English

TM ARDIS® INTERBODY SYSTEM

(Refer to 07.01471.001 for Ardis Interbody System instructions for use)

Important Notes:

Physician Counseling:

Before using a product placed on the market by Zimmer Biomet, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique, and the Reusable Instrument lifespan manual (1219-GLBL)).

Zimmer Biomet is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of Zimmer Biomet.

Surgical instruments and provisionals are intended to be used by orthopaedic surgeons, facility central process staff to handle, clean, and resterilize surgical devices, and sales representatives who interact with Health Care Professionals and Surgery Center Staff.
Sterilization case components are intended to facilitate the organization, identification, storage, transportation cleaning and sterilization reprocessing of instruments and provisionals.

These items are medical devices as identified with the MD symbol on the package label. Devices that have been terminally sterilized via gamma irradiation are represented with an R STERILE R . Devices which are provided non-sterile may be identified with the symbol NON STERILE on the package label. Single use devices sold sterile may be reprocessed if not used, unless labeling indicates the instrument is not to be reprocessed as indicated by the Do Not Resterilize symbol on the package label 2 STERILIZE .

Patient Counseling Information:

Complications and/or failure of spinal implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, smokers, physically active patients, and/or patients who fail to comply with postoperative treatment requirements. There is a risk that the implant may fracture or loosen from any variety of causes including, in the case of a fusion device, from failure to obtain fusion. Spinal implants are not as strong, reliable, or durable as natural, healthy tissues/bones, therefore such devices may require removal or revision. The patient must be counseled on all postoperative restrictions, particularly those related to occupational and recreational activities (e.g., sports) and the possibility that the implant or its components may be temporary, fail, or require revision.

DESCRIPTION:

The TM Ardis implant is a single device manufactured wholly from Trabecular Metal™ (porous tantalum) material, a highly porous, three-dimensional biomaterial designed for biologic fixation. The TM Ardis implant is a convex, straight TLIF or PLIF device for interbody fusion of the anterior column of the spine. TM Ardis is designed for fusion at one or two contiguous levels in the lumbosacral region (L2-S1). The superior and inferior surfaces of the device are textured and convex to provide increased stability. The device also has

two slots on the posterior end of the device to mate with the insertion instrument. The height is measured at the device's tallest point.

These implants are intended for single use only and must not be reused under any circumstances.

The TM Ardis system contains implants, offered in a variety of cross-sectional geometries and sizes to accommodate different patient anatomy and physician preference, and instrumentation for insertion and neural element protection. Additionally, the TM Ardis System utilizes the Ardis Instrumentation System for site preparation and trailing.

The Ardis instrumentation system (refer to 07.01471.001 for instructions for use) is comprised of instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel, and/or polymeric materials.

The instrument cases may be multi-layered with various trays, holders and silicone mats to hold surgical instrumentation in place during handling and storage.

The perforated instrument cases allow sterilization of the contents to occur in an FDA cleared steam autoclave utilizing a sterilization cycle that has been validated by the user for equipment and procedures employed at the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared sterilization wrap to maintain sterility.

For detailed information concerning the identification of the product (such as device name, ref.no.), please refer to the labelling on the package and/or the marking on the device.

MATERIALS:

Implants: Trabecular Metal (porous tantalum).
Instruments: Stainless Steel, Aluminum, Silicone Rubber, Radel, AlTiN PVD coating, TiN PVD coating, Nylon.

INDICATIONS:

Inside the United States Indications (06-701-XXXX):

The TM Ardis® Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2- S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The TM Ardis® Interbody System device is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

Outside the United States Indications (06-702-XXXX):
The TM Ardis® Interbody System is indicated for use as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non- operative treatment.

The TM Ardis® Interbody System device is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

CONTRAINDICATIONS:

1. Active local infection in or near the operative region.

2. Active systemic infection and/or disease.

3. Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.

4. Known or suspected sensitivity to the implant materials.

5. Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).

6. Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs.

7. Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g., current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury).

8. Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure, or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy, and multiple sclerosis.

9. Pregnancy.

10. Patients unwilling to follow postoperative instructions, especially those in athletic and occupational activities.

11. Morbid obesity.

12. Conditions other than those indicated.

13. Prior surgical procedure using the desired operative approach.

14. Current metastatic tumors of the vertebrae adjacent to the implant.

15. Symptomatic cardiac disease.

16. Skeletal immaturity.

17. Grossly distorted anatomy.

18. Prior fusion at the level(s) to be treated.

UTILIZATION AND IMPLANTATION:

1. A surgical technique is available to instruct the user on the proper use of instrumentation and site preparation. Instruments are available to size and implant the components.

2. The appropriate placement of the components helps avoid inappropriate loading of the components and may improve service life of the implants.

3. The surgeon must be familiar with the appropriate technique to implant the supplemental fixation and the associated instruments. To obtain a surgical technique, please contact your local sales representative or call Zimmer Biomet Spine at 800-655-2614 (US) or +33 (0)5 56 00 18 20 (International).

WARNINGS:

1. Surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and alcohol abuse may lead to unsuccessful results.

2. 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 and transmission of infectious agents.

3. Appropriate device selection is crucial to obtain proper fit and to decrease the stress placed on the implant.

4. Components of competitive spinal systems should not be used with the TM Ardis device.

5. Delayed healing can lead to fracture or breakage of the implants due to increased stress and material fatigue. Patients must be fully informed of all the risks associated with the implant and the importance of following postoperative instructions regarding weight bearing and activity levels to facilitate proper bone growth and healing.

6. Implants must not be modified or otherwise processed in any way.

7. Care must be taken to avoid using dissimilar metals in contact with one another, as corrosion may occur. Additional fixation instrumentation that is used to stabilize the affected level must be made of compatible materials, such as titanium or titanium alloy. Corrosion may accelerate metal fatigue and lead to failure of the implant.

8. The implant must be handled carefully following the manufacturer's instructions to prevent damage to the implant.

9. Once a device has been implanted, it must never be reused. If the package is damaged or opened but the device is not used, or if the expiration date has passed, the device must be returned to Zimmer Biomet. The device *must not* be resterilized by the end user.

10. The surgeon must be familiar with the appropriate technique to implant the supplemental internal fixation and the appropriate hardware.

11. *Results may be worse with multilevel disease. Supplemental fixation is required.* The surgeon should be familiar with fixation techniques and appropriate hardware. Only supplemental fixation made of titanium or titanium alloy should be used with Trabecular Metal devices.

12. MRI Compatibility:

    - The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

    - The TM Ardis Device has not been evaluated for safety or compatibility in the MR environment.

    - The TM Ardis Device has not been tested for heating or migration in the MR environment.

    - Patients with previous spinal surgery at the level(s) to be treated may have different clinical

outcomes compared to those without a previous surgery.

SURGEON PRECAUTIONS:

1. The implantation of an 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. The surgeon must have a thorough knowledge of the mechanical and material limitations of surgical implants made of Trabecular Metal and be thoroughly familiar with the surgical technique for implanting the TM Ardis device for the given Indications for Use.

3. Based on fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

4. The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning the surgery. Additionally, the packaging and implant should be inspected for damage prior to implantation.

5. In the event that removal of the implant is considered (e.g. due to loosening, fracture, corrosion or migration of the implant; infection; increased pain, etc.), the risks versus benefits should be carefully weighed. Such events can occur even after healing, especially in more active patients. Appropriate postoperative care must be given following implant removal to avoid further complication.

6. The surgeon must be thoroughly familiar with the options for supplemental internal fixation systems and the associated surgical techniques.

7. Implants must be fully seated within the inserter prior to use. Care must be taken not to over-tighten the implant-inserter assembly. Additionally, care must be taken not to manipulate the inserter implant interface in a way not recommended by the surgical technique.

8. The surgeon must ensure that the implant is properly seated prior to closing of the soft tissue.

9. Extreme caution must be used around the spinal cord, nerve roots and blood vessels.

PATIENT PRECAUTIONS:

1. Postoperative care instructions are extremely important and must be followed carefully. Non-compliance with postoperative care instructions could lead to failure of the device and the possibility of additional surgery to remove the device.

2. The patient should limit activities that result heavy lifting until a physician determines solid bony fusion is achieved.

3. An orthotic brace may be worn following surgery for support. The attending physician, based upon each patient's clinical progress, will determine whether a brace is appropriate and, if necessary, the length of time the brace is prescribed.

4. Non-steroidal anti-inflammatory and steroidal drugs should be avoided for at least 45 days, or as directed by a physician, postoperatively.

POSSIBLE ADVERSE EFFECTS:

As with any surgical procedure, certain complications may result.

1. Potential complications associated with the device itself include:

    - Bone lysis associated with particulate metal debris,
    - Device bending,
    - Device fracture,
    - Device loosening,
    - Device migration.

2. When using autogenous bone graft, failure to properly fill and/or compress the graft material into the area surrounding the implant may result in delayed healing and/or nonunion.

3. If either the iliac crest, fibula or rib are utilized as a secondary donor site for bone graft material, associated complications which may occur include; hematoma requiring treatment, persistent donor site pain, pelvic instability (iliac crest only), nerve damage with sensory loss, deep or superficial wound infection, herniation (iliac crest only) or excessive bleeding.

4. Possible other Adverse Effects associated with use of the TM Ardis device include:

    - Abscess,
    - Adjacent segment disease,
    - Adverse reaction to anesthesia,
    - Allergic reactions to prophylactic antibiotics or blood transfusions,
    - Allergic reaction to the implant(s),
    - Anesthetic or post-anesthetic reactions,
    - Anterior longitudinal ligament penetration,
    - Arachnoiditis,
    - Arrhythmia,
    - Atelectasis,
    - Back pain,
    - Bladder dysfunction,
    - Bone or vertebral fracture during insertion of the device,
    - Bone lysis associated with particulate metal debris from the supplemental internal fixation,
    - Bone resorption,
    - Bursitis,
    - Cauda equina syndrome,
    - Cellulitis,
    - Cerebrovascular accident,
    - Constipation,
    - Cord injury,
    - Death,
    - Decreased leg strength,
    - Decreased reflexes,
    - Deep vein thrombosis,
    - Delayed union or nonunion,
    - Disc herniation,
    - Donor site events (if additional donor site is necessary)
    - Dural tear, leak
    - Failure of instrumentation,
    - Foot drop,

- Fracture of pedicle bone,
- Graft failure (fracture, resorption, etc.),
- Graft expulsion,
- Great vessel damage,
- Hematoma,
- Hemorrhage,
- Ileus,
- Incisional hernia,
- Incisional pain,
- Infection throughout the body (systemic),
- Infection of the wound,
- Ischemia,
- Leg pain,
- Loss of spinal curvature,
- Loss of reduction,
- Malpositioned screws,
- Myocardial infarction,
- Neurapraxia,
- Nerve root injury,
- Organ, nerve, blood vessel or muscle damage,
- Osteoporosis local to implant site,
- Pain,
- Painful hardware,
- Paralysis,
- Screw loosening,
- Screw migration,
- Pneumonia,
- Pseudarthrosis,
- Pulmonary embolism,
- Radiculopathy,
- Recurrent deformity,
- Reflex sympathetic dystrophy (RSD),
- Scar formation,
- Seroma,
- Spinal stenosis,
- Spondylolisthesis,
- Subsidence of the implant,
- Swelling,
- Syringomyelia,
- Thromboembolism,
- Thrombophlebitis,
- Thrombosis,
- Tumor formation and/or recurrence,
- Urinary tract infection,
- Wound dehiscence.

5. Complications which may be associated with thoracotomy include:

- Acute respiratory distress syndrome,
- Atelectasis,
- Pneumothorax,
- Pulmonary contusion,
- Upper respiratory tract infection.

6. Additional complications that are not anticipated may also occur.

7. Reoperation may be necessary to correct adverse effects.

IMPLANT STERILITY:

The TM Ardis devices are sterilized by means of ^{60}Co gamma irradiation at a minimum dose of 25 kGy. The date of the component sterilization or expiration is printed on the outer package label. Resterilization of components is specifically not recommended. Both outer and inner package (inner contains the component) seals should be thoroughly inspected for defects or leaks before using the implant.

INSTRUMENT PROCESSING INSTRUCTIONS:

The instructions provided in this package insert have been validated by Zimmer Biomet as being capable of preparing orthopaedic devices for use. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Instrument Use and Care:

1. Failure to follow these instructions could result in instrument or provisional breakage and potential adverse effects on user(s) or patients.

2. Except for general surgical instruments and/or those instruments described in the product-specific surgical technique, use only instruments and provisionals specifically designed for use with their associated devices.

3. Misuse reduces useful life and/or increases injury risk. Repeated processing according to these instructions has minimal effect on Zimmer Biomet's reusable manual instruments. End of life is normally determined by wear and damage due to use.

Warnings:

1. Instruments must be **thoroughly cleaned** prior to sterilization. Instruments that are not clean may not be effectively sterilized. Do not use devices suspected to be unclean.

2. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

3. Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

4. When handling sharp instruments, use extreme caution to avoid injury.

5. Unless otherwise indicated, instrument sets are provided non-sterile and must be sterilized prior to use.

6. Do not reuse instruments labeled for single use only. Reuse may adversely affect performance of the instrument. Re-use 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 re-use of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

7. Flash autoclaving should be avoided whenever possible. Instruments should never be flash autoclaved in an instrument case.

8. Do not subject plain or anodized aluminum components to acidic ultrasonic cleaning agents or stainless steel to chlorine or chloride-based agents. Corrosion or discoloration may occur.

9. Do not use cutting/sharp instruments with dull or deformed edges or instruments/ provisionals that are deformed, corroded, damaged or worn. They may not perform as intended.

10. Do not clean polyetherimide components with phenol-based detergents. Crazing or cracking may occur.

11. Do not alter a device in any way unless this is expressly envisaged in the design and in the product-specific surgical technique.

12. Do not stack instruments or place heavy instruments on top of delicate devices.

Precautions:

1. Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Inspect all instruments prior to use.

2. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.

3. Polymer provisionals may show eventual surface degradation from the heat and chemicals used in hospital cleaning and steam sterilization. Replace the provisional when degradation makes cleaning difficult or if the surface becomes chalky.

4. Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

5. Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.

6. Rasps – A rasp must advance each time it is struck with a mallet. There is a higher risk of bone fracture or rasp impaction when it does not advance or if the rasp is dull.

7. Cannulated instruments – Clean cannulated instruments intraoperatively to prevent accumulation of debris.

8. Guide Wires—Check the guide wire position frequently using fluoroscopy to prevent unintended guide wire advancement and/or penetration into the surrounding tissues.

9. Any decision to leave or remove broken instruments (e.g., drill fragments) is left to the surgeon's discretion and must take into account the associated risks.

10. Metal instruments or fragments can be located by radiography or fluoroscopy. Nonmetal instruments or fragments may not be located by radiography or fluoroscopy, and should be accounted for at the end of

the surgical procedure.

11. Polymer fragments can be located by medical ultrasonography examination, depending on the size, location, and properties of the polymer.

12. Only devices manufactured and/or distributed by Zimmer Biomet should be included in Zimmer Biomet instrument trays. Zimmer Biomet's validated reprocessing instructions are not applicable to Zimmer Biomet trays that include devices not manufactured and/or distributed by Zimmer Biomet.

Cleaning:

1. Instruments must be cleaned in accordance with institution protocols and procedures prior to sterilization.

2. Thoroughly clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments, as cleaning can be difficult. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.

3. Loosen and/or disassemble instruments with removable parts. Refer to the TM Ardis Interbody System Surgical Technique (LIP-46) for TM Ardis Inserter disassembly instructions.

4. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturer's instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes.

If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. Zimmer Biomet Spine recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.

Disinfection Instructions

1. Completely submerge instruments in an enzyme solution and allow to soak for a minimum of 5 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush.

2. Remove the device from the enzyme solution and submerge in purified water for a minimum of 2 minutes.

3. Rinse the device in purified water for a minimum of 2 minutes or until thoroughly clean and there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.

4. Ultrasonic cleaners can be used as an adjunct to the manual cleaning process described above. Completely submerge the device in the cleaning solution and sonicate for 10 minutes at 45-50 kHz.
5. A high level disinfectant can be used to render instruments safe to handle after cleaning. The disinfectant used should be a FDA-cleared chemical agent such as Cidex® OPA. Disinfectant soak times should be performed per the disinfectant manufacturer's instructions. The instruments should be thoroughly rinsed in purified water for a minimum of 4 minutes or longer if specified by the disinfectant manufacturer.

6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Inspection:

1. Carefully inspect each instrument to ensure it is visibly clean and all visible blood and soil has been removed, this is the endpoint of the cleaning process, only at this point may the instrument be sterilized. If the instrument is not visually clean, repeat the cleaning and disinfection processes. If after multiple cleaning processes, the instrument cannot be made visibly clean, do not use and contact customer service or your Zimmer Biomet Spine representative for a replacement.

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 cases, do not use and contact customer service or your Zimmer Biomet Spine representative for a replacement.

4. If corrosion is noted, do not use and contact customer service or your Zimmer Biomet Spine representative for a replacement.

5. See Reusable Instrument Lifespan Manual 1219-GLBL for guidance on determining reusable instrument suitability for use (https://labeling.zimmerbiomet.com/).

Sterilization:

All instruments are supplied visually clean and non-sterile and must be sterilized by the hospital prior to use. The instruments should be steam sterilized in their specific case, tray, and lid. For trays that bear the material designation “Stainless Steel” at the bottom, center of the tray, use Sterilization **Cycle 1** or **Cycle 2** (Table 2). For Aluminum trays that do not bear the material designation “Stainless Steel” at the location specified, default to Sterilization **Cycle 3** (Table 3). See Table 2 and Table 3 for the recommended sterilization parameters that have been validated by Zimmer Biomet to provide a 10^{-6} sterility assurance level (SAL).

These prevacuum sterilization cycles are not considered by the FDA to be standard sterilization cycles. Use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators and sterilization containers) that have been cleared by the US Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments.

The hospital is responsible for in-house procedure for the inspection and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.

Sterilizer manufacturer recommendations should **always** be followed. When sterilizing multiple instruments sets in one sterilization cycle, ensure that the manufacturer’s maximum load is not exceeded.

Ethylene oxide (EO), gas plasma and dry heat sterilization methods are **not recommended** for sterilization of Zimmer Biomet reusable instruments. Steam (moist heat) is the recommended sterilization method for Zimmer Biomet instruments.

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed. Instruments should be positioned to allow the sterilant 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 disassembled.
Remove all instrument packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all instrument kits used in surgery as well as any unused instrument kits that were in the surgical suite.
Provisionals and other instruments are used to determine sizing before the sterile package needs to be

opened. Provisionals and instruments should be sterilized in accordance with institution sterilization protocols and procedures. Instruments must be cleaned in accordance with institution protocols and procedures prior to sterilization. Further, all sterilization methods must comply with the appropriate AAMI/ANSI/ISO guidance's and standards, and a sterility level of 10^{-6} must be achieved.

Table 2. Recommended Steam Sterilization Parameters for Stainless Steel Cases

Cycle Number	Method	Cycle Type	Temperature	Exposure Time	Wrap	Dry Time
Cycle 1	Steam	Pre-vacuum	132°C 270°F	4 minutes	2 times	80 minutes
Cycle 2	Steam	Pre-vacuum	134°C 273°F	3 minutes	2 times	90 minutes

Note: Do not stack instrument cases directly on top of each other during sterilization, doing so may prevent the kits from fully drying.

Table 3. Recommended Steam Sterilization Parameters for Aluminum Cases (not for TM Ardis)

Cycle Number	Method	Cycle Type	Temperature	Exposure Time	Wrap	Dry Time
Cycle 3	Steam	Pre-vacuum	132°C 270°F	15 minutes	2 times	60 minutes

Note: Cycle 3 has been specifically validated for PEEK Ardis Instruments housed in aluminum cases. The TM Ardis Instruments should never be sterilized in these aluminum cases.

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

Additional information can be found in the Zimmer Biomet Manual Orthopaedic Surgical Instruments: Recommendations for Care, Cleaning, Maintenance and Sterilization (97-5000-170-00). To obtain this document, please contact your local sales representative or call Zimmer Spine Biomet at 800.655.2614 (US) or +33 (0)5 56 00 18 20 (International).

Important Notice

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INSTRUMENT CARE-SPECIAL PRECAUTIONS:

Proper handling, decontamination (including prerinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments and provisionals. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., drill bits, reamers, rasps, gauges, guides, and chisels), driving instruments (e.g., drivers, mallets, tamps, pins, extractors, and impactors) and provisionals.
These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.

Storage and Handling:

Non-sterile provided instruments are to be stored in the appropriate packaging that protects the instruments from damage or in an appropriate instrument tray. Instruments must be examined for possible damage before use. Protective caps or other protective elements must not be removed until immediately before use.

Transportation:

- Transport instruments in their designated instrument trays.
- Instrument trays ensure that every instrument is kept in a way that they do not receive any damage and that their functionality is preserved during transportation.

Reporting Problems:

The user and/or patient should report any suspected serious incident related to the device by informing the manufacturer and the competent authority of the respective EU Member State in which the serious incident has occurred.

Disposal Information:

After use, the instrument is a potential biohazard, since it may be contaminated with blood or other body fluids, bone or tissue. Handle and dispose of product in accordance with accepted medical practice and with applicable local, state and national laws and regulations. Any sharp objects should be disposed immediately after use into a sharps container conforming to EN ISO 23907-1 or equivalent following the requirements in 2010/32/EU directive or equivalent national laws. The sharp instruments must not be bent, broken or re-sheathed prior to disposal.

Please contact Zimmer Biomet at the following number if you have additional questions. In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-574- 267-6131.

Contents of This Package Sterile Unless Damaged or Opened.

Made in the USA

Zimmer Trabecular Metal Technology, Inc.
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Fax: 973 884 6084

EC|REP
Biomet GSCC B.V.
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4836 LD
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Fax +31 786292889

CE 1639 Single Use | Do Not Use If Package Is Damaged | Attention, See Instructions for Use | STERILE R Sterilized Using Irradiation | Rx Only

Cat #: PI047, Rev. D
03/20