Cleaning und Disinfecting Instructions of Champions® Instruments

Mechanical Cleaning and Disinfection:

1. Place instruments in a suitable container in the thermo-disinfector so that the spray jet can be directed at the products.
2. Place process chemicals in the machine, according to the instructions of the thermo-disinfector manufacturer and on the product label.
3. Start the Vario thermal disinfection program. The thermal disinfection is performed.
   Consider the A-value and the national standard (EN/ISO 15883).
4. After the program process, remove the products from the thermo-disinfector and dry them (preferably with compressed air, according to the recommendations of the Robert-Koch-Institut, a German organization that is responsible for disease control/prevention).
5. Visually inspect for intactness and cleanliness. If you see visible residues after the mechanical preparation, repeat cleaning and disinfecting until you do not see any residues. This is not applicable for articles that cannot be reprocessed.

Manual Cleaning and Disinfection (Alternative)

1. Place instruments in the ultrasonic or instrument bath, which is filled with detergents and disinfectants (Close the cover).
2. For chemical disinfection in the ultrasonic or instrument bath, observe manufacturer instructions concerning concentration and application time. The application time, which shall not fall below the minimum time, starts when the last instrument or system component is in the bath.
3. After their application time, rinse the instruments thoroughly with suitable water (to avoid residues, rinse with completely desalinated water (VE)).
4. Dry instruments (preferably with compressed air, according to the recommendations of the Robert Koch Institut).
5. Visually inspect for intactness and cleanliness. If you see visible residues on the instruments, repeat cleaning and chemical disinfecting until you do not see any visible residues. This is not applicable for articles that cannot be reprocessed. The Robert-Koch-Institut recommends that cleaning and disinfecting should preferably be performed mechanically.

Sterilization in the Autoclave:

All instruments can be sterilized. When sealing the sterilization film, take care that the film is not under tension. The components can be sterilized per steam sterilization in the vacuum procedure at 134°C in a machine according to DIN EN 13060. For this procedure, meet the following requirements: steam sterilization in the vacuum procedure at 134°C in a machine according to DIN EN 13060; validated processes.

- Fractional pre-vacuum (Type B)
- Sterilization temperature: 134°C
- Holding time: at least 5 minutes (full cycle)
- Drying time: at least 10 minutes

In order to avoid stains and corrosion, the steam must be substance-free. The limit values of feed water and steam condensate substances are defined in DIN EN 13060. When sterilizing several instruments, do not overload the sterilizer. The instructions of the machine manufacturer are to be followed. Do not use corroded system components. In order to reduce the risk of fracture, do not use damaged instruments!

Please note: Observe the legal regulations concerning medical device reprocessing, valid in your country (e.g. www.rki.de). The manufacturer assures that the preparation methods mentioned above is suitable for preparing the concerned instruments for its re-use. The medical device operator is responsible for the preparation with suitable equipment by qualified staff, according to the valid RKI-recommendations. For this routine check-ups of the validated mechanical processing procedures are necessary. In addition, the operator must carefully evaluate the effectiveness and possible disadvantageous consequences resulting from any deviation from the procedure described here.

Safety and Liability

Worn or damaged instruments or system components are to be discarded immediately and to be replaced by new ones. The above mentioned instructions for use are to be followed. The instruments or system components shall only be used for the mentioned purpose. There will be a risk of injury if safety instructions are not followed.

Liability

Before using the products, users are obliged, on their own responsibility, to check the products for suitability and possibility of use for their intended purpose. Damage partially caused by the user will limit or completely exclude the liability of Champions-Implants GmbH. This is especially applicable when the user has ignored instructions for use or safety instructions, or when he/she has accidentally misused the product.

Shelf Life:

All components are supplied in a sterile condition. Sterile products are labeled with the STERILE sign.

If medical devices are re-sterilized by the end-user, any responsibility will be void – regardless of the sterilization method.

The medical devices are only sterile if still in their closed original blister packaging.

The shelf life until its first use is indicated on the label. The hourglass symbol refers to the expiry date.

After their first use, the instruments are to be processed according to care instructions in this user manual.

The indication LOT refers to the batch number.

Storage:

The product has to be stored in a dry place in its original package at room temperature. Unsafe storage can cause product failure and damage to the material.

Notes:

- The blister package is only to be opened immediately before use.
- The manufacturer reserves the right to change the design of the product, components or its packaging, to revise instructions for use as well as pricing and delivery terms. Liability is limited to replacement of defective products.
- Further claims of any kind are excluded.
- Dispose of used instruments according to the regulations of the Robert-Koch-Institut.

Symbols:

	Manufacturer
	Use by
	Maximum permissible rotation speed: 250 min^{-1}
	Single use only
	Keep dry
	Consult Instructions for Use
LOT	Batch number
REF	Article number
STERILE R	Gamma sterilized
RX only	Application restricted to dentists or specialists
	Bar code

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CE 0297

ANL Nr. 2 E Rev. 2015-10

GA Desinfektionsanleitung englisch A4 Rev. 4/2105-10
18.03.16
ANL Nr. 2 E Rev. 2015-10