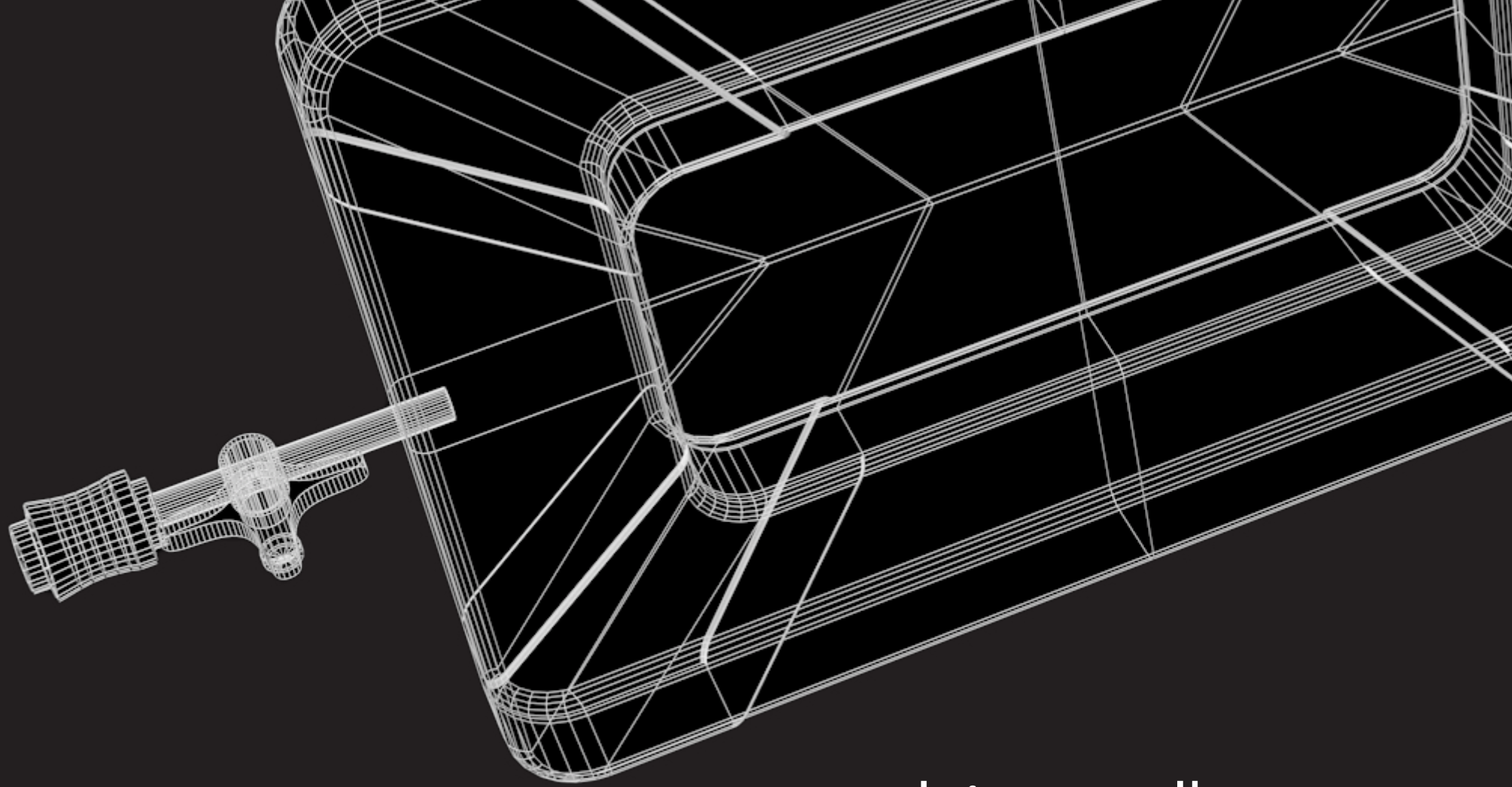


CLOVER NEXT®

Lipocell

INDICATIONS FOR USE – LIPOCELL®:

- Musculoskeletal disorders: osteochondral lesions and moderate to severe osteoarthritis in patients not eligible for prosthetic surgery; use in association with surgical repair for tendon or ligament injuries.
- Spinal surgery: use in association with disc herniation removal procedures for the modulation of inflammatory processes, stimulation of disc repair processes, and prevention of adhesions.
- Maxillofacial surgery and dentistry: volumization, tissue regeneration, and functional improvement.
- Coloproctology: conditions such as fecal incontinence, anal fistulas (recurrent and non-recurrent), rectourethral fistulas, and Crohn's disease with perianal complications.
- Gynecology: vaginal atrophy, with support of the regeneration of damaged tissues and vaginal rejuvenation.
- Urology: urinary incontinence and vesicouterine fistulas.
- Management of complex wounds, ulcers, and diabetic foot: biological stimulation activity through modulation of inflammatory processes and support of tissue regeneration.
- Aesthetic surgery: use as a filler for the breast and face.
- Plastic surgery: use as a biological filler for the correction of breast ptosis, breast remodeling, and post-surgical reconstruction in patients with mammary hypoplasia or thoraco-mammary deformities; treatment of scars and support of healing processes and deep tissue regeneration, also in association with surgery.
- Trichology: support of hair regrowth and hair thickening.
- Otorhinolaryngology: glottic insufficiency.

Autologous adipose tissue is rich in mesenchymal cells capable of differentiating into osteoblasts (bone cells), chondrocytes (cartilage cells) and connective tissue cells. This ability promotes the regeneration of damaged joint tissues. Once purified, adipose tissue can modulate the immune system, significantly reducing inflammation and pain at the injection site.

Lipocell® is a patented system at the European level.
The device boasts six dedicated scientific publications and more than 20,000 procedures performed.

Lipocell® ensures a "gentle" processing method that preserves vasculo-stromal niches, the entire extracellular matrix, and the regenerative potential of the autologous tissue.

The procedure requires a small harvest of adipose tissue — determined according to the desired final volume (equal to 20% of the initial volume) — from the abdomen, gluteal region or inner thigh. Harvesting is performed using dedicated blunt cannulas with ovoidal ports, allowing a fully atraumatic technique.

The collected tissue is processed using a patented semipermeable tubular membrane that removes pro-inflammatory oily and hematic components.
The treated tissue preserves both its physical structure, which ensures high mechanical performance for the graft, and intact vasculo-stromal cellular niches.

Lipocell® is a technology designed to enhance the biological properties of adipose tissue.
Fat is one of the adult tissues richest in mesenchymal cells with high regenerative potential.

These cells, contained within the vasculo-stromal niche, are pluripotent and can differentiate into specialized cell types depending on the graft site.

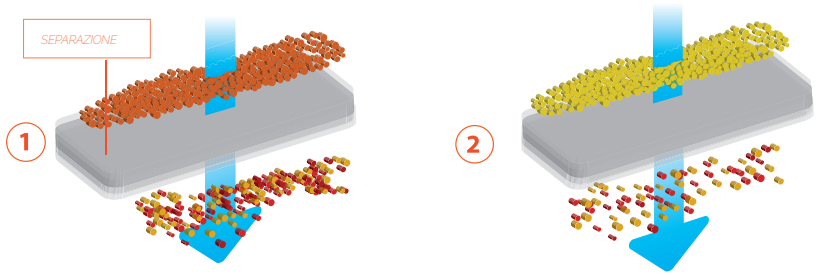
They also respond to signals from compromised tissues by releasing anti-inflammatory cytokines and growth factors that promote tissue healing.

Technology

The Lipocell® device features a semipermeable membrane capable of separating adipose tissue from oily and hematic residues through continuous washing with lactated Ringer's solution or normal saline.

This "tissue dialysis" preserves the integrity of the extracellular matrix, minimizing cellular stress.

The final product is purified adipose tissue reduced into clusters.



High regenerative potential

The atraumatic processing and purification of the tissue allow the intact vasculo-stromal niche to act as a natural scaffold for the cells through trophic and anti-inflammatory activity aimed at tissue regeneration.

Simple, effective, safe procedure

Lipocell® is a closed-circuit system; the entire process takes place in a sterile field, minimizing the risk of contamination.

The procedure is simple, fast, reproducible and applicable across multiple therapeutic areas (orthopedics, pain therapy, plastic and reconstructive medicine and surgery, general surgery).

Features

- Closed circuit
- Blunt-tipped cannulae with ovolidal holes for atraumatic lipoaspirate collection.
- Patented tubular filter
- Total purification of pro-inflammatory blood and oil residues
- Integrity of the niche vasculo-stromal
- Minimal handling and mechanical stress

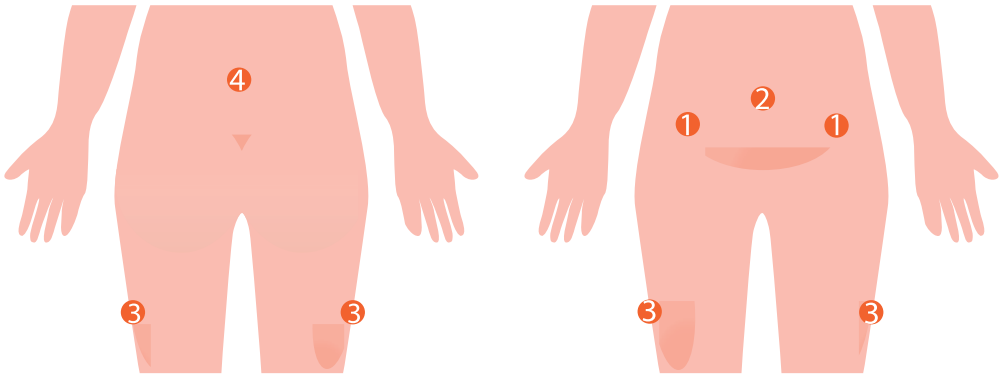
A small liposuction

Adipose tissue is harvested through a small liposuction procedure from subcutaneous fat, preferably in the abdominal region.

The patient is placed in the supine position and two symmetric access points are created between the lumbar and iliac abdominal areas (1), or alternatively a single periumbilical access (2). Depending on patient characteristics, alternative harvest sites can be selected, such as trochanteric fat bilaterally (3) or lumbar fat (4).

A harvest of approximately 60–90 ml of lipoaspirate is performed, yielding between 8 and 18 ml of final product ready for infiltration.

The procedure is performed under local anesthesia via infiltration of the preparation solution for liposuction, preceded by mild sedation.



Infiltration

Preparation solution for abdominal liposuction

The purpose of the infiltration is to prepare the adipose tissue for harvesting.
Adrenaline, through vasoconstriction, reduces bleeding during aspiration, while lidocaine provides anesthetic effect.

Normal saline, in addition to exerting further pressure with vasoconstrictive effect, induces tumescence that facilitates harvesting with the aspirating cannulas.

After making an incision at the points indicated in the illustration, use the infiltration cannula (16G), connecting it to 60ml syringes filled with the preparation solution.
It is crucial to infiltrate the solution homogeneously during the retrograde motion of the cannula (blunt-tip with ovoidal ports, facilitating harvesting and ensuring an atraumatic process).
Avoid transverse movements with the cannula.

Once 2/3 of the preparation solution has been infiltrated, it is necessary to wait 7–10 minutes before performing the harvest.
Digital manipulation of the infiltrated area may be performed to improve distribution of the solution.

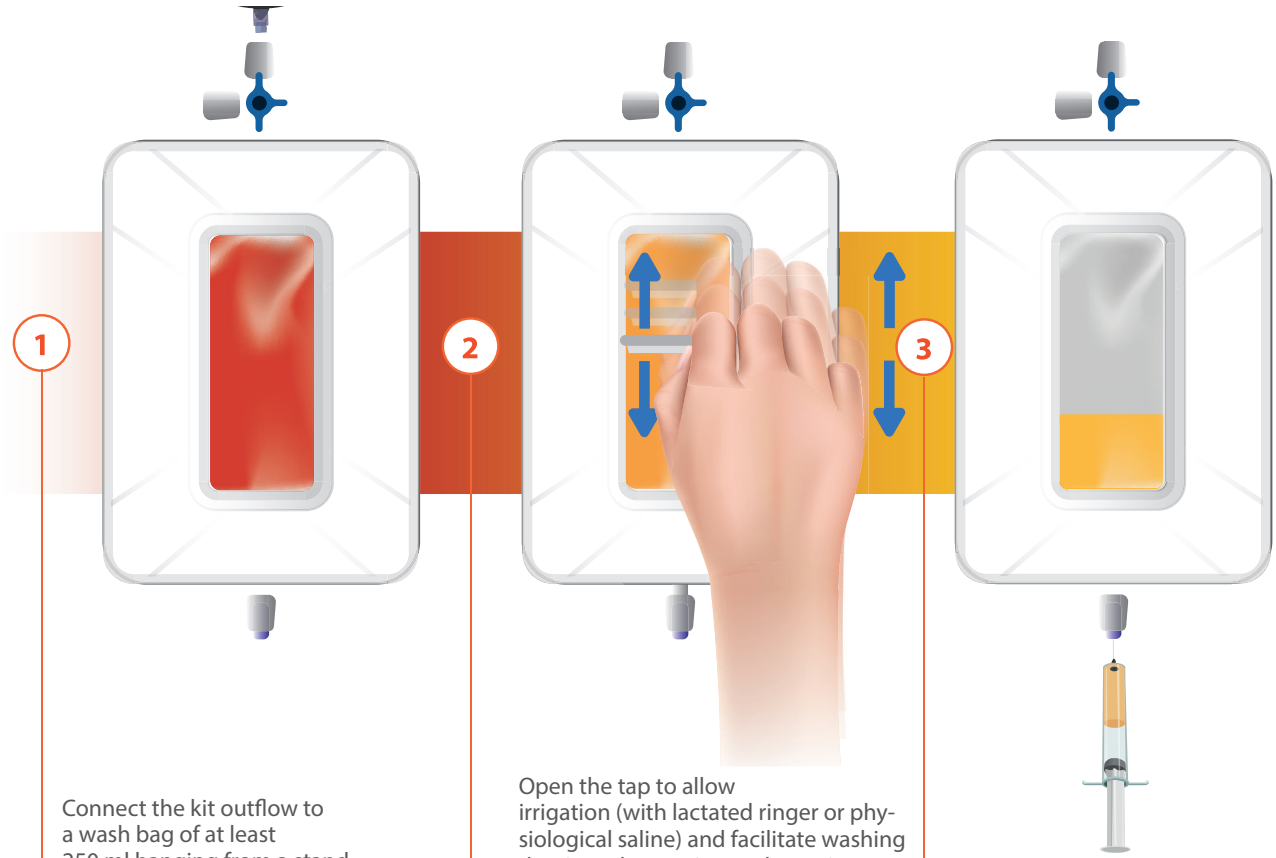
Withdrawal

After approximately 10 minutes, the aspirating cannula (13G) is connected to the self-locking syringe. The locking mechanism, activated once the cannula has entered the subcutaneous adipose layer, creates negative pressure within the syringe, facilitating collection of the lipoaspirate.

Avoid transverse movements with the cannula.

Once the required adipose tissue has been collected, dress the harvest area.
At the end of the procedure, a compressive dressing is recommended to limit the formation of ecchymosis and hematomas.
An elastic compression garment, typically worn for about one week, helps reduce this occurrence.

If the harvested product appears particularly dense, it can be transferred into the provided 2.5-ml syringes or into smaller luer-lock syringes to facilitate extrusion during grafting.
The needle included in the kit may be used, or alternative needles with a recommended gauge of 18G or 20G.



1. Connect the kit outflow to a wash bag of at least 250 ml hanging from a stand. Drop the waste bag instead waste bag.
Insert the obtained lipoaspirate through the 'IN' port of the device.

2. Open the tap to allow irrigation (with lactated ringer or physiological saline) and facilitate washing the tissue by moving and pressing gently the bag with the comb with which provided with the kit. Continue until the tissue has taken on the typical yellow colour and the irrigation in the waste tube is clear.

3. Close the irrigation tap and remove excess wash solution with the help of the spatula. Connect a 10 ml syringe to the 'OUT' port of the device and collect the final product ready for use.

REV02IT
02|09|24

CLOVER NEXT®

Clover Orthopedics s.r.l.
M. info@cloverorthopedics.com
W. cloverorthopedics.com

T. +39 02 457 902 31
F. +39 02 457 902 66

CE
0426

SISTEMA DI GESTIONE QUALITÀ CERTIFICATO
ITALCERT
UNI CEI EN ISO 13485:2016
UNI EN ISO 9001:2015