

st'RIM

Patent pending

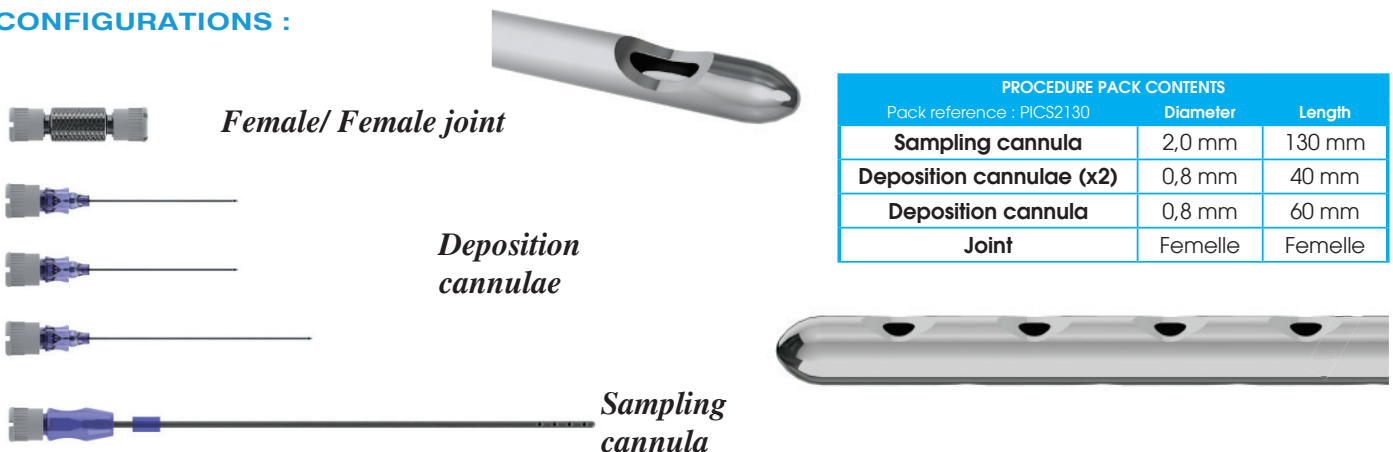
Procedure Pack
for Micro Fat Transfer

INDICATIONS :

st'RIM procedure pack is suitable for micro fat transfer technique used to model the outline of a person's figure.

Micro re-injections increase the possibilities for use of autologous fat and enable to widen indications in reconstructive surgery: improvement of scars, burn marks, scleroderma.. but also in cosmetic surgery where autologous fat becomes the best filling product not only for its volumetric efficiency but also for its long term trophic qualities.

CONFIGURATIONS :



The patented geometry of the orifices was designed specifically to obtain a harvested fat that is composed of volume calibrated cell units.

The size of the sampling cannula orifice's and the size of the deposition cannula orifice's are fitting to the size of the smallest viable unit of fat cells.

Each canula can be bent to adapt it to anatomical outlines.

cannula have inner surface treatment and external surface treatment to insure the integrity of the host tissue and of the graft tissue.

SURGICAL QUALITIES :

st'RIM Single-use sterile procedure pack strictly comply with surgical aseptic requirements to prevent any cross-contamination by micro-organisms or by residual tissue.

st'RIM offers constant high-level performances and surgical qualities, without any risk of deterioration linked to re-use.

st'RIM single-use products generate genuine savings compared to the use and risks of re-usable equipment.

STERILITY AND PACKAGING

- Sterile single use device
- Sterilized with ethylene oxide according to ISO11135 standard
- Box of 5 units
- Shelf-life: 5 years
- Avoid storage at extreme temperatures and humidity
- Packaging: double package

REGULATIONS - CE MARKING

- Device of class IIa according to the European directive 93/42/CEE modified by the directive 2007/47/CE
- Notified body: GMED
- ISO 9001: certificate n° 12104 rev.2
- ISO 13485: certificate n° 12107 rev.2
- Device made in France by the Thiebaud company
- GMDN Code: 36107
- CE Marking: 2010
- Does not contain latex
- Does not contain any biological component

SUP311D



THIEBAUD BIOMEDICAL DEVICES

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MICRO RE-INJECTIONS OF AUTOLOGOUS FAT

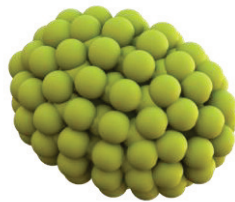
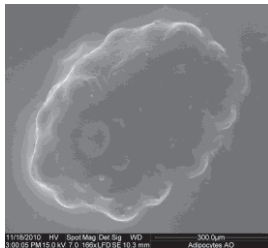
SURGICAL TECHNIC BY PR. MAGALON

Most of the time, the intervention is performed under local anaesthesia, sometimes under regional or general anaesthesia.

1. Infiltration-Sampling

The first step consists in anaesthetising the entry point with Xylocaine 1% with adrenaline.

Use a 3cc-syringe and a 30 Gauge needle. The entry point is made with a 14 gauge (2mm) needle. The microsampler (harvesting cannula) is used for the infiltration and sampling. For the infiltration we use Xylocaine 1% with adrenaline which can be diluted 3 or 4 times with physiological serum. Sampling is performed using a 10cc-syringe with a low suction technique with less than 1cc vacuum.



Gauged fat parcel obtained with microsampler.
Aproximative size 600 x 400 μM. Number of adipocytes : about 170.



Centrifugation

Sampling is then centrifuged during 3 minutes at 3000 rpm. The lower space containing the infiltration liquid is then emptied. Normally, there isn't any oil. A female-female joint enables to transfer the fat from the 10cc-syringe to 1cc-syringes. It is important to place the joint on the full 10 cc-syringe and to let fat show on the edge of the joint before placing the 1cc-syringe to fill it up, so as to avoid air bubbles.



2. Reinjection

The entry points are anaesthetised with Xylocaine 1% with adrenaline. It's not necessary to anaesthetise the area where the fat tissue is going to be re-injected. The corneal layer is pierced with a 21 gauge- or 0.8mm-needle, the position of the needle is that in which we want to introduce the dropper (deposition micro cannula). The intervention is going to follow the steps defined in advance. It is possible to make several layers and to cross them as micro grafts are about 700 microns and contain several hundred cells. The small size of samples enables to deposit the fat superficially as close as possible to the dermal layer. This technique is non-invasive. It was made possible thanks to very high quality material whose characteristics have been validated by many experimental studies.



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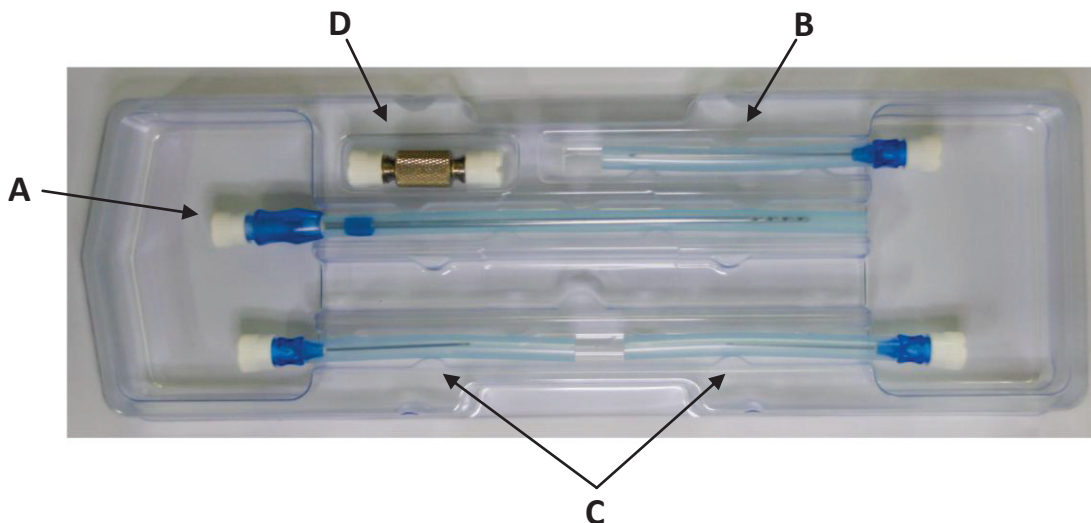
SURGICAL PROCEDURE PACK FOR MICRO FAT TRANSFER

1 Microsampler 2 mm 14 G / 130 mm (A)

1 Dropper 0,8 mm 21 G / 60 mm (B)

2 Dropper 0,8 mm 21 G / 40 mm (C)

1 Female / Female connector (D)



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