CE SPACE Allograft Package Insert

Description
CE SPACE allograft from consenting human cadaveric donor, which is recovered, processed and packaged using aseptic techniques, and provided terminally sterilized for use in lumbar interbody fusion surgery.

Donor Selection and Screening (Summary of Records)
Tissue Banks International's commitment to tissue safety begins with donor screening. Potential donors are screened for high-risk behavior and contraindications to transplant through medical/social history interview, review of medical records, assessment of the donor's body, and review of post-mortem examination results (when applicable).

Individuals with risk factors for, conditions indicating, clinical evidence of, and/or physical evidence of infectious diseases, or communicable disease agents or diseases at the time of death are ineligible for donation. Examples include, but not limited to the following:

- HIV/AIDS, including risk factors such as injectable drugs for non-medical use, or high-risk behavior
- Viral hepatitis
- Sepsis/systemic infection
- West Nile Virus
- Human transmissible spongiform encephalopathy (TSE), including Creutzfeldt-Jakob Disease (CJD)
- Dementia, or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology
- Epstein Barr virus
- Malaria
- Malignancy
- Autoimmune, connective tissue, and collagen diseases
- Communicable disease risks associated with xenotransplantation
- Other infectious diseases or disease of unknown etiology

Donors are also excluded for conditions or behaviors that significantly affect tissue quality.

All donors are subject to viral marker testing by a CLIA certified laboratory on a hemodilutionally qualified blood sample and found to be negative or non-reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)
- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody total (HBCAb)
- Hepatitis C virus (HCV Ab and HCV NAT)
- Syphilis by rapid plasma regain (RPR) or other serological tests

Tissue from this donor has passed bacteriological testing by a CLIA certified laboratory.

Donor eligibility determination made by TBI/Tissue Banks International staff in compliance with U.S. Food and Drug Administration (FDA) regulations and American Association of Tissue Banks (AATB) Standards.

Storage and Handling
CE SPACE allograft is supplied ready to use, no rehydration necessary.

- It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.
- The allograft is saline preserved, store between 2°C and 4°C. DO NOT FREEZE.
- The packaging system used for this allograft meets or surpasses established standards for the safe delivery of tissue to the physician.

Contraindications
The allograft should not be implanted into sites with active or latent infection and/or active metastatic processes.
Potential Complications
The allograft may not elicit the intended response for the recipient (fusion/union with adjacent tissue). The host site may become infected. The allograft may not provide mechanical support and collapse, or cause an inflammatory response. Resorption or collapse of the adjacent bone may also occur. While efforts are made to ensure the safety of the tissue, current available technologies may not prevent the transmission of disease, including hepatitis and HIV.

Precautions
The allograft is considered sterile as long as the packaging is not opened or damaged. Inspect the integrity of the package upon receipt and before use. Do not use the allograft under the following conditions:
• The container in which the tissue is stored is damaged or the label has been removed or defaced.
• The indicated expiration date has passed.
• Recommended storage conditions have not been maintained.

WARNING
• Unused allograft, whole or partial, may not be repackaged or resterilized.
• This allograft is intended for single patient use only.
• While every effort has been made to ensure the quality of this allograft, TBI / Tissue Banks International makes no claims concerning the biologic or biomechanical properties. As with any allograft, despite strict screening, testing and quality control procedures, there is potential for transmission of infectious agents to the recipient.
• The allograft may include trace amounts of processing agents including such as iodine, ethanol, hydrogen peroxide, Gentamicin and Vancomycin.

Sterility Control
CE SPACE allograft is provided sterile following an internationally recognized validation method and monitoring process, in combination with a proprietary irradiation system using gamma radiation from cobalt-60 source material, to a target dose of 17 to 23 kGy. Each sterilization lot also undergoes destructive bacteriological quality control testing by a CLIA certified laboratory before release for use.

Directions for Use
This allograft is intended for one-time use only for a single patient, and by a licensed physician. It is important to utilize aseptic techniques when unpacking the allograft. If the allograft is not used within approximately two hours of opening, assure continued sterility and keep at 2°C to 8°C. Use opened allograft within 24 hours or discard. DO NOT STERILIZE/RESTERILIZE.

Prepare Allograft for Use:
Follow the allograft preparation steps described below prior to surgery. The outer peel pouch is not considered sterile. Inner bottle and allograft are considered sterile.
1. Examine pouch for package integrity. Do not use if there is evidence that the pouch is damaged or sterility has been compromised.
2. Aseptically present the bottle onto a sterile field.
3. Remove the metal safety-sealing band from the bottle and stopper.
4. Remove the stopper of the bottle. Pour the contents of the bottle into a sterile preparation basin on the sterile field. The allograft is ready to use and requires no further preparation.
5. If the allograft is not to be used within approximately two hours of opening, assure its continued sterility and keep at 2°C to 8°C. Use the opened allograft within 24 hours or discard.

Tissue Tracing
The physician is responsible for completing the recipient records for the purpose of tracing tissue post-use. Complete the CE SPACE Usage Report Card included with each allograft in detail and return as indicated.

Adverse Reactions
The physician is responsible for reporting all adverse reactions that may be potentially attributable to the allograft to TBI / Tissue Banks International’s Quality Assurance Group. Call 800-922-3100.

TBI / Tissue Banks International is accredited by the American Association of Tissue Banks. TBI/Tissue Banks International is a non-profit, non-governmental network of eye and tissue banks. CE SPACE allografts are prepared by TBI/Tissue Banks International, 880 Harbour Way South, Richmond, California 94804, and distributed by Aesculap Implant Systems, LLC, 3773 Corporate Parkway, Center Valley, PA 18034, 800-234-9179. SOP - AIS - 5800525 REV 03