.2.3 Autologous: In reference to transplantation biology, a situation in which the donor and the recipient of the tissue are the same person. Tissue originating from within one's self. Derived from an organism's tissue or DNA.

3.2.4 Collagenase: Any various enzymes that catalyze the hydrolysis of collagen and gelatin.

3.2.5 Cytoplasm: Protoplasm (clear aqueous fluid) surrounding the nucleus of a cell.
3.2.6 Ester: Any of a class of organic compounds corresponding to the inorganic salts and formed from an organic acid and an alcohol.
3.2.7 Fraction 0: A sample of PLA taken just after the wash and digest process and before centrifugation isolation of cells.
3.2.8 Hermetically: Completely sealed, especially against the escape or entry of air.
3.2.9 Hydrolysis: Decomposition of a chemical compound by reaction with water.
3.2.10 Lipoaspriate: The material (fatty tissue and fluid) that is withdrawn with a negative pressure apparatus (syringe or suction device).
3.2.11 Lumen: The inner open space or cavity of a tubular organ, as of a blood vessel or an intestine.
3.2.12 Progenitor Cell: A partially specialized cell (parent cell) that can give rise to related cells, but not a wide variety of cell types.
3.2.13 Reagent: A solution which contains chemicals which when added to the tissue causes a reaction. This could be either an anticoagulant or collagenase solution.
3.2.14 Subcutaneous: Located or placed just beneath the skin.
3.2.15 Triglycerides: A naturally occurring ester of the fatty acids and glycerol that is the chief constituent of fats and oils.

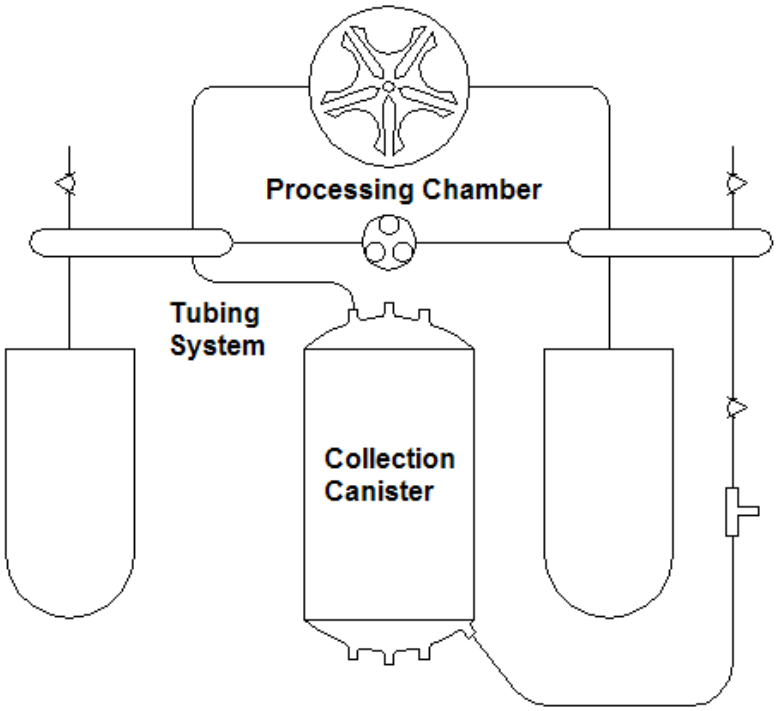
4.0 Reference Documents

4.1 Celution Clinical Product Requirements Document
4.2 Celution Clinical Electrical Design Specification
4.3 ISO-10993 (a set of harmonized standards that address the biological evaluation of medical devices)
4.4 USP 151 (Pyrogen Test)
4.5 LWI-9301
4.6 LWI-9608

5.0 Ergonomics, Functions & Configurations

5.1 System Function & Configuration – The systems primary function, as a disposable-set, is to interface with a hardware unit that will assist in the collection of tissue samples, washing of collected tissue sample, digestion of collected tissue sample and separation of progenitor cells from the collected tissue sample. The disposable set is configured into three major assemblies, see figure below. The first assembly is called the *collection*

canister. The collection canister is a modified Stem-Source Canister, an existing product (Pt. #1550008). The collection canister has two primary functions. The first function of the collection canisters is to collect tissue for processing. The second function is to wash and digest the collected tissue. The second assembly is called the *tubing system*. The tubing system is an organized cluster of interconnected tubing designed to interface with the Celution Clinical Cell Concentration Device. The tubing system has one primary function, which is to allow safe transfer of fluids during the processing of tissue. The third assembly is called the *processing chamber*. The processing chamber is a multi-chambered assembly designed to isolate cells by means of centrifugal force. The processing chamber has three primary functions. The first function is to allow the introduction and removal of fluids in a safe and sterile manner. The second function is to act as a sterile containment area during process. The third function is to facilitate the collection of isolated cells in a sterile manner. These three assembles comprise a full disposable set that interfaces with the Celution Clinical Cell Concentration Device. Ergonomic specifications for the disposable set and subcomponents are described in this section of the document.



5.1.1 Collection Canister Properties – The collection canisters outer body is constructed of a clear polycarbonate material. This material was selected because of its relevant physical and biocompatible properties. The polycarbonate construction allows the canister to maintain user supplied warm saline between 348C and 408C for 30 minutes for digestion of tissue. The polycarbonate construction also allows the canister to withstand sterilizations processes. The clear feature of the material makes it easy for the user to identify fluid levels.

5.1.2 Collection Canister Size and Limits – The collection canister was designed to contain 1000 ml of blood/saline and tissue mixture for processing. The size of the interior filter was carefully matched to the outer size of the canister as to be able to process human adipose tissue between 200ml and 500ml volumes.

5.1.3 Collection Canister Tissue Collection – The collection of tissue can be done using one of three available methods. The first method allows tissue introduction through a Toomey docking port. This is accomplished by connecting the Toomey docking adapter (Pt. ######) to a female quick-disconnect fitting (Colder Pt. #MPC17006T03), see figure below. This method of introducing tissue into the canister is to be done in the sterile field to insure sterility. The second method allows tissue introduction through a vacuum assisted suction tube. This is accomplished by connecting the suction tube to the female quick-disconnect fitting (Colder Pt. #MPC17006T03). After securing the suction tube to the canister a vacuum line is connected, see figure below. The third method allows tissue introduction through a standard Luer locking port. This is accomplished by connecting the adapted Luer lock port (Pt. #######) to a female quick-disconnect fitting (Colder Pt. #MPC17006T03), see figure below.

5.1.4 Collection Canister Tissue Washing – The canister is equipped with ports that allow the free passage of liquid and or tissue. As pictured below, a saline line can be secured to the canister to allow the introduction of sterile saline for the purpose of washing tissue samples.

5.1.5 Collection Canister Tissue Digestion – The canister is designed to facilitate digestion of tissue samples. The digestion process starts after the tissue has been sufficiently washed. To begin the digestion process warm saline is allowed to inter the canister

through the saline line or thought a mechanical port septum, see figure below. After the introduction of warm saline, enzymes are manually introduced through a mechanical port-septum. This will be accomplished with a Luer locking syringe.

5.1.6 Graphics & Labeling
5.1.7 Performance Critical Components
5.1.8 Hardware Interface
5.1.9 User Interface

6.0 Operation and Performance Specifications
7.0 Environmental Specifications
8.0 Regulatory and Safety Specifications
9.0 Clinical Trials
10.0 Calibration, Service & Warranty Specifications
11.0 System Elements

11.1
11.2 Description of Systems Components – The system is constructed of the following items:
11.2.1 Collection Canister, See Figure 5.2.1
11.2.1.1 Canister Top Lid (1550002)
11.2.1.2 Canister Cylinder (1550005)
11.2.1.3 Canister Bottom Lid (1550004)
11.2.1.4 Sterile Vent
11.2.1.5 Tube Segment, Vent Line
11.2.1.6 Hose Barbed Fitting, Vent Line
11.2.1.7 Tube Segment, Input line
11.2.1.8 Female Quick Disconnection, Input Line
11.2.1.9 Hose Barbed Fitting, Saline Line
11.2.1.10 Hose Barbed Fitting, Vacuum Line
11.2.1.11 Hose Barbed Fitting, Output Line
11.2.1.12 Gap Free Clamp SST-303 (5200106)
11.2.1.13 Filter Element (5300014)
11.2.1.14 Graduation Label (3200057)
11.2.1.15 Hose Pinch Clamp
11.3 Description of Systems Mode of Operation

12.0 Interface Specifications
13.0 Specifications
14.0 Operation and Performance Requirements
15.0 Standards & Compliance
16.0 Accompanying Documents

Revision History