OsteoCentric Integrity-SI® Fusion System
Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

Federal US law restricts the sale of Integrity-SI® Fusion implants by or on the order of a physician only.

Device Description:

The Integrity-SI Fusion System consists of partially and fully threaded, self-tapping cannulated titanium implants designed to be inserted across sacroiliac joint providing stability for joint arthrodesis. The surgical implants are available in various sizes to accommodate patient anatomy. The 10mm and 12mm diameter screws are offered in partially and fully threaded version in lengths from 40-110mm, in 5mm increments. The 10mm and 12mm screws also include a pre-assembled washer for improved joint compression. The fully threaded 6.5mm diameter screws are offered for additional rotational stability in lengths of 30-70 mm, in 5mm increments and are only intended for use in conjunction with a primary 10mm or 12mm screw. The Integrity-SI Fusion implants, the Blade-X® decortication instrument blade, and the surgical instruments are provided non-sterile in steam sterilization instrument tray.

The Integrity-SI Fusion System is only intended for use with autograft or allograft material.

Indications for Use:

The Integrity-SI Fusion System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Contraindications:

Contraindications for the Integrity-SI Fusion System include the following:

1. Deformities or anatomic variations that prevent or interfere with placement of the Integrity-SI Fusion implants
2. Tumor of sacral or ilial bone
3. Active infection at treatment site
4. Unstable fracture of the sacrum or ilium that involves the sacroiliac joint
5. Allergy to metal implants

Potential Adverse Events:

As with other surgical procedures that are used to treat sacroiliac joint conditions, the risks associated with the Integrity-SI surgical procedure include, but are not limited to the following:

1. Negative or adverse reactions to anesthesia
2. Muscle damage
3. Hematoma or seroma
4. Bruising and/or local swelling
5. Hemorrhage or bleeding
6. Vascular injury or damage that could result in catastrophic or fatal injury
7. Neurological deficit, nerve root or peripheral nerve irritation, damage, or injury
8. Damage to lymphatic vessels and/or lymphatic fluid exudation
9. Injury to pelvis and intra-pelvic structures
10. Pulmonary or systemic embolism
11. Thrombosis and/or thrombophlebitis
12. Would infection, deep infection, and/or peritonitis
13. Wound dehiscence
14. Death
15. Radiation exposure

The potential risks specifically associated with the implants and instruments of the Integrity-SI system include, but are not limited to the following:

1. Pain, discomfort, and/or abnormal sensations due to the presence of the implant in the body
2. Infection
3. Muscle pain due to altered biomechanics
4. Instrument failure resulting in a complication
5. Migration, loosening, or fracture/failure of the implant resulting in a complication
6. Loss of fixation/stabilization or failure to achieve SI joint fusion
7. Nerve root or peripheral nerve root irritation due to local swelling or altered biomechanics
8. Irritation or sensitivity to the implants due to an allergic reaction to the metal implants
9. Negative response to wear debris from the metal implants
10. Failure to improve symptoms and/or function
11. Increased pain at operative or adjacent levels
12. Need for re-operation or removal of the implant(s)
13. Potential difficulty delivering a fetus vaginally due to the restriction of the SI joint by the implanted device

Warning and Precautions:

1. Women with the potential for childbearing should be cautioned that vaginal delivery of a fetus may not be advisable following fusion of the SI joint. If a pregnancy is possible or occurs, women should review delivery options with her physician.
2. Carefully read and follow all instructions prior to use, including cleaning and sterilizations methods.
3. Patient adherence to post-operative physical activity instructions from physician is important to support long-term service life of the implant(s).
4. Careful attention to the appropriate selection of implant size is necessary. Pre-operative imaging including X-rays and/or CT scans may be helpful in appropriate selection of size and surgical navigation pre-operative planning of pelvic anatomy.
5. Appropriate patient selection is critical since factors such as patient size, weight, and medical history may influence the possible success or failure of the Integrity-SI Fusion implant system.
6. Do not use any components from opened or damaged packaging.
7. If placing the Integrity-SI Fusion implants in an open procedure, the surgeon should take care not to destabilize the joint prior to implant placement.

Single-use Device:

Implants and blades may not be reused as they are intended for single use only.

Non-Sterile Products:

The Integrity-SI Fusion System implants as well as the Blade-X decortication instrument blade are provided non-sterile in an Implant steam sterilization case/tray. Any unused implants or blades may be steam sterilized. The Integrity-SI Fusion surgical instruments are provided separately, non-sterile in a steam sterilization instrument tray. The instruments and implants must be sterilized prior to use following the Integrity-SI Instrument Hospital Cleaning and Sterilization Instructions, USA.

Magnetic Resonance Environment:

It is important to note that the Integrity-SI Fusion 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 the Integrity-SI Fusion implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Directions for Use:

For detailed information, refer to the OsteoCentric Surgical Technique Guide prior to using the Integrity-SI Fusion System.

Instrument Cleaning and Sterilization:

The hospital and hospital staff are responsible for processing and/or reprocessing appropriately using the materials, equipment, and processes outlined in this document. In addition, the hospital is responsible for ensuring that the staff and personnel within the reprocessing facility have been adequately trained to perform the steps outlined in this document. All equipment and processes used should be validated and monitored regularly. Any deviation from the processes outlined in these instructions should be appropriately documented and evaluated for effectiveness to avoid in adverse outcomes or issues related to cleanliness or sterilization.

Proper safety equipment and Personal Protective Equipment (PPE) should be employed when handling contaminated or potentially contaminated materials, devices, and equipment. Proper PPE includes, but may not be limited to gown, mask, goggles or face shields, gloves, and shoe covers. In addition, universal precautions should be exercised by all personnel working with and/or handling contaminated devices and devices with sharp points. It is the responsibility of the hospital to ensure that proper PPE is used and that all personnel handling contaminated or potentially contaminate devices are properly trained in PPE and the handling and disposal of devices with sharp points.

Warnings and Precautions:

- Integrity-SI Fusion instruments and implants are critical devices and must be terminally sterilized by steam sterilization prior to surgical use.
- Prior to sterilization and promptly following each procedure, thoroughly clean all instruments and implants according to the procedures outlined below. The parameters for sterilization and sterilization processes listed below are only valid for devices that have been properly cleaned.
- All instruments and implants should not be allowed to dry properly before reprocessing so as to effectively clean and remove contaminants including blood, body fluids, bone and tissue debris, and other contaminants.
- Soaking the instruments or implants in disinfectants should be avoided as this may lead to discoloration or corrosion.
- Contaminated instruments and implants should not be rinsed with hot water (water temperatures greater than 45 °C), concentrated alcohol, certain liquid chemical sterilants, or certain disinfectants such as glutaraldehyde or ortho-phthaladldehyde as these may cause protein-based contaminants to denature rendering them difficult to remove.
- Do not use silicon or oil-based lubricants as these may inhibit sterilization.

Point of use care:

Wipe blood and/or debris from device immediately following the surgical procedure to prevent it from drying onto the surface. Flush cannulated devices with water to prevent the drying of soil and/or debris to the inside. Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. Devices should be covered with a towel dampened with water to prevent blood and/or debris from drying.

These recommendations are for processing reusable devices. Reusable devices include certain surgical instruments, instrument trays and cases. The information provided does not apply to implants.

Cleaning Agents and Water:

- Select enzymatic cleaning solutions that are intended to breakdown blood, body fluids, fat, and tissue. Enzymatic solutions designed specifically for the breakdown of fecal matter or other organic contaminants are not suitable choices for orthopedic instruments.
- Ensure that the appropriate cleaning agents is selected for the cleaning equipment in which they are used and follow the cleaning agent manufacturer's recommendations for water quality, temperature, exposure times, and concentration.
- Natural pH enzymatic cleaning agents should be used as alkaline or acidic agents may cause corrosion or discoloration of the stainless steel and aluminum instrument or the titanium implants.
- During manual cleaning procedures, it is recommended that cleaning agents with low foaming surfactants should be used to ensure visibility of the instruments and implants during cleaning.
- Avoid the use of hard water. Only purified water that has been filtered using deionization, reverse-osmosis, or ultra-filtration should be used for all final rinsing.
- All cleaning agents should be easily and completely rinsed from devices to prevent residue buildup.

Manual Cleaning Tools:

- Do not use metal cleaning tools such as metal or wire brushes, scouring pads, etc. to clean the instruments as these may damage the surface of the instruments.
- To properly clean the instruments manually, the user facility may use tools such as soft-bristled brushes, pipe cleaners (multiple diameters and lengths), low-linting cloths, and flushing tools for cannulated instruments such as syringes, water guns, etc. All brushes and cleaners should be appropriately sized to pass down or through cannulations while maintaining contact with all internal surfaces.

Manual Cleaning Procedure – Instruments Only:

1. Disassemble the Blade-X instrument (refer to instructions at the end of this document).
2. Clean instruments as soon as possible after use. Thoroughly rinse the instruments under running tap water to remove gross contamination. Do not allow blood, tissue, and debris to dry on the instruments.
3. Prepare an enzymatic cleaner such as Enzol® (or equivalent), per manufacture's recommendations.
4. Fully immerse the articles in the solution and actuate the articles while immersed in the solution to ensure complete penetration of cleaning solution. Flush all hard-to-reach areas of the instruments with the prepared detergent using a syringe.
5. Soak all instruments in the prepared solution for a minimum of 10 minutes.
6. Following the 10-minute soak, using a soft bristled or nylon brush, scrub the instruments paying close attention to hard-to-reach areas until all evidence of soil is removed. Do not use metal scouring pads. Pay particular attention to crevices, lumens, cannulations, mated surfaces, connections, and other hard to reach areas. A syringe and/or pipe cleaners of various sizes may be used to clean the lumens and other hard to reach areas. Actuate the articles while brushing to clean matted surfaces and movable parts.
7. Thoroughly rinse the instruments under running tap water for a minimum of 1 minute. Flush all lumens, holes, and hard to reach areas using an appropriately sized syringe filled with tap water.

8. Prepare a mild detergent such as Prolystica® 2X (or equivalent), per manufacture's recommendations. Place the instruments in a suitable wash basket with adequate space to ensure proper flow of process fluids to the lumen or cannula of each instrument. An irrigating rack/MIS instrument rack may be appropriate for use. If available, connect cannulations to flushing hoses or ports.
9. Fully immerse the articles in the prepared solutions and sonicate the articles for a minimum of 15 minutes at the frequency recommended by the manufacturer of the unit.
10. Following sonication, remove the articles and rinse the articles under running reverse osmosis/deionized/ultra-filtered (RO/DI/UF) for a minimum of 3 minutes ensuring all lumens, cannulas, holes, and crevices are flushed vigorously and until all evidence of detergent is removed.
11. Dry the instruments with a soft cloth and/or compressed air.
12. Inspect each individual instrument to ensure that there is no visible debris.
13. If visible debris remains, repeat cleaning steps 1-10 for the contaminated instruments.
14. All instruments should be inspected prior to use or cleaning for corrosion, pitting, discoloration, cracking, or anything that might indicated excessive wear or improper function. If any part shows excessive wear or improper function, return to OsteoCentric for a replacement.
15. Return the instruments to the proper location in the instrument tray.

Automated Cleaning Procedure – Instrument Case/Tray and Implant Case/Tray:

The following steps should be completed in sequence:

1. Prepare an enzymatic cleaning solution using lukewarm water as per the manufacturer's recommendation.
2. Fully immerse the devices and allow to soak for a minimum of two (2) minutes.
3. Following the soak time, flush any lumens of the device using a syringe.
4. Rinse the devices under lukewarm running water for a minimum of one (1) minute, while agitating the devices. Agitation includes actuating all movable parts, such as opening and closing hinges and moving the devices around under the running water.
5. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of device components. Use a syringe to flush any lumens.
6. Place the devices back into the designated locations of the case/tray and load the case/tray set into an automated washer (Getinge 86-Series, Steris 444, or equivalent).
7. The washer cycle parameters are as follows:

Phase	Recirculation Time (min.)	Water Temperature	Detergent
Pre-Wash 1	2:00	Cold Water	N/A
Wash 1	4:00	Hot Water	Enzymatic Cleaner
Wash 2	3:00	60 C (140 F)	Mild Detergent
Rinse 1	2:00	Hot Water	N/A
Dry	7:00	N/A	N/A

a) Utilize OptiPro or Enzol enzymatic cleaner or equivalent.
b) Utilize Prolystica® 2X mild detergent or equivalent.
c) Only purified water that has been filtered using deionization, reverse-osmosis, or ultra-filtration should be used for all final rinsing.
d) Visually examine to determine if all adherent visible soil has been removed. Repeat the cleaning procedure if visible debris is detected.

Steam Sterilization Instructions – Instrument Case/Tray and Implant Case/Tray

1. All instruments and implants should be inspected prior to use or sterilization for corrosion, pitting, discoloration, cracking, or anything that might indicated excessive wear or improper function. If any part shows excessive wear or improper function, return to OsteoCentric for a replacement.
2. Visually inspect the instrument tray and the implant tray and content for dry blood or other contaminants.
   - Check the inner diameter of the tissue dilators, 24mm cannula, and the 12mm sleeve.
   - Check the inner diameter (cannulation) of the 4.0mm, 6.0mm, 7.5mm, and 12mm drillbits.
   - Check the inner diameter (cannulation) of the small and large hex drivers.
   - Ensure the BladeX cutting blade was removed and discarded properly.
   - Check the inner surfaces, mating surfaces, and crevices of the Blade-X instrument.
   - Check the inner diameter (cannulation) of the graft tube and suction tube.
   - Check the inner diameter of the depth gauge and impactor.
   - Check the inner diameters (cannulation) of the 2.0 guide wire.
   - Check the inner implants and blades for any contamination.
3. Return the instruments and unused implants to their designated location in the sterilization tray.
4. Any instruments or implants not stored in the tray should be sterilized individually per validated hospital procedure.
5. Sterilize the Integrity-SI instruments and implants prior to use according to the following parameters:

Method	Steam
Cycle Type	Pre-Vacuum
Pre-Condition	3 Pre-Conditioning pulses
Temperature	132°C (270°F)
Full Cycle Time	4 minutes
Minimum Dry Time	30 minutes
Configuration	Double wrapped using an FDA cleared wrap

Blade-X® Disassembly/Assembly:

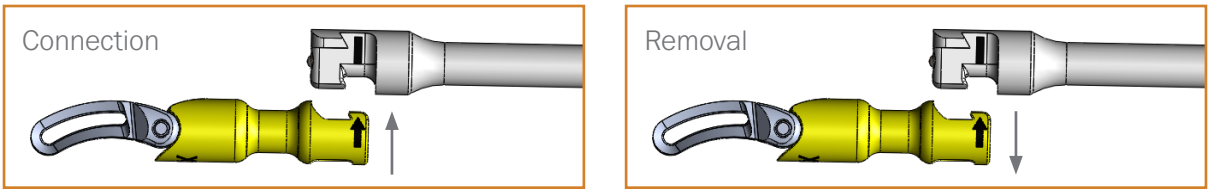
This disassembly procedure is intended for the post-surgical cleaning and sterilization of the Integrity-SI Blade-X instrument. The Blade-X blade is provide non-sterile in the Implant steam sterilization case/tray.

The blades are for single use only and is not intended for reprocessing.

Unused blades may be re-steam sterilized.

Blade Removal:

The Blade-X blade is supplied non-sterile and housed in the Implant steam sterilization case/tray. The blade is inserted onto the Blade-X central shaft by sliding the blade onto the shaft from the side, as indicated in the picture below. The blade will click into place when properly installed. The blade is removed following a procedure (prior to cleaning and sterilization) by sliding the blade in the direction opposite the insertion arrow.



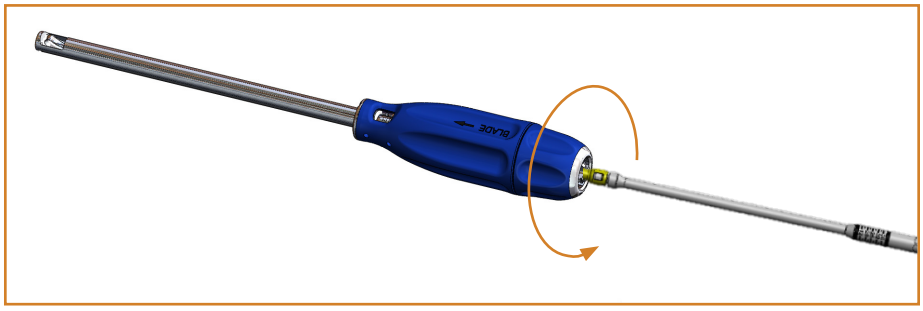
To disassemble the instrument, turn the knob on the Blade-X handle counterclockwise until the blade is fully retracted into the shaft and the central shaft can be pulled out of the instrument. Remove the blade by sliding it in the opposite direction of the arrow marked on the blade. The Blade-X instrument and the central shaft both have designated locations in the sterilization tray.

Note: Re-assembly should be done in the operating room, since the blade must be inserted on the central shaft before the instrument is fully assembled.

To re-assemble the Blade-X instrument assembly for surgery, first attach the desired blade size to the central shaft. Next, insert the central shaft and blade into proximal end of the Blade-X instrument leading with the blade. Take care to ensure that the arrow and the word “BLADE” on the Blade-X handle are in line with the arrow and “BLADE” laser mark on the central shaft. Insert the central shaft until it is fully seated, and the threads are able to engage when the Blade-X Knob is rotated.

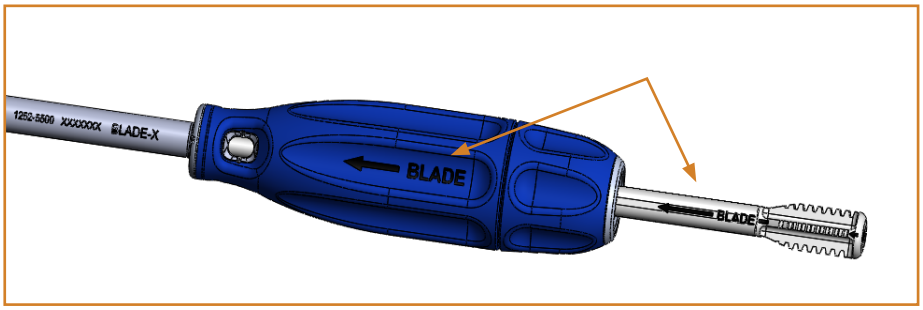
Discard of any used Blade-X blades according to standard practices for sharps and place the central shaft and Blade-X instruments in their appropriate places in the sterilization tray before reprocessing.

For removal: rotate knob counterclockwise to retract blade until the central shaft can be pulled out of the Blade-X instrument.



Direction of insertion: central shaft and Blade into Blade-X - opposite direction for removal.

Central shaft insertion with “BLADE” aligned.



Storage and Handling:

1. Store all packaged implants and instruments at room temperature.
2. Handle all implants and instruments with care to prevent damage.

OsteoCentric TECHNOLOGIES

Symbols Glossary:

Symbol	Symbol Title	Reference Number	Explanatory Text
	Catalogue number	5.1.6.(1)	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Batch Code	5.1.5.(1)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Prescription only	N/A	Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Consult instructions for use	5.4.3(1)	Indicates the need for the user to consult the instructions for use.
	Do not reuse	5.4.2(1)	Indicates a medical device that is not to be re-sterilized.
	Manufacturer	5.1.1.(1)	Indicates the medical device manufacturer.
	Date of Manufacture	5.1.3.(1)	Indicates the date when the medical device was manufactured.
	Non-Sterile	5.2.7(1)	Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged - consult instructions for use	5.2.8(1)	Indicates that a medical device should not be used if package has been or opened damaged. User should consult the instructions for use for additional information.
	Caution	5.4.4(1)	Indication that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action to avoid undesirable consequences.

(1) ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

OsteoCentric TECHNOLOGIES

Manufacturer:

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OsteoCentric SI FUSION | UnifiMI An OsteoCentric Technology | BladeX

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