celution® IV

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Celution® IV System

The Celution 800/IV System is a CE-Marked medical technology developed by Cytori to enable real-time access to a concentrated, single cell suspension of autologous, clinical-grade Adipose-Derived Regenerative Cells (ADRCs). The IV System uses two processing reagents. The first releases ADRCs from the adipose tissue, and the second ensures the system's output is a single-cell suspension suitable for safe reinfusion into the patient's blood stream when used in conjunction with the Cytori syringe filter. This provides clinicians with a same-day, cost effective cell therapy option using a patient's own readily available cells.

The Celution IV System is composed of 4 core components:

1. Celution IV Device

- Fully Automated
- Multi-language Display
- Processes **100–425 mL** of Tissue

The Celution 800/IV Device is intended for use only with the Celution 805/IV Consumable Set, Celase® reagent, Intravase® reagent, and macro syringe filter.

2. Celution IV Consumable Set

- Sterile, Single-use
- Closed-system
- Intuitive Installation and Removal
- Includes Procedure Accesories

3. Celase Reagent

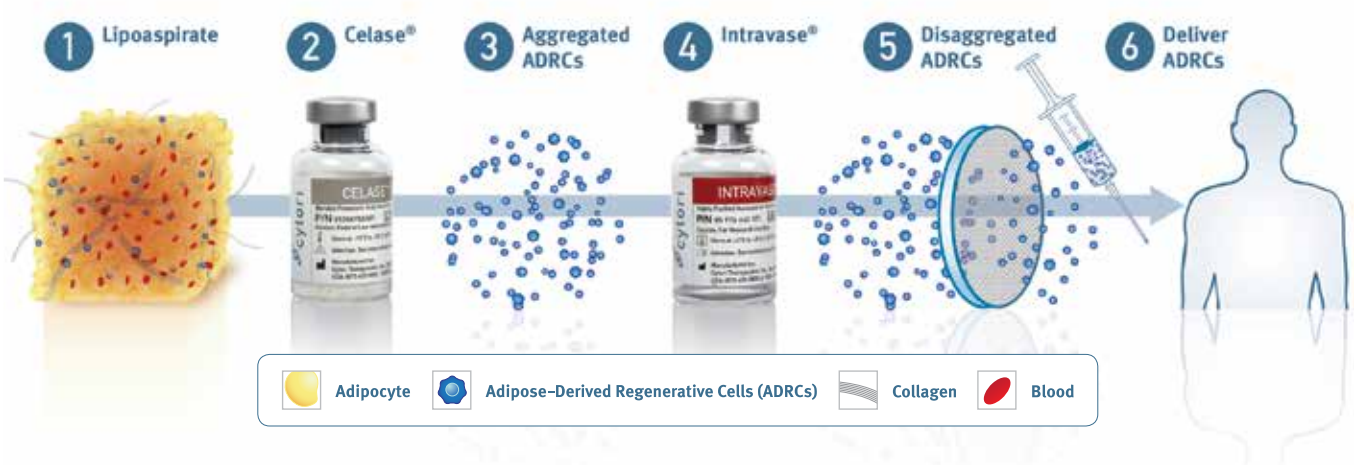
Initial digestion to release ADRCs from adipose tissue.

4. Intravase Reagent & Macro Syringe Filter

Additional optimization to ensure safe intravascular delivery.

- Sterile Processed
- GMP Compliant
- Mammalian Tissue Free

How Does it Work?



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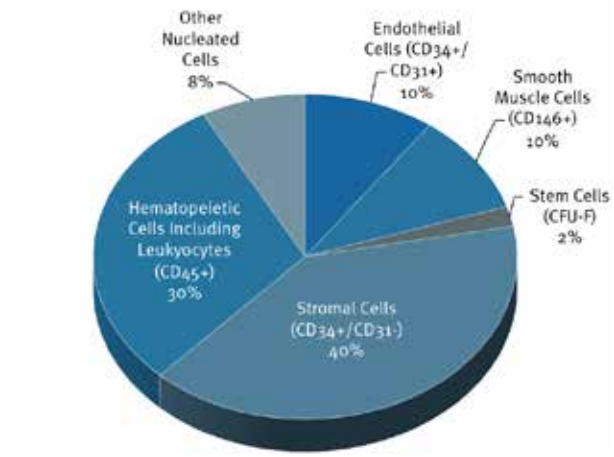
Key Benefits of Celution Procedures

Celution System	Physician	Patient
Real-time access to ADRCs	Decreased Procedure Time	Reduced Cost of Treatment
Autologous Cell Source	Minimal Immune Risk	Personalized Treatment
Closed System	Sterile Processing	Minimal Risk of Contamination

ADRC Average Yield and Composition

ADRCs are a fresh (non-cultured), clinical grade and clinically relevant heterogeneous population of cells from the Stromal Vascular Fraction (SVF) of cells from adipose tissue.

- Viable Cell Yield: 2–4 x 10^5 cells/g (average)



Processing Volume and Times

Average process time displayed to the user

Adipose Tissue Volume (mL)	Time (minutes)
100	~90
425	~125

Many factors such as surgical technique, patient population, and donor site affect the cell yield obtained from the Celution IV System. These numbers are based on averaged results from internal Cytori studies. Individual results may vary.

Technical Specifications

Dimensions

Width:	96 cm (38 in)
Height:	99 cm (39 in)
Depth:	61 cm (24 in)
Weight:	99 kg (218 lbs)

Electrical Power Requirements

Voltage:	100 – 240 V~
Current:	2.5 A
Frequency:	50 – 60 Hz
Fuses:	4 A/250 VAC
Phase:	Single
Power cord:	2 wires plus ground (earth) connector, IEC320 plug, 3-prong medical grade

Operational Environment

Operational Temperature Limit: 15° – 30° C (59° – 86° F)
Storage Temperature Limit: -40° – 60° C (-40° – 140° F)
Operational Humidity Range: 10 – 95% non-condensing
Humidity Range Storage: 10 – 95% non-condensing

System Control Characteristics

Sound Signals

The Celution IV Device audio alarm alerts users when a component or mechanical malfunction occurs

Control Panel

The control panel consists of 3 keys (BACK, NEXT, STOP) and a 32 character by 4 line display

Compliance Standards

EMC Compliance Standard

IEC 60601-1-2: 2001
CISPR 11:1997 Group 1, Class A
EN55011:1998, Amendment A2: 2002 Group 1, Class A

Electrical Compliance Standard

IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007)
Classification: Class I, Type B, Ordinary, Continuous Operation

Design and specifications are subject to change without notice.

CE 0086

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