PLIF Spacer. An allograft spacer for posterior lumbar interbody fusion.

Processed by MTF, designed and available through Synthes Spine.
The PLIF Spacer has been engineered to meet the specific demands of posterior lumbar interbody fusion procedures. Six precise implant heights accommodate individual patient anatomy.

**PLIF Spacer dimensions**

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<th>Frozen Item Number</th>
<th>Anterior Height (mm)</th>
<th>Posterior Height (mm)</th>
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The design of the PLIF Spacer is based on sound engineering principles, extensive research of anatomical geometry from published literature, and mechanical testing.

**Compressive strength**

In the lumbar spine, axial compression is the major cause of failure. Tests were conducted to ensure that the PLIF Spacer could withstand the loads in the lumbar spine. The ultimate compressive strength of the vertebral body is 8,000 N. The design goal for the PLIF Spacer was to achieve compressive strength of at least 8,000 N. Loads greater than this would result in failure of the vertebral body before failure of the implant. Test results show that the PLIF Spacer has a compressive strength above 25,000 N (Figure 1).

**Resistance to expulsion**

Resistance to implant expulsion is a major factor in the design of intervertebral spacers. The PLIF Spacer is designed with sawtooth-shaped teeth to increase resistance to pullout. Pullout testing was conducted to ensure that the PLIF Spacer was able to resist expulsion. An axial preload (450 N) and a side (shear) load were applied to the implant to determine the pullout strength. Test results (Figure 2) show that the PLIF Spacer had pullout strength of (1,053 N ± 80 N), more than three times the pullout strength of a comparable design without teeth (234 N ± 38 N).

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Quality is our first priority
The Musculoskeletal Transplant Foundation (MTF) is a national consortium of medical schools, academic institutions and recovery organizations involved in the aseptic recovery, processing and distribution of bone and related soft tissue for use in transplant surgery. Its quality and safety standards consistently meet or exceed the requirements of the American Association of Tissue Banks (AATB) and the guidelines for screening and testing of tissue donors set forth by the Food and Drug Administration (FDA).

Donor screening and testing
Prior to donation, the donor’s medical/social history was screened for disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by MTF’s 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
- HTLV-I/II antibody
- Hepatitis C antibody
- Syphilis

In addition to the testing listed above, HIV-1 Nucleic Acid Amplification Testing (NAT) was performed. Furthermore, donors recovered on or after May 1, 2004 were tested for HCV utilizing the HCV NAT testing method. The results of all serological testing were negative. This allograft tissue has been determined to be suitable for transplantation.

Since 1991, over 65,000 donors have been approved and processed, with more than 3.5 million allografts distributed. MTF’s testing and processing meet or exceed all American Association of Tissue Banks (AATB) standards and FDA regulations, and MTF maintains an exemplary safety record.

Donor criteria and selection
The age criteria for donors is 15–70 years for males and females. This allows the selection of tissue with denser construction.

All potential donors must pass through an extensive quality assurance process. Screening begins with a comprehensive medical and social history that includes the cause of death. Tissue and blood samples are tested for infectious diseases that include hepatitis, HIV, and syphilis. An MTF physician with infectious diseases or pathology background evaluates all information and determines whether or not the tissue may be released for processing.

Processing
To maintain biological integrity, MTF processes all tissue by using aseptic techniques in class 10 (certified) clean rooms. This eliminates the need for terminal sterilization by high-dose gamma irradiation or ethylene oxide gas, which have been shown to compromise the biological and biomechanical integrity of allograft tissue.*

Some tissues MTF distributes are exposed to a low-dose gamma radiation as a means of reducing bioburden. For these tissues the container label will specify “PRETREATED WITH LOW-DOSE GAMMA IRRADIATION.”

All tissue is computer-tracked from recovery through testing, processing, packaging and distribution.

Storage and handling
Frozen
Frozen tissue has been preserved between −40°C and −90°C until time for shipping and is shipped on dry ice. It is recommended that the graft be stored on dry ice, or in a −40°C to −90°C freezer until the time of surgery. Refer to the tissue information sheet that accompanies the tissue for more detailed information on storage and handling.

Freeze-dried
The decision to rehydrate MTF freeze-dried tissue forms prior to transplantation should be based on the surgeon’s preference. Refer to the package insert that accompanies the tissue for more detailed information on storage and handling.

Synthes Spine
The PLIF Allograft Spacers are designed by and available through Synthes Spine.

Synthes Spine was founded in 1991 and is dedicated to designing and developing new spinal instruments and implant systems.

To order, call Synthes Customer Relations at 800-522-9069
Fax: 877-534-1560

* Documentation is available on request. To receive documentation materials, please contact MTF at 800-433-6576.