SeaSpine™

Pocket Strip

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Fillable Demineralized Bone Matrix Strip

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DESIGN RATIONALE

The Pocket Strip is 100% human allograft, composed of demineralized bone matrix and donor matched human musculoskeletal tissue. This natural biologic scaffold features a deep recess for additional grafting material.

FEATURES

Flexible Handling

- The hydrated graft is pliable – able to be folded, twisted and molded
  - Folds to retain added graft materials
  - Bends to conform to the defect site and make contact with the decorticated bone
- The graft is cohesive and maintains integrity during irrigation

Hydration

- Graft hydrates in at least 3 minutes
- Alternative hydration options provide flexibility
  - Reduce hydration time to achieve firm yet pliable handling
  - May be hydrated *in situ*
- Hydrate with sterile saline, sterile water, blood, bone marrow aspirate or platelet rich plasma (PRP)
- Hydrating fluid is retained within the implant at the graft site

Verified Osteoinductive Potential

- This 100% human allograft is a scaffold with verified osteoinductive* potential
- The demineralized bone matrix (DBM) is sterilized through the Cancelle® SP DBM sterilization process, which is designed to preserve protein activity and physical structure of the tissue
- Each lot is tested for osteoinductivity following irradiation

*DBM or representative finished implant is either assayed in vivo in the modified athymic nude rat for bone formation or *in vitro* for endogenous BMP-2 as a surrogate test marker for osteoinductive potential. Because the combination of various proteins is responsible for osteoinductive potential, DBM when assayed *in vitro*, is also screened for the presence of BMP-7.

Findings from an in vitro assay or animal model are not necessarily predictive of human clinical results.

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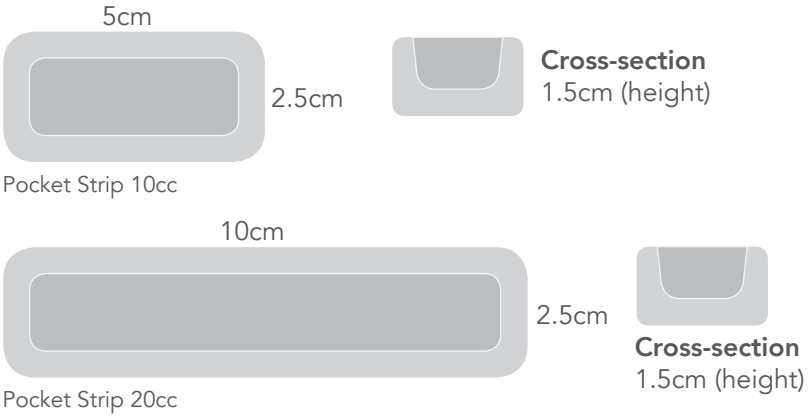
The Pocket Strip is designed to deliver additional graft materials to the implant site

- The simple design includes a deep recess for packing in local autograft or other grafting material such as blood or bone marrow aspirate
- The cavity in the 5cm strip holds approximately 5cc of additional graft material
- The cavity in the 10cm strip holds approximately 10cc of additional graft material
- When hydrated and filled, the graft can be folded to enclose and hold added graft materials
- Hydrate with bone marrow aspirate and add allograft chips to provide a graft with the three essentials of bone formation – osteoinductive potential, osteoconductive and osteogenic properties

Sizing

- Sizes to accommodate filling bone voids in single, multi-level, and posterior lumbar fusion procedures
- A 10cc 5cm x 2.5cm strip is a typical size bone void filler for a single-level fusion procedure
- A 20cc 10cm x 2.5cm strip is a typical size bone void filler for a multi-level fusion procedure



Due to the inherent variation of human tissue, actual dimensions may vary.

Safety

The highest level of safety is provided through redundant safeguards, including stringent donor screening, laboratory testing and validated tissue processing (including viral inactivation and terminal sterilization). The tissue sterilization processes applied to Pocket Strip achieve a Sterility Assurance Level (SAL) of 10^{-6}. The carrier component is sterilized through the Biocleanse® Tissue Sterilization Process and the DBM component is sterilized through the Cancelle® SP DBM sterilization process, which is designed to preserve naturally occurring protein and maintain osteoinductive potential.

- Stringent Donor Screening
- Independent CLIA Laboratory Testing
- BioCleanse Tissue Sterilization Process– a validated, proprietary sterilization process that thoroughly penetrates tissues to remove blood, lipids and marrow, inactivates or removes HIV, hepatitis, fungi and spores, yet preserves biomechanical and structural integrity
- Cancelle SP DBM Sterilization Process– a validated chemical sterilization process that virally inactivates DBM, yet does not adversely affect the osteoinductive potential. The Cancelle SP process includes terminal sterilization by low temperature, low dose gamma irradiation

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Reference	Description
58050100	Pocket Strip, 5cm x 2.5cm, 10cc
58100200	Pocket Strip, 10cm x 2.5cm, 20cc

Warnings

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunology reactions to the implant.

Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function. Fragmentation, displacement and/or disintegration of the implant at the surgical site may compromise its integrity and/or function.

Precautions

Prior to use, the surgeon must become familiar with the implant and the surgical procedure.

Do not use this implant in load-bearing applications without appropriate stabilizing hardware.

SeaSpine

For more information or to place an order, please contact:
Phone 866.942.8698 | Fax 800.471.3248
Irvine.customerservice@SeaSpine.com | **SeaSpine.com**

Manufacturer:
RTI Surgical, Inc.
11621 Research Circle, Alachua, FL 32615
Phone 361.418.8888

Distributed by:
IsoTis OrthoBiologics, Inc.
2 Goodyear, Suite A, Irvine CA 92618
Phone 800.550.7155 | Fax 800.471.3248 | **SeaSpine.com**
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