InTice™-C Porous TI Cervical Interbody System
Instructions for Use

GENERAL INFORMATION

The InTice™-C Porous TI Cervical Interbody System is an intervertebral fusion device, generally box or oval-shaped, and available in a variety of shapes and sizes to accommodate the individual patient anatomy. The implants are made from highly porous commercially pure titanium (CP-TI Grade 2) that complies with ASTM F67. The material is formed into an integrated titanium scaffold, *OsteoSync*™ Ti (manufactured by Sites Medical), which assists in securing the implant in the intervertebral space. The formed titanium material has a porosity created by a designed hole pattern and the superior and inferior surfaces of the implant also have a tooth pattern to help resist implant dislodgement or expulsion once placed in its desired location. The hollow center of the implant allows the device to be packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The single use implants are provided sterile and should not be reused under any circumstances.

INDICATIONS FOR USE

The InTice™-C Porous TI Cervical Interbody System is intended for spinal fusion procedures at one level (C2 – T1 inclusive) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should receive at least six (6) weeks non-operative treatment prior to treatment with the InTice™-C Porous TI Cervical Interbody System.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine (i.e. posterior cervical screw and rod systems and anterior cervical plate systems).

CONTRAINDICATIONS

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems or manufacturers.
5. Grossly distorted anatomy caused by congenital abnormalities.

6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Reuse or multiple uses.

⚠ WARNINGS

1 System instruments are provided non-sterile and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

2 As with all orthopedic and neurosurgical implants, none of the system implants should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

3 The system has not been evaluated for safety and compatibility in the MR environment. The safety of the system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

The InTice™-C Porous TI Cervical Interbody System is used for the correction and stabilization of the spine. This system is intended to be used to facilitate the development of a spinal fusion by providing stabilization until the spinal fusion occurs. This system is not intended to be the sole means of spinal support. Use of this product without a bone graft, or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, and/or breakage of the device(s) will occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful

utilization of this device by the surgeon. Furthermore, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion. 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 have an impact on the performance of the InTice™-C Porous TI Cervical Interbody System.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

PREOPERATIVE MANAGEMENT

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. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts must be clean and sterile before use.

INTRAOPERATIVE MANAGEMENT

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
4. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.

5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
7. Implants should not be reused under any circumstances.

INSTRUCTIONS FOR USE

For additional instructions regarding the proper use and application of all InTice™-C Porous TI Cervical Interbody System implants and instruments, please refer to the InTice™-C Porous TI Cervical Interbody System Surgical Technique Manual (available at no charge upon request).

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity.
3. Rigid external orthosis/bracing should be utilized until fusion is confirmed clinically and radiographically.
4. During explantation, care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

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. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.

8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (pseudarthrosis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death

PACKAGING, LABELING, AND STORAGE

The implants of the InTice™-C Porous TI Cervical Interbody System are supplied clean and STERILE. The implants are delivered packaged in double-wrapped Tyvek/PET pouches, boxed and individually labeled. The implants may be delivered individually or as a complete set. Boxes and pouches should be inspected for damage that may affect the integrity of the sterile packaging prior to use. Use care in handling and storage of the implant components.

The accompanying instruments are provided clean and NON-STERILE and are contained within specially designed trays which are to be sterilized directly. Instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments have been damaged during the storage processes.

STERILIZATION

All instruments are provided clean and non-sterile and must be sterilized before use. Instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile instruments should be autoclave sterilized using the following validated cycle parameters:

Saturated steam method, pre-vacuum air removal, 270^{o} F (132^{o} C), 4-minute exposure time, 30-minute dry time, in a double–wrapped case configuration.

Use FDA cleared sterilizers and sterilization packaging materials/accessories (wraps, biological indicators, chemical indicators, etc.) for sterilization of instruments.

DO NOT stack instrument trays during sterilization.

CLEANING OF INSTRUMENTS

⚠ Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments and trays prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. 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 (Enzol® Enzymatic Detergent or equivalent) to delay drying.

2. Loosen and disassemble instruments with removable parts in accordance with **Table 1** below.

Table 1 – Instruments Requiring Disassembly for Cleaning

Part Number	Instrument Name	Disassembly Instructions
X003-0015, X003-0016, X034-0015, X034-0020	Inserter Assembly	Ensure that the inserter threaded rods have been properly unthreaded and removed from the inserter assembly prior to cleaning.
X003-0022, X034-0017, X034-0023	Inserter Threaded Rod	

3. **Table 2** below describes the required steps for thoroughly cleaning the system instruments.

Table 2 – Cleaning Parameters

Step	Agent / Instructions	Time (mm:ss)
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	3:00
	Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for three (3) minutes. While submerged, use a soft bristle brush that is intended for use with surgical instruments, to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.	
2. Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for one (1) minute.	
3. Ultrasonic Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for ten (10) minutes.	
4. Ultrasonic Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for one minute.	
5. Inspection	Unaided eye	
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. If instruments are not dry, use filtered pressurized air or lint-free wipes to dry.

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INSPECTION

1. Carefully inspect each instrument and tray to ensure all visible blood and soil has been removed. Repeat cleaning if necessary.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation.
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 Xtant Medical representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Xtant Medical representative for a replacement.

Manufacturer:

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

REF
Part Number
X098-2003-EN Rev A
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