X SERIES™ Power System | Sterilization and Cleaning Guidelines

Preparation for Cleaning

1. Place the handpiece in the “safe - off” position.
2. Disconnect power cords and remove the batteries.
3. Remove and dispose of single-use cutting consumables in an appropriate container.
4. Remove all attachments.
5. If using the Aseptic battery, open lid and remove battery from housing.

Cleaning Tip:

For complete information about dismantling the device, refer to the instructions included with your specific Zimmer Biomet X Series Power System.

REQUIRED WASHING VALIDATION

Cleaning and Disinfection Procedure

Contamination Removal

Rinse product with RO or distilled water, removing any visible organic material. Apply detergent with a non-shedding cloth and, as necessary, with a soft bristle to remove any visible soil paying attention to exposed parts, narrow cavities and difficult to reach areas.

1

Rinse

Rinse carefully with RO or distilled water for a minimum of 30 seconds so that all detergent is fully removed.

2

Drying

Dry the device utilizing a dry, non-shedding cloth. Medical-quality filtered air may be utilized if available.

3

Disinfection Application

Apply the recommended pH value detergent disinfectant to a non-shedding cloth. Cover the device’s surface area with the saturated cloth.

4

Manual Disinfection

After 30 minutes contact time, wipe the device contact surfaces, joints, and mated areas utilizing the cover cloth.

5

Final Rinse

Rinse carefully with RO or distilled water so that all the detergent is fully removed.

6

Final Drying

Dry the device utilizing a dry, non-shedding cloth. Medical-quality filtered air may be utilized if available.

7

OPTIONAL AUTOMATED WASH

Cleaning and Disinfection Procedure

Contamination Removal

Rinse product with RO or distilled water, removing any visible organic material. Apply detergent with a non-shedding cloth and, as necessary, with a soft bristle to remove any visible soil.

Rinse

Rinse product with RO or distilled water.

Drying

Dry the device utilizing a dry, non-shedding cloth. Medical-quality filtered air may be utilized if available.

Automated Washer

Place entire device into the automated washer, placing implements so that holes are aligned downward. Detergent should not exceed a pH value of 10.8.

Warning:

Never immerse or submerge your Zimmer Biomet X Series Power System in water or cleaner.

Validated Automatic Washer Cycle

Step	Minimum Time	Recommended Temperature
Pre-Wash	2 Minutes	Water Temperature 20°C (68°F)
Cleaning	5 Minutes	Water Temperature 55°C (131°F)
Neutralizing	2 Minutes	Water Temperature 20°C (68°F)
Rinse I	2 Minutes	Water Temperature 20°C (68°F)
Rinse II (Final)	5 Minutes	Water Temperature 93°C (200°F)
Drying	35 Minutes	Chamber Temperature 99°C (210°F)

Sterilization Validation

Steam Cycle Type	Temperature (Celsius/Fahrenheit)	Steam Dwell Time	Minimum Dry Time**
Pre-Vacuum	132° C/270° F	4 Minutes*	30 Minutes
Pre-Vacuum	134° C/273° F	3 Minutes*	30 Minutes
Gravity	132° C/270° F	15 Minutes	45 Minutes
IUSS	132° C/270° F	4 Minutes	No Dry Time
IUSS	134° C/273° F	3 Minutes	No Dry Time

* Steam Dwell Time may be extended to a maximum 18 minutes.

** Dry Time is highly dependent on sterilization load size. Dry Time may need to be increased in 5-minute increments for larger loads.

Note: Sterilization parameters on this document are not intended for Sterilizable battery.

The referenced sterilization cycle parameters listed in this manual have been validated and provide a sterile result by steam sterilization according to ANSI/AAMI/ISO 17665-1:2006, Sterilization of Health Care Products. Part 1: Moist Heat. The steam sterilization process for these products has been validated to provide a sterility assurance level (SAL) of 10-6 or better when using the prescribed sterilization case.

Packaging used in the sterilization of these devices shall: follow EN ISO 11607; be suitable for the chosen sterilization method; provide sufficient protection of the device as well as protection of the packaging to prevent mechanical damage; be the appropriate type/grade for weight of device.

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