1. With the patient in a direct lateral decubitus position and secured in place, identify the location of the disc space with AP and lateral fluoroscopic images.

2. Reattach the Outer Shaft and Funnel.

3. Place instruments in ultrasonic cleaner, ensuring that all instruments are disassembled for cleaning.

4. Rotate the instruments below the surface of the cleaner and actuate all buttons and levers a minimum of 30 minutes.

5. NOTE: Instruments can be removed from the ultrasonic cleaner at any time after cleaning.

6. Rinse instruments in tap water for a minimum of 2 minutes for each disassembled component. Clean all buttons and levers while rinsing to facilitate debris removal.

7. Brush with a soft non-abrasive brush and a non-abrasive toothbrush. Rinse with enzymatic cleaner for a minimum of 30 minutes while rinsing during the rinse cycle.

8. Rinse in enzymatic cleaner for a minimum of 2 minutes for each disassembled component. Clean all buttons and levers while rinsing to facilitate debris removal and to eliminate any trapped air bubbles.

9. Ensure there is no contact between the instruments, and allow instruments to soak in enzymatic cleaner for a minimum of 20 Minutes.

10. Follow the soak procedure, rinse again, and allow instruments to soak in enzymatic cleaner for a minimum of 20 Minutes.

11. Rinsing in ultrasonic cleaner, ensuring that all instruments are disassembled and submerged with a freshly prepared solution of pH neutral enzymatic cleaner (prepared according to the manufacturer’s instructions) will facilitate debris removal and to eliminate any trapped air bubbles. Allow instruments to soak in the solution while sonicating for a minimum of 20 Minutes.

12. Maintain distraction during implant placement.

13. Form fluid leakage.

14. Tissue or nerve damage.

15. Revision surgery.


17. Allergic reaction to the implant material.

18. Bone fracture or fracture at the site of fusion.


20. Tissue or nerve damage.

21. Revision surgery.

22. Pain.

23. Allergic reaction to the implant material.
8. Rinse in hot water
   a. Rinse instruments under hot (110°F minimum) running water and rinse for a minimum of 3 minutes.
   b. Actuate all buttons and levers while rinsing, and ensure water penetrates all cracks, crevices, lumens, and orifices.
   c. Jet Flush with hot water
   d. Use a 60ML syringe filled with hot water (110°F minimum) to jet flush all joints/cracks and gaps in the instruments two (2) times. Actuate all buttons and levers while flushing.
9. Final Rinse
   a. Rinse all instruments using AAMI TIR37 compliant rinse water for 2 minutes.
10. Dry
    f. Dry instruments with a soft, lint free cloth
    g. Dry the instruments with filtered pressurized air
    h. Optional: Heated dry in a 90-120° instrument dryer
11. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
12. Steam autoclave per sterilization instructions.

Storage
- Sterile packaged implants should be stored at controlled room temperature out of direct sunlight.
- Product Tyvek package should be inspected prior to use for signs of damage or tampering.
- Sterile implants have a shelf life of 5 years.

Sterilization Instructions
1. Implants are supplied STERILE and System instruments are supplied NON-STERILE.
2. Use of the sterilizer shall comply with the manufacturer’s user instructions for sterilizers.
3. The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
4. Non-sterile devices should be sterilized by steam sterilization (autoclaving). For sterilization of DualX™ LLIF instruments, the following parameters should be used.

Tray System
Pre-Vacuum Steam Sterilization
Cycle: 3
Temperature: 270°F (132°C)
Time: 4 minutes
Dry Time: 30 minutes
Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554 or equivalent) using sequential wrapping techniques.
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Caution
- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect Innovative instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

Symbols and Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Use Only</td>
<td>REF Catalogue Number</td>
</tr>
<tr>
<td>Use By Date</td>
<td>Sterile, Method of Sterilization Using Irradiation</td>
</tr>
<tr>
<td>Batch Code</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td>Manufacturer (MFR)</td>
</tr>
<tr>
<td>Attention, See Instructions for Use</td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td>Caution, Consult Accompanying Documents</td>
<td>Do not use if sterile package is damaged</td>
</tr>
</tbody>
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