Appendix H

Draft Package Label

REF XXXX QTY 001

LOT XXXXXX YYYY-MM

Collagen Scaffold

Bovine Type I Collagen

ReGen
Biologics

Manufacturer:
ReGen Biologics Inc.
545 Penobscot Drive
Redwood City, CA 94063
USA

XX°C
X°C

Caution: Federal law restricts this device to sale by or on the order of a physician

XXXX-MM/YYYY

Appendix I

Draft Instructions for Use

Draft Instructions for Use for the (CS™)

Device Description
The Collagen Scaffold (CS) is comprised primarily of bovine type I collagen (nominally 99%) derived from Achilles tendon, and small quantities of glycosaminoglycans (GAGs: chondroitin sulfate and sodium hyaluronate). The device serves as a resorbable scaffold that is replaced by the patient's own tissue.

Intended Use

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

Contraindications
- Use in patients allergic to bovine or bovine derived products or who have a history of multiple severe allergies, allergies to animal derived products, or an overly sensitized immune system
- Patients with systemic or local infection
- Evidence of osteonecrosis in the targeted area
- Patients with medical history of severe degenerative osteoarthrosis
- **Patients without an intact meniscal rim and anterior and posterior horns**

Warnings
- If device is contaminated, unsterile, damaged, torn or has been improperly handled or altered without authorization, do not implant under any circumstance. **Do not resterilize.**

Precautions

- Rehydrate device prior to placement
- Place device in maximal contact with healthy tissue to encourage cell ingrowth and tissue remodeling
- Following surgery, physical activity should be limited to the rehabilitation protocol.
- No studies have been conducted to evaluate the effects of device remodeling when used in patients having received systemic administration of corticosteroids, antineoplastics, immunostimulating, or immunosuppressive agents within 30 days of surgery.
- No studies have been conducted to evaluate use in pregnant or lactating mothers.
- No studies have been conducted to evaluate use in patients with relapsing polychondritis, rheumatoid arthritis, or inflammatory arthritis.

Potential Complications

Complications that may occur with use of surgical mesh materials include: infection, adhesion, sterile effusion, fistula formation, seroma formation, inflammation, instability, pain, and recurrence of defect. Complications associated with the surgical procedure and anesthesia may include hematoma, and neurological, cardiac or respiratory deficit. Device-related complications that may occur include: stretching or tearing of the device, restricted freedom of movement, prolonged post-operative rehabilitation, delayed or failed incorporation of the device, allergic reaction, and immunologic reaction.

Storage and Handling

- Careful handling is required to avoid damage to the device
- The CS must be stored in the original packaging, unopened.
- The package containing the CS must be stored at temperatures between 2°C and 25°C (36°F to 77°F).

Sterilization

The CS is gamma irradiated. **Do not resterilize.**

Suggested Instructions for Use

Note: Use aseptic techniques during handling of the CS device

1. Aseptically remove the CS device from its sterile packaging and place in sterile field.
2. Rehydrate the CS device in a sterile dish using sterile irrigation solution
3. Surgically prepare the targeted graft site using standard techniques.
4. Remove any unstable or degenerative tissue, and carefully prepare a bleeding bed, as needed. For best results, the CS should be placed in an area with good tissue contact.

5. Trim the fully hydrated CS device to the desired size and shape for the targeted area.
6. Suture the CS in place using non-resorbable suture with a recommended suture spacing of 4-5 mm. **Use extreme care to avoid damaging any surrounding neurovascular structures.**
7. Complete the standard surgical procedure
8. Discard any unused portions of the CS device

Pictograms

⚠	"Follow the Instructions for Use"
⊗	"Not to be re-used"
⌛	"To be used by... (Year, Month)"
STERILE R	"Sterile" and "Sterilization by irradiation"
🌡	"Temperature limitation"

Trade marks

ReGen® is a registered trademark of ReGen Biologics, Redwood City, CA 94063, USA and Franklin Lakes, NJ 07417, USA.

Manufactured by: ReGen Biologics, Redwood City, CA 94063, USA

Appendix J

Final Study Reports of Viral Inactivation

Final Report

EVALUATION OF INACTIVATION/REMOVAL OF BOVINE VIRAL DIARRHEA VIRUS FROM SPIKED TEST ARTICLE

Quality Assurance Statement

Appendix 1

Study Flow Diagram

Appendix 2

$TCID_{50}$ Assay Data

Final Report

Quality Assurance Statement

Appendix 1

Viral Interference Data

Appendix 2

Procedural Batch Records for ReGen Biologics, Inc.'s Recovery Procedures

Final Report

Quality Assurance Statement

Appendix 1

Study Flow Diagram

Appendix 2

$TCID_{50}$ Assay Data

Final Report

Quality Assurance Statement

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Final Report