

DermaSpan™ Acellular Dermal Matrix

Reinforcement of Lateral Ankle
Stabilization Procedure

Surgical Protocol by
Charles Zelen, DPM, FACFAS

BIOMET®

One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally-invasive surgical technique, advanced biomaterials, or a custom, patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

DermaSpan™ Acellular Dermal Matrix

Contents

Reinforcement of Lateral Ankle Stabilization

- Perform Primary Repair 2
- Apply DermaSpan™ Acellular Dermal Matrix 2
- Tack DermaSpan™ ACD in Place 3
- Augment Repair–Apply Running Sutures 3
- Part Numbers 4
- Indications and Contraindications 5

DermaSpan™ Acellular Dermal Matrix

Reinforcement of Lateral Ankle Stabilization



Figure 1

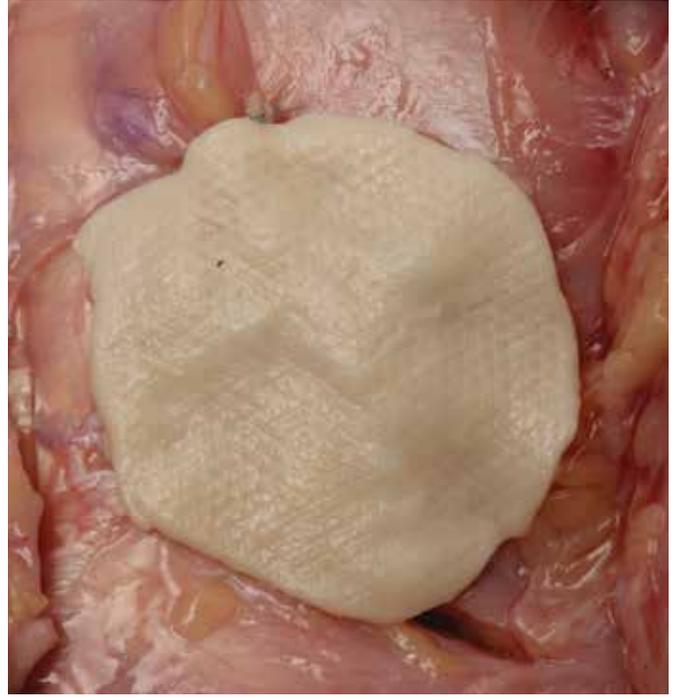


Figure 2

Perform Primary Repair

Utilizing a #2 MaxBraid™ suture, reduce the laxity in the Peroneus Brevis and Peroneus Longus tendons as necessary (Figure 1).

Apply DermaSpan™ Acellular Dermal Matrix

Rehydrate an appropriate sized DermaSpan™ Acellular Dermal Matrix per the rehydration instruction in the Instructions for Use. Place the DermaSpan™ ACD on the lateral face of the repair region ensuring that the Dermal side of the graft is contacting the tendons and the Basement side is away from the tendons. Note this is critical to allow for appropriate tissue integration of the graft during the healing process.

Align the DermaSpan™ ACD so that it evenly covers the entire repair region. The DermaSpan™ ACD should run from the lateral fibular periosteum to the inferior extensor retinaculum. Trim the DermaSpan™ ACD as necessary to appropriately cover the repair site (Figure 2).

This surgical technique is utilized by Charles Zelen, DPM, FACFAS. Biomet does not practice medicine. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

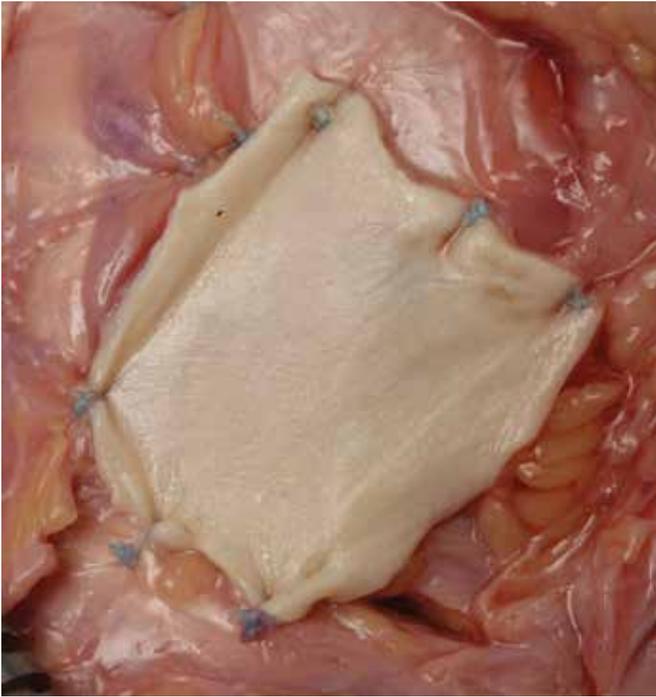


Figure 3

Tack DermaSpan™ ACD in Place

Apply tack sutures with 2-0 MaxBraid™ sutures. The first three sutures should be placed into the inferior extensor retinaculum and DermaSpan™ ACD. Hold the ankle and foot in a dorsiflexed and everted position. Place three more tack sutures through the DermaSpan™ ACD and the lateral fibular periosteum (Figure 3).



Figure 4

Augment Repair– Apply Lateral Trap Running Sutures Circumferentially

Utilizing 2-0 MaxBraid™ suture, apply lateral trap–running sutures around the perimeter of the DermaSpan™ ACD. Ensure that the sutures run through the DermaSpan™ ACD and the soft tissues surrounding the repair site including the strong area of the lateral fibular periosteum and the inferior extensor retinaculum (Figure 4). The tack sutures from initial placement may be removed at the end of the procedure, if preferred.

DermaSpan™ Acellular Dermal Matrix

Part Numbers

Non-mesh

Part Number	Size	Thickness
48-0700404	4 cm – 4 cm	0.5 mm – 0.9 mm
48-0700408	4 cm – 8 cm	0.5 mm – 0.9 mm
48-1100407	4 cm – 7 cm	0.8 mm – 1.4 mm
48-1100510	5 cm – 10 cm	0.8 mm – 1.4 mm
48-1100505	5 cm – 5 cm	0.8 mm – 1.4 mm
48-0900307	3 cm – 7 cm	0.9 mm – 1.99 mm
48-0900407	4 cm – 7 cm	0.9 mm – 1.99 mm
48-0900412	4 cm – 12 cm	0.9 mm – 1.99 mm
48-0900416	4 cm – 16 cm	0.9 mm – 1.99 mm
48-0900510	5 cm – 10 cm	0.9 mm – 1.99 mm
48-0900612	6 cm – 12 cm	0.9 mm – 1.99 mm
48-0900616	6 cm – 16 cm	0.9 mm – 1.99 mm
48-0900812	8 cm – 12 cm	0.9 mm – 1.99 mm
48-0900816	8 cm – 16 cm	0.9 mm – 1.99 mm
48-0901212	12 cm – 12 cm	0.9 mm – 1.99 mm
48-0901620	16 cm – 20 cm	0.9 mm – 1.99 mm
48-2000307	3 cm – 7 cm	2.0 mm – 3.5 mm
48-2000407	4 cm – 7 cm	2.0 mm – 3.5 mm
48-2000412	4 cm – 12 cm	2.0 mm – 3.5 mm
48-2000416	4 cm – 16 cm	2.0 mm – 3.5 mm
48-2000510	5 cm – 10 cm	2.0 mm – 3.5 mm
48-2000612	6 cm – 12 cm	2.0 mm – 3.5 mm
48-2000616	6 cm – 16 cm	2.0 mm – 3.5 mm
48-2000812	8 cm – 12 cm	2.0 mm – 3.5 mm
48-2000816	8 cm – 16 cm	2.0 mm – 3.5 mm
48-2001212	12 cm – 12 cm	2.0 mm – 3.5 mm
48-2001620	16 cm – 20 cm	2.0 mm – 3.5 mm

Mesh

48-0400404M	4 cm – 4 cm	0.4 mm – 0.8 mm
48-0400408M	4 cm – 8 cm	0.4 mm – 0.8 mm

Indications for Use

DermaSpan™ ACD is processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and nonspecific inflammatory responses. It is to be used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. It may also be used for supplemental support, protection, reinforcement or covering of tendon. Each package of DermaSpan™ ACD is intended for use in one patient, on a single occasion by a licensed physician, surgeon, dentist or podiatrist.

Contraindications

Use of DermaSpan™ ACD in patients exhibiting autoimmune connective tissue disease is not recommended. When applied properly DermaSpan™ ACD has been shown to support the migration of host cells from wound margins and surrounding tissue. Conditions that could inhibit migration of host cells include, but are not limited to the following:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Low vascularity of the surrounding tissue
- Local or systemic infection
- Mechanical trauma
- Poor nutrition or general medical condition
- Dehiscence and/or necrosis due to poor revascularization
- Specific or nonspecific immune response to some component of the allograft
- Inability to cooperate with and/or comprehend post-operative instructions
- Infected or nonovascular surgical sites

DermaSpan™ ACD may contain trace amounts of processing agents listed in the Warnings section of the insert. DermaSpan™ ACD should not be used in patients sensitive or allergic to these specific agents.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

This material is intended for the sole use and benefit of the Biomet sales force and physicians. It is not to be redistributed, duplicated or disclosed without the express written consent of Biomet.

For product information, including indications, contraindications, warnings, precautions and handling instructions, see the package insert and patient risk information at www.biomet.com.



One Surgeon. One Patient.®

Responsible Distributor
Biomet
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA