

XYcor[®] Expandable Spinal Spacer System

GENERAL INFORMATION:

The XYcor Expandable Spinal Spacer System (XYcor System) is an intervertebral body fixation system consisting of implants with various widths, heights, and lordosis to accommodate individual patient pathology. The system implants are manufactured from implant grade titanium (Ti 6Al 4V per ASTM F136) and the instruments are manufactured from surgical grade stainless steel. The implants are intended for use with supplemental spinal fixation; such as the Alphatec Spine Zodiac[®] Spinal Fixation System, Aspida[™] Anterior Lumbar Plating System, ILLICO[®] MIS Posterior Fixation System, ILLICO[®] FS Facet Fixation System, the BridgePoint[™] Spinous Process Fixation System, or the Arsenal[™] Spinal Fixation System.

INDICATIONS:

When used as an Intervertebral Body Fusion device, the XYcor Expandable Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The XYcor Expandable Spinal Spacer System is intended for use with autograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

When used as a Vertebral Body Replacement device, the XYcor Expandable Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable partial or total vertebral body due to tumor or trauma (i.e. fracture). VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The XYcor Expandable Spinal Spacer System is intended for use with autograft and / or allograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

CONTRAINDICATIONS:

The XYcor System is contraindicated for:

1. Active systemic infection or localized or spinal infection; Morbid obesity;
2. Signs of local inflammation;
3. Fever or leukocytosis;
4. Demonstrated allergy or foreign body sensitivity to any implant materials;
5. Any medical or surgical condition which would preclude or impede the potential benefit of spinal implant and/or spinal fusion surgery, which could include, but not be exclusive to, elevated erythrocyte sedimentation rate, unexplained inflammatory / disease processes, elevation of white blood cell count (WBC), marked left shift in the white blood cell count differential;
6. Distorted anatomy, due to congenital or remote post traumatic/post infectious abnormalities;
7. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication as this condition may limit the degree of obtainable correction and/or height restoration, the amount of mechanical fixation, and/or the quality of the bone graft);

8. Any case in which a bone graft and fusion technique or where fracture fixation is not performed or required;
9. Any operative case utilizing the mixing of dissimilar metals from different components;
10. Patients having inadequate soft tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
11. Any case not described in the indications;
12. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, smoking, occupation, or lifestyle may interfere with their ability to follow postoperative instructions and/or activity restriction guidelines and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

WARNINGS:

The implants are provided sterile:

- a. Do not re-sterilize implants.
 - b. Do not use implants if package is opened or damaged or if expiration date has passed.
1. Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudarthrosis (i.e., non-union), fracture of the vertebra, vertebral endplate injury, neurological injury, and vascular or visceral injury.
 2. The potential for satisfactory anterior column support is increased by the selection of the proper device size. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. 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.
 3. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
 4. Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Avoid coupling of stainless steel with XYcor Spinal Implants.
 5. This system has not been evaluated for safety and compatibility in the MR environment; this system has not been tested for heating or migration in the MR environment.
 6. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.

PRECAUTIONS:

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 on the performance of the intervertebral body fusion device.

1. The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct handling of the implant is extremely important. Contouring of this titanium implant should not be done. The operating surgeon should avoid notching, scratching or reverse bending of the implants.
4. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

POSSIBLE ADVERSE EFFECTS:

This list may not include all complications caused by the surgical procedure itself.

1. Bending or fracture of implant.
2. Loosening and or collapse of the implant.
3. Implant material sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
9. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10. Bursitis.
11. Paralysis.
12. Death.
13. Spinal cord impingement or damage.
14. Fracture of bony structures.
15. Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome, Types I and II, including dyesthesias / hypesthesias.
16. If a pseudarthrosis occurs with XYcor Implant, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.

IMPORTANT NOTIFICATION TO THE OPERATING SURGEON:

Spinal surgery, and particularly vertebral body replacement / corpectomy, should only be undertaken by a spine fellowship trained surgeon after the surgeon has completed hands-on training in various methods of spinal fixation, and particularly those applicable to the XYcor

System. The surgeon should have a thorough knowledge about spinal anatomy and biomechanics. A surgical technique manual is available for detailed instructions on the correct use/indications of XYcor System for use in vertebrectomy / corpectomy and should be reviewed by the surgeon and operative team prior to any use of the implant and its techniques. The contents of this manual alone are not adequate for complete instruction in the use of this device. Even experienced spine surgeons may require additional skills best acquired by working with a surgeon experienced with the XYcor System and technique or through a course of formal instruction with laboratory/bench training. Lack of experience or expertise with these implants and/or techniques may result in complications.

Titanium implants cannot be fabricated/constructed to last and/or function indefinitely, given the constraints / limitations imposed by anatomy and surgical materials. The purpose of the XYcor System is to provide immediate spinal stability when used in conjunction with supplemental internal fixation and to allow consolidation of a fusion mass. If any implant breaks/fails, the decision to remove it, and the approach selected, must be made by the surgeon, who must take into consideration the condition of the patient and the risks associated with planned removal and/or the presence of a failed implant.

POSTOPERATIVE IMMOBILIZATION:

Postoperative external immobilization, i.e. bracing and/or casting is recommended, at the surgeon's discretion, as is a comprehensive postoperative core stabilization physical therapy program. Instructions to the patient to reduce stress on the implant(s) are an equally important component of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure and delayed/non-union.

REPROCESSING OF REUSABLE INSTRUMENTS – Important information for all instruments General Information for all Instruments:

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the *CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008"*.
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 "Water for the reprocessing of medical devices, 2014"* for example, DI / RO water.

Instrument Preparation:

- Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to lubrication and sterilization.
- All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (*Hinge-Free*® for example).

Cleaning Instructions for all Instruments:

- Instruments must be cleaned prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Disconnect all handles/knobs prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents of travel.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- Visually inspect each instrument and tray for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely. Visual inspection must be performed at each cleaning to determine if an instrument/ tray is acceptable for use. If an instrument/tray is not acceptable for use, return to the manufacturer.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps for Instruments

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as <i>Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner</i> or equivalent, per manufacturer's recommendations and submerge device in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the device using an appropriately sized soft bristled brush, such as a Spectrum Surgical code #M-16 or 45-542 (or equivalent), to brush the lumen for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for the hard to reach areas and repeat 3 times.
Step 4	Rinse devices in DI / RO water for a minimum of 1 minute.
Step 5	Prepare cleaning solution, such as <i>Prolystica® 2X Concentrate Alkaline Detergent</i> , per manufacturer's recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse devices with DI / RO water to remove all detergent residues.
Step 7	Dry devices with a clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

Step 1	Complex instruments, such as those with cannulas, lumens, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe with ambient temperature tap water where debris could become trapped. Place them into the Washer/Disinfector and process through a standard surgical instrument cycle.
Step 2	PreWash, cold tap water, 2 minutes.
Step 3	Enzyme wash using cleaner such as <i>Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner</i> or equivalent, per manufacturer's recommendations, hot tap water, 1 minute.
Step 4	Detergent wash using detergent such as <i>Prolystica® 2X Concentrate Alkaline Detergent</i> , per manufacturer's recommendations, hot tap water (66°C/150°F), 2 minutes.
Step 5	Rinse 2 times, hot tap water, 15 seconds.
Step 6	Purified water rinse (66°C/150°F), 10 seconds.
Step 7	Hot air dry (115°C/239°F) for at least 10 minutes.

STERILIZATION / RESTERILIZATION:

- All instruments are provided non-sterile and must be steam sterilized prior to use in the trays provided, using the validated cycle parameters in Table 1.
- Alphatec products have been validated to achieve sterility using FDA cleared sterilization accessories (sterilization wraps, container and filters).
- Trays must be double wrapped and individual instruments must be double wrapped or sealed in sterilization pouches, so as to allow steam to penetrate and make direct contact with all surfaces.
- Instrument sets have been validated in standard configurations. No additional items should be added to the set for sterilization.

Table 1 – Sterilization Parameters

Method	Cycle Type	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

Sterilization Notes:

The cycle conditions in **Table 1** were validated and are considered adequate to achieve a SAL of 10⁻⁶

These parameters are consistent with the appropriate version of *ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.

XYcor Inserter-Remover: Accessories, Disassembly and Cleaning Instructions



XYcor Inserter-Remover (PN 38500)
(shown without accessories)

XYcor Accessories XYcor Inserter-Remover Collets



XYcor Remover Collet (PN 38501)



XYcor Inserter Collet (PN 38502)

XYcor Wrench (PN 38506) (needed for disassembly of Collets)



XYcor Inserter-Remover Impactors



XYcor Impactor, XX mm (PN 38505-XX)



XYcor Impactor, Remover (PN 38505-01)

XYcor Inserter-Remover Tamps



XYcor Remover Tamp, XX-XX mm



XYcor Inserter Tamp, XX-XX mm

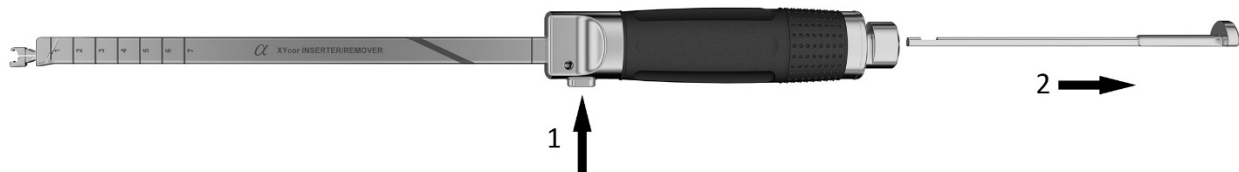
Disassembly of XYcor Inserter-Remover

Prior to cleaning the XYcor Inserter-Remover you must disassemble completely. To disassemble, remove all attached handles and any accessories that may be attached (Tamp, Impactor, Collet, Slap Hammer). See Disassembly instruction below.

To disassemble the Tamp and Impactor:

1. Press and hold the button on the inserter
2. Slide impactor out
3. Slide Tamp out
4. Release the button

Slide the Impactor out:

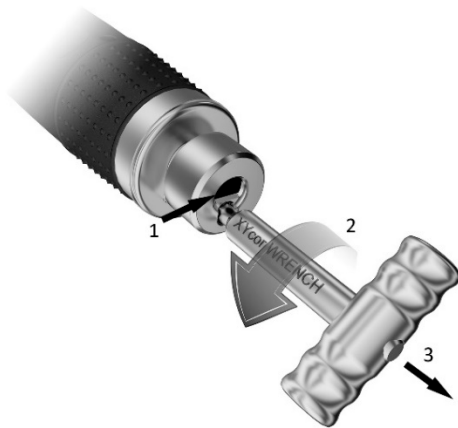


Slide the Tamp out:



To disassemble the Collet

1. Insert Wrench into the hexagonal hole
2. Turn Wrench counter-clockwise, until Collet is loose
3. Remove Wrench
4. Slide Collet out



Slide the Collet out:

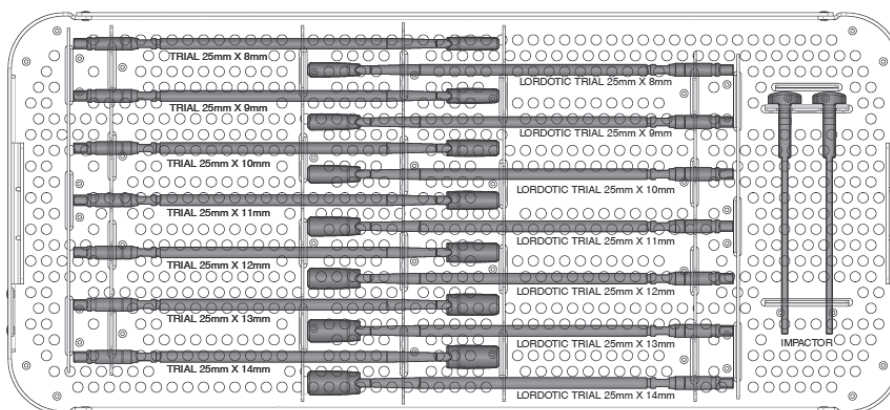
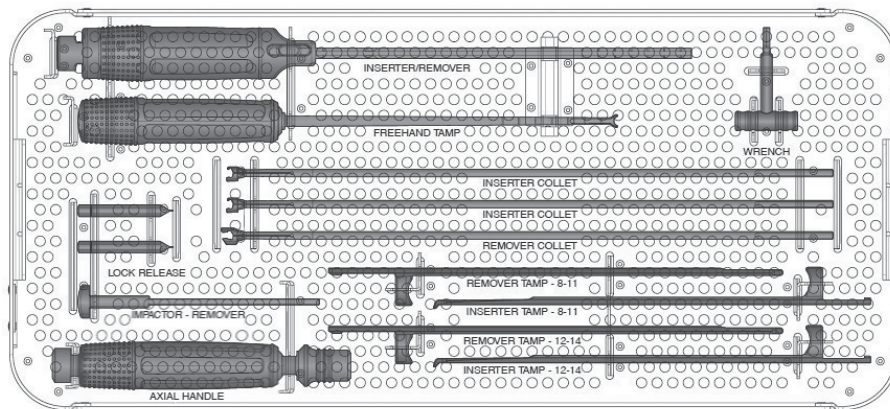


Cleaning of the XYcor Inserter-Remover and Accessories

After disassembly, clean the XYcor Inserter and Accessories as you would all instruments in the XYcor System, per the **“REPROCESSING OF REUSABLE INSTRUMENTS – Important information for all instruments”** section of this IFU.

The XYcor Inserter requires no re-assembly.

Ensure each component is placed separately in the inserts using the brackets as indicated by the text and instrument outlines. Inserts shown below.





RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

COMPLAINT HANDLING/REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, fax, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@alphatecspine.com

For Surgical Technique Guides or additional information regarding the products, please contact Alphatec Spine, Inc. Customer Service directly at customerservice@alphatecspine.com

R_xonly Caution: Federal law (USA) restricts these instruments to sale by or on the order of a physician.

For a listing of Symbols and Explanations, see alphatecspine.com/eifu

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