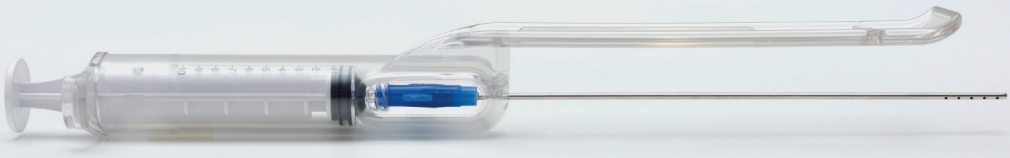
SEFFILLER®



The new age of
AUTOLOGOUS REGENERATIVE THERAPY (ART) IN AESTHETIC MEDICINE

EASY - SAFE - STANDARDIZED - EFFECTIVE

USER MANUAL

USER VIDEO MANUAL

DEVICE DESCRIPTION AND USE

The SEFFILLER® medical device is designed for **Physicians** who want to improve skin trophism and restore volumes.
SEFFILLER® is a disposable sterile medical device to be used on a single patient in order to facilitate and standardize the harvesting and preparation of micro fragmented subcutaneous adipose tissue.
Several studies have proved that the subcutaneous adipose tissue is made of adipose cells and stromal tissue (SVF) containing mesenchymal cells and especially adipose derived stem cells (ADSCs).
Such procedure involves the guided harvesting and grafting of micro fragmented adipose tissue with the components of the medical device SEFFILLER®.
The guide permits to carry out the harvesting procedure in an easy, safe and standardized way. The cannula enables to harvest the adipose tissue with the suitable characteristics for subcutaneous grafting (i.e. it is already micro fragmented), without the need for further major manipulations. The tissue is therefore washed and transferred in suitable syringes and injected in the same patient (autologous grafting) in order to improve tissue trophism and favour reparative processes.

ABSOLUTE CONTRAINDICATIONS

– Ongoing infections in the area of tissue harvesting or grafting.
– Presence of malignancies in the area of tissue harvesting or grafting.
– Pregnancy or breast-feeding.
– Anticoagulant therapy or severe coagulation disorder.
– Allergy to local anesthetic.
– Dysmorphophobia.
– Ongoing immunosuppressive therapies.
– Debilitated subjects.

RELATIVE CONTRAINDICATIONS

– Strong tobacco addiction.
– Presence of non-resorbable material in harvesting or grafting area.

WARNINGS

1. This is a disposable device. Reusing the SEFFILLER® system may cause infections and the transmission of communicable diseases.
2. This device is sterile. The sterility of the product is guaranteed only if the package is intact.
3. Operate aseptically:
a) do not use the device if the sterile package is damaged or not perfectly sealed;
b) use the device immediately after opening the outer package.
4. This product must only be used by QUALIFIED MEDICAL STAFF, who are responsible for its correct use.
5. This device cannot be resterilized. Do not autoclave.
6. Do not use the device after the expiry date on the label.
7. Before use and during transport of the device, the **surrounding temperature must range between 5°C and 40°C.** Excessive temperatures may compromise the reliability of the device.
8. Utmost caution is necessary when using this device on patients in precarious state of health.
9. This device is not meant for removal of adipose tissue in a body remodeling treatment or weight reduction.
10. During the procedure do not force the guide. In case of breakage of parts of the guide **interrupt immediately** the procedure.
11. The harvesting procedure must be performed in body areas where the pinch test is=or>4cm.

12. In order to guarantee the traceability of the product, please put the sticker identified by "**Consenso - Consent**" and **QR code** located on the bottom of SEFFILLER® box on the form for the informed consent to be signed by the patient.

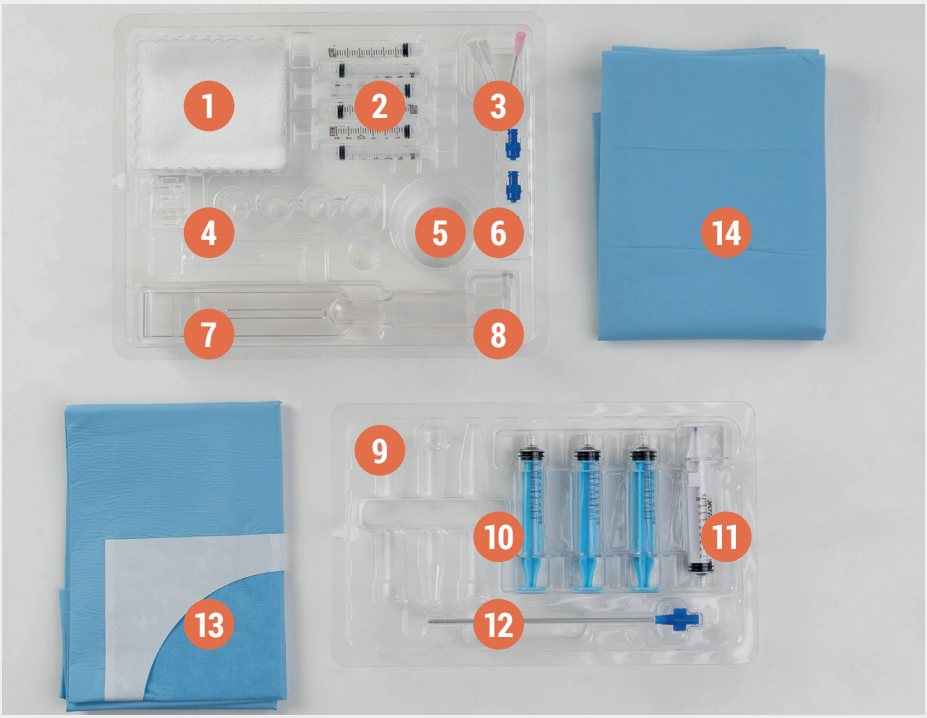
CAUTIONS

1. The use of this device is limited only to those **physicians who have been specially trained**.
2. The procedure outcomes may vary depending on the patient's age, state of health, life habits and surgical site as well as on the physician's experience.
3. Results achieved may not be definitive.
4. The quantity of tissue harvested must be limited to what is actually needed.
5. The surgical field needs to be completely sterile. Please follow medical standards designed to guarantee the maintenance of sterility during the procedure (e.g. do not touch the non-sterile parts of the patient or operator such as garments, jewellery, glasses, phones, etc.).

UNDESIRED EFFECTS

Undesired effects deriving from the procedure may be: asymmetries, infection, inflammation, hematomas, ecchymoses, skin irregularities, scar healing defects, skin dyschromia, fat necrosis, oil cysts, allergic reactions.

CONTENTS OF THE MEDICAL DEVICE SEFFILLER®



THE STERILE BAG INSIDE THE BOX CONTAINS:

1. Gauze swabs
2. 3 ml luer lock syringes
3. Needles with different caliber and length
4. Connectors for luer lock syringes
5. Cups
6. Plugs for luer lock syringes
7. Guide
8. Lower tray
9. Upper tray
10. 10 ml blue “reservoire” luer lock syringes
11. VacLok® syringe
12. Infiltration and harvesting cannula
13. Drape with opening
14. Drape

MEDICAL DEVICE UNPACKAGING

STEPS IN WHICH YOU DO NOT NEED TO WEAR GLOVES
(not present in the package).

1. Take the package out of the box keeping the label upwards.

2. Open the package by pulling apart the upper and lower sides of the package.

3. Slide the package content on the Mayo table, keeping the label upwards. Do not touch the inner content.

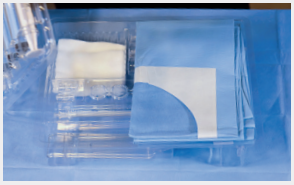
STEPS IN WHICH YOU MUST WEAR STERILE GLOVES
(not present in the package).

4. Wear sterile gloves.

5. Remove gently label and tape.

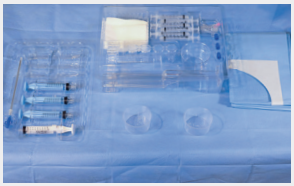
6. Grab the drape edge wrapping the medical device and spread it on the Mayo table without touching the table top.

7. Repeat procedure no. **6** for the other 3 edges.



8. Arrange the two parts of the shaped tray so all the components face up.

9. Place the medical device components on the drape as is more convenient for the operator.



STEPS IN THE PROCEDURE

The procedure is to be performed in sterile conditions: the skin should be carefully cleaned with a disinfecting solution both in the harvesting area and in the implantation area prior to the procedure. Do not compromise the sterility conditions during the procedure. You should absolutely avoid any contact with non-sterile parts of the patient or operator (e.g. do not touch the non-sterile parts of the patient or operator such as garments, jewellery, glasses, phones, etc.)

HARVESTING

The area where the tissue is harvested should be chosen based on the following criteria:

- adequate quantity of subcutaneous adipose tissue;
- size of the area: the harvesting area should be at least 20 cm in diameter;
- the most common harvesting areas are: abdomen, hips and the trochanteric region.

Harvesting phases:

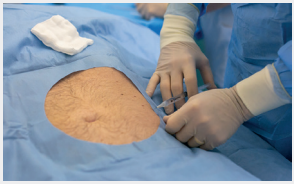
A. PREPARATION

A1. Clean the skin with a disinfecting solution.
A2. Lay the drape with opening in position.

B. INFILTRATION OF LOCAL ANAESTHESIA

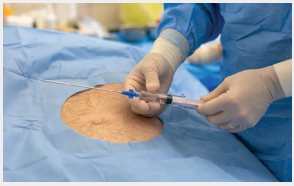
The local anaesthetic is NOT included with the SEFFILLER® medical device. Using local aneasthetics containing adrenalyn is recommended.

B1. Choose the spot for insertion of the cannula: it should be 1 cm out of the perimeter of the harvesting area (about 20 cm in diameter).
B2. Use the 27G needle to inject the anaesthetic solution.



B3. Make an opening in the skin with the 18G needle.

B4. Connect the multi-hole harvesting cannula with the 10 ml luer lock syringe containing local anaesthetic.



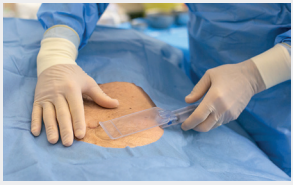
B5. Insert the syringe with the cannula into the guide.

B6. The cannula connected to the 10 ml VacLok® syringe must be inserted into the hilt of the guide.

B7. Rotate the syringe so that the barrel flanges get caught in the locks at the back of the guide.

B8. Insert the tip of the cannula into the skin opening perpendicularly until the guide stops.

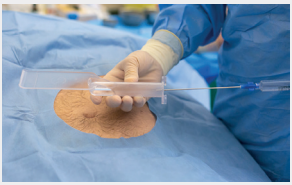
B9. Rotate the cannula by 90 degrees so as to set the guide parallel and adhering to the skin plane.



B10. Infiltrate the local anaesthesia with a back and forth movement of the cannula while maintaining the guide parallel and adhering to the skin.
The anaesthetic solution should be injected in the whole harvesting area. If more anaesthetic is necessary, repeat the same procedure from step **B5** after recharging your syringe with more anaesthetic solution.
B11. WAIT 10 MINUTES.

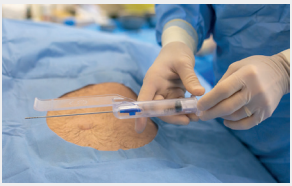
C. HARVESTING OF TISSUE

C1. Connect the multi-hole harvesting cannula with the 10 ml VacLok® syringe. Make sure the VacLok® syringe graduated scale is turned upwards and visible.



C2. Insert the syringe with the cannula into the guide.

C3. The cannula must be inserted in the guide hilt.



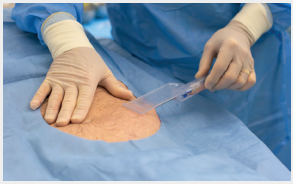
C4. Rotate the syringe so that the barrel flanges get caught in the locks at the back of the guide.

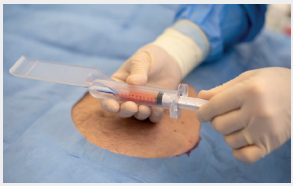
C5. Insert the tip of the cannula into the skin opening perpendicularly until the guide stops.

C6. Rotate the cannula by 90 degrees so as to set the guide parallel to the skin plane and the cannula in the subcutaneous plane.

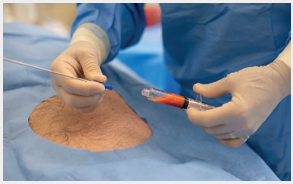
C7. While holding the guide with your dominant hand, pull the syringe plunger back and rotate it clockwise so as to block the plunger and create the vacuum in the syringe barrel.

C8. While maintaining the guide parallel and adhering to the skin, move the cannula back and forth with a fan movement in the whole harvesting area. The cannula must not come out of the skin hole beyond the reference line on the guide.
The tissue will be sucked into the barrel. Stop as soon as you have collected 5 ml of tissue in the syringe.

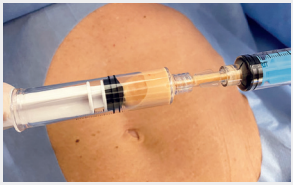




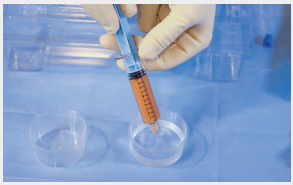
C9. Pull out the cannula from the skin.
C10. Rotate the syringe until the plunger flange is released from the lock at the back of the guide.
C11. Pull out the syringe, disconnect the cannula and attach the transfer.



C12. Connet the 10ml syringe to the other opening of the transfer, then rotate the VacLok® plunger counter clockwise for ¼ of a turn and transfer the tissue into the 10 ml syringe.

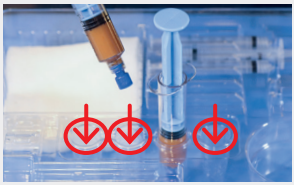


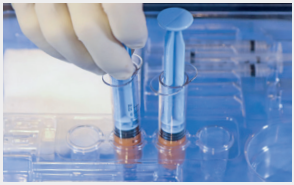
C13. Fill the syringe with sterile saline solution (NOT included in the medical device) you previously poured into the cylindrical container.



C14. Use the luer lock plug to close the syringe.

C15. Put the syringe (plug down) in one of the four specific holes of the lower tray. Repeat the procedure from step C1 to step C15 until you have from one to three 10 ml syringes of tissue according to the treatment plan.





PREPARATION OF TISSUE

After some minutes the syringes in the lower tray will show a separation by gravity of the tissue (top) from the saline solution (bottom).

D. WASHING THE TISSUE

D1. Pull out the syringe from the lower tray, hold it in a vertical position (DO NOT TILT nor TURN UPSIDE DOWN), remove the plug, discard the washing saline solution while retaining all the tissue inside the syringe.

D2. Put the plug back in position and the syringe back in the lower tray.
D3. Repeat the steps **D1** and **D2** for all the syringes in the lower tray.

E. TRANSFERRING TISSUE TO GRAFTING SYRINGES

E1. Remove the blue plug.
E2. Connect the luer lock transfer connector.

E3. Connect the 3 ml syringe at the other end of the transfer connector.

E4. Transfer the tissue (except the oily part on top) in the 3 ml syringe.

E5. Use the blue luer lock plug to close the 3 ml syringe.
E6. Repeat the procedure from step **E1** to step **E5** until all the tissue contained in the 10 ml syringes is transferred to 3 ml syringes.

GRAFTING

F1. Remove the plug from the 3 ml syringe containing 2.5 ml of tissue and connect either a needle or a microcannula according to the physician's habit.
F2. Disinfect the grafting area.
F3. Proceed by injecting the tissue with a needle or microcannula (not present in the device) in the anatomical area and in the quantity requested by the treatment indication.

DISPOSAL

In case of use on patients with contagious bacterial and/or viral infections, some components could result highly contaminated.
Once used, do not dispose of the device with domestic waste. The device must be treated as a **Special Waste**.
Please deliver your used device to an authorised collection center.
Contact the Local Authorities to learn about the disposal regulations of such waste.

NOTE

SYMBOLS GLOSSARY

	Caution, consult accompanying documents
	Consult instructions for use
	Do not use if package is damaged
	Do not re-use
	Use-by date
LOT	Batch code
	Production Date
STERILE EO	Sterilized using ethylene oxide
	Temperature limit
	Manufacturer
REF	Catalog identification
	Do not Resterilize
Rx only	Prescription Use Only
NON-PYROGENIC	Non-Pyrogenic

SEFFILLER®

FOR THE GUIDED HARVESTING AND GRAFTING
OF MICRO FRAGMENTED ADIPOSE TISSUE

seffiller.com

CE 0425

Il prodotto SEFFILLER® è conforme alle prescrizioni della direttiva 93/42/CEE sui dispositivi medici.

The product SEFFILLER® complies with the requirements of the directive 93/42/CEE on medical devices.

SEFFILINE
Via delle Lame, 98
40122 Bologna - Italy
+39 051 6494945