DESCRIPTION

The Orthofix Collage™ Osteoconductive Scaffold - Putty (Orthofix Collage™ Putty) 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 Orthofix Collage™ Putty 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 Orthofix Collage™ Putty quickly imbibes fluids, making it easy to combine with bone marrow aspirate.

The Orthofix Collage™ Putty guides the regeneration of bone across the defect site into which the putty 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

Orthofix Collage™ Putty, combined with bone marrow aspirate, is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. Orthofix Collage™ Putty 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), Orthofix Collage™ Putty is resorbed and replaced with bone during the healing process.

CONTRAINDICATIONS

Use of Orthofix Collage™ Putty 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

Orthofix Collage™ Putty 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 Orthofix Collage™ Putty.
- Do not use to repair bone defects where soft tissue coverage cannot be achieved as complete postoperative wound closure is necessary.

ORTHOFIX®

Manufactured for Orthofix Inc.
3451 Plano Parkway
Lewisville, TX 75056
888-298-5700

COLLAGE™
Osteoconductive Scaffold

PUTTY

ORTHOFIX®

8500001000

CG-1103-PL-US

PRECAUTIONS

- Rinse surgical gloves to remove any glove powder prior to handling Orthofix Collage™ Putty.
- The radiopacity of Orthofix Collage™ Putty 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.
- Single Use Device: Orthofix Collage™ Putty 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. 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.

ADVERSE EVENTS

As with other bone grafting materials, the following complications are potential complications for Orthofix Collage™ Putty: 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. Orthofix 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.

SAFETY

Orthofix Collage™ Putty is manufactured with a collagen component containing bovine Achilles tendon, which is classified by European Standards as 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 manufacturing process for Orthofix Collage™ Putty 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).

DIRECTIONS FOR USE

Prior to using Orthofix Collage™ Putty, 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 Orthofix Collage™ Putty.

Orthofix Collage™ Putty should be combined with bone marrow aspirate. The volume of fluids mixed with the putty should be roughly equal to half the dry volume of the putty. For instance, 7.5cc of fluid should be added to the 15cc unit of dry putty. The putty can then be kneaded to improve the handling characteristics. Additional fluid may be added until desired consistency is achieved. The final wet volume of the putty will be equal to roughly 70% of the initial dry volume (corresponds to a 30% reduction in volume). After mixing and kneading gently into the desired shape, insert the material into the surgical site. To maximize bone formation, Orthofix Collage™ Putty 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°- 25° C / 50°- 77° F). Avoid excessive heat or humidity. Do not refrigerate.

HOW SUPPLIED

Orthofix Collage™ Putty is supplied sterile, in single use, double peel packages in a variety of sizes. Contents of the package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged.

PRODUCT INFORMATION DISCLOSURE

THE MANUFACTURER HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS.
THE MANUFACTURER AND ITS DISTRIBUTORS EXCLUDE ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, EXCEPT THE MANUFACTURER'S STANDARD WARRANTY.
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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 manufacturer's 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 Orthofix Inc.
- Credit will be issued for goods returned prior to 30 days from ship date. Returns for credit must be processed within 30 days of the original ship date. This assumes that the product returned is not damaged and can be verified to have not been used or opened and is at minimum within 120 days of its expiration date.

SYMBOLS USED ON LABELING

Store at room temperature (10°- 25° C / 50°- 77° F). Avoid excessive heat or humidity. Do not refrigerate.


Consult instructions for use

Rx ONLY Caution: Federal (USA) law restricts this device to sale by or on the order of a physician


Do not reuse

Lot number


Expiration date

Sterilized using irradiation


Do not use if package is damaged

Catalog number


Do not resterilize

This product does not contain and is not manufactured with Dry Natural Rubber or Natural Rubber Latex