Streamline TL instructions for use

NON-STERILE IMPLANTS
NON-STERILE INSTRUMENTS

DESCRIPTION

The Streamline TL Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of thoracic, lumbar, and/or sacral/iliac spine. The system includes a variety of rods, screws (poly-axial, fixed, and reduction), connectors, set screws and other connecting components used to build a spinal construct. The implant components of the system are manufactured from the implant grade titanium alloy (ASTM F136). Rods are also available in cobalt chromium (ASTM F1537). Components are available in various sizes to accommodate differing patient anatomy and can be rigidly locked into a variety of configurations. The components of this system should not be used with components of any other system or manufacturer, unless permitted by the product labeling. The implants are provided non-sterile and are supplied with instrumentation to facilitate use of the device components, as well as general manual surgical instruments.

INDICATIONS FOR USE

The Streamline TL Spinal Fixation System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2) or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudarthrosis, and failed previous fusion.

CONTRAINDICATIONS

The implant is contraindicated and should not be used including but not limited to, patients with the following:

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of non-union and/or implant breakage.

Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

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 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.

One of the potential risks identified with this system is patient death. Other potential risks which may require additional surgery, include:

- Device component fracture
- Loss of fixation
- Non-union
- Fracture of the vertebrae
- Neurological injury
- Vascular or visceral injury

The components of this device are manufactured from biocompatible implant grade materials. Mixing of certain implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

No implant and screw system can withstand the forces of sudden dynamic loads such as falls or other accidents.

PRECAUTIONS

Prior to use the surgeon must become familiar with the device system and the surgical procedure. Use surgical instrumentation, accessories, and surgical technique guide where provided with this device system. 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. Preoperative planning and patient anatomy should be considered when selecting pedicle screw diameter and length. 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.

Implants are for single patient use only, on a single occasion. If re-used, single use implants may not perform as intended and could cause serious injury.

Implants can break when subjected to the increased loading associated with delayed union or non-union. Internal fixation devices are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. Based on fatigue testing results, when using the system, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system. 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 bending, loosening, or breakage. Patients should be fully informed of the risks of implant bending, loosening, or breakage.

Only rods and crosslinks are intended to be bent or contoured. Bending of components other than rods and crosslinks may lead to premature material fatigue of the implant. If bending or contouring of components other than rods or crosslinks occurs, those components must be discarded. Scratched or notched components bent components other than rods or crosslinks, or components that have received a reverse bend must not be used and should be returned to the manufacturer or evaluation.

Avoid creating a sharp bend or reversing a contour in the rod, as this may lead to premature material fatigue of the implant. Do not bend the rod in the reverse direction, as this may introduce micro fractures that compromise its strength. If reverse rod bending or excessive bending has occurred, the bent rod must be discarded. Please contact the manufacturer with any questions regarding contouring rod prior to surgery.

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, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion 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.

Surgical implants must never be re-used. 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.

Do not re-use instruments that are labeled for single use only. Re-use may adversely affect performance and may compromise patient and/or operator safety.

Correct handling of the implant is extremely important. Contouring of the 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 fatigue life and may cause fracture.

Removal of the implant after healing. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk 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 risk involved with a second surgery.

Adequately instruct the patient about the risks and benefits of the surgery and the device prior to and after the surgery. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture of the device. The product is neither designed nor intended to withstand such use. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing (non-union). An active, debilitated, or demented patient who cannot properly use weight supporting devices or follow instructions may be particularly at risk for bending or fracture of the device(s) during postoperative rehabilitation.

It is extremely important that the physician provides clear directions and warnings and obtains the utmost compliance from the patient postoperatively:

- Partial- or non-weight bearing may be recommended or required to achieve firm bone union.
- Warn patient against sudden changes in position, strenuous activity, falls smoking, mechanical vibrations or shocks that may loosen the devices and consuming alcohol or other drugs including any over the counter (nonprescription) anti-inflammatories (e.g., aspirin, ibuprofen, naproxen) unless specifically instructed to do so.
- The patient's mobility should be restricted as appropriate, and directed by the physician, to allow bony union.
- Device presence may cause pain, discomfort, abnormal sensations, and increased risk of infection. Instruct the patient to seek medical attention if sudden changes in appearance at the surgical site are noticed or if an unexplained increase in pain is experienced.

The patient must be made aware of the limitations of the implant. Internal fixation devices are temporary devices that cannot support the patient's weight or movement beyond the time typically necessary for bone healing or fusion. Physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that an implant is not as strongas normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing including falls or other high energy events such as auto accidents. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be advised 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. Provide the patient with load bearing restrictions. The patient should be advised to inquire if any questions exist regarding the appropriate activities or environments during the healing process.

Instruments are subject to damage during use as well as long-term potentially damaging effects such as wear. Damage may result in significant risks to safety and/or inability to function as intended. If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon's responsibility to carefully consider the risks and benefits of retrieving the fragments. If the fragment is retained in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

PATIENT SELECTION

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

- **The patient's weight.** An overweight or obese patient can produce loads on the device which can lead to bending, loosening, or breakage of the appliance and the operation.
- **The patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial walking, running, lifting or muscle strain, the resultant forces can cause bending, loosening, breakage of the device.
- **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 bending, loosening, breakage or other complications.
- **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 relief.
- **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- **Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the Streamline TL implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3-Tesla
- Maximum spatial field gradient of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for (Normal Operating Mode)

Under the scan conditions defined above, the Streamline TL implant is expected to produce a maximum temperature rise less than 3.5°C (6.3°F) after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 40 mm from the Streamline TL implant when imaged with a spin echo pulse sequence and a 3 Tesla MRI system.

When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional components.

GENERAL INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect the success of the surgical procedure.

- All users are expected to read the instructions for use that accompany all devices being utilized with these implants.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use if the implant or packaging is damaged
  - Do not use if there are discrepancies in label information
- Promptly report all product defects and patient adverse events to the manufacturer (see Product Complaints section).

REPROCESSING INSTRUCTIONS

If applicable, additional instructions for use are included in the surgical technique guide available from the manufacturer.

Non-Sterile Implants:
Implants are supplied clean and non-sterile.

- Implants taken directly from an unopened package must be sterilized per the instructions below prior to introduction into a sterile surgical field or (if applicable) return of the product to the manufacturer.
- Unless just removed from an unopened package, implants must be cleaned and sterilized per the instructions below prior to introduction into a sterile surgical field or (if applicable) return of the product to the manufacturer.
- Implants are single-use and should not be re-used or re-processed if previously implanted or engaged. Inspect implants visually for damage, gross contamination or contamination by dried biological residue. If damage, gross contamination or dried biological residue is observed on the implant, it must be discarded.
- Unused Non-Sterile implants subject to the sterile surgical field may be recleaned and re-sterilized per the instructions below.

Non-Sterile Instruments:
Instruments are supplied clean and nonsterile.

- Instruments taken directly from an unopened package must be sterilized per the instructions below prior to introduction into a sterile surgical field or (if applicable) return of the product to the manufacturer.
- Unless just removed from an unopened package, instruments must be cleaned and sterilized per the instructions below prior to introduction into a sterile surgical field or (if applicable) return of the product to the manufacturer.
- To minimize corrosion and prolong the usable life of instruments used during surgery, remove gross traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasivepads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
  - Damage such as but not limited to, wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
  - Proper function including but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.
- Instruments that show signs of damage or an inability to function should not be used and should be returned to the manufacturer.

CLEANING

1. Disassemble the device(s), if applicable. See surgical technique manual for specific instructions.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristle brush or soft, lint-free cloth.
3. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C (92-110°F)), per the manufacturer's recommended instructions.
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten (10) minutes.
5. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features under running water, to rinse thoroughly.
6. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C (92-110°F)), per the manufacturer's recommended instructions.
7. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels. Use a softbristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to detergent solutions. Clean device under water to prevent aerosolization of contaminants.

8. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features to rinse thoroughly under running water.
9. Visually inspect device for residual soil. If present, repeat steps 1-8 above.
10. Gently dry the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue-free.
11. Reassemble device(s), if applicable, following instructions in the surgical technique manual.

AUTOMATED (MECHANICAL) CLEANING:

Pre-Cleaning

1. Disassemble instruments, as applicable. See surgical technique manual for specific instructions.
2. Rinse the device components under running lukewarm tap water (22-43° C (72-110°F)) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
3. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4. Fully immerse the device components in the fresh, newly prepared neutral pH enzymatic cleaning solution for a minimum of five (5) minutes.
5. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the cleaning solution.
6. Remove the device components from the cleaning solution and place in a bath of lukewarm tap water (22-43° C (72-110°F)) for a minimum of one (1) minute. Ensure that the device components are fully immersed. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the water.

Automated Cleaning

1. Place the device components in the automated washer.
2. Perform the automated cycle per instructions in the table below.
3. Visually inspect the device. It should be clean, dry and residue-free.
4. Reassemble instruments, if applicable, following instructions in the surgical technique manual.

AUTOMATED (MECHANICAL) CLEANING PARAMETERS			
Cycle	**Time (Minutes)**	**Minimum Temperature**	**Detergent**
Enzyme wash	4:00	Hot water 60°C (140°F)	Enzymatic cleaner (neutral pH) prepared per manufacturer's instructions
Wash	2:00	Hot water	Neutral detergent prepared per manufacturer's instructions
Rinse	2:00	Heated deionized or high purity water 70°C (158°F)	N/A
Dry	15:00	80°C (176°F)	N/A

STERILIZATION

Independent testing has shown the following conditions to be effective:

Method	Steam
Cycle	Pre-vacuum (Wrapped)
Temperature	132°C (270°F)
Recommended Exposure Time	4 Minutes
Recommended Dry Time	40 Minutes

- Use of an FDA cleared wrap is recommended to ensure product sterility.
- Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted.
- The values specified here (duration/temperature) can achieve a sterility assurance level (SAL) of at least 10-6.

LIMITED WARRANTY

THIS LIMITED WARRANTY GIVES THE ORIGINAL PURCHASER SPECIFIC LEGAL RIGHTS. THE ORIGINAL PURCHASER MAY HAVE ADDITIONAL OR ALTERNATIVE LEGAL RIGHTS UNDER CONTRACT OR STATUTE, WHICH VARY FROM JURISDICTION TO JURISDICTION. NOTHING IN THIS LIMITED WARRANTY SHALL BE CONSTRUED AS LIMITING SUCH ADDITIONAL OR ALTERNATIVE LEGAL RIGHTS. THE LEGAL MANUFACTURER OF THE PRODUCT, AS REFLECTED ON THE PRODUCT LABEL (THE "MANUFACTURER"), EXTENDS THIS LIMITED WARRANTY TO THE ORIGINAL PURCHASER OF THE PRODUCT. SUCH WARRANTY DOES NOT EXTEND TO ANY SUBSEQUENT TRANSFEREE OF THE PRODUCT. THIS LIMITED WARRANTY COVERS MALFUNCTIONS OR DEFECTS IN MATERIALS AND WORKMANSHIP FOR A PERIOD OF ONE (1) YEAR FROM THE DATE OF PURCHASE, OR FOR THE REMAINING SHELF LIFE, WHICHEVER IS LESS (THE "LIMITED WARRANTY PERIOD"). WITH RESPECT TO ANY SUCH MALFUNCTIONS OR DEFECTS OCCURRING IN THE PRODUCT DURING THIS LIMITED WARRANTY PERIOD, THE ORIGINAL PURCHASER'S REMEDY SHALL BE LIMITED AS FOLLOWS: THE MANUFACTURER, IN ITS SOLE DISCRETION, WILL EITHER: (A) REPAIR OR REPLACE SUCH PRODUCT (OR PART THEREOF) AT NO CHARGE; OR (B) REFUND TO THE ORIGINAL PURCHASER THE PURCHASE PRICE PAID FOR SUCH PRODUCT. UNDER THIS LIMITED WARRANTY, ALL OTHER EXPRESS AND IMPLIED WARRANTIES FOR THE PRODUCT, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES AND CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE SPECIFICALLY EXCLUDED. IF AND TO THE EXTENT A JURISDICTION DOES NOT ALLOW EXCLUSION OF IMPLIED WARRANTIES IN A LIMITED WARRANTY, THE MANUFACTURER ADDITIONALLY LIMITS THE DURATION OF ANY IMPLIED WARRANTY TO THE DURATION OF THE LIMITED WARRANTY PERIOD. UNDER THIS LIMITED WARRANTY, NO WARRANTIES WHETHER EXPRESS OR IMPLIED, WILL APPLY AFTER THE LIMITED WARRANTY PERIOD HAS EXPIRED. THE MAXIMUM AMOUNT OF THE MANUFACTURER'S LIABILITY UNDER THIS LIMITED WARRANTY WILL BE NO MORE THAN THE PURCHASE PRICE PAID FOR THE PRODUCT THAT IS THE SUBJECT OF ANY CLAIM UNDER THIS LIMITED WARRANTY. UNDER THIS LIMITED WARRANTY, THE MANUFACTURER DOES NOT ACCEPT ANY LIABILITY BEYOND THE REMEDIES PROVIDED IN THIS LIMITED WARRANTY, OR FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, INCLUDING, WITHOUT LIMITATION, ANY LIABILITY FOR THIRD-PARTY CLAIMS FOR DAMAGES. THIS LIMITED WARRANTY IS SUBJECT TO THE LAWS OF THE COUNTRY (WITHOUT REFERENCE TO ITS CONFLICTS OF LAW RULES) WHERE THE MANUFACTURER OF THE PRODUCT HAS ITS REGISTERED SEAT OF BUSINESS. ANY AND ALL DISPUTES IN RELATION TO THIS LIMITED WARRANTY SHALL BE EXCLUSIVELY CONFERRED TO THE COURTS IN SUCH REGISTERED SEAT OF BUSINESS OF THE MANUFACTURER.

PRODUCT COMPLAINTS

Complaints or dissatisfaction with the device quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a Health Care Professional, whether via a customer or user of the product, should be immediately conveyed to the attention of our distributor via telephone, FAX or written correspondence sent by express mail. It is important to note that when filing a complaint, the following information must be included in order to properly respond to the complaint:

Name and address; nature of the complaint; the component(s) trade name and catalog number; applicable lot number(s); and notification of whether or not a written report from the distributor is being solicited.

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A complete symbols glossary is located at http://www.xtantmedical.com/healthcare professionals/labeling

Symbol Definitions	
	Reference Number
	Batch Number
	Manufacturer
	Material(s)
	Single Use
	Caution, consult instructions for use
	Non-Sterile
	MR Conditional
	Prescription Only

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