

INSTRUCTIONS FOR USE

MAPS Kit™ Micro Adipose Processing System

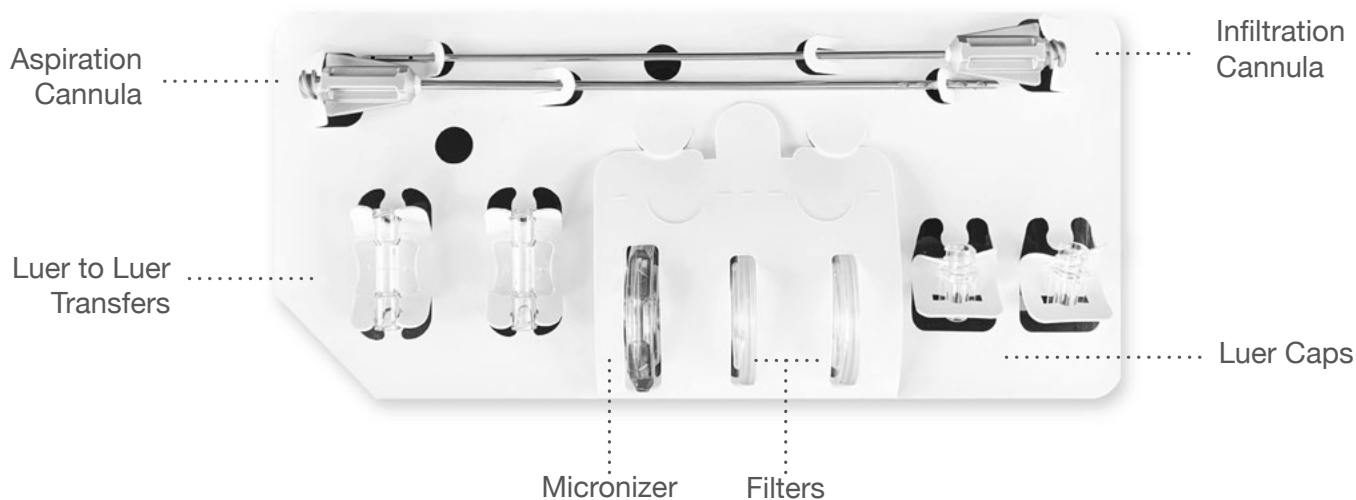
Description:

The MAPS Kit™ is a single use, sterile, component-based system intended for the harvesting, cleaning, and resizing of adipose tissue. It contains an infiltration and aspiration cannula, filters, and an adipose resizer allowing for the transfer of both micro and milli fat back into the same patient during the same surgical procedure.

Components:

Components	Quantity
Infiltration Cannula	1
Aspiration Cannula	1
MAPS Filter	2
Micronizer	2
Female Luer to Luer Transfer	2
Luer Caps	2
VacLok Syringe	1

Diagram:



Intended Use:

The MAPS Kit™ is a sterile, single use medical kit intended for use during medical procedures involving low volume lipoaspiration, processing, cleaning, and transferring of autologous adipose tissue.

The device is intended for use in the following surgical specialties when the transfer of adipose tissue is desired: plastic and reconstructive surgery, facial plastic surgery, dermatologic surgery, general surgery, gynecological surgery, orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal surgery, urological surgery, thoracic surgery, and laparoscopic surgery.

Only legally registered and marketed accessory items, such as needles, cannulas, and syringes, should be used with the MAPS kit. If the prepared adipose tissue is to be transferred, it should only be used without any further manipulation such as centrifugation.

Contraindications:

The MAPS Kit™ should not be used for any intravenous, intraocular, or intrathecal applications.

Precautions and Warnings:

- Single Use Only - the MAPS kit is not meant for reuse or autoclaving.
- For autologous use only.
- Collection, processing, and transfer of the patient's tissue should occur under aseptic/sterile conditions.
- The disposable syringe and kit must be properly discarded following standard biohazard guidelines after each use.
- Sealed sterile packages containing the MAPS kit must be inspected before opening. If seal is broken, contents may not be sterile. Discard if packaging is damaged or opened.
- The adipose tissue should be transferred within 4 hours of collection within the same surgical procedure.
- This kit requires the physician to understand how to perform tumescent lipo-harvest and transfer.

Additional material will be required including sterile 0.9% USP Saline, lidocaine, epinephrine, sodium bicarbonate, syringes, needles, sterile gloves, sterile drapes, and a sterile field.

Preparation:

1. It is recommended to have a sterile field prepared with ancillary components and drugs required for tumescent liposuction and transfer.
2. It is recommended to have the patient prepared and draped before opening the MAPS kit contents.
3. Open MAPS carton and pull back the Tyvek seal from tray to expose sterile contents.
4. Use sterile gloves to either remove contents onto a sterile field or leave within sterile cavity until use.
5. Open and remove VacLok syringe from pouch and place in sterile field until use.

INSTRUCTIONS

Infiltration:

- Use the infiltration cannula provided and attach it to the tumescent syringe that contains the tumescent solution.
- Infiltrate tumescent fluid into the planned harvested region and wait the appropriate amount of time for the tissue to numb and vasoconstrict.
- It is recommended you use a separate syringe than the VacLok to infiltrate.

Aspiration:

- Attached desired aspiration cannula to the VacLok syringe.
- When the cannula is inside the patient, pull back and lock syringe at 10ml or 15ml mark which provides 0.3 to 0.4 ATM (10-12inHg), harvest adipose tissue until pressure is lost.
- Use female to female luer to luer to transfer lipoaspirate into separate syringe. A 60ml syringe is recommend until desired volume of tissue is harvested.
- Use the provided luer caps to protect aspirate when not transferring.

Processing:

- Once the desired amount of adipose tissue is harvested there may be additional steps recommend performing depending upon the quality and type of tissue desired for transfer be that millifat (1.2mm) or microfat (600µm).
- It is recommended to filter and wash lipoaspirate aspirate at least once before transfer or resizing.

Washing/Filtering:

- Attach MAPS filter to luer end of syringe with lipoaspirate.
- Let gravity separate vertically, luer connector on bottom, for 1-2 mins.
- Take syringe and place over a waste bin.
- Push the syringe plunger with the lipoaspirate syringe into waste or attached syringe until some resistance is felt and no further fluid can be pushed through.

Caution: pushing too hard may damage the adipose tissue.

- Attach female to female luer connector to tissue syringe, attach syringe with amount of saline. that would fill the adipose syringe to capacity.
- Agitate for 30 seconds by inverting back and forth.
- Let gravity separate, attach MAPS filter again, and push out remaining fluid into waste bin.
- Tissue should then be clean and ready for transfer or resizing.

Resizing:

- To create microfat; transfer clean aspirate via luer to luer into a 10-12ml sterile syringe.
- Attach luer end of syringe to luer end of MAPS micronizer.
- Attach syringe of same size to the other luer end of the micronizer.
- Gently but firmly pass pack and forth for 3-5 times until tissue becomes homologous.
- Let gravity separate in syringe via the convenient holes within the MAPS insert, remove extra fluid into waste bin.

Transfer:

- Use luer connector to transfer tissue into desired size transfer cannulas if desired.

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

REF

Reference Number



Use by



Do not re-use. For single use only



Do not re-sterilize



Store at 59°F to 86°F (15°C to 30°C)



Manufacturer



AQ Therapeutics Inc.
340 Goddard
Irvine, CA 92618
www.aqtherapeutics.com

LOT

Lot Number

STERILE R

Sterilized using Gamma Radiation



Do not use if package is damaged



Keep package dry



See Instructions For Use