ChoiceSpine™
Propelling Spinal Surgery

ALTES® Buttress Plating System
Instruction for Use

Rx only | Implants | NON STERILE

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Description:
The ALTES Buttress Plating System consists of plates and screws. The plate is shaped to conform to the anatomy of the anterior spine. It features two screws, which engage the vertebral body and prevent rotation. A unique locking mechanism of the screw prevents the plate and screws from releasing. The plates are available in three sizes; 20mm, 25mm, and 30mm. The self-tapping round head and locking head screws are placed in a 12 degree divergent angle, and are available in two diameters; 4.5mm and 5.0mm, and three lengths; 15mm, 20mm, and 25mm. The components are manufactured from titanium alloy (Ti-6Al-4V ELI as described by ASTM F136) and have a smooth anodized color-coded finish. The ALTES Buttress Plating System components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

Indications for Use:
The ALTES Buttress Plating System is intended for anterior intravertebral 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:
Contraindications for the ALTES Buttress Plating System are similar to those of other systems of similar design, and include, but are not limited to:

- Smaller juvenile patients weighing less than 30kg.
- Patients with significant osteoporosis or metabolic bone disease.
- Patients with greater than Grade 1 spondylolisthesis, spondylolysis or significant bony defect in the lumbar spine.
- Patients with a history of abdominal radiation treatment or abdominal vascular graft surgery.
- Patients who have had previous abdominal surgery with significant vascular scarring.
- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Morbid obesity.
- Pregnancy.
- Grossly distorted anatomy due to congenital abnormalities.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- 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.
- Suspected or documented metal allergy or intolerance.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- 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.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance. Any case not needing a bony fusion.

Cautions, Precautions, Warnings, and Possible Adverse Effects

Warnings and Precautions:
The ALTES Buttress Plating 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 ALTES Buttress Plating System is only a temporary implant for the lumbar spine. The system is also used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the ALTES Buttress Plating System is utilized**.**

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

Preoperative:
A successful result is not 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.
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.

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.

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.

All components and instruments must be cleaned and sterilized prior to use. Additional sterile components should be available in case of unexpected need.

Intraoperative:
Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.
Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of these products. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration or implants of if pulsatile erosion of the vessels occurs because of close apposition of the implants.

Bone grafts must be placed in the area to be fused.
Some degree of corrosion occurs on all implanted metal and alloys. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct. Different manufacturers use different materials, varying tolerances and design configurations. Components of the ALTES Buttress Plating System must not be used with components from any other system or manufacturer.
This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine**.**

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

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. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Patients should be fully informed of the risks of implant failure.
Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.

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 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).

After solid fusion occurs, these devices serve no functional purpose and should be removed. In some cases, 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/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. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the ALTES Buttress Plating System components should ever be reused under any circumstances.

Possible Adverse Effects:
Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

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. 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
5. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
6. Misalignment of anatomical structures or loss of spinal mobility
7. Bone graft donor complications including pain, fracture or wound healing problems
8. Atelectasis
9. Retropulsion of graft
10. Cessation of any potential growth of the operated portion of the spine
11. Fracture, damage, degenerative changes or instability of any bone above and/or below the level or surgery.
12. Gastrointestinal system compromise
13. Bone loss due to resorption or stress shielding
14. Death
15. Nonunion, delayed union.
16. Infection, early or late.
17. Decrease in bone density due to stress shielding.
18. Pain, discomfort, or abnormal sensations due to the presence of the device.
19. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, other types of urological compromise, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia.
20. 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.
21. Bursitis.
22. Reflex sympathetic dystrophy.
23. Paralysis.
24. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CFS leak or fistula and possible meningitis.
25. Spinal cord impingement or damage.
26. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.

Additional surgery may be necessary to correct some of these potential adverse effects.

How Supplied:
NON STERILE The ALTES Buttress Plating System instruments and implants are provided clean but non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:
All instruments and implants are supplied to the health care facility clean but non-sterile. Implants are single use only but need to be sterilized before each use. Additionally, all instruments 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. Implants that have been implanted and then removed must be discarded.

Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

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

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected, and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:
The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling. When appropriate, disassemble instruments prior to cleaning.

Automated Cleaning:
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz per 1 gal water
Wash 1	2:00	60°C	Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instrument(s) from washer & visually inspect for soil. Repeat if necessary.

Mechanical Cleaning (Ultrasonic):
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

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

- Refer to ASTM standard F1744-96, “Standard Guide for Care and Handling of Stainless Steel Surgical Instruments” for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Sterilization:
ChoiceSpine instruments and implants are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments and implants are recommended to be steam sterilized by the hospital using the following process parameters (Alternative methods or cycles may be used but should be validated according to hospital practices and procedures):
All devices must be placed in appropriate caddy/case prior to steam sterilization.

Steam Sterilizer Type: Pre-vacuum
Temperature: 132°C
Duration: 4 minutes
Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature).

Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures.

Single Use Only:
Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Storage and Handling:
Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implant in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is opened, damaged or wet. Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled.

Limitations and Restrictions:
Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved.

These instructions have been validated as being capable of sterilizing these ChoiceSpine implants.

Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Patient Education:
It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the ALTES Buttress Plating System components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Surgical Technique Manual:
The ALTES Buttress Plating System Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

Product Complaints:
The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to ChoiceSpine immediately. Furthermore, if any of the implants “malfunction” (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Caution:
Federal Law (USA) restricts this device to sale by or on the order of a physician.

Information:
See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

For product complaints please contact:
ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:
ChoiceSpine, LLC
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400 Erin Drive
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Phone: 865-246-3333; Fax: 865-588-4045
customerservice@choicespine.com

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
	Authorized representative in the European Community