Important Information on the RELIANCE MIS SPINAL SCREW SYSTEM

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON: RELIANCE MIS Spinal Screw System implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed. Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves. The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION RELIANCE MIS SPINAL SCREW SYSTEM: The **Posterior RELIANCE MIS Spinal Screw System** consists of longitudinal rods, monoaxial screws, polyaxial screws, reduction screws, cannulated poly axial screws, cannulated reduction screws, hooks, reduction hooks, set screws, and transverse connectors. The **Anterior RELIANCE MIS Spinal Screw System** consists of two MIS Spinal rods, monoaxial screws, staples, and set screws. The Anterior staples, washers, and screws are intended to be attached to the lateral aspect of the vertebral bodies from T5 to L4, and SHOULD NOT be attached to the anterior aspect. Furthermore, only Titanium components should be used anteriorly. (See Precautions section.)

Refer to the Anterior RELIANCE MIS Spinal Screw System Technique Manual for important implant assembly instructions.

The RELIANCE MIS Spinal Screw System components are available in titanium alloy conforming to ASTM F-136 specifications as well as stainless steel conforming to ASTM F-138 specifications. Furthermore, various rods of the RELIANCE MIS Spinal Screw System are available in Cobalt Chrome conforming to ASTM F-75 specifications. Components of the differing diameter rod systems are NOT interchangeable. The components of one material should not be used with components of another material, with the exception that the Cobalt Chrome rods may be used with titanium alloy implants. The extension tabs on the reduction screw and hook components are intended to be removed intraoperatively.

INDICATIONS: The Reliance MIS Spinal Screw System is a pedicle screw systems intended to provide immobilization and stabilization of MIS Spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, MIS Spinal tumor, and failed previous fusion (pseudarthrosis). The Reliance MIS Spinal Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. When used posteriorly, the Reliance MIS Spinal Screw System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for spondylolisthesis, trauma (fracture and/or dislocation), MIS Spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine. The Reliance MIS Spinal Screw System when used with staples and two rods as an anterior thoracic/lumbar screw fixation system, is indicated for spondylolisthesis, trauma (fracture and/or dislocation), MIS Spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). When used in a percutaneous, posterior approach with MIS Instrumentation, the Reliance MIS Spinal Screw System components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); MIS Spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

USAGE WARNING: The safety and effectiveness of pedicle screw MIS Spinal systems have been established only for Spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, Spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTION: The implantation of pedicle screw MIS Spinal systems should be performed only by experienced MIS Spinal surgeons with specific training in the use of this pedicle screw MIS Spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device. Refer to the individual system surgical technique manuals for additional important information. RELIANCE MIS Spinal Screw System components should not be used with components from other manufacturers. Stainless steel components may interfere with the quality of imaging obtained using MRI. When using spine rods, use the shortest rod possible for each procedure. Minimal rod length will reduce the possibility of interference with other bony structures. When using spine rods, it is important that the rods be contoured to mirror or to create the desired anatomic curves. During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment. When using anterior thoracic/lumbar screw fixation systems, staples are available to optimize proper staple/screw/rod alignment and stability. After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system. These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the MIS Spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a MIS Spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by MIS Spinal fusion, the devices can not be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

POSTOPERATIVE MOBILIZATION: Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

CONTRAINDICATIONS: Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of MIS Spinal anchors and thus preclude the use of this or any other MIS Spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. **MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. **The patient's weight.** An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

B. **The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

C. **A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

D. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

E. **Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. **CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.

If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

5. **CORRECT PLACEMENT OF ANTERIOR MIS SPINAL IMPLANT.** Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
9. Bursitis.
10. Paralysis.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. MIS Spinal cord impingement or damage.
17. Fracture of bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Packaging: Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Reliance Medical Systems. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately resterilize all implants and instruments which have been previously in the operation area. This process must be performed before handling or returning products to Reliance Medical Systems.

Symbols Used in Labelling	
	Do Not Reuse
	Non-Sterile
	Caution: Federal (USA) law restricts this device to sale and use by, or on the order of a physician
	Caution, consult accompanying documents

Cleaning and Decontamination: All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field.

Implant Cleaning and Decontamination:

Manual Cleaning: Rinse implants under warm water to remove gross soil. Soak in Enzol prepared per manufacturer's recommendations for at least 55 seconds. Scrub the entire implant using a soft bristled brush paying close attention to hard to reach areas. Use a syringe and pipe cleaner to clean cracks, crevices, and other hard to reach areas. Remove the implants from the detergent and rinse under lukewarm water for at least one minute. Prepare Prolystica 2x concentrate neutral detergent according to manufacturer's recommendations. Immerse implants in detergent for at least one minute. Scrub the entire implant using a soft bristled brush paying close attention to hard to reach areas. Use a syringe and pipe cleaner to clean cracks, crevices, and other hard to reach areas. Remove the implants from the detergent and rinse under lukewarm water for at least one minute. Dry implants using a clean soft cloth and filtered pressurized air (less than 40 psi). Ensure that the devices are thoroughly cleaned. Visually inspect the implants for any visible soil. If visible soil remains, repeat the entire cleaning procedure.

Automated Cleaning:

Rinse implants under warm water to remove gross soil. Set washer to high, and use the following parameters:

Phase	**Time (minutes)**	**Temperature**	**Detergent Type and Concentration**
Pre-Wash	02:00	Cold tap water	N/A
Enzyme Wash	01:00	Hot tap water	Enzol 1oz/gallon
Wash 1	02:00	Heated 66°C	Prolystica 2x Concentrate neutral detergent 1/8 oz./gallon
Rinse 1	00:15	Hot tap water	N/A
PURW rinse	00:10	66°C	N/A
Drying	07:00	115.5°C	N/A

Ensure that the implants are thoroughly cleaned. Visually inspect the implants for any visible soil. If visible soil remains, repeat the entire cleaning procedure.

Implant Sterilization: Unless marked sterile and clearly labeled as such, the RELIANCE MIS Spinal Screw System System components, as well as those implants from other Reliance Medical Systems MIS Spinal systems specifically indicated for use with the RELIANCE MIS Spinal Screw System device, described in this insert are provided non-sterile and must be sterilized prior to use. If the Reliance Medical Systems the MIS implant caddies described in this insert are sterilized by the hospital individually and on their side, they should be sterilized individually and on their side. Reliance Medical Systems recommends the usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation.

NOTE: The following note applies to the process parameter identified with the * below: For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come onto contact with the central nervous system.

Dynamic-Air-Removal (Prevacuum) Steam Sterilization Cycle

NOTE: RELIANCE MIS Spinal Screw System implant caddies should be wrapped and sterilized individually and on their side.

Item	Exposure time at 132°C (270°F)	Drying Time
Wrapped Individual Implant Caddies	4 minutes	30 minutes

Instrument Cleaning and Decontamination:

Certain instruments may require dismantling before cleaning. All inserters should be disassembled by unthreading and removing the internal shaft. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device

Manual Cleaning: Rinse items under warm water to remove gross soil. Soak in Enzol prepared per manufacturer's recommendations for at least 55 seconds. Actuate moving parts to ensure all surfaces are reached. Scrub the entire device using a soft bristled brush paying close attention to hard to reach areas. Use a syringe and pipe cleaner to clean cracks, crevices, and other hard to reach areas. Remove the devices from the detergent and rinse under lukewarm water for at least one minute. Prepare Prolystica 2x concentrate neutral detergent according to manufacturer's recommendations. Immerse devices in detergent for at least one minute. Actuate moving parts to ensure all surfaces are reached. Scrub the entire device using a soft bristled brush paying close attention to hard to reach areas. Use a syringe and pipe cleaner to clean cracks, crevices, and other hard to reach areas. Remove the devices from the detergent and rinse under lukewarm water for at least one minute. Dry devices using a clean soft cloth and filtered pressurized air (less than 40 psi). Ensure that the devices are thoroughly cleaned. Visually inspect the devices for any visible soil. If visible soil remains, repeat the entire cleaning procedure.

Automated Cleaning: Rinse items under warm water to remove gross soil. Set washer to high, and use the following parameters:

Phase	**Time (minutes)**	**Temperature**	**Detergent Type and Concentration**
Pre-Wash	02:00	Cold tap water	N/A
Enzyme Wash	01:00	Hot tap water	Enzol 1oz/gallon
Wash 1	02:00	Heated 66°C	Prolystica 2x Concentrate neutral detergent 1/8 oz./gallon
Rinse 1	00:15	Hot tap water	N/A
PURW rinse	00:10	66°C	N/A
Drying	07:00	115.5°C	N/A

Ensure that the devices are thoroughly cleaned. Visually inspect the devices for any visible soil. If visible soil remains, repeat the entire cleaning procedure.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Instrument Sterilization: Unless marked sterile and clearly labeled as such, the RELIANCE MIS Spinal Screw System System components, as well as those implants from other Reliance Medical Systems MIS Spinal systems specifically indicated for use with the RELIANCE MIS Spinal Screw System device, described in this insert are provided non-sterile and must be sterilized prior to use. If the Reliance Medical Systems components described in this insert are sterilized by the hospital in a tray or case, they should be sterilized in the tray or case provided by Reliance Medical Systems. Reliance Medical Systems recommends the usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation.

NOTE: The following note applies to the process parameter identified with the * below: For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come onto contact with the central nervous system.

Dynamic-Air-Removal (Prevacuum) Steam Sterilization Cycle

Item	Exposure time at 132°C (270°F)	Drying Time
Wrapped Instruments	4 minutes	30 minutes

LIMITED WARRANTY AND DISCLAIMER: RELIANCE MEDICAL SYSTEMS PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF A SURGICAL TECHNIQUE IS NEEDED, OR IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT:

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