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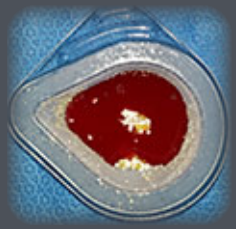

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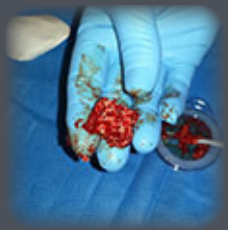

CELLING BIOSCIENCES
SOLUM IV
Surgical Technique

Instructions for Use

PLEASE READ PRIOR TO USE

DESCRIPTION

Solum IV™ is a resorbable porous calcium phosphate bone void filler for use as a bone graft substitute or bone void filler. It is an osteoconductive implant with a multidimensional porosity similar to human cancellous bone and acts as a scaffold for the in-growth of new bone.

Solum IV is composed of porous hydroxyapatite granules and a Type A porcine gelatin based carrier. Solum IV consists of porous ceramic granules composed of greater than 95 % hydroxyapatite (HAp) which are slowly resorbed and replaced by bone over a period of years. The product forms a cohesive and adhesive dough with a putty-like consistency upon hydration, which allows the shape of the implant to conform to the defect maximizing direct contact with viable host.

INDICATIONS

Solum IV™ is intended for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (i.e. extremeties and pelvis) in conjunction with an equal volume of bone marrow aspirate. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

CONTRAINDICATIONS

Use of Solum IV® is contraindicated in the presence of one or more of the following clinical situations:

1. Fractures of the epiphyseal plate.
2. Metabolic or systemic bone disorders that affect bone or wound healing.
3. Fractures for which stabilization of the fracture is not possible.
4. Significant vascular impairment proximal to the graft site.
5. Infected or contaminated wounds, or fractures for which intraoperative tissue coverage is not planned or possible.
6. Acute or chronic infections in the surgical area (soft tissue infections, inflammatory, bacterial bone disorders, osteomyelitis).
7. Impaired calcium metabolism.
8. Treatment with steroids or other drugs affecting calcium metabolism.
9. Immunosuppressant therapy.
10. Use in the area of the open epiphyseal plate.
11. Patients allergic to collagen products.

WARNINGS

Solum IV does not possess sufficient mechanical strength to support the reduction of a fracture site prior to soft and hard tissue in-growth or to support a load. Standard internal fixation techniques such as the use of plates and/or screws must be followed to obtain rigid stabilization. External stabilization alone is not sufficient to achieve the rigidity necessary for bony in-growth of the Solum IV material. Solum IV must not be used to gain screw purchase or to stabilize screw placement. Screws used with Solum IV and fixation devices must attain rigid fixation into the host bone.

Complete postoperative wound closure is essential. Solum IV must not be used to repair metaphyseal defects where complete soft tissue coverage cannot be achieved.

This system has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment.

PRECAUTIONS

Solum IV is intended for use only by surgeons familiar with bone grafting and rigid fixation techniques. Solum IV granules are radiopaque and the radiopacity may mask underlying pathological conditions. Solum IV is intended for single use only.

1. Do not apply Solum IV dry to defect.
2. Do not resterilize Solum IV.
3. For best results, Solum IV should fill the defect and contact viable bone as much as possible. Over-filling the defect site should be avoided.
4. If necessary, wipe excess material from any unintended area(s).
5. Care should be taken to not disturb the Solum IV or to remove it during irrigation once it is in place.
6. Discard any un-used Solum IV.
7. Solum IV has no weight bearing function. Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.
8. Always follow recommended mixing instructions when rehydrating Solum IV.

STORAGE

Solum IV should be stored at room temperature 15-30˚ C (59-86˚ F). The shelf life of Solum IV is clearly indicated on product labels.

LIMITED WARRANTY

SpineSmith products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties, merchantability, or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consulation, contact SpineSmith for current information.

For product information or questions pertaining to sales and services, please contact your local sales representative or SpineSmith customer service.

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Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

STERILIZATION

Solum IV is provided sterile by prior exposure to gamma irradiation. Solum IV cannot be resterilized by any method. Excess material and opened, but unused product must be discarded. Inspect the package of any sterile product for structural integrity prior to use. If the seal or outer container is broken or otherwise damaged, the product must be assumed to be nonsterile and must be discarded.

MATERIALS PROVIDED

Solum IV is packaged with a spatula in a double sterile barrier system consisting of an outer heat-sealed foil pouch with a Chevron peel opening and an inner tray with heat-sealed Tyvek lid. This package is contained in a tamper evident box along with patient labels and instructions for use.

MIXING & HANDLING

1. **PREPARE FOR MIXING**
   - **Remove plastic seal from box.**
   - **Remove inner pouch from the box.**
   - **Open pouch to sterile field allowing scrub tech, nurse or appropriate personnel in the sterile field to remove spatula and peel pack cup.**
   - **Shake cup prior to opening to properly mix Solum IV and gelatin.**

2. **HYDRATE**
   - **Instruct personnel in sterile field to open peel pack cup containing the Solum IV granules and gelatin.**
   - **Obtain a 1:1 volume of bone marrow aspirate equal to the volume of the Solum IV package.**
   - **Pour the bone marrow aspirate into the peel-pack cup with gelatin and granules.**

3. **MIX**
   - **Mix fluid into granules and gelatin with spatula**
   - **Allow mixture to set, stirring occasionally for 3 to 15 minutes until desired consistency. Do not allow mixture to become dry.**

4. **GRAFT PLACEMENT**
   - **Solum IV may now be applied directly to the bone void or surgically created osseous defect, or formed by hand into desired shape.**
   - **If mechanical fixation of the void is required standard internal fixation techniques should be used in conjunction with Solum IV.**

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