

## ROSA Shoulder System



### Cleaning, Disinfection and Sterilization Aid

#### Cleaning the Robotic Unit

Make sure the device is turned off and unplugged before cleaning. After each use, clean the covers, panels and Robotic Arm with a damp cloth with mild disinfectants, ethanol (70%) or Isopropyl Alcohol (70%).

Use a mild alkaline detergent to remove scuffs and stains. Do not use solvents that may damage or discolor paint finishes or plastic components. Read the labels of the cleaning products carefully. Both the cloth and the cleaning product must be approved for use in an operating room.

Robotic and Optical Units are not waterproof. Be careful not to spill or splash liquids where they can enter electronic assemblies.

<p> Never attempt to clean the device when it is connected to a power supply. To avoid electrical discharges, always unplug the device from the wall outlet before cleaning or disinfecting it.</p>	<p> IPX0 protection: Device without special protection against the penetration of liquids. Do not pour any liquid over the device.</p>
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#### Cleaning the Optical Camera

##### Camera Housing



Clean the camera housing only if required. Clean the whole surface of the camera using a lint-free, soft cloth dampened with a non-abrasive and mild detergent with mild disinfectants, ethanol (70%) or Isopropyl Alcohol (70%).

##### Illuminator Filters and Lenses

Clean the illuminator filters and lenses only if required. Carefully wipe them using a damp cloth (Isopropyl Alcohol 70%) that is suitable for optical glasses. Remove fingerprints and pay attention not to cause damage or scratches.



### Instrument Reprocessing (Cleaning and Sterilization Methods)

<p> Before every surgery, the user must verify that all instruments are clean, lubricated and sterilized as per instructions.</p>	<p> For reusable instrument cleaning and sterilization, refer to:</p> <ul style="list-style-type: none"> <li>• Zimmer Biomet Instrument Care, Cleaning, Maintenance and Sterilization Instructions (97-5000-170-00)</li> <li>• Reusable Instrument Lifespan Manual (1219.X)<sup>1</sup></li> <li>• Surgical Instrument Package Insert (803.030)</li> <li>• Surgical Instrument Package Insert (803.006)</li> <li>• Instrument/Provisional Use, Care and Sterilization (87-6203-991-99)</li> <li>• Instrument/Provisional Use, Care and Sterilization (87-6203-999-99)</li> <li>• Instructions for the Care, Cleaning, Maintenance, Handling, and Sterilization of Biomet Surgical Instruments and Instrument Cases (01-50-1539)</li> </ul>
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<sup>1</sup> X refers to the latest revision number available, applicable to all references of 1219.X in this document

## Steam Sterilization (Autoclave)

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

<sup>1</sup> 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.

<sup>2</sup> Drying times vary according to load size and should be increased for larger loads.

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

### ROSA Shoulder System Instrument Kit

In addition to the Surgical Instrument Package Insert (803.030) cleaning and sterilization requirements, the instruments listed in the table below require additional cleaning instructions from the following list:

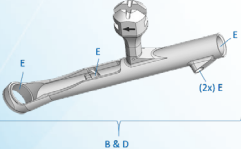
- A. Requires disassembly
- B. Requires water jet to flush difficult to access areas
- C. Screw/unscrew components while flushing the area
- D. Requires a minimum of 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E. Screws/mechanisms should be checked and lubricated with a medical surgical lubricant after each cleaning as determined upon inspection

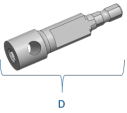
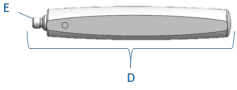
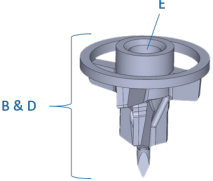
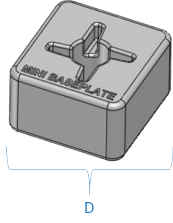
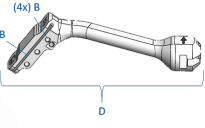
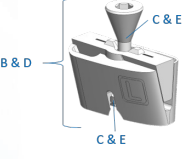

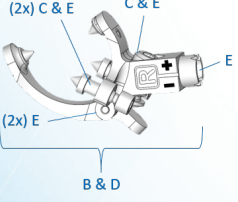
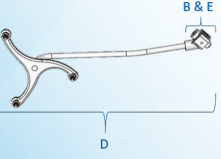
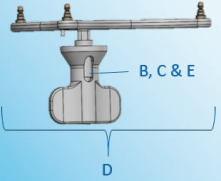


Lubrication of the instruments, especially the ROSA Shoulder Glen Core (20-8087-100-02), is essential to maintain integrity during use and should be performed after cleaning, before sterilization (803.030). See Figure 1.

\*The pre-cleaned ROSA Shoulder Glen Core (20-8087-100-02) must be manually lubricated (e.g. immersed in solution for a defined amount of time without rinsing) as per instrument lubricant manufacturer's Directions for Use. It is additionally recommended to add lubricant to the automated washer/disinfectors. Dispense at equipment manufacturer's recommendations.

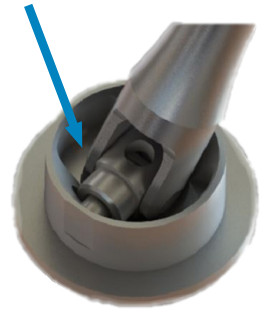
Ensure all parts are inspected and tested following lubrication. Verify the functionality of the parts, ensuring correct movement of the instruments in all possible positions without any jamming. Refer to 1219.X for further information to assist in determining whether a reusable instrument has worn to an extent that it is no longer suitable for use.

Instrument	Description	Sterilization & Specific Cleaning Instructions	Part Number
	ROSA SHOULDER INTERFACE ASSY	<b>B C D E</b>	20-8087-900-00
	ROSA SHOULDER GLEN FRAME	<b>B D E</b>	20-8087-100-01
	ROSA SHOULDER GLEN CORE	<b>B D E*</b>	20-8087-100-02
	ROSA SHOULDER GLEN LINK	<b>B D E</b>	20-8087-100-03

	<b>ROSA SHOULDER REAMER DRIVER</b>	<b>D</b>	20-8087-101-00
	<b>ROSA SHOULDER GLEN HANDLE</b>	<b>D E</b>	20-8087-102-00
	<b>ROSA COMPREHENSIVE MINI RT</b>	<b>B D E</b>	20-8087-123-00
	<b>ROSA ALLIANCE MOD VAULT RT</b>		20-8087-126-00
	<b>ROSA ALLIANCE MONO VAULT RT</b>		20-8087-127-00
	<b>ROSA ALLIANCE FOSSA RT SZ 1</b>		20-8087-128-00
	<b>ROSA ALLIANCE FOSSA RT SZ 2</b>		20-8087-129-00
	<b>ROSA ALLIANCE FOSSA RT SZ 3</b>		20-8087-130-00
	<b>ROSA ALLIANCE FOSSA RT SZ 4</b>		20-8087-131-00
	<b>ROSA ALLIANCE FOSSA RT SZ 5</b>		20-8087-132-00
	<b>ROSA COMPREHENSIVE BLOCK</b>	<b>D</b>	20-8087-125-00
	<b>ROSA ALLIANCE BLOCK</b>		20-8087-133-00
<b>ROSA REAMER BLOCK</b>		20-8087-134-00	
	<b>ROSA SHOULDER CUT GUIDE LEFT</b>	<b>B D</b>	20-8087-200-00
	<b>ROSA SHOULDER CUT GUIDE RIGHT</b>		20-8087-201-00
	<b>ROSA SHOULDER SCAPULA REF L</b>	<b>B C D E</b>	20-8087-300-00
	<b>ROSA SHOULDER SCAPULA REF R</b>		20-8087-301-00
	<b>ROSA SHOULDER SCAPULA REF ROD</b>	<b>D</b>	20-8087-302-00
	<b>ROSA SHOULDER HUMERAL REF</b>	<b>B C D E</b>	20-8087-400-00
	<b>ROSA SHOULDER HUM REF ROD L</b>	<b>B D E</b>	20-8087-401-00
	<b>ROSA SHOULDER HUM REF ROD R</b>		20-8087-402-00
	<b>ROSA TRACKER PLATFORM</b>	<b>B C D E</b>	20-8087-504-00

	<b>ROSA HUMERAL VALIDATION TOOL</b>	<b>B D E</b>	20-8087-600-00
	<b>ROSA ALLIANCE MONO VT</b>		20-8087-601-00
	<b>ROSA ALLIANCE MOD VT</b>		20-8087-602-00
	<b>ROSA ALLIANCE 2 PEG VT</b>		20-8087-603-00
	<b>ROSA COMPREHENSIVE MINI VT</b>		20-8087-604-00

Ensure the entire Universal Joint mechanism on the ROSA Shoulder Glen Core (20-8087-100-02) is manually fully lubricated



Manually move shaft in all possible positions and directions relative to the rest of the ROSA Shoulder Glen Core to ensure full coverage of lubricant within the mechanism

**Figure 1: Instructions for Lubrication of ROSA Shoulder Glen Core**

The ROSA Base Reference Frame, ROSA Front Clamp and ROSA Monitor Clamp will not be sterilized and therefore should be cleaned with a damp cloth before use in a surgery.

ISO 17664-1 Sterilization of medical devices: Information to be provided by the manufacturer for the processing of resterilizable medical devices

ISO 17665-1 Sterilization of healthcare products: Moist heat- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

For additional information on sterilizing, cleaning and disinfecting, refer to Chapter 15 Post-operative Guide/Maintenance in the ROSA Shoulder User Manual and Surgical Technique (4285-GLBL-en).

**Please visit [www.zimmerbiomet.com/ROSAShoulder](http://www.zimmerbiomet.com/ROSAShoulder) for additional information.**

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