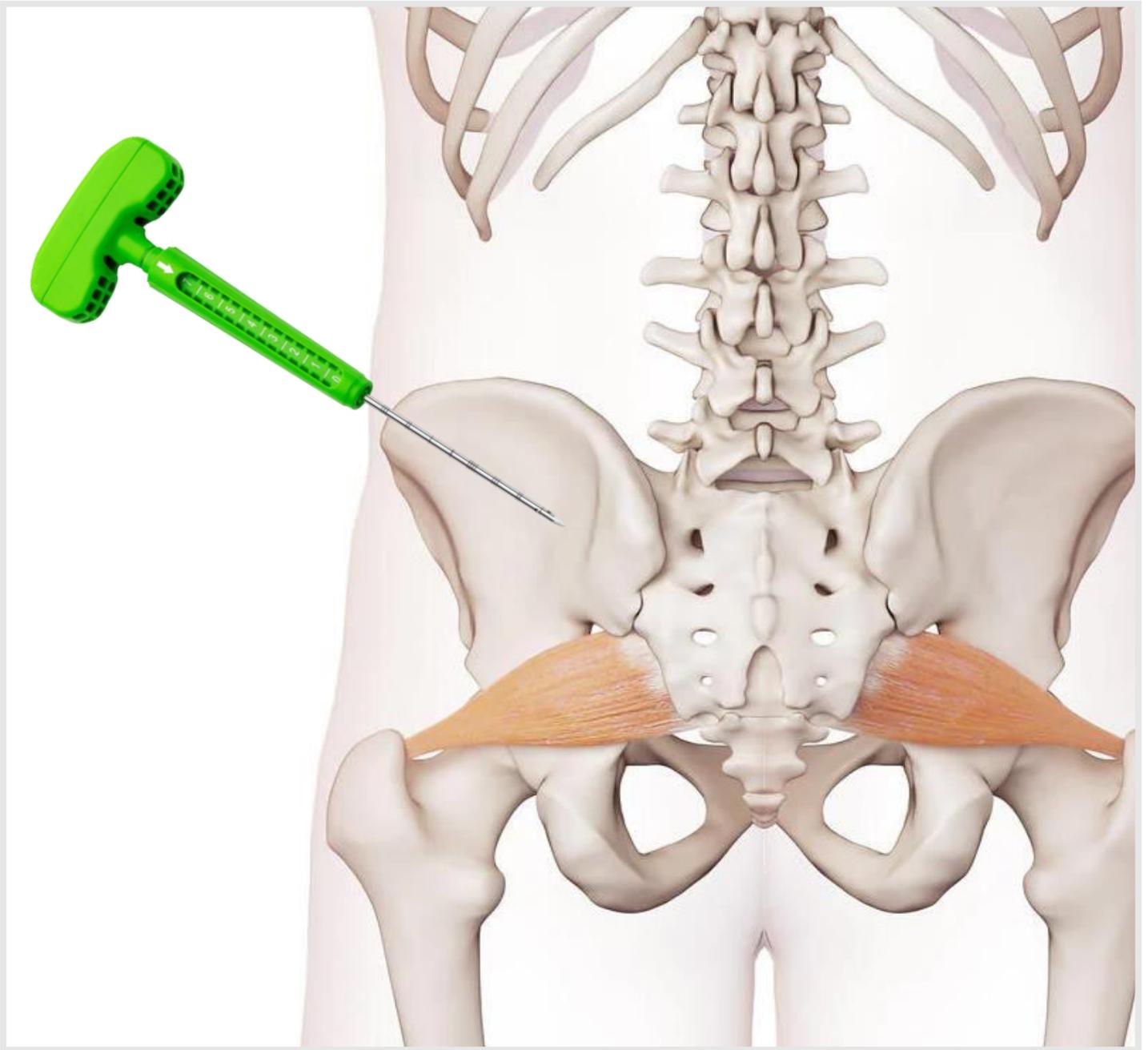


MARROW-STEM

BONE MARROW MESENCHYMAL
STEM CELLS SELECTION KIT



Surgical technique

SP3TM
medica

Index

COMPANY PROFILE	4
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MARROW-STEM

Introduction	6
Applications	7
Marrow-stem: feautres.....	8
Surgical technique	10

UNLUX SYSTEM

Unlux system	17
Surgical technique	18



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 Sr., 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.



EXPERIENCE



COUNTRIES SERVED

OUR PRODUCT LINES:



SPINE SURGERY



ORTHO-BIOLOGICS



ASSISTED
REPRODUCTION
TECHNOLOGY



INTENSIVE 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**.

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.

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**.



Clean Room



OUR SERVICES:



ENTIRE IN-HOUSE PRODUCTION



RESEARCH & DEVELOPMENT



OEM & PRIVATE LABEL SERVICES



MARKETING SUPPORT



INTERNAL REGULATORY AND QUALITY DEPARTMENTS



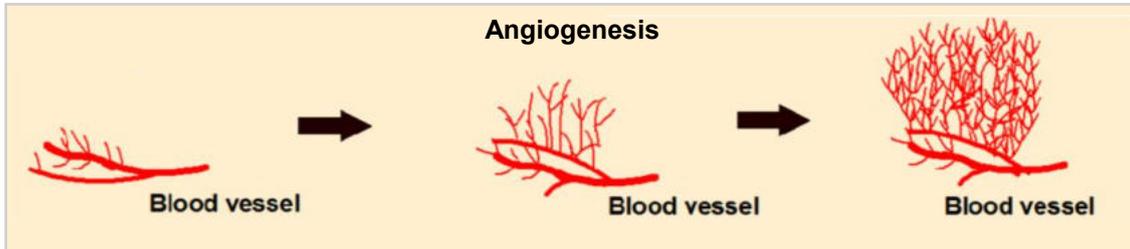
FOUR WEEKS DELIVERY

Introduction

The common goals in orthopedics and spinal surgery employing mesenchymal cells are mainly two:

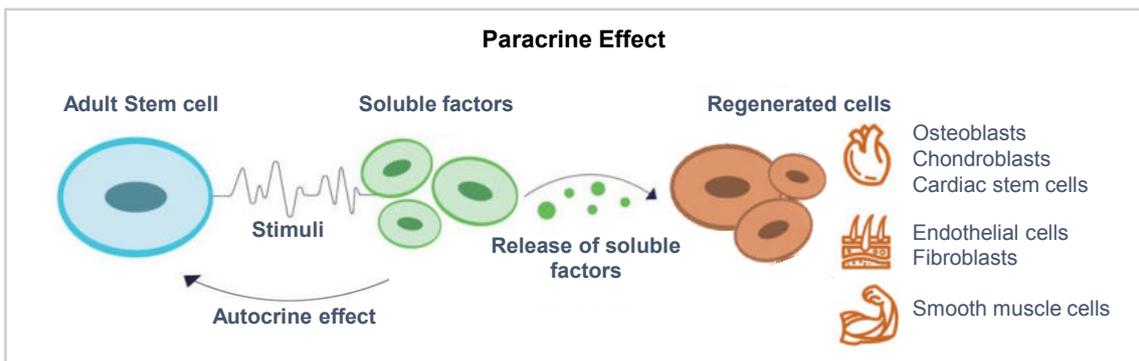
1. ANGIOGENESIS:

development of new blood vessels from existing ones

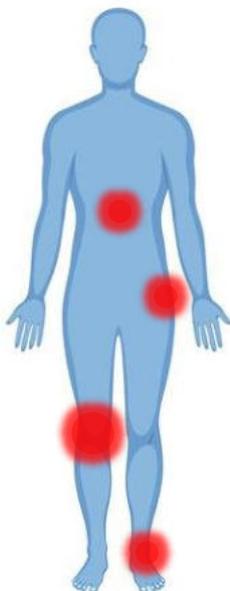


2. PARACRINE EFFECT:

starting from cytokines - small proteins - which bind to specific receptors on the membrane and communicate to the cell a specific instruction as the stimulus to grow or differentiate.



Extraction site:



Ability to perform extraction at **low morbidity** applicable to various anatomical sites:

- iliac crest
- proximal tibia
- distal femur
- calcaneus
- vertebral body

Application

Bone marrow MSC concentrate can be used to accelerate the natural healing process and can be combined to other kind of bone substitute to create an enhanced bone graft.



Bone marrow
MSC concentrate

BONE MARROW MSC → SOFT TISSUE APPLICATION

- Point of care therapy

Indication:

- Intraarticular infiltrations
- Cartilage regeneration
- Tendinopathy
- Pain therapy
- Bone cysts



Bone marrow MSC concentrate +
any kind of bone substitute

ENHANCED BONE SUBSTITUTE → BONY FUSIONS

Can be used to enhance any kind of bone substitute (homologous, synthetic or xenograft origin).

Indication:

- Bone cysts
- Spinal fusions
- Acetabular revision (revision surgeries)
- Foot & ankle fusions open wedge osteotomies



Bone marrow MSC concentrate +
autologous bone dowel

AUTOLOGOUS BONE DOWEL

Bone marrow MSC concentrate can be used in combination with an autologous bone dowel to accelerate the natural bone regeneration process.

Indication:

- Avascular necrosis
- Bone Marrow Lesions BMLs
- Pseudarthrosis and consolidation delays



Bone marrow MSC concentrate +
any kind of bone substitute +
autologous bone dowel

VASCULARIZED GRAFT

By mixing the selective aspirate of stromal mesenchymal cells with an autologous bone graft, in addition to any synthetic, homologous or xeno bone substitute, the creeping substitution process is accelerated. The resulting graft will be extremely effective, similar to a vascularized graft with high regenerative potential.

Indication:

- Bone regeneration
- Trauma procedures & fractures
- Pseudarthrosis and consolidation delays

Marrow-Stem

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 closed distal tip of the **Trocar**.



INNOVATIVE

Thanks to the closed distal tip and the selective lateral micrometric aspiration a **high cellular yield is guaranteed relatively to a reduced quantity 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, machinery and related costs.

FEATURES:

SINGLE STEP DEVICE

Faster and easier procedure

CENTRIFUGE FREE

No processing time

POINT OF CARE THERAPY

Minimally invasive procedure

MICROMETRIC GEAR

0,5 cm cannula retraction every 360° rotation

RESIDUAL RETRACTION CONTROL

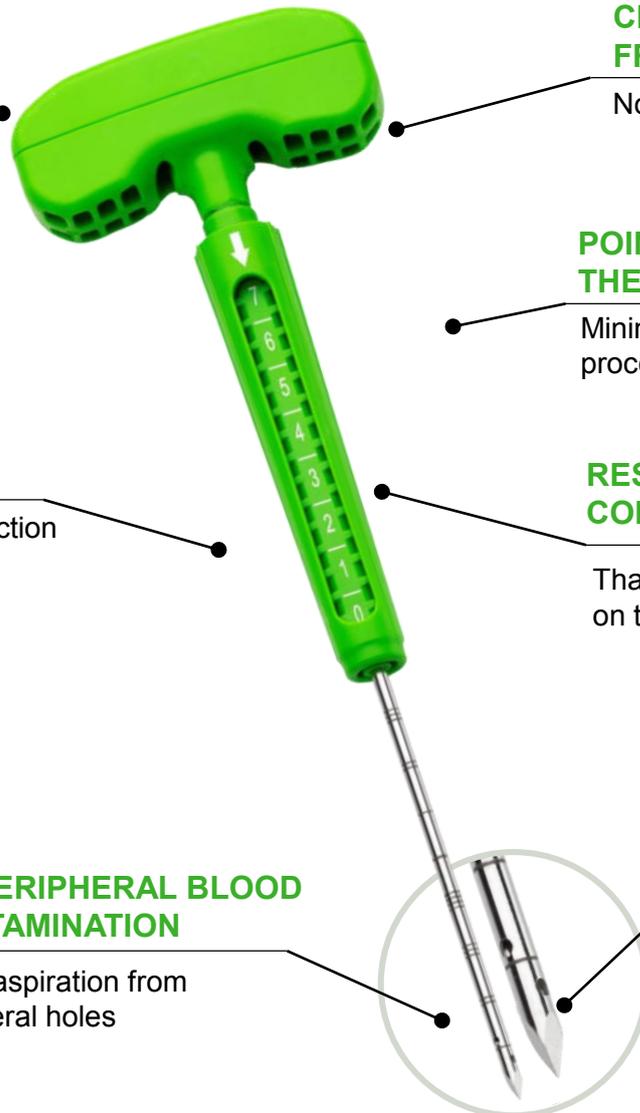
Thanks to the numbers printed on the gear window

NO PERIPHERAL BLOOD CONTAMINATION

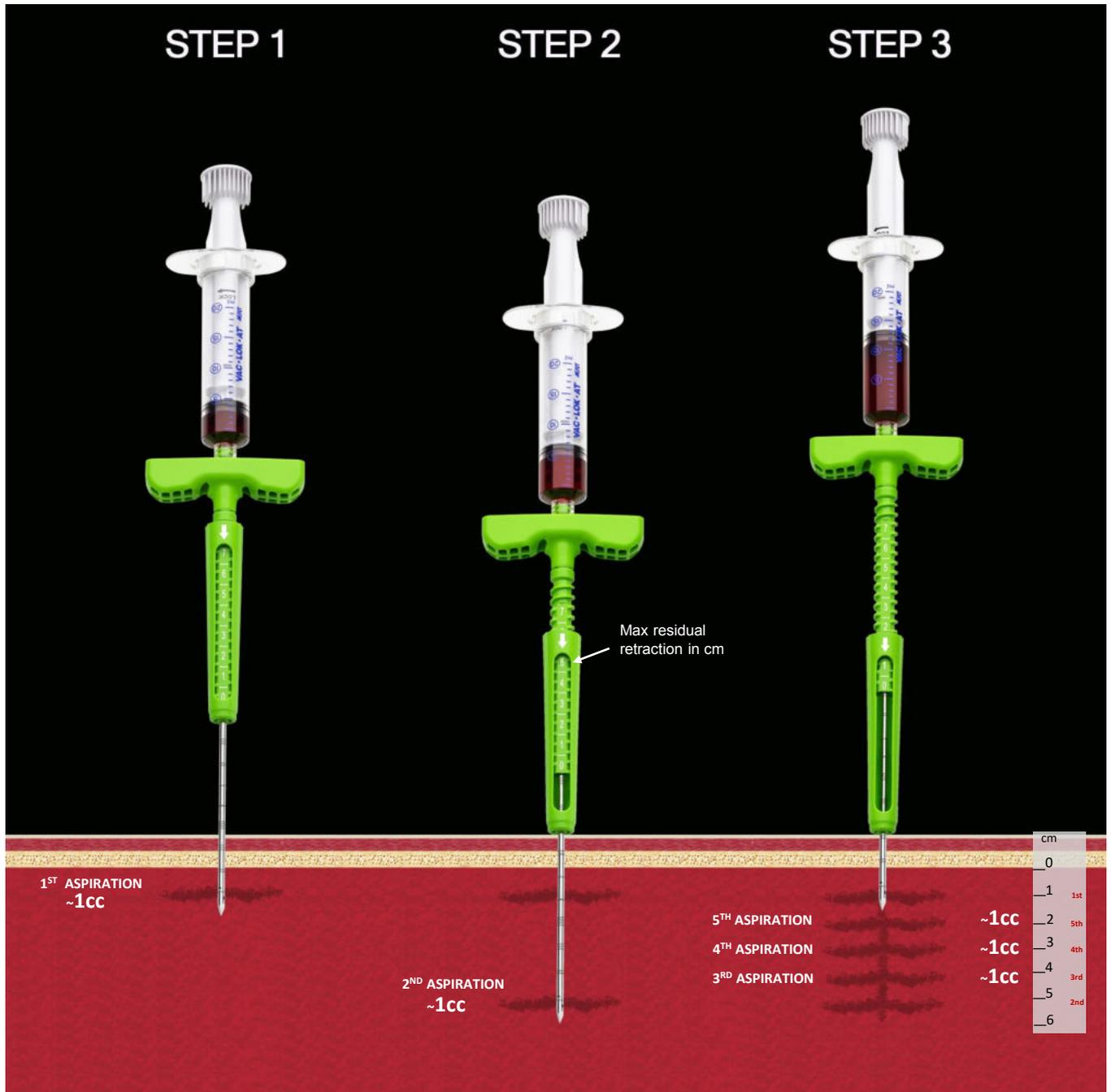
100% aspiration from the lateral holes

CLOSED & SEALED DISTAL TIP

High cellular yield

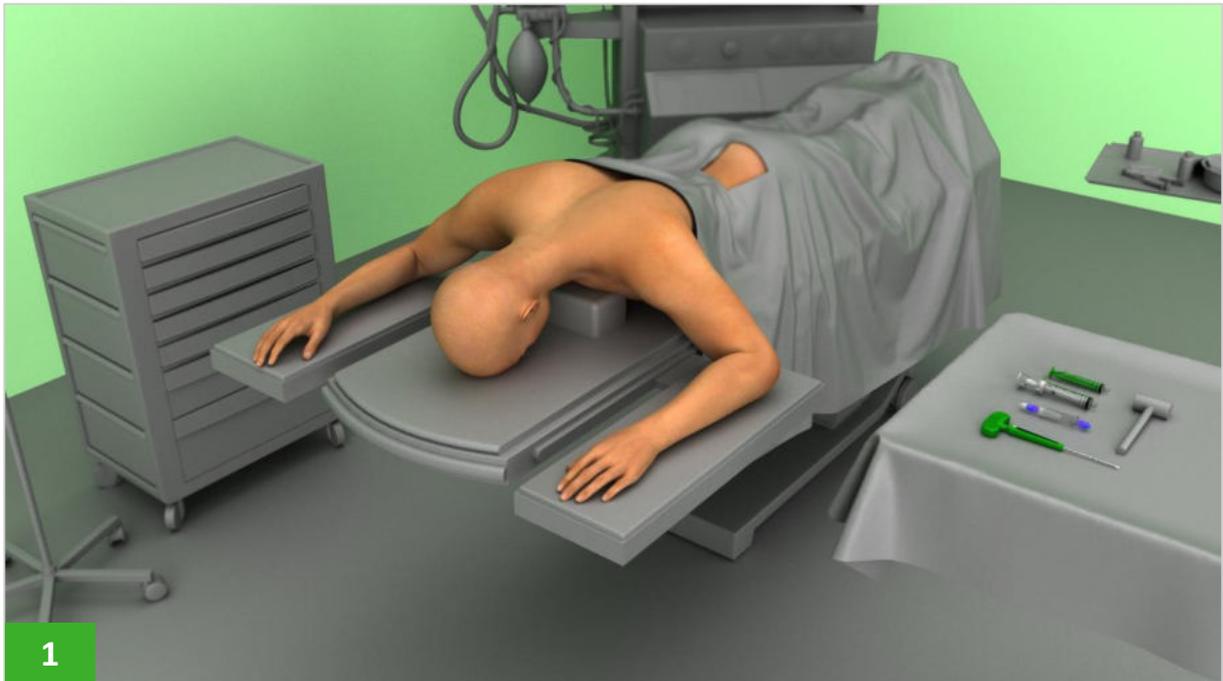


How does it work?



Aspiration example	CANNULA LENGTH under the cortical (cm)	NUMBER ON THE GEAR WINDOW	BONE MARROW ASPIRATED (cc)	TOTAL VOLUME ASPIRATED
1 st aspiration	2 cm	7cm	~1 cc	~1 cc
2 nd aspiration	6 cm	5cm	~1 cc	~2 cc
3 rd aspiration	5 cm	4cm	~1 cc	~3 cc
4 th aspiration	4 cm	3cm	~1 cc	~4 cc
5 th aspiration	3 cm	2cm	~1 cc	~5 cc

Surgical technique



Position the patient on the surgical table according to the selected marrow aspiration area and anaesthetize the patient (*fig. 1*).

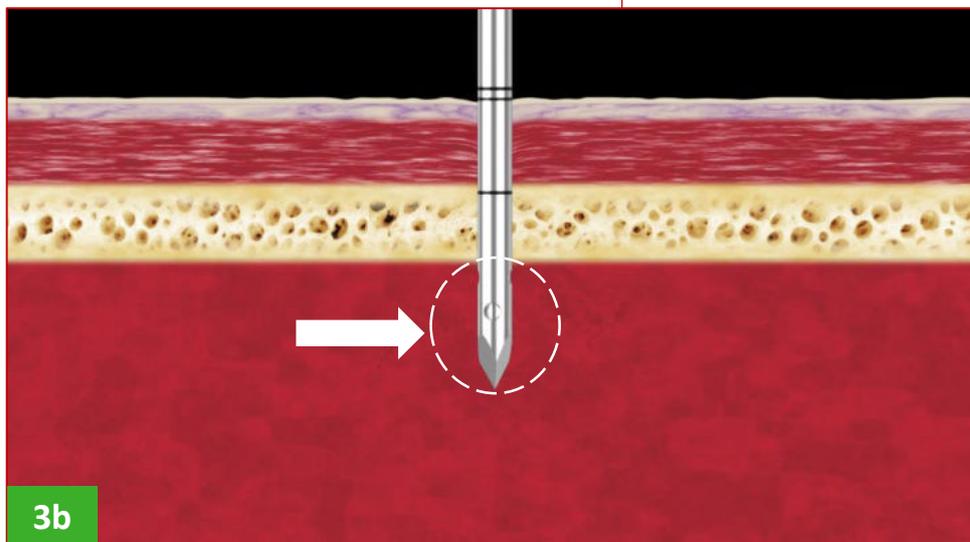
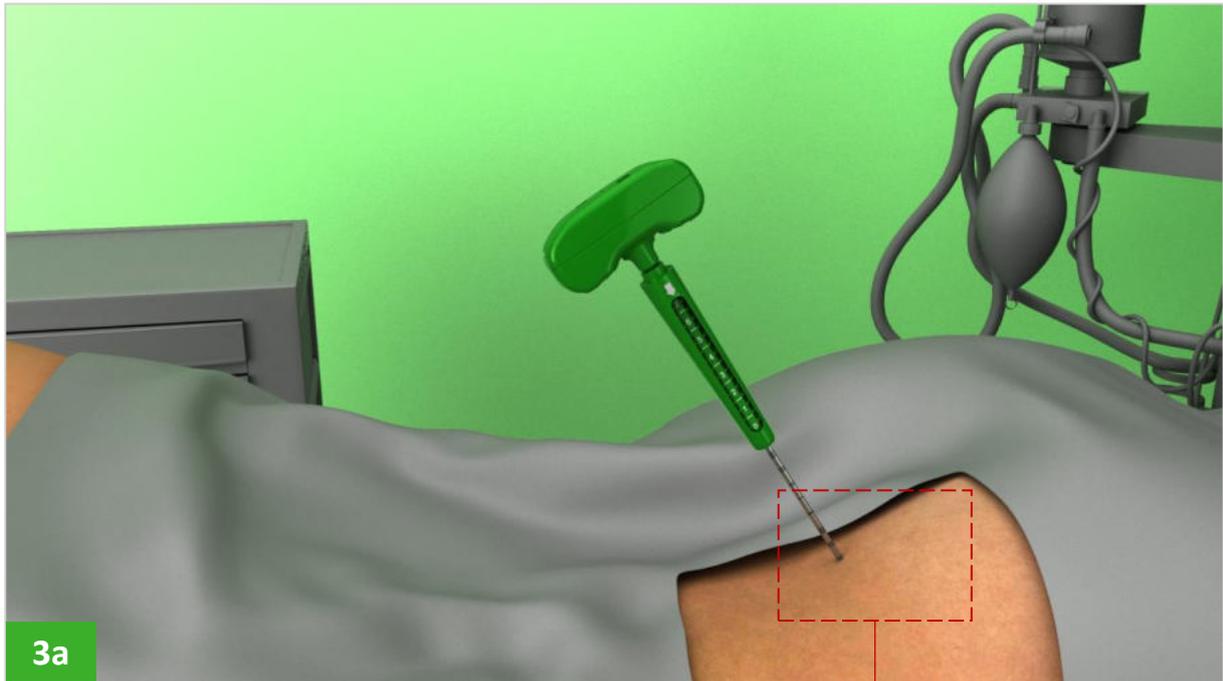


Proceed with the priming of the syringe (*fig. 2-a*) and **MARROW-STEM** device (*fig. 2-b*) with ACD-A anticoagulant and fill the Vaclok syringe (*fig. 2-c*) with 20% of anticoagulant considering the total amount of marrow aspiration.



ATTENTION: previously check patient's allergy to ACD-A anti-coagulant

Surgical technique

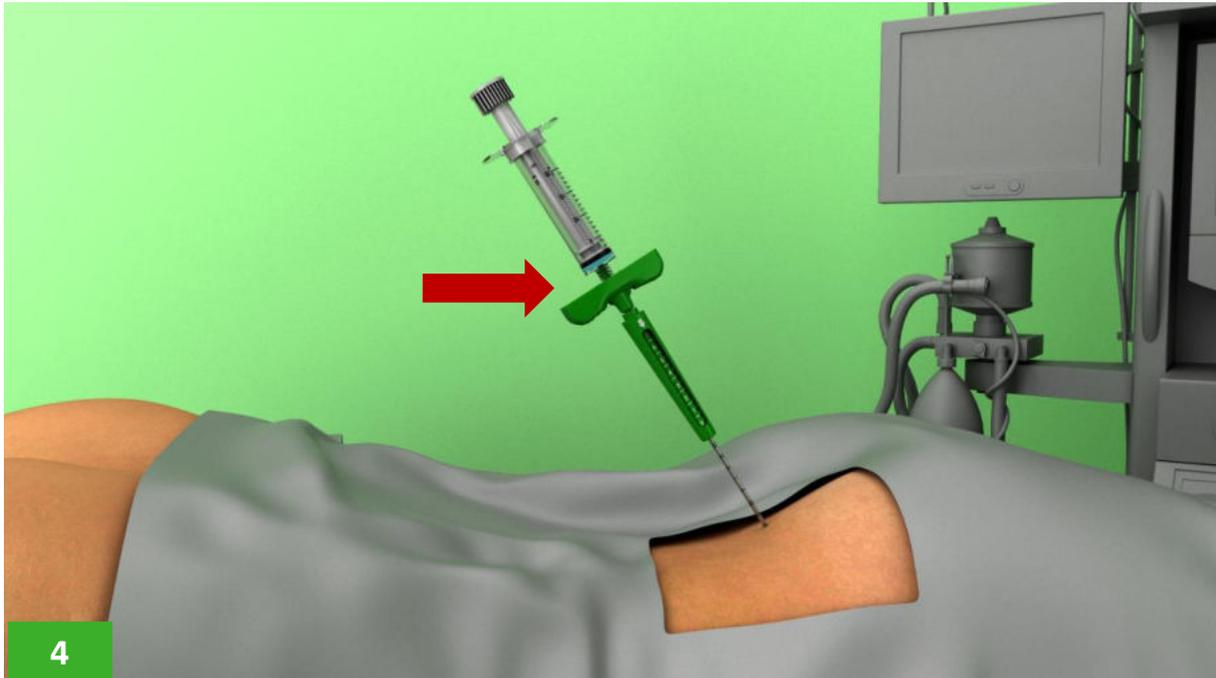


Position **MARROW-STEM** device on prechosen aspiration site and introduce the tip (*fig.3a*) beyond the distal cortical edge.

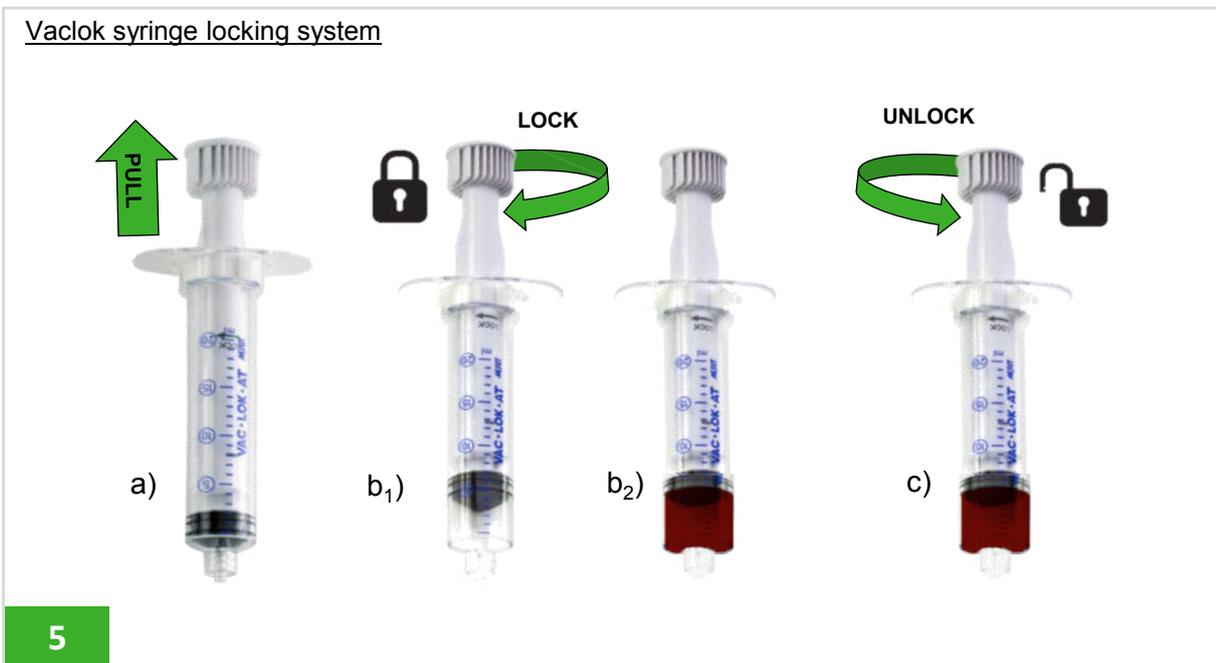
Check that all the lateral holes are located under the cortical bone (*fig.3b*).

Gently tap the handle if needed.

Surgical technique



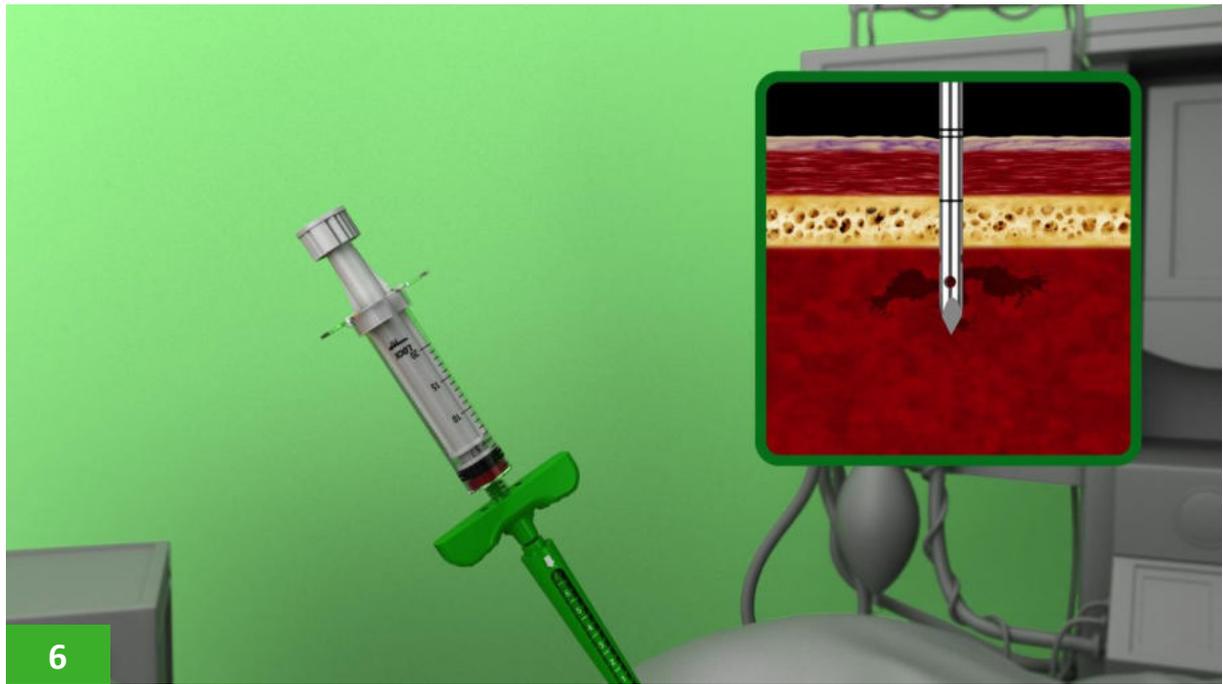
Remove internal stylet and connect the Vaclok syringe (prefilled with the ACD-A anticoagulant) to **MARROW-STEM** device (fig.4).



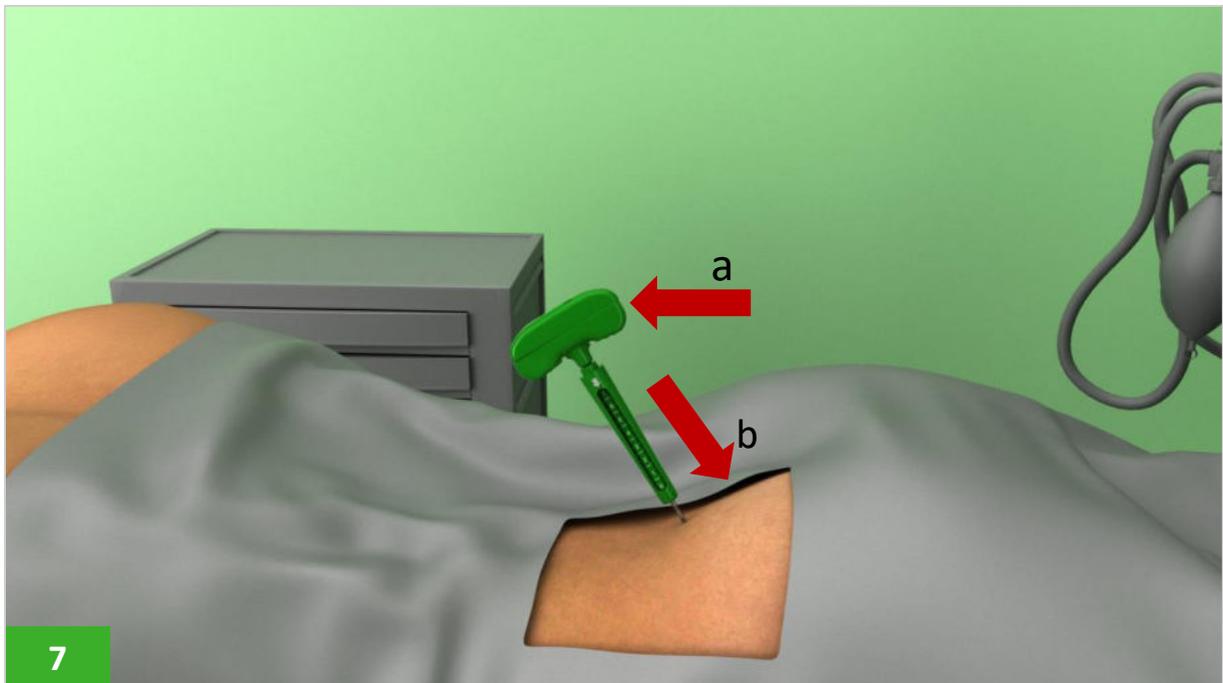
The Vaclok syringe provided with the kit allows a controlled bone marrow aspiration:

- pull back the syringe plunger till the desired amount of cc to be aspirated (fig.5-a).
- turn the syringe plunger to lock it (fig.5-b₁) and wait till the bone marrow fills the syringe (fig.5-b₂)
- turn the syringe plunger to the opposite direction to unlock it for another aspiration (fig.5-c).

Surgical technique

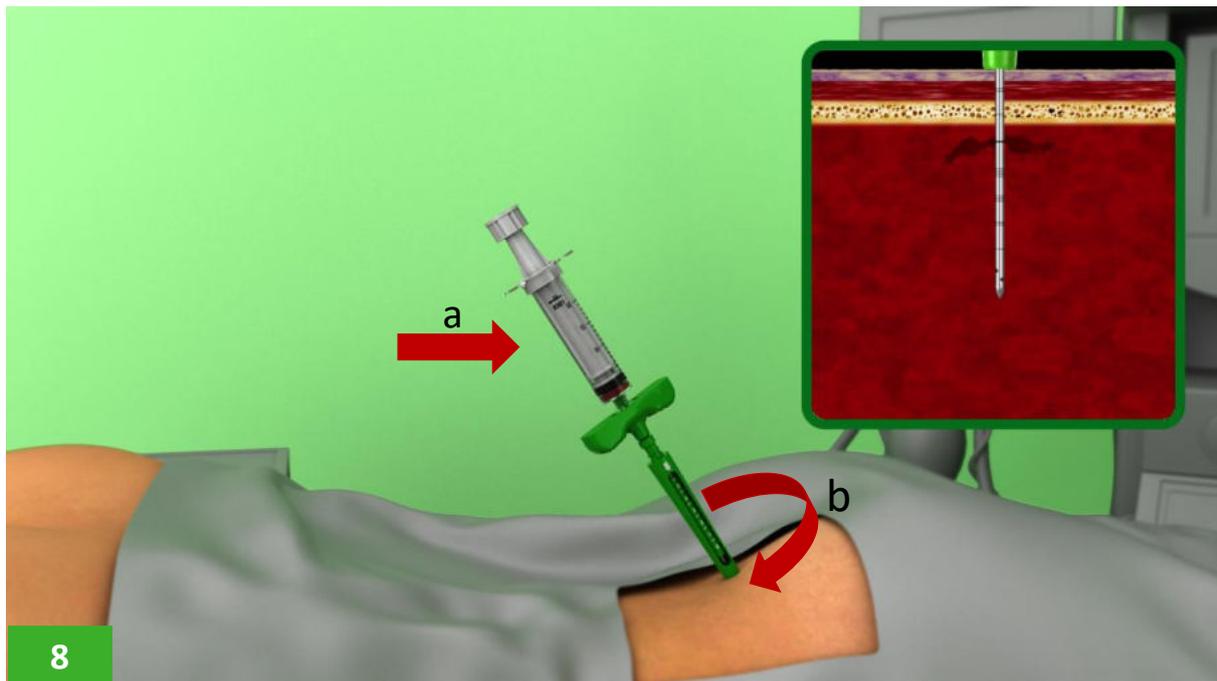


Aspirate the first cc of bone marrow just below the cortical bone (*fig.6*).



Disconnect the syringe and reinsert the stylet (*fig.7-a*).
Push the device deeper till the prechosen depth (*fig.7-b*).

Surgical technique



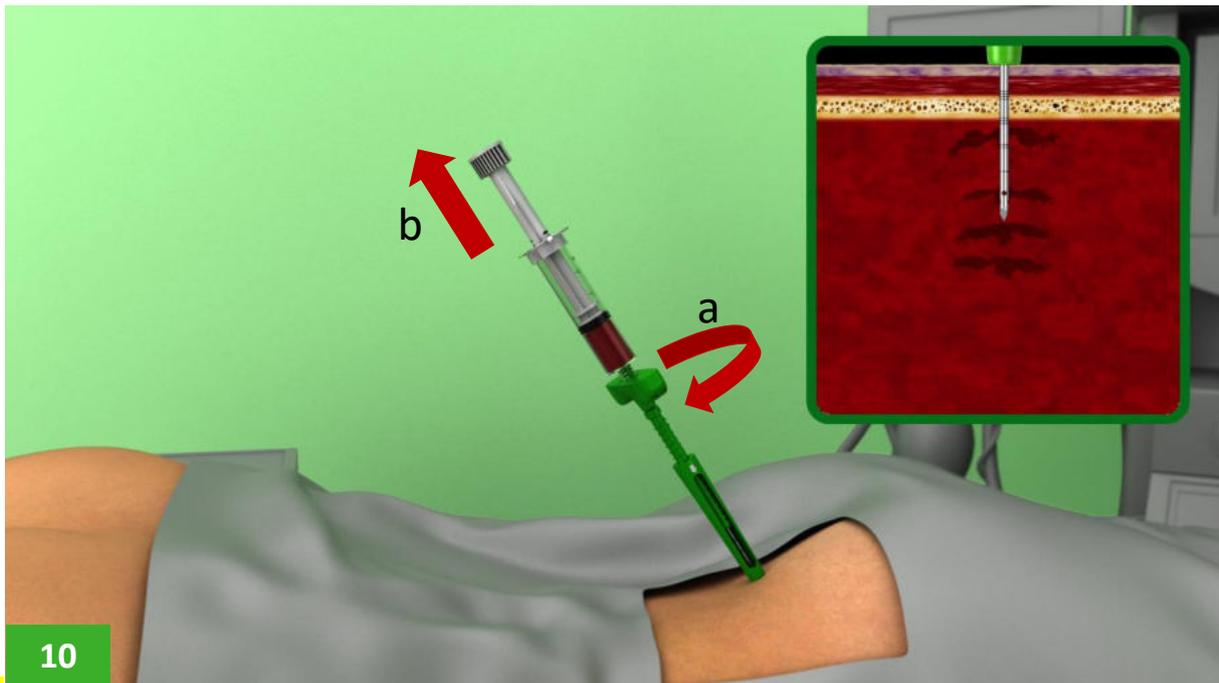
Remove the stylet and reconnect the syringe (*fig.8-a*) and adjust the gear into contact with the skin (*fig.8-b*).

Refer to the number indicated by the white arrow to control the needle's retraction: the number shown indicates the residual excursion in cm (see aspiration example table on page 7).

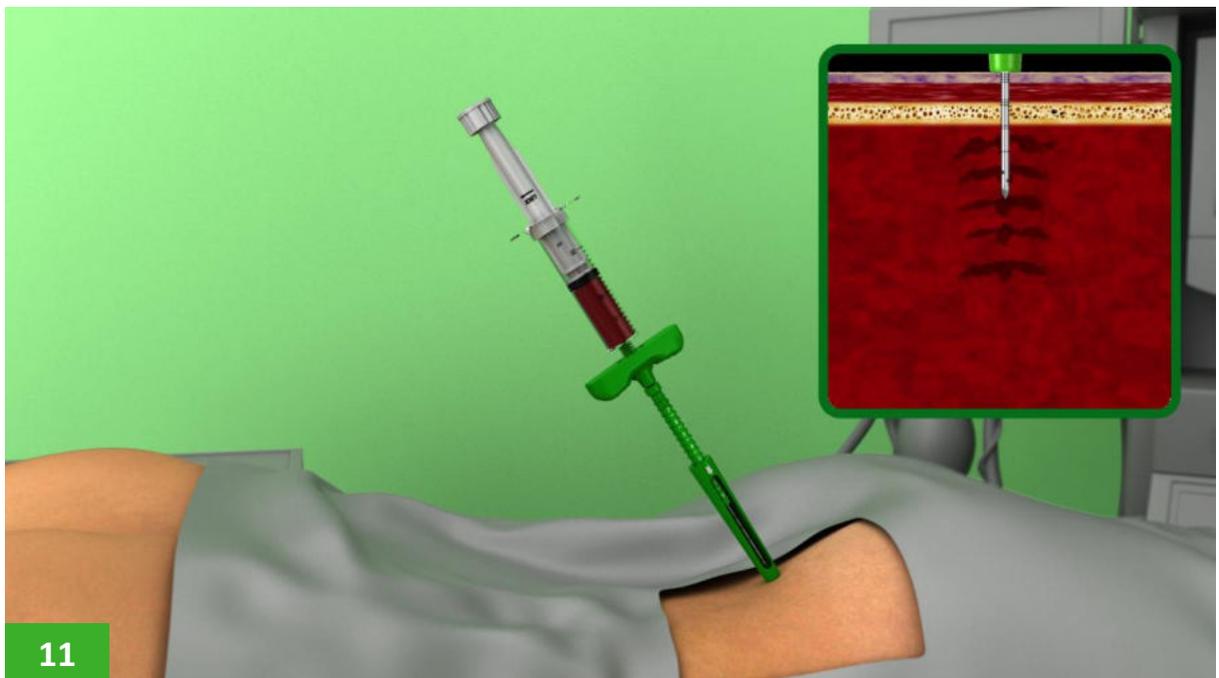


Unlock the syringe plunger, pull it back to create a negative pressure and lock it. Aspirate approximately 1 cc of bone marrow (*fig.9*).

Surgical technique



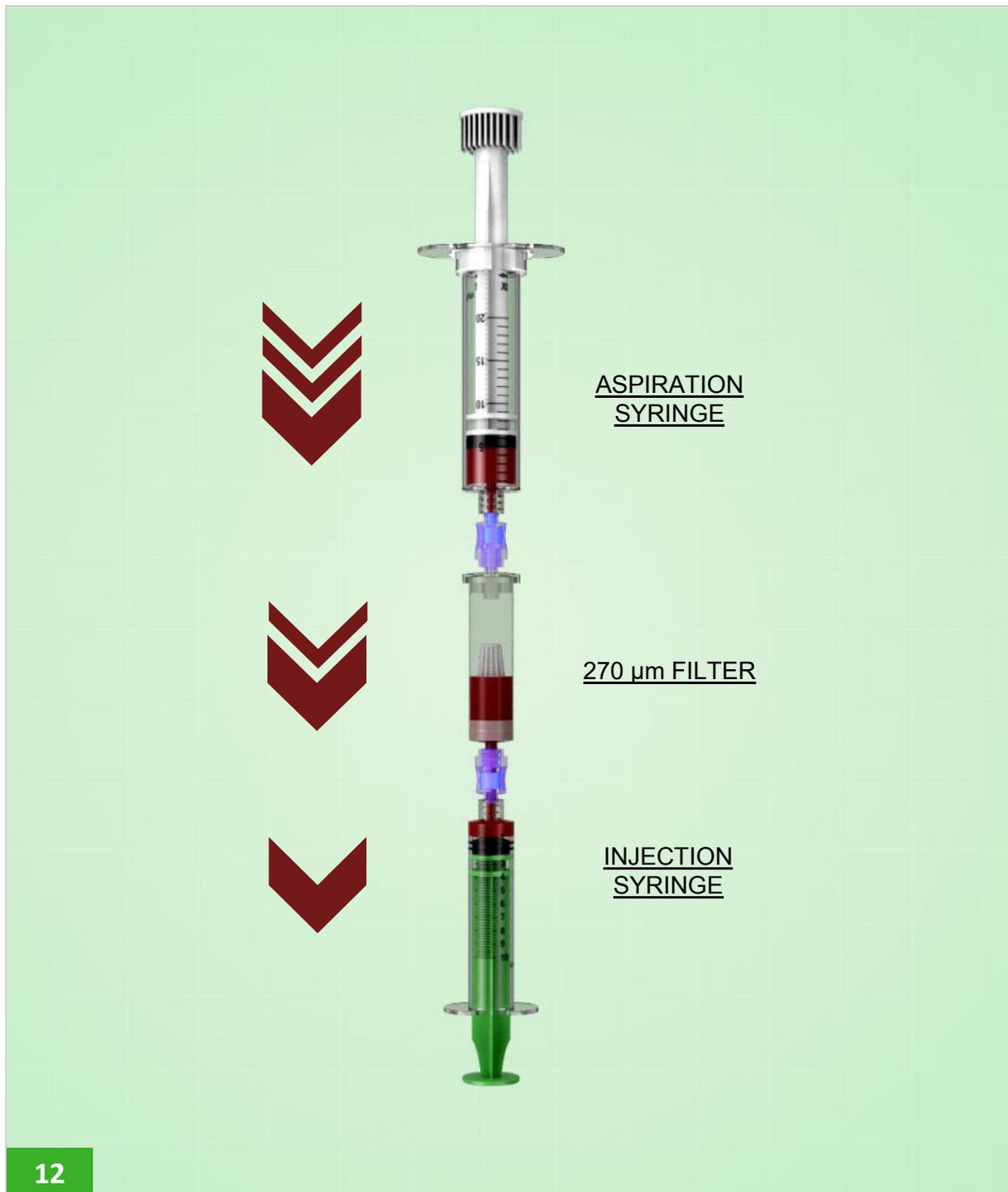
Holding the gear still, rotate the handle 360° clockwise (*fig.10-a*) to progressively pull back the cannula, then aspirate the bone marrow (*fig 10 b*).



Repeat the controlled aspiration process until the desired quantity of bone marrow has been obtained (*fig.11*).

The complete excursion of the gear allows the coverage up to 7 cm of the aspiration site. Once the operation has been completed, extract Marrow-Stem device and proceed with the medication.

Surgical technique



If necessary, the obtained marrow aspirate can be filtered to remove clots or cellular coagulation or aggregation using the 270-micron purification filter connected to the syringes supplied with the kit (*fig.12*).

Unlux system



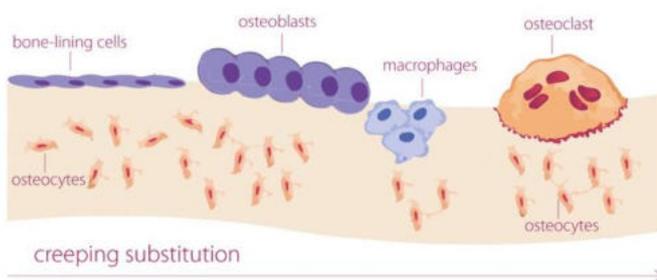
UNLUX SYSTEM can be used in combination with **MARROW-STEM DEVICE** to exploit the access created to take a bone graft from the iliac crest with low morbidity and invasiveness for the patient, obtaining an autologous autograft with osteoconductive, osteoinductive and osteogenic properties.

With this particular system, called “UNLUX”, it is possible to avoid the dislocation maneuver when the sample is being withdrawn. Due to its particular features, specific technical aspects of this device have been patented.

MAIN FEATURES:

- Minimally invasive autologous bone graft harvesting technique.
- Can be used in combination with **Marrow-Stem** and other bone substitute to produce a vascularized graft with osteoconductive, osteoinductive and osteogenic properties.
- The “Trocar” tip stylet guarantees fast and non-traumatic penetration.
- The ergonomic handle improves grip and the precision of the operation.
- The ultra-sharp crown tip of the cannula facilitates the removal of an intact bone graft.

CREEPING SUBSTITUTION



Creeping substitution is the process of remodelling a bone graft: by mixing the selective aspirate of stromal mesenchymal cells with an autologous bone graft, in addition to any other synthetic or homologous or xeno bone substitute, the creeping substitution process is accelerated.

VASCULARIZED GRAFT



AUTOLOGOUS BONE DOWEL

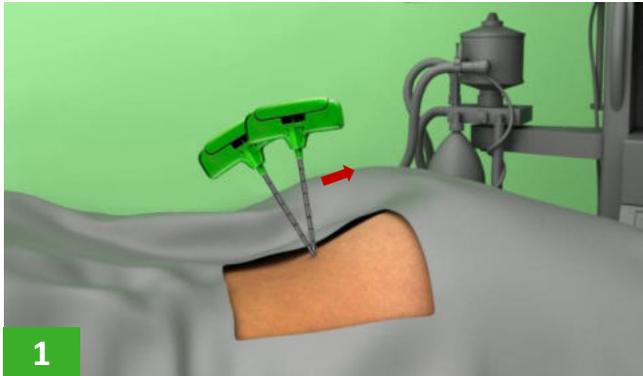
SELECTED BONE MARROW MSC

ANY KIND OF BONE SUBSTITUTE

The resulting graft will be extremely effective, similar to a vascularised graft with high regenerative potential.

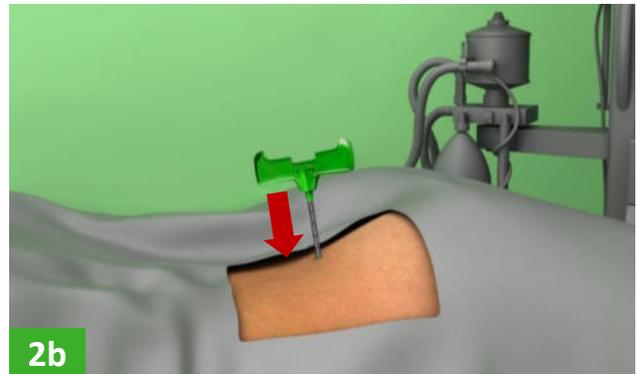
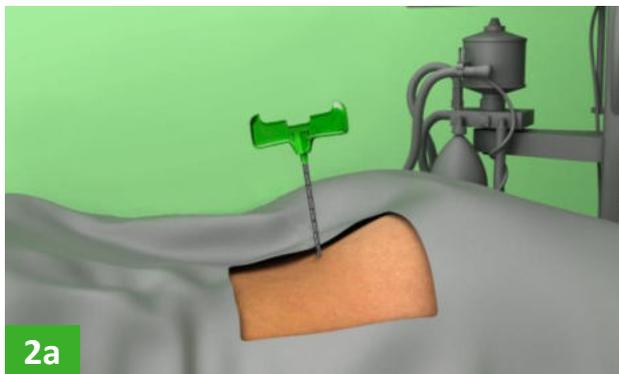
Surgical technique

UNLUX SYSTEM needle allows users to harvest a bone dowel from the planned aspiration site.

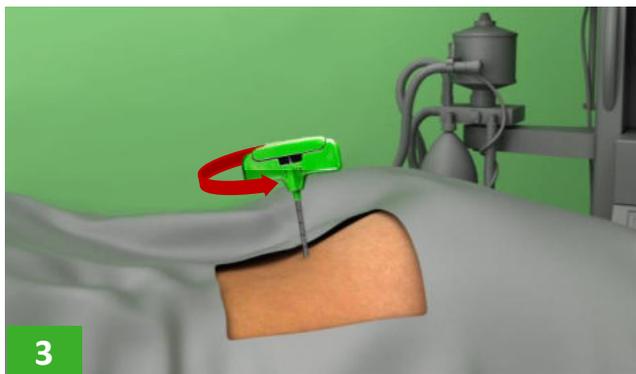


1. Insert the needle, with the stylet, in the access previously created with Marrow-Stem device. Once past the cortical bone, adjust the inclination angle of the cannula to reach a new sampling site (*fig. 1*).

Progress forward by rotating the needle to the right and left. When the resistance decreases, the medullary cavity has been entered.

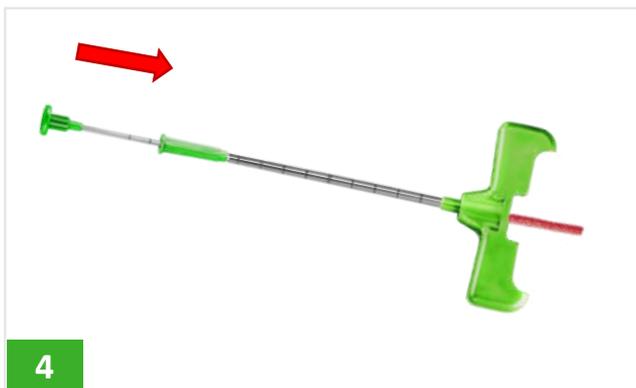


2. Remove the stylet (*fig. 2a*) and advance into the medullary cavity for about 4-5 cm (*fig. 2b*).



3. Insert the UNLUX cannula and rotate the entire device 360° twice, cutting a fragment of bone marrow tissue from the distal part, without damaging it and avoiding its dislocation (*fig. 3*).

Extract the entire UNLUX system (needle, cannula and stylet) from the patient.



4. Remove the UNLUX stylet from the cannula. To extract the bone dowel, insert the finger protection device and the extractor in the opposite side from the needle handle (*fig. 4*).



Contact us for further information:



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