

MARROWSTIM™

concentration system



Concentrating the Power of Stem Cells

BIOMET®
BIOLOGICS, INC.

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Would you like to improve your Treatment by:

- Improving tissue regeneration?
- Accelerating wound healing?
- Reducing swelling?
- Stimulating bone healing?
- Reducing the risk of infection?

Do you recognize these problems as a result of:

Delayed Wound Healing

- Increased risk of infections

Soft Tissue Swelling

- Pain
- Longer immobilisation
- Decreased range of motion

Pseudarthrosis

- Longer immobilisation
- Re-operation

Infection

- Need for antibiotics
- Re-operation

Leading to:

- Higher costs
 - More nursing care
 - Longer hospital stay
 - Increase in narcotics
 - Longer rehabilitation
- Dissatisfied patients, surgeons and nursing personnel
- Revisions / surgical failure



Published literature has shown that:

The Proof

In Hard Tissue

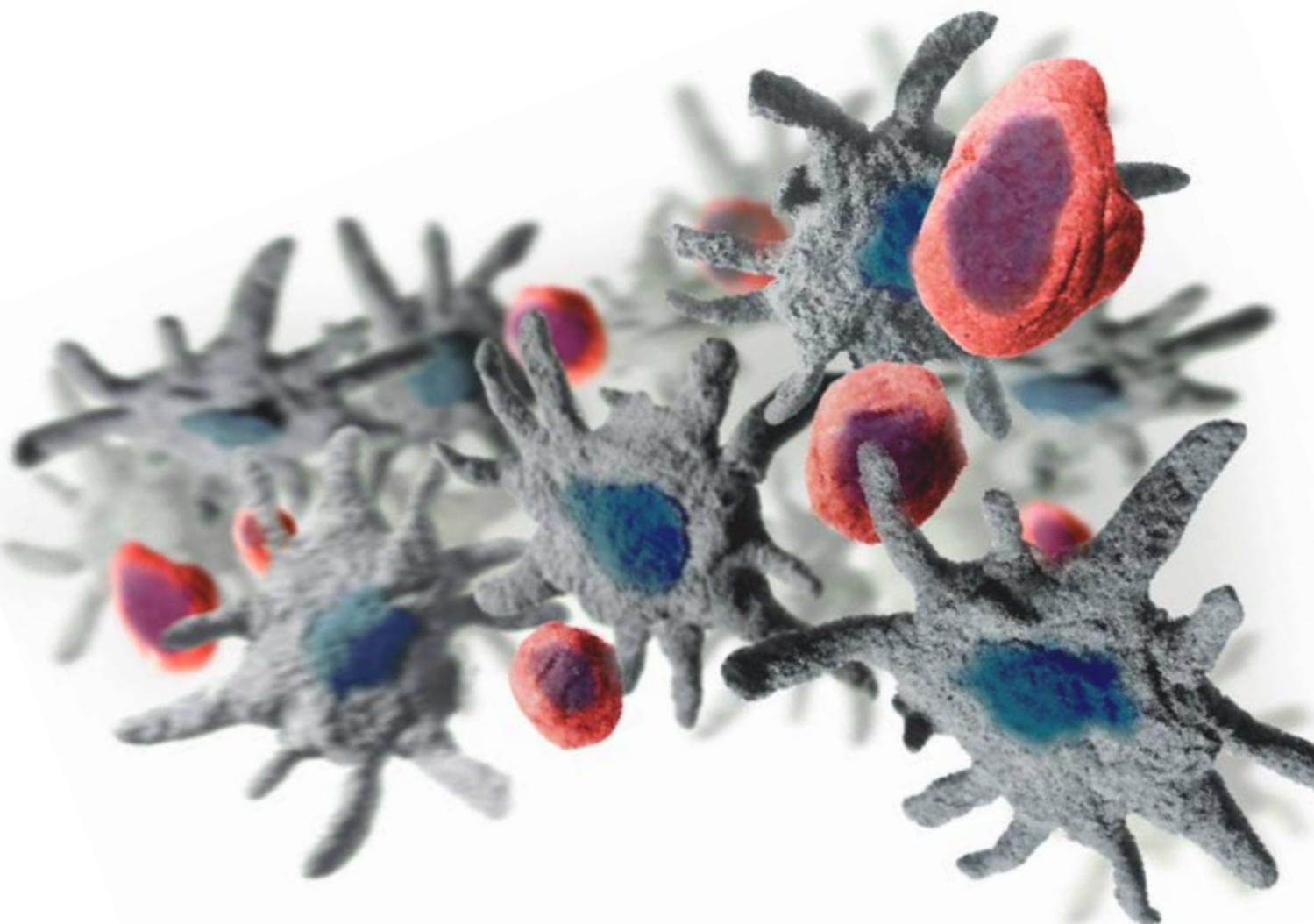
- Bone marrow-derived stem cells can significantly improve bone formation in cases of bone nonunion¹⁻³
- Bone marrow-derived stem cells can significantly reduce joint pain and increase joint function in osteonecrosis⁴⁻⁵
- Bone marrow-derived stem cell-enriched allograft is as effective as autograft when used in bone grafting and spinal fusion procedures⁸⁻¹⁰

In Soft Tissue

- Bone marrow-derived stem cells can induce healing in recalcitrant chronic wounds and diabetic ulcers¹¹⁻¹²
- Bone marrow-derived stem cells can help revascularize an ischemic limb¹⁴⁻¹⁶
- Bone marrow-derived stem cells can assist in vascular anastomosis¹⁷
- Bone marrow-derived stem cells can help prevent scar tissue formation and preserve heart function after myocardial infarction¹⁸⁻¹⁹

In General

- Bone marrow-derived stem cells can reduce morbidity, blood loss and operating time²⁰
- Bone marrow aspirate contains white blood cells, which are critical in fighting infection²¹

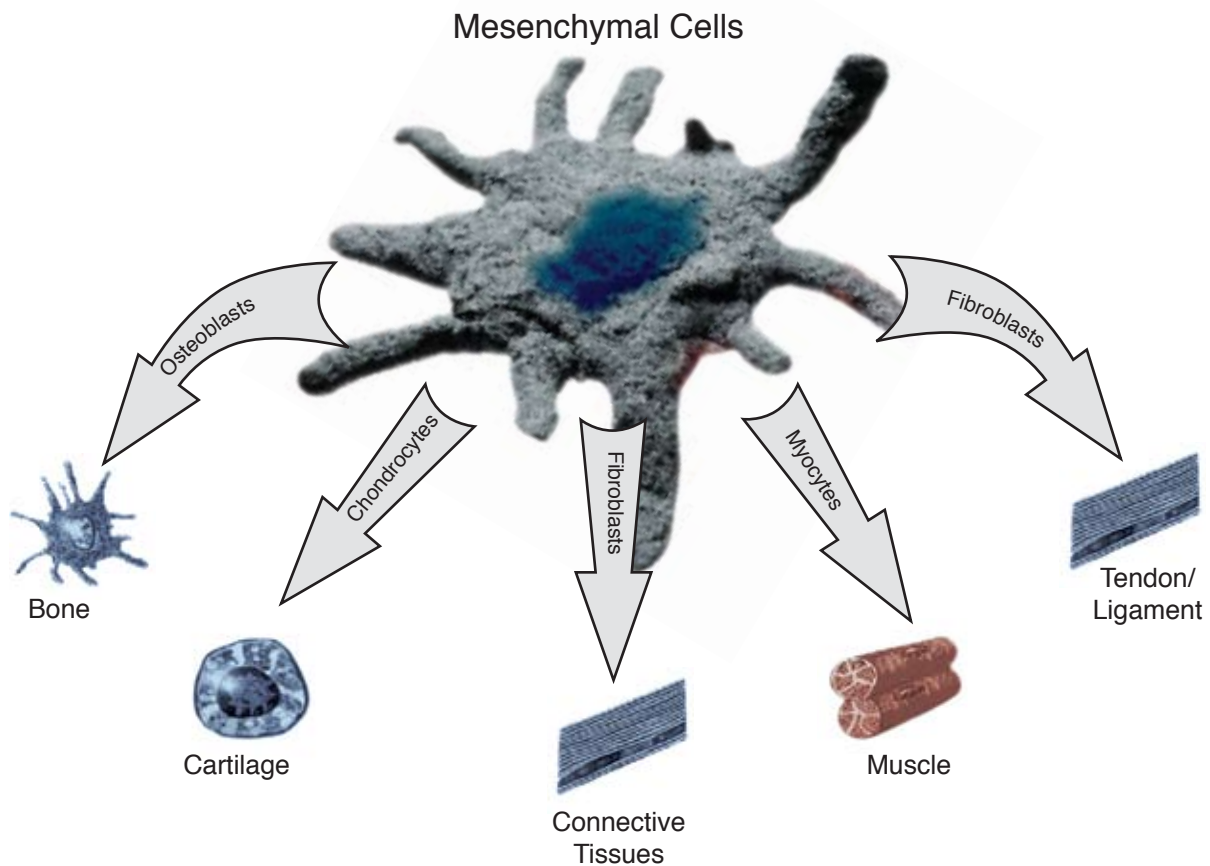


Marrowstim™ Concentration System is the next generation in hard and soft tissue grafting.

The presence of stem cells makes the iliac crest graft very appealing. This graft provides the surgical site with the scaffold, cells and signals necessary for successful bone healing. However, graft site morbidity coupled with a complicated and time consuming harvest make it difficult to justify the use of this graft in many different procedures. As a result, the use of autologous bone marrow aspirate (BMA) for bone grafting has been advocated as a means to provide an osteogenic cell source.⁶ The Marrowstim™ Concentration System enables stem cells from the iliac crest to be easily and efficiently concentrated and transferred to a surgical site with or without graft material. The ability of the Marrowstim™ device to recover and concentrate the nucleated cell population eases the concern of peripheral blood dilution during the marrow aspiration.

Why nucleated cell concentrate?

Bone marrow aspirate contains mesenchymal stem cells, which are able to proliferate and differentiate into a number of different soft and hard tissues. Utilising Marrowstim™ technology, these stem cells can be concentrated at the patient's point of care. Clinical evidence suggests cellular concentration positively affects the clinical outcome of bone grafting procedures.^{1,20}



What is the Marrowstim™ Concentration System?

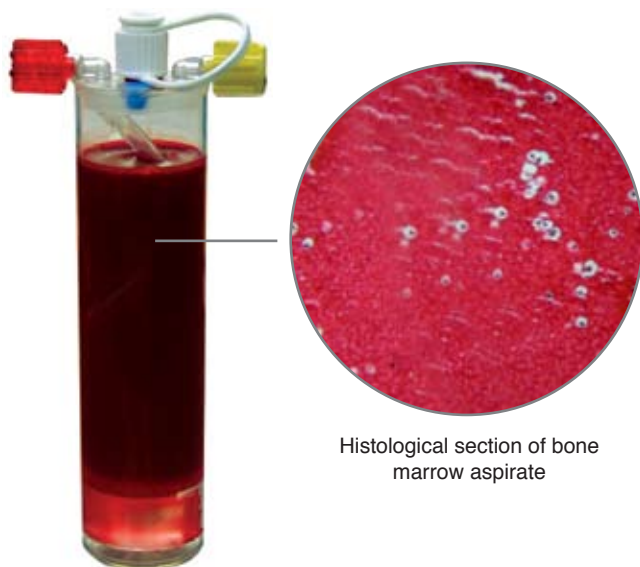
Marrowstim™ Concentration System uses a proven technology to concentrate powerful stem cells, which are obtained with the Marrowstim™ aspirate needle. This user friendly kit provides all components needed to obtain concentrated stem cells.



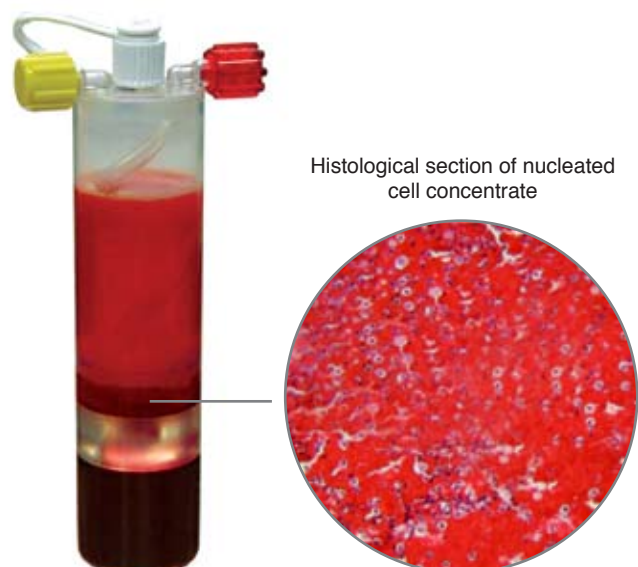
Marrowstim™ Concentration System consists of

Proven Marrowstim™ Technology

- Consistent 6.1x concentration of total nucleated cells compared to baseline level²¹
- 79% recovery of total nucleated cells (TNC's)²¹
- Consistent 6.9x concentration of mononuclear cells compared to baseline level²¹
- 80% recovery of mononuclear cells²¹
- 15 minute centrifugation spin makes implementation feasible in a point of care setting



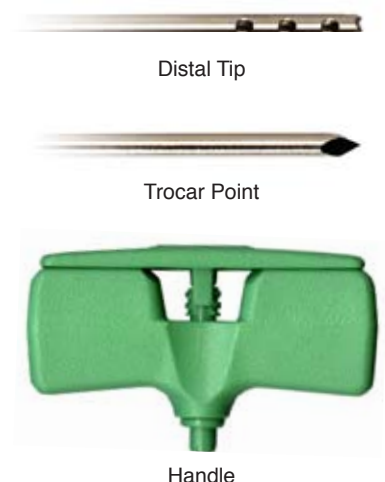
Histological section of bone marrow aspirate



Histological section of nucleated cell concentrate

Specially designed aspirate needle with the following features:

- Five (5) holes placed at the distal tip, allowing for better aspiration
- Stylet, with its trocar point, makes it possible to easily penetrate the bone marrow cavity
- Ergonomically designed handle enables a safer maneuverability, since the force needed to penetrate the bone marrow cavity is homogenously distributed over the entire palm of the hand rather than locally
- Two (2) stylets for surgeon convenience



Marrowstim™ Concentration System Instructions

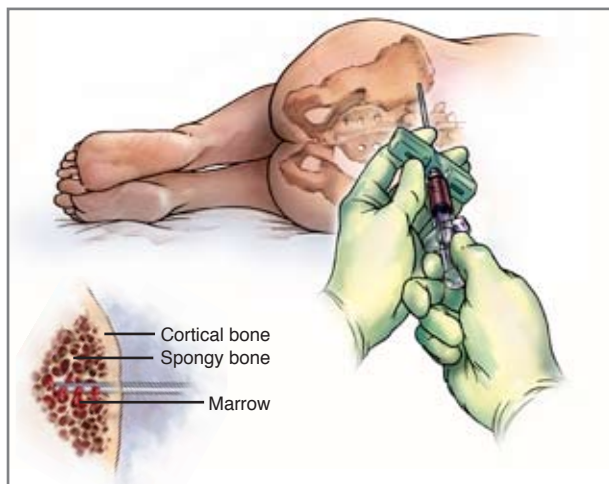


Figure 1



Figure 2

Step 1: Anticoagulation

Rinse MarrowStim™ bone marrow aspirate needle, disposable and two 30ml syringes with anticoagulant to ensure inner surfaces are coated. This will prevent clotting of bone marrow during aspiration. Perform **one** of the following techniques.

Method 1:

Heparin only technique (heparin not supplied in these kits):

Draw 3ml heparin solution (1000 U/ml) into a sterile 30 ml syringe; ensure the heparin coats the entire inner surface of the syringe and set aside. Draw 10ml heparin solution into a second sterile 30ml syringe; ensure the heparin coats the entire inner surface of the syringe. Remove inner trocar from BMA needle. Attach the second 30ml syringe to the BMA needle and prime with heparin, ensuring 3ml of heparin remains in the 30ml syringe. Remove BMA needle and replace the trocar.

Method 2:

ACD-A with heparin coating technique (heparin not supplied in these kits):

Heparin Coating:

Draw 10 ml heparin solution (1000U/ml) into a sterile 30ml syringe. Pull syringe plunger back completely, ensuring the heparin coats the entire inner surface of the syringe. After coating the syringe, push the plunger completely down on syringe to dispense all remaining heparin. Draw 10 ml heparin solution into a second sterile 30ml syringe. Pull syringe plunger back completely, ensuring the heparin coats the entire inner surface of the syringe. Remove inner trocar from BMA needle. Attach the second 30ml syringe to the BMA needle and prime with heparin, ensuring all heparin has been dispensed from the syringe through the needle. Remove BMA needle and replace the trocar.

ACD-A:

Draw 6ml ACD-A into each of the heparin coated 30ml syringes.

For the Marrowstim™ Mini System, only one 30ml syringe of anticoagulated marrow is utilised.

Step 2: Prepare Patient

After suitable anesthesia is achieved, place the patient in the lateral decubitus position. Using sterile technique, prepare the skin with antiseptic and drape. (Figure 1)

Step 3: Position Needle

Hold the needle with proximal end in palm and the index finger against the shaft toward the tip. (Figure 2)

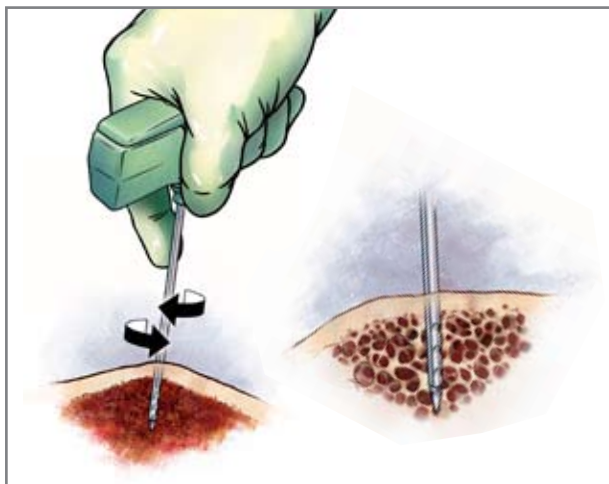


Figure 3

Step 4: Advance Needle

Using gentle but firm pressure, advance the needle, rotating it in an alternating clockwise/counterclockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance. All of the side holes at the distal end of the needle must be introduced into the marrow cavity beyond the cortical bone, otherwise air with extra bony soft tissue may appear with the aspirated marrow. (Figure 3)

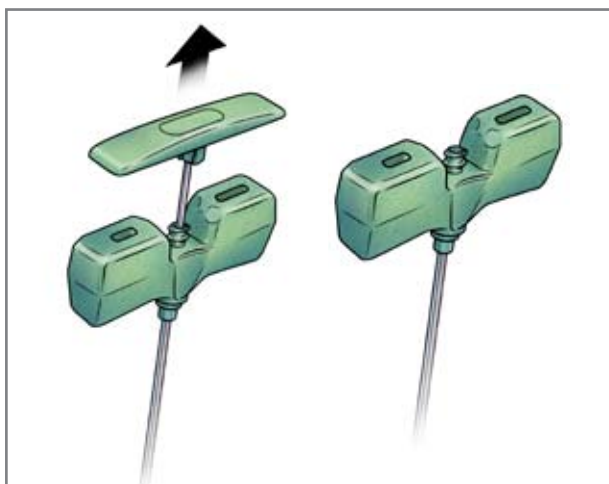


Figure 4

Step 5: Remove Stylet/Trocar

Once needle is in place, remove the stylet by pulling straight out. (Figure 4)

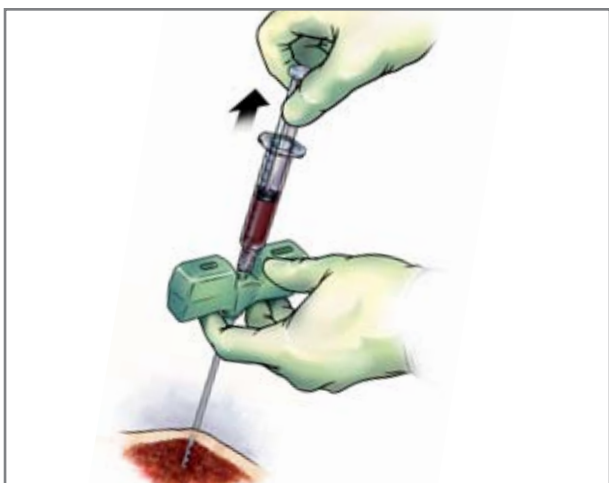


Figure 5

Step 6: Aspirate Marrow

Follow the BMA needle manufacturer package insert (steps 7–9) to obtain a total of 60ml anticoagulated bone marrow aspirate (3ml heparin with 27ml BMA per 30ml syringe **or** 6ml ACD-A with 24ml BMA per 30ml syringe). (Figure 5)

For the Marrowstim™ Mini System, only one 30ml syringe of anticoagulated marrow is utilised.

Preparation of the Marrowstim™ and Mini Marrowstim™ Concentration Systems



Figure 1

Step 1: Load

Ensure BMA from only one patient is processed per spin.

Unscrew cap on centre port No. 1 and remove cap and green packaging post. (Figure 1)



Figure 2

Slowly load both aspirate filled 30ml syringes (6ml of ACD-A and 24ml of bone marrow aspirate per syringe or 3ml of heparin and 27ml of BMA per syringe), for a total of 60 ml of anticoagulated marrow into centre port No. 1. (Figure 2)

Mini Marrowstim™ Concentration System: Slowly load one 30ml syringe of anticoagulated marrow into centre port No. 1.



Figure 3

Remove protective cover on white tethered cap and discard. Screw white cap onto centre port No 1. (Figure 3)

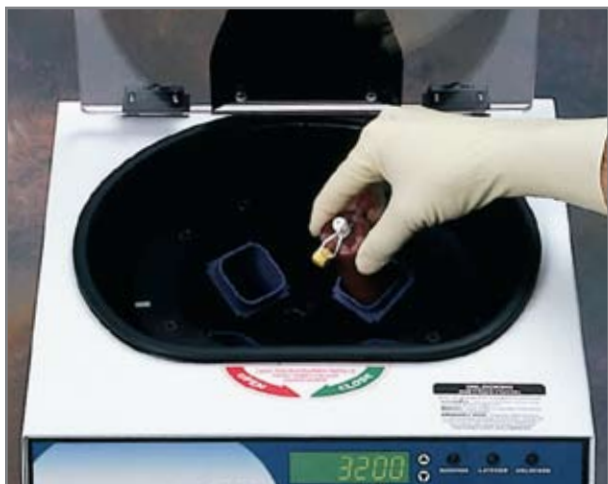


Figure 4

Step 2: Balance

Press red button to release lid of centrifuge. Open and place the tube into the centrifuge. (Figure 4)

Mini Marrowstim™ Concentrate Kit: If using the mini kit, the purple mini buckets must be inserted into the centrifuge.



Figure 5

Insert Marrowstim™ Concentration System counterbalance with 60ml of sterile saline or a second Marrowstim™ disposable with BMA (when processing two tubes) into opposite side of centrifuge. (Figure 5)

Mini Marrowstim™ Concentrate Kit: Fill purple mini counterbalance with 30ml of sterile saline and place into opposite side of centrifuge.



Figure 6

Step 3: Spin

Close lid. Set speed at 3200 RPM and time to 15 minutes. Press green button to start spin. Once spin is completed, press red button to release lid and open. (Figure 6)

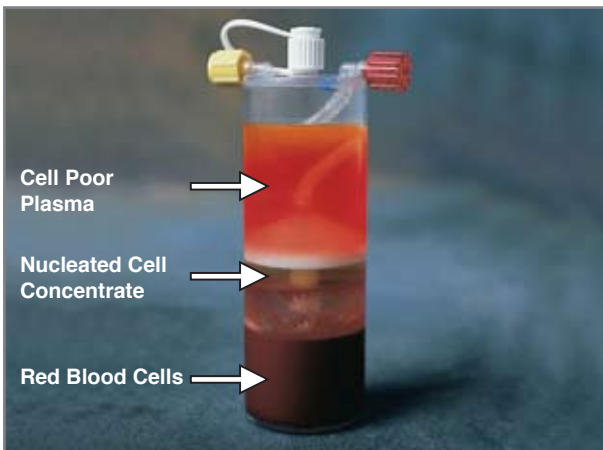


Figure 7: Nucleated cell concentrate (NCC) processed with the Marrowstim™ Concentration System

Remove Marrowstim™ tube from centrifuge and ensure BMA has separated into three distinct layers. (Figure 7).



Figure 8

Step 4: Cell Poor Plasma (CPP) Extraction

Remove yellow cap on side port No. 2 and connect a sterile 30ml syringe. Invert the tube and withdraw the cell poor plasma. (Figure 8)



Figure 9

Step 5: Suspend Nucleated Cell Concentrate (NCC)

While holding the tube in the upright position, shake vigorously for 30 seconds to suspend the cellular elements. (Figure 9)



Figure 10

Step 6: Nucleated Cell Concentrate (NCC) Extraction

Remove red cap from side port No. 3 and connect a sterile 10ml syringe to extract the nucleated cell concentrate. (Figure 10)

Application possibilities for Marrowstim™ Concentration System

Hard Tissue

Bone Marrow Aspirate

Orthopedics

- Delayed Union and Nonunion^{1-3,22}
- Avascular Necrosis^{4,5}
- Spinal Fusion^{8-9,23}
- Cartilage Regeneration²⁴⁻²⁶

Bone Marrow Aspirate + Platelet-rich Plasma

Orthopedics

- Osteonecrosis³²
- Bone Regeneration^{7,33}

Cranio/Maxillofacial

- Periodontal Repair³⁴⁻³⁵
- Alvedar Bone Regeneration³⁵⁻³⁶

Bone Marrow Aspirate + Demineralized Bone Matrix

Orthopedics

- Delayed Union and Nonunion^{7,20}
- Bone Cysts²⁸⁻²⁹

Bone Marrow Aspirate + Fibrin Sealant

Orthopedics

- Bone Regeneration³⁰

Soft Tissue

Bone Marrow Aspirate

Wound Healing

- Chronic Wounds¹²
- Ischemic Ulcers¹¹

Cardiovascular Surgery

- Myocardial Infarction¹⁸⁻¹⁹
- Peripheral Vascular Disease¹⁴⁻¹⁶

Bone Marrow Aspirate + Fibrin Sealant

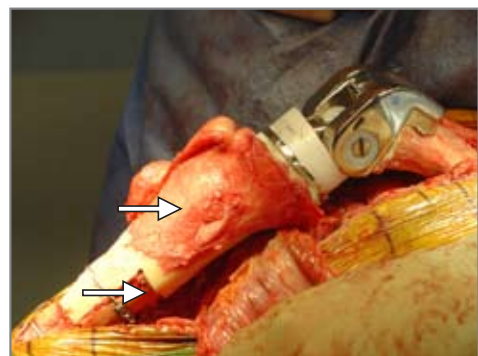
- Vascular Anastomosis¹⁷



Nucleated cell concentrate, platelet-rich plasma and Bonus® DBM applied to a fibula nonunion.



Nucleated cell concentrate and Bonus® DBM in spine surgery.



Nucleated cell concentrate and Bonus® DBM applied to a knee revision.



Nucleated cell concentrate and Bonus® DBM applied to a hip revision.

Marrowstim™ Concentration System and Bonus® DBM

DBM is an ideal balance between allograft and autograft. It promotes bone growth by providing osteoinductive growth factors and an osteoconductive scaffold. The Marrowstim™ Concentration System provides concentrated stem cells, which have been advocated as a means to provide an osteogenic cell source in a variety of procedures. This powerful combination provides the surgeon with the scaffold, cells, signals and nutrition necessary for successful bone healing. (Table 1)

	Bonus® DBM (with Stem Cells)	Traditional DBM
Scaffold	Yes	Yes
Signals	Yes	Yes
Cells	Yes	No
Nutrition	Yes	No

Table 1

Patient-specific demands require options

Surgery is not an assembly line. Each patient has specific needs. The powerful stem cells obtained with and concentrated by the Marrowstim™ concentration system can be easily transferred to hydrate synthetic, allograft and autograft bone in a variety of methods. This allows the surgeon to customize according to the application. For use with the Bonus® DBM, the following ratios should be useful, depending on the desired handling characteristics. (Table 2)

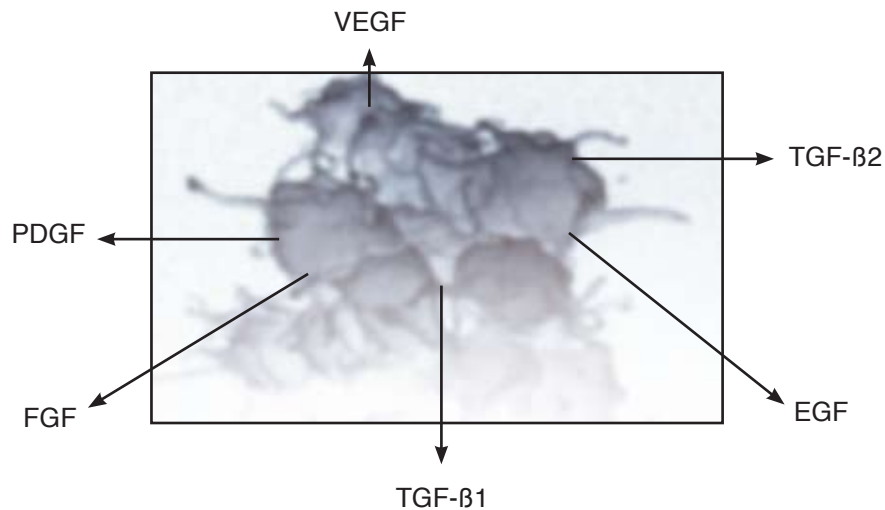
Liquid to Bonus® DBM Ratio	Application	Delivery	Handling Consistency
10cc: 10cc, 5cc: 5cc or 1cc: 1cc	Percutaneous injections, Contained defects	Fine bead nozzle, BOS™ needle	Flowable gel
6cc: 10cc, 3cc: 5cc or .6cc: 1cc	Standard packing, Molding	Fine bead nozzle, Log	Putty
4cc: 10cc, 2cc: 5cc or .4cc: 1cc	Very bloody environments with heavy irrigation	Log only	Crunchy

Table 2



Advantages of Adding Platelet-rich Plasma to Stem Cells

Utilising the GPS® II System the patient's own platelets, which travel through the blood stream, can be collected into a highly concentrated formula. When platelets become activated, growth factors are released.



Platelet Derived Growth Factor (PDGF-aa, PDGF-ab, PDGF-bb)

- Stimulates cell replication
- Promotes angiogenesis
- Promotes epithelialisation
- Promotes granulation tissue formation

Vascular Endothelial Growth Factor (VEGF)

- Promotes angiogenesis

Fibroblast Growth Factor (FGF)

- Promotes proliferation of endothelial cells and fibroblasts
- Stimulation of angiogenesis

Transforming Growth Factor (TGF-β1, TGF-β2)

- Promotes formation of extracellular matrix
- Regulates bone cell metabolism

Epidermal Growth Factor (EGF)

- Promotes cell differentiation and stimulates re-epithelialisation, angiogenesis and collagenase activity

The addition of platelet-rich plasma (PRP) to bone marrow aspirate has been shown to stimulate proliferation of mesenchymal stem cells *in vitro*.^{37,38} *In vivo*, PRP addition to bone marrow stem cells and allograft has contributed to better allograft integration and increased bone formation.³⁹

Ordering Information

Description	Catalog Number
Biomet Biologics Manual Spray Applicator Kit (Tip not included)	800-0250
Two 12ml Syringes	Two 1ml Syringes
Two Syringe Assembly Sets	Three Liquid Transfer Cups
One Plastic Tray Complete with Sterile Drape	
Malleable Dual Cannula Tip 20 Gauge x 4 inch Length	800-0202
Malleable Dual Cannula Tip 20 Gauge x 7 inch Length	800-0203
Blending Connector Tip Single Cannula	800-0204
Malleable Dual Cannula Tip 20 Gauge x 10 inch Length	800-0206
Drucker 230 Volt 50–60 Hz Centrifuge	755VES-230V
Graft Preparation System	800-0300
Biomet Biologics Standard Non-Sterile Counterbalance (Blue)	800-0508
Biomet Biologics Mini Non-Sterile Counterbalance (Purple)	800-0505
Biomet Biologics Spare Bucket Kit (Drucker Centrifuge; 2 Blue Buckets)	7431
Biomet Biologics Mini Spare Bucket Kit (Drucker Centrifuge; 2 Purple Buckets)	7433
5ml Bonus® DBM	48-DBM1
10ml Bonus® DBM	48-DBM2
1ml Bonus® DBM	48-DBM4
Autologous Thrombin Spray Tip (Pack of 10; To be used with 800-0204)	ST-3 Tip

If autologous thrombin is needed, ordering information can be found in the Clotalyt Brochure (BBI0004).



Spray Applicator Kit (800-0250)



Malleable Dual Cannula Tip 20 Gauge x 4 inch Length (800-0202)
20 Gauge x 7 inch Length (800-0203)
20 Gauge x 10 inch Length (800-0206)



Blending Connector Tip Single Cannula (Includes two Flexible Sheaths) (800-0204)



Drucker 230 Volt 50–60 Hz Centrifuge (755VES-230V)



Graft Preparation System (800-0300)



Biomet Biologics Standard and Mini Non-Sterile Counterbalance (800-0508 [Standard; Blue]) (800-0505 [Mini; Purple])



Biomet Biologics Spare Bucket Kit (7431 [Blue])



Biomet Biologics Mini Spare Bucket Kit (7433 [Purple])



5ml Bonus® DBM (48-DBM1)



10ml Bonus® DBM (48-DBM2)





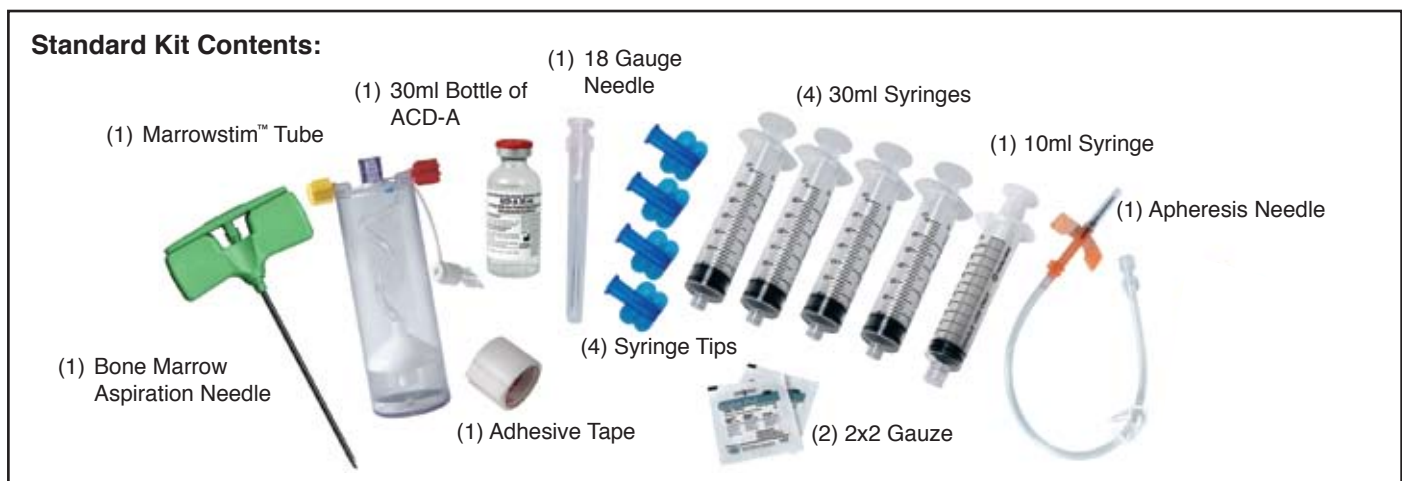
1ml Bonus® DBM (48-DBM4)



Autologous Thrombin Spray Tip (ST-3 Tip)

Ordering Information

Description	Catalog Number
<p>Marrowstim™ Standard Kit with 30 ml ACD-A</p> <p>Contents:</p> <p>One Disposable 60ml Marrowstim™ Tube</p> <p>One 10ml Syringe</p> <p>Four 30ml Syringes</p> <p>One 18 Gauge Centesis Needle</p> <p>One 18 Gauge Safety Apheresis Needle</p> <p>One 30ml Bottle of ACD-A</p> <p>One Bone Marrow Aspiration Needle</p> <p>One Adhesive Tape 54 Inch</p> <p>Two 2x2 Gauze</p> <p>Four Syringe Tips</p> <p><i>Provides 6ml of concentrated BMA from 60 ml of anticoagulated aspirate.</i></p>	<p>800-0613A</p> 
<p>Marrowstim™ Mini Kit with 30 ml ACD-A</p> <p>Contents:</p> <p>One Disposable 30ml Mini Marrowstim™ Tube</p> <p>One 10ml Syringe</p> <p>Three 30ml Syringes</p> <p>One 18 Gauge Centesis Needle</p> <p>One 18 Gauge Safety Apheresis Needle</p> <p>One 30ml Bottle of ACD-A</p> <p>One Bone Marrow Aspiration Needle</p> <p>One Adhesive Tape 54 Inch</p> <p>Two 2x2 Gauze</p> <p>Four Syringe Tips</p> <p><i>Provides 3ml of concentrated BMA from 30ml of anticoagulated aspirate.</i></p>	<p>800-0612A</p> 



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Package Insert

Biomet Biologics, Inc.
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581 USA

01-50-1436
Date: 07/07

3. Early or late postoperative infection.
4. Pain at bone marrow harvest site.

MarrowStim™ and MarrowStim™ Mini Concentration Systems with ACD-A

ATTENTION OPERATING SURGEON

FOR INTERNATIONAL USE ONLY

NOTE: FOR SINGLE-USE ONLY. Discard the entire disposable system after one use, using an acceptable method for devices potentially contaminated with blood products.

DESCRIPTION

MarrowStim™ Concentration System with ACD-A

The MarrowStim™ Concentration System with ACD-A separates up to 60ml of the patient's bone marrow components by density through the use of the MarrowStim™ cell separator.

MarrowStim™ Mini Concentration System with ACD-A

The MarrowStim™ Mini Concentration System with ACD-A separates up to 30ml of the patient's bone marrow components by density through the use of the MarrowStim™ Mini cell separator.

The above listed systems are to be used with a centrifuge distributed by Biomet Biologics, Inc. ("BBI").

Heparin, utilized in the anticoagulation step of the Instructions for Use, is not supplied in these systems.

MATERIALS

The materials used for syringes, needles, tubing, connectors, and cell separators consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

All components in these systems are packaged, labeled and sterilized as indicated by their manufacturer's labeling.

All components in these systems are latex-free.

ACD-A is an anticoagulant supplied by Citra Anticoagulants, Inc., Braintree, MA, and manufactured by Cytosol Laboratories, Inc., Braintree, MA. For further information regarding ACD-A Anticoagulant, please contact the supplier at 1-800-299-3411.

The ACD-A provided is only for use with the MarrowStim™ and MarrowStim™ Mini Concentration Systems.

INDICATIONS FOR USE

The MarrowStim™ and MarrowStim™ Mini Concentration Systems with ACD-A are designed to be used for the safe and rapid preparation of autologous concentrated bone marrow aspirate (cBMA) from a small sample of bone marrow aspirate at the patient's point of care. The cBMA can be applied to a surgical site or can be mixed with graft material prior to application to a surgical site as deemed necessary by the clinical use requirements.

WARNINGS AND PRECAUTIONS

1. Single use device. Do not reuse.
2. Use proper safety precautions to guard against needle sticks.
3. Do not use sterilized components of this system if package is opened or damaged.
4. Use prepared cBMA within 4 hours after aspirating bone marrow from patient.
5. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
6. The patient is to be made aware of general risks associated with bone marrow aspiration. These risks include, but are not limited to: hemorrhage, seroma formation, infection, and/or persistent pain at the site of aspiration.
7. Follow manufacturer instructions when using centrifuge. Use only a BBI centrifuge (IEC centrifuge or The Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
8. Follow manufacturer package insert for the bone marrow aspirate (BMA) needle.

POSSIBLE ADVERSE EFFECTS

1. Damage to blood vessels, hematoma, delayed wound healing, and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.

STERILITY

The MarrowStim™ and MarrowStim™ Mini cell separators are sterilized by exposure to a minimum dose of 25kGy gamma irradiation. All other MarrowStim™ and MarrowStim™ Mini Concentration System components are sterilized by their respective suppliers as indicated on their labeling. Do not resterilize. Do not use past expiration date.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

MarrowStim™ Concentration System

1. **REMOVE:** Remove BMA needle from its sterilized package. Remove the inner trocar from the BMA needle, and set aside.
2. **ANTICOAGULATION: Perform ONE of the following techniques.**

METHOD 1 (Heparin only technique):

Heparin: Draw 3ml heparin solution (1000 U/ml) into a sterilized 30ml syringe; ensure the heparin coats the entire inner surface of the syringe and set aside. Draw 10ml heparin solution into a second sterilized 30ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the second 30ml syringe to the BMA needle and prime with heparin, ensuring 3ml heparin remains in the 30ml syringe. Remove BMA needle and replace the trocar.

METHOD 2 (ACD-A with Heparin coating technique):

Heparin: Draw 10ml heparin solution (1000 U/ml) into a sterilized 30ml syringe. Pull syringe plunger back completely, ensuring the heparin coats the entire inner surface of the syringe. After coating the syringe, push the plunger completely down on syringe to dispense all remaining heparin. Draw 10ml heparin solution into a second sterilized 30ml syringe. Pull syringe plunger back completely, ensuring the heparin coats the entire inner surface of the syringe. Attach the second 30ml syringe to the BMA needle and prime with heparin, ensuring all heparin has been dispensed from the syringe through the needle. Remove BMA needle and replace the trocar.

ACD-A: Draw 6ml of ACD-A into each of the two heparin-coated syringes.

3. **ASPIRATION:** Follow the BMA needle manufacturer package insert to obtain a total of 60ml anticoagulated BMA (3ml heparin mixed with 27ml BMA per 30ml syringe **OR** 6ml ACD-A mixed with 24ml BMA per 30ml syringe), using the syringes prepared in the previous step.
4. **LOAD: ENSURE BMA FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the cell separator remains upright.** Unscrew cap on center port #1 of the cell separator. Remove and discard cap and green packaging post. Attach and slowly load both 30ml anticoagulated, BMA-filled syringes one at a time into center port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap back onto port #1. Place cell separator filled with anticoagulated BMA into the BBI centrifuge.
5. **BALANCE:** Fill blue counterbalance tube (800-0508) with an amount of sterilized saline/water equal to that of BMA plus anticoagulant dispensed in the cell separator. Place counterbalance directly opposite from aspirate-filled separator in centrifuge.
6. **SPIN:** Close centrifuge lid. Set speed for 3.2 (x 1,000 rpm) and set the time to 15 minutes. Press the start button. Once spin is complete, open centrifuge and remove cell separator.
7. **EXTRACT PLASMA:** Unscrew yellow cap on port #2, and save cap. Connect sterilized 30ml syringe, tilt cell separator toward port #2, and extract plasma. Remove the 30ml syringe from port #2, cap with a sterilized syringe cap, and set aside. Replace yellow cap on port #2.
8. **SUSPEND cBMA:** Holding the cell separator in the upright position, shake tube vigorously for 30 seconds.
9. **EXTRACT cBMA:** Immediately after suspending the cBMA, unscrew the red cap on port #3. Attach sterilized 10ml syringe to port #3, and extract the cBMA. Remove the 10ml syringe, and cap with a sterilized syringe cap.
10. **APPLY:** Apply cBMA to surgical site, with or without graft material as required.

MarrowStim™ Mini Concentration System

1. **REMOVE:** Remove BMA needle from its sterilized package. Remove the inner trocar from the BMA needle, and set aside.
2. **ANTICOAGULATION: Perform ONE of the following techniques.**

METHOD 1 (Heparin only technique):

Heparin: Draw 10ml heparin solution (1000 U/ml) into a sterilized 30ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the syringe to the BMA needle and prime with heparin, ensuring 3ml heparin remains in the 30ml syringe. Remove BMA needle and replace the trocar.

METHOD 2 (ACD-A with Heparin coating technique):

Heparin: Draw 10ml heparin solution (1000 U/ml) into a sterilized 30ml syringe. Pull syringe plunger back completely, ensuring the heparin coats

the entire inner surface of the syringe. Attach the 30ml syringe to the BMA needle and prime with heparin, ensuring all heparin has been dispensed from the syringe through the needle. Remove BMA needle and replace the trocar.

ACD-A: Draw 6ml of ACD-A into the heparin-coated syringe.

- ASPIRATION:** Follow the BMA needle manufacturer package insert to obtain 30ml of anticoagulated BMA (3ml heparin mixed with 27ml BMA **OR** 6ml ACD-A mixed with 24ml BMA) using the syringe prepared in the previous step.
- LOAD: ENSURE MARROW FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the cell separator remains upright.** Unscrew cap on center port #1 on the cell separator. Remove and discard cap and green packaging post. Attach and slowly load the 30ml anticoagulated, BMA-filled syringe into center port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap back onto port #1. Place cell separator into the BBI centrifuge.
- BALANCE:** Fill purple counterbalance tube (800-0505) with an amount of sterilized saline/water equal to that of BMA plus anticoagulant dispensed in the cell separator. Place counterbalance directly opposite from aspirate-filled separator in centrifuge.
- SPIN:** Close centrifuge lid. Set speed for 3.2 (x 1,000 rpm) and set the time to 15 minutes. Press the start button. Once spin is complete, open centrifuge and remove cell separator.
- EXTRACT PLASMA:** Unscrew yellow cap on port #2, and save cap. Connect sterilized 30ml syringe, tilt cell separator toward port #2, and extract plasma. Replace yellow cap on port #2.

- SUSPEND cBMA:** Holding the cell separator in the upright position, shake tube vigorously for 30 seconds.
- EXTRACT cBMA:** Immediately after suspending the cBMA, unscrew the red cap on port #3. Attach sterilized 10ml syringe to port #3, and extract the cBMA. Remove the 10ml syringe, and cap with a sterilized syringe cap.
- APPLY:** Apply cBMA to surgical site, with or without graft material as required.

These devices are only approved for distribution outside the United States.

MarrowStim™ and Biomet Biologics™ are trademarks of Biomet Manufacturing Corp.

Comments regarding these devices can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683.

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HS HOSPITAL SERVICE S.p.A.

GENERAL USE INFORMATION:

- Bone Marrow Transplantation needle.

WARNINGS AND PRECAUTIONS:

- ⊗ This device is designed to be used by a physician.
- Δ These instructions are not meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device..
- Δ Check if the inner package is unopened and damaged. In case of damaged inner package, do not use the product.
- Δ Check the expiry date and the gauge.
- Δ Possible allergic reactions should be considered.
- Δ After use consider it as waste material.
- Δ Store in a cool and dry place, protect from light .
- Δ Use of the device is restricted only to physician .
- Δ Ethylene Oxide sterilized.
- Δ Sterility and integrity guaranteed only if observed, with the prescribed conditions.
- Δ It must be used only in hospitals.

INSTRUCTIONS FOR USE:

1. After suitable anesthesia is achieved, place the patient in the ventral supine position.
2. Using sterile technique, prepare the skin with antiseptic and drape.
3. Hold the needle with the proximal end in palm and the index finger against the shaft near the tip. This position stabilizes the needle and allows for better control.
4. Introduce the needle through the skin and bring it into contact with the posterior iliac crest.
5. Using gentle, but firm pressure, advance the needle, rotating it in an alternating clockwise/counterclockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance. (All of the side holes at the distal end of the needle must be introduced into the marrow cavity beyond the cortical bone, otherwise air and extra bony soft tissue may appear with the aspirated marrow).
6. Once needle is in place, remove the stylet by rotating the upper section 90°, and pulling straight out.
7. Attach a syringe with a luer taper to the hub of the bone marrow harvest needle using a firm push and twist motion.
8. Apply suction by withdrawing the syringe plunger. Remove the syringe with the harvested marrow.
9. Repeat the harvest procedure until an appropriate amount of marrow is obtained to satisfy the clinical requirement.



Sterile - Non pyrogenic - Disposable
Sterile if unopened and undamaged inner packaged

⊗ NOT FOR USE Δ WARNING

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