ACS Allograft Cartilage Scaffold --International

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY. Aseptically Processed. Passes USP <71> Sterility Tests. Not Terminally Sterilized. THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR WHOSE LEGAL NEXT-OF-KIN HAS GIVEN PERMISSION FOR THE BONE AND CONNECTIVE TISSUE TO BE DONATED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

DESCRIPTION
ACS Allograft Cartilage Scaffold is composed of cancellous bone and articular cartilage. ACS is provided preloaded in an inserter. ACS is available in various sizes. The description of the tissue, lot number, expiration date, product code, size, and additional information are printed on the allograft container label.

ACS is intended for use with the MTF ACS Instruments.

INDICATIONS FOR USE
ACS is machined to specific dimensions for repair of osteochondral defects. ACS is for single patient use only.

CONTRAINdications
ACS is contraindicated in the following circumstances:
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Pott’s disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site

- Incomplete skull growth
- Inability to cooperate with and/or comprehend post-operative instructions

ADVERSE EFFECTS
Possible adverse effects of using ACS include, but are not limited to:
- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Hypercalcemia or transient hypercalcemia
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response

Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

CAUTIONS
Do not sterilize. Trace amounts of Gentamicin, Primaxin, and Amphotericin B antibiotics may be present. Trace amounts of Polysorbate-80, Ethanol, and Hydrogen Peroxide may be present. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No β-lactam antibiotics are used during the processing of tissue in ACS products.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases such as HIV or Hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of the careful donor selection and serological testing.

DONOR SCREENING & TESTING
Prior to donation, the donor’s medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Advisory Board.

Donor blood samples taken at the time of recovery were tested by a CLIA licensed facility for:
- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-1/2 antibody
- Syphilis

In addition to the testing listed above, HIV-1 and HCV Nucleic Acid Amplification Testing (NAT) were performed. The results of all serological testing were negative. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1270 and Part 1271 Human Tissue Intended for Transplantation, as applicable. All procedures for donor screening, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks.

INSTRUCTIONS FOR USE
To make ready for use, open the package using aseptic/sterile techniques.

ACS is packaged in a plastic inserter. Care should be taken to apply gentle, even force to the inserter when extruding ACS.

Instruction for use for the ACS Inserter:
Note: It is recommended that the ACS Reusable (Lesion Gauge, Depth Gauge, Dilator, Mallet and Chamfer Disk), and Single Use (Lesion Reamer, Guide Pin and Knife) Instrument kits be used for insertion of the ACS Scaffold.

1. Choose appropriate Lesion Gauge from the sterilization tray to completely cover the defect. Ensure one of the legs of the Lesion Gauge is at the 12 o’clock position. The other 2 legs will be at 4 and 8 o’clock.
2. Insert the Guide Pin to a depth of 20 mm.
3. Remove the Lesion Guage.
4. Prepare the defect using the appropriate size Lesion Reamer. Drill to the appropriate depth between 9mm and 15mm.
5. Using the Depth Gauge, note the defect depth at the 12, 4 and 8 o’clock position.
6. Insert the appropriate color coded Dilator over the Guide Wire and gently dilate the defect to the appropriate depth. It is recommended to leave the Dilator in place until graft insertion.
7. Remove ACS inserter from package. Gently twist the inserter so that it is in the unlocked position according to the image on the inserter. Note: Do not remove the color coded Cutting Guide or the Red Depth Stop Tab.
8. Using the markings on the inserter plunger, extrude the graft to the appropriate length according to defect’s minimum depth measurements previously recorded. Note: Do not extrude graft further than 9mm as indicated on the inserter.
9. Gently twist the inserter so that it is in the locked position according to the image on the inserter. Use the knife provided to cut the graft to length using the cutting surface as a guide.
10. In the event that depth measurements are different at 12, 4 and 8 o’clock, two options are available. If differences between depth measurements are less than 1mm, cut graft to the shortest length. If differences between depth measurements are greater than 1mm, cut graft to longest length and use chamfer edge on the knife provided to refine scaffold length.
11. Remove cutting surface from end of graft and red stop from the plunger.
12. Use appropriate size color coded Chamfer Disk and using a twisting motion, chamfer graft edges.
13. Remove the Dilator and the Guide Wire from the defect site.
14. Position graft in correct orientation, gently twist the inserter so that it is in the unlocked position and advance the plunger using the Mallet provided to set the graft in place. Note: Back end of inserter push rod may be used as a tamp if necessary.
15. Cycle knee several times to ensure graft is flush with the articular surface.

ACS must not be used under any of the following circumstances:
- If the container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the container label has passed.

**STORAGE**

Store ACS at ambient temperature. No refrigeration or freezing is required. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

**PATIENT RECORD**

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. This will allow MTF to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. A TissuTrace® Tracking Form and peel-off stickers have been included with each package of tissue. Record the patient ID, the name and address of the transplant facility, allograft tissue information (using the peel-off stickers) and comments regarding the use of the tissue on the TissuTrace® Tracking Form. *Outside of the United States:* Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

**REFERENCES:**

1. Current Standards for Tissue Banking. AATB. McLean, VA.