STEMPIA

Operation Manual

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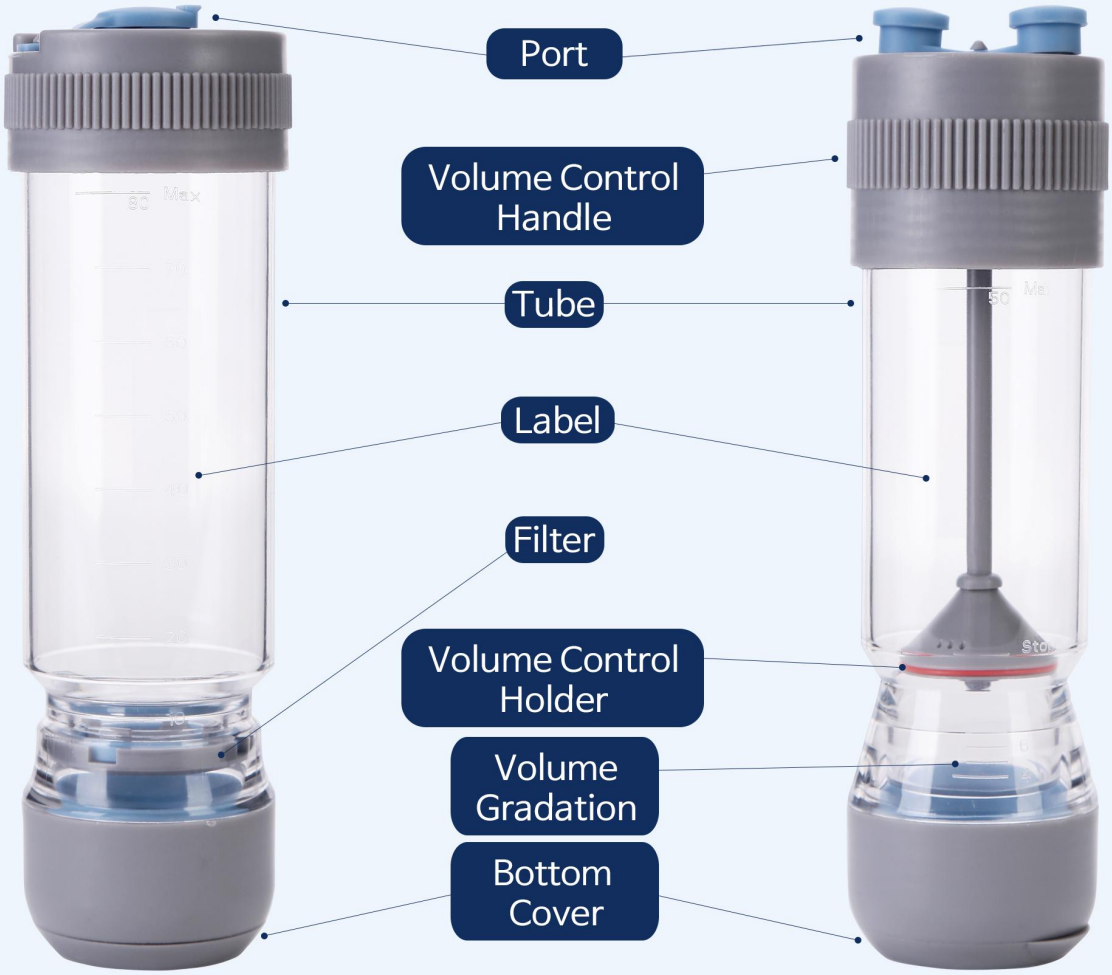
1. Purpose of use

Isolating SVF from lipoaspirate(adipose tissue) safely and effectively

2. Parts and Structure



Stage 1 : Isolation

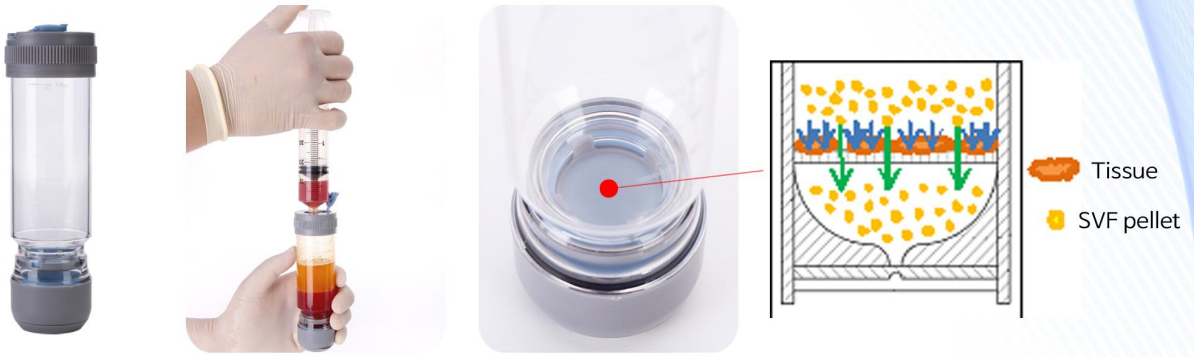
Stage 2 : Concentration

	Stage 1 : Isolation	Stage 2 : Concentration
SIZE	140*38mm	
CAPACITY	Maximum 80mL (Fat 40mL)	Maximum 50mL
MATERIAL	Tritan, PP, Silicon *Tritan : Eco-friendly material in which any endocrine-disrupting chemicals and bisphenol-A(BPA) have not been detected	
STERILIZATION	Gamma Sterilize	
CERTIFICATION	FDA, CE, ISO9001, ISO14001	

3. Features

This product helping a user isolate SVF easily and safely is a set product composed with two Tubes. Features are as following.

Stage 1 : Isolation

Purpose	Isolating SVF easily in a short time
Structure	
Features	• Possible to isolate maximum of 40mL fat tissue • Filter out unnecessary tissue through the equipped filter • Prevent external contamination through the enclosed tube structure

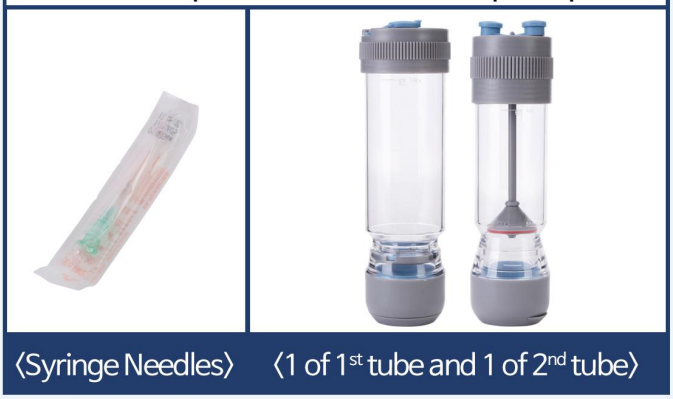
Stage 2 : Concentration

Purpose	Washing and concentrating isolated SVF
Structure	
Features	• Easy to wash and remove enzyme repeatedly • Possible to control volume from 4mL to 9mL • Prevent external contamination through the enclosed tube structure

4. Check points before use

- Basic Composition for 40mL Fat Isolation : Needles, one set of 1st and 2nd tube

Basic Composition for 40mL lipoaspirate



〈Syringe Needles〉 〈1 of 1st tube and 1 of 2nd tube〉

Basic composition for isolation is each 1st and 2nd tube in which isolate 40mL fat. Dedicated needle(21G x 13mm length) is only available with STEMPIA kits and enough needles are provided with the kit basically.

- Isolation of larger volume of lipoaspirate than 40mL

Ex) For 160mL lipoaspirate isolation : 1st tube x 4ea and 2nd tube x 1ea, needles

Composition of tubes for 160mL lipoaspirate

〈Syringe Needles〉 〈4 of 1st tube and 1 of 2nd tube〉

To isolate 160mL lipoaspirate, four of 1st isolation tubes and one of 2nd concentration tube are necessary. If four 1st tubes can be placed in centrifuge at one time, balance tube for 1sttube may not be necessary. Based on N-BIOTEK centrifuge, 4 tubes are maximum quantity to place in the centrifuge at a time. Ensure the weight of 4 tubes is all same for balancing before centrifugation. After centrifugation of 4 tubes at one time, extract 10mL of sample from each tube of four 1st tubes. And put total 40mL samples to 2nd tubes for washing process.

Before the washing process, centrifuge 40mL extracted solution one time so the cells are settled down to bottom of tube. After the centrifugation, turn the volume control handle untill 4mL. This makes SVF layer separated from above layer. Then, dispose of solution above the volume control holder and remain the 4mL of SVF layer. After this, take the standard washing procedure described in concentration section in this manual.

5. Preparation items before use

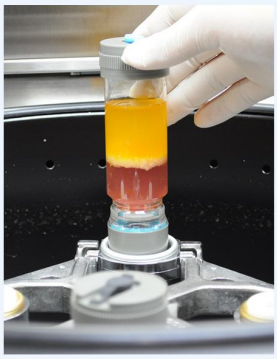
1) Check the condition of packing whether it is damaged or opened or any impurities inside.
2) Check the outside of product to check whether there is any crack or broken part.
3) Ensure all caps of ports and bottom cover are properly closed to avoid leaking.
4) Prepare necessary consumables such as a needle(21G*13mm), syringe, enzyme.
5) Prepare necessary equipment such as Centrifuge with rotor and buckets, Shaking incubator, digital balance, LED Cell Activator.(optional choice for use)
   N-BIOTEK recommend N-BIOTEK's centrifuge, multi work station. (Beauty cell™)
   All protocol here in manual is based on using N-BIOTEK equipment.

6. Isolation Protocols

Stage1 : Isolation

① Inject 1:1 volume of lipoaspirate and enzyme into 1st tube through the syringe port.

② Mix the fat with enzyme using Shaking Incubator with setting 37℃ and 150rpm for 30~40minutes.



③ After completing tissue dissociation, measure the weight of 1st tube and get a balance tube ready with same weight for balance. Then, centrifuge the tube at 1500rpm for 5 minutes.

④ After the centrifugation, open the bottom cover of 1st tube and extract 10mL of sample which including SVF.

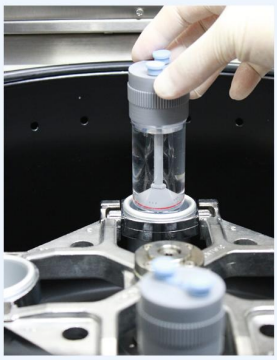
Stage 2 : Concentration

① Turn the volume control handle in count clockwise to lift the holder up to the point, "stop".

※ Open both of tube caps

② Inject extracted SVF and inject washing solution into the tube.

※ Open both of tube caps



③ Put the tube in centrifuge and put the balance tube at count part. Then, centrifuge it at 1500rpm for 5 minutes.

④ Turn the volume control holder to 4mL

※ Open both of tube caps

※ After third time centrifuge adjust volume in 4~9mL.

⑤ Open the caps and remove washing solution through syringe port.

※ Open both of tube caps

Conduct 1~5 process
Two more time
"Totally three times of centrifugation for washing process"
After third time centrifugation, injecting volume can be adjusted in 4~9mL.

⑥ After disposal of washing solution, shake the tube by hand gently.

⑦ Open the bottom cover and extract final volume of solution including SVF.

⑧ SVF is ready

7. Cautions

1) Do not inject contents more than the maximum capacity of each tube.
2) Must open both 2 inlets in case of injecting solution or removing supernatant liquid.
3) Use a 21Gx13mm syringe when extracting solution through the bottom.
4) Replace the syringe needle with extra needles if one needle is blocked.
5) This product is a disposable product. Dispose each Kit after using once.

8. Storage and Maintenance

1) Always store the product at clean place.
2) Keep the product out of direct sunlight and store at a place where is cool and not humid.
3) Store the product carefully not to mix with other contamination material.
4) Possible to store and use until 3 years after the manufacture date.

9. Contact

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