Important Information on the RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM IMPORTANT NOTE TO OPERATING SURGEON

The RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM implants, like other 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 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 pseudoarthrosis develops. 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, LLC 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.

DESCRIPTION

The RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM contains screws and hooks in a variety of configurations based upon rod diameter. These include a Titanium alloy based Ø3.5mm rod configuration, a Titanium alloy based Ø4.0mm rod configuration and a Titanium alloy based Ø4.5mm rod configuration. All configurations, regardless of rod size, are available in Ø3.5mm, Ø4.0mm, and Ø4.5mm major screw diameters. These screw diameters are offered in lengths ranging from 10mm to 20mm, with the Ø4.0mm, and Ø4.5mm available up to 50mm. All of these screws are available in both mono-axial and poly-axial options. The poly-axial screws in all of these configurations have an internal taper bushing that circumferentially grasps the rod when the device is locked. Additionally, both the mono-axial and poly-axial screws have a double lead thread.

In addition to the screw sizes mentioned above, reduction-tabbed screws are also available. The reduction-tabbed screws are available in all of the previously mentioned sizes. The RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM also offers a series of crosslink connectors. Furthermore, the RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM includes a series of hooks for attaching to the posterior elements of the cervico-thoracic spine. All of the components discussed above are fabricated from Titanium alloy and should not be used with implants of a different material.

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 STERILIZATION

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:

CAUTIONS

Do not use steel wool or abrasive cleaners.

Avoid solutions containing iodine or high chlorine content.

Only place Reliance Medical devices with similar metallic composition in an ultrasonic cleaner.

Soiled or used Reliance Medical devices should not be loaded in a graphic case and cleaned in a mechanical washer. Long, narrow cannulations, blind holes, and intricate parts require particular attention during cleaning.

All devices must be thoroughly cleaned.

Reliance Medical implants are critical devices and must be terminally sterilized prior to use. The sterilization parameters are only valid for devices that are properly cleaned. The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.

LIMITS ON REPROCESSING

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Reliance Medical surgical instrumentation. End of life is normally determined by wear and damage due to use.

Some of the instruments may be reused, prior to use, these instruments should be inspected to ensure they are working properly. There may be small defects and stress patterns which may lead to early breakage. All instrumentation, especially reusable instruments, should be routinely inspected prior to each usage for wear and tear or other signs of stress. To that end, any corrosion, pitting, discoloration, signs of wear (cracks, rounded edges, notches, especially on the distal tips), and/or signs of distress found during inspection should deem the instrument as unsatisfactory. If the instrument is deemed to be unsatisfactory, it should not be used during surgery and should be immediately returned to the address on this Package Insert.

POINT OF USE CARE

Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface. Flush cannulated devices with sterile water to prevent the drying of soil and/or debris to the inside.

Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. Devices should be covered with a towel dampened with purified water to prevent blood and/or debris from drying.

PREPARATION FOR DECONTAMINATION

It is recommended that devices should be reprocessed as soon as is reasonably practical following use. Disassemble device, if applicable, prior to cleaning.

Remove sharp devices for manual cleaning or place into a separate tray.

Lumens/cannulas of devices should be manually processed prior to cleaning.

Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris.

Reliance Medical devices must be cleaned separately from Reliance Medical instrument and graphic trays. Lids should be removed from trays for cleaning process, if applicable.

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.

INSTRUMENT CLEANING AND DECONTAMINATION:

Certain instruments may require dismantling before cleaning.

All screwdrivers and hook drivers should be disassembled by removing the internal shaft and outer tube.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

CAUTIONS

Do not use steel wool or abrasive cleaners.

Avoid solutions containing iodine or high chlorine content.

Only place Reliance Medical devices with similar metallic composition in an ultrasonic cleaner.

Soiled or used Reliance Medical devices should not be loaded in a graphic case and cleaned in a mechanical washer. Long, narrow cannulations, blind holes, and intricate parts require particular attention during cleaning.

All devices must be thoroughly cleaned.

Reliance Medical instruments are critical devices and must be terminally sterilized prior to use. The sterilization parameters are only valid for devices that are properly cleaned. The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.

LIMITS ON REPROCESSING

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Reliance Medical surgical instrumentation. End of life is normally determined by wear and damage due to use.

Some of the instruments may be reused, prior to use, these instruments should be inspected to ensure they are working properly. There may be small defects and stress patterns which may lead to early breakage. All instrumentation, especially reusable instruments, should be routinely inspected prior to each usage for wear and tear or other signs of stress. To that end, any corrosion, pitting, discoloration, signs of wear (cracks, rounded edges, notches, especially on the distal tips), and/or signs of distress found during inspection should deem the instrument as unsatisfactory. If the instrument is deemed to be unsatisfactory, it should not be used during surgery and should be immediately returned to the address on this Package Insert.

POINT OF USE CARE

Wipe blood and/or debris from device throughout surgical procedure to prevent it from

drying onto the surface. Flush cannulated devices with sterile water to prevent the drying of soil and/or debris to the inside.

Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. Devices should be covered with a towel dampened with purified water to prevent blood and/or debris from drying.

PREPARATION FOR DECONTAMINATION

It is recommended that devices should be reprocessed as soon as is reasonably practical following use. Disassemble device, if applicable, prior to cleaning.

Remove sharp devices for manual cleaning or place into a separate tray.

Lumens/cannulas of devices should be manually processed prior to cleaning.

Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris.

Reliance Medical devices must be cleaned separately from Reliance Medical instrument and graphic trays. Lids should be removed from trays for cleaning process, if applicable.

MANUAL CLEANING:

All screwdrivers and hook drivers should be disassembled by removing the internal shaft and outer tube.

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:

All screwdrivers and hook drivers should be disassembled by removing the internal shaft and outer tube. 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.

STERILIZATION:

Unless marked sterile and clearly labeled as such, the RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM components, as well as those implants from other Reliance Medical Systems spinal systems specifically indicated for use with the RELIANCE POSTERIOR CERVICAL-THORACIC 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

INDICATIONS AND USAGE

CAUTION: U.S.A. Law restricts this device 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 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.

The RELIANCE POSTERIOR CERVICAL-THORACIC SYSTEM is intended to promote fusion of the cervical spine and cervicothoracic junction (C1-T3), and is indicated for the following:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- revision of previous cervical spine surgery
- tumors

The use of the mini polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

Hooks and Rods

The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4–T12), or lumbar spine. Pedicle screws are intended for placement only in T1-T3 as a means of anchoring the system.

POSTOPERATIVE MOBILIZATION:

Until maturation of the fusion is confirmed by radiographic examination, external immobilization (such as bracing) may be recommended, based on physician judgment. 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

- Active systemic infection or an infection localized to the site of the proposed implantation.
- Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system.
- Patients who have been shown to be safely and predictably treated without internal fixation.
- Open wounds.

RELATIVE CONTRAINDICATIONS:

Relative contraindications include any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis or osteopenia), obesity, certain degenerative diseases, and foreign body sensitivity.

WARNING: The safety and effectiveness of pedicle screw 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 neurological 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 spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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

WARNINGS

The following are specific warnings, precautions and 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 before surgery.

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.

In addition, please refer to the Surgical Technique Manual regarding details of safe placement of the screws and hooks.

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 that 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., that come into contact with other metal objects, must be made from like or compatible materials.

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

A. 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.

B. 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.

C. 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, orthopedic devices can only be considered a delaying technique or temporary remedy.

D. 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.

E. 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. PRE-OPERATIVE INSPECTION OF REUSABLE INSTRUMENTS. Some of the instruments may be reused, prior to use, these instruments should be inspected to ensure they are working properly. There may be small defects and stress patterns which may lead to early breakage. All instrumentation, especially reusable instruments, should be routinely inspected prior to each usage for wear and tear or other signs of stress. To that end, any corrosion, pitting, discoloration, signs of wear (cracks, rounded edges, notches, especially on the distal tips), and/or signs of distress found during inspection should deem the instrument as unsatisfactory. If the instrument is deemed to be unsatisfactory, it should not be used during surgery and should be immediately returned to the address on this Package Insert.

3. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should be done only 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 that may become the focal point for eventual breakage of the implant.

4. BENDING THE CONSTRUCT. Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended that a new construct is contoured correctly rather than reverse bending the over-contoured construct.

5. 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 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 refracture or deformity. 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 in a second surgery.

6. 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 participating in any type of sports. 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.

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 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. 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.
10. Bursitis.
11. Paralysis.
12. Screw back-out, possibly leading to implant loosening, and/or reoperation for device removal.
13. Damage to lymphatic vessels and/or lymphatic fluid exudation.
14. Spinal cord impingement or damage.
15. Fracture of bony structures.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.
17. Death.

The Reliance Posterior Cervical-Thoracic System has not been evaluated for safety and compatibility in the MR environment. The Reliance Posterior Cervical-Thoracic System has not been tested for heating or migration in the MR environment.

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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