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BLACK WIDOW ANTERIOR BUTTRESS PLATE

This package insert covers the Black Widow Anterior Buttress Plate 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

The Black Widow Anterior Buttress Plate is designed for preventing migration or expulsion of allograft or autograft in the thoracolumbar to S1 spinal region. Specific system features include:

- Plate uniquely shaped to conform to anterior spine anatomy.
- Two pegs which engage the vertebral body and prevent rotation.
- An extremely low profile plate with a full radius around the perimeter and a screw that sits flush with the anterior surface of the staple.
- A self-tapping screw in multiple lengths.

The plates have a 6-degree bend, and are available in various sizes. The selftapping cancellous screws have a 6.0mm major diameter and are available in various lengths. The components of the Black Widow Anterior Buttress Plate are manufactured from titanium (Ti-6AI-4V ELI per ASTM F136) and have a smooth anodized finish.

The Black Widow Anterior Buttress Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing.

INDICATIONS

The Black Widow Anterior Buttress Plate, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

CONTRAINDICATIONS

1. Smaller juvenile patients weighing less than 30kg.
2. Patients with significant osteoporosis or metabolic bone disease.
3. Patients with greater than Grade I spondylolisthesis, spondylolysis or significant bony defect in the lumbar spine.
4. Patients with a history of abdominal radiation treatment or abdominal vascular graft surgery.
5. Patients who have had previous abdominal surgery with significant vascular scarring.
6. Active systemic infection or infection localized to the site of the proposed implantation is contraindications to implantation.
7. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is relative contraindications.
8. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at higher risk of implant failure. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

CAUTION: Do not place 2 buttress plates in one vertebral body.

WARNINGS

This spinal device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of surgical implants, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. See the surgical technique manual for important instructions. Black Widow Anterior Buttress Plate components should not be used with components of spinal systems from other manufacturers.

WARNINGS AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES WARNINGS

Black Widow Anterior Buttress Plate implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions on their activities in the postoperative period and to examine the patient postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed. The components of the Black Widow Anterior Buttress Plate are manufactured from titanium (Ti-6AI-4V ELI) per ASTM F136.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used or if a pseudarthrosis develops or in patients with severe or multiple preoperative curves.

The surgeon may determine to remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

1. CORRECT SELECTON OF THE IMPLANT IS EXTREMELY IMPORTANT.

The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

- others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
- Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
- Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement

PRECAUTIONS

- CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. 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.
- REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not

removed following the completion of its intended use, any of the following complications may occur:

- Corrosion, with localized tissue reaction or pain;
- Migration of implant position resulting in injury;
- Risk of additional injury from post-operative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult;

(5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. 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.

- ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. 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 maybe particularly at risk during postoperative rehabilitation.
- CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANTS. 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 of implants or if pulsatile erosion of the vessels occur because of close apposition of the implants.

MAGNETIC RESONANCE ENVIRONMENT

The Black Widow Anterior Buttress Plate 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.

POSSIBLE ADVERSE EFFECTS

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.
5. Post-operative 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, tethering of nerves in scar tissue, paraesthesia, or sensory loss.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, spinal cord impingement or damage. 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, vertebral endplate injury, vascular or visceral injury. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Non-union (pseudo-arthrosis), delayed union, mal-union.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels
17. Bursitis
18. Reflex sympathetic dystropy
19. Cessation of any potential growth of the operated portion of the spine.
20. Pain, discomfort, or abnormal sensations due to the presence of the device.
21. Loss of or increase in spinal mobility or function.
22. Inability to perform the activities of daily living.
23. Death.

PREOPERATIVE MANAGEMENT (added from Savannah as general information)

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 and implants should be processed and sterilized prior to use.

POSTOPERATIVE CARE AND MOBILIZATION

Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. 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. 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.

Following are specific warnings, precautions, and adverse effects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

SINGLE USE

Reuse of a single use device that has come in 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 bio-contaminants should be discarded. Separate inserts for implants from the instrument tray prior to and during any processing.

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.

All disassemble instruments must be disassembled prior to cleaning.

Devices must be free of packaging material prior to cleaning. 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 de-ionized (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

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. Pay special attention to the lumens of the external shafts of disassembled instruments.
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/de-ionized (RO/DI) water for a minimum of three 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 three 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.

INSPECTION

1. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
2. 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 Spinal Elements representative for a replacement.
3. If corrosion is noted, do not use and contact customer service or your Spinal Elements representative for a replacement.

STERILIZATION

Implants and instruments are provided non-sterile and must be sterilized before use. 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 Container	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. These 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). Instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be re- sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be scrapped.

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

Manufacturer: SPINAL ELEMENTS
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REF	Catalog Number	MAT	Material
LOT	Batch Code	QTY	Packaged Quantity
	Manufacturer		Date of Manufacture
	Caution, Consult Accompanying Documents		Do Not Re-Use
NON-STERILE	Device Not Sterile		

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

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

℞ Only Prescription Only