MONDEAL
MEDICAL SYSTEMS GMBH

Instructions for
Cleaning, disinfection and sterilization

Notes on cleaning, disinfection and sterilization

Basic Instructions for cleaning, disinfection and sterilization of implants and instruments from MONDEAL Medical Systems GmbH (hereinafter referred to as MONDEAL).

All implants, instruments and containers of MONDEAL systems that are delivered **NON-STERILE** must be cleaned, disinfected and sterilized before each use; this also applies to the first use after delivery (after removal of the protective packaging for transport).
Effective cleaning and disinfection is an essential requirement for effective sterilization.

Contaminated Implants must be disposed of in line with local requirements. They must not be reprocessed. Re-using single-use products can impair the structural integrity of the implants and increases the risk of functional failure, which can lead to injuries to and/or illness in the patient. Re-using single-use products also creates a contamination risk, e.g., due to transmission of germs from patient to patient. This can result in injury to and/or illness in the patient and/or user.
Unused but contaminated implants should be cleaned and disinfected separately before being placed back in the implant tray.
We recommend that you no longer use heavily contaminated instruments and those that are hard to clean (e.g., with small dimensions, cannulated screws or encrustations in places that are difficult to clean) and dispose of them immediately if safe processing cannot be guaranteed.

As part of your responsibility for the sterility of the implants, please ensure during application that, in principle, only sufficiently validated device-specific and product-specific methods for cleaning/disinfection and sterilization are used, that the equipment used (cleaning and disinfection unit, sterilizer) is regularly maintained and tested, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal provisions in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different specifications with regard to effective deactivation of prions.

Basic principles

If possible, a machine method should be used for cleaning and disinfection of the instruments (cleaning and disinfection unit/disinfector). Manual methods – even using an ultrasonic bath – should only be used when a machine method is unavailable, as these are significantly less effective and reproducible.[1]
Pre-treatment must be carried out in both cases.

[1]The use of a manual cleaning and disinfection method must be backed up by an additional product- and method-specific validation, which is the responsibility of the user.

Selection of cleaning agents, disinfectants and devices

When selecting the cleaning agents, disinfectants and devices used, it must be ensured at all stages that:

- These are suitable for the intended use (e.g., cleaning, disinfection, ultrasonic cleaning)
- The cleaning agents and disinfectants are non-protein-fixing (aldehyde-free)
- These are proven to be effective (e.g., VAH/DGHM or FDA approval or CE marking)
- The cleaning agents and disinfectants are suitable for the products and are compatible with the products
- The manufacturer's instructions, e.g., with regard to concentration, exposure time and temperature, are adhered to

When using **cleaning aids**, as well as during pre-cleaning, it must be ensured that:

- Only clean, lint-free cloths and/or soft brushes are used (never metal brushes or steel wool)
- If necessary, aids are used, such as cleaning pens, syringes, cannulas, bottle brushes for cannulated products or products with lumens.

For **drying** the products, MONDEAL recommends lint-free disposable cloths or medical compressed air.

With regard to water quality, MONDEAL recommends using demineralized and purified water (e.g. aqua purificata) for the cleaning, disinfection and rinsing steps.

Pre-treatment for cleaning, disinfection and sterilization

- Coarse impurities should be removed from the products immediately after use (within a maximum of 2 hours).
- In order to enable efficient cleaning and disinfection, products that consist of several parts and which can be dismantled are to be dismantled according to the product-specific instructions for use, if applicable, and the instructions in the section "Special instructions".
- Use clean water or a suitable disinfectant solution for cleaning the products and individual parts (see chapter "Selecting cleaning agents, disinfectants and devices").
- To remove impurities manually, use a soft brush or a clean, lint-free cloth, but never metal brushes or steel wool.
- Move movable parts back and forth, clean cannulated products using cleaning wire, and syringes and cannulas and larger lumens with a bottle brush, if necessary.
- The products should be inspected visually and, if necessary, pre-treatment should be repeated until no visible contaminants are left.

Please bear in mind that the disinfectant used during the pre-treatment is only for personal protection and is no substitute for the disinfection stage conducted at a later point, after cleaning has taken place.

Machine cleaning/disinfection

When selecting the cleaning agents and disinfectants, the chapter "Selecting cleaning agents, disinfectants and devices" must be observed. Likewise, the concentrations specified by the manufacturer of the cleaning agent and, if applicable, disinfectant must be adhered to, without fail.

When selecting the disinfector, it must be ensured that the following phases are part of a cleaning process, in accordance with EN ISO 15883:

Phase	Temperature	Duration	Action
Rinsing	cold	1 min.	rinse with cold water
Cleaning	55°C	10 min.	add the cleaning agent
Neutralization	cold	2 min.	neutralize with cold water
Thermal disinfection	≥ 93°C	5 min.	with demineralized and purified water; do not add any additional cleaning agent
Drying	≥ 100°C	20 min.	drying process

When inserting the implants and instruments into the cleaning and disinfection unit, make sure that the products do not touch each other and that they are aligned in such a way that no large liquid residues are able to remain on or in the product.
It is important to ensure that the products are well rinsed and that there is no foam residue.

Proof of the products' basic suitability for effective machine cleaning and disinfection was provided by an independent accredited testing laboratory using the "Miele PG 8535" cleaning and disinfection unit (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent "Neodisher mediclean forte" (Dr. Weigert GmbH & Co. KG, Hamburg). In doing so, the method described above was observed.

Inspection (implants and instruments)

Check all implants for damage and contamination after cleaning and disinfecting and prior to sorting into the implant containers and discard damaged and soiled implants.

Check all instruments after cleaning and disinfection for damage (e.g. corrosion, damaged surfaces, chips, etc.), contaminants and functionality. Damaged instruments must be discarded. In addition, instruments with lumens (e.g. cannulated drills) must be checked for patency, cutting instruments for sharpness, and rotating instruments for deflections. Instruments that are still dirty must be cleaned again.

Care of the products

Care products (paraffin-based/white-oil-based, biocompatible, steam-sterilizable and vapor-permeable) should be applied in a targeted manner to joints, locks or threads and sliding surfaces.
Do not use silicone-containing care products.

The disassembled instruments are reassembled for the following sterilization process.

Packaging

Sort the cleaned and disinfected instruments into the sterilization containers and package them in disposable sterilization packs (single or double packaging) and/or sterilization containers that meet the following requirements:

- accord with DIN EN ISO/ANSI AAMI ISO 11607 and EN 868-2 to -10
- suitable for steam sterilization (temperature resistant up to min. 137 °C (279 ° F), sufficient vapor permeability)
- adequate protection of the products or sterilization packaging against mechanical damage
- regular maintenance according to the manufacturer's specifications (sterilization containers)

Sterilization

Use only the following listed sterilization methods for sterilization; other sterilization methods are not permitted.
All NON-STERILE products can be sterilized with steam in autoclaves (DIN EN 13060 or DIN EN 285).

Proof of the basic suitability of the instruments and implants for effective steam sterilization was provided by an independent accredited testing laboratory using the steam sterilizer "Lautenschläger ZentraCert" and the fractionated vacuum method. In the process, the method described above was observed:

Method	Fractionated or dynamic vacuum method	Flow, gravitation method
Duration of exposure	≥ 4 min.	Not recommended
Temperature	132°C / 134°C	Not recommended
Drying time	> 20–30 Min.	Not recommended

MONDEAL recommends sterilization according to the fractionated or dynamic vacuum method. The use of the less effective gravitation method is only permissible if the fractionated vacuum process is unavailable; it also requires significantly longer sterilization times
If the user uses procedures other than those that are recommended, these must be validated by the user.
Ultimate responsibility for the validation of sterilization technology and equipment lies with the user.

Outside the US: The duration of sterilization can be extended to 18 minutes to comply with WHO recommendations and the Robert Koch Institute (RKI).

Do not use flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or sterilization of thermolabile goods such as plasma or peroxide sterilization.

After sterilization, the products must be stored in the sterilization package dry and dust-free.

Proof of the basic suitability of the products for effective steam sterilization was provided by an independent accredited testing laboratory using a steam sterilizer "ZentraCert", from Lautenschläger, and the fractionated vacuum method.

Repeated sterilization of unused implants

MONDEAL Implants are, in the unused condition, suitable for repeated sterilization according to the cycle parameters mentioned under chapter "Sterilization".
The maximum cleaning and sterilization number is 50 cycles to maintain the color coding and biocompatibility of the products.

Special instructions

Implant and instrument containers:
When necessary, please only clean/disinfect the implant and instrument containers when empty for best results.

Holding device
Disassemble the holding device into the collet, blade and sliding sleeve.
Rinse out the sliding sleeve during pre-cleaning at least 3 times using a disposable syringe (min. 10 ml, larger volumes for larger diameters).

Cannulated screwdriver blades:
Remove the blade from the screwdriver handle.
Rinse the blade during pre-cleaning at least 3 times using a disposable syringe (min. 10 ml, larger volumes for larger diameters).

Screwdriver handles/cannulated screwdriver handles:
Remove the blade from the screwdriver handle.
Operate the screwdriver handle several times during pre-cleaning.
Rinse the cannulated screwdriver handles during pre-cleaning at least 3 times using a disposable syringe (min. 10 ml, larger volumes for larger diameters).

Device for measuring depth:
During pre-cleaning, move the probe back and forth several times and disassemble if this is intended for cleaning.

Forceps/plate cutters:
Operate the forceps several times during pre-cleaning.
With the plate cutter, take particular care that the space between the joints is thoroughly rinsed and that the plate cutter is only inserted horizontally into the cleaning and disinfection unit.

Further instructions, if applicable, are described in the product-specific instructions for use!

Additional information

You can request further information on the products (e.g., instructions for use, surgical techniques) from your contact person. In addition, you will find all the information on the Internet at www.mondeal.de.

MONDEAL Medical Systems GmbH

Am Gewerbering 7
78570 Mühlheim an der Donau

Tel.+49 7463 99307 0
Fax: +49 7463 99307 33
Email: mail@mondeal.de
Website: www.mondeal.de

Indications and symbols on labels

REF	Item Number
QTY	Quantity
LOT	Batch code
NON STERILE	Non sterile
	Do not re-use
	Manufacturer
	Date of manufacture
	Caution
	Consult instructions for use
CE 0297	Marking for medical devices in risk class IIa and IIb for EU
CE	Marking for medical devices in risk class I for EU