REGENERATIVE & ORTHO-BIOLOGICS

BPB medica

INDEX

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 years of 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.

1968 — MEDICAL BUSINESS BEGINNING: The founder, Carlo Bellini Sr, started his business in the medical field, founding some of the most important companies of our medical district

1999 — BIOPSYBELL S.r.l. FOUNDATION: Carlo Bellini Sr's daughter founded Biopsybell S.r.l.: Biopsy as the initial core business and Bell as the Bellini family name.

2008 — THIRD GENERATION OF THE FAMILY: Carlo Bellini, founder's nephew, joined the company and focused on export sales development.

2012 — THE EARTHQUAKE: The company was damaged by a heavy earthquake: the family worked hard to keep the production open. After only 2 weeks from the EQ, the company was back in business.

2014 — SPINE SURGERY: Development and launch of Spine product line.

2015 — EXPORT EXPANSION: Export success: 41 foreign countries served (35%TNR).

2016 — NEW SITE: The intensive growth of the last few years required a new and bigger production site.

2018 — A.R.T. LINE: Development and launch of Assisted Reproduction product line.

2019 — EXPORT ORIENTED: 70 country served (70% TNR).

2020 — REGENERATIVE & ORTHO-BIOLOGICS: Development and launch of Regenerative Medicine & Ortho-Biologics product line.

2020 — AESTHETIC LINE: New production line for Aesthetic and Reconstructive surgery.

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.

OUR NUMBERS

50 YEARS
OF EXPERIENCE

70
COUNTRIES SERVED

500
CUSTOMERS

10.000.000
PROCEDURES
performed with our devices

OUR PRODUCT LINES

- SPINE SURGERY
- ORTHO-BIOLOGICS
- ASSISTED REPRODUCTION
- BIOPSY
- INTENSIVE CARE
- AESTHETIC

BPB MEDICA™ provides painstaking service to its clientele and its primary aim is product quality. Our **internal Regulatory and Quality Departments** offer full-service support to our customers in the following activities:

- Quality Systems
- Regulatory Affairs
- Technical documents preparation
- Clinical experimentation
- Vigilance
- Formation
- OEM and Private Label regulatory and quality support

Our **Quality Department** 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.

Thanks to the **internal R&D Department**, BPB MEDICA™ conducts constant research in the reference pathologies with an aim to ever-better qualifying and improving its production standards and aiding the development of new products. Functional tests are performed by **R&D Department** in concert with Quality Department to demonstrate the product performance and to make sure that new products maintain their functional characteristics even in the worst case.

BPB MEDICA™ is an established and experienced contract medical equipment manufacturer, with:

- Advanced ISO 8 cleanroom facility for manual & automatic assembly and packaging.
- Metal refinishing department for cutting, grinding, sharpening, cleaning, echogenic marking, sealing, and reduction.
- Moulding department with vertical and horizontal moulding machines.
- Computerised warehouse with top-selling items always available in stock ready to be shipped within 24 hours.

OUR SERVICES

QUALITY & REGULATORY DEP.
Our primary aim is product quality together with painstaking service. Our regulatory and quality teams conduct rigorous tests to this purpose.

OEM & PRIVATE LABEL SERVICES
À la carte production, with customer's brand name and custom colour. Full-service support of Regulatory and Quality documentation.

RESEARCH & DEVELOPMENT
Constant research to increase production and quality standards while developing new products.

MARKETING SUPPORT
Video tutorial, case report, presence at the major medical congresses, organization of training and courses.

PRODUCTION PROCESS CONTROL
Complete manufacturing process carried out internally, from design to final packaging.

FOUR WEEKS DELIVERY
Thanks to the optimization of the production process, we satisfy our customer's orders within 4 weeks.

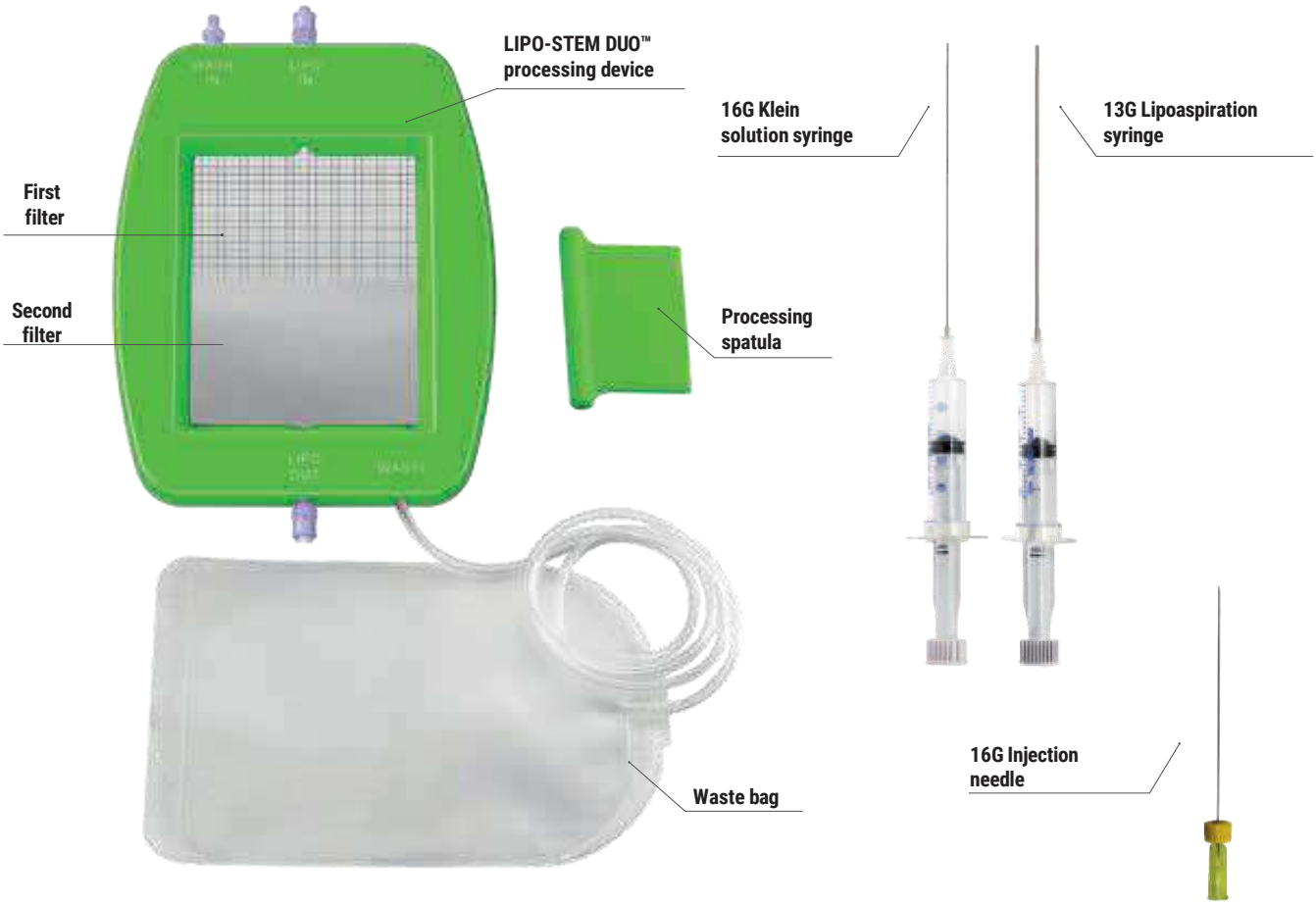
CUTTING, GRINDING & ELECTROPOLISHING

CLEANROOM

MOULDING DEPARTMENT

LIPO-STEM DUO™

MICROFRAGMENTATION, PURIFICATION AND PROCESSING KIT FOR ADIPOSE TISSUE MSCs



LIPO-STEM DUO™ is a closed-circuit single-use kit for adipose tissue microfragmentation, processing and purification without any centrifuge and with minimal manipulation. The filtering system consistently microfragments the adipose tissue while maintaining the biological properties of the original tissue intact and maximizing the regenerative potential.

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

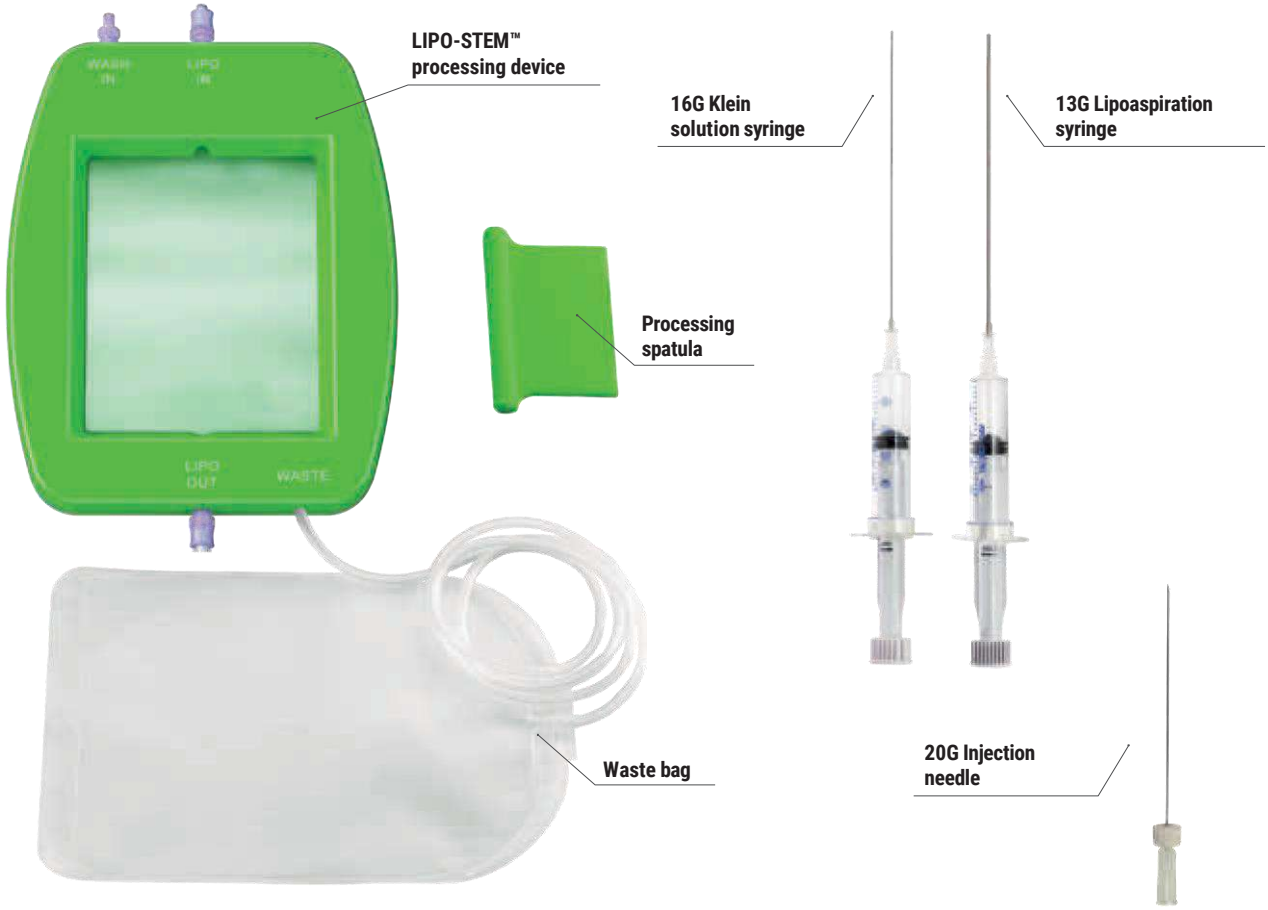
The collection and processing bag is equipped with two filters:

- the first filter microfragments the adipose tissue, while retaining the eventual fibrotic tissue
- the second filter with a denser mesh retains the microfragmented adipose tissue that is washed with saline solution eliminating all the oily and blood residues which might cause inflammation of the treated tissues.

The final microfragmented and purified product is an autologous adipose tissue rich in mesenchymal stem cells (MSCs) that keeps the biological properties of the original tissue intact and can easily be injected through very thin needles. The whole extracellular matrix acts as a natural structure for the cells increasing their vitality and contributing to the natural tissue regeneration process.

LIPO-STEM™

PURIFICATION AND PROCESSING KIT FOR ADIPOSE TISSUE MSCs



LIPO-STEM™ is a closed-circuit single-use kit for adipose tissue purification without any centrifuge and with a minimal manipulation.

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

The sophisticated filtering and washing system preserves the entire vascular stromal niche architecture and volume of the lipoaspirate and improves the cells' capacity to respond to regenerative stimuli.

The final purified product is a viscous fluid that keeps the biological properties and volume of the original tissue intact.

FEATURES

TIME EFFICIENT

- Processes up to 400 ml of adipose tissue in 10 minutes.
- Centrifuge free: saving on time, personnel and tools.
- All-in-one system that processes, purifies and microfragments a high-quality adipose tissue rich in mesenchymal cells.
- Ready to use autologous adipose tissue transplant

MINIMAL MANIPULATION

- Preservation of the biological properties of the cells.
- Complete preservation of tissue architecture and stromal niche components.
- Continuous saline solution washing eliminates any traumatic action that may damage the extracellular matrix.
- Sampling and processing in a sterile closed-circuit environment eliminating the risk of contamination.

EASY TO USE

- No centrifugation is required, and no machinery loan and maintenance.
- Day hospital procedure.
- Simple and reproducible technique in a single surgical time while maintaining the highest standards for fat grafting.
- Compared to centrifugation, minimize the staff training and OR preparation and clean-up.
- Only 1 operator is required.

APPLICATIONS

SPINAL SURGERY

PAIN THERAPY & WOUND HEALING

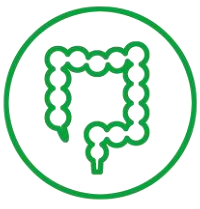
ORTHOPAEDICS & SPORT MEDICINE

VULNOTHERAPY

PLASTIC AND RECONSTRUCTIVE SURGERY

MAXILLOFACIAL SURGERY

UROGYNAECOLOGICAL SURGERY



COLOPROCTOLOGY

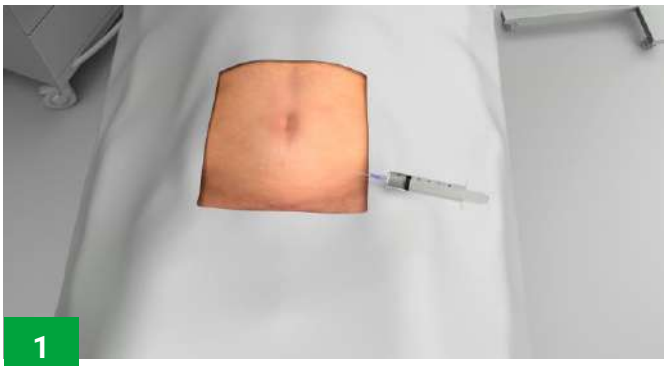
EU: HEALTHCARE PROFESSIONALS MUST VERIFY FOR EVERY TYPE OF APPLICATION THE MONOFUNCTIONALITY OF USE.

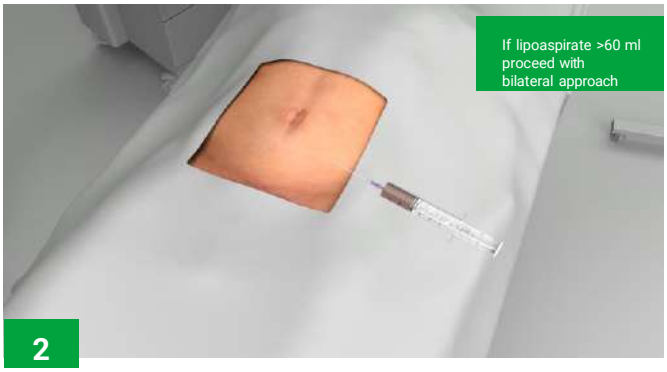
SURGICAL TECHNIQUE:

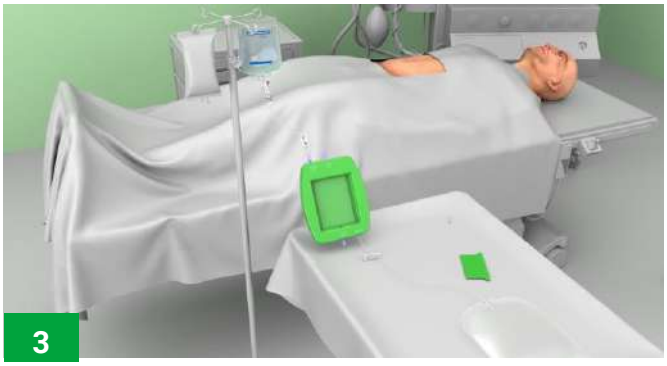
1. Infiltrate the Klein solution in the selected harvest site using the 16G Klein cannula.
2. Harvest the adipose tissue from the anaesthetized area using the 13G aspiration cannula.
3. Connect a 2 L saline bag to the device's "WASH IN" valve.
4. Insert the harvested adipose tissue into the device's "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 it as needed.

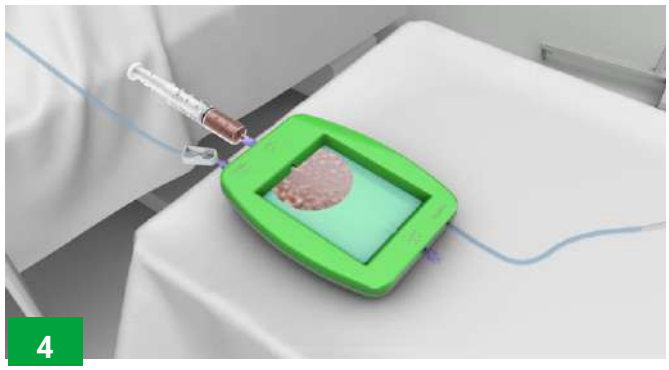
STANDARD KIT COMPOSITION:

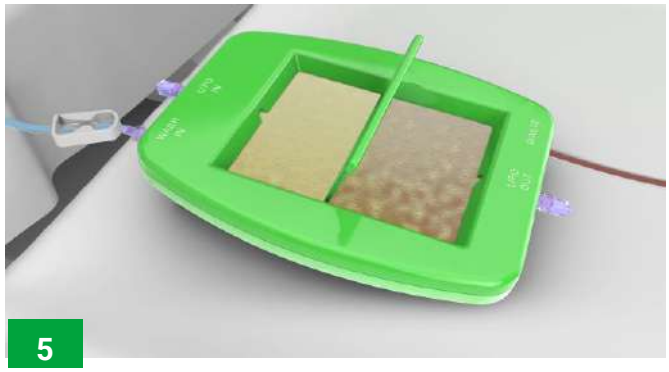
- N. 1 x LIPO-STEM™ or LIPO-STEM DUO™ processing bag and waste bag.
- N. 1 x Processing spatula
- N. 2 x 60 ml syringes for Klein's solution
- N. 2 x 60 ml Vaclok syringes for liposuction
- N. 1 x 16G cannula for injection of Klein's solution
- N. 1 x 13G cannula for liposuction
- N. 1 x 16G (LIPO-STEM™) or 20G (LIPO-STEM DUO™) infusion needle
- N. 2 x 10 ml syringes for infusion
- N. 2 x 3 ml syringes for infusion
- N. 2 x Combi caps LLF/LLM
- N. 2 x Male Luer Cap, Non vented, Red
- N. 1 x Infusion line with air inlet
- N. 1 x Open side clamp

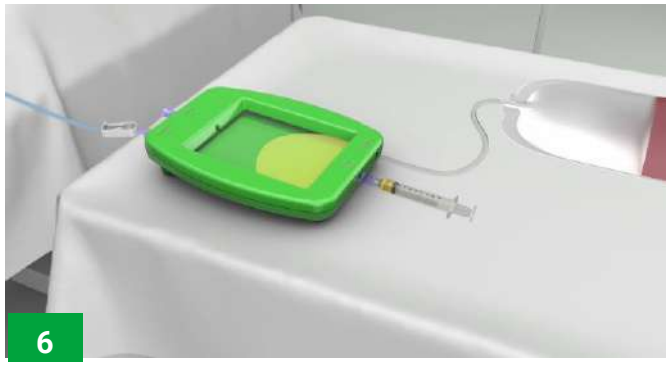












***Please refer to the surgical technique document and instructions for use**

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. With its innovative features, MARROW-STEM™ optimizes the cellular yield and minimizes the contamination of peripheral blood, thanks to a micrometric system for lateral aspiration and the closet distal tip of the device.

INNOVATIVE

- Closed & sealed distal tip: guarantees a high cellular yield.
- 100% lateral aspiration: no peripheral blood contamination.
- Micrometric gear: 0,5 cm cannula retraction every 360° rotation.

EASY

- Single-step device: faster and easier procedure.
- Point of care therapy: minimally invasive procedure.
- Residual retraction control thanks to the numbers printed on the gear window.

CONVENIENT

- Centrifuge free: saving on time, personnel and tools.
- No processing time: ready to use bone marrow MSCs concentrate.
- Minimizes staff training, OR preparation and clean-up.

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

FIELDS OF APPLICATION:

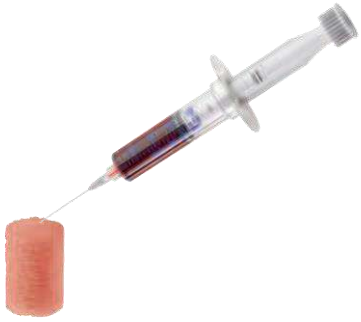
The bone marrow aspirated with **MARROW-STEM™** can be injected to accelerate the natural healing process, or can be combined with other kinds of bone substitutes to create an enhanced bone graft.

BONE MARROW MSC CONCENTRATE

INDICATIONS:

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

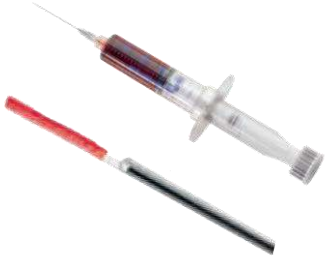
BONE MARROW ASPIRATE + ANY KIND OF BONE SUBSTITUTE



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

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.
5. The 270 µm filter provided in the kit allows the separation from possible contamination of bone fragments, oil and fat.

STANDARD KIT COMPOSITION:

- No. 1 MARROW-STEM™ MSCs aspiration device
- No. 1 270 µm filter
- No. 1 VacLok AT syringe 20 ml
- No. 1 injection syringe 10 ml

***Please refer to the surgical technique document and instructions for use**

UNLUX SYSTEM™

CREEPING SUBSTITUTION

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 the process shall be accelerated.
The result will therefore be an extremely strong graft, like a vascularized 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.

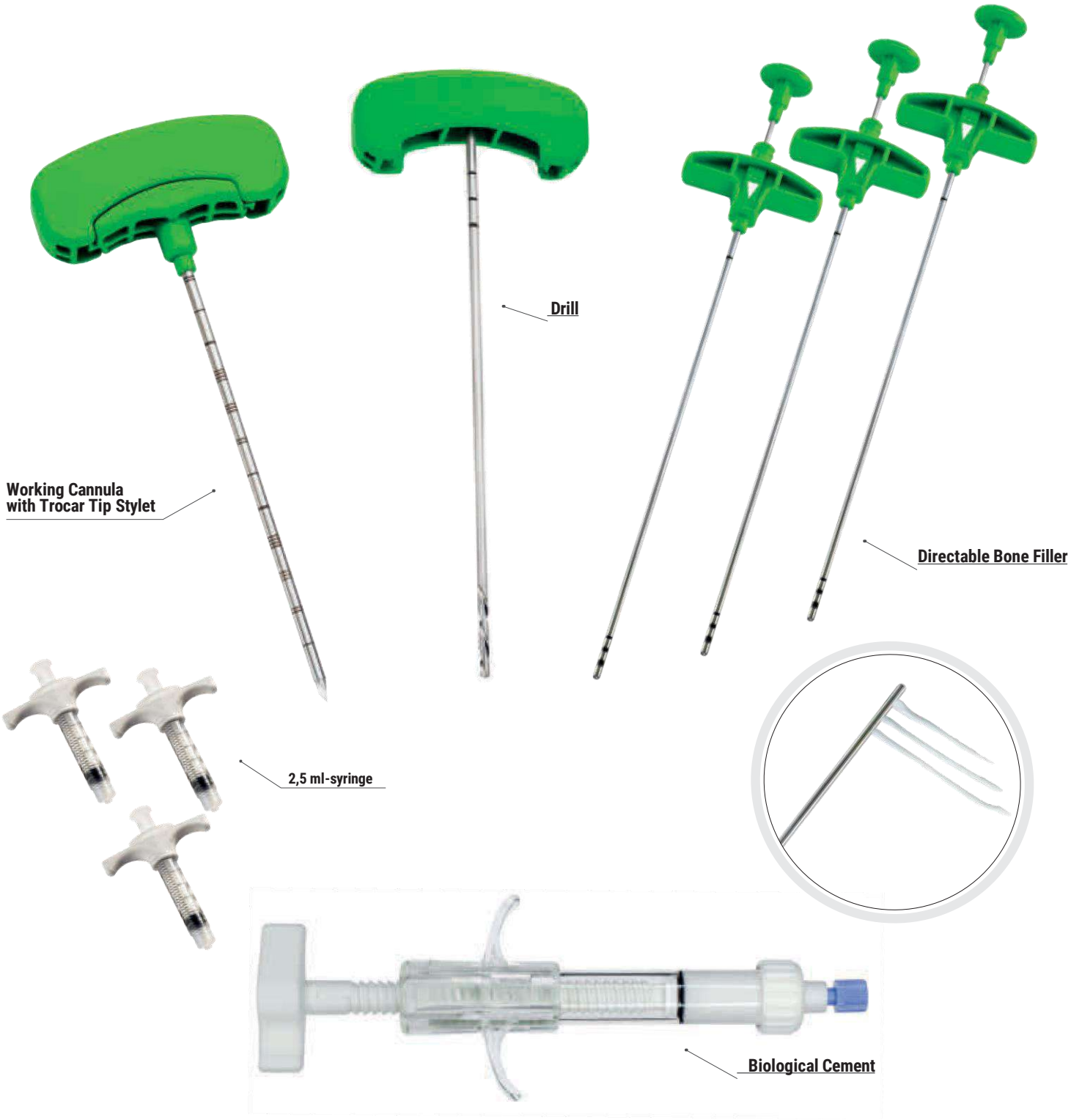
ENHANCED VASCULARIZED GRAFT

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

ORTHOPLASTY™

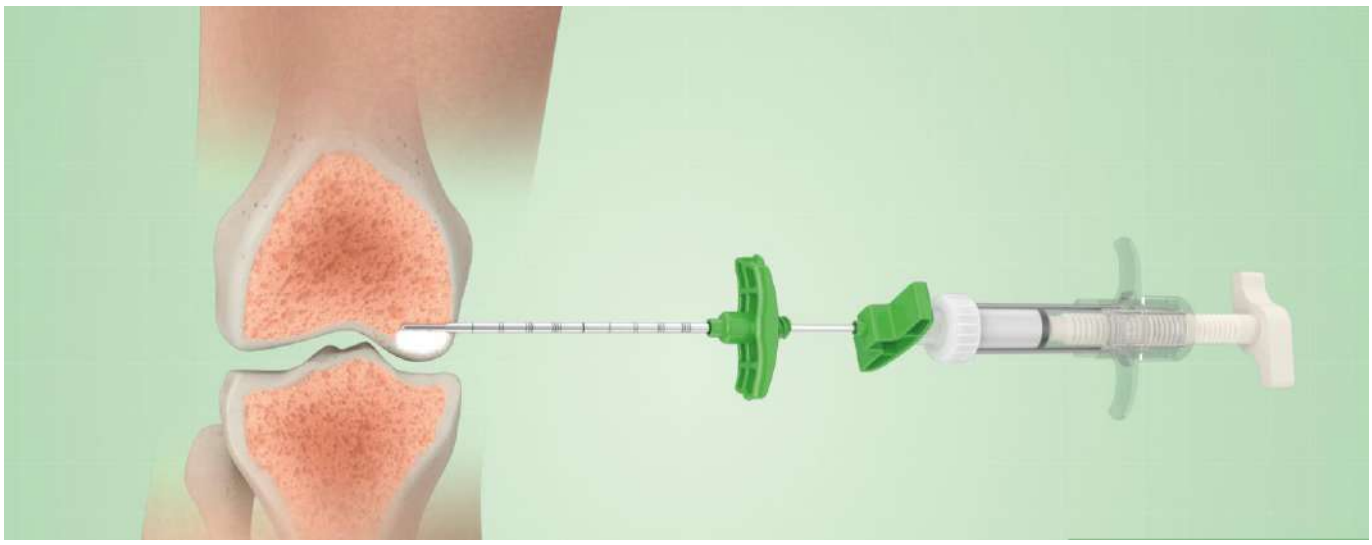
SUBCHONDRAL BONE PLASTY

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 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 a 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: 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:

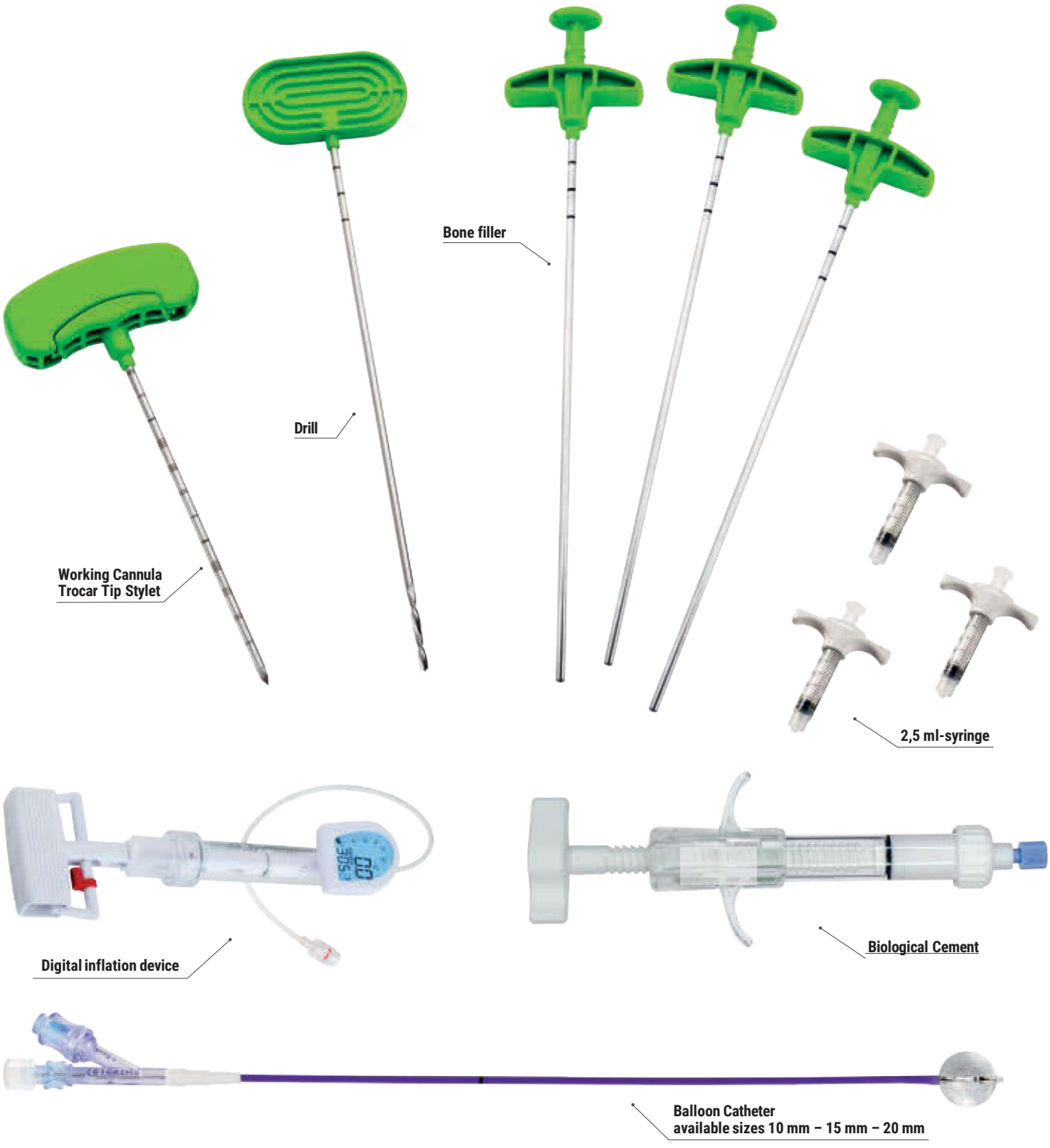
- No. 1 Working Cannula + Trocar Tip Stylet
- No. 1 Drill
- No. 3 Directable Bone Filler + 3 Syringes (2,5 ml)
- No. 1 Biological Cement*

*** Can be sold without biological cement**

OSTEOPLASTY™

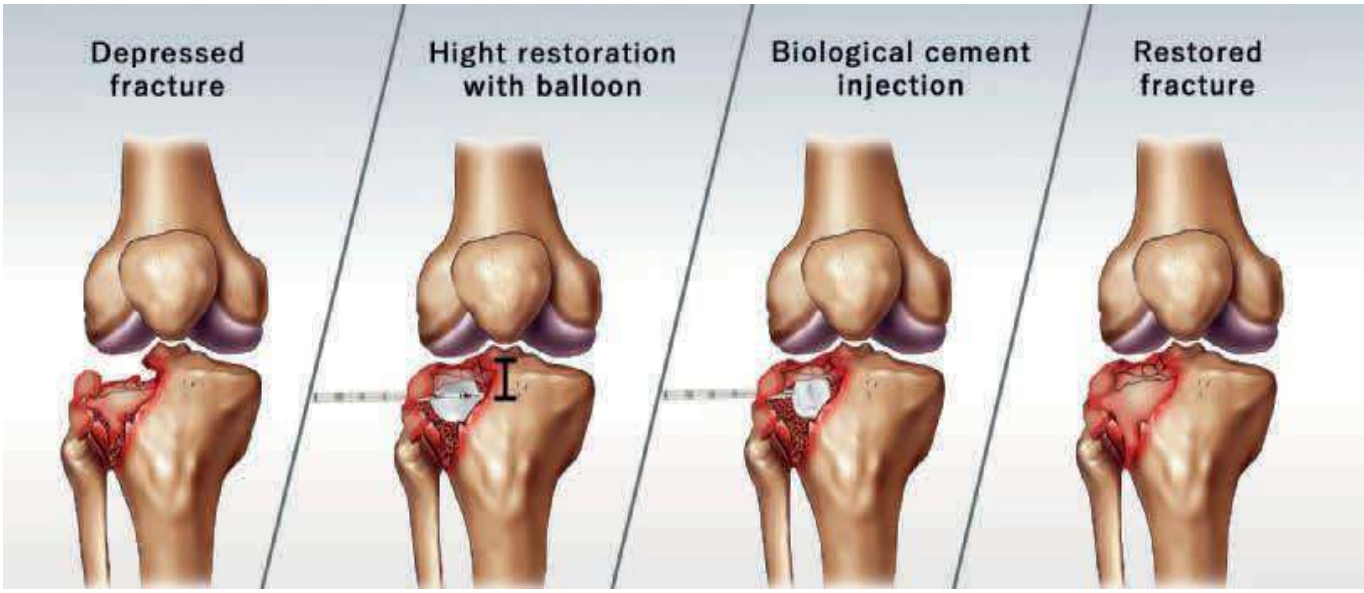
METAPHYSEAL BALLOON AUGMENTATION

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:

- 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 a wet environment only: no time pressure during application.
- Truly biologic: composed of micro-crystalline, calcium-deficient hydroxyapatite – the primary component of bone.
- Supports load-sharing properties (up to 45 MPa).
- Radiopaque paste: 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 a bone substitute until the space is filled under fluoroscopic guidance.
7. Plating may be implemented before or after the filling of a 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 15 mm or 20 mm)
- No. 1 Digital Inflation Device
- No. 1 Biological Cement*

*** Can be sold without biological cement**

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FDA (Establishment Registration Number) 9617616

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