MARROW CELLUTION™

BONE MARROW HARVESTING SYSTEMS

# ASPIRATE TO APPLICATION™

## *Without Centrifugation*

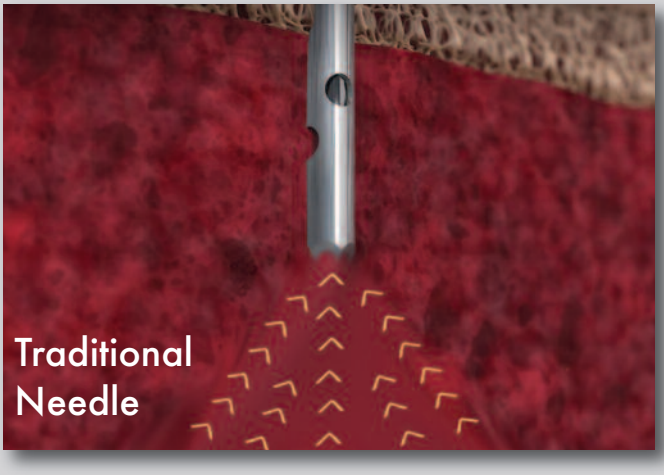
Bone Marrow Aspirate Collected With The Marrow Cellution™ System Has Shown An Increase In Key Stem And Progenitor Cells When Compared To Centrifuged Marrow From Leading Systems

CE 0086 FDA

The patent pending Marrow Cellution™ systems maximize the yield of stem and progenitor cells by giving the clinician the ability to efficiently harvest bone marrow from multiple levels within the medullary space, while restricting dilution caused by peripheral blood.

## What are the Limitations of a Traditional Needle?

Traditional bone marrow aspiration needles aspirate primarily through an open-ended cannula, which leads to excess peripheral blood dilution and inadequate collection of key stem and progenitor cells. For this reason a high volume of bone marrow aspirate must be collected and then manipulated (i.e. centrifuged) before being applied for regenerative therapies.

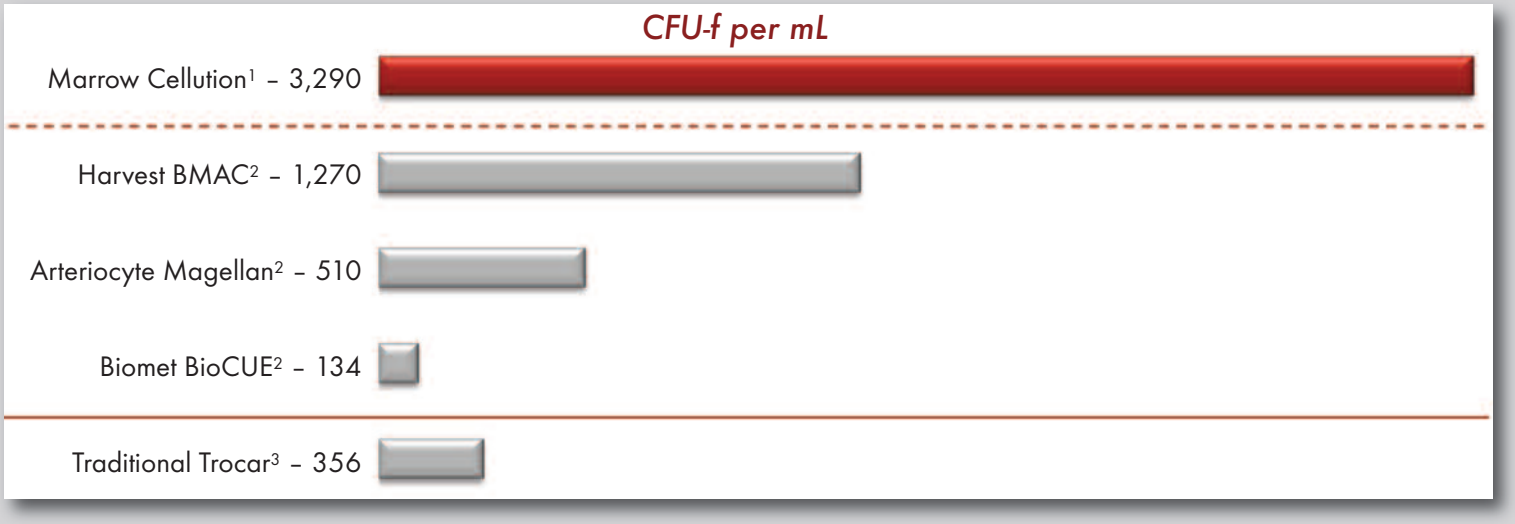



## How Does the Marrow Cellution™ System Overcome These Limitations?

The unique design of the Marrow Cellution™ system offers two key features that are not capable with a traditional needle:

- Closed-tip aspiration cannula that restricts aspiration through the side holes of the cannula and away from the channel caused by the tip of the needle, avoiding excess peripheral blood infiltration.
- A mechanical means for measured controlled retraction of the aspiration cannula to collect bone marrow aspirate from multiple geographies inside the medullary space with a single puncture.


## Competitive Performance




1. Scarpone M, et al. Marrow Cellution Bone Marrow Aspiration System and Related Concentrations of Stem and Progenitor Cells. White Paper 2015.
2. Hegde V, et al. A prospective Comparison of Three Approved Systems for Autologous Bone Marrow Concentration Demonstrated Non-Equivalency in Progenitor Cell Number and Concentration. J Orthop Trauma. 2014 Oct; 28(10):591-8
3. McLain R, et al. Aspiration of Osteoprogenitor Cells for Augmenting Spinal Fusion: Comparison of Progenitor Cell Concentrations from the Vertebral Body and Iliac Crest. J Bone Joint Surg Am. 2005 Dec; 87(12): 2655-2661.

# PRODUCT DETAILS

Marrow Cellution™ is offered in two unique styles – both utilizing the same patent(s) pending technique for optimized bone marrow aspiration.

| Style | Description | Catalog # | Effective Length |
|---|---|---|---|
| MC-RAN-11C  | The MC-RAN-11C includes an 11 gauge introducer needle, an 11 gauge blunt stylet, and a 14 gauge aspiration cannula. This version is available in multiple sizes and may be used in the Iliac Crest, Pedicle, Calcaneous or Tibia | MC-RAN-11C | 3.5″ |
| | | MC-RAN-11CSTS (Designed for obese patients) | 4.5″ |
| | | MC-RAN-11CT (Designed for calcaneous tibia and/or pediatrics) | 2.25″ |
| MC-RAN-8  | The MC-RAN-8 includes a swaged tip 8 gauge introducer needle, an 8 gauge blunt stylet, a 14 gauge aspiration cannula and a specially designed cancellous bone extraction tool to harvest bone dowels for grafting procedures after bone marrow aspirate has been collected. | MC-RAN-8 | 3.5″ |
| | | MC-RAN 8T (Designed for calcaneous, tibia and/or pediatrics) | 1.25″ |

## KEY BENEFITS

### Reduce the Cost of Utilizing Biologics

The Marrow Cellution™ System delivers a better regenerative solution at a reduced cost compared to the industry leading solutions.

### Minimize O/R Time

Centrifugation systems typically require 20 minutes or more of spin time during the surgical procedure, not to mention the additional support time needed for preparation and cleanup of the equipment.

### Minimize Sterility Challenges

Centrifugation systems require passing the BMA off the sterile field for processing and back on for implantation. The Marrow Cellution™ System eliminates the additional steps where infection concerns must be managed.

### Minimize Sample Waste

Centrifugation systems typically discard 80% of the aspirate due to the high levels of peripheral blood. Worse, significant numbers of the desired cells (approx. 40%) are discarded because as these cells increase in density prior to division, they are processed into the undesired red cell centrifuge component and thus discarded, substantially limiting the regenerative potential of the resulting sample.

### Minimize Use of Anti-Coagulants

Centrifugation systems require at least 10% dilution by volume for the addition of anti-coagulant to allow the sample to separate, and also require another 10% dilution in the form of a neutralizing agent such as thrombin and calcium chloride in order for the marrow to clot in the graft. The Marrow Cellution™ System eliminates these requirements.

### Eliminate the Need to Filter

Protocols require the marrow to be filtered prior to centrifugation. Cells bound within a clot cannot be counted but they can be delivered to the patient when mixed with graft material or injected. This is not the case when clots are filtered out prior to centrifugation. Filtering takes additional time, but more importantly, filtering reduces regenerative potential.

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