ASPIRE MEDICAL INNOVATION

Aspire Medical Innovation | Einsteinstr. 167 | D-81677 München

To: Whom it may concern,

Munich, 06. Mar.2018

Declaration of Distinction *(Dichiarazione di Infungibilità)*
The Marrow Cellution System (Maximized Cell Recovery & Percutaneous Bone Grafting)
vs. Standard Biopsy Needle Technology

Unlike any other system on the market, the Marrow Cellution™ Bone Marrow Aspiration & Cancellous Bone Graft Harvesting System is a unique, novel, patent pending bone marrow access and retrieval device that incorporates features designed to minimize limitations of traditional trocar needles. Marrow Cellution™ maximizes stem and progenitor cell recovery while minimizing peripheral blood infiltration. Because fluid, under force, follows the path of least resistance, trocar needles with side ports aspirate primarily through the distal end of the cannula. This leads to excessive blood collection, requiring additional manipulation, i.e. centrifugation or chemical separation in a laboratory.

Marrow Cellution™ accesses aspirate flow collected exclusively laterally as the tip of the aspiration cannula is closed allowing marrow collection perpendicular to and around the channel created by the device. It incorporates technology to precisely reposition the retrieval cannula within the marrow space after each aspiration. These features achieve a clinicians' desire for a single entry point.

A single puncture with Marrow Cellution™ provides high quality bone marrow aspirate and cancellous bone graft, collected from numerous sites within the marrow geography. The autologous, cancellous minimally invasive harvested graft is comprised of intact solid cores which are osteoconductive, osteoinductive, and osteogenic in nature. Normal cancellous graft is collected in a significantly more invasive manner and is morselized, diminishing its osteogenic properties.

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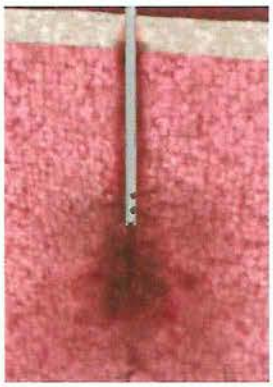
Traditional Aspiration Techniques

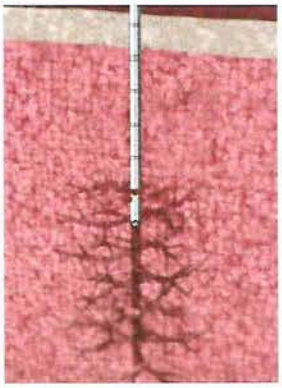


Traditional open ended (distal) trocars are designed to operate for small biopsy volumes (1-2ml). After aspirating the first 1-2ml of bone marrow, peripheral blood fills the vacated space, limiting the additional harvest of key stem and progenitor cells.

Further aspiration attempts diminish the number of total nucleated cells (TNC). Cells in the aspirate drop dramatically due to the lower viscosity of blood following the path of least resistance through the distal end channel, minimizing efficiency of side channels.

Aspiration of larger quantities of bone marrow, typically required for most clinical indications, necessitates further manipulation and volume reduction processing steps such as, centrifugation or chemical gradient separation in a laboratory.

Marrow Cellution Technology



Marrow Cellution™ allows for easy access through soft tissue and cortical bone. A fenestrated blunt trocar is then introduced to create access for closed end, side port aspiration stylet. The design minimizes trauma to cancellous bone and marrow, thereby mitigating pooling of peripheral blood.

The patent pending design consists of a closed end stylet which forces aspiration of marrow laterally from the marrow space. The manual rotation of the handle allows the fenestrated stylet to be raised to a desired position in a new level of undisturbed marrow for subsequent aspiration aliquots.

From a single stick, Marrow Cellution™ is the only system on the market capable of collecting up to 10ml of high quality bone marrow that does not require any external manipulation. The Marrow Cellution is equivalent or superior to other systems that require additional manipulation steps such as centrifugation or chemical separation in a laboratory.

In summary, the Marrow Cellution System significantly reduces peripheral blood contamination thereby eliminating the requirements for additional process steps (i.e. centrifugation), is minimally invasive thereby diminishing post harvesting morbidity, never leaves the sterile field thereby reduces cross contamination.

Scott Shea
President & CEO

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