Surgical Technique

A-Link Z
STAND ALONE
ALIF INTERBODY SYSTEM

EACH SURGEON EVERY PATIENT
making total support a reality...again.

844.228.4890 | AcuitySurgical.com
A-Link Z is a spinal device that is implanted in the intervertebral body space via an anterior approach to improve stability of the spine while supporting fusion. Components are offered in different shapes and sizes to meet the requirements of the individual patient anatomy. A-Link Z is made from titanium alloy (Ti-6Al-4V ELI) with an optional interbody component composed of and polyetheretherketone (PEEK) with tantalum markers.

Indications

A-Link Z is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral body space.

A-Link Z is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

A-Link Z may be used as a stand alone device when all four (4) vertebral body bone screws are used. If the physician chooses to use fewer than the four (4) screws, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEATURES/BENEFITS</td>
<td>1</td>
</tr>
<tr>
<td>PRODUCT OVERVIEW</td>
<td>2</td>
</tr>
<tr>
<td>INSTRUMENT OVERVIEW</td>
<td>4</td>
</tr>
<tr>
<td>PRE-SURGERY PREPARATION</td>
<td>7</td>
</tr>
<tr>
<td>SURGICAL EXPOSURE &amp; SITE PREPARATION</td>
<td></td>
</tr>
<tr>
<td>POSTOPERATIVE CARE</td>
<td></td>
</tr>
<tr>
<td>REMOVING THE A-LINK Z IMPLANT</td>
<td>13</td>
</tr>
<tr>
<td>PACKAGING</td>
<td></td>
</tr>
<tr>
<td>INSTRUMENT CLEANING &amp; DECONTAMINATION</td>
<td>14</td>
</tr>
<tr>
<td>INSTRUMENT STERILIZATION</td>
<td></td>
</tr>
<tr>
<td>COMPLAINTS</td>
<td>17</td>
</tr>
<tr>
<td>CONTRAINDICATIONS</td>
<td>18</td>
</tr>
<tr>
<td>WARNINGS / PRECAUTIONS</td>
<td>19</td>
</tr>
</tbody>
</table>
## Features/Benefits:

**AN EVIDENCE-BASED SYSTEM BACKED BY DISTINCTIVE TOTAL SUPPORT**

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior Column Zero Profile</td>
<td>reduces or eliminates potential for great vessel interference</td>
</tr>
<tr>
<td>Enhanced porous structure</td>
<td>increases bone in-growth to endplate (titanium only)</td>
</tr>
<tr>
<td>Lag screws</td>
<td>loads the graft compressively to promote fusion</td>
</tr>
<tr>
<td>Locking plate</td>
<td>provides visual and audible confirmation of fully seated screw to prevent backout</td>
</tr>
<tr>
<td>Simple instrumentation</td>
<td>enhances surgeon efficiency and placement of screws</td>
</tr>
</tbody>
</table>

**UNITARY TITANIUM FRONT VIEW**

**UNITARY TITANIUM CONSTRUCT**

**MODULAR TITANIUM CONSTRUCT**
**PRODUCT OVERVIEW**

**ASSEMBLED TITANIUM CONSTRUCT**
*(LATERAL VIEW)*

**SCREWS**

<table>
<thead>
<tr>
<th>diameter</th>
<th>length</th>
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</thead>
<tbody>
<tr>
<td>5.0</td>
<td>20 / 25 / 30 mm</td>
</tr>
<tr>
<td>5.5</td>
<td>20 / 25 / 30 mm</td>
</tr>
</tbody>
</table>

**COVER PLATE**

**UNITARY TITANIUM AVAILABLE SIZES**

<table>
<thead>
<tr>
<th>Lordosis</th>
<th>Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 deg</td>
<td>-</td>
</tr>
<tr>
<td>16 deg</td>
<td>-</td>
</tr>
<tr>
<td>12 deg</td>
<td>11, 13, 15, 17, 19</td>
</tr>
<tr>
<td>7 deg</td>
<td>11, 13, 15, 17, -</td>
</tr>
</tbody>
</table>

*also available in a 20 deg, 13mm height*

32 X 21 EXTRA SMALL UNITARY ASSEMBLY*

32 X 24 SMALL UNITARY ASSEMBLY

36 X 26 LARGE UNITARY ASSEMBLY

40 X 30 EXTRA LARGE UNITARY ASSEMBLY
MODULAR TITANIUM AVAILABLE SIZES

<table>
<thead>
<tr>
<th>Lordosis</th>
<th>Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 deg</td>
<td>11, 13, 15, 17, 19</td>
</tr>
<tr>
<td>7 deg</td>
<td>11, 13, 15, 17</td>
</tr>
</tbody>
</table>

*Modular Peek Construct available upon request*
INSTRUMENT OVERVIEW

10-00033 | COMPACT IMPLANT RETAINER

10-00034 | SMALL OBLIQUE RETAINER

10-00035 | LARGE OBLIQUE RETAINER

10-00036 | CONE GUIDE INERTER

10-00030 | MODULAR IMPLANT INERTER

10-00037 | CONE GUIDE STRAIGHT BONE AWL

10-00040 | CONE GUIDE ANGLED AWL

10-00038 | CONE GUIDE STRAIGHT SCREWDRIVER
INSTRUMENT OVERVIEW

10-000039 | CONE GUIDE STRAIGHT SCREWDRIVER, SLOTTED TIP

10-000041 | CONE GUIDE ANGLED SCREWDRIVER

10-000029 | COMPACT COVER PLATE SCREWDRIVER

10-000043 AXIAL HANDLE

10-000042 RATCHETING STRAIGHT HANDLE

10-000014 TORQUE HANDLE

10-000044 SLAP HAMMER
PRE-SURGERY PREPARATION

All titanium implants and instruments are provided non-sterile and should be sterilized prior to use. See instructions below. Assembled PEEK constructs are provided sterile upon request.

Note: the modular titanium construct must be pre-assembled in the implant caddy prior to sterilization. To assemble, place the interbody cage in the caddy with the mating holes facing up. Assemble the palm axial handle (10-000043) to the compact implant retainer (10-000033) and thread in the cone guide inserter (10-000036). Assemble the corresponding plate to the compact implant retainer by turning the handle in a clockwise direction. Align the tabs of the plate into the interbody cage mating holes and push together. If necessary, use a mallet to lightly impact the handle until the posterior face of the plate is against the anterior face of the interbody cage. Confirm the press fit assembly by gently pulling on the interbody cage.

Review and inspect all instrumentation and implants prior to use.

• Replace or add any needed components for the planned surgery.
• Primary surgeon must be fully experienced with the required spinal fusion techniques.
• Please read the Instructions for Use (IFU) for a list of warnings, cautions, contraindications, risks and product description.

SURGICAL EXPOSURE & SITE PREPARATION

1. Prepare, position and drape the patient in the usual fashion.

2. Expose the affected levels via a standard anterior approach incision and tissue dissection.

3. Perform any necessary bone and tissue removal.
4. Remove disc material and prepare endplates using the appropriate instruments. Use a combination of curettes, rasps, osteotomes, disc shavers or box chisels to remove the disc material and cartilage from the vertebral endplates.

5. After preparing the intervertebral disc space, insert the trials to determine the size of the desired implant, starting with the trial with the smallest footprint and height.

   a. Assemble the straight ratcheting handle (10-000042) to the cone guide inserter (10-000036) and insert it into the compact implant retainer (10-000033).

   b. Assemble the trial (10-321XXX, 10-324XXX, 10-325XXX or 10-330XXX)

   c. Select the trial using radiographic imaging to fit the anatomic conditions, and insert progressively increasing height of the trials until the appropriate height distraction is achieved. **Note:** Use of trials is recommended to ensure usage of an appropriate sized implant.

   d. Oblique inserter holes may also be utilized to insert the trials from an antero-lateral approach. Utilize the small oblique retainer (10-000034) or large oblique retainer (10-000035) in place of the compact implant retainer.
6. Select the appropriate unitary cage or modular plate and interbody cage assembly.

7. To utilize the cone guide insertion method with the unitary cage, select the appropriate cone guide according to the implant height selected.
   
   a. If an 11mm or 13mm implant height is selected, use the small cone guide (10-000031)

   b. If a 15mm, 17mm, or 19mm implant height is selected, use the large cone guide (10-000032)

   c. Thread the cone guide inserter (10-000036) through the cone guide to retain it.

   d. Align the mating nubs of the cone guide with the implant and fully thread the cone guide inserter into the cage in a clockwise direction to secure the cone guide.
Note: If a modular assembly is selected, the cone guide method cannot be utilized. Using the plate inserter, attach the implant by aligning the hex and threading the plate retainer in a clockwise direction. The modular implant inserter (10-000030) may also be utilized.

Note: Optionally, the same instrumentation may be used to connect to the oblique holes of the unitary cage for an antero-lateral insertion.

8. Insert the assembled implant into the disc space. Slight impaction may be used to gently advance the implant into the prepared disc space. Radiographically confirm the position and placement of the implant.
9. Prepare the bone for the screws using either the cone guide straight bone awl (10-000037) or cone guide angled awl (10-000040) attached to a ratcheting handle through each tube of the cone guide.

10. Insert the screws (11-00XXXX) using either the cone guide straight screwdriver (10-000038), cone guide straight screwdriver, slotted tip (10-000039), or cone guide angled screwdriver (10-000041) attached to a ratcheting handle through each tube of the cone guide. Once all screws are inserted, unthread and remove the cone guide.
11. For all implants, use the cover plate assembly (11-360003) to secure all screws, preventing them from backing out.

   a. Assemble the compact cover plate screwdriver (10-000029) and attach it to the torque handle (10-000014).
   b. Connect the two prong tip of the compact cover plate screwdriver to the screw of the cover plate assembly. Secure the screw to the screwdriver by threading the outer sleeve down to clamp the two prong tip.
   c. Insert the cover plate into the interbody assembly and ensure the cover plate aligns properly with the mating features on the front of the implant.  
      Note: to aid in alignment of the cover plate assembly, unthread the cover plate screw from the cover plate 1 to 2 turns before inserting into the implant.
   d. Tighten the cover plate assembly to the implant to the limit of the torque handle (~12 in-lbs).

12. Inspect final implant for correct position and assembly.
1. Unscrew the cover plate using the compact cover plate screwdriver and attach it to the torque handle (10-000014).
2. Remove all screws using the screwdriver (10-000038) or angled screwdriver (10-000041) attached to a ratcheting handle.
3. Assemble the straight ratcheting handle (10-000042) to the cone guide inserter (10-000036) and compact implant retainer (10-000033). Insert the tip of the cone guide inserter into the implant.
4. Attach the slap hammer (10-000044) to the cone guide inserter and tap until the implant is removed from the disc space.

MAINTAINING DEVICE EFFECTIVENESS

Prior to using the A-Link Z device, check all sets and confirm that all instruments and implants are present. Inspect all set components for functionality to ensure that there is no damage prior to use. Immediately return any damaged components to Acuity Surgical without using them.
Acuity Surgical instruments are not supplied sterile. Before sterilization, instruments must be cleaned using the following procedures.

**Caution:** Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or alkaline cleaners may damage some devices, particularly instruments. Such cleaning solutions should not be used.

**Note:** Some instruments may require disassembly prior to cleaning.

**Machine Cleaning Instructions (Recommended)**

1. **Prepare cleaning detergent**
   - a. Prepare an enzymatic detergent, following the manufacturer’s instructions for preparation and use.
   - b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   - c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. **Prepare devices for soaking**
   - a. To prevent injury, separate out sharp and pointed devices and handle with care.
   - b. Disassemble devices with removable parts.
   - c. Open hinged, toothed or threaded joints.
   - d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. **Clean and soak in bath**
   - a. Immerse devices in prepared bath.
   - b. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in water, ensuring that all visible soil is removed.
   - c. Whenever applicable:
     - i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
     - ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
     - iii. Repeatedly operate/bend/articulate movable joints while cleaning.
     - iv. Brush the inside of hollow spaces along their entire length.
   - d. Allow devices to soak in detergent bath for the manufacturer’s recommended soaking time.
4. **Load devices into washer**
   a. Place devices so they do not collide during operation.
   b. Place heavy items at the bottom and hollow objects in the washing machine baskets.
   c. Ensure that no part is obstructed by large objects.
   d. Place articulating instruments in the fully open position and cannulated instruments horizontally.
   e. Place disassembled instruments in the washing machine baskets.

5. **Washing and drying cycles**
   a. 2 minutes: Prewash with cold water; drain.
   b. 5 minutes: Detergent wash with hot water; drain.
   c. 2 minutes: Neutralize with neutral pH detergent; drain.
   d. 2 minutes: Rinse with hot water; drain.
   e. Dry with hot air at a maximum of 115°C.

6. **Inspect**
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumens, cannulae, crevices, serrations, threading, etc.
   b. If visible soil remains, repeat the cleaning procedure.

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**Manual Cleaning Instructions**

1. **Prepare cleaning detergent**
   a. Prepare an enzymatic detergent, following the manufacturer’s instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. **Prepare devices for soaking**
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. **Clean and soak in bath**
   a. Immerse devices in prepared bath.
   b. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in water, ensuring that all visible soil is removed.
   c. Whenever applicable:
      i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
      ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
      iii. Repeatedly operate/bend/articulate movable joints while cleaning.
      iv. Brush the inside of hollow spaces along their entire length.
   d. Allow devices to soak in detergent bath for the manufacturer’s recommended soaking time.
4. **Rinse**
   a. Remove the devices from the soak bath.
   b. Thoroughly rinse the devices under running water for a minimum of 1 minute.
   c. Thoroughly flush cannulae, lumens and holes.

5. **Ultrasonic bath**
   a. Prepare an ultrasonic bath containing a blood-dissolving detergent, following the manufacturer’s instructions for preparation and use.
   b. Cover/seal the devices during transport from the rinse to the ultrasonic bath to prevent contamination.
   c. Place devices in the ultrasonic bath.
   d. Ensure that the devices are completely submerged and do not overlap.
   e. Sonicate for 15 minutes. To avoid corrosion, do not exceed 15 minutes.

6. **Rinse in sterile water**
   a. Thoroughly rinse the devices with purified water (i.e., RO or DI) for a minimum of 3 minutes.

7. **Dry**
   a. Dry the devices with single-use, non-shedding absorbent wipes and/or medical quality compressed air (e.g., interiors of cannulae).
   b. Be sure to completely dry the devices immediately after rinse to inhibit corrosion.

8. **Inspect**
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
   b. If visible soil remains, repeat the cleaning procedure.
INSTRUMENT STERILIZATION

The A-Link Z system is provided non-sterile and should be cleaned and sterilized by the user. The following standard steam sterilization cycle should be used for the A-Link Z sterilization case:

- Sterilizer Type: Prevacuum
- Preconditioning pulses: 4
- Minimum Temperature: 132° C
- Full Cycle Time: 4 minutes
- Dry Time: 60 minutes
- Open Door Time: 15 minutes
- Cool Down Time: 30 minutes
- Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or equivalent) using sequential envelope folding techniques.

COMPLAINTS

Any healthcare professional (e.g. a surgeon using a product) who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the system should notify Acuity Surgical. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, telephone, fax or otherwise notify Acuity Surgical as soon as possible. All complaints should be accompanied by the name(s), reference(s), and batch number(s) of the component(s). The person formulating the complaint should give as many details as possible and state the response required. For further information, kindly contact Acuity Surgical.

Acuity Surgical
14215 Proton Rd.
Dallas, TX 75244
Phone: 844.228.4890
Fax: 866.616.2789
acuitysurgical.com
Contraindications may be relative or absolute. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

- Allergy to PEEK or titanium, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Known or suspected infection/immune system incompetence. Acute or chronic infectious diseases of any etiology or localization.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Morbid Obesity.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open Wounds.
- Pregnancy.
- Any other medical or surgical condition which would negate the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from two different systems.
- Any case requiring the mixture of stainless steel with titanium, or stainless steel with cobalt chrome alloy implant components.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Previous history of infection.
- Prior fusion at the level to be treated.
- Alcoholism or heavy smoking.
- Patients whose activity, lifestyle, occupation, mental capacity, substance abuse, or mental illness may impede compliance with post-operative restrictions and precautions during healing and thus increase the risk of implant failure.
- Any patient unwilling to follow post-operative instructions.
- Inadequate tissue coverage over the operative site.

In the presence of relative contraindications, the physician should weigh the relative risks and benefits when deciding whether a patient is a suitable candidate for these devices.
WARNINGS

- Risks associated with general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is also recommended that the advantages and disadvantages of surgery, the implants, as well as alternative treatment methods be explained to the patient.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Discard all damaged or mishandled implants.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to stresses placed on it, or small defects may exist, which may lead to fracture of the implant.
- Implants removed from a patient or that have come in contact with bodily tissues or fluids should never be reused at risk of contamination of the patient.
- Under no circumstances are dissimilar metals to be used in the same construct.
- Based upon fatigue testing results, physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the device.
- Do not use if package is opened or damaged or if expiration date has passed.

PRECAUTIONS

A-Link Z is for single use only.

Only experienced spinal surgeons with specific training in the use of vertebral implants should perform the implantation of this system. The surgical procedure is technically demanding and presents a risk of serious injury to the patient.

A-Link Z components should not be used with components of any other system or manufacturer.

Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. Before the operation the surgeon must have acquainted himself or herself with the specific technique for insertion of the product. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the post-operative period. An appropriate range of implant sizes must be available at the time of the operation.

Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.

Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken if signs of failure are observed. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants. The implant can be removed after bony healing.

Correct selection and placement of the implants is extremely important. Implant selection must be based upon the bone defect to be treated as well as the patient’s weight, height, occupation, and degree of physical activity.

A-Link Z may be used as a stand alone device when all four (4) screws are used. If the physician chooses to use fewer than the four screws, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.