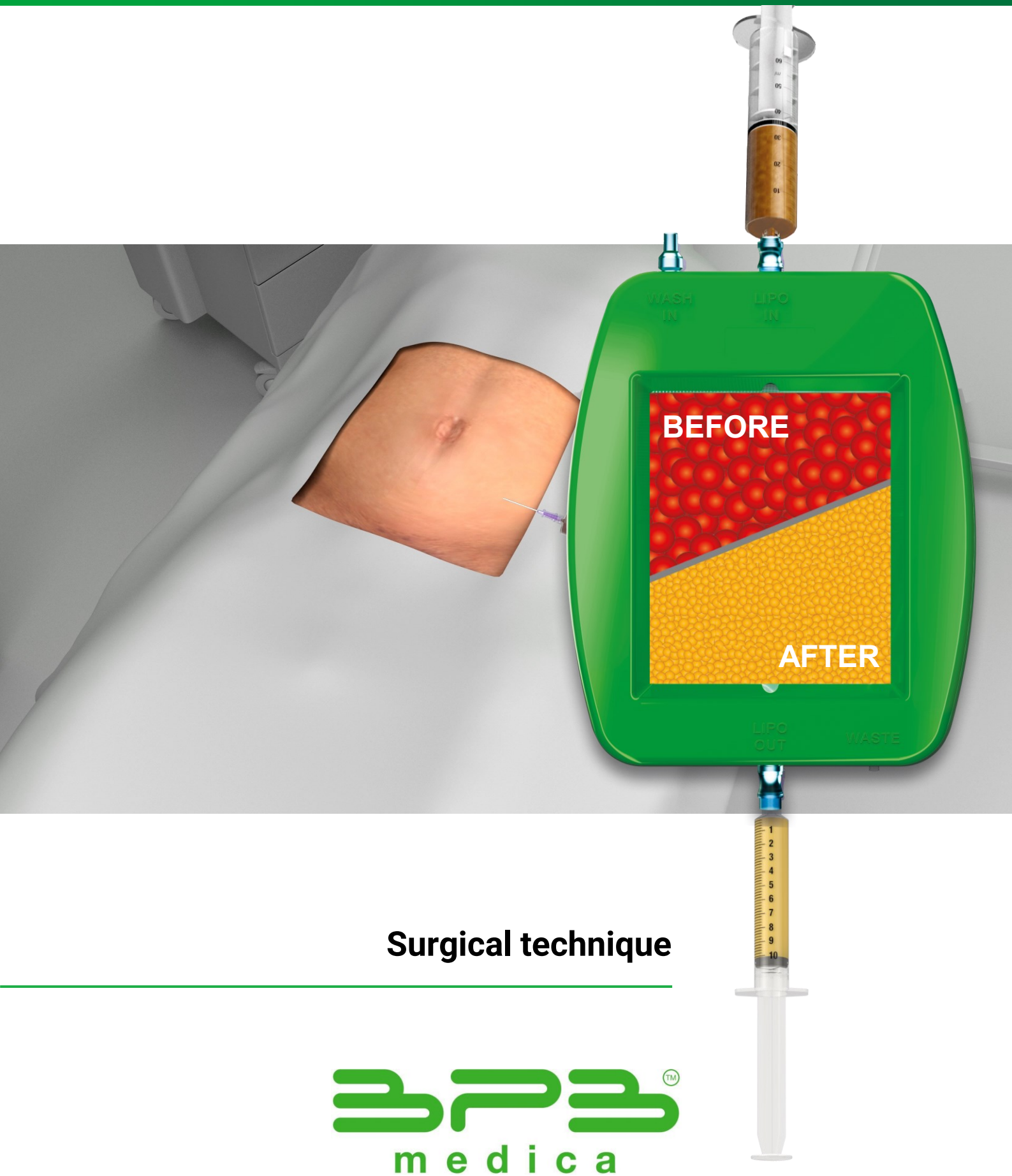
LIPO-STEM/DUO™

Microfragmentation, purification and processing kit for adipose tissue MSCs



Surgical technique

bps medica

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Our company

BPB MEDICA™ is an Italian manufacturing company specializing in the design, production and marketing of high-quality healthcare products for medical use and medical surgery devices.

BPB MEDICA™ was founded in 1999 by the Bellini family, boasting thirty year's experience in the biomedical sector. The founder, Carlo Bellini Sr., started the business in 1968 and has passed down ethics, integrity and spirit of sacrifice to his heirs. Today BPB MEDICA™ has leveraged its **50 years of experience** to develop new innovative product lines, growing the company on the international level.

BPB MEDICA™'s philosophy is to grow alongside the needs of patients, doctors and hospital staff in general. Backed by the experience acquired by the company's specialized technical personnel and thanks to newly-adopted technologies, BPB MEDICA™ has quickly managed to make a name for itself in the domestic and international markets.

50 YEARS
OF EXPERIENCE

70
COUNTRIES SERVED

OUR PRODUCT LINES:

SPINE

ORTHO-BIOLOGICS

ASSISTED REPRODUCTION

BIOPSY

INTENSIVE CARE

AESTHETIC

Our company

Cutting department

Moulding department

BPB MEDICA™ operates with state-of-the-art production machinery and equipment and **the entire production process is carried out in-house** (from design to final packaging).
As a manufacturing company, besides the traditional business model (BPB MEDICA™ -> DISTRIBUTOR), BPB MEDICA™ can also offer **OEM and private label services**.

Cleanroom

Thanks to the **internal R&D Department** BPB MEDICA™ conducts constant research on the reference pathologies to ever-better qualifying, improving its production standards and aiding the development of new products.

BPB MEDICA™ provides painstaking service to its clientele and its primary aim is product quality. The **internal Regulatory and Quality Departments** conduct rigorous tests, from the raw materials to the equipment and the finished product. This allowed the company to obtain **CE, ISO 13485** and the establishment registration by **FDA**.

ISO 13485
BUREAU VERITAS
Certification

FDA

CE 0123

OUR SERVICES:

- **ENTIRE IN-HOUSE PRODUCTION**
- **RESEARCH & DEVELOPMENT**
- **OEM & PRIVATE LABEL SERVICES**
- **MARKETING SUPPORT**
- **INTERNAL REGULATORY AND QUALITY DEPARTMENTS**
- **FOUR WEEKS DELIVERY**

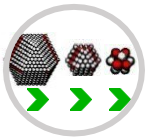
LIPO-STEM/DUO™

LIPO-STEM™ and **LIPO-STEM DUO™** are innovative, closed-circuit, disposable devices for collecting, microfragmenting and purifying lipoaspirate, intended for autologous implants without the use of enzymes or centrifuge.

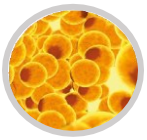
Thanks to a sophisticated system of filtering and washing chambers, LIPO-STEM™ and LIPO-STEM DUO™ preserve the entire vascular stromal niche architecture of the lipoaspirate and improve the cells' capacity to respond to regenerative stimuli.
The processing of adipose tissue takes place in the operating theatre with minimum handling in one single surgical session.

Both LIPO-STEM™ and LIPO-STEM DUO™ are provided with a dense mesh that retains the adipose tissue while washing it with saline solution and eliminating all the oily, blood and Klein solution residues which might cause inflammation on the treated tissues.
LIPO-STEM DUO™ is also equipped with an additional filter that microfragments the adipose tissue excluding the eventual fibrotic tissue from the processed adipose tissue.

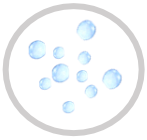
FEATURES:



MICROFRAGMENTATION
Progressive reduction of adipose clusters through a sophisticated filtering system.



TISSUE PURIFICATION
Blood, oil and Klein solution content complete removal from adipose tissue.



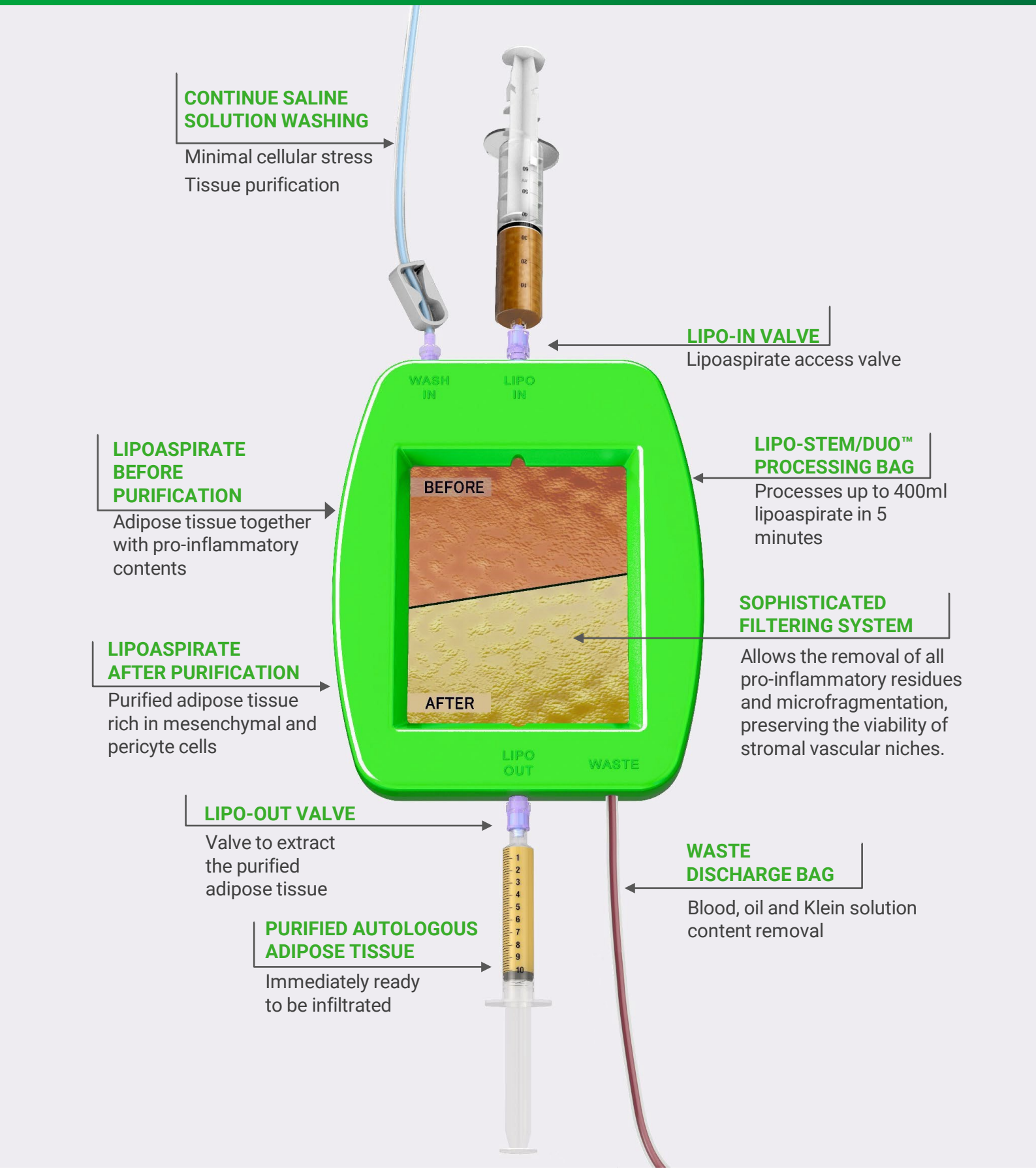
MINIMAL CELLULAR STRESS
Immersion in the saline solution to minimise cell trauma during fragmentation.

HIGH-QUALITY CELLS
Maintenance of the architecture of stromal vascular niches, rich in mesenchymal and pericyte cells.

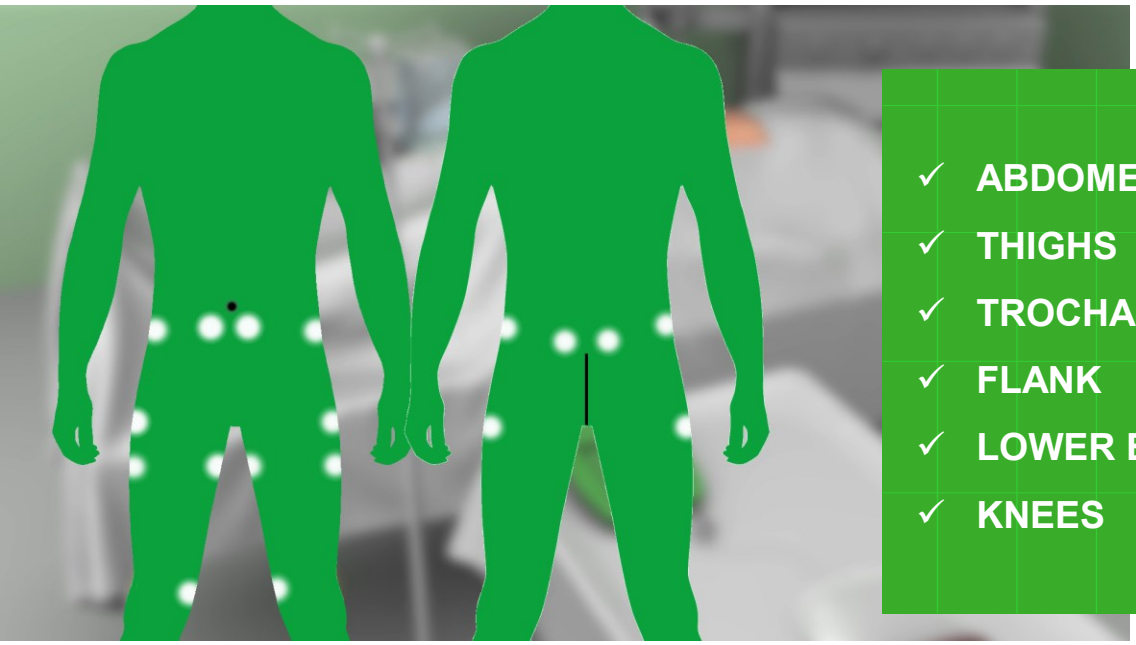
The gradual reduction of adipose clusters results in a vital natural scaffold that can be easily vascularised and, thanks to widespread cellular dissemination, facilitates the physiological regenerative process of tissues.
The resulting product is a fluid autologous adipose tissue that can be easily infiltrated into the injury site using small diameter needles.

Displayed device colours are indicative.

How does it work?



Pre-operative plan



- ✓ ABDOMEN (PREFERRED)
- ✓ THIGHS
- ✓ TROCHANTERIC REGION
- ✓ FLANK
- ✓ LOWER BACK
- ✓ KNEES

IDENTIFICATION OF THE ASPIRATION SITE

Adipose tissue can be aspirated via small liposuction from the subcutaneous tissue.

If the planned amount of lipoaspirate exceeds 60 ml, it is recommended to perform liposuction avoiding patient's asymmetries using symmetrical accesses; whilst for the periumbilical, just one access is possible, according to the amount of tissue to be harvested.

Depending on the patient, it may be possible to select other alternative aspiration sites.

PATIENT SETTING

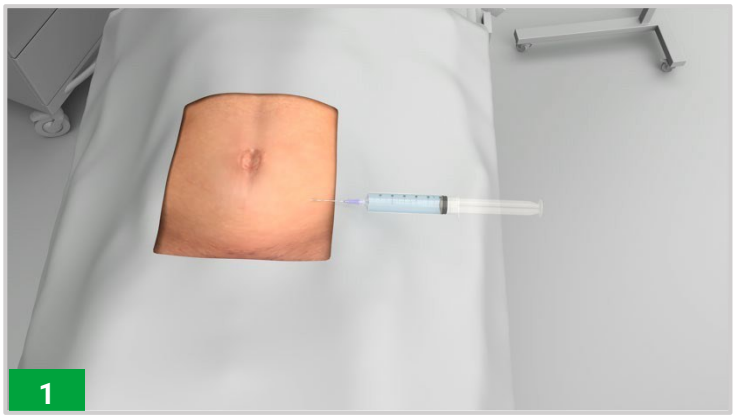
- Position the patient on the surgical bed according to the selected aspiration site and proceed with mild sedation if needed.

- Prepare the Klein solution: it causes local anaesthesia, accompanied by temporary vasoconstriction to reduce bleeding and allows to create the tumescence necessary for the liposuction.
  According to the patient's needs and comorbidities, fill a sterile bowl with:
  - 20 ml of 2% lidocaine
  - 0.5 ml of 1mg/ml adrenaline
  - 250 ml of saline solution

- Infiltrate about 150-200 ml of Klein solution; to obtain a lipoaspirate of more than 60 ml, infiltrate a larger volume of Klein solution maintaining the ratio of 3:1 (infiltrate: lipoaspirate).

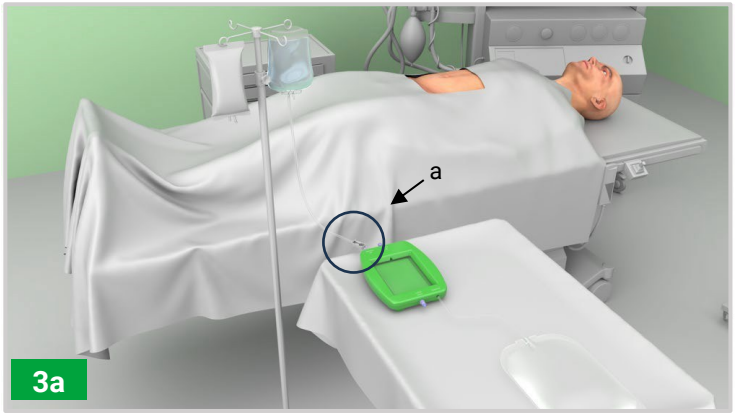
Surgical technique

In the abdominal area, inject 2 ml of 2% lidocaine and make a small incision approximately 10 cm laterally from the navel to facilitate insertion of the cannulas.



- Fill a 60 ml syringe with Klein solution, connect it with a 16G infiltration cannula and insert the cannula into the abdomen through the incision *(fig.1)*.
- Infiltrate the solution, using fan-shaped movements being careful not to make transverse movements. It is also advisable to place one hand on the abdomen to control the advancement of the cannula parallel to the skin.

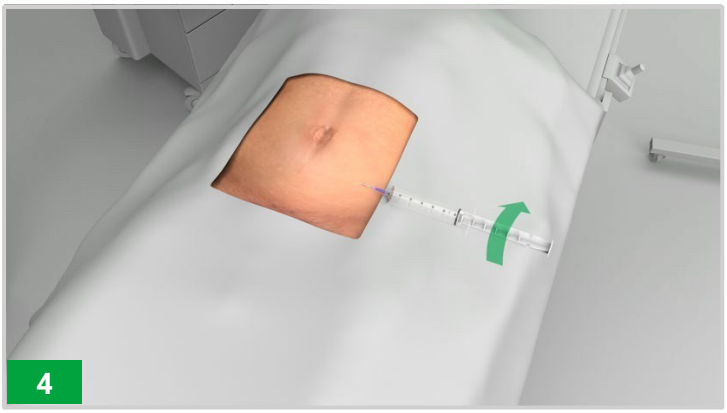
- Wait at least 7-8 minutes from the infiltration before proceeding with the aspiration of the adipose tissue.



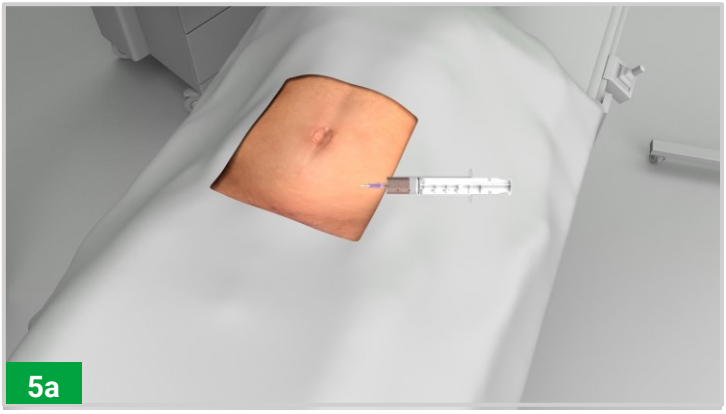
- Hang 1 litre of saline solution to a stand and connect the bag to the device's WASH IN valve *(fig. 3a)*.
- Open the clamp connected to WASH IN *(fig. 3-a)* to fill the LIPO-STEM™ or LIPO-STEM DUO™ device with the saline solution while getting the waste tube closed with the open clamp provided into the kit *(fig.3b)*, taking care, immediately after, to let all the air out.

- We suggest keeping the device in a vertical position while filling it with saline solution, to facilitate the complete release of the air.

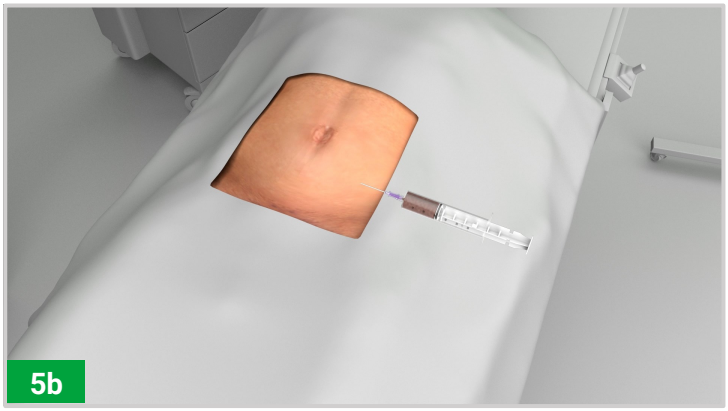
Surgical technique



- Connect the lipoaspiration cannula (13G) to a 60 ml VacLok syringe.
- Enter through the incision, maintaining your hand on the abdomen.
- With the cannula inserted in the subcutis, pull the VacLok plunger and rotate it to block the plunger, thus creating a negative internal pressure *(fig.4)*.



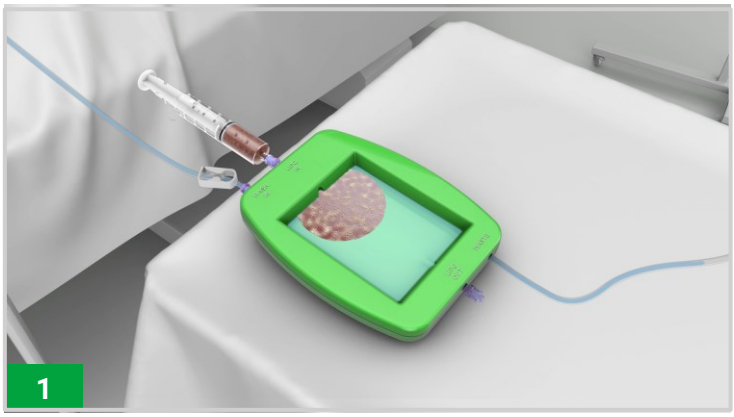
- Proceed to lipoaspiration from areas previously infiltrated carrying out fan-shaped movements while avoiding transverse movements *(figg.5a – 5b)*.



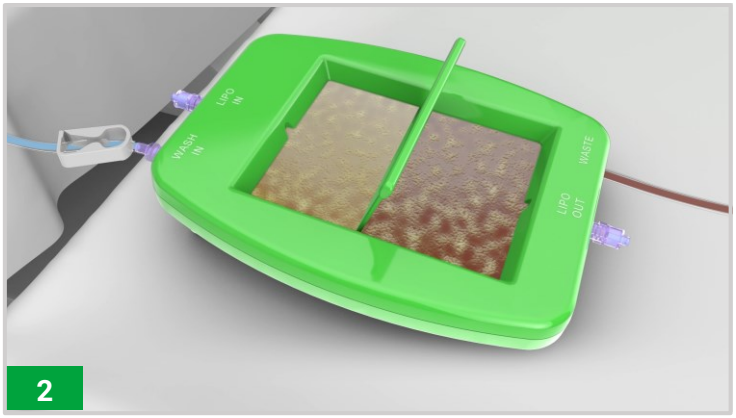
- Once the expected amount of lipoaspirate has been reached, extract the cannula from the patient and, if necessary, proceed with the application of the sutures.

If the planned amount of lipoaspirate exceeds 60 ml it is necessary to proceed with a bilateral approach.

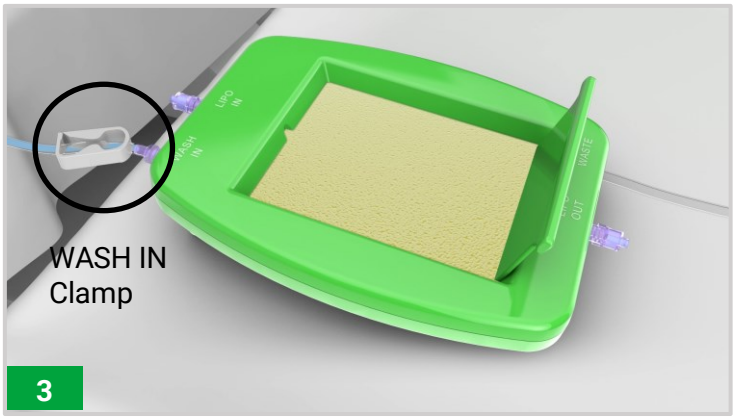
Processing



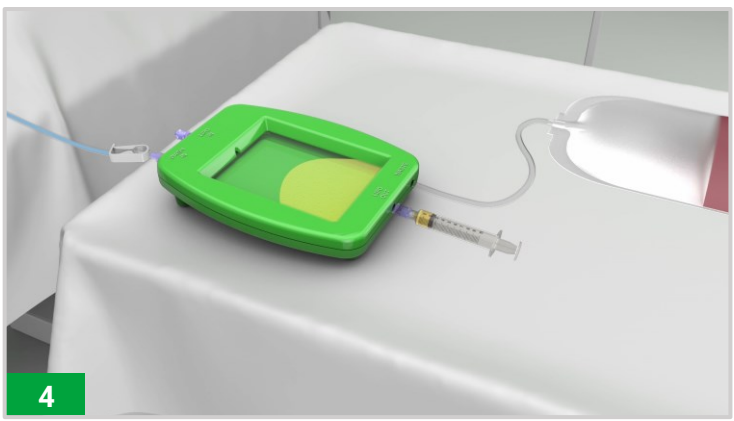
- Introduce the lipoaspirate from the device's "LIPO IN" valve into the processing bag previously filled with saline solution *(fig.1)*.



- Gently move the provided spatula on the filters to microfragment the adipose tissue and facilitate the complete washing of the tissue, eliminating all oily, bloody and Klein solution pro-inflammatory residues *(fig.2)*.



- Continue until the adipose tissue becomes pale yellow and the connection tube to the waste bag flushes clear liquid *(fig.3)*.
- Close the clamp connected to "WASH IN" to stop the saline solution flow and remove, with the help of the spatula, any excess solution.



- Connect the 10 ml syringe to the device's "LIPO OUT" valve and withdraw the obtained adipose tissue *(fig.4)*.
- The resulting product is an autologous adipose fluid tissue that can be easily infiltrated into the site to be treated using small-diameter needles. LIPO-STEM™ kit is provided with a 16G infiltration needle, while LIPO-STEM DUO™ (that performs microfragmentation) is provided with a 20G infiltration needle.

- At the end of the operation, it is recommended to apply compressive dressings to the patient to limit bruising. Keeping a compression garment for few days will limit this phenomenon.

Fields of application

ORTHOPAEDICS

WOUND CARE

MAXILLOFACIAL SURGERY

PLASTIC, RECONSTRUCTIVE AND AESTHETIC SURGERY

SPINAL SURGERY

UROGYNAECOLOGY

PAIN THERAPY

COLOPROCTOLOGY

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ISO 13485 BUREAU VERITAS Certification
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