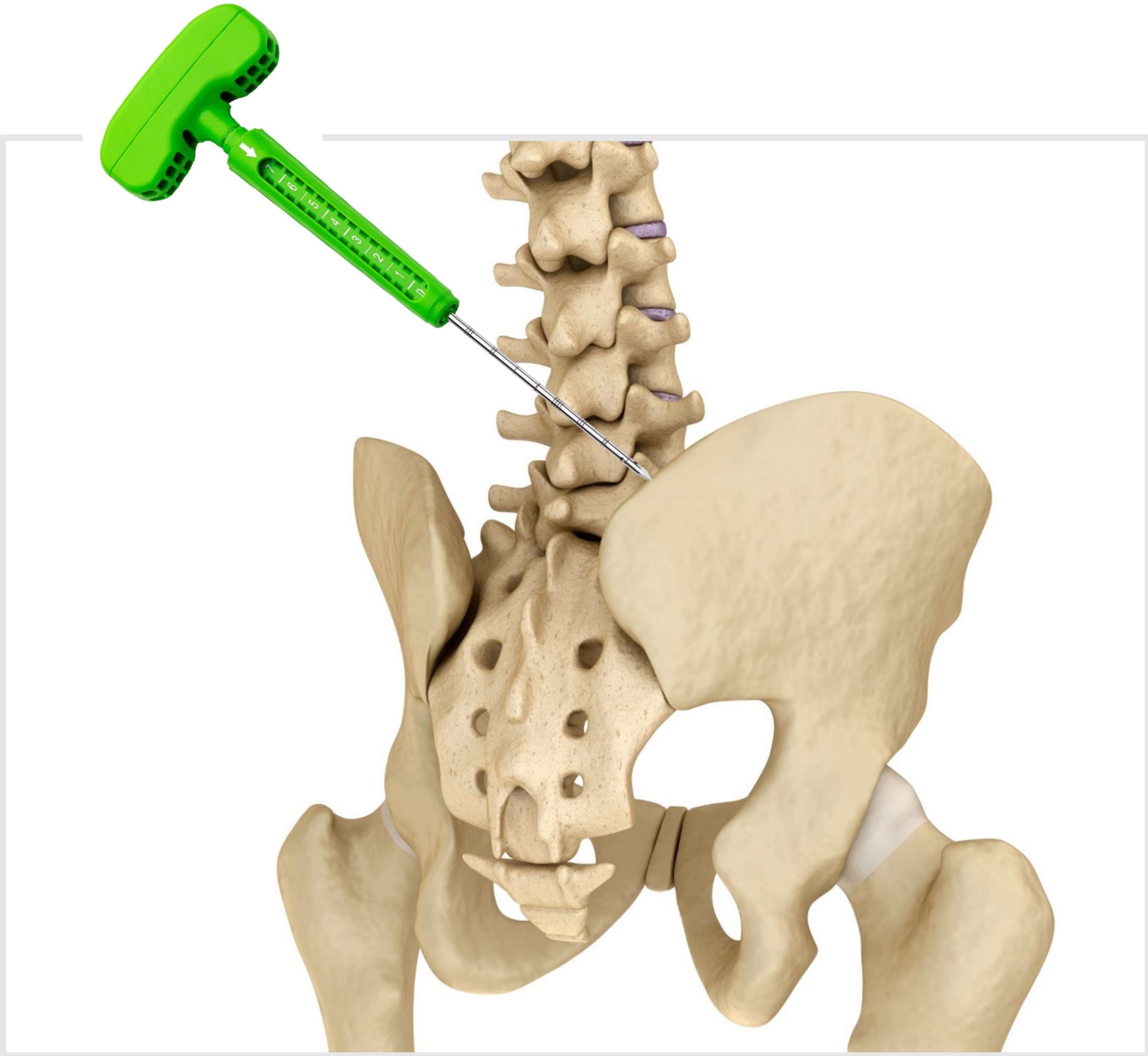
MARROW-STEM™

BONE MARROW MESENCHYMAL STEM CELLS SELECTIVE ASPIRATION KIT



Surgical technique

3P3 medica

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

50 YEARS
OF EXPERIENCE

70
COUNTRIES SERVED

OUR PRODUCT LINES:

SPINE

ORTHO-BIOLOGICS

ASSISTED REPRODUCTION

BIOPSY

INTENSIVE CARE

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 with an aim to ever-better qualifying, 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**

MARROW-STEM™

MARROW-STEM™ is a disposable device for the selective aspiration of bone marrow rich in mesenchymal cells which optimises the cellular yield by minimizing the contamination of peripheral blood thanks to a selective micrometric system for lateral aspiration and the closed distal tip, its innovative features.

INNOVATIVE

Thanks to the closed distal tip and selective lateral micrometric aspiration a **high cellular yield is guaranteed without the need for a large amount of bone 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

MICROMETRIC GEAR

0,5 cm cannula retraction every 360° rotation

NO PERIPHERAL BLOOD CONTAMINATION

100% aspiration from the lateral holes

CENTRIFUGE FREE

No processing time

POINT OF CARE THERAPY

Minimally invasive procedure

RESIDUAL RETRACTION CONTROL

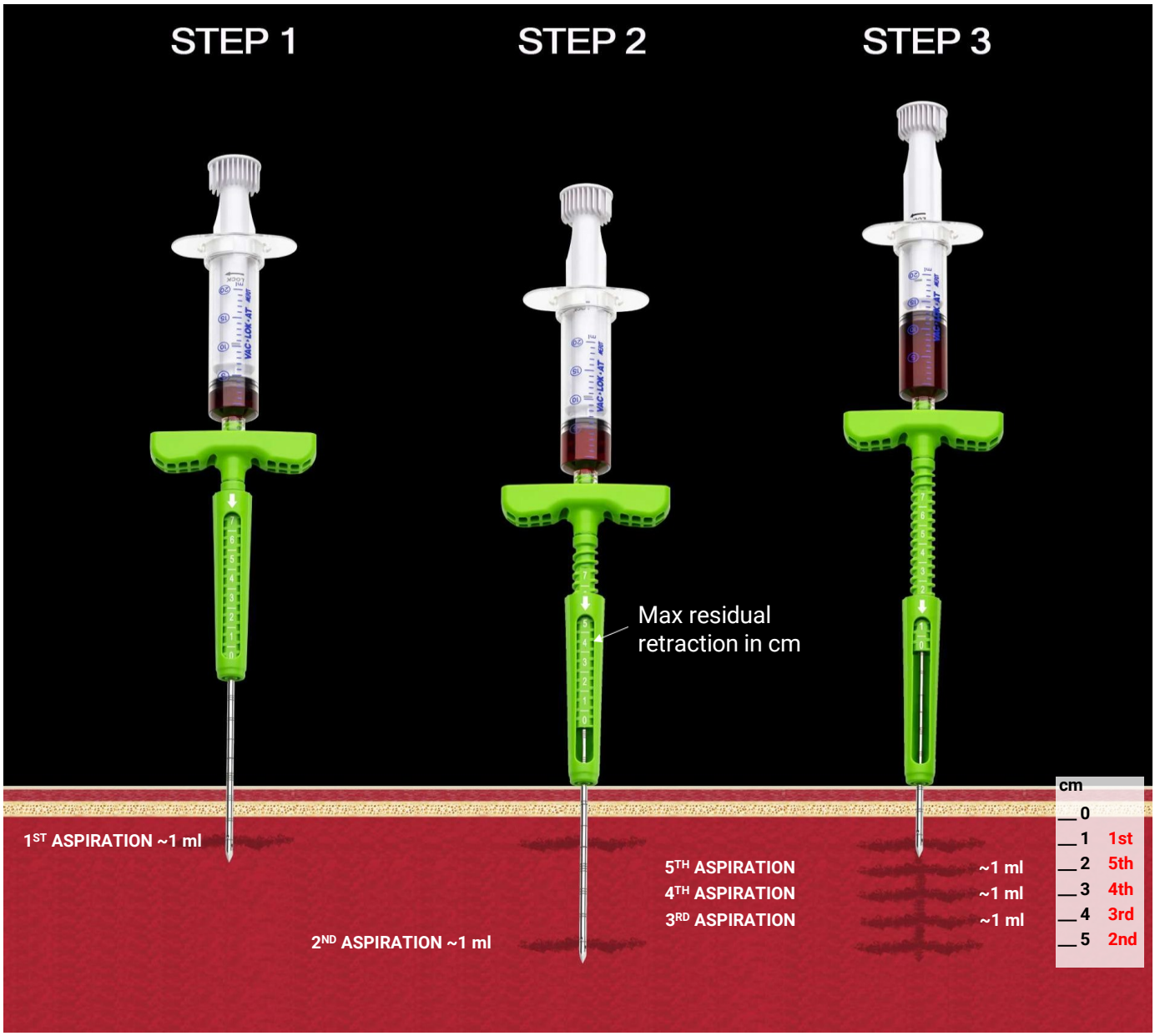
Thanks to the numbers printed on the gear window

CLOSED & SEALED DISTAL TIP

High cellular yield

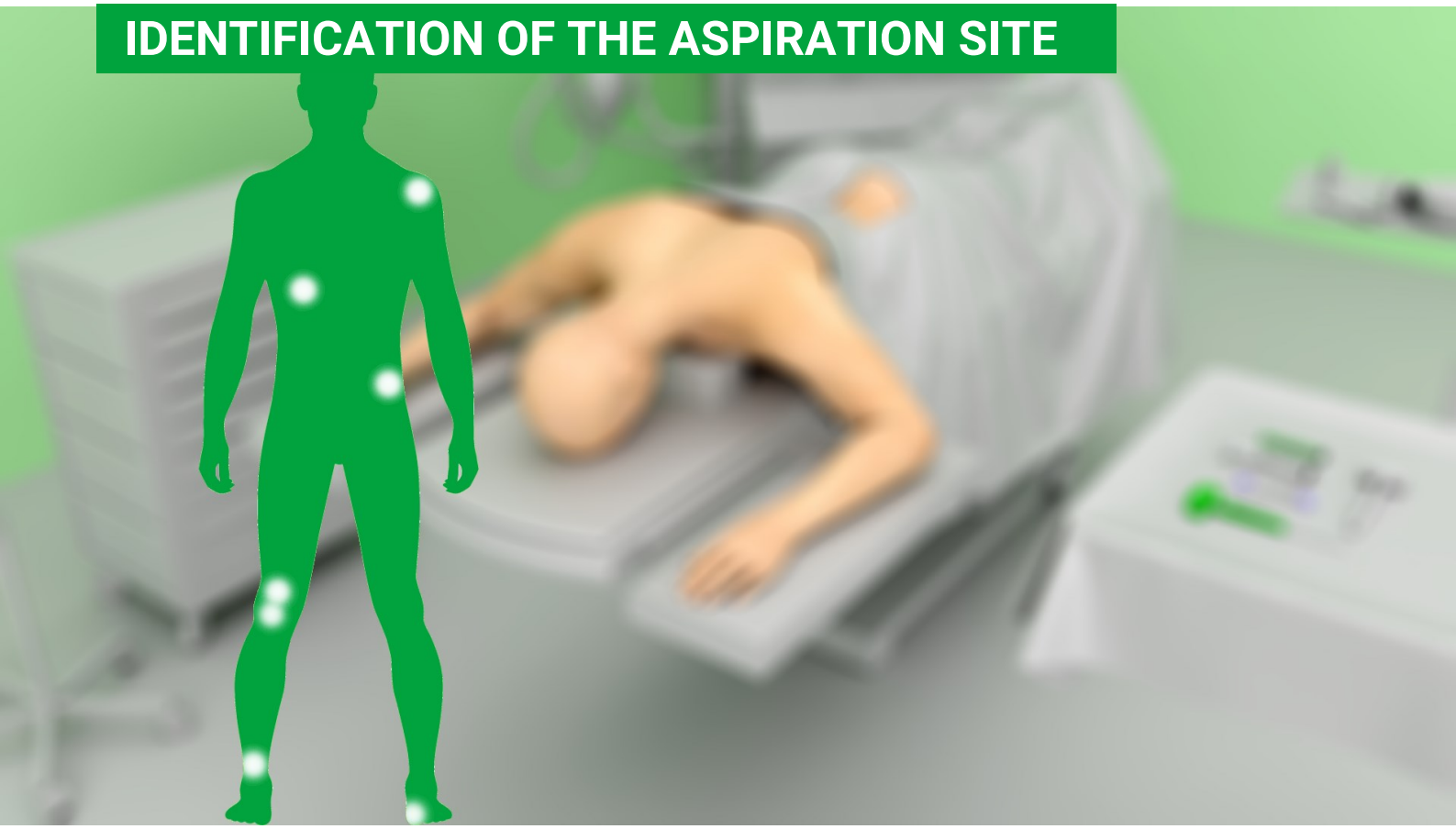
Displayed device colours are indicative.

How does it work?



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

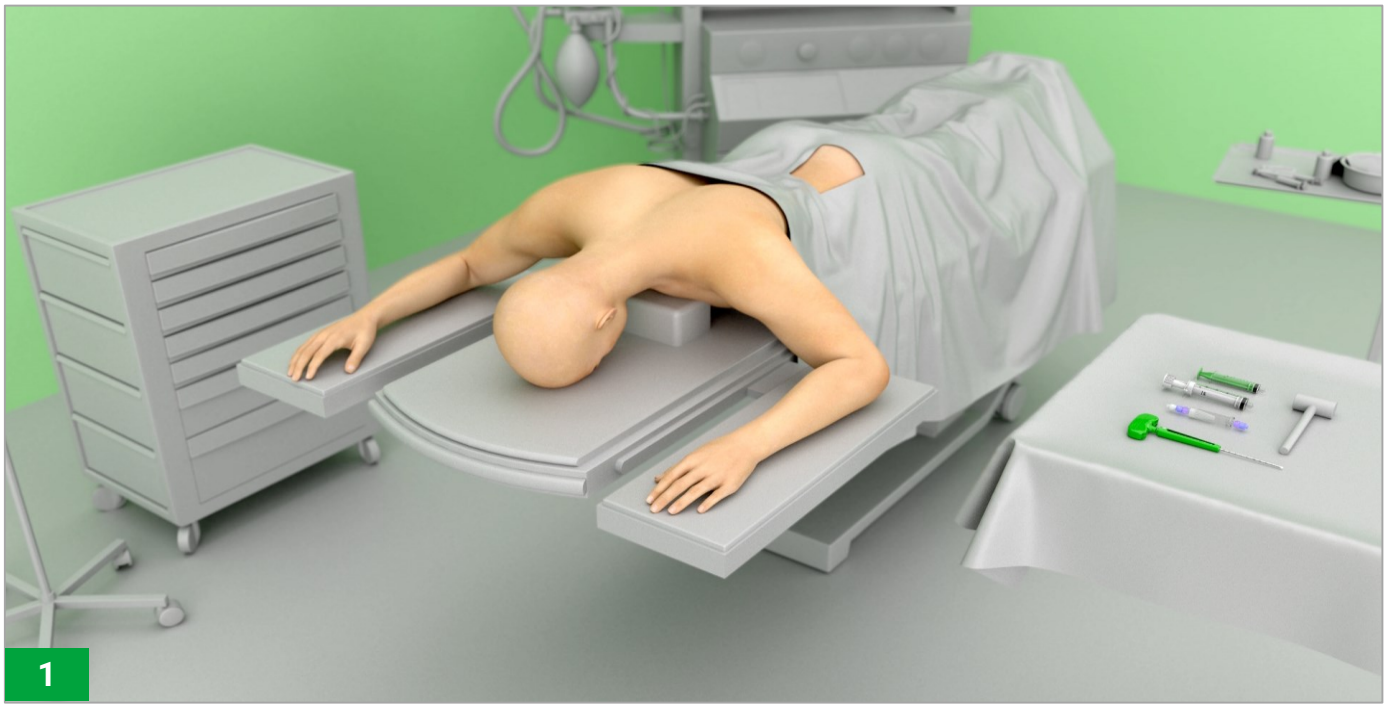
IDENTIFICATION OF THE ASPIRATION SITE



Bone marrow can be aspirated via a percutaneous approach from the subchondral bone. Various anatomical sites are achievable to perform extraction at low morbidity:

- Iliac crest
- Proximal tibia
- Distal femur
- Calcaneus
- Distal tibia
- Proximal humerus
- Vertebral body

Surgical technique



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Patient positioning on the surgical table according to the selected marrow aspiration area. Proceed with anaesthesia (local or general)*(fig.1)*.

2a

2b

2c

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

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

Priming of the device

To prevent clot formation during bone marrow aspiration, flush the harvesting devices with an anticoagulant, preferably Heparin. Cultures of bone marrow aspirate taken with the use of Heparin return a greater formation of CFU-f and a higher frequency of CFU-f than cultures of bone marrow aspirate taken with the use of sodium citrate.
Ensure that the concentration of Heparin is at least 1000 units/ml, preferably 2000 units/ml.
In order to extend the time of resistance to coagulation of the bone marrow aspirate, before aspiration load into the collection syringe a quantity of anticoagulant equal to 20% of the volume of bone marrow aspirate to be collected. 10 ml of heparin is usually sufficient to both prime the entire device and leave the 20% amount in the syringe.
If a more concentrated Heparin is available, dilute it with sterile saline or PBS (Phosphate buffered saline) to reach a concentration of 2000 units/ml according to this chart:

Heparin concentration	ml of Heparin	ml of saline solution/PBS	Total ml of rinse solution	Total heparin units
2.000 units/ml	10	0	10	2000
5.000 units/ml	4	6		
10.000 units/ml	2	8		

Suggested procedure for the anticoagulant flush:

1. Prepare 10 ml of sterile anticoagulant in a sterile bowl.

2. Draw 7 ml of anticoagulant into the 20 ml Vac-lock syringe and carefully rinse all the inside walls of the syringe.

3. Remove the internal stylet of MARROW-STEM™ and connect the anticoagulant-filled syringe to MARROW-STEM™.

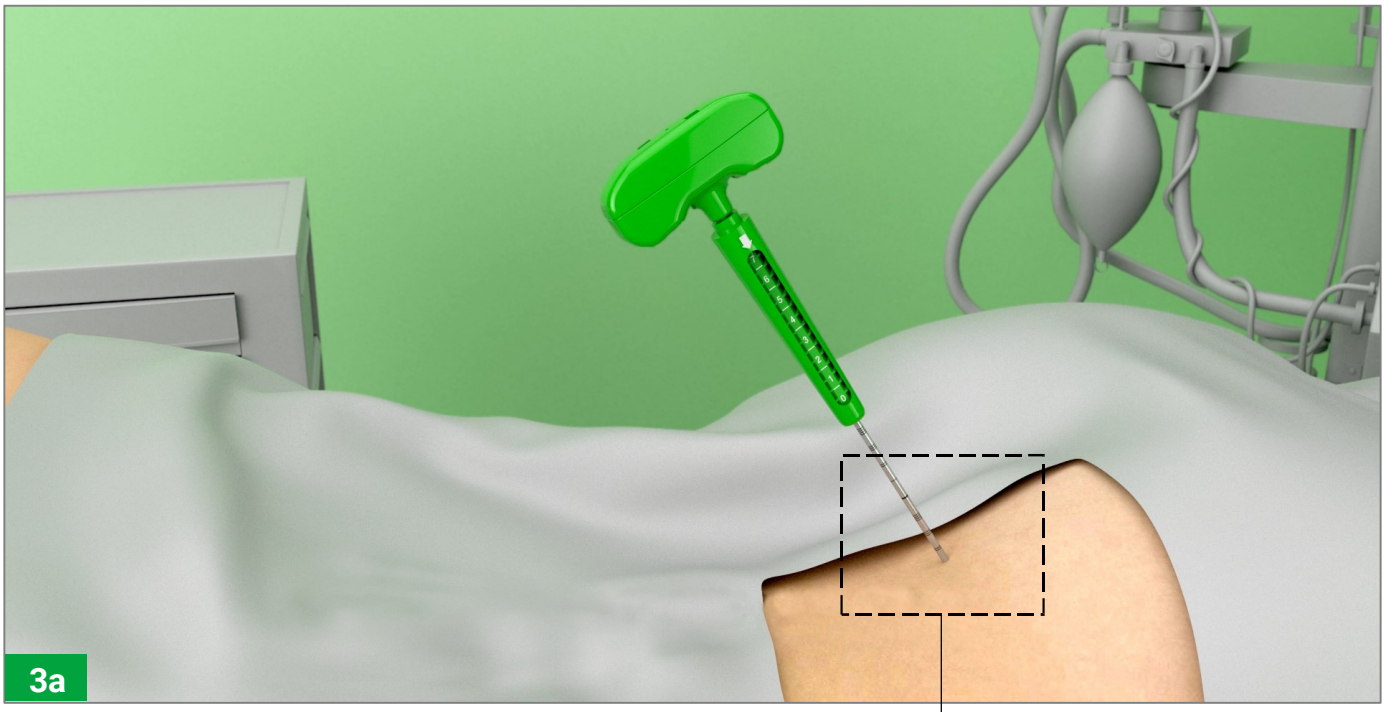
4. Inject anticoagulant to wet the MARROW-STEM™ internally and disconnect the syringe.

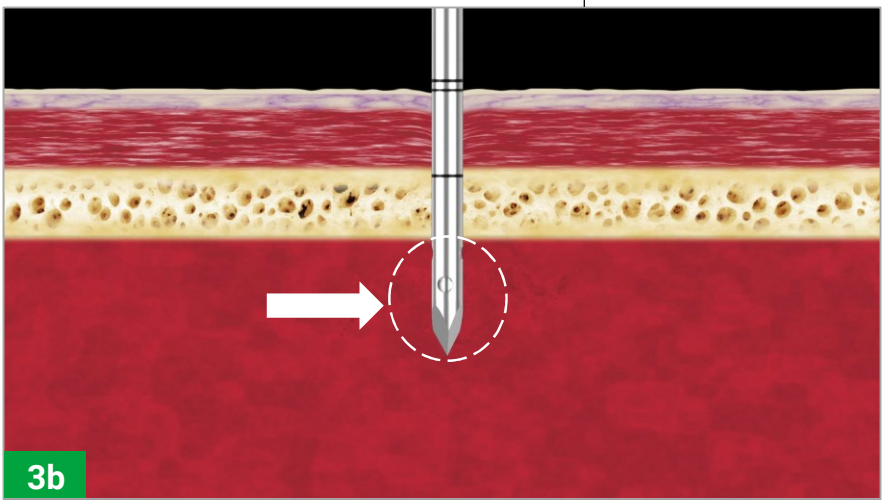
5. Aspirate the anticoagulant again with the syringe and wet the entire length of the MARROW-STEM™.

6. Thoroughly rinse the stylet along its entire length. If you use the filter, rinse it along with the injection syringe.

7. Withdraw an amount of anticoagulant equal to 20% of the total aspirate to be collected and leave it in the syringe during the procedure.

Surgical technique



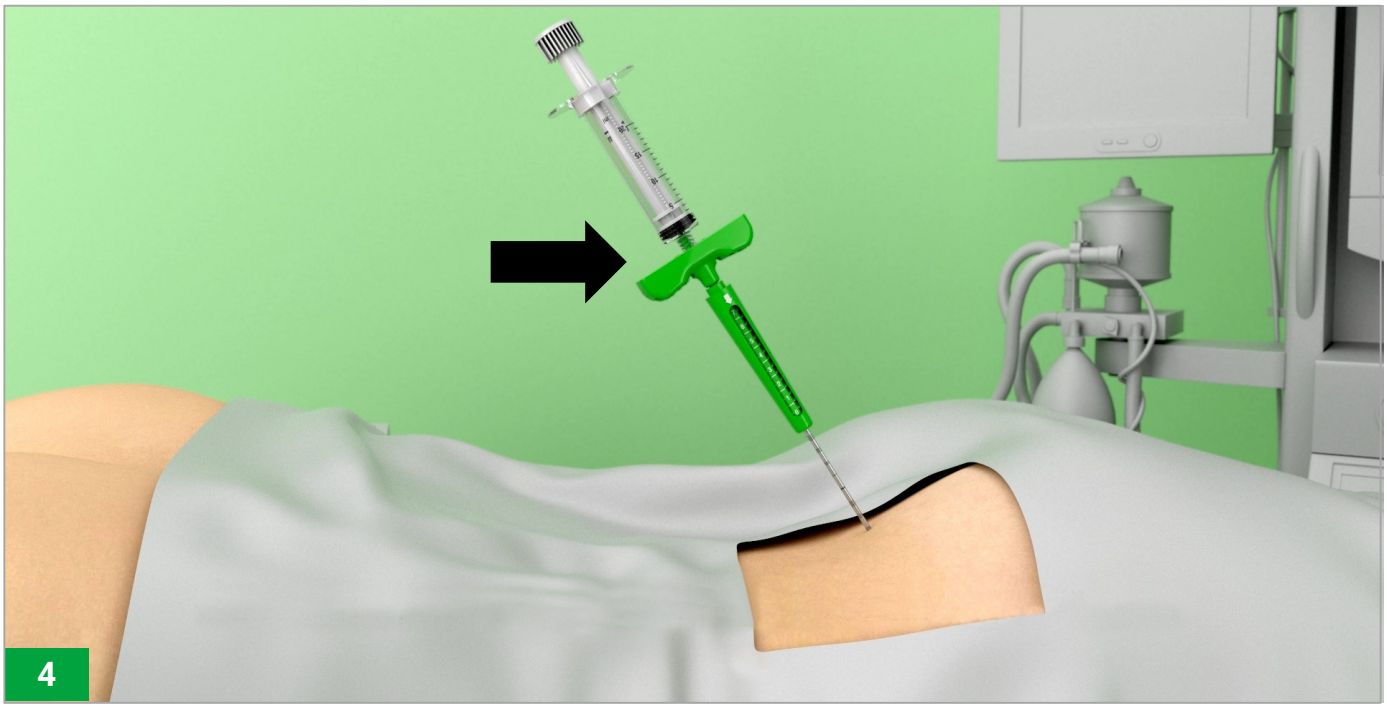


Make a small incision on the prechosen aspiration site, position the MARROW-STEM™ device and introduce the tip *(fig.3a)* beyond the distal cortical edge.

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

Gently tap the handle if needed.

CAUTION: Check in advance for any patient allergies to anticoagulant



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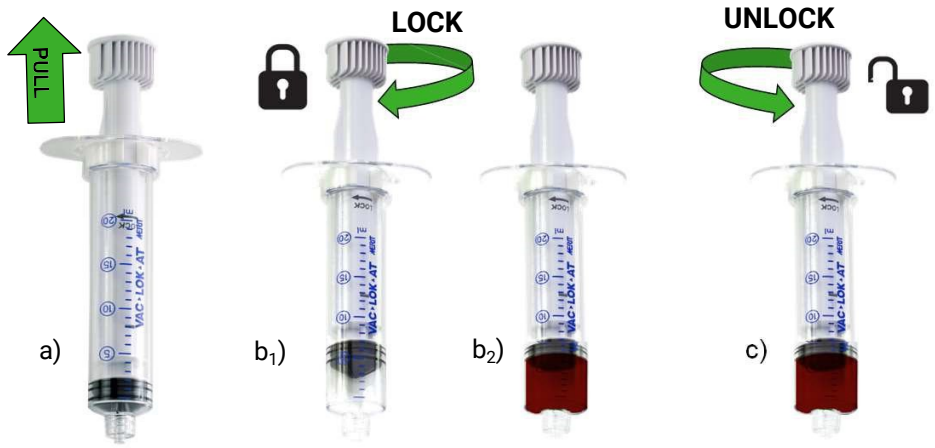
Remove the internal stylet and firmly connect the Vaclok syringe (prefilled with the anticoagulant) to the MARROW-STEM™ device *(fig.4)*.

Vaclok syringe locking system



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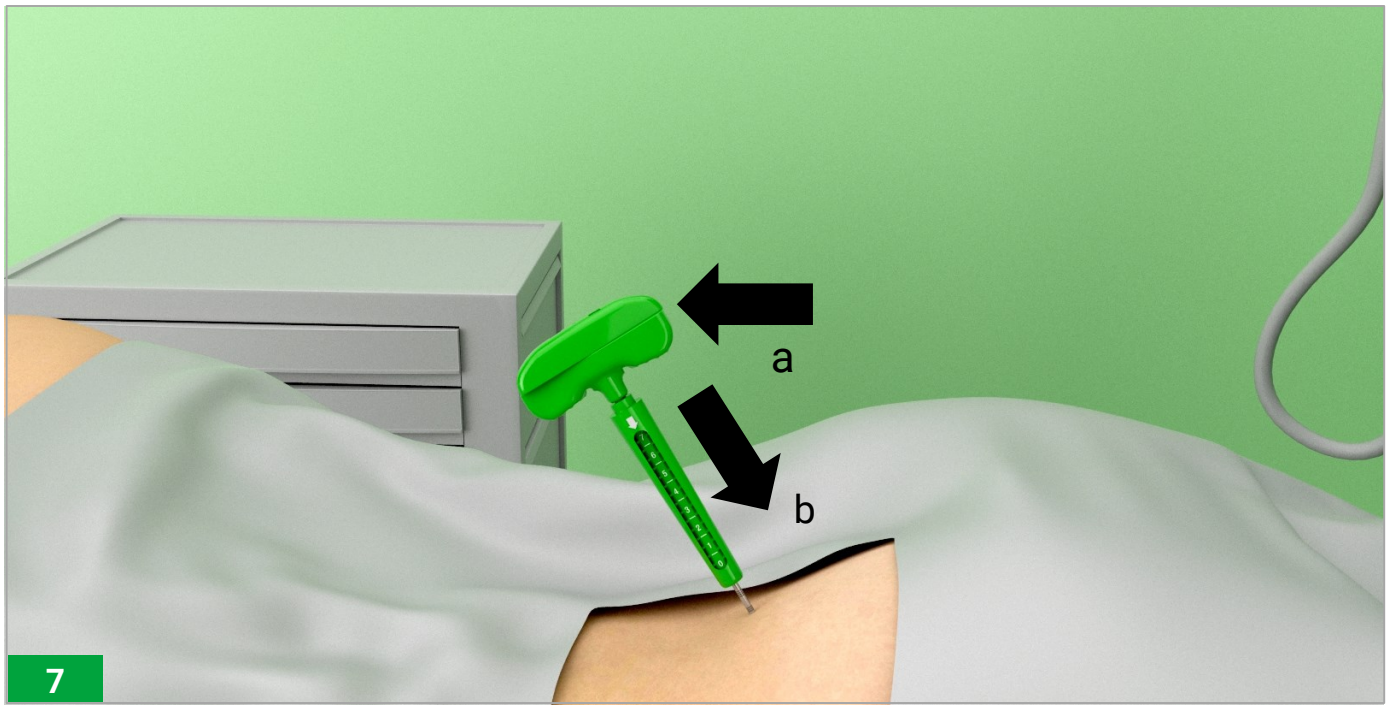
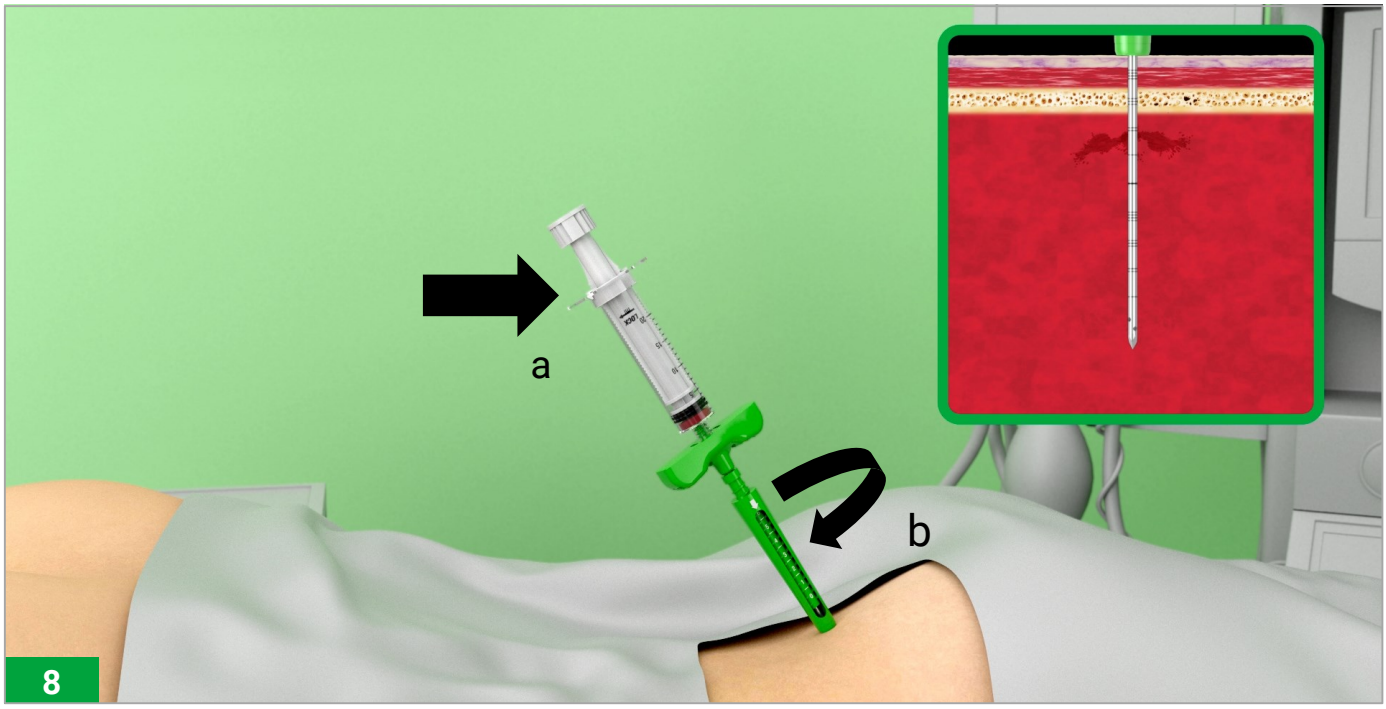
The Vaclok syringe provided with the kit allows a controlled bone marrow aspiration:
a) pull back the syringe plunger till the desired amount of ml is aspirated *(fig.5-a)*.
b) turn the syringe plunger to lock it *(fig.5-b_1)* and wait till the bone marrow fills the syringe *(fig.5-b_2)*
c) turn the syringe plunger in the opposite direction to unlock it for further aspiration *(fig.5-c)*.

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



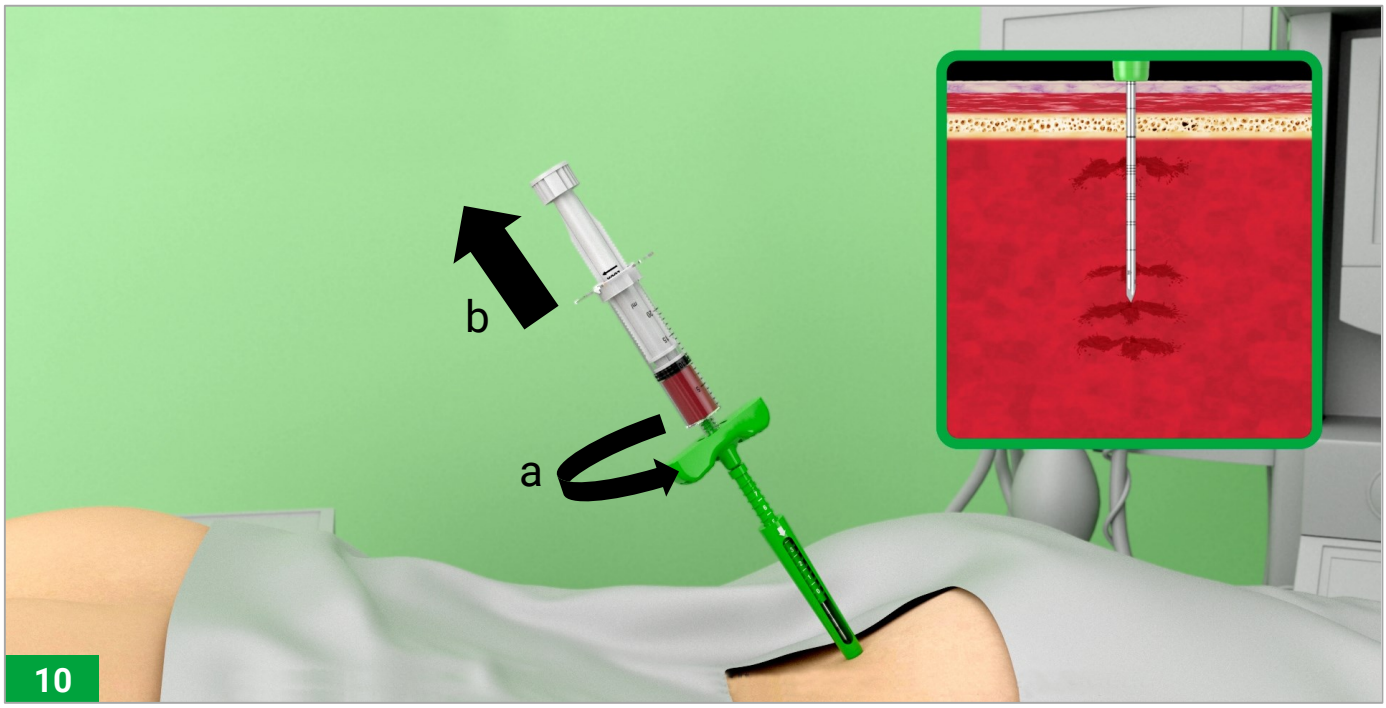
Disconnect the syringe and reinsert the stylet (*fig.7-a*). Push the device deeper to the prechosen depth *(fig.7-b)*.



Remove the stylet, reconnect the syringe (*fig.8-a*) and adjust the gear into contact with the skin (2) *(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).

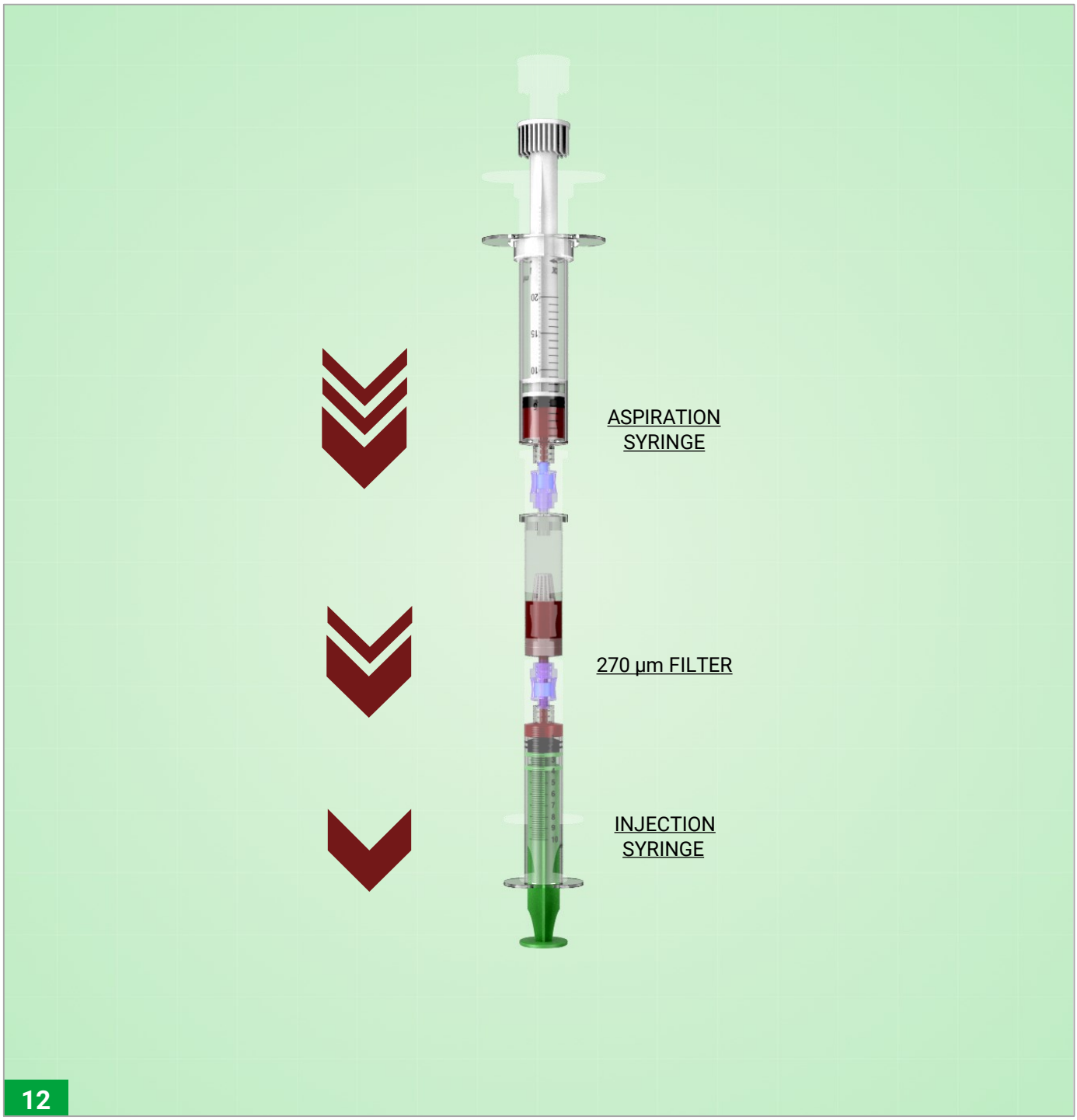
Unlock the syringe plunger, pull it back to create negative pressure and lock it. Aspirate approximately 1 ml of bone marrow *(fig.9)*.



Holding the gear still, rotate the handle 360° counterclockwise (*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 of up to 7 cm of the aspiration site. Once the operation has been completed, extract the MARROW-STEM™ device and proceed with the medication.



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If necessary, the obtained marrow aspirate can be filtered to remove clots or bone residues by connecting the VacLok syringe to the 270-micron purification filter and to the second syringe supplied with the kit (fig.12).

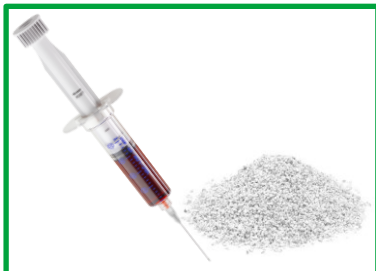
Application

Bone marrow MSCs aspirate can be used to accelerate the natural healing process of tissues and can be combined with autologous bone graft or any other kind of bone substitute to create an enhanced bone graft and boost the bone remodelling process.

Bone marrow MSCs aspirate

BONE MARROW MSCs SELECTIVE ASPIRATE INFILTRATION
- Point of care therapy

Indication:
- Intra-articular infiltrations
- Condropathies
- Tendinopathies
- Pain therapy
- Bone cysts



Bone marrow MSCs aspirate + any kind of bone substitute

ENHANCED BONE SUBSTITUTE FOR BONY FUSIONS
BONE MARROW MSCs SELECTIVE ASPIRATE can be used to enhance any bone substitute (homologous, synthetic or xenograft origin).

Indication:
- Bone cysts
- Spinal fusions
- Revision surgeries
- Foot and ankle fusions
- Open wedge osteotomies

Bone marrow MSCs aspirate + autologous bone dowel

ENHANCED AUTOLOGOUS BONE DOWEL
BONE MARROW MSCs CONCENTRATE can be combined with an autologous bone dowel to accelerate the natural bone regeneration process.

Indication:
- Avascular necrosis
- Bone Marrow Lesions
- Trauma procedures
- Pseudoarthrosis and consolidation delays

Bone marrow MSCs aspirate + any kind of bone substitute + autologous bone dowel

VASCULARISED GRAFT
Mixing the BONE MARROW MSCs SELECTIVE ASPIRATE with an autologous bone graft and any homologous, synthetic or xeno bone substitute boosts the creeping substitution process. The resulting graft will be extremely effective, similar to a vascularised graft with high regenerative potential.

Indication:
- Massive bone loss
- Pseudoarthrosis and consolidation delays

Contact us for further information:

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ISO 13485 BUREAU VERITAS Certification

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