Important Information on the RELIANCE BUTTRESS WASHER SYSTEM

Caution: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Reliance Medical Systems anterior spinal 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 on their activities in the postoperative period and to examine the patient 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 or if a pseudarthrosis develops or in patients with severe or multiple preoperative curves. The surgeon may determine to 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.

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.

USAGE CAUTION:

USA Law restricts these devices to sale by or on the order of a physician. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of surgical implants, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. See the surgical technique manuals for each Anterior Spinal System for important instructions. Reliance Medical Systems spinal system components should not be used with components of spinal systems from other manufacturers.

DESCRIPTIONS:

After solid fusion occurs, these devices serve no functional purpose and may be removed. In most cases, removal is indicated because the implants are not intended to transfer or 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.

WARNING:

These Anterior Spinal device systems are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The Reliance Buttress Washer System consists of washers, staples, and screws. The washers are available in six sizes, 15mm, 20mm, and 25mm diameters, as well as 15x20mm, 17x25mm, and 20x30mm. The self-tapping cancellous screws are offered in 4.5mm, 5.5mm, and 6.5mm major diameter and are available in lengths of 15mm, 20mm, 25mm, and 30mm. The components of the Reliance Buttress Washer System are manufactured from titanium and have a smooth anodized finish.

INDICATIONS

The Reliance Buttress Washer System is intended to stabilize the bone graft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

Contraindications Specific to Reliance Buttress Washer System

- Smaller juvenile patients weighing less than 30kg.
- Patients with significant osteoporosis or metabolic bone disease.
- Patients with greater than Grade I spondylolisthesis, spondylolysis or significant bony defect in the lumbar spine.
- Patients with a history of abdominal radiation treatment or abdominal vascular graft surgery.
- Patients who have had previous abdominal surgery with significant vascular scarring.

CAUTION: Do not place 2 buttress washers in one vertebral body.

CLEANING AND STERILIZATION

Implants and Instruments of the Reliance Buttress Washer System are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer, effective sterilization may be achieved using the following parameters:

Cycle: Pre-Vacuum
Temperature: 270° F
132° C
Exposure time: 6 min.

POSTOPERATIVE CARE AND 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. 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 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. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon.

CONTRAINDICATIONS

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis may prevent adequate fixation of the spinal anchors and thus preclude the use of this or any other temporary internal fixation implant. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia are relative contraindications. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at higher risk of implant failure. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert. Following are specific warnings, precautions, and adverse effects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects which 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, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES 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, wires, 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 which 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 re-implanted. 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. REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed following 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 post-operative 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 re-fracture. 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. 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 SPINAL IMPLANTS. 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 these products. 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. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia.
8. 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.
9. Bursitis.
10. Reflex sympathetic dystrophy.
11. Paralysis.
12. 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.
13. Death.
14. Spinal cord impingement or damage.
15. Fracture of bony structures.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.
17. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.

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