

Cleaning, Disinfection and Sterilization Aid

Cleaning the Robotic and Optical Units

Make sure the device is turned off and unplugged before cleaning. After each usage, clean the covers, panels and the Robotic Arm with a damp cloth (e.g. alcoholic wipes).

If necessary, use a mild alkaline detergent to remove scuffs and stains. Do not use any solvents that may damage or discolor paint finishes or plastic components. Read the labels of the cleaning products carefully. Both the cloth and 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.



Never attempt to clean the device when it is connected to power supply. To avoid electrical discharges, always unplug the device from the wall outlet before cleaning or disinfecting it.



IPX0 Protection: Device without special protection against the penetration of liquids. Do not pour any liquid over the device.



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 (e.g. alcoholic wipes).

Illuminator Filters and Lenses

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



Instrument Reprocessing (Cleaning and Sterilization Methods)



Before every surgery, the user must verify that all instruments have been sterilized.



For reusable instruments, also refer to the instrument's package insert.

Reusable instruments must be cleaned after use prior to sterilization. They should not be sterilized in the protective bag or packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment.

Reusable instruments require the following manual cleaning steps:

1. All multi-components instruments should be disassembled and pre-soaked in an enzyme solution, then scrubbed with a soft bristle brush to remove all visible soil.
2. Use a water jet to flush difficult-to-access areas and closely mated surfaces. For threaded interfaces, screw/unscrew components while flushing the areas.
3. Next, ultrasound cleaning (sonication) in an enzyme solution is recommended in all cases to complete the cleaning steps with minimum cycle times of five minutes and for those instruments with difficult to access areas, cycle times of at least 10 minutes.
4. Finally, in all cases, a thorough rinse is required. Normally, screws and other mechanisms should be checked and lubricated with a medical grade surgical lubricant after each cleaning as determined upon inspection.

The above instructions that are instrument-type dependent are indicated in the ROSA Knee User Manual and Surgical Technique (2300-GLBL-en) as applicable to each instrument.

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.


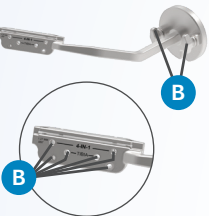


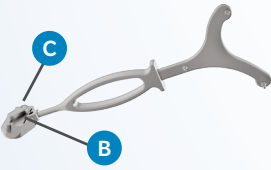
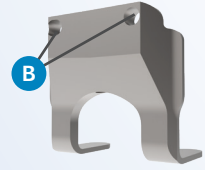

² Drying times vary according to load size and should be increased for larger loads.

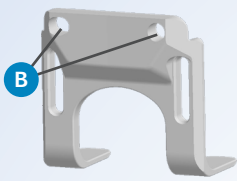
³ Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of environment and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

ROSA Knee System Instrument Kit

- 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 grade surgical lubricant after each cleaning as determined upon inspection.

Instrument	Description	Sterilization & specific cleaning instructions	Part Number
	ROSA Base Reference Frame	Autoclave B C D E	20-8020-002-00

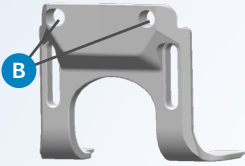
Instrument	Description	Sterilization & Specific Cleaning Instructions	Part Number
	ROSA Arm Instrument Interface	Autoclave B D E	20-8020-004-00
	ROSA Persona® TKA cut guide A ROSA Persona TKA cut guide B ROSA NexGen® TKA cut guide A ROSA NexGen TKA cut guide B ROSA Vanguard® TKA cut guide A ROSA Vanguard TKA cut guide B	Autoclave B D E	20-8020-007-00 20-8020-008-00 20-8020-009-00 20-8020-010-00 20-8020-011-00 20-8020-012-00
	ROSA Registration Pointer	Autoclave D	20-8020-013-00
	ROSA Arm Reference Frame	Autoclave B D E	20-8020-015-00
	CAS Universal Validation Tool Body	Autoclave B C E D	20-8000-010-06
	CAS Posterior and Distal Condyles Digitizer	Autoclave B D	20-8000-010-17
	ROSA Knee Condyle Digitizer, Small	Autoclave B D	20-8020-190-00



**ROSA Knee Condyle Digitizer,
Medium**

Autoclave **B D**

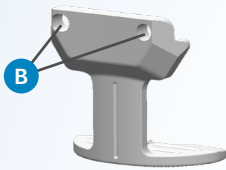
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**ROSA Knee Condyle Digitizer,
Large**

Autoclave **B D**

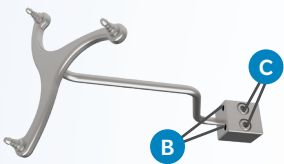
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ROSA Knee Tibia Validation Tool

Autoclave **B D**

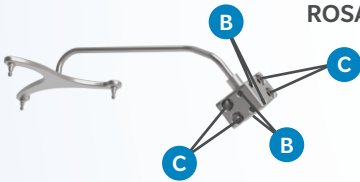
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2 Pins Reference Femur TS3

Autoclave **B C D E**

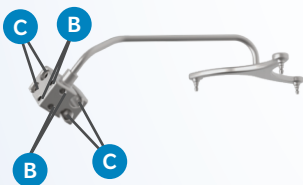
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ROSA Tibia Reference A

Autoclave **B C D E**

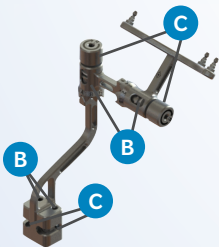
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ROSA Tibia Reference B

Autoclave **B C D E**

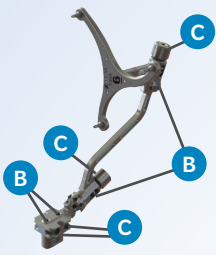
20-8020-029-00



ROSA Polyaxial Reference Size 3

Autoclave **B C D E**

20-8020-037-00



ROSA Polyaxial Reference Size 6

Autoclave **B C D E**

20-8020-038-00



ROSA Pin Stabilizer, 60mm

Autoclave **B D**

20-8020-039-00



**ROSA Stabilizer Tissue Deflector,
60mm**

Autoclave **D**

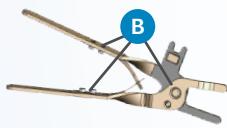
20-8020-040-00



**Hexagonal Screwdriver
3.5 mm**

Autoclave **D**

00-5120-087-00



CAS Navitracker® Pliers

Autoclave **B D E**

20-8000-070-05



Trocar Pin Screw Driver

Autoclave **D**

00-5901-021-00

Disposables

Description	Sterilization & Specific Cleaning Instructions	Part Number
Headless Trocar Drill Pin CAS 3.2 mm	Autoclave (single-use)	20-8000-000-16
Vanguard Quick Release Trocular Pin	Autoclave (single-use)	32-486255
Vanguard Sterile Quick Release Drill Pin	Provided sterile (single-use)	32-486265
ROSA Checkpoint Screw 13mm	Provided sterile (single-use)	20-8020-158-00
Navitracker Kit A - Knee	Provided sterile (single-use)	20-8000-000-07
Fix Fluted Pin 3.2x150 mm	Autoclave (single-use)	20-8000-000-01
Fix Fluted Pin 3.2x80 mm	Autoclave (single-use)	20-8000-000-02
Fix Fluted Pin 3.2x150 mm	Provided sterile (single-use)	20-8000-000-10
Fix Fluted Pin 3.2x80 mm	Provided sterile (single-use)	20-8000-000-11
ROSA Robotic Unit Drape	Provided sterile (single-use)	20-8020-080-00
ROSA Arm Drape	Provided sterile (single-use)	ROSAS00055
Monitor Drape	Provided sterile (single-use)	ROSAS00056

ISO 17664:2017 Sterilization of medical devices: Information to be provided by the manufacturer for the processing of resterilizable medical devices

ISO 17665-1:2006 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 13 Post-operative Guide/Maintenance in the ROSA Knee User Manual and Surgical Technique (2300-GLBL-en).

Please visit www.zimmerbiomet.com/ROSAKnee for additional information.

Please refer to the ROSA Knee User Manual, found at labeling.zimmerbiomet.com for additional information.

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