EN

1. Product Handling

Devices not returned to DJO should be treated as biohazardous material and disposed of in accordance with local laws and regulations.

<table>
<thead>
<tr>
<th>Country</th>
<th>Distributor Name</th>
<th>Distributor Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Korea</td>
<td>BioImplant Technology</td>
<td>1029 Yeongdeok-dong, Gheung-gu, Yongin-si, Gyeonggi-do, Korea, 16950 #2101 U-Tower</td>
</tr>
<tr>
<td>Denmark</td>
<td>Innosurge Trauma</td>
<td>Alsikevej 16 DK-8920 Randers NV</td>
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<tr>
<td>Belgium</td>
<td>Orthogrow Distribution</td>
<td>DaVincilaan 1 1930 Zaventem Belgium</td>
</tr>
<tr>
<td>South Africa</td>
<td>MedHold</td>
<td>MSI Business Park 68 Rigger Road Spartan Kempton Park Gaulteng 1619</td>
</tr>
<tr>
<td>Mexico</td>
<td>Daonsa</td>
<td>Miguel Hidalgo 2428 Pte, Obispado, 84010 Monterrey, N.L., Mexico</td>
</tr>
<tr>
<td>Columbia</td>
<td>Pemca-Venezuela / Pemca-Columbia</td>
<td>Cra. 15 No. 88-64 / Edificio Tome Zimma / Oficina 705 y 713 Bogota D.C., Colombia</td>
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<tr>
<td>Saudi Arabia</td>
<td>Al-Ewan Medical Company</td>
<td>Prince Nasar Ibn Farhan Al Saud, AlMursiat, Riyadh 12461, Saudi Arabia</td>
</tr>
<tr>
<td>Turkey</td>
<td>Armoni Medikal</td>
<td>Gazi Mahalles Yavuz Kanat Sok. Pasifik Plaza No. 34 Yenimahalle 06560 Ankara, Turkey</td>
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</tbody>
</table>

0400-0146 Rev. YD 2020-11
A printable copy of the IFU for this device can be located at: www.djosurgicalifu.com. A paper copy can be requested via phone at +1-800-520-8976.

REUSABLE INSTRUMENT DESCRIPTION

DJO Surgical® instrumentation consists of devices and their accessories used in surgical procedures. Implantation of DJO Surgical® products should only be performed with DJO Surgical® instrumentation or instrumentation distributed by DJO Surgical®. DJO Surgical® instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and detailed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with FDA cleared sterilization wrap to maintain sterility. Instruments are provided non-sterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.

WARNINGS

Automated cleaning may not be thorough enough. Carefully inspect each instrument to ensure that all visible blood residue and other contaminants have been removed.

CAUTION

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

REPROCESSING LIMITATIONS

DJO Surgical® instruments can be steam sterilized and repeat sterilization will not adversely affect them. If problems related to instrument sets are identified when using our instruments or instrument cases, please bring it to the attention of DJO Surgical® for investigation. The lifetime of an instrument is typically limited by normal wear and damage due to use.

DISCLAIMER

DJO Surgical® instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. DJO Surgical® has verified through laboratory testing that our instrument cases are suitable for the sterilization cycles listed in the sterilization section of the IFU. It is the user’s responsibility to verify that equipment is performing as intended, and conditions are achieved.
INSTRUCTIONS FOR USE

POINT OF USE PREPARATION
Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after the completion of the surgical procedure. If cleaning must be delayed, place instruments in a covered container with pH neutral enzymatic detergent to delay drying. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Wash all instruments whether or not they were used or were inadvertently contacted with blood. Disassemble instruments with removable parts; loosen instruments with movable parts, as applicable.

DECONTAMINATION
Decontamination is for the purpose of microbial inactivation. Saturate the surface completely with full strength intermediate disinfectant/cleaner* (e.g. Cavicide) and allow to remain in contact with devices for 5 minutes.

A. MANUAL CLEANING: ALL INSTRUMENTS
1. **Pre-Cleaning:** Remove all visible soil by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g. MetriZyme) and disassemble/loosen instruments, if suitable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. Scrub with the appropriate soft brush until visibly clean; actuate through the full range of motion.
2. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. MetriZyme) and sonicate for 10 minutes. Ultrasonic cleaners can be used with hot water per the manufacturer's recommended temperature; however, room temperature was qualified. Be aware that baking patterns, water temperature, and other external factors may change the effectiveness of the equipment.
3. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes three (3) times.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. DJO Surgical® has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

B. MANUAL CLEANING: INSTRUMENTS WITH CANNULAS, LUMENS, OR HOLES
1. **Pre-Cleaning:** Follow the “Pre-Cleaning” and “Washing” steps in Section A. Manual Cleaning – ALL INSTRUMENTS.
2. **Washing:** After ultrasonic cleaning, in a fresh enzymatic cleaning bath use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub any cannula, lumen, or hole(s). Push in and out, using a twisting motion to remove debris. Use a syringe filled with enzymatic neutral pH cleaning solution to flush hard to reach internal areas.
3. **Rinsing:** Flush the instrument paying special attention to the cannulations, lumens, and/or holes with deionized or distilled water. For example, a minimum of 2 minutes three (3) times.

C. MANUAL CLEANING: ARTICULATING INSTRUMENTS
1. **Pre-Cleaning:** Follow the “Pre-Cleaning” and “Washing” steps in Section A. Manual Cleaning – ALL INSTRUMENTS.
2. **Washing:** After ultrasonic cleaning, immerse the instrument in fresh neutral pH enzymatic cleaning solution to avoid aerosol generation. Actuate movable mechanisms through full range of motion, such as knobs, hinges, box locks, or spring-loaded retractable features. For instruments with flexible shafts, bend or flex the instrument under the neutral pH cleaning solution while brushing the flexible areas. For instruments with internal cavities, after actuating components in the neutral pH cleaning solution, fully open components and use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the internal cavities. Use a syringe filled with enzymatic neutral pH cleaning solution to flush hard to reach internal areas.
3. **Rinsing:** Actuate and/or retract movable parts while rinsing with deionized or distilled water. For example, a minimum of 2 minutes three (3) times. For instruments with flexible shafts, flex the instrument while rinsing.

AUTOMATED CLEANING
DJO Surgical® instruments may be washed and/or disinfected by using an automated washer-disinfector unit utilizing thermal disinfection after completing the manual cleaning methods. Temperatures, cycles, and disinfectant type used should be as instructed by manufacturer of the washer-disinfector unit. For ultrasonic cleaning below the manufacturer’s specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place within the instrument case with the lid removed, and do not touch or overlap. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments.

DRIYING
Ensure device is dry prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored. Filtered compressed air may be used prior to air drying if available.

MAINTENANCE INSPECTION AND TESTING
After cleaning, the instruments (disassembled, if applicable) should be visually inspected. Check for misalignment, burns, bent, or fractured tips. Mechanically test the working parts (e.g. hinges) to verify that each instrument functions throughout its intended range of motion. Place instruments in appropriate configuration within the instrument case and wrap with protective FDA cleared sterilization wrap according to AAMI / AORN guidelines.

Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:
1. Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair returned for servicing.
2. Only use an instrument for its intended purpose.
3. When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.
4. If instruments appear to be damaged in such a way that may compromise the performance of the instrument, contact your DJO Surgical® representative for a replacement.
5. Visually inspect the instrument and check for damage and wear, movable parts should have smooth movement, locking mechanisms should function securely.

TRANSPORT
Compliance with the general precautionary measures for handling contaminated/bio-hazardous materials is required.

STERILIZATION
Instruments supplied by DJO Surgical® have been thoroughly cleaned, inspected and tested for proper function prior to shipment. Unless otherwise indicated, these instruments are NOT STERILE and must be sterilized prior to use. Instruments provided outside of instrument sets should be fully loosened/disassembled and wrapped in FDA cleared sterilization wrap per AAMI ST.79/AORN Guidelines. Flash (immediate-use) steam sterilization by exposure at 132°C / 270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled prior to processing.

The following are minimum cycles required for steam sterilization that has been validated by DJO Surgical® under laboratory conditions to achieve a SAL of 10^-4 with components loosened or disassembled. DJO Surgical® has data on file.

**Sterilization with a Pre-Vacuum Sterilizer (Hi-VAC):**
270°F (132°C), 5-minute exposure time, and a 30-minute dry time.

**Sterilization with a Gravity Displacement Sterilizer:**
270°F (132°C), 30-minute exposure time, and a 30-minute dry time.
Instruments must be thoroughly dried to remove residual moisture before they are stored. Instruments or instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped instruments or instrument cases to prevent damage to the barrier. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling.

2. Product Description

The devices covered by this IFU are the instruments used to implant DJO Surgical implantable devices, as well as the instrument cases used to store said instruments for cleaning and transportation.

The following devices are covered by IFU 0400-0221 and not this IFU:

- FA XALT TRIAL (803-99-039)
- FA FMP INSTRUMENT (803-99-018)
- FA RSP GLENOID (804-99-11)
- 3D KNEE GAP BALANCER (S-200775)
- RSP HALF MOON REAMERS (804-06-012, 804-06-013, 804-06-014)
- FA EXPRT REV 1 (800-99-092)
- FA EXPRT REV 2 (800-99-093)
- FA DAA GENERAL (803-99-102)
- FA DAA RETTRACTOR (803-99-103)
- FA TURON RETRACT (804-99-020)
- FA TURON HUMERAL STEM (804-99-117)
- FA TURON GLENOID (804-99-118)
- FA TURON HUMERAL HEAD (804-99-119)
- FA RSP HUMERAL (804-99-011)
- FA RSP GLENOID (804-99-011)
- FA RSP MONOBLOCK LTD RELEASE (804-09-025)
- FA RSP SIZE 44 INST (804-09-024)
- FA EMP DRF FEM PREP (800-99-094)
- FA EMP TIB PREP (800-99-095)
- FA EMP PAT TOOL KIT (800-99-096)
- FA EMP BONUS KIT (800-99-097)
- FA EMP 3D TRL CORE LT (800-99-098)
- FA EMP 3D TRL CORE RT (800-99-099)
- FA ALTIVATE RSP HUM PREP (804-99-120)
- FA ALTIVATE RSP HUM TRLS (804-99-121)
- FA EMP 3D TRL PREP OUT SML (800-99-101)
- FA EMP 3D TRL PREP OUT LG (800-99-102)
- FA EMP INS TRL SCRS (800-99-103)
- FA LR FMP CUP INSERTER (803-99-098)
- FA FMP ACET REAMER (803-99-033)
- FA XALT INST (803-99-040)
- FA MIS HIP (803-99-029)
- FA TAPERFILL INSTRUMENTS (803-99-170)
- FA TAPERFILL INSTRUMENTS – 7MM (803-99-170)
- FA TAPERFILL BROCACHES (803-99-171)
- FA H TAPERFILL BROACH 7MM POST (803-99-172)
- FA TAPERFILL BIG LUG FT BROACH (803-99-172)
- FA EMP 3D CR TRL PREP OUT LG
- FA EMP 3DCR TRL PREP OUT SML
- FA EMP CR TRL CORE LT
- FA EMP CR TRL CORE RT
- FA EMP PS FEM TRL CAP CORE (800-99-117)
- FA EMP PS FEM TRL CORE (800-99-117)
- FA EMP PS INS TRL CORE (800-99-118)
- FA EMP PS TRL PREP OUT L CAP (800-99-108)
- FA EMP PS TRL PREP OUT SML (800-99-108)
- FA EMP PS TRL PREP OUT S CAP (800-99-107)
- FA EMP PS TRL PREP OUT SML (800-99-107)
- FA EMP 3D + CR COMP OUT LG
- FA EMP 3D + CR COMP OUT SML
- FA EMP 3D COMP OUT LG
- FA EMP 3D COMP OUT SML
- FA EMP COMP PAT TOOL KIT
- FA EMP CR COMP OUT LG
- FA EMP CR COMP OUT SML
- FA EMP TIB PREP 2
- FA ALTIVATE RSP 44
- FA ALTIVATE RSP HUM TRLS SML
- FA EMP CEM STEM AUG PREP
- FA EMP TIB PREP COMPLETE
- FA EMP PS TRL PREP OUT SML 2
- FA EMP PS TRL PREP OUT LG 2
- FA EMP VVC INS TRL CORE
- FA ALTIVATE RSP REVISION
- FA EMPOWR ACET GENERAL INST
- FA EMPOWR ACET MIS HANDLES
- FA EMPOWR ACET TRL NEO 100DH
FA H EMPWR ACET OFFSET TR LNRS
FA H EMPOWR ACET ANCILLARY
FA H EMPOWR ACET GEN INST V2
FA S ALTIVATE RSP SHORT
FA K EMP PARTIAL
FA K EMP PARTIAL PREP 1 OF 2
FA K EMP PARTIAL TRIAL 2 OF 2
FA S ALT ANATOMIC CS EDGE
FA K EMP FEM PREP

The following devices are covered by IFU 0400-0248 and not this IFU.
FA K EMP PS FEM TRL CAP CORE (800-99-117)
FA K EMP PS FEM TRL CORE (800-99-118)
FA K EMP PS TRL PREP OUT L CAP (800-99-108)
FA K EMP PS TRL PREP OUT LG (800-99-108)
FA K EMP PS TRL PREP OUT S CAP (800-99-107)
FA K EMP PS TRL PREP OUT SML (800-99-108)
FA S ALT ANATOMIC HUM STEM (804-99-125)
FA S ALT ANATOMIC HUM HEAD (804-99-126)
FA S ALT ANATOMIC GLENOID (804-99-127)
FA S TURON KEELED GLENOID (804-99-128)
FA H EXPR REV HIP REAMERS (803-99-095)
FA H EXPR REV HIP GENERAL (803-99-096)
FA H FMP STR CUP INSERTER (803-99-101)
DOUBLE OFFSET BROACH HANDLE, LEFT (803-03-084)
DOUBLE OFFSET BROACH HANDLE, RIGHT (803-03-085)
FA H XNE 10DH EXT (803-99-111)

3. Indications
Reference the applicable implant IFU for Indications.

4. Intended Use
Reference the applicable implant IFU for device Intended Use.

5. Contraindications
Reference the applicable implant IFU for Contraindications.

6. Precautions and Warnings
Reference the applicable implant IFU for Precautions and Warnings.

7. Preoperative Planning and Postoperative Care
Reference the applicable implant IFU for Preoperative Planning and Postoperative Care.

8. MRI Safety
N/A

9. Adverse Effects
Reference the applicable implant IFU for Adverse Effects.
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the relevant Competent Authority as defined in EU 2017/745.

10. Lifetime of Device
DJO Surgical does not define the maximum number of uses appropriate for re-usable instruments. While the expected lifetime of surgical instruments may be subject to a multitude of factors such as patient characteristics, surgeon experience, amount of use, and surgical technique, evaluating the time between the release of an instrument from production and the return of that instrument to the manufacturer from the user can give an indication of its expected lifetime.

Based on this information, Powered Instruments have shown to last as short as 5 days in the field or as long as 9.5 years in the field, with an average lifetime of 2.8 years. Non-Powered Impaction or Extraction Instruments have shown to last as short as 3.5 months in the field or as long as 18 years in the field, with an average lifetime of 2.8 years. Non-Powered Guide Instruments have shown to last as short as 35 days in the field or as long as 9.1 years in the field, with an average lifetime of 2.9 years. Non-Powered, Non-Impaction/Extraction, & Non-Guide Instruments have shown to last as short as 56 days in the field or as long as 9.3 years in the field, with an average lifetime of 3.5 years.

As product data continues to be collected, these lifetime estimates may be re-evaluated and adjusted if required. Users should note that careful inspection of the instrument before use is the best method of determining the end of serviceable life.

11. Trademarks and Patents
Reference the applicable implant IFU for Trademarks and Patents.

Icon Key:

ISO 15223-1 5.4.2

Single use – do not reuse
<table>
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<tr>
<th><strong>Expiration Date</strong></th>
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<td>ISO 15223-1 5.2.4</td>
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<td>ISO 15223-1 5.2.7</td>
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<td><strong>Non-sterile</strong></td>
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<td><strong>See “Instructions for Use”</strong></td>
<td>ISO 15223-1 5.4.3</td>
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<td><strong>Manufacturer</strong></td>
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<td><strong>Quantity of items in package</strong></td>
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**STERILE**

**STERILE R**

**STERILE H₂O₂**

**NON STERILE**
Authorized Representative in European Community

Catalog Number

Do not resterilize

Do not use if package is damaged

MR Safe

MR Conditional

MRI Unsafe

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

Importer

Medical Device
Bone Cement Usage – The following legends are displayed on the product labeling to indicate bone cement usage:

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<th>Usage</th>
<th>Legend</th>
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<tbody>
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<td>Implants intended to be used with bone cement</td>
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</tr>
<tr>
<td>Implants intended to be used without bone cement</td>
<td>CEMENTLESS</td>
</tr>
<tr>
<td>Implants intended to be used optionally</td>
<td>NO LEGEND</td>
</tr>
</tbody>
</table>

German Translation goes here.

French Translation goes here.

Spanish Translation goes here.

Italian Translation goes here.