

# Specification Guide

**ONELOCK<sup>®</sup>**  
Spine System

Low Profile, High Reliability



With the widespread acceptance of spine stabilization using pedicle screws, a wide variety of rod based pedicle screw systems are available to the operating surgeon. In spite of continuous development and evolution in designs, many systems leave critical areas unaddressed, thereby, posing challenges to the operating surgeon.

Some of these areas include –

Multiple lock nuts and the associated  
“fiddle factor”

•  
Cross threading of inner screws and outer nuts

•  
Occasional rod slippage - usually caused by spreading of the screw head under pressure from the lock screws or set screws

•  
Multiple implant components, requiring careful, precise and time consuming pre-operative assembly



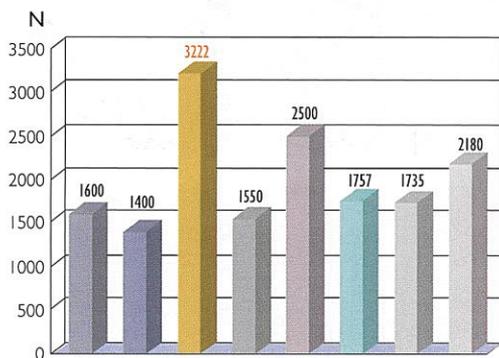
**ONELOCK<sup>◇</sup>**

ONELOCK<sup>◇</sup> is a breakthrough in spine screw technology. With near zero head splay, absence of cross-threading & proven biomechanical results, ONELOCK<sup>◇</sup> brings a new world of performance and reliability to discerning spine surgeons.

# Breakthrough Design

Most systems try to control spreading of the screw head using a counter force. In contrast, the ONELOCK<sup>®</sup> system brings about a paradigm shift by eliminating the forces which cause the screw head to spread in the first place!

## Validated System<sup>c</sup>



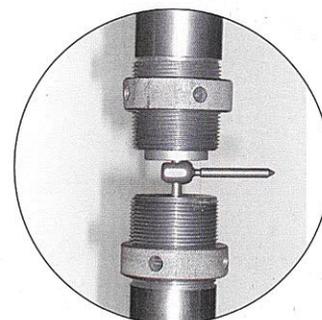
The ONELOCK<sup>®</sup> Screws and Rods have been tested in accordance with the protocols defined in the ASTM F : 1798 standard. The screw-rod connection has been validated for its ability to withstand axial and torsional forces while the implant construct has been validated for its resistance to spinal bending moments. Test results demonstrate the clear superiority of the ONELOCK<sup>®</sup> system to many contemporary spine stabilisation systems<sup>c</sup>.



LOW PROFILE

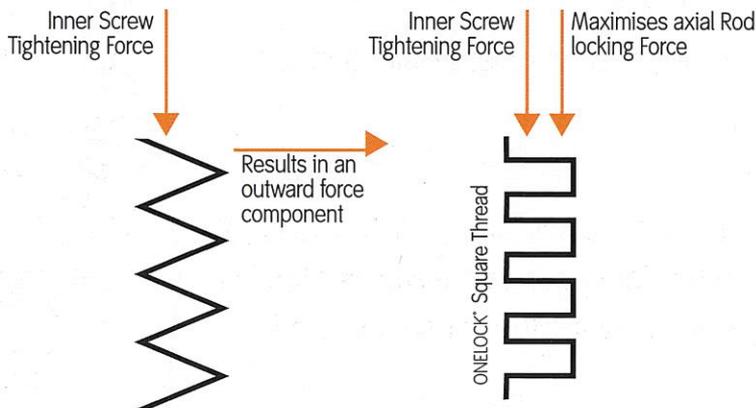


THE PROPRIETARY SCREW HEAD DESIGN



## Critical Design Element

### SQUARE THREAD GEOMETRY





**MULTI-AXIAL ROD REDUCER**  
For the difficult 3-D reductions

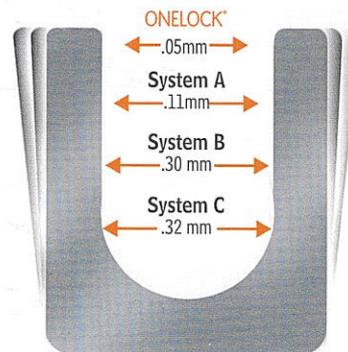


**CO-AXIAL ROD REDUCER**  
Great tool for in-line reductions

The proprietary head profile which eliminates residual outward forces.

## Lowest Head-Spread

At 0.05mm<sup>a</sup>, ONELOCK<sup>®</sup> has the lowest Head-Spread<sup>b</sup>, at recommended tightening torque, when compared to other contemporary spine systems that utilise a single inner screw.



<sup>a</sup> Biomechanical Analysis of a New Generation Posterior Derotation system : The ONELOCK<sup>®</sup> Spine Screw Rod System. Dr Swapnil Keny, Dr (Prof) Ram Chadha et al, presented at SICOT 2005

<sup>b</sup> As per available, latest information

<sup>c</sup> Data on file

# The ONELOCK<sup>®</sup> Implant Range

## ONELOCK<sup>®</sup> Monoaxial Screw

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)



Ø 4.5mm Blue	Ø 5.5mm Light Blue	Ø 6.25mm Purple	Ø 7.00mm Golden	Length (mm)
J0230.4525	J0230.5525			25
J0230.4530	J0230.5530	J0230.6230	J0230.7030	30
J0230.4535	J0230.5535	J0230.6235	J0230.7035	35
J0230.4540	J0230.5540	J0230.6240	J0230.7040	40
J0230.4545	J0230.5545	J0230.6245	J0230.7045	45
J0230.4550	J0230.5550	J0230.6250	J0230.7050	50

## ONELOCK<sup>®</sup> Reduction Screw

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)



Ø 5.5mm Light Blue	Ø 6.25mm Purple	Ø 7.00mm Golden	Length (mm)
J0232.5535	J0232.6235	J0232.7035	35
J0232.5540	J0232.6240	J0232.7040	40
J0232.5545	J0232.6245	J0232.7045	45
J0232.5550	J0232.6250	J0232.7050	50

## ONELOCK<sup>®</sup> Multiaxial Screw

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)



Ø 4.5mm Blue	Ø 5.5mm Light Blue	Ø 6.25mm Purple	Ø 7.00mm Golden	Length (mm)
J0231.4525	J0231.5525			25
J0231.4530	J0231.5530	J0231.6230	J0231.7030	30
J0231.4535	J0231.5535	J0231.6235	J0231.7035	35
J0231.4540	J0231.5540	J0231.6240	J0231.7040	40
J0231.4545	J0231.5545	J0231.6245	J0231.7045	45
J0231.4550	J0231.5550	J0231.6250	J0231.7050	50

## ONELOCK<sup>®</sup> Facet Hook

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

J0831.00



## ONELOCK<sup>®</sup> Supralaminar Hook

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

J0832.00



## ONELOCK<sup>®</sup> Infralaminar Hook

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

J0833.00



## Staple for Anterior fixation

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

J0710.00



## ONELOCK<sup>®</sup> Inner Locking Screw

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

J0430.00



Illustrations not to scale. Specifications subject to change without notice

## ONELOCK<sup>®</sup> Plain Rod

Titanium (Ti, ISO5832-2)



Ø 6.00mm (Hard)	Ø 6.00mm (Soft)	Length (mm)
J0311.6050		50
J0311.6070		70
J0311.6090		90
J0311.6120		120
J0311.6150		150
J0311.6200		200
J0311.6250		250
J0311.6300		300
J0311.6350	J0312.6350	350
J0311.6600		600

## ONELOCK<sup>®</sup> Transverse Process Hooks

(With Inner Locking Screw)

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

Left

J0834.00



Right

J0835.00



## ONELOCK<sup>®</sup> Cross Connector, 6mm system

Titanium- Vanadium Alloy (Ti<sub>6</sub>Al<sub>4</sub>V, ELI)

30-35mm

J0836.01



35-45mm

J0836.00



45-55mm

J0836.02



# ONELOCK<sup>®</sup> Implant Sets

## ONELOCK<sup>®</sup> IMPLANT SET

ONELOCK <sup>®</sup> Implant Case	Qty.
D0106.1201 Aluminium Case	1
D0102.1412 Screw Rack, Lowback Implant Set	1
D0102.1413 Tray for Rods, Lowback Implant Set	1
D0102.1414 Tray1 for Screws, Lowback Implant Set	1
D0102.1415 Tray2 for Screws, Lowback Implant Set	1



ONELOCK <sup>®</sup> Implants - 6mm System	Qty.
J0230.4525 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 4.50mm X Length 25mm	4
J0230.4530 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 4.50mm X Length 30mm	4
J0230.4535 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 4.50mm X Length 35mm	4
J0230.4540 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 4.50mm X Length 40mm	4
J0230.5530 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 5.50mm X Length 30mm	2
J0230.5535 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 5.50mm X Length 35mm	4
J0230.5540 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 5.50mm X Length 40mm	4
J0230.5545 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 5.50mm X Length 45mm	4
J0230.5550 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 5.50mm X Length 50mm	2
J0230.6235 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 6.25mm X Length 35mm	4
J0230.6240 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 6.25mm X Length 40mm	4
J0230.6245 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 6.25mm X Length 45mm	4
J0230.6250 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 6.25mm X Length 50mm	2
J0230.7035 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 7.00mm X Length 35mm	2
J0230.7040 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 7.00mm X Length 40mm	2
J0230.7045 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 7.00mm X Length 45mm	2
J0230.7050 ONELOCK <sup>®</sup> TI, Monoaxial Screw Ø 7.00mm X Length 50mm	2
J0231.4525 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 4.50mm X Length 25mm	2
J0231.4530 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 4.50mm X Length 30mm	2
J0231.4535 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 4.50mm X Length 35mm	2
J0231.5530 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 5.50mm X Length 30mm	2
J0231.5535 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 5.50mm X Length 35mm	4
J0231.5540 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 5.50mm X Length 40mm	4
J0231.5545 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 5.50mm X Length 45mm	4
J0231.6235 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 6.25mm X Length 35mm	4
J0231.6240 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 6.25mm X Length 40mm	4
J0231.6245 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 6.25mm X Length 45mm	4
J0231.7035 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 7.00mm X Length 35mm	2
J0231.7040 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 7.00mm X Length 40mm	2
J0231.7045 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 7.00mm X Length 45mm	2
J0231.7050 ONELOCK <sup>®</sup> TI, Multiaxial Screw Ø 7.00mm X Length 50mm	2
J0232.5535 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 5.50mm X 35mm Length	2
J0232.5540 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 5.50mm X 40mm Length	2
J0232.5545 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 5.50mm X 45mm Length	2
J0232.6235 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 6.25mm X 35mm Length	2
J0232.6240 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 6.25mm X 40mm Length	2
J0232.6245 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 6.25mm X 45mm Length	2
J0232.7040 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 7.00mm X 40mm Length	2
J0232.7045 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 7.00mm X 45mm Length	2
J0232.7050 ONELOCK <sup>®</sup> TI, Reduction Screw, Ø 7.00mm X 50mm Length	2
J0710.00 Staple For Anterior Fixation, Titanium	4
J0311.6050 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 50mm	2
J0311.6070 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 70mm	2
J0311.6090 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 90mm	2
J0311.6120 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 120mm	2
J0311.6150 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 150mm	2
J0311.6200 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 200mm	2
J0311.6250 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 250mm	2
J0311.6300 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 300mm	2
J0311.6350 ONELOCK <sup>®</sup> Plain Rod, TI, Hard, Ø. 6.0mm, Length 350mm	2
J0312.6350 ONELOCK <sup>®</sup> Plain Rod, TI, Soft, Ø. 6.0mm, Length 350mm	2
J0836.00 ONELOCK <sup>®</sup> TI, Cross Connector, 35 to 45mm, 6mm System	1
J0836.01 ONELOCK <sup>®</sup> TI, Cross Connector, 30 to 35mm, 6mm System	1
J0836.02 ONELOCK <sup>®</sup> TI, Cross Connector, 45 to 55mm, 6mm System	1
J0831.00 ONELOCK <sup>®</sup> TI, Facet Hook	6
J0832.00 ONELOCK <sup>®</sup> TI, Supralaminar Hook	6
J0833.00 ONELOCK <sup>®</sup> TI, Infralaminar Hook	6
J0834.00 ONELOCK <sup>®</sup> TI, Transverse Process Hook, Left	6
J0835.00 ONELOCK <sup>®</sup> TI, Transverse Process Hook, Right	6

## IMPORTANT INFORMATION ON THE ONELOCK® SPINE SYSTEM

### Purpose

The ONELOCK® Spine System is designed to aid in the surgical stabilization of the spine. The system is intended to help augment the development of a solid spinal fusion. These implants are intended to be removed after the development of a solid fusion mass. The system is intended for use only in the thoracic, lumbar, and/or sacral levels of the posterior and the thoracic and lumbar levels of the anterior spine.

### Description

The ONELOCK® Spine System is a rod-based system. ONELOCK® implant components, are available in titanium / titanium alloy. The device components can be locked into a variety of configurations, with each construct being tailored specifically to the requirements of each individual case. Specific instrumentation is available to enable implantation of the various components of the device.

In the ONELOCK® Titanium range, Pedicle Screws, Hard Rods, Hooks, Transverse Connectors and related components are made out of Titanium 6- Al-4V alloy as described by the ISO Standard, ISO 5832-3. The Titanium ONELOCK® Soft Rods which enable easier contouring are made out of a carefully selected grade which complies with the ISO standard ISO 5832-2.

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.

### Indications, Contraindications and possible Adverse Effects

#### Indications

The specific indications for the ONELOCK® Spine System are as follows:

1. 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)
2. Spinal Canal Stenosis
3. Spondylolisthesis
4. Deformities of the spine, eg. Scoliosis, kyphosis, lordosis.
5. Trauma of the thoracic, thoraco-lumbar or lumbar spine.
6. Unsuccessful previous attempts at spinal fusion.
7. Stabilization following resection of spinal tumours.

All components of the ONELOCK® Spine System are limited to non-cervical use. The ONELOCK® Spondylolisthesis Reduction Screw is intended for use as a reduction / pedicle screw only in patients having severe spondylolisthesis (Grades 3 and 4) which need to be supplanted by the use of autogenous bone grafting or a spinal fusion cage.

#### Contraindications

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation
3. Fever or leukocytosis
4. Morbid obesity
5. Pregnancy
6. Mental Illness
7. 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.
8. 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.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. For pedicle screw cases, missing or congenitally deformed lumbar pedicles.
12. Any case requiring the mixing of metals from two different components.
13. Any patient having inadequate tissue coverage over the operative site.
14. Any case not described in the Indications.
15. Any patient unwilling to cooperate with the post-operative instructions.

#### 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:

1. Early or late loosening, disassembly, bending and / or breakage of any or all of the components.
2. Foreign body (allergic) reaction to implants, corrosion products and debris including metallosis, tumor formation, staining, and/or auto-immune disease.
3. Post-operative change in spinal curvature, loss of correction, height and/or reduction.
4. 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.
5. 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.
6. 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.
7. Scar formation possibly causing neurological compromise around nerves and/or pain.
8. Non-union (or pseudarthrosis). Delayed union. Mal-union.
9. 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.
10. Graft donor site complications including pain, fracture or wound healing problems.
11. Bone loss or decrease in bone density, possibly caused by stress shielding.
12. Loss of bowel and/or bladder control or other types of urological system compromise.
13. Cauda equina syndrome, neurological deficits, (transient or permanent), neuropathy, bilateral paraplegia, reflex deficits and/or arachnoiditis.
14. Herniated nucleus pulposus, retracted graft atelectasis, ileus, gastritis.
15. Hemorrhage, hematoma, phlebitis, seroma, embolism, stroke, excessive bleeding, wound necrosis, wound dehiscence or damage to blood vessels.
16. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
17. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
18. Change in mental status
19. Death.

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

#### Warnings and Precautions

##### 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.

#### Additional preoperative, intraoperative and postoperative precautions:

##### Pre-operative Precautions:

1. Patients that do not meet the criteria described in the indications should not be selected for surgery.
2. Patients with contraindications such as those described above should be avoided.
3. 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.
4. The ONELOCK® Spine System surgical technique manual should be read. Further directions for use of this system will be provided upon request.
5. Appropriate and detailed pre-operative planning must be used to determine the type of construct required, prior to the beginning of surgery.
6. 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.
7. Except for the components listed under the system description in the catalog section, or unless otherwise explicitly stated in another Adler document, the ONELOCK® Spine System components should not be combined with components of other spinal systems.
8. 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.

##### Intra-operative Precautions:

1. Detailed instructions as provided in the most current ONELOCK® Spine System surgical technique manual should be carefully followed.
2. 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.
3. 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.
4. 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.
5. Where 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.
6. Image guidance in the form of a C-arm image intensifier or equivalent must be used to position implant components.
7. 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 overlap or select a spine screw that is, either too long, too large or smaller than the tap size. Overlapping or using an incorrectly sized screw may cause nerve damage, hemorrhage and / or loosening.
8. Bone graft should be used to facilitate proper fusion below and around the location of the implant components.
9. 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.
10. 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.

##### Post-operative Precautions:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. 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.
2. 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.
3. The consequences of permanent bony fusion, including the permanent loss of mobility at the point of spinal fusion must be explained to the patient. The patient must be taught to compensate for the permanent physical restriction in body motion.
4. 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 injury results.
5. All implant components of the ONELOCK® Spine System 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. If the implant components are not removed subsequent to completion of their intended use, the following complications may ensue. 1) Corrosion combined with localized pain or tissue reaction. 2) Migration of position of the implant, resulting in injury. 3) Postoperative trauma with the risk of additional injury. 4) Bending, loosening and/or breakage of implant components which may make removal more difficult or even impractical. 5) Possibly increased risk of infection. 6) Bone loss due to stress shielding. 7) Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.
6. Any retrieved implant components should be treated in such a manner so as to render further use / re-use of the components, impossible.

**Packaging and Application** All implant components should be checked for intact packaging on receipt. In case a loaner or consignment set of instruments and implant components is used, all instruments and implants must be carefully checked for completeness and all components should be carefully inspected for absence of damage prior to use.

##### Sterilization

Unless specifically supplied pre-sterile and clearly labeled as such, all implant components and instrumentation must be sterilized prior to use in surgery using standard sterilization cycles and process parameters. All packaging materials must be removed prior to sterilization. Only sterile implants and instruments must be used in surgery. All instruments and implants must be cleaned and dried immediately following use in surgery using standard procedures for operative surgical instruments. This process must invariably be performed in case of loaner or consignment instruments and implants being returned to the distributor.

##### Further information

For further information concerning use of this system, please check with Adler Customer Service at the addresses given overleaf or e-mail to [adler-in.info@smith-nephew.com](mailto:adler-in.info@smith-nephew.com)

Manufactured by

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To see instructions for use please visit :  
<http://www.adler-healthcare.com>

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