OPTIVU™ SHOULDER SURGICAL INSTRUMENT PACKAGE INSERT

NON STERILE

℞ Only

SURGICAL INSTRUMENTS

For detailed information concerning the identification of the product (such as name, reference number, description, qualitative composition, quantitative information etc.) please refer to the labeling on the package and/or the marking on the device.

IMPORTANT INFORMATION FOR THE INTENDED USER

Before using an MR Surgical product, the intended user should review and understand the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., the applicable User Manual, product literature, written Surgical Technique). MR Surgical is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection and similar matters outside the control of MR Surgical.

INTENDED PURPOSE

For information about the intended purpose, refer to the corresponding system User Manual.

PATIENT TARGET GROUP

The surgical instruments are developed to support medical device systems aimed at treating individuals requiring orthopaedic joint replacement or treatment.

INTENDED USERS

Surgical instruments are intended to be used by:

- Physicians/Surgeons trained to perform orthopedic surgical procedures with the device;
- Nurses trained to prepare the operating room, prepare and handle the instruments, and assist with the surgery procedure;
- Other MR Surgical authorized representatives.

These reprocessing instructions are intended to be used by:

- Hospital personnel that work with contaminated or potentially contaminated medical devices.

INDICATIONS AND CONTRAINDICATIONS FOR USE

OptiVu Shoulder is contraindicated for patients with implantable cardioverter-defibrillators (ICDs) or pacemakers.

For more information about indications and contra-indications, refer to the associated system User Manual and/or Surgical Technique.

CLINICAL BENEFITS, PERFORMANCE AND RESIDUAL RISK

For more information about clinical benefits, performance, residual risks and undesirable side effects, refer to the associated system User Manual and/or Surgical Technique.

The clinical benefit or clinical performance is determined based on the MR Surgical orthopedic systems used in conjunction with Surgical Instruments.

A) PRECAUTIONS AND WARNINGS ⚠

The following are warnings related to the use of the reprocessing instructions addressed by this insert. Precautions and warnings related to the use of MR Surgical applications are included in the Surgical Technique or User Manual.

- Universal Precautions should be observed by all healthcare professionals working with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft- bristled, nylon brushes and/or pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Soiled surgical instruments which have dried are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, fluorine chloride, bromine, bromide, iodine or iodide are corrosive and should not be used.
- Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) be difficult to remove.
- Do not clean polyetherimide components with phenol-based detergents. Crazing or cracking may occur.
- Polysulfone components may show eventual crazing and/or cracking due to steam boiler chemicals and lubricants.
- Sharp-edged instruments (i.e., reamers, bits) should not be reused once they become significantly dulled from general use. It is also recommended that such instruments not be re-sharpened by the physician or hospital.
- Precautions should be taken to prevent injuries caused by sharp instruments, pins or screws when handling these devices during and after surgical procedures and during reprocessing.
- During the surgery, verify that the pin or screw is properly secured into the surgical drill during installation and removal.
- Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Use caution in positioning the pins or screws such to avoid injuring veins or arteries, and such to avoid areas which may interfere with other instrumentation or implant components. If the screw or pin is not properly secured into the bone, its performance could be compromised during insertion and removal.
- Minimize excessive heat buildup due to friction between metallic components and adjacent surfaces, whether it be bone or other metallic surfaces. Excess heat buildup in instruments in contact with bone may cause heat necrosis and lead to early failure of the component.
- If applicable, if during surgery this instrument and/or those attached to it are interfered significantly, for example in a manner affecting their being secured to bone, instrument should be re-secured and bone registration or digitization should be repeated.

BEFORE EVERY SURGERY

- The user must verify that the components used with the systems are in good condition.
- Tool calibration, if applicable, must be done as described in the User Manual of the given applications.
- The instruments shall be inspected for excessive bending or other damage such as excessive wear or deterioration prior to use to ensure that they are in good working order. Bends in the instruments may affect system accuracy. If the components are not in good working condition, the system should not be used and technical support should be contacted.
- If applicable, Trackers shall be securely assembled to the intended instruments.
- The instruments must be processed, cleaned, and sterilized before every surgery.
- Verify if the pins diameter and length are compatible with the surgical drill using the information provided on the packaging labels.

B) INITIAL TREATMENT AT THE POINT OF USE

- Remove excess body fluids and tissue from instruments with a disposable, non- shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to- reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

C) PREPARATION BEFORE CLEANING

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components. If a part is lost, notify your MR Surgical representative when the instrument set is returned.
- Instructions for instrument assembly/disassembly and device specific cleaning aids can be found in the User Manual of each specific system.
- Neutral pH, enzymatic, and alkaline cleaning agents with low foaming surfactants are recommended by MR Surgical.
- Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing.
- Instruments made totally or partly of polymers must not come into contact with strong acids or lyes, organic or ammonia-containing solvents, aromatic and/or halogen hydrocarbons or oxidizing chemicals.
- Aluminum and materials containing aluminum must never come into contact with substances containing mercury. Even the smallest traces of mercury can lead to considerable corrosion.
- Reusable instruments must be processed, cleaned, and sterilized between patient uses (also see Instructions under section I for Special Instructions for Generic Instrument Cases). Specific cleaning and maintenance instructions as applicable to each instrument are provided in the Surgical Technique or User Manual
- Screws and other mechanisms should be checked and lubricated with a medical grade surgical lubricant after each cleaning or as determined upon inspection.

Note: Drill bits, reamers, rasps and other cutting devices should be carefully inspected after point-of-use processing with alkaline detergents to ensure that cutting edges are fit for use.

- Only agents with proven efficacy (FDA approved or VAH listed) should be used. As a large variety of cleaning agents and disinfectants exist around the globe, MR Surgical does not recommend any specific brand.
- Agents used during the validation of these processing instructions are as follows:
  - **Enzymatic and Neutral Detergents:** STERIS ValSure® Enzymatic Cleaner and ValSure® Neutral Detergent or STERIS Prolystica® 2X Enzymatic Presoak and Cleaner and Prolystica® 2X Concentrate Neutral Detergent.
  - **Alkaline Detergent and Neutralizer:** STERIS ValSure® Alkaline Detergent and ValSure® Neutral Detergent or Dr. Weigert neodisher® FA and neodisher® Z Acid Neutralizer.

- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

The combination of manual and automated cleaning instructions shown in Table 1 must be used to clean the instruments and the tray, case, and lid components. Instruments must be removed from the tray or case during the cleaning.

Table 1: Cleaning/Disinfecting Options

Method	Description	Section
Combination of Manual and Automated Cleaning Using Enzymatic and Neutral Detergents	Enzymatic soak and scrub, followed by enzymatic sonication, followed by automated washer/disinfector cycle with enzymatic and neutral detergents.	D
Combination of Manual and Automated Cleaning Using Alkaline Detergent and Neutralizer	Alkaline soak with sonication followed by automated washer/disinfector cycle with alkaline detergent and neutralizer.	E

D) COMBINATION CLEANING/DISINFECTION

INSTRUCTIONS USING ENZYMATIC AND NEUTRAL DETERGENTS

1. Rinse soiled instruments, trays, cases, and lids under running cold tap water for a minimum of one minute. Remove gross soil and debris using a soft bristled, nylon brush.
2. Completely submerge the instruments, trays, cases, and lids in an enzyme solution and allow to soak for 10 minutes. Instruments must be removed from the trays or cases during the cleaning. Use a soft nylon-bristled brush to gently scrub the device for a minimum of one minute and until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon- bristled brush (i.e. pipe cleaner).

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

3. Remove instruments, trays, cases, and lids from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
4. Completely submerge the instruments, trays, cases, and lids in an enzyme solution and sonicate for 10 minutes at 40±5 kHz. Instruments must be removed from the trays or cases during the cleaning.
5. Remove instruments, trays, cases, and lids from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
6. Place instruments, trays, cases, and lids in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. Instruments must be removed from the trays or cases during the cleaning. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 2: Typical U.S. Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minutes prewash with cold tap water
2	20 seconds enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 seconds cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66°C/146-150 °F)
6	15 seconds hot tap water rinse
7	2 minutes thermal rinse (80-93 °C/176-200°F)
8	10 seconds purified water rinse with optional lubricant (64-66°C/146-150 °F)
9	7 to 30 minutes hot air drying (116°C/240°F)

Note: The washer-disinfector manufacturer's instructions should be strictly adhered to. A washer/disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

7. Orthopedic instruments with any features such as multiple components, lumens/cannulations, blind holes, mated surfaces, connectors and internal mechanisms should be cleaned following the rigorous manual or combination cleaning procedure.

Note: Use only cleaning agents recommended for the specific type of automated washer/disinfector. Only agents with proven efficacy (FDA approved, CE mark or VAH-listed) should be used. As a large variety of cleaning

agents and disinfectants exists around the globe, MR Surgical does not recommend any specific brand.

8. Proceed to section F for Inspection and Maintenance. A thorough visual inspection to ensure effective cleaning is recommended prior to sterilization.

E) COMBINATION CLEANING/DISINFECTION INSTRUCTIONS USING ALKALINE DETERGENT AND NEUTRALIZER

1. Rinse soiled instruments, trays, cases, and lids under running cold tap water for a minimum of one minute. Remove gross soil and debris using a soft bristled, nylon brush.
2. Completely submerge the instruments, trays, cases, and lids in an alkaline (pH ≤12) solution and allow to sonicate for 10 minutes at 40±5 kHz. Instruments must be removed from the trays or cases during the cleaning.
3. Remove instruments, trays, cases, and lids from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
4. Place instruments, trays, cases, and lids in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. Instruments must be removed from the trays or cases during the cleaning. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 3: Typical EU Automated Washer-Disinfector Cycle for Surgical Instruments

Step	Description
1	5 minutes prewash with cold tap water
2	10 minutes alkaline cleaning agent wash at 55°C
3	2 minutes rinse with neutralizer
4	1 minute rinse with cold tap water
5	Disinfection at 93°C with hot purified water until A0 3000 is reached (approx. 10 minutes)
6	40 minutes hot air drying at 110°C

Note: The washer-disinfector manufacturer's instructions should be strictly adhered to. A washer/disinfector with approved efficacy (e.g. FDA approval, and validation according to ISO 15883) should be used.

5. Orthopedic instruments with any features such as multiple components, lumens/cannulations, blind holes, mated surfaces, connectors and internal mechanisms should be cleaned following the rigorous manual or combination cleaning procedure.

Note: Use only cleaning agents recommended for the specific type of automated washer/disinfector. Only agents with proven efficacy (FDA approved or VAH-listed) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, MR Surgical does not recommend any specific brand

6. Proceed to section F for Inspection and Maintenance. A thorough visual inspection to ensure effective cleaning is recommended prior to sterilization.

F) INSPECTION AND MAINTENANCE

1. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/ disinfection process.
2. Visually inspect for completeness, damage and/or excessive wear.

Note: If damage or wear is noted that may compromise the function of the instrument, contact your MR Surgical Representative for a replacement.

3. Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
4. If necessary, hinged, rotating, or articulating instruments can be lubricated with an instrument product (e.g. Instrument Milk or equivalent lubricant) specifically designed for compatibility with steam sterilization. Make sure to spray an adequate amount of lubricant on the instrument, especially in hard-to-reach spaces. Properly rub in the lubricant for a few seconds afterwards and wipe off.

Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.

Note: Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

5. Check instruments with long slender features (particularly rotating instruments) for distortion.

G) PACKAGING

Packaging individual instruments

- Single devices should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in the table below. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
- The sterilization pouch or wrap used should be FDA cleared and compliant to ISO 11607-1.
- Standard medical grade, steam sterilization wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

Note: If sterilization wraps are used, they must be free of detergent residues. Reusable wraps are not recommended.

Packaging instrument sets in rigid trays and cases with lids

Safety Precaution: Instrument cases may be placed in an approved sterilization container with gasketed lids at the user's discretion. Consult your MR Surgical representative for the full list of approved sterilization containers. The total weight of the instrument set, case, and sterilization container, must not exceed 11.4kg/25lbs (other local limits below 25 lbs. may apply).

- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- The sterilization wrap used should be FDA cleared and compliant to ISO 11607-1.
- Trays and cases with lids may also be placed in an approved and FDA cleared sterilization container with gasketed lid for sterilization.
- The following list contains the approved rigid sterilization containers for use using these steam sterilization instructions:
    - Aesculap® SterilContainer™
    - Case Medical SteriTite®
    - OneTray®

Note: If using the OneTray® sterilization container, the only cycle that was validated by MR Surgical was the cycle using the 132 °C temperature for a four minute exposure time. In addition, the drying time using the OneTray® sterilization container was not validated by MR Surgical, because customers do not utilize a drying time when using the OneTray® in accordance with the OneTray® instructions for use.

- Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

Instrument trays and cases with defined, preconfigured layouts

- Areas designated for specific devices shall contain only devices specifically intended for these areas.
- Brackets designed for specific devices shall only contain devices specifically intended for them.
- Optional MR Surgical instruments should not be added to a reconfigurable tray unless a dedicated universal space or compartment has been included in the layout and the guidelines described below for universal trays without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by MR Surgical should be included in MR Surgical instrument trays. These validated reprocessing instructions are not applicable to MR Surgical trays that include devices that are not manufactured and/ or distributed by MR Surgical.
- Brackets designed to force disassembly of a complex device must not be altered to allow the assembled device to be inserted into the tray or case.
- To ensure devices are fully seated in their corresponding brackets and to prevent damage to tray contents, individual brackets should not overlap one another when inserted into the tray floor.

Note: Some individual brackets may be designated for assembly onto other "host" brackets. In these instances, the mating relationship between the brackets will be graphically depicted on the face of the "host" bracket.

- Bracket fasteners should be fully engaged with the tray floor to prevent unintended migration, damage and/or loss of tray contents.
- Wave springs positioned over the shaft of the bracket fasteners are intended to stabilize brackets by minimizing free-play between them and the tray floor. To ensure intended function, periodically inspect brackets for damaged and/or missing springs which can be replaced by contacting your MR Surgical representative.
- Identification tags and associated labels on trays should correspond to tray contents to ensure correct trays are available for use in surgery.
- Any manual tools provided by MR Surgical to aid in the removal of individual brackets must not remain in the instrument trays during reprocessing and are not intended for use in surgery.

H) STERILIZATION

- Instruments should not be sterilized in the protective bag or packaging supplied with them. They must be processed, cleaned, and disinfected prior to sterilization. The packaging method must be suitable for the items being sterilized and the sterilization process.
- All sterilizations should be performed using standard and regularly maintained equipment.
- The steam used for sterilization must be free from impurities.
- For instruments sterilized within instrument cases, wrapping in two layers of 1-ply polypropylene (or equivalent) is recommended. The sterilization wrap used should be FDA cleared and compliant to ISO 11607-1.
- Reusable instruments, pins and screws sold non-sterile, should be sterilized using the Steam Sterilization method as follows:

Table 4. Recommended Steam Sterilization Parameters

Steam Sterilization (Autoclave)

Cycle Type	Temperature[1]	Exposure Time[1]	Minimum Dry Time[2]	Minimum Cool Time[3]
Pre-Vacuum	132°C (270°F)	4 minutes	30 minutes	30 minutes

[1] Both the given cycle temperature and time can be increased to 134°C + 3°C (273.2°F + 5.4°F) and 18 minutes according to local requirements outside of the United States such as in the European Union.

[2] Drying times vary according to load size and should be increased for larger loads.

[3] Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

I) SPECIAL INSTRUCTIONS FOR GENERIC INSTRUMENT CASES (CASES WITHOUT DEFINED, PRECONFIGURED LAYOUTS OR CONTAINING UNDEFINED UNIVERSAL SPACES OR COMPARTMENTS)

Universal instrument trays and cases without defined, preconfigured layouts or containing undefined universal spaces or compartments should only be used under the following conditions:

- The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total sterilization package should not exceed 16kg/35lbs.
- Any device capable of disassembly must be disassembled prior to placement in the case.
- All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.
- The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicon mats may be used to keep devices in place.
- Only devices manufactured and/or distributed by MR Surgical should be included in MR Surgical instrument trays. MR Surgical validated reprocessing instructions are not applicable to MR Surgical trays that include devices that are not manufactured and/or distributed by MR Surgical.

J) STORAGE AND HANDLING

- Protective caps or other protective devices must not be removed until immediately before use.
- Instruments can be stored either in their original packing unopened or in the appropriate instrument tray, or in other suitable packing that protects the instruments from damage.
- The instruments and their components are subject to wear and therefore have to be considered as non-durable material. The integrity of the instruments has to be checked before use and if necessary, instruments must be returned to the responsible local representative for repair or disposal.
- For information on storage conditions, refer to the corresponding system User Manual.

Note: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set re-sterilized.

K) TRANSPORTATION

- The instruments are supplied in their designated instrument trays.
- The trays ensure that every instrument is kept in a way that they do not receive any damage and that their functionality is preserved during transportation.

L) DISPOSAL INFORMATION

After use, the instrument is a potential biohazard, since it may be contaminated with blood or other body fluids, bone or tissue. Handle and dispose of product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

ADVERSE EVENTS/COMPLAINT HANDLING

The user and/or patient should report any suspected serious incident or serious safety issue related to the device by informing the manufacturer and the competent authority of the member state in which the serious incident has occurred.

Note: These instructions are intended to assist the hospital and central supply management in developing procedures to attain safe and effective devices, both for hospital-owned and for loaned instrument sets.

Customer Service Information

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