Blustone Synergy Diamond SA Cervical System

Blustone Synergy
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System Contents:
- Sterile Implants- Single Use Only
- Non-Sterile Implants – Single Use Only
- Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION and INTENDED USE:
The Blustone Synergy Diamond Stand Alone (SA) Cervical System consists of the Diamond cervical plate assembly and cervical plate screws to be used in conjunction with the Blustone Synergy Interbody Fusion System SLATE cervical interbody fusion devices to form the Diamond Stand Alone Cervical System. The Diamond Stand Alone cervical system is designed to be used with allograft and/or autograft. Use of the Diamond SA Cervical System is intended to expedite the Anterior Cervical Device instrumentation procedure, while minimizing tissue disruption through a minimally invasive approach. The Diamond plate includes anterior nail spikes to resist rotation and two holes for insertion of the included bone screws as well as an integrated locking plate to resist bone screw backout. All implant components are available in various sizes to accommodate varying patient anatomy.

Do not use the Blustone Synergy Diamond SA Cervical System components with the components from any other system or manufacturer.

INDICATIONS:
The Blustone Synergy Diamond SA Cervical System are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. Degenerative Disc Disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non-operative treatment. The Blustone Synergy Diamond SA Cervical System may be used with additional supplemental fixation.

CONTRAINDICATIONS:
1. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindications may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:
The Blustone Synergy Diamond SA Cervical System implant components are made of polyether ether ketone (PEEK Zeniva ZA-500) that conforms to ASTM F2026. The devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device. The vertebral body attachment plate and screws are made from titanium alloy, Ti6Al4V(conforms to ASTM F136), and anodized Type 2 and 3, for color recognition, depending on component size.
The Blustone Synergy Diamond SA Cervical System is implanted using a combination of device specific class 2 and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

Removal/Revision:
The Blustone Synergy Diamond SA Cervical System may be removed or revised by inserting the torx-10 straight screwdriver into the center locking nut. Turn counter clockwise and remove the center locking nut and rotating locking ring from the implant site. Use the same screwdriver to remove the cervical plate screws. If angulation is difficult to properly align with the screw head, use the angled or ball ended screwdriver. Once the cervical plate screws are removed, the cervical plate assembly can be removed from the implant site. If bone has grown onto or over the cervical plate assembly, drilling or general bone removal instruments may be used to loosen the device. To remove the SLATE cervical interbody fusion system, place the SLATE inserter onto the front of the interbody device and rotate the knob clockwise to thread the inserter onto the SLATE cervical interbody. Pull the interbody out of the intervertebral space. If fusion has occurred, drilling or general bone removal instruments may be used to loosen the interbody. For revision or replacement, never reuse any removed components of the implanted system. Although they may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

CLEANING of INSTRUMENTS:
Clean all instruments prior to use, and as soon as possible after use. 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 or enzymatic solution to delay drying.

Disassemble instruments with removable parts. Specifically, the inserter instrument provided with the Blustone Synergy Diamond SA Cervical System is intended to be disassembled for cleaning and sterilization. To disassemble the inserter, twist handle in clockwise direction to disengage threads.

Two methods of cleaning Blustone Synergy re-usable instruments are provided in these instructions, **a manual method** and a method using an **automated washer disinfector.** Whenever possible the automated method should be used. The automated cleaning process is more reproducible and, therefore, more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used.

Staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.

Blustone Synergy does not recommend any specific cleaning and/or disinfection agent. For cleaning or disinfecting re-usable instruments, only specifically formulated cleaning agents and/or disinfectants should be used. Do not alter the concentrations specified by the detergent manufacturer.

The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing re-usable instruments should be carefully considered. Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes with less than 100 cfu/ml and 0.5 EU/ml is highly recommended.

Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in staining of the device or prevent effective cleaning and decontamination.

Pre-Cleaning

1. Remove gross soil using wipes and solution of cleaning agent.
2. Immerse re-usable instrument in solution of cleaning agent.
3. Ensure that all surfaces are thoroughly wetted.
4. Use a syringe to ensure that the cleaning solution reaches all parts of cannulations.
5. Ensure that air is not trapped within features of the device when immersing in the solution.
6. Soak for minimum recommended time by the detergent manufacturer's instructions.
7. Using suitable soft bristle brushes, clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.
8. Use a firm bristle brush for cleaning bone-cutting features such as drill tips broaches.
9. Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation.
10. **Caution: Never use metal brushes or steel wool for cleaning.**
11. Operate articulating devices and those with moving parts.
12. Rinse in running water until all traces of cleaning solution are removed.
13. Pay particular attention to cannulations and blind holes, as well as hinges and joints, between mating parts.
14. Visually inspect for any remaining soil and repeat the steps above if necessary.
15. Allow to drain on absorbent paper or transfer immediately to cleaning step.

Manual Cleaning and Disinfection

Equipment required for cleaning:
- Ultrasonic bath large enough to allow complete immersion of the re-usable instrument. (A frequency of 25 – 50 kHz is recommended. Do not exceed the temperature stated by the detergent manufacturer.)
- Cleaning agent intended for manual cleaning and suitable for ultrasonic

treatment. Do not exceed the concentration specified by the detergent manufacturer.
- Suitable brushes or cleaning wires to reach all parts of the device.
- Syringes (volumes 1 to 50 ml depending on the size of the
- channels to be rinsed)
- Fresh purified water, highly purified water or sterile water for rinsing purposes.

Procedure for cleaning:

1. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified by the detergent manufacturer.
2. Immerse the device completely and activate the bath for minimum of 15 minutes.
3. Using suitable brushes or cleaning wires, clean the device paying particular attention to rough surfaces and features that may be shielded from the brushing action.
4. Rinse for at least 1 minute in running water until all traces of cleaning solution are removed.
5. Pay particular attention to cannulations, blind holes, hinges, and joints between mating parts.
6. Rinse cannulations at least three times with a syringe (volume 1-50ml).
7. If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remains on the device, the cleaning step must be repeated as described above.

Automated Cleaning and Disinfection

Equipment required for automated cleaning/disinfection:

- Washer-disinfector with fundamentally approved efficiency (e.g. FDA approval according to ISO 15883), properly installed, qualified and regularly subjected to maintenance and testing.
- Approved thermal disinfection program with sufficient rinsing steps (A0 value > 3000 or application of at least 5 min at 90 °C).
- **Caution: Chemical disinfection programs are not recommended due to the potential for chemical residues to remain on the instruments. These residues could interfere with sterilization efficacy.**
- Cleaning agent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.

Procedure for automated cleaning/disinfection:

1. Load the re-usable instruments into the washer-disinfector.
2. Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.
3. Avoid contact between devices as movement during washing could cause damage, and washing action could be obstructed.
4. Arrange re-usable instruments so that cannulations are not horizontal and blind holes incline downwards to assist drainage.
5. Articulating devices should be in the open position.
6. Operate the washer-disinfector cycle.
7. Upon completion, unload the washer-disinfector.
8. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process.
9. Remaining wetness may be removed with filtered, compressed air or clean, lint-free wipes.
10. If additional drying is required, arrange instruments in a clean area or heat in an oven below 110°C.

STORAGE

Use care in handling and storage of implant and instrument components. Implants and instruments should be stored in their original packaging and protected from corrosive environments such as salt air, heat, moisture, direct sunlight, etc. until ready for use. Inspection and trial assembly are recommended prior to surgery to determine if instrument components or implants have been damaged during storage or prior procedures.

Please refer to the cleaning and sterilization instructions for re-use instructions for instruments.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. 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.
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 Blustone Synergy representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Blustone Synergy representative for a replacement.

STERILIZATION:

The Blustone Synergy Diamond SA Cervical system implants are provided either sterile or non-sterile. All implants are intended for single use only.

STERILE:

The Blustone Synergy Diamond SA Cervical System has undergone an ethylene oxide sterilization to a minimum of 10^{-6} Sterility Assurance Level, SAL, for devices marked “Sterile”. The process was validated for use with the Blustone Synergy Diamond SA Cervical System(implants only) in accordance with requirements followed in ISO 11135:2014 Sterilization of health-care products – Ethylene Oxide. In order to ensure sterility, implants must be used before the end of their expiration date indicated on the carton label. Prior to use, inspect the packaging pouch and pouch label for seal integrity. The purple indicator dot on the pouch should be GREEN, signifying EO exposure and product sterilization. If the device has been opened, damaged, or adulterated in any way, the device must not be used. In order to maintain sterility, aseptic techniques must be used when removing the implant from its packaging for surgical use.

NON-STERILE:

The Blustone Synergy Diamond SA Cervical System is provided non-sterile and is delivered to the customer in a surgical kit, which is comprised of implant caddies, instrument trays and cases. The following moist heat sterilization cycle, which results in a SAL of 10^{-6}, was validated for use with the Blustone Synergy Diamond SA Cervical System (implants and instruments) in accordance with applicable standards, including ANSI/AAMI ST79:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270ºF (132ºC)
Exposure Time:	4 minutes
Dry Time:	20 minutes
Wrap:	2 times utilizing FDA cleared wrap

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.

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace.

Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:

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

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. Do not use if package is opened or damaged or if expiration date (if applicable) has passed.
3. Care should be used in the handling and storage of the implant components. Implants and instruments should be stored at room temperature. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

    a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
    b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
    c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle

strain, the resultant forces can cause failure of the implant or subsidence.

d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.

e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.
3. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
4. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
5. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
6. ADEQUATELY INSTRUCT THE PATIENT. 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 body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
7. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Blustone Synergy Diamond SA Cervical System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Blustone Synergy Diamond SA Cervical System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS

Potential risks identified with the use of this device system, which may require additional surgery, include:

1. Pseudoarthrosis (i.e. non-union), delayed union.
2. Bending or fracture of implant.
3. Loss of fixation.
4. Fracture of the vertebra.
5. Anterior or posterior migration of the implant.
6. Allergic reaction to a foreign body.
7. Infection.
8. Decrease in bone density due to stress shielding.
9. Pain, discomfort, or abnormal sensations due to the presence of the device.
10. Loss of proper spinal curvature, correction height and/or reduction.
11. Vascular and/or nerve damage due to surgical trauma or presence of the device.
12. Visceral injury.
13. Neurological injury, including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
14. Paralysis.
15. Death.
16. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:

Blustone Synergy products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Blustone Synergy for current information.

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For product information, questions pertaining to sales and service, or to obtain a copy of the surgical technique manual, please contact your local sales representative or Blustone Synergy customer service.

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Symbol	Title	Meaning
	Consult instructions for use	Indicates the need for the user toconsult the instructions for use.
	Caution or Warning	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Non Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Manufacturer	Indicates the medical devicemanufacturer.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Sterilized by Ethylene Oxide Treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or open.
	Use by	Indicates the date after which the medical device is not to be used.
QTY	Quantity	Indicated the quantity contained in the package,
	Does not contain latex	Indicated that there is no presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	Indicates that the product is a medical device as defind in 21 CFR 801.109(b)(1) and FederalLaw (USA) resticts this device to sale by or on the order of a physician	