IsoTis

IsoTis® Pure Strip

Demineralized Bone Matrix Strip

IsoTis® Pure Strip

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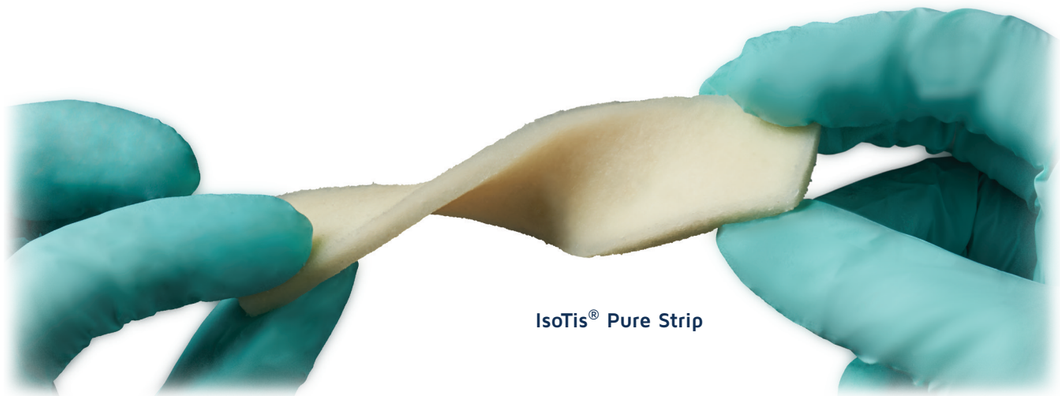
DESIGN RATIONALE

IsoTis® Pure Strips are scaffolds with verified osteoinductive* potential. Composed of 100% human tissue, the implants are designed specifically for use as bone void fillers in lumbar fusion procedures.

Demineralized Bone Matrix Strip



IsoTis® Pure Strip

FEATURES

Flexible Handling

- The hydrated graft is pliable and may be molded or cut as desired
- Conforms to the defect site and make contact with the decorticated bone
- The graft is cohesive and maintains integrity during irrigation

Hydration

- Hydrate with sterile saline, sterile water, blood, bone marrow aspirate (BMA) or platelet rich plasma (PRP)
- Hydrating fluid is retained within the implant at the graft site
- Graft hydrates in at least 3 minutes
- Alternative hydration options provide flexibility
  - May be hydrated in *situ*
  - Shorter hydration times will result in firmer handling

Verified Osteoinductive Potential

- This 100% human tissue 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 naturally occurring protein and physical structure of the tissue
- Osteoinductive (OI) potential is verified by 100% lot testing

*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.

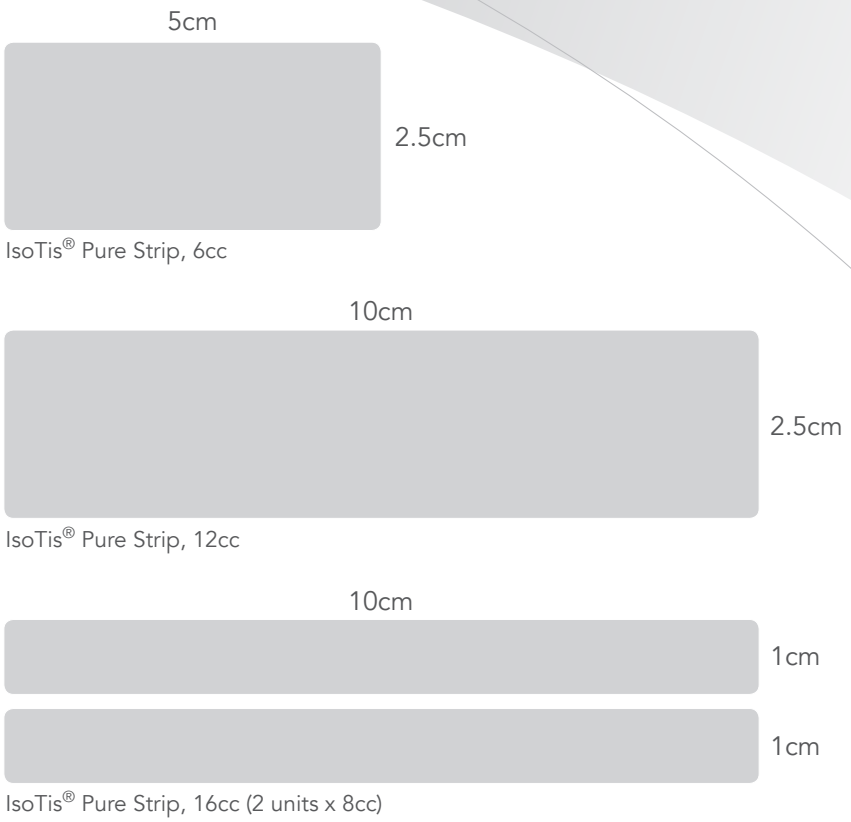
SAFETY

The highest level of safety is provided through redundant safeguards, achieving a Sterility Assurance Level (SAL) of 10^{-6}:

- Stringent donor screening
- Independent CLIA Laboratory Testing
- BioCleanse® Tissue Sterilization Process
- Cancelle® SP DBM Sterilization Process

Sizing

- Use 6cc size for filling bone voids in single level fusion procedures
- Use the 12cc or 8cc x 2 unit configurations for filling bone voids for longer fusion or deformity procedures



IsoTis® Pure Strip, 6cc

IsoTis® Pure Strip, 12cc

IsoTis® Pure Strip, 16cc (2 units x 8cc)

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

IsoTis Pure Strip

Reference	Description
06-2000-060	IsoTis® Pure Strip, 6cc (approx 5cm x 2.5cm)
06-2000-120	IsoTis® Pure Strip, 12cc (approx 10cm x 2.5cm)
06-2000-160	IsoTis® Pure Strip, 16cc (approx 10cm x 1 cm) x 2 units

SeaSpine

For more information or to place an order, please contact:

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