NON-NAVIGATED INSTRUMENTS
PACKAGE INSERT

℞ ***Federal (United States) law restricts this device to sale by or on the order of a physician.***

DESCRIPTION OF THE MEDICAL DEVICE

The Non-Navigated instruments are:

- Designed to be used in a surgical setting to prepare the patients disc space for implant insertion.
- Delivered **STERILE** and single use or **NON-STERILE** and reusable in a tray.

INTENDED USE

The Non-Navigated Instruments are intended to aide access to the surgical site and prepare the intervertebral disc space for interbody implantation.

LIMITATIONS

With the exception of any limitations present in the WARNINGS and POTENTIAL RISKS, and PRECAUTIONS sections, there are no additional limitations when Non-Navigated Instruments are used as intended.

TARGET PATIENT GROUP

Patients indicated for lumbar interbody fusion surgery requiring surgical access to the lumbar spine.

INTENDED USER

The Non-Navigated Instruments are intended for use by a physician only and should be used by experienced spine surgeons.

INTENDED USE ENVIRONMENT

The Non-Navigated Instruments are intended to be used in an operating room or surgical setting.

DEVICE LIFETIME

The expected lifetime of the Non-Navigated Instruments single-use instruments is intended for short-term (transient use defined by the time the instruments are functioning during the clinical procedure.

The expected treatment lifetime of the Non-Navigated Instruments reusable instruments is dependent on many factors including the method and duration of each use and the handling between uses. Careful inspection and functional testing of the devices before use, as described in this document, is the best method for determining the reusable instrumentation end of life.

MATERIAL

Instruments are manufactured from surgical grade Stainless Steel (ASTM F899), 316LVM Stainless Steel (ASTM F138), PPSU (ASTM D6394), Titanium Alloy (ASTM F136), Aluminum 6061 T6 (ASTM D6394), and Nitinol (ASTM F2063). Handles are made from surgical grade Stainless Steel (ASTM F899), Aluminum (ASTM B209/211/221) and silicone. Trays are manufactured from aluminum, stainless steel, and silicone.

HOW SUPPLIED

The Non-Navigated Instruments labeled as **STERILE** are exposed to a minimum dose of 25.0 kGy gamma radiation to obtain a minimum Sterility Assurance Level (SAL) of 10^{-6}. The packaging should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize.

All **NON-STERILE** Non-Navigated Instruments must be cleaned and sterilized prior to use according to the procedures outlined in this document.

Information on the status of sterilization (sterile or non-sterile) is contained on the product label.

WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. The surgeon must ensure that all necessary instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
2. All **STERILE** instruments are designed for **single patient use only and must never be reused** under any circumstances. Reuse may lead to adverse tissue reaction, tissue damage and/or minor surgical delay.
3. All **NON-STERILE** instruments must be cleaned and sterilized prior to surgery. Failure to do so may result in adverse tissue reaction, infection, and/or revision.
4. Non-Navigated Instruments should never be used as an implanted device.

PRECAUTIONS

Preoperative:

1. Only patients that meet the criteria described in the INTENDED USE/INDICATIONS FOR USE section should be selected. Surgeons must be aware of the content of this Instructions for Use (IFU) and the applicable Surgical Technique Manuals (STG) prior to device use.
2. Patient conditions and/or pre-dispositions such as those addressed in the CONTRAINDICATIONS section of the corresponding implant IFU should be avoided.
3. Care should be used in the handling and storage of the instruments. The instruments should not be scratched or otherwise damaged. Instruments should be protected during storage especially from corrosive environments.
4. Always verify that the **STERILE** instrument is within its expiration date. Under no circumstances should damaged instruments be used. Instruments provided **STERILE** that have already been in contact with body fluids or body tissues must not be re-sterilized. The risks associated with not following these precautions are adverse tissue reaction, hardware removal, and/or implant revision.
5. All **NON-STERILE** instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

POSSIBLE ADVERSE EFFECTS

1. Bending, loosening or fracture of the instruments;
2. Sensitivity to a metallic foreign body, including possible tumor formation;
3. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
4. Infection;
5. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
6. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
7. Pain or discomfort;
8. Bone fracture at, above or below the level or surgery (fracture of the vertebra);
9. Hemorrhage of blood vessels and/or hematomas;
10. Inability to resume activities of normal daily living;

Some adverse events may occur as part of the surgical procedure but are not related to the instruments. Any serious incident that has occurred in relation to the instruments should be reported to the manufacturer and the Health Authority local to where the user and/or patient is established.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The Non-Navigated Instruments are not intended to be used in the magnetic resonance (MR) environment. As such, the Non-Navigated Instruments have not been evaluated for safety and compatibility in the MR environment. Therefore, the safety of the Non-Navigated Instruments in the MR environment is unknown.

DIRECTIONS FOR USE

The operating surgeon is solely responsible for determining an operating plan that specifies and appropriately documents the surgical technique steps:

The following conditions must be fulfilled prior to application:

- All requisite instruments components are ready to hand.
- Operating conditions are highly aseptic.
- The instruments are cleaned and sterilized prior to use according to the procedures outlined in this document.
- The instruments are complete and in working condition.
- The operating surgeon and operating team are aware of and familiar with information concerning the operating technique and associated instruments; this information is complete and ready at hand.

For complete instructions regarding the proper use and application of all Non-Navigated Instruments, please refer to the Non-Navigated Instruments or Anatomic Access LLIF Retractor Surgical Technique Manuals, as applicable (provided with the System).

CARE AND HANDLING

Certain Instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

LIMITATIONS ON REPROCESSING

All instruments provided and labeled as sterile have undergone two reprocessing procedures: cleaning and gamma radiation sterilization. The **STERILE** instruments are not to be reprocessed under any circumstances.

Repeated processing has minimal effect on the **NON-STERILE** instruments. End of life is normally determined by wear and damage due to use.

POINT OF USE

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

CONTAINMENT AND TRANSPORTATION

It is recommended that reusable instruments are reprocessed as soon as reasonably practical following use.

All instruments labeled as single use only should be disposed of after use, per the DISPOSAL OF DEVICE section below. The **STERILE** instruments are not to be reprocessed under any circumstances.

PREPARATION FOR CLEANING

Remove excess soil with a clean, lint-free, disposable, absorbent cloth.

CLEANING (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the instruments by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other – load instruments in such a way that the parts can drain.
- Use a standard instruments cycle with the following parameters (at a minimum):

Enzyme Wash	Hot (40 - 65°C) (104 - 149°F) for 3 minutes
Neutral pH Wash	60°C (140°F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90°C (194°F) for 1 minute
Dry	82°C (180°F) for 6 minutes

- Determine if the instruments are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace an instrument that cannot be cleaned.

CLEANING (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the instruments by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft bristle brush while submerged in the detergent.
- Rinse the devices in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning. Replace an instrument that cannot be cleaned.

INSPECTION and FUNCTION TESTING

Visually inspect all instruments under normal lighting to ensure the cleaning was effective. Inspect for surface damage and wear. Check for staining, discoloration, corrosion, misalignment, burrs,

[1] ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

[2] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

bent or fractured tips. Where instruments interface with other devices, inspect to ensure that the instruments properly interface. Mechanically test the working parts to verify that each instrument functions correctly. Replace any instrument that is not functioning.

Verify the legibility of all markings. Replace any instrument that is unreadable.

Repeat the cleaning and/or replace the affected instruments as needed to ensure proper operation before proceeding with sterilization.

LUBRICATION

After each use of the Anatomic Access LLIF Retractor, the device shall be thoroughly cleaned and inspected to verify that all components are free of visible soil, debris, damage, and excessive wear prior to lubrication. Lubrication shall only be applied to Retractors that are clean, dry, and have successfully passed visual inspection per Inspection and Function Testing instructions listed above. Following lubrication, the instrument shall be prepared for packaging and sterilization.

Lubricant type: After cleaning and prior to sterilization, a non-silicone, steam-permeable, medical-grade surgical instrument lubricant[3] shall be used. This lubricant is a consumable product and should be replenished as needed. Contact your institution or authorized distributor for reordering information. Refer to the lubricant manufacturer's IFU for storage and handling requirements.

Caution: Use only non-silicone instrument lubricants that are compatible with steam sterilization and approved for use on reusable Non-Navigated Instruments. Oil-based and silicone-based lubricants have not been evaluated with this device and are not recommended, as they may coat and shield residual microorganisms, reduce the effectiveness of sterilization methods (e.g., steam), cause device functionality issues, or may not be biocompatible.

Quantity and method of application: Apply appropriate amount of the non-silicone instrument lubricant to produce a thin, uniform film. Lubricant shall be applied only to the functional and movable areas of the Anatomic Access LLIF Retractor, including joints, articulating mechanisms, and other moving interfaces. Lubricant shall only be applied to the Anatomic Access LLIF Retractor when it is clean and dry. Following application, actuate all movable components through their full range of motion to ensure even distribution of the lubricant. Alternative application methods may be used, provided all movable areas of the Anatomic Access LLIF Retractor receive adequate lubrication prior to sterilization.

Verification: Do not over-apply lubricant. The Anatomic Access LLIF Retractor must not be visibly wet prior to packaging and sterilization. Components shall move freely, without residual pooling or dripping. If excess lubricant is present (e.g., visible wetness, pooling, or dripping), remove it using a lint-free wipe before proceeding to the next step.

No special facilities, tools, or additional training beyond standard reprocessing personnel qualifications are required to perform this step.

DEVICE REPLACEMENT

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Warning: Do not attempt to repair any Non-Navigated instrument.

If a device is defective or damaged, request a replacement. Refer to section REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS for product problems.

PACKAGING FOR STEAM STERILIZATION

The Non-Navigated Instruments are not designed to be disassembled or reassembled. For sterilizing non-sterile instruments, the devices may be loaded in the open or neutral position, as applicable, and arranged in the specified instrument trays, or general-purpose caddies/trays to ensure adequate exposure of all surfaces. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared for the chosen sterilization cycle.

Visually inspect the instruments before loading them into the tray. Refer to INSPECTION and FUNCTIONAL TESTING section above.

STERILIZATION

For instruments provided **STERILE**, the sterilization method is noted on label. Sterile instrument components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged instruments are supplied in protective sterile barrier packaging. Inspect instrument package for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to customer service. Do not re-sterilize.

Instruments that are supplied **NON-STERILE** must be cleaned and sterilized prior to surgery.

Warning: The manufacturer does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, the manufacturer recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum		
Minimum Temp.	132°C (270°F)	132°C (270°F)	134°C (273.2°F)	135°C (275°F)
Exposure*	15 min	4 min	3 min	3 min
Dry Time	40 min	20 minutes		

**The manufacturer has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665. Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.*

The manufacturer recommends following ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

STORAGE

The Non-Navigated Instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

DISPOSAL

Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of Non-Navigated Instruments.

REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS

Report all Serious Events or Incidents to the manufacturer (see the manufacturer contact details below) and to your local Regulatory Authority.

If a device is defective or damaged, please include, at minimum, the following in your correspondence with the manufacturer:

- Device Part Number
- Device Lot Number
- Description of defect or damage
- Information on whether the device is available for return

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SYMBOL GLOSSARY

SYMBOL	MEANING
	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
	Medical Device
	Reference Number
	Lot Number
	Country of Manufacture / Date of Manufacture
	Consult Instructions For Use
	Do Not Re-Use
	Do Not Use If Package Is Damaged
	Do Not Re-Sterilize
	Non-Sterile
	Sterilized Using Irradiation
	Double Sterile Barrier
	Expiration Date
	Distributor
	Manufacturer
	Unique Device Identifier
	MR Conditional
	Patient Identification
	Patient Information Website
	Health Care Centre or Doctor
	Date Information was Entered or Procedure Took Place

[3] Steam sterilization validation testing was performed per ISO 17665:2024 using Preserve Instrument Lubricant (Aspen Surgical) according to the lubrication instructions provided herein.