Sonoma Orthopedic Products®
Sonoma Jones Bolt™ Instruments
Instructions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INTENDED USE
The Sonoma Jones Bolt™ Instruments are intended to aid in implanting and explanting the Sonoma Jones Bolt™ Implants and Compression Caps. Refer to the associated implants Instructions for Use and Surgical Technique Guide for further information.

DEVICE DESCRIPTION
Resterilizable instruments are provided non-sterile. Disassembly, proper cleaning and sterilization are required as described below before initial and subsequent use.

Sterile instruments are sterilized by gamma irradiation. Each package should be inspected prior to use to ensure package integrity. Devices in damaged packages should not be used and should be returned to the manufacturer.

Single-use instruments may be provided non-sterile or sterile. Disposable instruments typically include:
• Drills
• Wires and Pins
• Disposable Actuation Drivers
• All instruments denoted Single Use

WARNINGS AND PRECAUTIONS

Warnings
1. Do not reuse disposable instruments; they are for SINGLE USE ONLY. Reuse may increase the risk of infection. Additionally, cutting tools may become dull, causing them to no longer cut properly.
2. Instrument breakage or damage may occur when the instrument is subjected to excessive loads, speeds, or dense bone.

Precautions
1. Additional surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique before surgery. Proper surgical procedures and techniques are the responsibility of the medical professional. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience.
2. These devices have not been evaluated for use with components from other manufacturers. Use of other manufacturers’ devices in conjunction with these may damage the devices or cause injury to the user or patient.
3. Reusable instruments are made from metals and plastics designed to permit a long life. Inspect all instruments prior to use for damage or degradation.
4. Sterile, single-use instruments that have been opened but not used should not be resterilized. These instruments should be discarded or returned to the manufacturer.

Potential adverse events may be related to surgery in general or the device, including but not limited to metal sensitivity reactions and/or allergic reactions to foreign materials.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, incorrect choice of implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.

PACKAGING AND HANDLING
Resterilizable instruments are organized in a case. The case must be closed and sealed with its packaging intact upon receipt. In the case of restock, the set should be carefully checked for completeness. Inspect all devices prior to use. Any damaged or defective components should not be used and should be returned to the manufacturer.

Sterile devices are sterilized by gamma irradiation. Each package should be inspected prior to use to ensure package integrity. Devices in damaged packages should not be used and should be returned to the manufacturer.

Products should be stored in a cool, dry place and kept away from direct sunlight to maintain the integrity of the instruments and their respective packaging. The condition of all instruments and packaging must be checked before use.

**REUSABLE INSTRUMENT CLEANING AND STERILIZATION**

Reusable instruments are manufactured from metals and plastics designed to permit a long life when handled and maintained properly. End of functional life is normally determined by wear and damage due to use.

Clean instruments as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with cold water or an appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently made contact with blood or any part of the surgical field.

**Note:** Anodized aluminum instruments (Instrument Cases) should not come in contact with strong alkaline solutions or solutions containing iodine, chlorine, certain metal salts, or pH values above 11.

**Manual Cleaning Procedure**

1. Open lumens and joints of any instruments.
2. Rinse under cool running tap water to remove gross contamination.
3. Prepare neutral pH enzymatic detergent according to manufacturer’s instructions.
4. Soak fully immersed in the detergent bath for a minimum of five (5) minutes. If at any time during the soak the detergent becomes grossly contaminated, prepare a fresh batch using the manufacturer’s recommendations.
5. Brush the instruments using a soft-bristled brush ensuring all hard-to-reach areas are accessed. A syringe and pipe cleaner may be used, especially for lumens. If applicable, actuate the instrument while scrubbing.
6. Rinse in RO/DI (reverse osmosis/de-ionized) water for at least one (1) minute. A syringe and pipe cleaner may be used, especially for lumens, to assist the rinsing.
7. Repeat steps 4 – 6.
8. Open lumen and joints and fully immerse in the sonication unit.
9. Rinse with RO/DI water for at least one (1) minute. A syringe and pipe cleaner may be used, especially for lumens to assist in the rinsing.
10. Dry using clean lint-free cloth. Pressurized air (up to 40 psi) can be used to dry instruments if needed.
11. Inspect the instrument to ensure it has been thoroughly cleaned. If necessary, repeat the cleaning procedure.

**Maintenance**

1. Visually inspect the instruments and check for damage and wear.
2. Between uses, lubricate metal on metal moving parts with a water-soluble, sterilization capable lubricant in accordance with manufacturer’s instructions.

**INSPECT THE TOOLS**

Inspect each instrument for visible signs of damage. Do not reuse instruments that have signs of wear, discoloration, corrosion or are suspected to be damaged. Any damaged or defective components should not be used and should be returned to the manufacturer.

**STERILIZATION**

Resterilizable instruments should be sterilized using the following recommendations. This sterilization recommendation was developed using specific equipment for a Sterility Assurance Level (SAL) of $10^{-6}$ and results may vary depending on processing conditions, wrapping materials, or equipment. The cycle and conditions must
be demonstrated to produce sterility in your environment. **USA: Use only FDA cleared sterilization packaging materials.**

<table>
<thead>
<tr>
<th>Steam Sterilization Cycle Type</th>
<th>Temperature (minimum)</th>
<th>Exposure (minimum)</th>
<th>Dry Time (minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum (4 pulse minimum)</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>30 minutes</td>
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</tbody>
</table>

**WARRANTY:**
THE COMPANY REPRESENTS AND WARRANTS THAT THE SONOMA JONES BOLT™ INSTRUMENTS WILL CONFORM TO THE COMPANY’S SPECIFICATIONS AND COMPLY WITH ALL APPLICABLE FDA STANDARDS, AS SUCH STANDARDS MAY BE AMENDED FROM TIME TO TIME. THE COMPANY MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES REGARDING THE IMPLANT.

**MANUFACTURER**
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USA Patents 7,846,162, 7,914,533, 7,942,875 and 7,909,825. USA and International patents pending.

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