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MESENCHYMAL STEM CELLS IN SPINAL SURGERY: TRINITY® MULTIPOTENTIAL CELLULAR BONE MATRIX

Decades of intensive research have brought revolutionary developments to the spine and orthopedic fields with the emergence and use of biological material in bone grafting and spinal procedures. The growing interest in adult mesenchymal stem cells (MSCs) in particular has been generating excitement as the scientific and medical communities have a more comprehensive understanding of the cellular and molecular events related to bone formation. With more than 900,000 bone graft procedures performed annually in the United States,[1] including 250,000 spinal fusions, MSCs represent a powerful tool proven effective for bone regeneration with the potential for even more dramatic results.

Now, MSC-based therapeutics can be widely used in a clinical setting. Introduced at NASS in 2005, **Trinity® Multipotential Cellular Bone Matrix** is the first-ever, surgery-ready bone grafting product containing viable MSCs, retained and preserved in their native cancellous bone matrix. Trinity® Matrix, marketed by **Orthofix Spine/Blackstone Medical (Wayne, NJ),** is a minimally-manipulated, FDA-regulated human cellular and tissue-based allograft product with a rich source of stem cells with guaranteed osteogenic potential. Trinity Matrix is also unique in that it offers *all three elements* necessary for bone growth: osteoconductivity, osteoinductivity and osteogenesis, which has the potential for robust and consistent bone formation at the implant site. Trinity Matrix can be safely used in place of autograft in virtually every surgical indication where autograft is generally chosen as a bone void filler. Research has shown that allogeneic MSCs can be safely used in therapeutic applications.[2,3,4] Trinity Matrix, mimicking the biologic profile of autograft, eliminates the potential morbidity associated with iliac crest autograft harvesting, including the reduction of operating time, blood loss and post-operative pain.

Bone grafts can provide structural support, fill voids, and improve repair of skeletal deficiencies. Harvesting autograft, traditionally from the patient's iliac crest, has long been the gold standard for obtaining bone graft[5] for spinal fusion[6,7] and other orthopedic procedures. However, as noted above, harvesting autograft from the iliac crest has potential morbidity and also may be in limited supply in certain patients.

"I have used Trinity Matrix extensively in cervical and lumbar fusion and, over the past two years, have not had any infections, immune responses, or ectopic bone growth, and in cervical cases, no retropharyngeal swelling or other cervical compromises."

Timothy Peppers, MD

The processing for Trinity Matrix removes any immunogenic hematopoetic cells and associated antigens in donated marrow-bearing bone. Extensive testing is performed on every lot to ensure the product meets specific standards and is suitable for implantation. Trinity Matrix meets FDA regulations (21 CFR part 1271) governing human cellular and tissue-based products as well as all applicable state regulations.

The ability to eliminate the need for autograft harvest is a reason that one surgeon has been using Trinity Matrix, but Dr. Timothy Peppers of CORE Orthopaedics at Scripps-Encinitas has been using it for the safety factor as well. "I have used Trinity Matrix extensively in cervical and lumbar fusion and, over the past two years, have not had any infections, immune responses, or ectopic bone growth, and in cervical cases, no retropharyngeal swelling or other cervical compromises."

Dr. Raymond J. Linovitz, Director of Research and Education at Blackstone Medical, Inc., notes that to date, well over 100,000 cc's of Trinity Matrix have been implanted in approximately 10,000 patients. "We have not seen the problems that you would worry about when using an allograft product—we have not found any etopic bone growth and, in the cervical fusion patients, we have not seen any retropharyngeal swelling or airway problems." Dr. Linovitz remarks further that "We are encouraged by the very compelling anecdotal evidence that our interbody fusion rates are high and approaching, if not at, those of autograft. The number of surgeons feeling that the product is safe and efficacious continues to grow and more and more surgeons are using it."

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To Learn More

For more information about TRINITY™ Multipotential Cellular BoneMatrix, contact Terry Zielinski, Director of Communications, at 1-888-298-5400, ext. 2819, or visit the company's Web site at www.blackstonemedical.com.

Contraindications

Trinity Matrix is contraindicated in patients who have sensitivities to the antibiotics (Vancomycin, Gentamycin, and Amphotericin B) used in the manufacture of Trinity Matrix and therefore should not receive it. Trinity Matrix is for the repair, reconstruction, or replacement of bone. Therefore, it should not be used for soft tissue repair or in non-osseous sites.

References:

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