Butrex® Lumbar Buttress Plating System

GENERAL DESCRIPTION

The Butrex® Lumbar Buttress Plating System is intended for anterior screw fixation to the L1 to S1 spine. The Butrex System consists of a variety of shapes and sizes of bone plates and screws. The components are manufactured from titanium alloy (Ti 6Al 4V ELI) as described by ASTM F136. Components of the Butrex System should not be used with components from any other system or manufacturer. The Butrex System components are provided non-sterile. The products must be steam sterilized by the hospital prior to use.

INDICATIONS FOR USE

The Butrex® Lumbar Buttress Plating System is intended for anterior intervertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease (DDD). DDD is defined as follows: back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

CONTRAINDICATIONS

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity.
3. Pregnancy.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.
8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.

⚠ WARNINGS

1. This device is not cleared for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. System implants and instruments are provided non-sterile and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.
3. Since the Butrex System does not provide intervertebral fixation, a separate intervertebral fixation construct, such as posterior pedicle screws, must be used for proper stabilization to be achieved.
4. As with all orthopedic and neurosurgical implants, none of the Butrex System implants should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.
5. The Butrex System has not been evaluated for safety and compatibility in the MR environment. The safety of the Butrex System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
6. To avoid the risk of vascular injury, the plate MUST be placed caudal to the bifurcation of the great vessels.

PRECAUTIONS

The Butrex System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

The Butrex System is only a temporary implant used for the anterior buttressing of a lumbar intervertebral bone graft. This device system is not intended to be used as a means of spinal support or fixation. Bone grafting must be part of the spinal fusion procedure in which the Butrex System is utilized. Use of this product without a bone graft or in cases that develop into a nonunion will not be successful. The spinal implant cannot withstand body loads. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

After the spine is fused, these devices serve no functional purpose and should be removed. 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/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 risk versus benefits when deciding whether to remove the implant.

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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.

INSTRUCTIONS FOR USE

For additional instructions regarding the proper use and application of all Butrex implants and instruments, please refer to the Xtant Medical Lumbar Butrex Buttress Plating System Surgical Technique Manual (available at no charge upon request).

A successful result is not always achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Use of the Butrex System should only be considered when the following preoperative, intra-operative and postoperative conditions exist.

PREOPERATIVE MANAGEMENT

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those mentioned in the contraindications should not be considered.
3. Device components should be received and accepted only in packages that have not been damaged or tampered with. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. All components and instruments must be clean and sterile prior to use. Additional sterile components should be available in case of unexpected need.

INTRAOPERATIVE MANAGEMENT

1. The vertebral levels to be fixated should be well visualized with a linear anterior surface so that the plate will mount flush with the anterior lumbar and/or sacral spine. The Butrex System implants come with a standard lordotic curve. When the configuration of bone cannot be fitted with an available temporary fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent more than absolutely necessary. The components should not be reverse bent at the same location.

2. The appropriate sized plate should be selected with the plate holes directly anterior to the vertebrae to be fused.
3. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae.
4. The Butrex System incorporates resilient locking arms with tabs which seat on a corresponding locking surface of the placed bone screw head. After placement of the screw, the resilient arm should be visualized with the locking tab positioned over the lateral portion of the screw head.
5. Removal of screws, if desired, is accomplished by laterally moving the resilient arm away from the screw head using the included screw removal instrument. With lateral pressure on the resilient arm the locking tab will move lateral to the screw head, allowing for screw removal using the standard hex screwdriver.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat from the curing process may cause neurological damage and bone necrosis.

POSTOPERATIVE MANAGEMENT

The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
2. If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).
3. During explantation, care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
4. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Non-union (pseudarthrosis)

6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis
7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
8. Misalignment of anatomical structures or loss of spinal mobility
9. Bone graft donor complications including pain, fracture or wound healing problems
10. Atelectasis
11. Retropulsion of graft
12. Cessation of any potential growth of the operated portion of the spine
13. Vascular damage resulting in excessive bleeding.
14. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise.
15. Fracture, damage, degenerative changes or instability of any bone above and/or below the level or surgery.
16. Gastrointestinal system compromise
17. Bone loss due to resorption or stress shielding
18. Death

PACKAGING, LABELING, AND STORAGE

The implants are supplied clean and NON-STERILE. They must be sterilized (see below). The implants are delivered in packages. These must be intact at the time of receipt. The implants may be delivered as a complete set. Implants and instruments are contained within specially designed trays which can be sterilized directly. Use care in handling and storage of the implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.

STERILIZATION

All Butrex System implants and instruments are provided clean and non-sterile and must be sterilized before use. All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameters:

Saturated steam method (pressure 41.9 psia, 205.5 kPa), pre-vacuum air removal (3 pulses), 270° F (132° C), 4-minute exposure time, 30-minute dry time, in a double–wrapped case configuration. Note: Most sterilizers automatically control pressure to ensure saturated steam and may not be adjusted by the user.

Use FDA cleared sterilizers and sterilization packaging materials/accessories (wraps, biological indicators, chemical indicators, etc.) for sterilization of instruments.

DO NOT stack instrument trays during sterilization.

CLEANING OF INSTRUMENTS

⚠ Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments and trays prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
2. No instruments within this system require disassembly as part of the cleaning process.
3. The following table describes the required steps for thoroughly cleaning the system instruments.

Table 1 – Cleaning Parameters

<table>
<tr><th rowspan="2">Step</th><th colspan="2">Agent</th><th>Time (mm:ss)</th></tr>
<tr><th colspan="3">Instructions</th></tr>
<tr><td rowspan="2">1.
Initial Clean</td><td colspan="2">Enzol Enzymatic Detergent Solution (or equivalent)</td><td>3:00</td></tr>
<tr><td colspan="3">Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for three (3) minutes. While submerged, use a soft bristle brush that is intended for use with surgical instruments, to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.</td></tr>
<tr><td rowspan="2">2.
Rinse</td><td colspan="2">Deionized water</td><td>1:00</td></tr>
<tr><td colspan="3">Thoroughly rinse each instrument with deionized water including all channels to remove detergent for one (1) minute.</td></tr>
<tr><td>3.
Ultrasonic</td><td colspan="2">Enzol Enzymatic Detergent Solution (or equivalent)</td><td>10:00</td></tr>
</table>

Clean	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for ten (10) minutes.	
4. Ultrasonic Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for one minute.	
5. Inspection	Unaided eye	
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. If instruments are not dry, use filtered pressurized air or lint-free wipes to dry.

INSPECTION

1. Carefully inspect each instrument and tray to ensure all visible blood and soil has been removed. Repeat cleaning if necessary.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Xtant Medical representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Xtant Medical representative for a replacement.

Manufacturer:

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

REF

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