

er's loading instructions and close the chamber door. Start preprogrammed sterilization cycle per manufacturer's instructions.

The probe is ready for use after the sterilization cycle is complete including a minimum drying time of 30 minutes.

### 5.2 Sterrad® Sterilization (A Johnson&Johnson Process)

The Medistim PS probes can be sterilized using Sterrad®, a rapid, low-temperature and low-moisture technology designed for delicate instrument sterilization.

The following models can be used to sterilize the probe:

- Sterrad® NX
- Sterrad® 100S
- Sterrad® 100NX
- Sterrad® 200

The sterilization cycle involves the following steps:

1. Follow instructions for use for the Johnson&Johnson sterilization process to protect the probe from accidental damage during handling.
2. Clean the probe as described in Section 3 (Cleaning) and dry thoroughly. Place the dry probe in the probe box delivered with the probe or a Sterrad® instrument tray. Double wrap tray or box in CSR wrap.
3. Place the instrument tray(s) in the sterilization chamber according to manufacturer's loading instructions and close the chamber door. Start preprogrammed sterilization cycle per manufacturer's instructions.
4. The probe is ready for use after the sterilization cycle is complete. Normal cycle time is 28 - 75 minutes depending upon the model.

### 5.3 Renosem plasma Sterilization

The following Renosem models can be used to sterilize the probe:

- Reno-S20
- Reno-S30
- Reno-D50
- Reno-S130
- Reno-S130D

The sterilization cycle involves the following steps:

1. Follow instructions for use for the Renosem sterilization process to protect the probe from accidental damage during handling.
2. Clean the probe as described in Section 3 (Cleaning) and dry thoroughly. Place the dry probe in the probe box and double wrap box in CSR wrap.
3. Place the instrument tray(s) in the sterilization chamber according to manufacturer's loading instructions and close the chamber door. Start preprogrammed sterilization cycle per manufacturer's instructions.
4. The probe is ready for use after the sterilization cycle is complete. Normal cycle time is 28 - 62 minutes depending upon the model.

**WARNING:**  
**NEVER INSERT A WET CONNECTOR TO THE SYSTEM AS THIS COULD CAUSE THE SYSTEM TO MALFUNCTION.**

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## Handling, Cleaning and Sterilization of the Medistim QuickFit™ TTFM Probes

(PS101011, PS101012, PS100021, PS100022, PS100031, PS100032, PS100041, PS100042, PS100051, PS100052, PS100071, PS100072)

Explanation of symbols on probe- and package labeling

 Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 93/42/EEC.

 "Follow instructions for use"

**IPX7** Protected against the effects of temporary immersion in water


 Quantity


 Date of Manufacture

 Manufacturer address

**Rx only** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

 Shipped NON-STERILE

 Serial Number

 Catalogue number

**Handling, Cleaning and Sterilization of the Medistim QuickFit™ TTFM Probes**

To guarantee that the probe performance is in accordance with the specifications during the entire lifecycle of the probe, Medistim has limited the number of sterilization cycles to 50. The probes are warranted against manufacturing defects for one year, limited to a maximum of 50 sterilization cycles.

**1 HANDLING**

The Medistim probes are delicate instruments made with very high precision and should be handled with care. Damage to the probe can cause measurements to be inaccurate or even impossible.

To ensure optimal performance and longevity of the probe, please note the following handling guidelines:

- Do not bend the steel reflector.
- Do not stretch the cable.
- Do not rotate the flexible distal portion of the probe around the probe center axis.
- Use care when coiling the probe cable - the cable should be wound in large loose loops, not tightly wrapped.
- Use care when cleaning the probe.
- Clean the probe immediately after use. Do not let blood dry on the probe.
- Use care not to cut the cable with sharp tools or in any way crush the cable.
- It is highly recommended that the probe's original packaging be used during shipment, handling, and storage.

Probes that have been damaged due to careless handling are not covered under warranty.

**2 CHECKING MECHANICAL INTEGRITY**

Prior to use and during the cleaning process, check each probe for mechanical integrity. The probes are delicate medical devices that may experience mechanical abrasion, which could damage them. Probes that show external signs of abrasion (visible cracks, small cuts in the probe cable, etc.) should be checked for mechanical integrity. In particular, carefully

examine the section between the flexible part of the probe and the probe handle. Probes with major mechanical malfunctions should not be used and should be replaced. Please contact your local representative or Medistim directly.

**3 CLEANING**

Wear protective gloves when removing the probe from the sterile field and when cleaning, as it may be stained with blood.

**Automatic washing machine:**

The PS probes can be cleaned in an automatic washing machine at a maximum temperature of 95°C, using non-aggressive detergents and at a drying temperature of maximum 100°C for up to 20min.

**Manual cleaning:**

After use, immerse the probe and soak for a minimum of five (5) minutes in a fresh, pH-neutral, enzymatic cleaning solution per manufacturer's instructions.

Use a soft-bristled brush moistened with cleaning solution to remove all traces of debris, being particularly thorough in the area of the probe head and locking slide.

Thoroughly rinse the probe under warm running (~30-43°C) tap water for a minimum of one (1) minute and until visibly clean. Wipe the probe with 70% isopropyl alcohol (IPA) and allow to air dry. Repeat this cleaning procedure if any remaining debris is observed on the probe.

**4 DISINFECTION**

Subsequent to the cleaning procedure described in section 3, the probe must be sterilized according to the method described in section 5 (Sterilization) in the user manual.

Additional disinfection is not required and may ultimately damage the probe. If, nonetheless, disinfection is performed, ensure that the disinfection solution used is listed by Medistim for use with the PS probe models

covered by this manual. For an updated list of disinfection solutions visit the Medistim homepage: [www.medistim.com](http://www.medistim.com).

Note! The connector must not be left to soak in disinfection solution.

When disinfection is performed, follow the manufacturers instructions applicable to the disinfection solution.

Please note that the cleaning procedure (see Section 3) must be administered prior to disinfection and/or final sterilization (see Section 5).

**WARNING:** damages due to use of disinfection solutions NOT LISTED BY MEDISTIM are not covered by the warranty.

**5 STERILIZATION**

**5.1 Steam Autoclave**

The PS series probes can be sterilized using steam autoclave for full cycles of four (4) minutes at 132°C or three (3) minutes at 134°C using prevacuum air removal in double-pouched or double-wrapped probe box up to three (3) Bar pressure and a duration of up to thirteen (13) minutes. Medistim guarantees that the PS probe series can be re-sterilized 50 times when handled in accordance with this procedure.

**WARNING: CLEANING SHALL ALWAYS BE PERFORMED PRIOR TO STERILIZATION**

The steam sterilization cycle involves the following steps:

Follow instructions for use for the autoclave sterilization process to protect the probe from accidental damage during handling. When sterilizing multiple devices do not exceed the maximum load as indicated in the manufacturer's instructions. Clean the probe as described in Section 3 (Cleaning) and dry thoroughly. Place the dry probe in a pouch specifically warranted by the steam autoclave sterilization manufacturer or in the probe box delivered with the probe. Place the pouch or probe container in the steam sterilization chamber according to manufactur-