

# Zimmer PSI – Automated cleaning instructions

## Addendum to Zimmer PSI Instructions For Use



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**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Materialise NV (manufacturer) states that the custom-made medical device with the product specifications and the product identification as mentioned in this document are in accordance to the essential requirements of Annex I of the Council Directive 93/42/EEC.

### Automated Cleaning instructions

1. Pre-rinse the guides and models under running tap water to remove gross soil. Use a soft bristled brush to remove soil from the surface of the guides and models. Use a syringe and/or long, narrow soft-bristled brush to flush cylinders and slots.
2. When available, clean the guides ultrasonically at the temperature and with a specially formulated detergent recommended by the manufacturer of the ultrasonic cleaning equipment. The detergent should be of neutral or near neutral pH (pH 7-11). Follow the manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners and medical equipment. After ultrasonic cleaning, rinse the guides using RO or DI water. Use a syringe to flush cylinders and slots.
3. Wash the guides and models using an automatic washer unit. It is recommended to use a detergent as recommended by the manufacturer of the automatic washer unit.
4. Dry the guides and bone models with filtered pressurized air and/or wipe with a soft lint-free cloth.

Manual Pre-rinse	Pre-Wash	Wash	Neutralize (if necessary)	Rinse	Thermal Disinfection	Drying
Minimum 1 minute  Running tap water, clean with tools	2 minutes at 30°C-80°C  Cold tap water	4 to 10 minutes at 60°C-80°C  The detergent should be of neutral or near-neutral pH (pH 7-11)	Minimum 2 minutes  Warm tap water with neutralizer	Minimum 2 minutes at 40°C-80°C  DI or PURW	Minimum 7 minutes at minimum 94°C	Dry with hot filtered air at minimum 90°C or wipe with soft lint-free cloth

For more information about the intended use of the *Zimmer PSI*, warnings, contra-indications, precautions, possible adverse effects and recommended cleaning and sterilization specifications please consult the *Zimmer PSI* IFU, included in the shipment package of each guide set.

### ADDITIONAL INFORMATION

For any additional information, please contact Materialise customer service.  
This is version 1 of the document and has been issued in June 2015.

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