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KARMA® FIXATION SYSTEM IMPLANTS AND INSTRUMENTATION

This package insert covers the Karma Fixation System and Manual Surgical Instruments that are used for the implantation of this system. Specific sections for implants and instrumentation highlight important user information for only those devices.

GENERAL INFORMATION

Implants

The Karma Fixation System consists of a strap with teeth along its length that interact with a latching mechanism. The leading tip of the device is tapered and smooth to help lead the strap through or around the bony structures to be secured. The strap tip is fed through the latch and made consecutively shorter or taut by pulling the strap through the latch. Once the desired loop length is reached, the unneeded portion of the strap may be cut off and discarded. The device is made from PEEK conforming to ASTM F2026 compounded with 7.5% barium sulphate, and Tantalum conforming to ASTM F560. The implant is intended for single use only and should not be reused under any circumstances. Reuse may result in serious injury or death.

Instruments

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments.

Components from this system should not be used in conjunction with components from other systems.

INDICATIONS

The Karma Fixation System is a temporary implant to be used in orthopedic surgery. The Karma implant is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. Karma Fixation System is designed for a posterior approach. The indications for use include the following applications:

1. Spinal trauma surgery: Karma implants can be used in sublaminar wiring techniques;
2. Spinal degenerative surgery: Karma implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

CONTRAINDICATIONS

1. Patients with known or probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be inappropriate to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing bone graft and fusion.
12. Any case not described in the indications for use.
13. Reuse or multiple use.

WARNINGS

Implants and instruments are provided non-sterile and must be cleaned and sterilized prior to use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing

temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Precaution: Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of the device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

MAGNETIC RESONANCE ENVIRONMENT

The Karma Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SINGLE USE

Reuse of a single use device that has come into contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death.

Implants that have directly come in contact with the patient or biocontaminants should be discarded. Separate inserts for implants from the instrument tray prior to and during any processing.

POSSIBLE ADVERSE EVENTS

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
5. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, persistent CSF leakage, meningitis.
8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
10. Loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
13. Soft tissue injury, vascular, or visceral injury.
14. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Non-union (pseudoarthrosis), delayed union, mal-union.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of or increase in spinal mobility or function.
18. Bone loss or decrease in bone density, possibly caused by stress shielding.
19. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
20. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
21. Inability to perform the activities of daily living.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments should be cleaned and sterilized prior to use.
9. All implants should be sterilized before use.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. Caution should be taken not to overtighten implants, instruments, and interfaces between implants and instruments.
6. Before closing the soft tissue, all locking/securing mechanisms should be tightened. Recheck the tightness of all components after finishing to ensure that none loosened during the tightening of other components.
7. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in the spinal position.
3. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process.
4. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
5. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
6. The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position, possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening and 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; (7) bone loss due to stress shielding; and (8) potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

CLEANING AND MAINTENANCE

GENERAL INFORMATION

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments.

CLEANING AND MAINTENANCE

All implants and instruments must be free of packaging material prior to sterilization. All instruments must be free of bio-contaminants prior to sterilization. Implants that have directly come in contact with the patient or bio-contaminants should be discarded. Separate implant caddies from the instrument tray prior to and during any processing.

Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

AUTOMATED CLEANING INSTRUCTIONS

All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

PRE-AUTOMATED WASHER: MANUAL CLEANING

1. Disassemble all instruments that come apart for cleaning.
2. Rinse under running tap water to remove gross contamination. Use a syringe, wire guide and/or pipe cleaner (as appropriate to the presented cleaning challenge) to push debris out of lumens/cannulations or other hard to reach areas. Pay special attention to lumens of the external shafts of disassembled instruments.
3. Prepare Enzol® (or equivalent neutral or mild pH enzymatic cleaner) according to manufacturer recommendations using warm tap water. Fully immerse devices in the enzymatic cleaner solution and allow to soak for a minimum of 1 minute. While soaking, actuate the instruments through a full range of motion (as appropriate) to allow complete penetration of the cleaning solution. Instruments that do not disassemble may require additional soaking.
4. After the soak, remove the instruments and wipe any soil or debris using a disposable towel. Then, place the instruments into a fresh batch of enzymatic cleaning solution using warm water. Scrub the entire surface of the devices with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas. A minimum of 60ml of detergent should be used when flushing lumens and cannulations. Ensure no soil is visible in the rinse stream.
5. Remove from enzymatic cleaner solution and rinse with reverse osmosis or deionized (RO/DI) water for a minimum of 30 seconds to remove any residual cleaner solution. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
6. Prepare Prolystica® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water in an ultrasonic bath. Fully immerse into the sonication bath and sonicate for a minimum of 10 minutes.
7. Remove from the detergent solution and rinse by agitating and actuating in RO/DI water for a minimum of 30 seconds to remove any residual detergent and until no sign of soil is seen in the rinse stream. While rinsing, thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.

AUTOMATED CLEANING

8. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Process per the cycle below. These are minimum validated parameters:

Phase	Recirculation Time	Water Temp	Detergent Type (if applicable)
Pre-wash	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	Enzol or equivalent per manufacturer's instructions
Wash	2 minutes	65.5°C	Prolystica or equivalent per manufacturer's instructions
PURW Rinse	2 minutes	43°C	N/A

Drying	15 minutes	90°C	N/A
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9. If needed, dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
10. Visually examine devices to ensure all visible soil has been removed.
11. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
12. After cleaning, an instrument lubricant (i.e. Steris Hinge-Free® or equivalent) should be applied to moving devices to maintain fluid movement between components. Pay special attention to the instruments called out in system specific sections.

MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Disassemble all instruments that come apart for cleaning.
2. Rinse under running tap water to remove gross contamination. Use a syringe, wire guide, and/or pipe cleaner (as appropriate to the presented cleaning challenge) to push debris out of lumens/cannulations or other hard to reach areas.
3. Prepare Enzol (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations using warm tap water. Fully immerse devices in the enzymatic cleaner solution and allow to soak for a minimum of 20 minutes. After the soak, scrub devices with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas. A minimum of 60ml of detergent should be used when flushing lumens and cannulations.
4. Remove from enzymatic cleaner solution and rinse with reverse osmosis/deionized (RO/DI) water for a minimum of 3 minutes to remove any residual cleaner solution. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
5. Prepare Prolystica (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water in an ultrasonic bath. Fully immerse into the sonication bath and sonicate for a minimum of 10 minutes.
6. Remove from the detergent solution and rinse with RO/DI water for a minimum of 3 minutes to remove any residual detergent and until no sign of soil is seen in the rinse stream. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
7. Repeat Steps 5 and 6.
8. Dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
9. Visually examine devices to ensure all visible soil has been removed.
10. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
11. After cleaning, an instrument lubricant (i.e. Steris Hinge-Free® or equivalent) should be applied to moving devices to maintain fluid movement between components. Pay special attention to the instruments called out in system specific sections.

STERILIZATION

Implants and all instruments are provided non-sterile and must be sterilized before use. Implants and instruments must be free of packaging material and biocontaminants prior to sterilization. Non-sterile implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Gravity Displacement	270°F (132°C)	15 minutes	45 minutes
	Steam	Pre-vacuum	270°F (132°C)	10 minutes	60 minutes
Rigid	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

*Note: Rigid containers must have a minimum of 2 filters and require a 30 minute cooldown period post sterilization.

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. These parameters were validated to a sterility assurance level (SAL) of 10⁻⁶. The Gravity Displacement, 270°F (132°C), 15-minute and Pre-Vacuum, 270°F (132°C), 10-minute sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization

wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).


INFORMATION


 Catalog Number


 Material

 Batch Code

 Packaged Quantity

 Manufacturer

 Date of Manufacture

 Caution, Consult
Accompanying
Documents

 Do Not Re-Use

 Device Not Sterile

 Prescription Only

 Instruction for Use are provided electronically at ifu.spinalelements.com

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Patent: patent.spinalelements.com

For additional information regarding any of Spinal Elements' devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.