REGENERATIVE & ORTHO-BIOLOGICS

BPB medica

INDEX

OUR COMPANY

BPB MEDICA™ is an Italian manufacturing company specialized in the design, production and marketing of high qualitative 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, started the business in 1968 and has passed down to his heirs ethics, integrity and spirit of sacrifice. Today BPB MEDICA™ has leveraged its **50 years experience** to develop new innovative product lines, growing the company on 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 on the domestic and international markets.

50 YEARS
EXPERIENCE

70
COUNTRIES SERVED

OUR PRODUCT LINES:

- SPINE SURGERY
- ORTHO-BIOLOGICS
- ASSISTED REPRODUCTION TECHNOLOGY
- INTESIVE CARE
- BIOPSY

Cutting department

Molding 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, beside the traditional business model (BPB MEDICA → DISTRBUTOR), BPB MEDICA™ can also offer **OEM and private label services.**

Clean Room

Thanks to the **internal R&D Department** BPB MEDICA™ conducts constant research and avails itself of scientific consultancy of influential physicians in the reference pathologies with an aim to ever better qualifying and improving its production standards and aiding the development of new products.

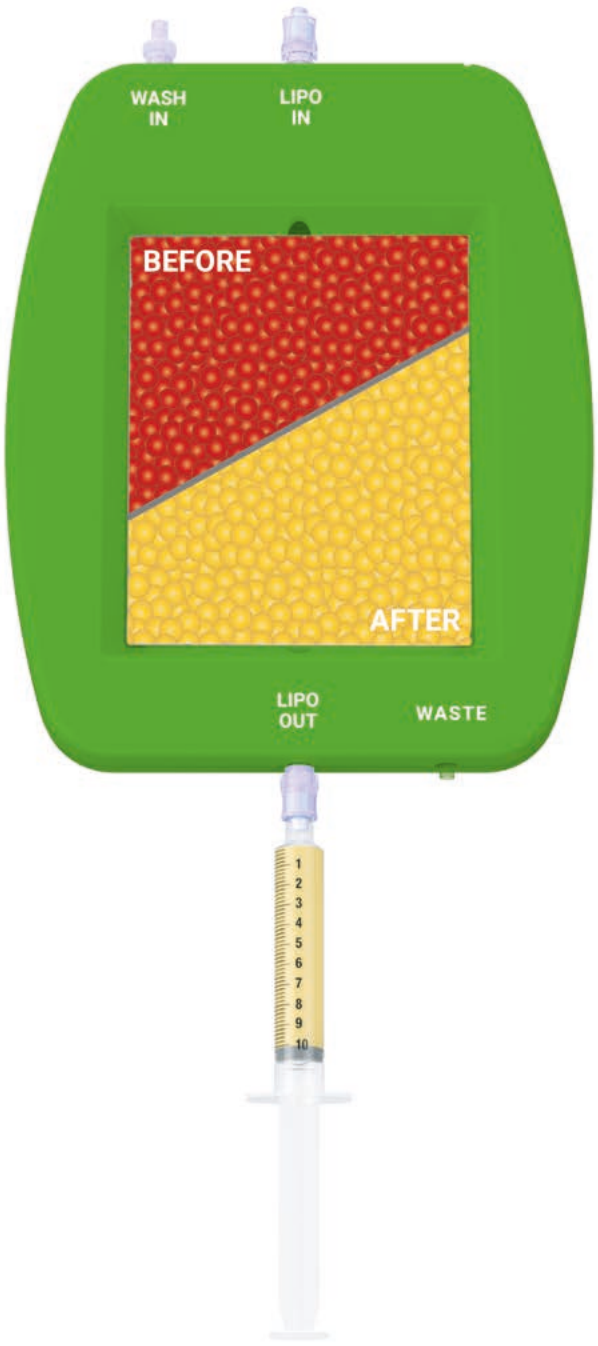
BPB MEDICA™ provides painstaking service to its clientele and its primary aim is product quality. The **internal Regulatory and Quality Departments** conducts rigorous tests, from the raw materials to the equipment and the finished product. This allowed the company to obtain **CE, ISO 13485** and the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

OUR SERVICES:

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

LIPO-STEM

PURIFICATION AND BANKING KIT FOR ADIPOSE TISSUE AND RELATED CELLS



LIPO-STEM is a closed-circuit single-use kit for liposuction and processing of adipose tissue in an operating theatre (also in one-step surgery procedures) which avoids any centrifugation.

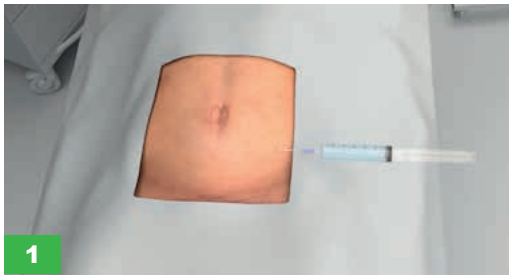
The entire processing phase of the liposuctioned tissue occurs inside the device as a result of continuous saline solution washing. This allows the reduction of stress to cells, eliminating any traumatic action that may damage the extracellular matrix and its essential trophic and anti-inflammatory function.

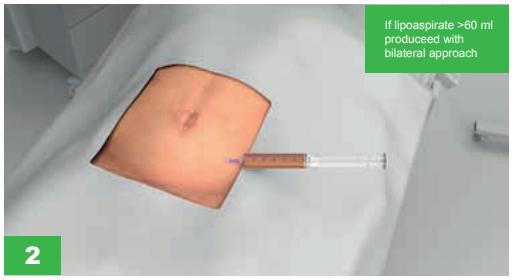
The collection and processing bag is equipped with two membranes. The first's >500 µm mesh microfragments the drawn tissue and reduces the size of the adipose cluster, preserving its biological properties and maximising the regenerative potential. The second, with a 50 µm mesh, retains the reduced (microfragmented) adipose cluster that is washed with saline solution, eliminating all the oil and blood residues which might cause inflammation of the treated tissues.

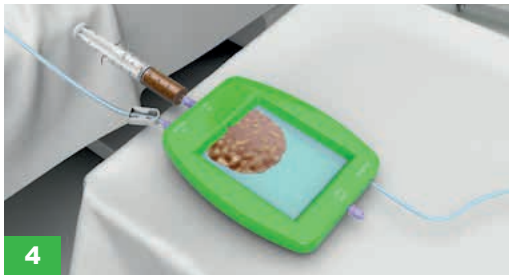
The final microfragmented and purified product is a viscous fluid that can easily be injected into tissues or joints with thin 28/30G needles. The end product is a compound and purified microfragmented autologous adipose tissue that keeps the biological properties of the original tissue intact. The whole extracellular matrix acts as a natural structure for the cells, increasing their vitality and contributing to the natural tissue.

FIELDS OF APPLICATION:

- ORTHOPAEDICS & SPORT MEDICINE
- PAIN THERAPY
- SPINAL SURGERY
- VULNOTHERAPY
- MAXILLOFACIAL SURGERY
- PLASTIC AND RECONSTRUCTIVE SURGERY
- GENERAL /UROGYNAECOLOGICAL SURGERY







BENEFITS:

- Adipose tissue microfragmentation.
- Complete kit for sampling and processing adipose tissue and mesenchymal cells.
- No centrifugation required.
- Compete preservation of tissue architecture and stromal niche components.
- Reduced stress during processing in order not to alter the biochemical properties of the cellular tissue and preserve the extracellular matrix (thanks to the physiological fluid).
- Total purification of blood and oily waste as potential cause of inflammation.
- Minimal manipulation of the cellular structure thanks to a simple and reproducible technique in a single surgical washing and microfragmentation time.
- Sampling and processing in a sterile closed-circuit environment that allows adipose tissue banking and cryopreservation.

SURGICAL TECHNIQUE:

1. Infiltrate the Klein solution in the selected harvest site using the 16G Klein cannula
2. Harvest the adipose tissue from the anesthetized area using the 13G aspiration cannula
3. Connect a 2L saline bag to the Lipo-stem "**WASH IN**" valve
4. Insert the harvested adipose tissue in the Lipo-stem "LIPO IN" valve
5. Support the purification of the adipose tissue using the spatula
6. Once the final product acquires a clear yellow colour, retrieve it from the dedicated "**LIPO OUT**" valve and use as needed

STANDARD KIT COMPOSITION:

- No. LIPO-STEM system with filtrating bag + waste bag
- No. 1 Infusion with clamp
- No. 1 Klein cannula 16G
- No. 1 Lipo-aspiration cannula 13G
- No. 1 Cannula 16G x 50mm
- No. 2 Combi caps LLF/LLM
- No. 2 Luer connectors LLF/LLF
- No. 2 VacLok syringes 60ml
- No. 2 Syringes 60ml
- No. 2 Syringes 10ml
- No. 2 Syringes 3ml

MARROW-STEM

BONE MARROW MESENCHYMAL STEM CELLS ASPIRATION KIT

MARROW-STEM is a disposable device for the selective aspiration of mesenchymal cells from the bone marrow which, with its innovative features, optimises the cellular yield and minimises the contamination of peripheral blood thanks to a micrometric system for lateral aspiration and the closet distal tip of the **Trocar**

INNOVATIVE

Thank to the closed distal tip and selective lateral micrometric aspiration a **high cellular yield related to a reduced volume of marrow aspirate**.

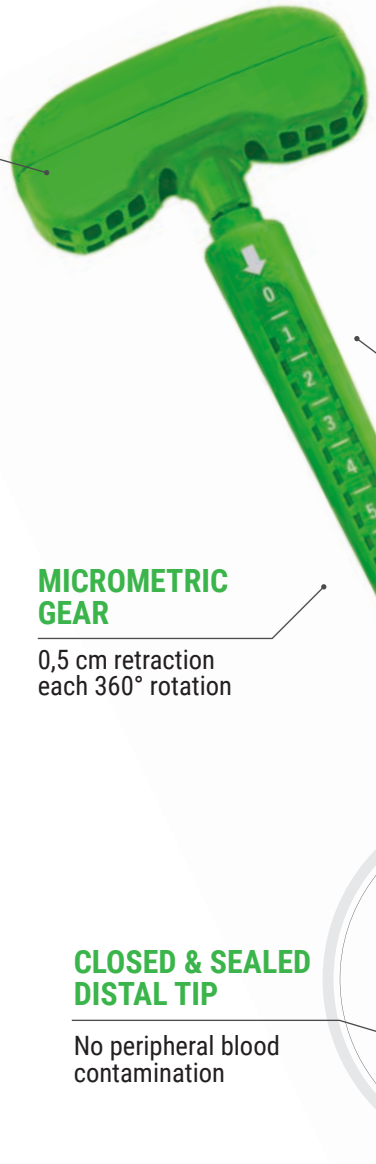
EASY

The selective micrometric aspiration device allows, in a few steps, the aspiration of **high-quality marrow aspirate**

CONVENIENT

Centrifugation is not needed, saving on time, personnel and tools.

FEATURES:



SINGLE STEP DEVICE

Faster and easier procedure

CENTRIFUGE FREE

Reduction in time, cost, operating theatre personnel

MICROMETRIC GEAR

0,5 cm retraction each 360° rotation

CLOSED & SEALED DISTAL TIP

No peripheral blood contamination

LATERAL ASPIRATION

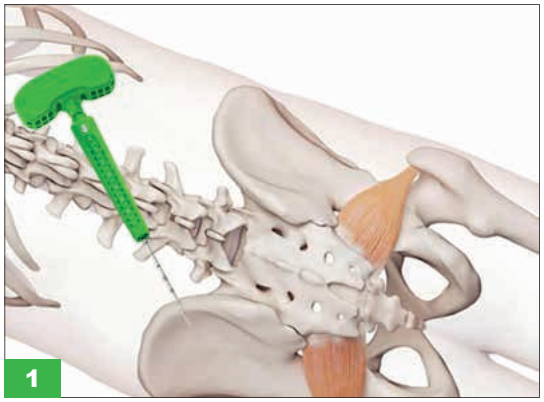
High cellular yield related to a reduced volume of marrow aspirate

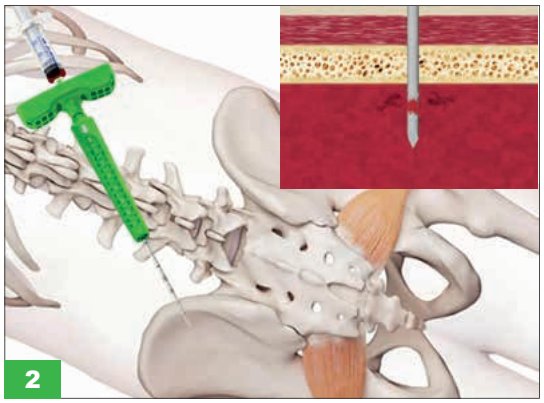
KIT INCLUDES:

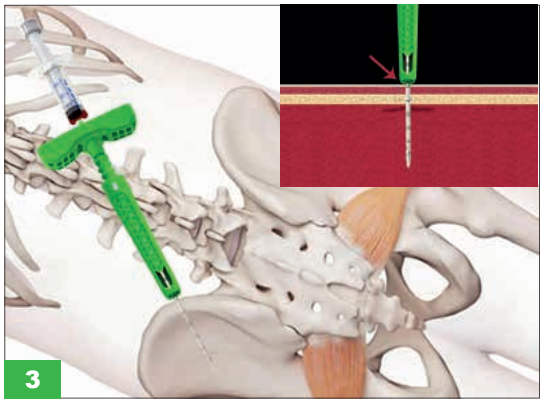
Aspiration syringe

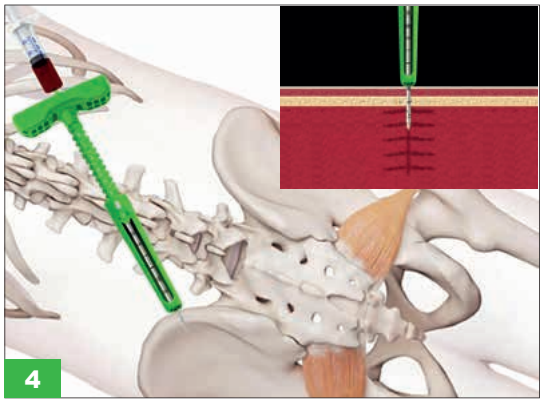
Filtering system

Injection syringe









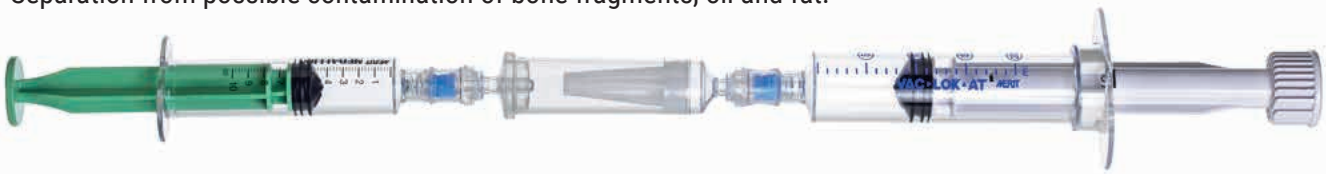
BENEFITS:

- Allows for a single sampling hole for the micrometric collection of high-quality bone marrow from multiple sites within the most suitable anatomic sampling region.
- Guarantees multiple multidirectional aspirations from the same sampling site.
- Ensures sampling of both pure stem cells and progenitor cells at the same time, preventing possible. contamination from peripheral blood thanks to the closed tip and lateral recruitment.
- Suitable for marrow sampling from the anterior and posterior iliac crest, the vertebral body, the tibial plate and the distal femoral access.
- The filter makes it possible to purify the marrow from oily res dues and bone fragments.
- Reduced number of surgical steps.
- Single-use and non-reusable.
- No centrifugation required, and a reduced volume of bone marrow is necessary for aspiration.

SURGICAL TECHNIQUE:

1. Introduce Marrow-Stem tip at least 2 cm beyond the cortical.
2. Remove the internal stylet, connect the VacLok syringe and aspirate the first cc of marrow.
3. Introduce the cannula till preferred depth and adjust the gear until in contact with the skin.
4. The rotation of the handle retracts the cannula 0,5 cm allowing to aspirate from a fresh site, with no peripheral blood contamination.

Separation from possible contamination of bone fragments, oil and fat.



FIELDS OF APPLICATION:

The bone marrow aspirated with **MARROW-STEM** can be injected to accelerate the natural healing process, or can be combined to other kind of bone substitute to create an enhanced bone graft.

BONE MARROW MSC CONCENTRATE

INDICATIONS:

- BONE CYSTS
- INTRAARTICULAR INFILTRATION
- TENDINOPATHY
- PAIN REDUCTION (FACET JOINTS)

BONE MARROW ASPIRATE + ANY KIND OF BONE SUBSTITUTE

INDICATIONS:

- SPINAL FUSIONS
- BONE MARROW LESIONS
- FOOT & ANKLE FUSIONS

BONE MARROW ASPIRATE + AUTOLOGOUS BONE DOWEL

INDICATIONS:

- AVASCULAR NECROSIS
- BONE MARROW LESIONS
- BONE REGENERATION
- TRAUMA PROCEDURES & FRACTURES

STANDARD KIT COMPOSITION:

- No. 1 MSC aspiration device
- No. 270 µ filter
- No. 1 VacLok AT syringe 20ml
- No. 1 Injection syringe 10ml

UNLUX SYSTEM

CREEPING SUBSTITUTION

Creeping substitution is the process of remodelling a bone graft.

UNLUX SYSTEM allows the removal of an osteomedullary core sample from the iliac crest with a low risk of infection and low invasiveness for the patient, obtaining an autologous bone graft with osteoconductive, osteoinductive and osteogenetic properties.

This procedure may be further enhanced in combination with **MARROW-STEM**: by mixing the selective aspirate of mesenchymal stromal cells with an autologous bone dowels, in addition to any other bone substitute of animal, homologous or synthetic origin, the creeping substitution process shall be accelerated.
The result will therefore be an extremely strong graft, like a vascularised graft, capable of achieving a very fast regeneration rate and being of high quality with an extremely high density.

BENEFITS:

- Minimally invasive harvesting of intact bone dowels.
- Low risk of infection and low invasiveness for the patient.
- Single access point.
- Autologous bone graft with osteoconductive, osteoinductive and osteogenetic properties.
- Very fast bone regeneration rate thanks to the combination of the autologous bone dowels with the selective aspirate of mesenchymal stromal cells.
- High bone quality and dense, mature bone remodelling.
- Restoration of the anatomy and function of the bone site.

SURGICAL TECHNIQUE:

1. Sampling of pure mesenchymal cells and progenitor cells following **MARROW-STEM** surgical technique.
2. By using the same access point, remove a spongy bone graft using the **UNLUX SYSTEM** device.
3. Mix the mesenchymal stromal cell aspirate with the bone substitute (of animal, homologous or synthetic origin) and envelop the autologous bone dowels.
4. Place the enhanced graft at the lesion site.

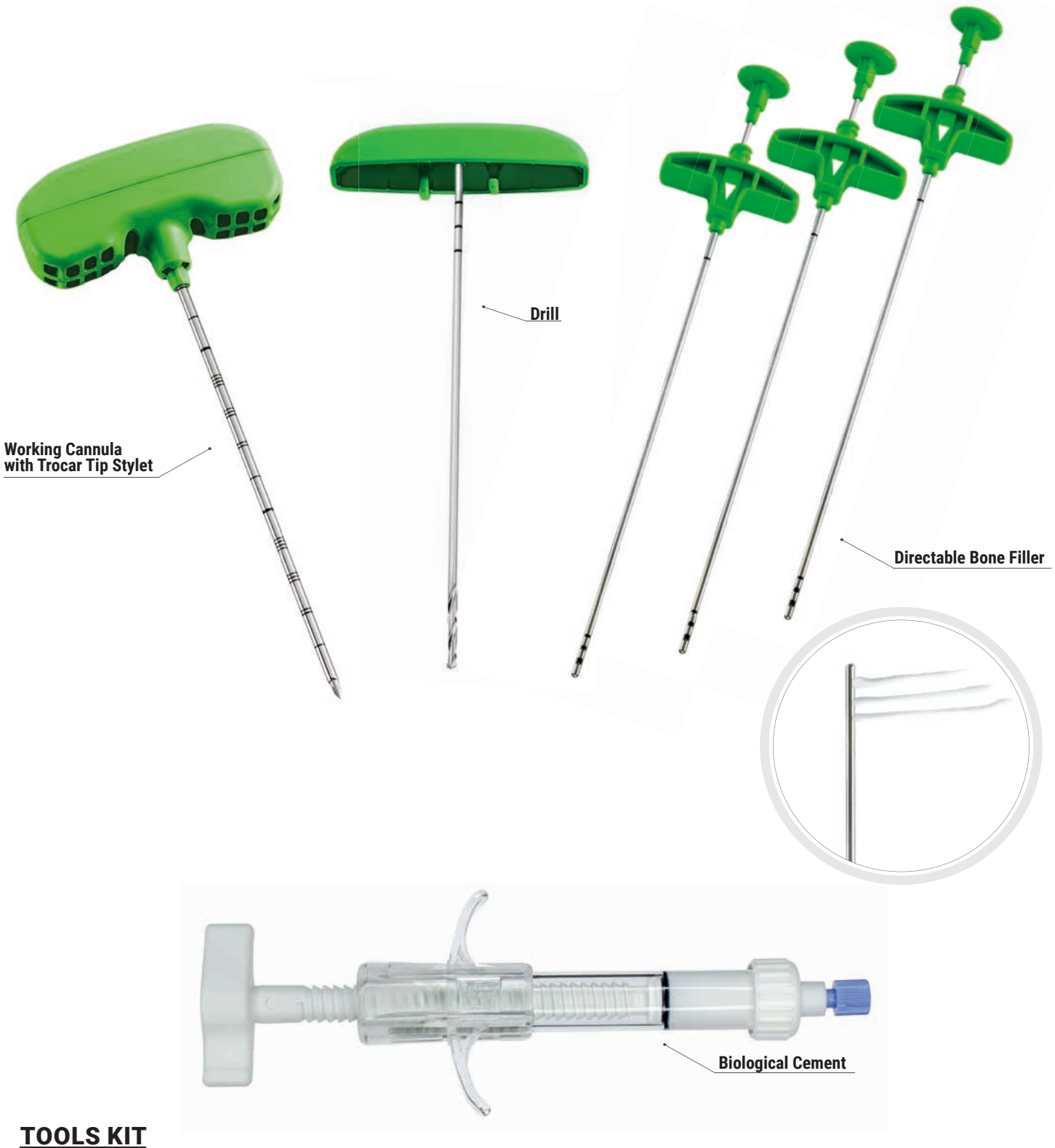
ENHANCED VASCULARIZED GRAFT

BONE MARROW MSC CONCENTRATE + **AUTOLOGOUS BONE DOWEL** + **ANY KIND OF BONE SUBSTITUTE**

ORTHOPLASTY

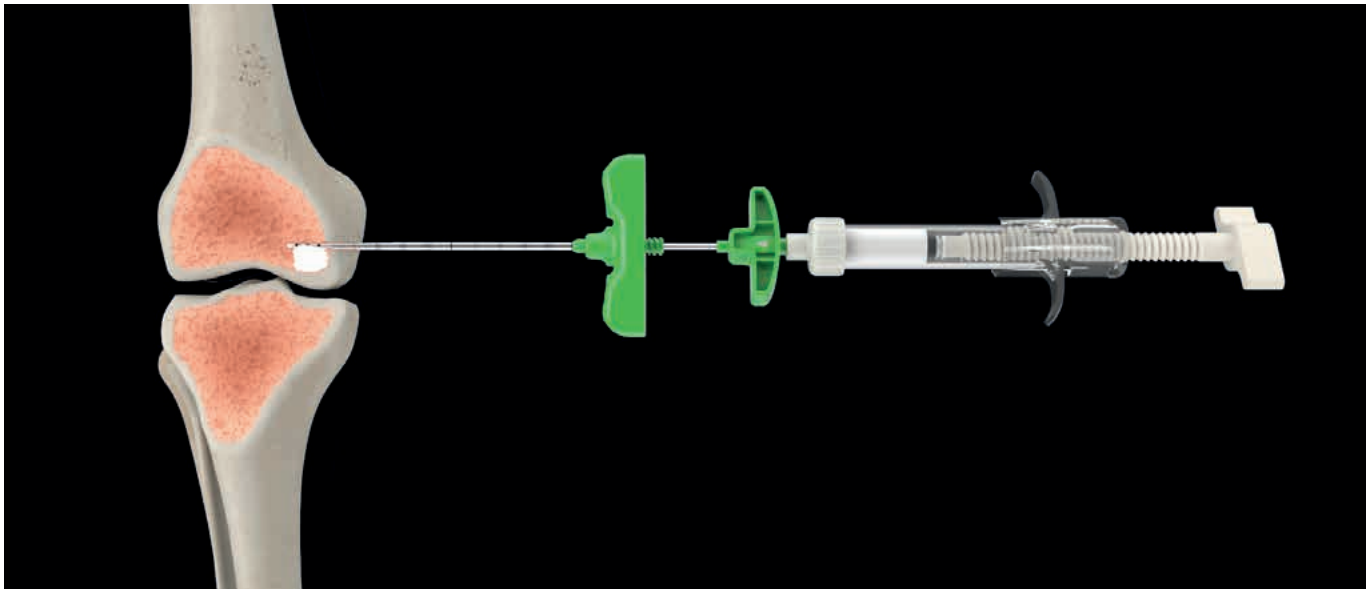
SUBCHONDRAL BONE PLASTY

Subchondral bone plasty is a minimally-invasive, fluoroscopically-assisted procedure that identifies and repairs subchondral bone defects, also known as Bone Marrow Lesions (BML). It is commonly executed in conjunction with arthroscopy to target and manage of findings inside the joint.



TOOLS KIT

***Can be sold without biological cement**



BENEFITS:

- Safe and precise MIS Approach.
- Reduces risk of infections.
- Ready-to-use bone substitute, no preparation needed
- Hardens in wet environment only: no time pressure during application.
- Truly biologic: composed of a micro-crystalline, calcium-deficient hydroxyapatite – the primary component of bone.
- Supports load-sharing properties (up to 45 MPa).
- Radiopaque paste: clearly visible under fluoroscopy and X-rays.
- Fast recovery after treatment.
- Bioresorbable during bone remodelling.

SURGICAL TECHNIQUE:

1. Identify the Bone Marrow Lesion (BML) using a fat-suppressed MRI (T2) and choose the optimal approach and trajectory.
2. Through intraoperative fluoroscopy, target the defect associated with the Bone Marrow Lesion (BML) linked to the MRI results.
3. Access the bone defect using Orthoplasty access tools kit.
4. Fill the bone defect with INNOTERE Paste-CPC under fluoroscopic guidance.

STANDARD KIT COMPOSITION:

- No. 1 Working Cannula + Trocar Tip Stylet
- No. 1 Drill
- No. 3 Directable Bone Filler
- No. 1 Biological Cement*

*** Can be sold without biological cement**

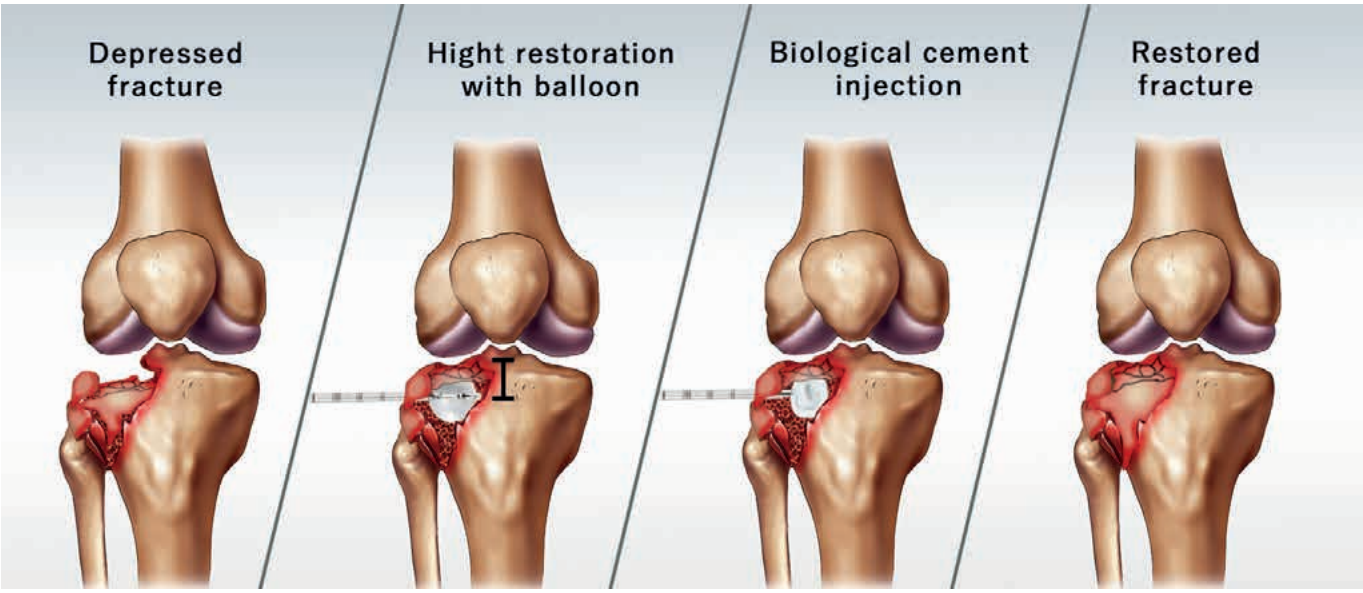
OSTEOPLASTY

METAPHYSEAL BALLOON AUGMENTATION

Osteoplasty kit is a minimally invasive system for reducing and restoring bone height and alleviating related pain in different types of fracture, such as tibial plateau, calcaneus and distal radius injuries.

Tools Kit

***Can be sold without biological cement**



BENEFITS:

- Totally minimally-invasive solution.
- Useful for bone height restoration.
- Without plating techniques: applicable for non-load bearing defects.
- With plating techniques: applicable for load bearing defects.
- Reduced risk of infection.
- Ready-to-use bone substitute, no preparation needed.
- Hardening in wet environment only: no time pressure during application.
- Truly biologic: composed of a micro-crystalline, calcium-deficient hydroxyapatite – the primary component of bone.
- Supports load-sharing properties (up to 45 MPa).
- Radiopaque paste: clearly visible under fluoroscopy and X-rays.
- Fast recovery after treatment.
- Bioresorbable during bone remodelling.

SURGICAL TECHNIQUE:

1. Identify the best surgical trajectory.
2. MIS access to the entry point through cannula and trocar stylet under fluoroscopic guidance.
3. Remove the stylet from the cannula and insert the drill under the depressed area of bone.
4. After removing the drill, insert and inflate the inflatable balloon catheter through the cannula centred at the area of depressed fragments.
5. Once the injury has been adequately reduced, deflate and remove the catheter balloon from the cannula.
6. Fill the created cavity with bone substitute until the space is completely filled under fluoroscopic guidance.
7. Plating may be implemented before or after the filling of bone substitute.

STANDARD KIT COMPOSITION:

- No. 1 Working Cannula + Trocar Tip Stylet
- No. 1 Drill
- No. 3 Bone Fillers + 3 Syringes (2,5 ml)
- No. 1 Balloon Catheter (10 mm or 15mm or 20mm)
- No. 1 Digital Inflation Device
- No. 1 Biological Cement*

*** Can be sold without biological cement**

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