	Instructions for use for Adler Spine Implants	Doc. No.: IU/3
		Rev. No.: 08
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For use by an Accredited Orthopaedic Surgeon only

1. ***Purpose:***

As is the case with any temporary internal fixation device, these devices have a finite useful life. Patients need to be informed that any activity, especially in the post-operative period, increases the risk of loosening, bending or breakage of the implant components. Metallic implants cannot be made to last indefinitely due to the limitations imposed by contemporary materials and anatomical needs. The fundamental purpose of these implants is to provide temporary internal support while the fusion mass is consolidating. The likelihood of implant failure increases if bone graft has not been used, if a pseudarthrosis develops, or if patients have severe or multiple pre-operative deformities.

2. ***Description:***

The Zeta, OneLock and OneLock DualThread (DT) Spine Systems are rod based systems comprising of Spinal Rods, Mono-axial, Multi-axial and Reduction Screws, Spinal Hooks, Staples and Transverse Connectors. The reduction screws in the Zeta and OneLock Systems feature extended tabs that must be broken intra-operatively using the specific instrumentation provided. OneLock DT screws are designed as thread forming screws with the potential for higher pull-out resistance due to bone compaction while insertion. These screws must necessarily be used in conjunction with OneLock Instrumentation, especially the OneLock pedicle probe that is designed to create a pedicle entry hole with a suitable diameter. The VSP plate and screw system consists of VSP Posterior stabilisation spinal plates and VSP Pedicle Screws.

Zeta spine system components are available in Titanium alloy conforming to ASTM F 136 (ELI) and AISI 316L Stainless Steel. Soft Titanium rods are available in CP Titanium conforming to ISO 5832-2. OneLock Spine System components are available in Titanium Alloy conforming to ASTM F 136 (ELI), with soft rods conforming to ISO 5832-2 and special Chrome-Cobalt Rods conforming to ASTM F 1537.

VSP Spinal Plates and VSP Pedicle Screws are available in materials conforming to ISO 5832 series of standards & ASTM F138.

The ZETA range of interbody spacers comprises of Mesh Cages, TLIF and PLIF cages and Bullet Cages. These spacers are available in Titanium alloy conforming to ASTM F 136 (ELI), AISI 316L Stainless Steel, CP Titanium conforming to ISO 5832-2 and Peek conforming to ASTM F2026-2.

The CerviEdge anterior cervical spine system includes Anterior Cervical Plates, Cervical Screws, Rescue Screws and Locking Screws. CerviEdge anterior cervical spine system components are available in Titanium Alloy conforming to ISO 5832-3, ASTM F 136 (ELI).

Adler Mediequip warrants that these devices are fabricated from the material specifications defined herein. No other warranties, expressed or implied, are made.

Stainless Steel is not compatible with titanium or titanium alloys. Implant components made from different metal alloys must not be used together in a construct. As with all metallic implants, none of the implant components should ever be reused under any circumstances.

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3. *Indications:*

The Zeta and OneLock Spine systems are Rod based Pedicle Screw Systems intended to immobilize and stabilize spinal segments in skeletally mature patients as an adjunct to fusion to treat various acute and chronic instabilities or deformities of the Thoracic, Lumbar and Sacral Spine, as described below:

- Degenerative Disc Disease (defined as back pain of discogenic origin combined with degeneration of the disc which is confirmed by radiographic studies and patient history)
- Spinal Canal Stenosis
- Degenerative Spondylolisthesis
- Pseudoarthrosis
- Deformities of the spine, e.g. Scoliosis, Kyphosis, Lordosis
- Trauma of the thoracic, thoraco-lumbar or lumbar spine
- Unsuccessful previous attempts at spinal fusion
- Stabilization following resection of spinal tumors

The VSP Spine System is a plate based Pedicle Screw System intended for posterior use to immobilize and stabilize spinal segments in skeletally mature patients as an adjunct to fusion to treat various acute and chronic instabilities of the thoracic, lumbar and sacral spine, including degenerative disk decease, spinal canal stenosis, degenerative Spondylolisthesis, Pseudoarthrosis, Trauma of the thoracic, thoracolumbar or lumbar spine, Unsuccessful previous attempts at spinal fusion and stabilisation following resection of spinal tumors.

The Zeta range of Interbody Spacers are interbody fusion devices intended to stabilize spinal segments and promote spinal fusion during the normal healing process following surgical correction of disorders of the spine. These devices can be inserted between two vertebral bodies to provide support and correction during interbody fusion procedures. The hollow geometry of these devices allows them to be packed with autogenous bone graft. These devices are intended to be used in conjunction with posterior / anterior fixation systems such as Zeta or OneLock.

The CerviEdge Anterior Cervical System is indicated as an adjunct to anterior cervical discectomy and fusion surgery carried out to treat degenerative disorders of the Cervical Spine, Tumors, Trauma and deformity.

4. *Contraindications:*

Contraindications include, but are not limited to:

- Infection, local to the operative site
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental Illness
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and the amount of mechanical fixation
- Suspected or documented metal allergy or intolerance
- Any case not needing a bone graft and fusion

- For pedicle screw cases, missing or congenitally deformed lumbar pedicles
- Any case requiring the mixing of metals from two different components
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any case not described in the Indications
- Any patient unwilling to cooperate with the post-operative instructions
- Any case where the implant components selected for use would be too large or too small to achieve a sucessful result

5. *Potential Adverse Effects:*

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to :

- Early or late loosening, disassembly, bending and / or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, , corrosion products and debris including metallosis, tumor formation, staining, and/or auto-immune disease.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and / or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
- Dural tears, infection, loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Fracture, microfractures, damage, resorption or penetration of any spinal bone (including the pedicles, sacrum, and / or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
- Graft donor site complications including pain, fracture or wound healing problems.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Cauda equina syndrome, neurological deficits, (transient or permanent), neuropathy, bilateral paralegia, reflex deficits, and/or arachnoiditis.
- Herniated nucleus pulposus, retropulsed graft, graft atelectasis.
- Hemorrhage, hematoma, phlebitis, seroma, embolism, stroke, excessive bleeding, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal complications including ileus, gastritis
- Reproductive system compromise, including sterility, impotance & retrograde ejaculation.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

6. *Warnings:*

Potential risks identified with the use of this device system, which may require additional surgery, include:

- Device component fracture

- Loss of fixation
- Non-union
- Fracture of the vertebra
- Neurological injury, and
- Vascular or visceral injury

Successful surgical results are not always achieved in every surgical situation. This fact is particularly relevant in spinal surgery where the possibility of compromised surgical results due to other unavoidable circumstances exists. This device is not intended to be the sole means of spinal support. The use of this device will not be successful in the absence of bone graft or in cases that lead to non-union. Spinal implants of any type will not withstand body loads without adequate bony support. In the event of adequate bony support not being available, loosening of implant components, bending, disassembly and / or breakage of the device may be a likely eventuality.

Preoperative planning, operative procedures, knowledge of surgical techniques, appropriate implant selection and placement and good reduction are critical considerations in successful application of this device by the surgeon. Proper patient selection and appropriate patient compliance to the surgeon's instructions, especially those concerning the post-operative period will greatly affect surgical outcomes. It has been documented that patients who smoke have an increased incidence of non-unions. Patients should be advised of this fact and warned of this possible consequence. Other candidates for poor results of spine fusion include alcoholics, obese patients, mal-nourished patients, patients with poor muscle and bone quality and / or nerve paralysis.

7. Pre-operative Precautions:

- Patients that do not meet the criteria described in the indications should not be selected for surgery.
- Patients with contraindications such as those described above should be avoided.
- Implants should not be scratched or damaged. Implants and instruments must be protected during storage, particularly from corrosive environments. Implant components and instruments must be stored and handled with care.
- Relevant technique manuals pertaining to Adler spine implants should be read. Further directions for use of this system will be provided upon request.
- Appropriate and detailed pre-operative planning must be used to determine the type of construct required, prior to the beginning of surgery.
- Since the system consists of various mechanical components which function together in an integrated manner, the operative surgeon and the assisting staff should be familiar with the various components before using the equipment, and should personally assemble the devices to ensure that all necessary instruments and implant components are available before surgery commences.
- Except for the components listed under the system description in the catalog section, or unless otherwise explicitly stated in another Adler document, the Adler spine implant components should not be combined with components of other spinal systems.
- Unless supplied sterile, all components of the system, implants and instruments, should be cleaned and sterilized before use. Additional components, particularly implants, should be available on hand in case of unexpected need. Non-sterile instruments or implants must not be used in surgery.

8. Intra-operative Precautions:

- Detailed instructions as provided in the most current Adler spine implants, surgical technique manual should be carefully followed.

- Extreme caution should be exercised at all times in the area around the spinal cord and nerve roots. This is particularly important while inserting hooks, screws and connectors. Damage to the nerves will cause loss of neurological functions.
- Intra-operative assembly of instruments and implant components must be performed with patience and care. Slippage of components or breakage of instruments may occur causing injury to the patient or operative personnel.
- Spinal rods must not be bent repeatedly or reverse bent. Contouring templates must be used to reduce the bending of the rods to the bare minimum necessary.
- Whenever possible, pre-cut rods of appropriate length should be used. In case rods need to be cut intra-operatively, they should be cut such that a flat, non-sharp surface, perpendicular to the rod axis is created. Cutting of rods must always be carried out outside the operative field. Both ends of the rod on either side of the rod cutter must be grasped while being cut to avoid accidental injury.
- Image guidance in the form of a C-arm image intensifier or equivalent must be used to position implant components.
- While using a tap, ensure that the diameter of the tap is not larger than the diameter of the spine screw that will be used. Do not overtap or select a spine screw that is, either too long, too large or smaller than the tap size. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage and / or loosening.
- Bone graft should be used to facilitate proper fusion at the level of instability.
- The use of bone cement in the spine is contraindicated as the effectiveness and safety of its use has not been adequately established. The use of bone cement will further make removal of the implant components difficult or impossible, apart from the likely neurological damage / bone necrosis on account of the heat generated by the curing process.
- Prior to closing of the soft tissues, all screws and nuts should be tightened according to the surgical technique. The tightness of all screws and nuts should be double checked to ensure that none of them have accidentally loosened during tightening of other components. Failure to perform a final check may cause loosening of other implant components.

9. Postoperative Precautions:

- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.
- The patient should be advised to refrain from smoking, consuming alcohol non-steroidals or aspirin during the bone graft healing process. Mechanical vibrations may compromise the probability of obtaining a successful surgical result. Considering this aspect, the patient must be warned to limit and restrict physical activity, especially lifting and twisting movements and any type of sports activities.
- The consequences of permanent bony fusion, including the permanent loss of mobility at the point of spinal fusion must be explained to the patient.
- In case of delayed union or non-union of the bone, immobilization of the surgical site becomes mandatory. Failure to do so will cause excessive and repeated stresses on the implant, which may cause eventual loosening, bending and / or breakage of the implanted device or its components. It is critical to maintain immobilization of the surgical site till bony union is established and confirmed

by radiography. In case a non-union develops or if any of the device components loosen, bend and/or break, immediate revision surgery is indicated before serious consequences result.

- All Adler spine implants are internal fixation devices. It is intended that these devices assist in the process of stabilizing the operative site during the normal process of healing. Subsequent to healing, these devices do not serve any further functional purpose and need to be removed. Removal is primarily indicated in most cases, as the implants are not intended to transfer or support forces applicable during normal activities.

10. Possible Adverse Effects:

- Corrosion combined with localized pain or tissue reaction.
- Migration of position of the implant, resulting in injury.
- Postoperative trauma with the risk of additional injury.
- Bending, loosening and/or breakage of implant components which may make removal more difficult or even impractical.
- Possibly increased risk of infection.
- Bone loss due to stress shielding.
- Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.

11. SPECIAL NOTE TO USERS:

Implant components that have been implanted and removed must never be re-used even if they appear undamaged due to the high risk of fatigue failure due to internally accumulated material stresses.

12. PACKAGING AND LABELING:

Implant components supplied in pre-sterile condition are packed in double packaging kept inside suitable size of outer box. Sterilisation is carried out using the gamma irradiation process indicated by STERILE R on the label or ETO Sterilisation Process indicated by STERILE EO on the label with a suitable dose of sterilization cycle depending on the materials contained by the implant. Packaging must be carefully checked for perforation or other damage prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery. Implants supplied in unsterile condition are indicated by NON-STERILE or NON STERILE on the label which must be properly sterilized by suitable method prior to surgery.

Metallic components may be re-sterilised using steam or ethylene oxide sterilization process. Re-sterilization of PE components is not permitted.

13. STERILISATION / RE-STERILIZATION:

Sterility and Handling:

- Correct handling of the implants prior to and during surgery is decisive for the success of surgical procedure. Implant components supplied in pre-sterile condition are individually packed in correspondingly labeled, radiosterilized (gamma sterilization, 25 kGy min.)/ ETO sterilized (Ethylene Oxide) protective packages.
- Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the “sterile” sticker that seals the outer box is intact, the sterility indicator button is of the right colour indicating a properly sterilized implant (red in case of Gamma Irradiation and Green in case of ETO sterilization) and that the implant is within the sterility period indicated on the label.
- Ensure that the surfaces of the implants are not damaged under any circumstances. Under no circumstances may implants that have been damaged, surgically implanted or removed again be reused.

RE-STERILIZATION:

- Re-sterilization of devices supplied in sterile form carries various risks. Various components of joint replacement prosthesis include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to closely controlled and monitored conditions. Small imperfections caused on the surfaces of metallic joint replacement components are known to increase the risk of fatigue failure. Such imperfections could be caused by improper handling by untrained staff. In consideration of the above re-sterilization of joint replacement prosthesis components by user facilities is not recommended.

For non-metal components: If packaging appears to be damaged, non-metal components should not be re-sterilized and used.

For metal components only: Adler recommends that if the packaging appears to be damaged, metal components should not be re-sterilized and used. If the packaging appears to be damaged and metal components are to be used however, then the device must be cleaned and re-sterilized prior to implantation, according to the following Instructions:

CLEANING (metal components only):

If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

- Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Recommended Steam Sterilisation Cycle Parameters:

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 Minutes and a minimum vacuum drying time of 30 minutes
- Flash Steam Cycle (Reusable Instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in gravity displacement cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilisation evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

NOTE: This is not a recommendation as to the sterilization parameters to be followed. The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's Sterilization equipment and Product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. Flash sterilization may be conducted, if applicable, according to the specific health care facility's policy.

14. STORAGE CONDITIONS:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

15. IMPORTANT INFORMATION:

The operative surgeon is responsible for carrying out the internal fixation procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer

In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant.

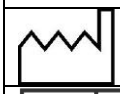
Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components or External Fixator Components predispose such components to premature failure.

Implant components from one manufacturer should not be used with those of another. In case such combinations are necessary, they would be possible only if the surgeon can ascertain that all implants being used are manufactured to correct dimensional specifications and tolerances and from chrome-nickel-molybdenum alloyed austenitic stainless steel complying with or compatible to the relevant standards referred to above.

Manufacturing Traceability Records for the device are available for 15years after the manufacturing date mentioned on the label.

16. Symbols Used in IFUs, Labels and Packaging Materials:

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		Keep away from heat /sunlight and radioactive sources
	Date of Manufacture YYYY-MM-DD		Manufactured by		Use by Date (Date of Expiry) YYYY-MM-DD
	European Authorised Representative		Do not re-sterilise		Do not use if package is opened or damaged
	Sterilised by radiosterilisation process		Consult instructions for use		Non Sterile
	Caution: check for specific warnings or precautions		Code Number / Part No.		Avoid moisture or water contact
	Sterilised by ETO Gas Sterilisation process		Recycle		To be sold only against prescription

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17. Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to adler-in.info@smith-nephew.com

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