CE 2797

IsoTis

DIRECTIONS FOR USE

IsoTis Mozaik™ Strip

DESCRIPTION
The IsoTis Mozaik™ Osteoconductive Scaffold – Strip (IsoTis Mozaik Strip) is a resorbable bone void filler made from a porous highly purified collagen matrix that has high purity tricalcium phosphate (TCP) granules dispersed throughout. The implant is provided sterile, non-pyrogenic, for single use in double peel packages.

The IsoTis Mozaik Strip bone grafting construct is designed to facilitate the repair of bony defects. In the dry state, the matrix has a three dimensional trabecular network of pores that resembles the pore structure of human cancellous bone. The IsoTis Mozaik Strip quickly imbibes fluids, making it easy to combine with bone marrow aspirate.

The IsoTis Mozaik Strip guides the regeneration of bone across the defect site into which the strip is implanted. New bone forms in apposition to the matrix surface when the graft is placed in direct contact with viable host bone. Ultimately the matrix is resorbed and remodeled into bone.

INTENDED USE AND INDICATIONS
IsoTis Mozaik Strip, combined with bone marrow aspirate, is intended for use in orthopedic surgery as a bone void filler to fill voids or gaps of the skeletal system in the spine not intrinsic to the stability of the bony structure. IsoTis Mozaik Strip is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), IsoTis Mozaik Strip is resorbed and replaced with bone during the healing process.

CONTRAINDICATIONS
Use of IsoTis Mozaik Strip is CONTRAINDICATED in the presence of any of the following:
- Growth plate fractures
- Segmental defects
- Conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware
- Significant vascular impairment proximal to the graft site
- Metabolic or systemic bone disorders that affect bone or wound healing
- Infected sites
- Osteomyelitis at the graft site
- Defect site stabilization is not possible
- Intraoperative soft tissue coverage is not planned or possible
- Direct contact with the articular space
- Conditions in which general bone grafting is not advisable
- Large defects that in the surgeon's opinion would fail to heal spontaneously

IsoTis Mozaik Strip should not be used in patients with a known history of hypersensitivity to bovine derived materials.

WARNINGS
- **Do Not Resterilize!**
- Do not use if the product package is damaged or opened.
- Do not use to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Screws must gain purchase in the host bone as opposed to the IsoTis Mozaik Strip.
- Do not use to repair bone defects where soft tissue coverage cannot be achieved as complete postoperative wound closure is necessary.

PRECAUTIONS
- Rinse surgical gloves to remove any glove powder prior to handling IsoTis Mozaik Strip.
- The radiopacity of IsoTis Mozaik Strip is comparable to that of bone and diminishes as it is resorbed. When evaluating x-rays, the radiopacity of the material may mask underlying pathological conditions.
- Avoid over-filling of the defect site.

ADVERSE EVENTS
As with other bone grafting materials, the following complications are potential complications for IsoTis Mozaik Strip: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis. Immunological reactions consisting of transient localized edema, swelling, and rash have been reported to occur with bone void fillers containing collagen. IsoTis OrthoBiologics, Inc. is not aware of any evidence that the device will be unsafe or ineffective in such patients, the safety and effectiveness of the device in these patients has not been established. Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of the bone void filler.

SINGLE USE DEVICE
IsoTis Mozaik Strip is supplied in a single-use package and is guaranteed to be sterile and non-pyrogenic unless opened or damaged. The product is intended for use as an absorbable implant and is not to be reused. Reuse of the device can result in contamination and/or disease transmission. Any attempts to resterilize or reuse the product will damage the matrix and impair its ability to function as intended. All unused pieces must be discarded in accordance with institutional procedures.

SAFETY
IsoTis Mozaik Strip is manufactured with a collagen component containing bovine Achilles tendon, which is classified by European Standards as a Class IC material (no detectable infectivity for Bovine Spongiform Encephalopathy (BSE)). The bovine tendon is known to be one of the purest sources of Type I collagen that is commercially available.

The collagen used to manufacture IsoTis Mozaik Strip is currently used in the manufacture of resorbable dural grafts, an artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for IsoTis Mozaik Strip meets European Standards for animal tissue sourcing, handling and inactivation of viruses and transmissible agents. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of Spongiform Encephalopathy pathogens.

A viral inactivation study for the collagen manufacturing process was conducted by an independent certified laboratory. In this study, the sodium hydroxide reduced the viral titer to non-detectable levels for the following viral strains: Human Immunodeficiency Virus Type I (HIV), Bovine Viral Diarrhea (BVD), Infectious Bovine Rhinotracheitis (IBR), Parainfluenza Virus Type 3 (PI3), Vesicular Stomatitis (VSV).

This product does not contain and is not manufactured with dry natural rubber or natural rubber latex.

DIRECTIONS FOR USE
Prior to using IsoTis Mozaik Strip, the surgeon should evaluate radiographs of the bony defect to assess the extent of the defect. This assessment should be used to guide the surgeon in his or her selection and placement of the bone void filler and fixation devices. Rinse surgical gloves to remove any glove powder prior to handling IsoTis Mozaik Strip.

IsoTis Mozaik Strip may be used in its given form or cut to a desirable size using a scalpel or scissors. After cutting, insert the material into the surgical site. Smaller pieces that have been cut from the scaffold may be used to fill in irregularly shaped voids in the site. IsoTis Mozaik Strip should be wetted with bone marrow aspirate. To maximize bone formation the IsoTis Mozaik Strip should fill the defect and be in contact with as much viable host bone as possible.

To prevent collapse and deformity secondary to functional loading, the implant site should be sufficiently stabilized by fixation. To ensure that the graft is not supporting load, anatomical reduction and rigid fixation in all planes must be obtained.

As with other bone defect repairs, typical postoperative patient management should follow along with the use of fixation devices.

STORAGE
- Store at room temperature (10°C to 30°C).
- Avoid excessive heat or humidity.
- Do not refrigerate

HOW SUPPLIED
IsoTis Mozaik Strip is supplied sterile, in single use, double peel packages in a variety of sizes. Contents of the package are guaranteed sterile and nonpyrogenic unless the package is opened or damaged.

PRODUCT INFORMATION DISCLOSURE
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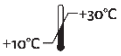
RETURNED GOODS POLICY

- Authorization from customer service must be obtained prior to returning product.
- Products must be returned in unopened packages with manufacturers' seals intact to be accepted for replacement or credit unless returned due to a complaint or product defect.
- Determination of a product defect will be made by IsoTis OrthoBiologics, Inc.
- Credit will be issued for goods returned prior to 90 days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.

	TEMPERATURE LIMITATION
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