

Manufacturer's Information

on the reprocessing
of re-sterilisable instruments
according to DIN EN ISO 17664



As at: 01/14
Revision: 1

Pins/Screws/Wires

Manufacturer:

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Products:

The present manufacturer's information applies to all surgical instruments supplied by Gebr. Brasseler, i.e. Kirschner wires, Steinmann pins, Guide pins, screws and pin drivers. Instruments delivered in non-sterile condition have to be prepared prior to first use.

General information:

Please follow the recommendations and instructions provided by the manufacturer of the washer disinfectant and the autoclave.

Limited number of reprocessing cycles:

The end of a product's service life depends on its degree of damage and wear. Frequent reprocessing does not affect the performance of these instruments.

Work station:

Hygienic precautions according to the provisions valid in your country.

Storage and transport:

Immerse instruments in a suitable detergent/disinfectant (alkaline, aldehyde-free) immediately after use on the patient to prevent residues from drying on the instruments (protein fixation). It is recommended to reprocess the instruments within one hour of use at the very latest.

Validated reprocessing procedure

Mechanical cleaning:

Equipment used:

- Washer disinfector (ca. Miele, with Vario TD-programme)*
- Neodisher MediClean forte (co. Dr. Weigert)

* Should the Miele washer disinfector be unavailable, please observe the parameters of the Vario TD-programme sequence (see fig. 1).

1. Immediately before mechanical reprocessing rinse instruments thoroughly under running water to prevent any residues of detergent/disinfectant from getting into the machine.
2. Place the instruments in the washer disinfector in such a way that the instruments are directly hit by the spray jet.
3. Start the Vario TD-programme (for diagram of program sequence see fig. 1) including thermal disinfection. Thermal disinfection takes place allowing for the A_0 value and observing national provisions (prEN/ISO 15883).

The cleaning procedure is carried out following the below pattern:

- 4 minutes' pre-wash with cold water
 - Emptying
 - 6 minutes' pre-wash with neodisher MediClean forte (co. Dr. Weigert) at 55°C
 - Emptying
 - 3 minutes' neutralization with warm tap water (>40°C)
 - Emptying
 - 2 minutes' intermediate rinse with warm tap water (>40°C)
 - Emptying
 - Thermal disinfection takes place allowing for the A_0 -value and observing national provisions (prEN/ISO15883)
4. Remove any residual moisture from the instruments with filtered compressed air, which does not lead to recontamination.

If after mechanical reprocessing there are still visible residues of contamination, repeat the cleaning and disinfecting process until no visible contamination is left. The cleaning agent neodisher MediClean forte can be used for this, provided that the instructions on the label are observed.

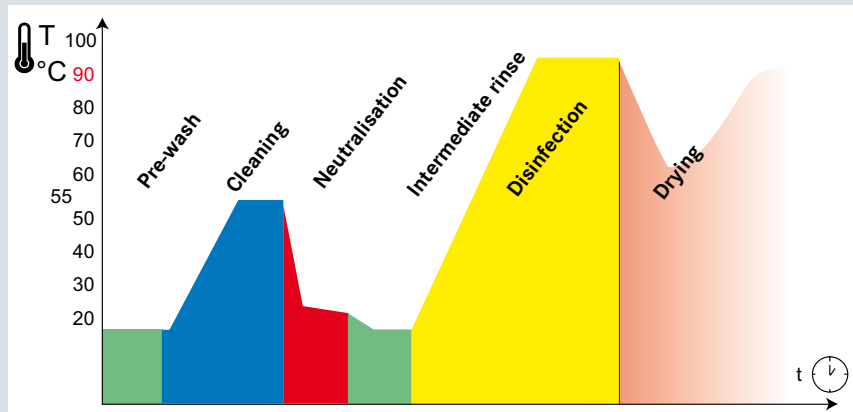


Fig. 1 Diagram of the programme sequence of the Vario TD-programme

Control and functional test:

Kirschner wires and Steinmann pins that show any signs of use have to be discarded immediately. These articles are designed for single use only. Guide pins and screws with the following defects have to be discarded without delay:

- Blunt and chipped blades
- Bent instruments
- Corroded surfaces

Check the instruments visually for possible damage and wear. Blades and threads should be even and free of nicks (the use of magnifying glasses is recommended).

Packaging:

Single pack: Standardised packaging material can be used. The bag must be large enough for the instruments to ensure that there is no pressure on the seal.

In the set: Place instruments onto the tray provided or onto universal sterilization trays. The instruments must be protected. Use an appropriate method to pack the tray.

Sterilization:

Steam sterilization using a fractionated vacuum process at 134°C in a device that complies with the provision of EN 285; with validated processes.

1. Fractionated pre-vacuum (4x)
2. Sterilisation temperature: 134°C
3. Hold time: 5 minutes (full cycle)
4. Drying time: 10 minutes

In order to prevent staining and corrosion, the steam must be free of particles. The recommended limits for particle contents in feed water and condensed steam are defined by standard EN 285.

Alternatively the gravity method at 2 bar, 121°C and hold time of 30 minutes can be used.

Plasma sterilization: Sterilizer Sterrad 100S. The procedure is carried out according to a fixed pattern.

Make sure not to exceed the maximum capacity of the sterilizer when sterilizing several instruments (follow the instructions of the device manufacturer).

Storage:

The goods must be protected from dust, moisture and recontamination during storage.

Universally valid notes:

Observe the legal provisions regarding the reprocessing of medical products valid in your country (e.g. www.rki.de).

The manufacturer confirm that the above detailed reprocessing methods are **suitable** for reprocessing the above named instrument group to enable their reuse.

The reprocessor is responsible for ensuring that the applied method is carried out with appropriate equipment and materials and by trained personnel at the reprocessing site and that it actually achieves the desired result.

To guarantee this, validations and routine controls of the process are necessary. Any deviation from the above detailed method (e.g. use of different chemicals) must be carefully checked by the operator to ensure effectiveness and to avoid possible adverse consequences.