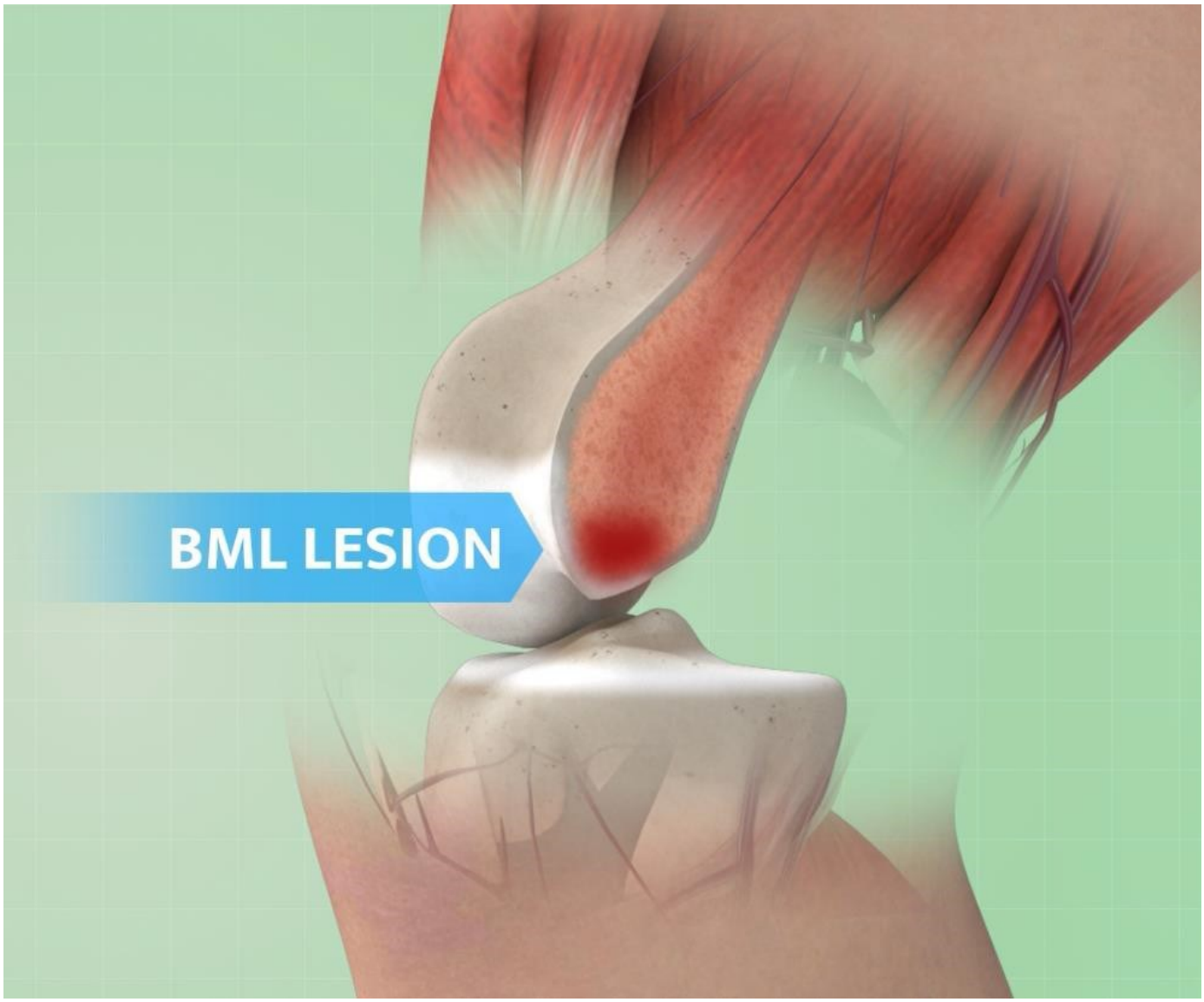
ORTHOPLASTY™

SUBCHONDRAL BONE MARROW LESIONS TREATMENT KIT



Surgical technique

BPB 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 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 an 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 the newly adopted technologies, BPB MEDICA™ has quickly managed to make a name for itself in the domestic and international markets.

50 YEARS
EXPERIENCE

70
COUNTRIES SERVED

OUR PRODUCT LINES:

SPINE

ORTHO-BIOLOGICS

BIOPSY

INTENSIVE CARE

ASSISTED REPRODUCTION

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 qualify and improve its production standards and aid 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

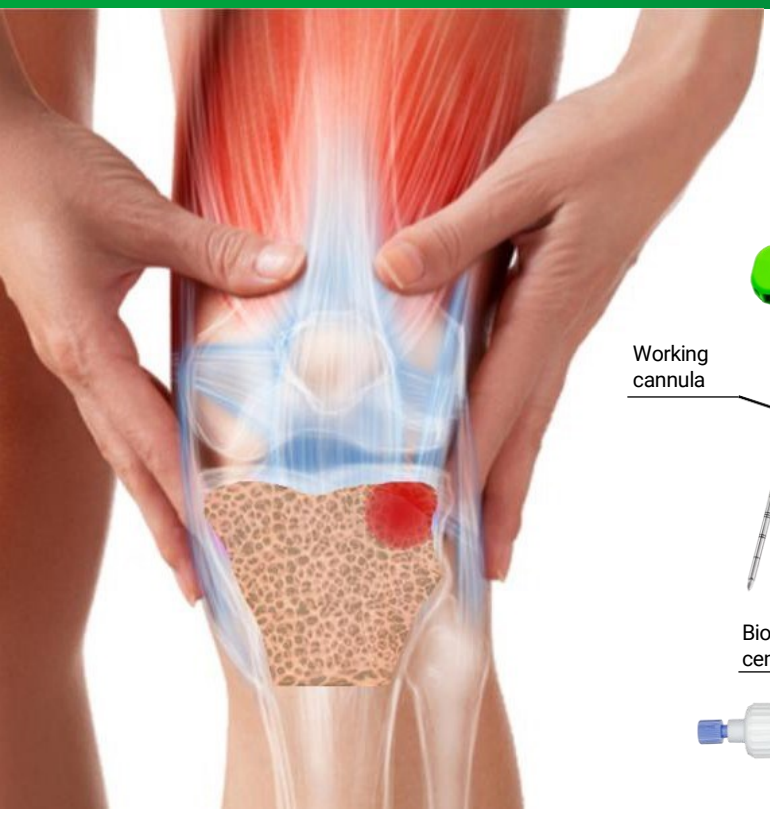
FDA

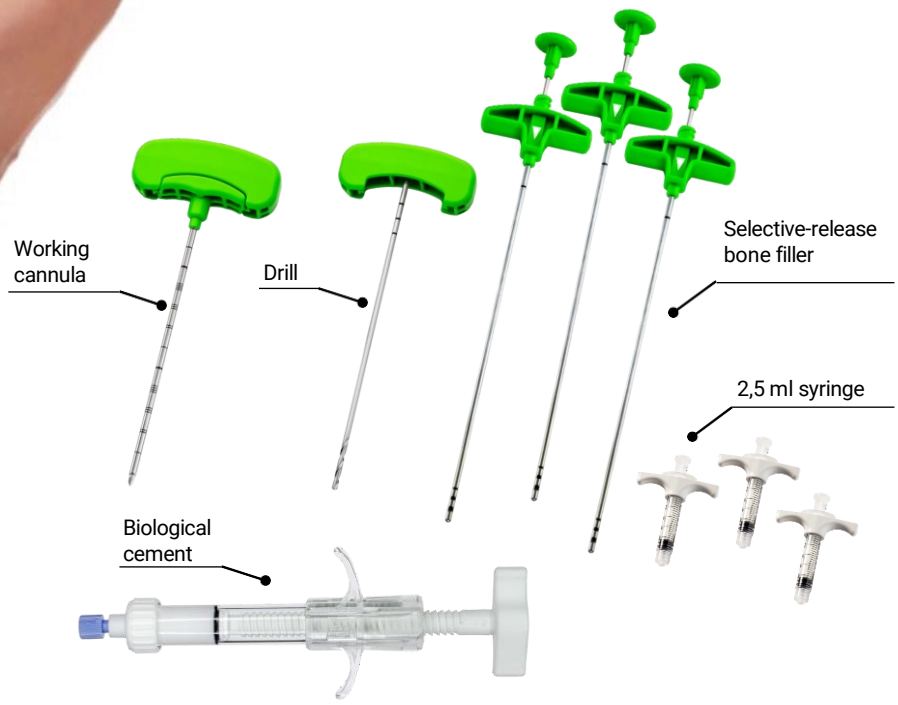
CE 0123

OUR SERVICES:

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

Introduction





ORTHOPLASTY™ is a disposable device for treating subchondral bone lesions.
The device is to be used for the delivery of bone cement in the subchondral bone, i.e. to repair subchondral bone defects (Bone Marrow Lesions - BML) or in avascular necrosis of the femur head or other bone sites, such as the ankle, shoulder, knee. The procedure is carried out with a minimally-invasive approach under fluoroscopy guidance along with arthroscopy, to target and manage findings inside the joint.

The pathology is classified as a SIFK (Subchondral Insufficiency Fracture of the Knee) and in the initial stages of SONK (Spontaneous Osteonecrosis of the Knee).
The patient that presents with this pathology, suffers from relatively early osteoarthritis and consults the clinical specialist as a result of intense pain that does not correspond to a significantly compromised radiographic scenario.

These lesions are not visible under x-ray and only a diagnostic confirmation using MRI reveals a hyper-intense uptake signal in sequences sensitive to T2 fluids (hydrogen) and STIR sequences.
The objective of the method is to reinforce subchondral bone lesions using the same principle as vertebroplasty and involves the percutaneous insertion, into the bone rarefaction site, of an appropriate bone substitute or an autologous bone graft enhanced with a concentrate of mesenchymal stromal cells.

FEATURES

- minimally-invasive percutaneous approach
- 20 minutes procedure
- rapid functional recovery
- pain relief after 1 day
- preservation of anatomical physiology for future operations

APPLICATION

Bone Marrow Lesions in the following areas:

- proximal humerus
- distal femur
- femural head
- proximal tibia
- ankle joint
- hip

Displayed device colours are indicative.

Indications and contraindications

The procedure described is indicated for the treatment of patients who have been diagnosed with BML and who do not respond to pharmacological treatment (between the third and sixth month after onset of the disease).

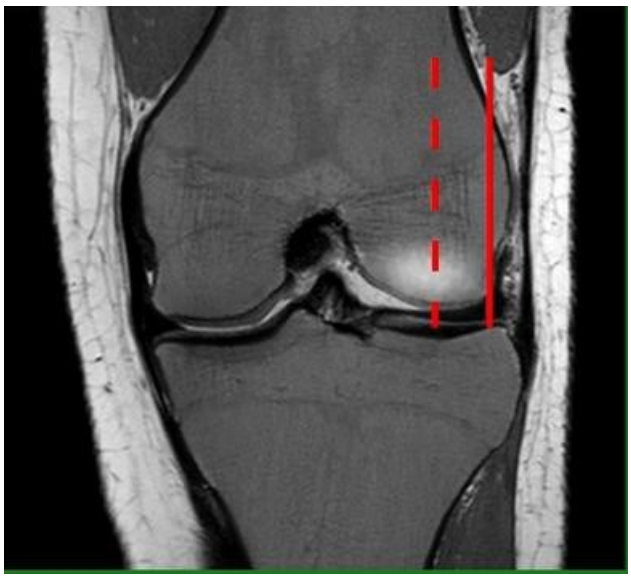
A post-treatment arthroscopic check is advised for any extrusions of biological cement from fracture lines.

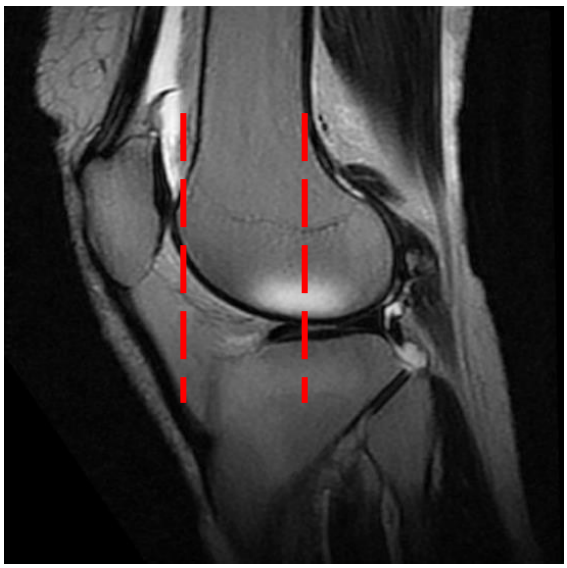
ATTENTION: The procedure requires the use of the ORTHOPLASTY™ device combined with a bone substitute in hardener paste certified for use in the proximal humerus, distal femur, proximal tibia and ankle joint areas. Please refer to the manufacturer's user manual for the bone substitute in hardener paste or PMMA to check the information relating to its use, contraindications, precautions, risks and side effects.

CONTRA-INDICATIONS:

- Existing acute or chronic infections, especially at the site of the operation
- Nonviable bone
- Metabolic bone disease
- Immunologic abnormalities
- Systemic disorders which result in poor wound healing
- Inflammatory bone disease
- Acute traumatic injuries with open wounds close to the defect which are likely to become infected

Pre-operation plan





Carry out a pre-operative plan via MRI to determine the main points of reference to:

- analyse the distance and depth between the joint and the lesion;
- determine the location of the lesion through anteroposterior (a/p – fig.1) and mediolateral (m/l – fig.2) projections.

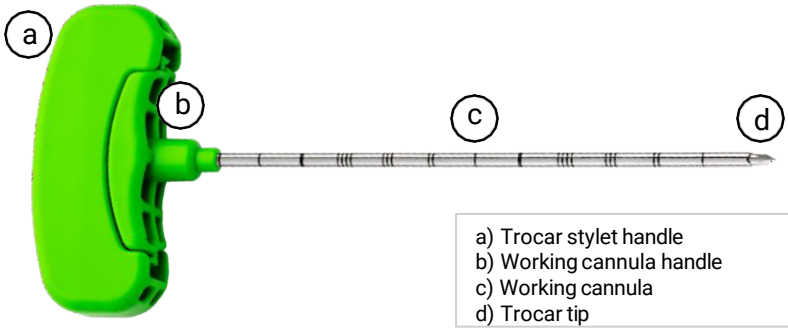
BMLs are not visible on intraoperative fluoroscopy. The pre-operative MRI is fundamental to surgically proceed under fluoroscopic guidance.

Characteristics

ORTHOPLASTY™ system is composed of a WORKING CANNULA WITH TROCAR TIP, a DRILL STYLET and a SELECTIVE-RELEASE BONE FILLER with lateral holes for the injection of cement in the area to be treated.

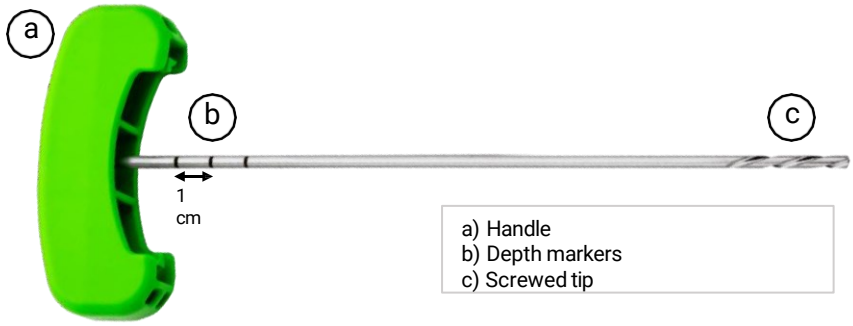
The device has to be used only in combination with medical devices intended for subchondral BML treatment such as biological bone cement certified and intended for this use.

- **WORKING CANNULA WITH TROCAR TIP:** made by an external cannula used as a working channel and an internal stylet with a trocar tip to access the subchondral bone. The needle has a plastic handle.



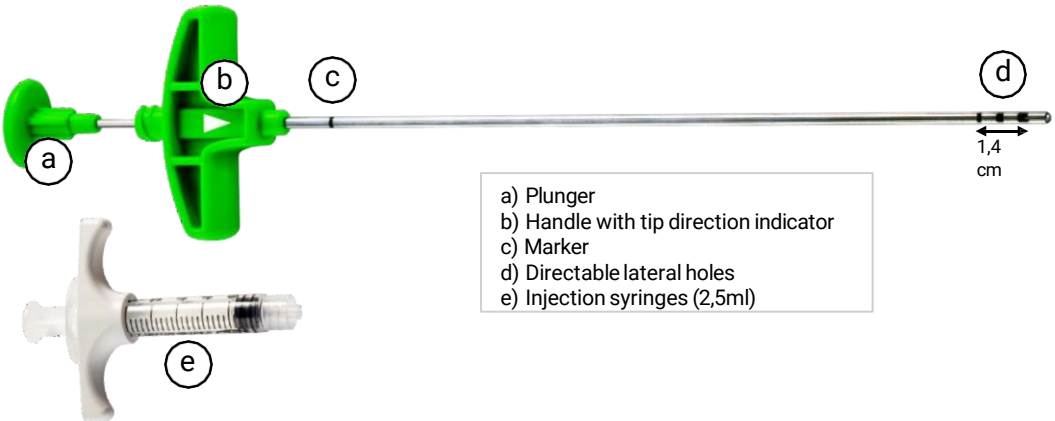
a) Trocar stylet handle
b) Working cannula handle
c) Working cannula
d) Trocar tip

- **DRILL STYLET:** composed of a metal part with a distal bone drill (screwed terminal portion) and a plastic handle. This device is used to dig into the bone to target the area to be treated.

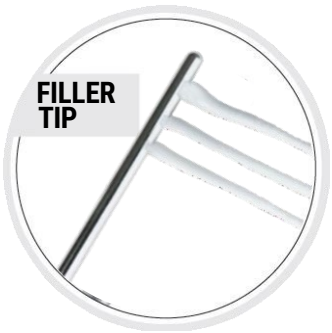


a) Handle
b) Depth markers
c) Screwed tip

- **SELECTIVE-RELEASE BONE FILLER:** is a cement infusion cannula (often referred to as the "filler" cannula) and consists of a steel cannula with a plastic handle, equipped with a pusher stylet. The lateral holes in the cannula allow a directable injection of the bone cement in the area to be treated. The plastic handle has a universal Luer-lock connection for filling the cannula with bone cement. Also, dedicated injection syringes with a Luer-lock connection are present in the kit.

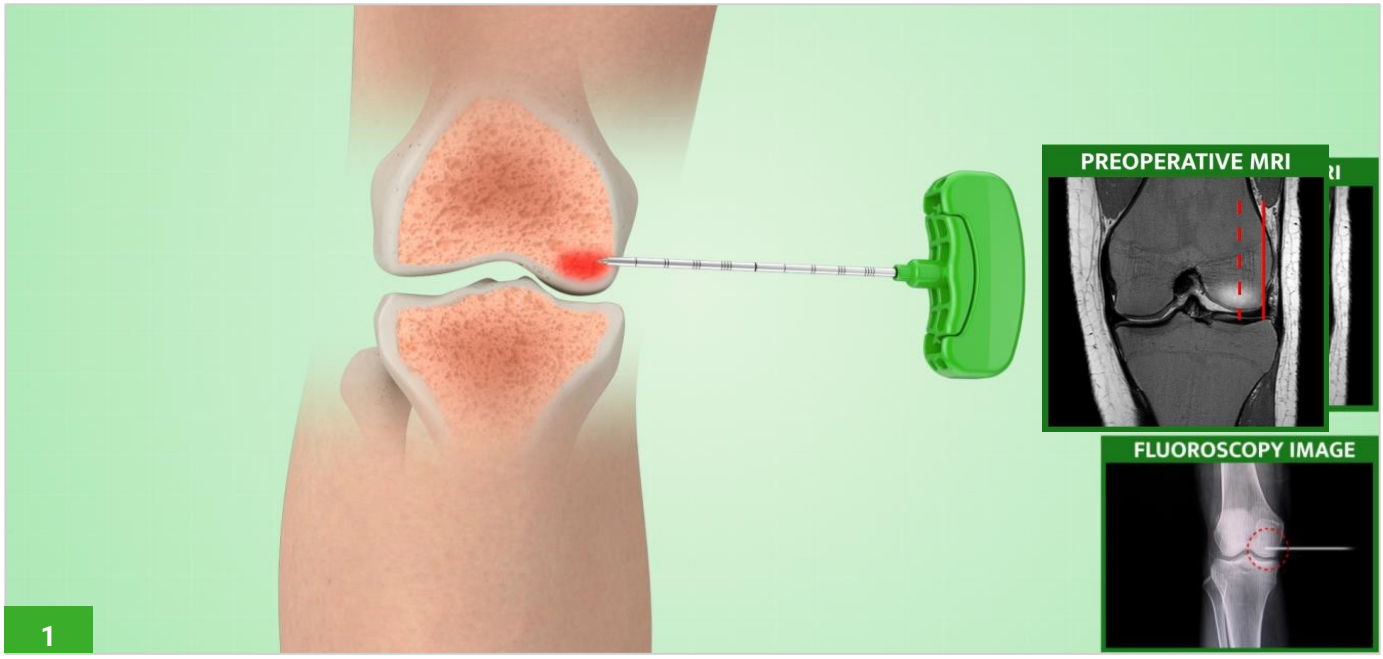


a) Plunger
b) Handle with tip direction indicator
c) Marker
d) Directable lateral holes
e) Injection syringes (2,5ml)

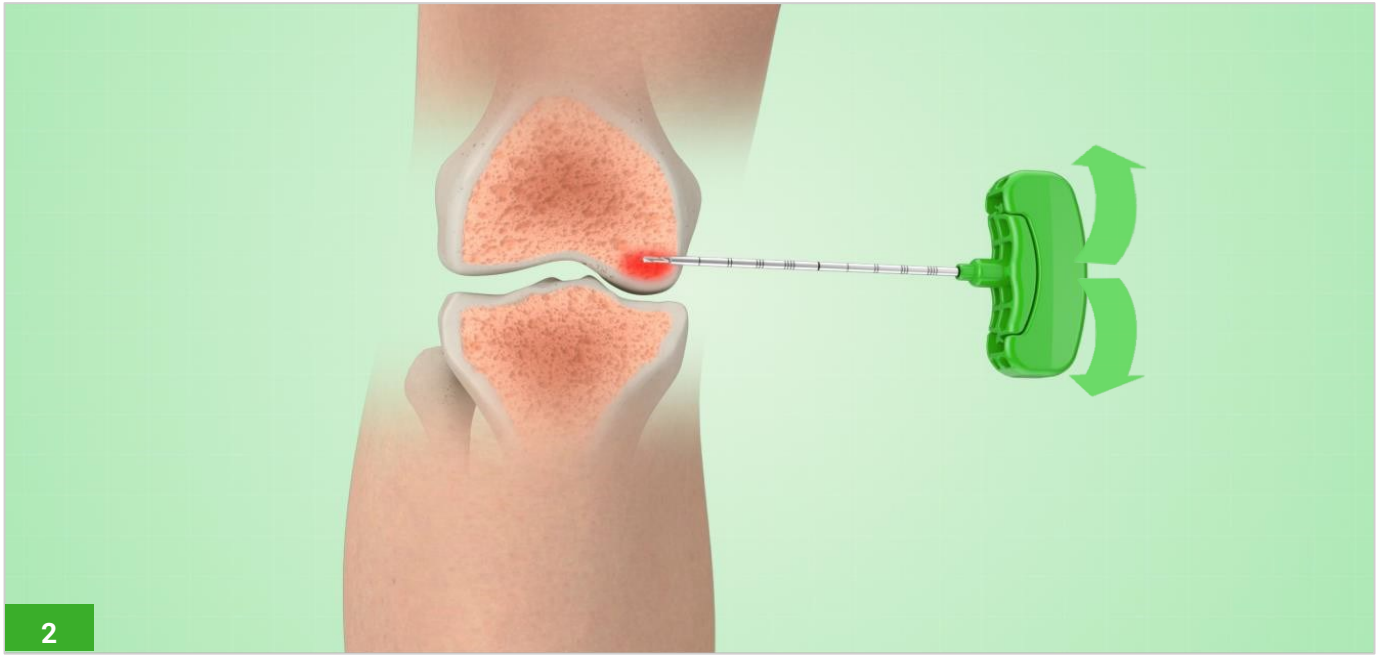


Surgical technique

Position the patient on the surgical bed and, under fluoroscopy guidance, start the procedure using the trocar to identify the access point in the BML area.

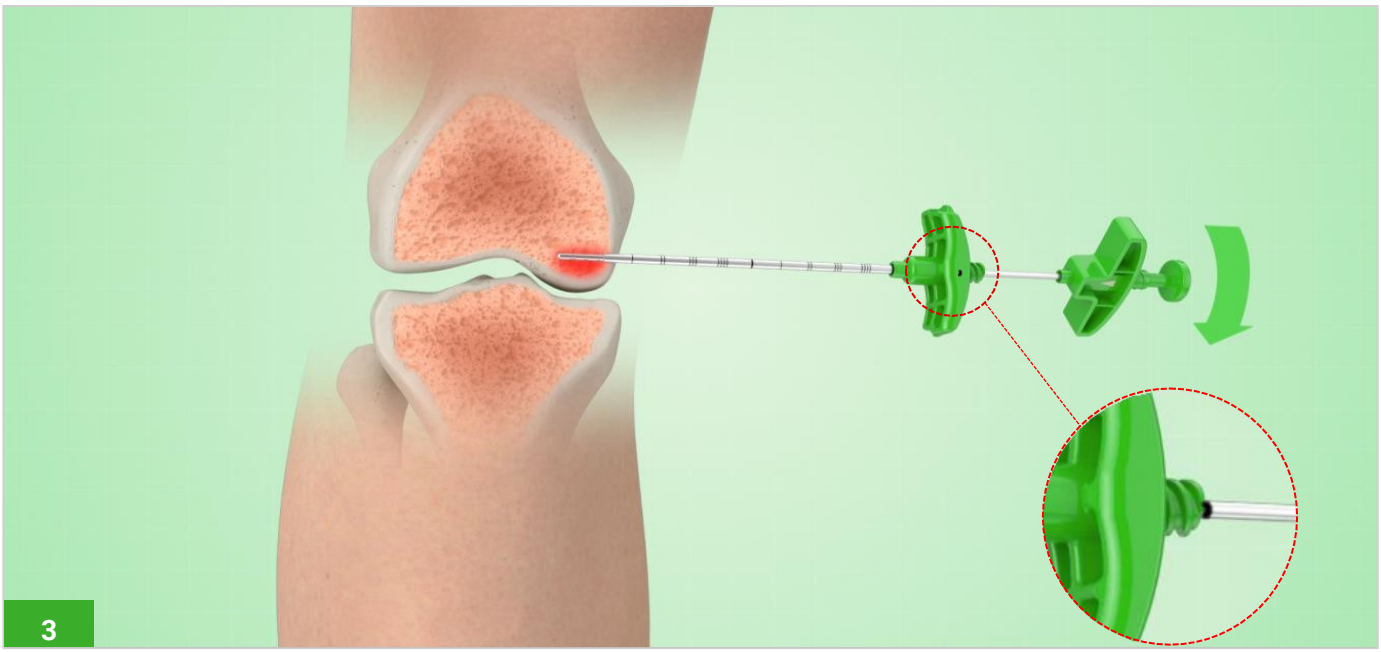


Once the trajectory is determined, access the lesion using the trocar *(fig.1)*. If necessary, facilitate the entry of the trocar by gently tapping the plastic handle with a hammer.

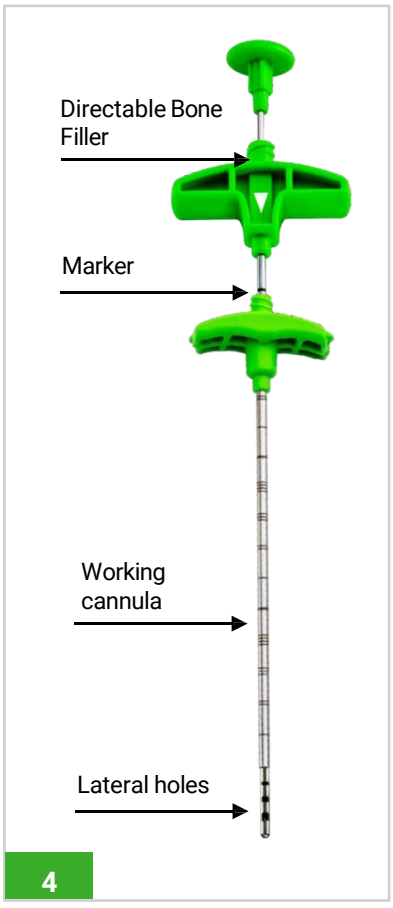


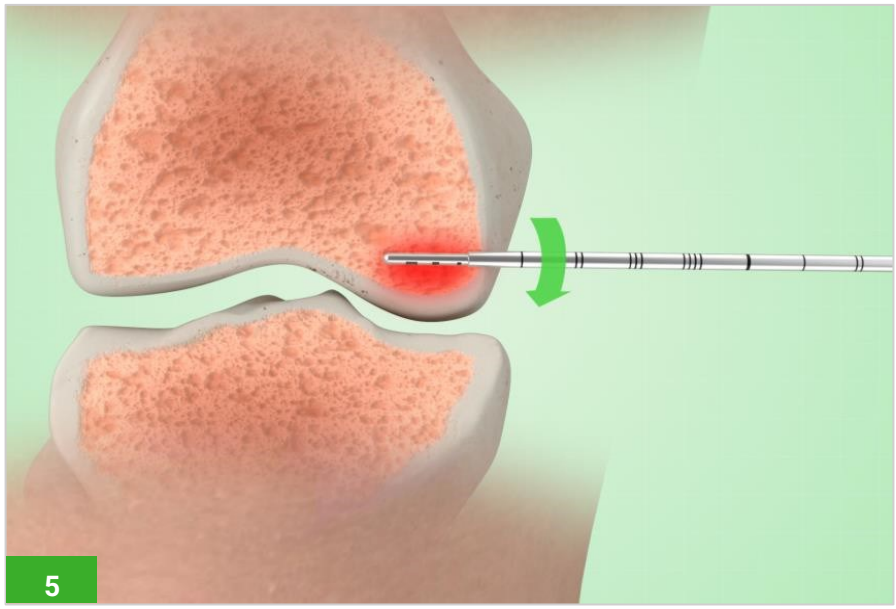
Remove the trocar stylet and leave the access cannula inserted.
Insert the drill into the cannula and attach it to the handle of the operating cannula *(fig.2)*. Rotate clockwise by 180° then counterclockwise to target the area to be treated. Using AP fluoroscopy as needed, continue drilling until the cannula is at the desired depth.

Surgical technique



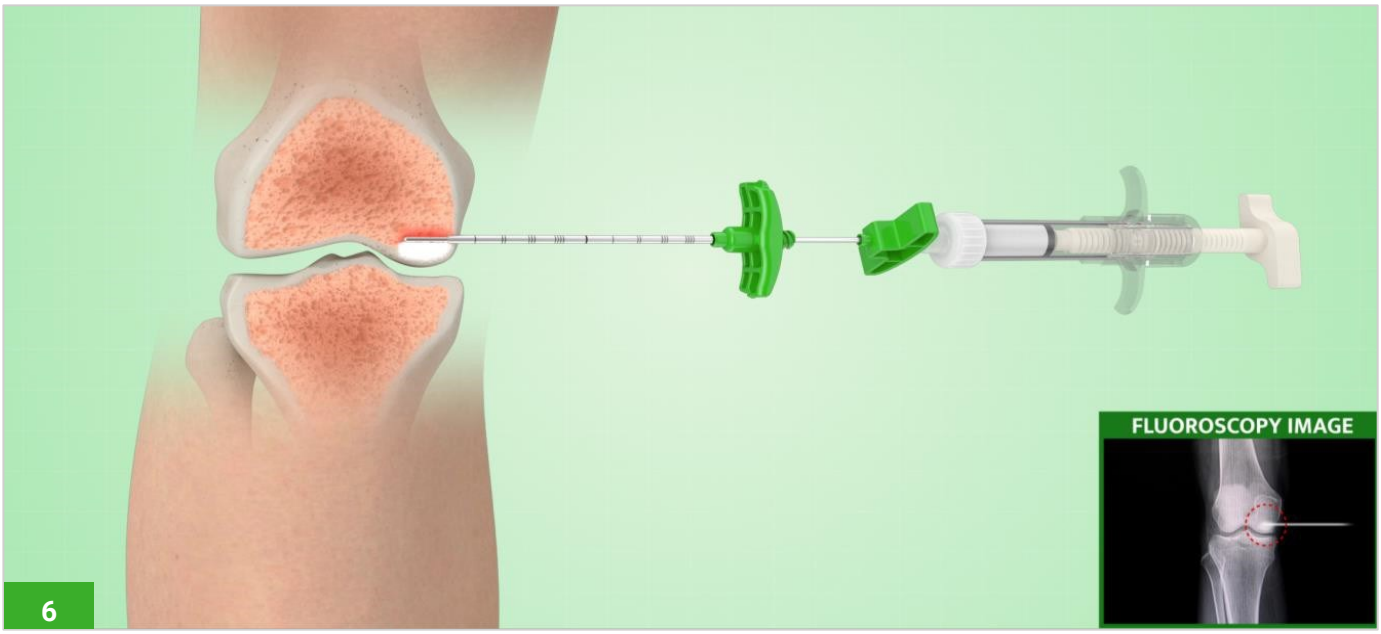
Remove the Drill and insert the Selective-release bone filler into the working cannula *(fig.3)*. Make sure that the black marker on the cannula reaches the handle of the Trocar: this ensures that all bone filler holes are out from the working cannula *(fig.4)*.



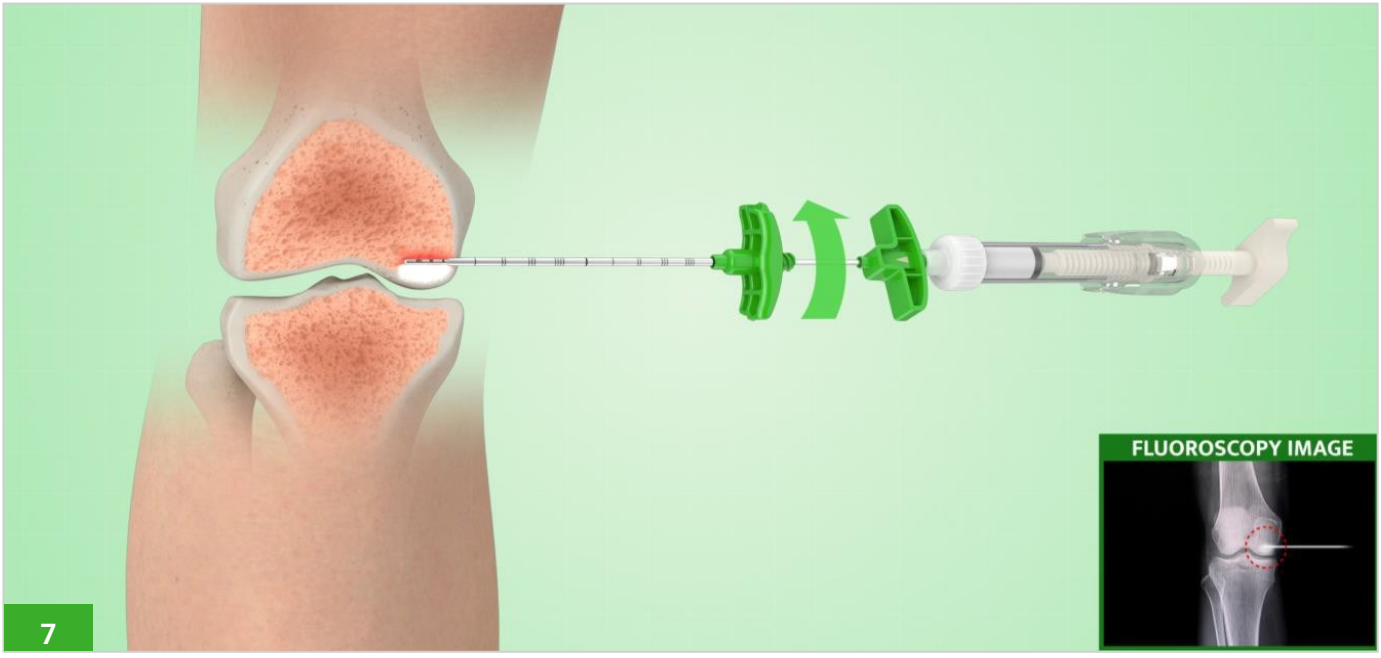


With the help of the arrow printed on the handle, manually rotate the lateral holes in the direction of the lesion *(fig.5)*.
Reconfirm position relative to preoperative plan, with AP and lateral fluoroscopy.

Surgical technique

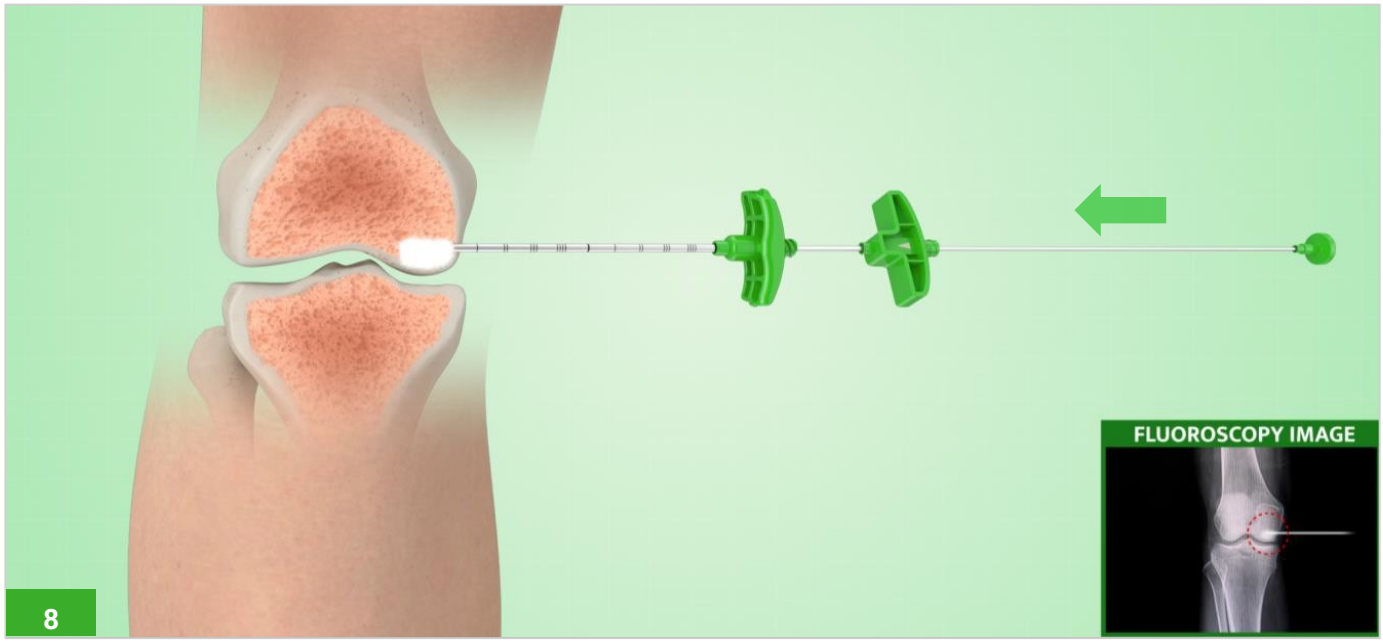


Connect the syringe prefilled with the Biological Cement to the Selective-release bone filler and inject the bone substitute into the lesion *(fig.6)*.
Alternatively, follow the IFU of the prechosen bone substitute.



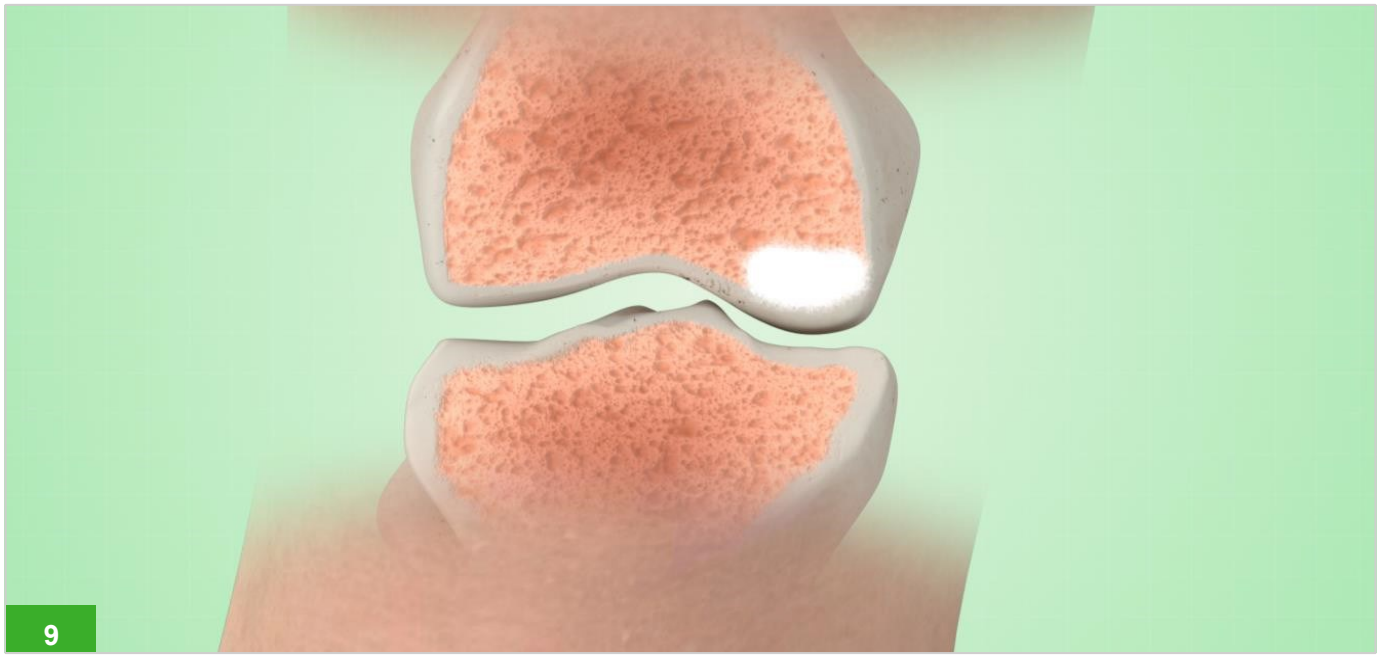
If necessary, adjust the direction of the holes to fill the whole lesion *(fig.7)*.

Surgical technique



Check the quantity of material injected under fluoroscopy guidance, ensuring the emptying of the remaining 0,7cc of the Selective-release bone filler through the plunger (a) before removing the access Trocar *(fig.8)*.

ATTENTION: Do not overfill the defect site. Overpressurizing the treatment area may lead to leakage and damage to the surrounding tissues.



A post-treatment arthroscopy check will allow the removal of any leakage of filling material from the subchondral bone microfractures.

Contact us for further information:

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ISO 13485
BUREAU VERITAS Certification
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BPB MEDICA™

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