Mini-Stem™ System

JTL-250-01-EU

Instructions For Use

DIRECTORY

English 2

ENGLISH

Mini-Stem™ Device Classification:

- European Union Medical Device Regulation ("MDR") 2017/745 – The **Mini-Stem™** System is classified as a Class IIa medical device under Annex VIII, Chapter 3, Rule 2.

INTENDED USE

The **Mini-Stem™ System** is a sterile closed-loop medical device intended for:

1) Harvesting of Adipose-Derived Stromal Vascular Fraction ("**SVF"**), and for
2) Producing micronized fat graft out of lipoaspirate. The **Mini-Stem™ System** allows for processing lipoaspirate of adipose tissue (fat) without exposure to the external environment.

The device is intended for use when the transfer of harvested adipose tissue or delivery of adipose-derived stromal cells are desired. This device is intended for use on or by the order of licensed and trained physicians who are aware of the potential side-effects, complications, limitations, and contraindications related to harvesting procedures of subcutaneous adipose tissue, tissue processing and subsequent fat grafting, and stromal vascular harvesting and application. This device can be used by any healthcare practitioner such as a Medical Doctor, Nurse or Laboratory technologist.

INTENDED POPULATION

The **Mini-Stem™ System** is intended to be used by licensed and trained physicians in a hospital or clinical setting where the transfer of harvested adipose tissue or delivery of adipose-derived stromal cells are desired. Patient selection or exclusion is at the complete discretion of the licensed and trained physicians.

Warnings and Precautions

Carefully read these Instructions For Use (IFU) which address the Warnings, Precautions, and Residual Risks for this Medical Device.

Device Performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

The **Mini-Stem™ System** must only be used by licensed and trained physicians, who are aware of the potential side effects, complications, limitations, and contraindications to subcutaneous adipose tissue aspiration, tissue processing and subsequent implantation.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

The **Use By Date** is marked on each package. Storage and/ or use beyond the **Use By Date** may result in product deterioration.

The **Mini-Stem™ System** is intended for SINGLE USE ONLY and MUST NOT BE Reprocessed, Washed, or Re-Sterilized for Reuse.
Note: Reprocessing or Re-Sterilization WILL NOT extend the **Use By Date**.

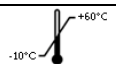
Each **Mini-Stem™ System** has a max capacity load volume of 250 ml.

Refer to the Instructions for Use on **Required Accessories** and **Equipment,** sold separately.

Always ensure to practice proper aseptic technique when handling patient tissues, **Mini-Stem™ System**, Accessories and Equipment.

After Patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

PACKAGING & STERILITY

	Before using, carefully visually inspect the integrity of the packaging. Do Not use if Package is opened or damaged.
	Contents Sterile within a Single Sterile Barrier System; Sterilized Using Irradiation.
	Do Not Resterilize.
	Single Use Only. Do Not Reuse. Reuse of device may result in adverse reaction as device is no longer sterile and heightened risk of contamination from re-use can result in infection requiring medical intervention.
	Store in a cool, dry place. Temperature Limitation: -10°C - 60°C

Refer to the **Symbol Legend** at the end of this document.

MINI-STEM™ SYSTEM COMPONENTS

The **Mini-Stem™ System** is comprised of the following:

- 1 **Mini-Stem™** centrifuge tube (250 ml).

The following **Accessories** are REQUIRED and MUST BE PURCHASED SEPARATELY:

- 4 Luer-Lock syringes (50cc/60cc) - sterile, non-pyrogenic (BD brand recommended)
- 2 Liposuction Luer Lock syringes - sterile, non-pyrogenic (Jointechlabs' FatLok recommended)
- 2 Luer Lock syringes (10cc) - sterile, non-pyrogenic.
- 1 Luer Lock syringe (5cc) - sterile, non-pyrogenic.
- 4 Luer Caps - sterile, non-pyrogenic.
- 1 Luer-to-Luer connector - sterile, non- pyrogenic.
- 1 Disposable Container for Liquid Collection.
- 1 SVF Collection needle - standard Luer Lock, sterile, 20gauge, 15 cm length.
- Alcohol pad(s) - 70% IPA.
- 18-gauge sterile needle.
- Sterile Gauze and 70% IPA for cleaning and disinfection.

REQUIRED EQUIPMENT and **MUST BE PURCHASED SEPARETELY**:

- Centrifuge System, 500ml bucket capacity and Variable Speed Setting ranging from 250g to 800g (**BioSpins**™ recommended).
- Incubated Shaker - for 37°C, 90-120 RPM range (**BioSpins**™ recommended).
- Cell Counter (**Muse**® by **Merck**® recommended)
- Lipoaspiration and Infiltration cannulas, 2.5 mm diameter, sterile (Jointechlabs brand recommended)
- Collagenase GMP grade Enzyme (**NordMark GmbH Biochemicals** Collagenase NB 6 GMP Grade Enzyme Recommended) for Stromal Vascular Fraction Harvesting.
- Ringer's Lactate, 250 ml, sterile - Injection Grade.
- Sterile 50ml/60 ml conical centrifuge tube, Clinical Grade

PRODUCT OVERVIEW

The **Mini-Stem™** is a sterile, single use device, designed to process or harvest biological material for single patient use. The device's mode of operation is based on manual shaking of the **Mini-Stem™** followed by centrifugation.

The principle behind the **Mini-Stem™** is based on its construction that includes:

- a compartment for lipoaspirate collection;
- screen-disperser, micronizing of the tissue into micro-agglomerate when centrifugal force is applied;
- compartment for collection and washing of micronized fat fraction; and
- filter for filtration of digested cells upon enzymatic tissue digestion protocol.

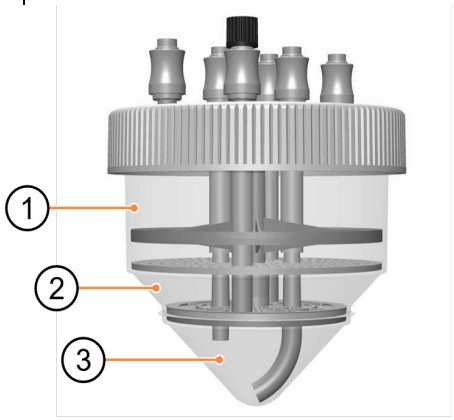
Refer to the descriptions and instructions below to become familiar with the system characteristics and functionality.

The **Mini-Stem™** is composed of:

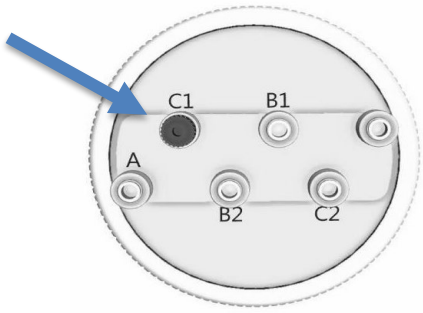
1. A cylindrical and conical tube of a medical grade polymer, providing 250 ml of total internal volume.
2. Internal components; and
3. Hermetically sealed locking cap.

The **Mini-Stem™** is divided into three (3) Compartments and by two (2) Screens (a Pre-Filter and a Filter screen)

1	**Top Compartment**: Between Cap and Pre-filter screen
2	**Intermediate Compartment**: Between the Pre-Filter screen and Filter screen
3	**Bottom Compartment** (under the Filter screen): conical part of **Mini-Stem™**



Located on the locking cap are clearly marked dedicated ports for each of the **Mini-Stem™** compartments. **Ports C1** and **C2** are designated for the **Intermediate Compartment** and **Ports B1 and B2** are designated for the **Bottom Compartment**. The dedicated ports allow for easy introduction and/or withdrawal of liquids, suspensions, liquefied biological substances and reagents. **Only Luer Lock syringes can be used for introduction or withdrawal of material in or from Mini-Stem™**.



A hydrophobic vented Luer valve is installed on the cap. Due to the sealed structure of the device, the valve prevents the creation of positive or negative air pressure inside the **Mini-Stem™** and preserves sterility.

PROCEDURE OVERVIEW

Caution	The **Mini-Stem™** is intended for **Single-Use Only** and cannot be washed, re-sterilized, re-processed, or reused.

The **Mini-Stem™ System** is intended for separation and concentration of adipose tissue through a centrifugation process.

Before starting a procedure, carefully open the device box to remove the **Mini-Stem™ System** and place it on a sterile prep table. When ready for the procedure, remove the device from the sterile barrier pouch and Central Sterile Room Wrap (CSR) wrap.

LIPOASPIRATE COLLECTION AND TRANSPORTATION

Lipoaspirate is collected directly into 60 cc syringe(s) connected by Luer-Lock tips with cannula, and immediately aseptically closed with a sterile syringe cap.

Record all patient data and label each syringe.

When transportation is required, collected lipoaspirate is transported to the processing area in a temperature-controlled cooler at **4-8 degrees Celsius**, preventing extreme temperature fluctuations.

Protocol for Stromal Vascular Fraction (SVF) Harvesting

Lipoaspirate is obtained by a licensed and trained physician. The **SVF Harvesting** procedure **MUST BE** performed within **16 hours from the time Lipoaspirate was extracted from patient.**

- **IF** SVF Harvesting is within **6 hours** from the time the Lipoaspirate was received, keep the Lipoaspirate at a temperature of **2-8°C**, undisturbed.
- IF SVF Harvesting is performed after **6 hours** from receipt of Lipoaspirate, perform **Decantation** (separation of adipose tissue from liquid phase) as described below and store Lipoaspirate at a temperature of **2-8°C.**

The SVF Harvesting should be scheduled within 2-4 hours of the scheduled re-implantation.

Total time required for the SVF Harvesting process is approximately 2 hours.

Before SVF Harvesting perform the following steps:

Warm up the Incubated Shaker to **37°C**, 1 hour in advance. Warm 250 ml of Ringer's Lactate to **37˚C.**

Prepare Collagenase enzyme with activity **22-24 Wunsch** and keep at ambient room temperature.

- Collagenase GMP grade Enzyme (**NordMark GmbH Biochemicals** Collagenase NB 6 GMP Grade Enzyme Recommended): Reconstitute **1g** in **8 ml** of Ringer's Lactate, following manufacturer's instructions. Use 1.0 ml of Collagenase Enzyme blend, which should contain **22-24 Wunsch of activity**.

- **Note**: Aliquots of 1.0 ml could be prepared and kept frozen in advance.

- If using an enzyme solution other than what's recommended in this Instruction for Use, please refer to that enzyme manufacturer's instructions.

SVF HARVESTING PROCEDURE

Caution	• Place the **Vented Luer Cap** on the counter port at each step of adding or collecting the liquids to and from the **Mini-Stem™** • Remove the **Vented Luer Cap** prior to Centrifugation.

1. Position syringes with lipoaspirate in a vertical position to allow gravitational separation of liquid fraction from fat (decantation). Release liquid fraction content from syringes into a separate disposable container.
2. While holding the **Mini-Stem™**, attach the syringe with Lipoaspirate to Port **A** and introduce up to **120 ml** of lipoaspirate into the **Mini-Stem™**.
3. Add 50ml of Ringer's Lactate in a 50/60cc syringe through the same port **A,** remove the Vented Luer Cap and temporarily place the Vented Luer Cap on a sterile gauze pad.
4. Rotate the **Mini-Stem™** gently in a circular manner.
5. Place the **Mini-Stem™** into a Centrifuge at **260g for 5 Minutes** (**If using Biospins™, select Program 1)**. Ensure to counterbalance the **Mini-Stem™** in the Centrifuge.
6. Place the **Vented Luer Cap** onto Port **B2**. Using a 60cc syringe aspirate 50cc-55cc of liquid fraction from Port **B1** and discard.

7. Introduce **Collagenase GMP grade Enzyme** into **Port A**. Add up to 100ml of Ringer's Lactate **prewarmed to 37°C** to Port **A**.
8. Remove the Vented Luer Cap from Port **B2**.
9. Place the **Mini-Stem™** onto the rack of the Incubated Shaker in the **upside-down position** for **45 minutes** at **37°C**. Rotation Speed set at 110 RPM.
10. Reassemble the Vented Luer Cap onto Port **C2** and add 50 ml of Ringer's Lactate through Port **C1**.
11. Remove Vented Luer Cap from Port **C2** and place the **Mini-Stem™** into a Centrifuge at **400g for 15 minutes** (**If using Biospins™, select Program 3).** Ensure to counterbalance the **Mini-Stem™** in the Centrifuge.
12. Reassemble the Vented Luer Cap onto Port **C1.** Utilizing 60cc syringe(s), slowly collect the supernatant liquid through Port **B2** (if feeling resistance, relocate the Vented Luer Cap on **B1**). If needed, use a second syringe.
13. Place the Vented Luer Cap onto Port **B2** and connect a 5cc syringe to Port **B1** for cell collection.
    Important: Apply "On/Off" pressure with the syringe on Port **B1** several times and collect the cell suspension into the syringe.
14. Transfer the cell suspension into a **50 ml Centrifuge Tube** prefilled with 20ml of Ringer's Lactate.
15. Place the 50ml Centrifuge Tube with the Cell Suspension into a Centrifuge at **260g for 5 minutes** (**If using Biospins™, select Program 1)**. Ensure to counterbalance the Centrifuge.
16. Use a 20cc syringe to aspirate all supernatant from the 50ml Centrifuge Tube.
17. Use a 5cc syringe connected to the SVF Collection needle to collect the pellet at the bottom of the 50ml Centrifuge Tube.
    Important: Apply "On/Off" pressure with the 5cc syringe several times during collection.

Useful Tips:

- The Vented Luer Cap, when attached, allows for introducing liquids into the **Mini-Stem™,** eliminating excessive pressure build up and splash back. **Avoid** wetting the Vented Luer Cap however, IF it does become wet, gently dab the Vented Luer Cap surface with Sterile Gauze to remove.
- During **Centrifugation**, ALWAYS **PAY CLOSE ATTENTION** to Volume and Weights of items placed in the Centrifuge. ALWAYS ENSURE the Centrifuge is properly counterbalanced.

Protocol for Tissue Processing to Produce Micronized Fat Graft

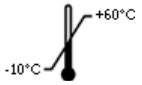
Caution	• Place the **Vented Luer Cap** on the counter port at each step of adding or collecting the liquids to and from the **Mini-Stem™** • Remove the **Vented Luer Cap** prior to Centrifugation.

1. Position syringes with lipoaspirate in a vertical position to allow gravitational separation of fat off liquid phase (decantation). Release liquid fraction content from syringes into disposable container. Attach the syringe with Lipoaspirate to Port **A** and introduce up to 150ml of Lipoaspirate into the **Mini-Stem™.**
2. Add 50 ml of Ringer's Lactate through port **A**. Remove the Vented Luer Cap and temporarily place onto a sterile gauze pad.
3. Rotate the **Mini-Stem™** gently in a circular manner for 10 seconds.
4. Place the **Mini-Stem™** into a Centrifuge at **260g for 5 Minutes** (**If using Biospins™, select Program 1)**. Ensure to counterbalance the **Mini-Stem™** in the Centrifuge.
5. Place the **Vented Luer Cap** onto Port **B2**. Using a 60cc syringe, aspirate 50cc of liquid fraction from Port **B1** and discard.
6. Introduce 100ml of Ringer's Lactate through Port **A**.
7. Remove Vented Luer Cap from Port **B2.** Place the **Mini-Stem™** into a Centrifuge at **360g for 5 minutes** (**If using Biospins™, select Program 2).** Ensure to counterbalance the **Mini-Stem™** in the Centrifuge.
8. Reassemble the Vented Luer Cap to Port **B2** and aspirate 60 ml of the liquid fraction through port **B1**.
9. Use a 60cc syringe to aspirate the fraction collected in the Intermediate Compartment through Ports **C1** or **C2**, while keeping the **Mini-Stem™** an angled position (**approximately 45**°). Then add 10ml of Ringer's Lactate through Ports **C1** or **C2**, while collecting the fat graft through the opposite Ports **C2** or **C1**. **Repeat until no more fat graft is extracted into collection syringes**.
10. Cap the extracted fat graft syringes and keep in **upside down position** for **5 minutes** to allow the collected micronized fat to separate from excessive liquids by gravitation. Discard the excess liquids.
11. To eliminate excess oil, keep the syringe(s) in **vertical position** and transfer the micronized fat through the **Luer-to-Luer Connector** into a new syringe, while leaving the oil behind. Cap the final syringe(s) until use.

OFF LABEL USE

Mini-Stem™ System is intended, without exception, for medical procedures requiring adipose tissue processing. Any other use is strictly forbidden.

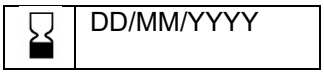
STORAGE



Mini-Stem™ System must be stored in a cool, dry place away from direct sunlight. Temperature Limitation: -10°C / +60°C.

DURATION, STERILITY & DISPOSAL

The **Use By Date** is marked on each package. Storage and/ or use beyond the **Use By Date** may result in product deterioration.



Before using, carefully visually inspect the integrity of the packaging. **Do Not Use** if Package is opened or damaged.

Mini-Stem™ System is sterilized by Irradiation and MUST NOT be re-sterilized.

Treat used, expired, or damaged devices as biohazardous waste. Dispose in accordance with hospital policy and local regulations.

TROUBLESHOOTING

This section provides information on how to resolve general technical problems that may be encountered during normal operation. For further assistance, contact **Jointechlabs,™ Inc**. Technical Service.

Problem	Most Likely Cause	Recommended Solution
The Centrifuge is vibrating.	Centrifuge was not adequately counterbalanced.	For proper counterbalance, use a mock device or centrifuge tube filled with water with same weight and capacity as the device.
When syringe is attached to one of the ports, contents isn't released or collected	Luer Lock is not secured properly.	Re-attach syringe using additional force to secure the Luer Lock. This should open the valve and allow for contents to pass through.
A snapping sound occurs when introducing or collecting contents from the **Mini-Stem™**	Due to the sealed design of the **Mini-Stem™**, positive and negative pressure could build up when introducing or collecting contents from the device.	During each step, make sure to attach the Vented Luer Cap on the opposite port, when introducing or collecting contents to and from the **Mini-Stem™**.

SURGICAL TECHNIQUE DISCLAIMER

These Instructions For Use are made available to healthcare professionals for the **Mini-Stem™ System**. This IFU is not intended to substitute formal clinical training or certification. Healthcare professionals performing liposuction, cell fractionation, aseptic technique, and cell injection are responsible for using appropriate surgical technique and best practices. **Jointechlabs™, Inc**. is not responsible for selection of the appropriate surgical technique to be used for each patient. Prior to use of the **Mini-Stem™ System,** healthcare professionals must refer to the warnings, precautions, indications, contraindications, and adverse effects in this IFU.

Mini-Stem™ System is a registered trademark of **Jointechlabs™, Inc**. in the United States of America and other select countries. All other trademarks are the property of their respective owners.

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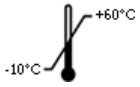
SYMBOL LEGEND

Symbol	English
	Conformite' Europeenne (CE Mark)
	Sterilized Using Irradiation
	Catalogue Number
	Authorized Representative in the European Community
	Single use, Do Not Re-Use
	Do not Resterilize
	Lot Number
	Use-by date (Expiration Date / Shelf Life)
	Consult Instructions for Use
	Keep dry
	Temperature Limits
	Do not use if package is opened or damaged
	Manufacturer
	Caution
	Medical Device
	Date of Manufacture
	Non- Pyrogenic
	Free of Natural Latex

Symbol	English
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Keep Away from Direct Sunlight
	Single Barrier System, aseptic technique required.

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CONTACT INFORMATION

TECHNICAL SERVICE

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