T-PLIF Spacer. An allograft spacer for transforaminal posterior lumbar interbody fusion.

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

- Precisely machined instrument slot ensures secure fit between implant and implant holder
- Pyramidal teeth on superior and inferior surfaces minimize migration and resist expulsion
- Beveled edge on distal end facilitates implant insertion
## T-PLIF Spacer Dimensions

<table>
<thead>
<tr>
<th>Item Number</th>
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<th>Anterior Height (mm)</th>
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<tr>
<td>004907</td>
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- **Central AP depth**: 9 mm
- **Total AP depth**: 11 mm
- **ML width**: 26 mm
- **Height**:

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**Synthes Spine**
Sound engineering principles, extensive anatomical research and mechanical testing are the basis for the T-PLIF design.

### Compressive Strength

Tests were conducted to ensure that the T-PLIF spacer withstands the compressive loads in the lumbar spine. The ultimate compressive strength of the vertebral body is 8000 N. The design goal for the T-PLIF spacer was to achieve compressive strength of at least 8000 N. Loads above this would result in failure of the vertebral body before failure of the implant. Test results show that the T-PLIF spacer has a compressive strength above 16,000 N (Figure 1).

### Resistance to Expulsion

Resistance to implant expulsion is a major factor in the design of intervertebral spacers. Pyramid-shaped teeth are machined on the superior and inferior surfaces of the implant to increase resistance to pushout. Testing was conducted to ensure that the T-PLIF spacers are capable of resisting expulsion at clinically relevant loads. An axial preload (450 N) and a side (shear) load were applied to the implant to determine the pushout strength. Test results (Figure 2) show that the T-PLIF spacer had pushout strength of 850 N, more than three times the pushout strength of a comparable design without teeth (234 N ± 38 N).

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Synthes instrumentation is designed to make the T-PLIF spacer implantation procedure quick and simple.

**Sets**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>105.125</td>
<td>T-PLIF Spacer Instrument Set (not shown)</td>
</tr>
<tr>
<td>105.151</td>
<td>T-PLIF Minimally Invasive Instrument Set</td>
</tr>
<tr>
<td>105.152</td>
<td>T-PLIF Auxiliary Instrument Set</td>
</tr>
</tbody>
</table>
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).

Testing
MTF is AATB-accredited and uses the most complete and technically advanced testing available to assure the safety of its allografts. MTF utilizes Nucleic Acid Testing (NAT by TMA) on every donor. NAT is a reliable test to confirm the presence or absence of HIV and HCV early, following exposure. MTF continues its very comprehensive testing for the following: HIV-1*, HIV-2*, HTLV-I, HTLV-II, HB Core, RPR, HCV-Ab, HBs Ag*, NAT, HCV-NAT.

Since 1991, over 50,000 donors have been approved and processed, with more than 2.5 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 unrivaled safety record.

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 (1.0–1.8 megarads) as a means of reducing bioburden prior to processing. For these tissues the container label will specify “PRETREATED WITH LOW-DOSE GAMMA IRRADIATION.” This low dose of radiation has been proven to effectively sterilize all nonsystemic bacterial and fungal contaminants.

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

Donor criteria and selection
The age criteria for donors is 15–65 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 at the site of recovery 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. MTF’s testing requirements exceed current AATB and FDA guidelines. A team of medical/technical specialists from the infectious disease and tissue banking fields evaluates all information, including test results.

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
It is recommended that freeze-dried tissue be reconstituted in saline prior to use. Refer to the tissue information sheet that accompanies the tissue for more detailed information on storage and handling.

Synthes Spine
The T-PLIF Spacer is 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 Service at 800-522-9069
Fax: 877-534-1560

* Tested using FDA-required test kits.
** A preliminary study of the use of high-dose gamma irradiation for the inactivation of HIV demonstrates that the commonly applied dose of 1.5–2.5 Mrads does not inactivate the virus. Inactivation would require a higher dose—on the order of 3.0–4.0 Mrads. However, doses over 2.5 Mrads have been shown to have a deleterious effect on the structural integrity of the allograft tissue. This information has been prepared by the Musculoskeletal Transplant Foundation based on the most current data and studies available. Full documentation is available on request. To receive a package of documentation materials, please contact MTF at 800-433-6576.