

TGI CIS OVERVIEW



SYSTEM OVERVIEW

The TGI Cell Isolation System is an easy-to-use automated platform that delivers a suspension of regenerative cells to a syringe in about one hour from a small sample of adipose tissue.

These regenerative cells are predominantly stromal cells collected from the microvasculature of the adipose tissue. Adipocytes are removed during processing using a patent-protected process.

CELL PRODUCT CHARACTERIZATION

Volume	35–40 mL
Regenerative cells per cc tissue	≥ 500,000
Cell Viability	≥ 70%
CD34 ⁺	≥ 60%



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THE COMPONENTS

DISPOSABLE	\$7,500
CIS Disposable	
Adipase™ Loading Kit	
Suspension Kit	
CIS Adipase	
Front-End Tissue Collection Kit	
High Volume LipiVage Fat	
Harvest, Wash & Transfer	
System	
Tissue Transfer Kit	
CIS INSTRUMENT	\$61,500
CIS Instrument Cart	\$1,200
Re-Useable Liposuction Cannula	\$130

THE PROCESS

The process of setting up the disposable and accessories, supplying liposuction-harvested adipose tissue, and performing a cell isolation process is made simple through the use of TGIs convenient platform components.

1. Patient preparation for liposuction (TGI SOP)
2. Simple adipose tissue harvest using TGI Front-End Kit (TGI SOP)
3. Instrument set-up (on screen instructions)
 - a. Load CIS Disposable
 - b. Reconstitute, load, and attach Adipase Syringe (TGI IFU)
 - c. Attach user-supplied medium bag to disposable fluidics set
 - d. Inject adipose tissue into centrifuge bowl
4. Press Go!
5. After one hour remove Product Syringe from CIS and perform manual suspension step (TGI IFU)
6. Transfer product to user-supplied application device.

The TGI CIS has not been evaluated by the US FDA for human use. It is available in the US for research use only.



TGI CIS INSTRUMENT



INSTRUMENT USE

The TGI Cell Isolation System (CIS) Instrument is a software-controlled electro-mechanical device which, in conjunction with the CIS Disposable, Adipase™, and user-supplied suspension medium, automatically isolates regenerative cells from adipose tissue.

The graphical user interface instructs the user through an easy to follow setup instructions to initiation of the automated process.

MANUFACTURING & SHIPPING

The TGI CIS Instrument is manufactured in a 21 CFR 820-compliant and ISO 13485-registered manufacturing facility that is production-monitored. The Instrument is shipped in a ISTA 2B-validated wooden shipping crate with wheels for easy transport; each has the following dimensions:

Shipping & Storage Dimensions:
Shipping Crate: 33" W x 28" H x 26" D – 191 lbs

DESIGN AND SAFETY COMPLIANCE

The TGI CIS Instrument software is a fully verified and validated software set designed in compliance with the following software guidances.

- **FDA 938** General Principles of Software Validation

The instrument was designed and tested in compliance with the following standards allowing for the affixing of the CE Mark for Laboratory Equipment:

- **IEC 61326** Electrical equipment for measurement, control and laboratory use – EMC requirements
- **IEC 61010-1** Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
- **IEC 61010-2-010** Particular Requirements For The Heating of Materials
- **IEC 61010-2-020** Particular requirements for laboratory centrifuges

Input Voltage	100–240 V
Current	6.3A, maximum
Frequency	50–60 Hz
Dimensions	26" W x 23.5" H x 21" D
Weight	118 lbs



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TGI CIS DISPOSABLE



CIS DISPOSABLE USE

Packaged in a tray designed to fit on the Instrument shelf, the single-use CIS Disposable contains the fluidics pathway and isolation chamber needed to isolate a cell product from adipose tissue.

The CIS Disposable has three connection points requiring user interaction during loading into the CIS Instrument.

- Luer port on the centrifuge chamber to accept adipose tissue from the TGI Tissue Collection Kit
- Luered port on the fluidics pathway to accept the supplied 60 cc syringe filled with Adipase
- Bag spike on the fluidics pathway to connect to a user-supplied media bag

STERILIZATION

The CIS Disposable is sterilized in by gamma irradiation to ISO 11137 and validated using the VD_{max} sterilization validation method.

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BIOCOMPATABILITY

- Sensitization (Maximization Method) – Saline Extract
- Sensitization (Maximization Method) – Oil Extract
- Cytotoxicity – MEM Elution
- Intracutaneous Reactivity Test
- Acute Systemic Injection Test
- Platelet & Leukocyte Counts
- Hemolysis Assay – Direct Contact Method
- Complement Activation C3a and SC5b-9 Assay
- Partial Thromboplastin Time (PTT)
- Pyrogen Test, Material Mediated Rabbit
- Mutagenicity, Ames Assay, Saline Extract
- Mutagenicity, Ames Assay, DMSO Extract

NON-PYROGENIC

The CIS Disposable fluidics pathway has been validated as non-pyrogenic following a Kinetic Chromogenic LAL Test validation according to USP <85>.

MANUFACTURING & SHIPPING

The TGI CIS Disposable is manufactured in an ISO 9001-registered manufacturing facility within class 10,000 cleanroom.

1 box of 2 units in a double poly bag:
Shipping: 15" x 12.25" x 10.5" – 5 lbs
Storage: 15" x 12.25" x 10.5"

1 box of 1 unit in a tray (pictured):
Shipping: 21.875" x 8.625" x 7" – 3 lbs
Storage: 21.0625" x 8.1875" x 6.6875"



TGI CIS ADIPASE



ADIPASE USE

TGI Adipase™ is a proprietary enzyme blend designed for use with the TGI CIS Instrument and Disposable.

The Adipase kit shown above contains these items:

- 30 cc glass vial sterile-filled with lyophilized Adipase
- 100 mL glass vial sterile-filled with water for injection (WFI)
- Instructions for Use

Using the 60 cc syringe and 18-gauge needle supplied within the CIS Disposable package, lyophilized Adipase can be easily reconstituted into a 60 cc suspension within the syringe and connected to the CIS Disposable as described on the graphical user interface of the CIS Instrument.

MANUFACTURING

The TGI Adipase is manufactured in compliance with current Good Manufacturing Processes (cGMP).

Adipase is stored at -20°C at an FDA-registered, cGMP-compliant facility until shipped to the user.

RELEASE TESTING

In addition to passing proprietary functional tests performed on each lot of Adipase, the following criteria are used to release a lot of Adipase:

- Ames Mutagenicity Assay
- USP <71> Sterility Test demonstrating no growth

SHIPPING AND STORAGE

Storage Conditions & Dimensions:

Storage: 3.875" x 4.578" x 2.281"
2 - 8°C

Adipase is shipped overnight on ice (domestic) or dry ice (international).

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TGI CIS ADIPOSE TISSUE COLLECTION KIT

COLLECTION KIT USE

The TGI Tissue Collection Kit allows tissue collection for optimal Cell Isolation System (CIS) performance and cell recovery.

The single-use kit consists of these components:

- High Volume LipiVage Fat Harvest, Wash & Transfer System
 - (1) Harvest filter syringe
 - (1) Pre-connected tubing to connect to vacuum source
 - (1) Female-to-female Luer adaptor
- Adipose Tissue Transfer Kit
 - (2) Sterile 60 cc Luer syringes
 - (2) Sterile male Luer plugs
 - (1) Backup sterile female-to-female Luer adaptor

Following a TGI-supplied SOP, the surgical team easily connects the tubing of the High Volume LipiVage harvester to a recommended vacuum source (see accessories). An approved 4 mm OD, 25 cm, tri-port cannula is then attached to the tip of the LipiVage harvester.

Using a vacuum of 18 in Hg, the surgical staff collects and transfers adipose tissue from the harvester to the supplied sterile 60 cc syringes using the female-to-female Luer adaptor.

Once the recommended volume of adipose tissue has been collected, the LipiVage harvester may be disposed and the tissue specimen is ready for processing by the TGI CIS.

HIGH VOLUME LIPIVAGE



The LipiVage harvester is an off-the-shelf, 510(k)-cleared and CE-marked device from Genesis Biosystems for use in the operating room.

ADIPOSE TISSUE TRANSFER KIT

The Adipose Tissue Transfer Kit is provided to the user for convenience.

STORAGE

Storage: 9" x 10" x 2" – 2 lbs
Room Temperature

Tissue Transfer Kit is combined with other kits for shipping convenience.

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TGI CIS ACCESSORIES

CIS INSTRUMENT CART



The CIS Instrument Cart is an OR-ready cart for easy transport of the CIS Instrument.

The cart comes equipped with lockable wheels to stabilize the instrument during use. A shelf located below the top platform can be used to store CIS Disposables, Front-End Collection Kits, and even the liposuction aspirator.

The cart comes with easy-to-follow assembly instructions.

Shipping Dimensions

39.0" x 31.0" X 13.0" – 82 lbs

LIPOSUCTION CANULA



The liposuction cannula is stainless steel and attaches by standard Luer connection to the High Volume Lipivage Harvester provided in the Front-End Collection Kit.

The 4 mm OD x 25 cm L cannula has a tri-port tip configuration. The cannula can be re-used after cleaning and autoclave sterilization.

Shipping Dimensions: 12.0" x 2.0" x 2.0" – 1 lb

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