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 instruments are:

- Manufactured from surgical grade stainless steel per ASTM F899 and Nitinol per ASTM F2063. Handles are made from surgical grade stainless steel per ASTM F899, aluminum per ASTM B209/211/221 and silicone.
- Designed to be used in a surgical setting to prepare the patients disc space for implant insertion
- Are reusable and provided non-sterile 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.

**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 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 per ASTM F899 and Nitinol per ASTM F2063. Handles are made from surgical grade stainless steel per ASTM F899, aluminum per ASTM B209/211/221 and silicone.

**HOW SUPPLIED**

The Non-Navigated instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

**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 instruments must be cleaned and sterilized prior to surgery.
3. Non-Navigated Instruments should never be used as an implanted device.

**PRECAUTIONS**

**Preoperative:**

1. Only patients that meet the criteria described in the indications should be selected.
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. All 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 Surgical Technique Manuals (provided with the system).

**CARE AND HANDLING**

**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 Processing**

Repeated processing has minimal effect on the 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 instruments are reprocessed as soon as reasonably practical following use.

**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 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)<br>(104 - 149°F)<br>for 3 minutes |
| **Neutral pH Wash** | 60°C (140°F)<br>for 3 minutes |
| **Rinse** | Ambient temperature<br>for 1.5 minutes |
| **Thermal Rinse** | 90°C (194°F)<br>for 1 minute |
| **Dry** | 82°C (180°F)<br>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 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, 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.

[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.

**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**

For sterilizing non-sterile instruments, the devices may be loaded into the specified instrument trays, or general- purpose caddies/trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are intended for pre-vacuum steam sterilization.

**STERILIZATION**

Instruments are supplied non-sterile and 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) | 135°C (275°F) |
| **Exposure*** | 15 min | 4 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 of Device**

For disposal of a product following an error in storage or improper use of the product, implants must follow the pathway for removal of hospital waste products in compliance with the procedures enforced within the institution.

**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

Manufactured by:
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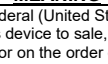
**SYMBOL GLOSSARY**

| 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 |
|  | Date of Manufacture / Country of Manufacture |
|  | Consult Instructions For Use |
|  | Non-Sterile |
|  | Distributor |
|  | Manufacturer |
|  | Unique Device Identifier |