System Name: 
**Alloquent™ ALIF Allograft Instrument System**

**Description:** The Alloquent™ ALIF Allograft Instrument System allows the surgeon to prepare and measure the intervertebral disc space during a lumbar fusion procedure. Trial sizers, corresponding graft sizes, help the surgeon to choose the appropriate size of allograft for a precise fit. The blade distractor or bullet distractor provide a means of distracting the intervertebral space. The graft holder and tamps will be used to fully place the graft.

The ALIF Allograft Instrument System includes:
- Trial Sizers with Removable Handles
- Graft Holder
- Bullet Distractors
- Blade Distractor with Interchangeable Blades
- Straight and Curved Impactors

The Anterior Lumbar Disectomy Case includes:
- Curettes with Modular Handles
- Modular Elevator
- Kerrisons
- Rongeurs
- Large Sypert Rongeur

The ALIF Allograft Instruments are provided non-sterile, and therefore, must be sterilized before each use.

**Cleaning:** All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments that have been previously taken into a surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

**Sterilization:** The Alloquent™ ALIF Allograft Instruments are supplied NON-STERILE. Prior to use, all components should be steam sterilized by the hospital using the recommended cycle:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
<td>30 minutes</td>
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</tbody>
</table>

**OR:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Prevac</td>
<td>270°F (132°C)</td>
<td>8 minutes</td>
</tr>
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</table>

**Product Complaints:** Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints, or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the company, Orthofix Inc., 3451 Plano Pkwy, Lewisville, TX 75056, USA, Telephone: 214-937-3030 or 1-888-298-5700, or via email at complaints@orthofix.com.

**INSTRUCTIONS FOR USE**

Important Information — Please Read Prior to Use