Preparation Instructions for the CAMLOG®/CONELOG® Implant System

The following descriptions contain detailed instructions on cleaning, disinfection and sterilization of the instruments and prosthetic components of the CAMLOG® and CONELOG® Implant Systems. Always observe the current validated legal national regulations and regulations on hygiene relating to dental/medical practices and hospitals. This applies in particular to the guidelines regarding effective prion inactivation.

For sterilizer and disinfector
As part of your responsibility for the sterility of the products in application, please observe the following:

- In general, use only adequately validated methods specific to the equipment and product for cleaning/disinfection and sterilization.
- Regularly check and service the equipment used (thermal disinfector, sterilizer).
- Observe the validated parameters in each cycle.

For U.S.: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2006.

Important information:
If not otherwise specified in the instruction manual, reusable CAMLOG® and CONELOG® products may be reprocessed as long as they are maintained in working condition according to the instruction manuals and processing procedures. CAMLOG® and CONELOG® products intended for single use must not be reused because safe preparation and/or functional safety cannot be ensured.

1 Instruments
The instruments used in the CAMLOG® and CONELOG® Implant Systems are supplied non-sterile unless they are explicitly marked as sterile. They must be cleaned, disinfected and sterilized before first use and every use. Thorough cleaning and disinfection is indispensable for effective sterilization.
In application, care should be taken that contaminated instruments are collected separately and are not returned to the instrument tray to prevent contamination of the loaded instrument tray.
After cleaning and disinfection, place the instruments back into the instrument tray. Then sterilize the fully loaded instrument tray.

Two procedures are described in the following for cleaning and disinfection prior to sterilization: a mechanical procedure under point 1.1 and a manual procedure under point 1.2. Wherever possible, the mechanical procedure described under point 1.1 should be employed.
When choosing a combined cleaning and disinfecting agent for initial disinfection and for manual cleaning and disinfection, one should make sure that:
- it is suitable for cleaning and disinfecting dental instruments.
- it is suitable for ultrasonic cleaning (no foam development).
- it has a proven efficacy for disinfection (e.g. VAH/DGHM listed, CE marking for EU, or EPA registered and FDA compliant for U.S.).
- it is compatible with the materials of the products to be cleaned and disinfected.
- it does not contain aldehyde (otherwise blood, secretions, tissue remains, etc. may stick).

The concentrations and application times as well as instructions for post-rinsing specified by the manufacturer must be observed.

**Caution! The procedure below must be observed exactly.**

### 1.1 Mechanical cleaning and thermal disinfection

#### 1.1.1 Initial disinfection:
Immediately after use, immerse all instruments in a bath containing combined cleaning and disinfecting agent. This serves for user safety and prevents the contaminants from drying. The cleaning and disinfecting agent used for pre-treatment is only for personal protection and may not take the place of the disinfection step to be performed after cleaning.

#### 1.1.2 Disassembly:
Completely disassemble all instruments consisting of several parts (see 1.4 Disassembly and Assembly of instruments). Remove depth stops from the drills.

#### 1.1.3 Pre-treatment after successful initial disinfection and disassembly

1. **Remove coarse contaminants from the instruments within a maximum of 2 hours after use.**
2. **Remove contaminants from instruments under running water using a soft brush (no metal bristles or steel wool).** The brush must be used exclusively for this purpose only. Brush until no visible contaminants remain. Some instruments have cavities. Remove all residues in these. Contamination should no longer be visible.
3. **Remove contaminants in the lumen of the internally irrigated drills, taps and drill extensions with the cleaning needle (Art. No. J5002.0012).**
4. **Rinse the lumen of the internally irrigated drills, taps and drill extensions with water at least three times using a cleaning cannula (Art. No. J5002.0020) and a syringe (at least 10 ml).** Contamination should no longer be visible.
5. **Full rinse of the instruments for at least one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml).**
6. **Rinse the lumen of the internally irrigated drills, taps and drill extensions with deionized water with at least five times using the cleaning cannula (Art. No. J5002.0020) and a syringe (at least 10 ml).**

#### 1.1.4 Disinfection of the pre-cleaned products in the thermal disinfector:

**1.1.4.1 Thermal disinfector (cleaning and disinfection device)**

When choosing the thermal disinfector (cleaning and disinfecting device), care should be taken that:
- In general, the thermal disinfector has a proven efficacy (CE marking, compliant with EN ISO 15883 in Europe or FDA clearance in the U.S.) and is validated specifically for the equipment and product.
- A proven program for thermal disinfection is used (A0 value > 3000 or – for older devices – at least 5 min. at 90°C / 194°F).
- The program used is suitable for the instruments and includes sufficient rinsing cycles.
- Only deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml) is used for rinsing.
- The air used for drying is filtered.
- The thermal disinfector (cleaning and disinfection device) is regularly checked and serviced.
Use only thermal disinfection that requires no disinfecting agent. Avoid using any rinse aids. There is a risk of disinfectant residues on the instruments when chemical disinfection is used.

### 1.1.4.2 Cleaning agents

When using cleaning agents, care should be taken that:

- In general, the cleaning agents are suitable for cleaning instruments made of metals and plastics.
- The chemicals used are compatible with the instruments.

We recommend the use of cleaning agents that require no neutralizing agents.

### 1.1.4.3 Worksteps

1. Place the disassembled and pretreated instruments in the thermal disinfector using a small parts basket. The instruments are not to come into contact with one another.
2. Start the program.
3. Remove the instruments from the thermal disinfector after program end.
4. Dry the instruments if necessary. Use compressed dry air, free of oil and with a low bacterial count. We also recommend the use of a sterile filter.
5. Inspect the instruments for signs of corrosion, surface damage, chipping or contamination. Remove damaged instruments from use. Re-clean and disinfect instruments which are still contaminated. Observe the maximum number of times drills may be used as prescribed in the instruction manuals.
6. Assembly: Reassemble all disassembled instruments (see 1.4 Disassembly and Assembly of instruments). Install the depth stops on the drills.
7. Packaging: Pack instruments for sterilization promptly. We recommend using disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S. It must be ensured that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C / 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.

### General note

The proof of general suitability for effective mechanical cleaning and disinfection was provided by an independent accredited testing laboratory taking into account the above-described procedure. A thermal disinfector (cleaning and disinfecting device) G 7836 CD (Manufacturer: Miele & Cie. GmbH & Co., Gütersloh) and neodisher medizym as the cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) were used. The procedure described above was taken into account.

### 1.2 Manual cleaning and disinfection

#### 1.2.1 Initial disinfection:

Immediately after use, immerse all instruments in a bath containing combined cleaning and disinfecting agent. This serves for user safety and prevents the contaminants from drying. The cleaning and disinfecting agent used for pre-treatment is only for personal protection and may not take the place of the disinfection step to be performed later after cleaning.

#### 1.2.2 Disassembly:

Completely disassemble all instruments consisting of several parts (see 1.4 Disassembly and Assembly of instruments) as well as removing all depth stops from the drills.

#### 1.2.3 Preliminary cleaning:

Remove coarse contaminants from the instruments within a maximum of 2 hours after use. For this purpose use a disposable cloth, running water, and a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only. Remove residues in areas with difficult access using an appropriate instrument. Remove firmly bonded tissue residues in the cooling channels of internally cooled instruments with the cleaning needle (Art. No. J5002.0012). The cooling channels in the internally cooled instruments and the drill extensions must be rinsed out at least three times with water using the cleaning cannula (Art. No. J5002.0020) and a syringe (at least 10 ml).
1.2.4 Combined cleaning and disinfection: Place the instruments in a bath of freshly prepared combined cleaning and disinfecting solution for the scheduled application time, making sure they are completely covered. The instruments are not to come into contact with one another. In case of persistent contamination use an ultrasonic unit. To completely remove residue, brush off the instruments with a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only. The cooling channels in the internally cooled instruments and the drill extensions must be rinsed out at least five times with the combined cleaning and disinfection solution using the cleaning cannula (Art. No. J5002.0020) and a syringe (at least 10 ml). Some instruments have cavities. Use a soft brush to remove residue in these cavities (no metal bristles or steel wool). The brush must be used exclusively for this purpose only.

1.2.5 Rinsing: Remove the instruments, rinse them completely for at least one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml). Take particular care in rinsing the area that have limited access. The cooling channels of internally cooled instruments and the drill extensions must be rinsed out at least five times using the cleaning cannula (Art. No. J5002.0020) and a syringe (at least 10 ml).

1.2.6 Drying: Dry the instruments. Use a loose lint free disposable cloth and compressed dry air, free of oil and with a low bacterial count. We also recommend the use of a sterile filter.

1.2.7 Inspection: Inspect the instruments for signs of corrosion, surface damage, chipping or contamination. Remove damaged instruments from use. Clean and disinfect still contaminated instruments again. Observe the maximum number of times drills may be used as prescribed in the instruction manuals.

1.2.8 Assembly: Reassemble all disassembled instruments (see 1.4 Disassembly and Assembly of instruments). Install the depth stops on the drills.

1.2.9 Packaging: Pack instruments for sterilization promptly. We recommend using disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S. It must be ensured that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C / 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.

1.3 Sterilization

- Permissible steam sterilization procedures are fractionated vacuum procedures (with sufficient product drying). Other sterilization procedures (including steam gravity sterilization) are not allowed.
- The sterilization time (exposure time at sterilization temperature) is at least 20 minutes at a minimum of 121°C / 250°F or at least 4 minutes at a minimum of 132°C / 270°F (not valid for U.S.).
- For U.S.: The sterilization time (exposure time at sterilization temperature) is at least 4 minutes at a minimum of 132°C / 270°F.
- A minimum drying time of 30 minutes is recommended for each of the cycles described above.

Care should be taken that:

- The maximum steam sterilization temperature is 138°C / 280°F.
- The surgical trays do not touch the walls of the steam sterilizer because high local temperatures over 160°C / 320°F may lead to deformation of plastic.
- The steam sterilizers used have CE marking and comply with the requirements of EN 13060 or EN 285 in Europe or have FDA clearance in the U.S.
- In general, use only adequately validated methods specific to the equipment and product for sterilization according to ISO 17665.
- Regularly check and service the sterilizers used.
- Observe the validated parameters in each cycle.

**Warning!** All non-sterile packed CAMLOG® and CONELOG® products must not be sterilized in the CAMLOG original packaging!
1.4 Disassembly and Assembly of instruments
The following instruments must be disassembled prior to cleaning and disinfection:


Disassemble the cardanic driver in three parts by loosening the clamping screw with a screwdriver hex. After reassembling, the clamping screw must be tightened carefully by hand with a screwdriver hex.


To disassemble the drivers for bar abutments remove the bolt by turning out. Reassemble by turning in.

- Drivers for impression posts and healing caps for bar abutments (for CAMLOG® and CONELOG® Ø 3.3/3.8/4.3 mm: Art. No. J5300.0027; Ø 5.0/6.0 mm: Art. No. J5300.0028).

To disassemble the drivers for impression posts and healing caps for bar abutments remove the bolt by turning it counter-clockwise. Reassemble by turning clockwise.


To disassemble the adapter for screw implants, long, remove the bolt by turning it counter-clockwise. Reassemble by turning clockwise.


To disassemble the adapter for screw implants, long, remove the bolt by turning it counter-clockwise. Reassemble by turning clockwise.


2 Prosthetic Components
The prosthetic components of the CAMLOG® and CONELOG® Implant System are supplied non-sterile unless they are explicitly marked as sterile. They must be used one time only and solely on one patient. They must be cleaned and disinfected before and after each use on a patient, (e.g. for shipping to the dental laboratory). We recommend additional sterilization. Thorough cleaning and disinfection is indispensable for effective sterilization. Two cleaning/disinfection procedures are described: a mechanical procedure under point 2.1 and a manual procedure under point 2.2. The mechanical procedure described under point 2.1 is to be preferred.
When choosing a combined cleaning and disinfecting agent for initial disinfection and for manual cleaning and disinfection, one should make sure that:

- it is suitable for cleaning and disinfecting dental instruments.
- it is suitable for ultrasonic cleaning (no foam development)
- it has a proven efficacy for disinfection (e.g. VAH/DGHM listed, CE marking for EU, or EPA registered and FDA compliant for U.S.).
- it is compatible with the materials of the products to be cleaned and disinfected
- it does not contain aldehyde (otherwise blood, secretions, tissue remains, etc. may stick).

The concentrations and application times specified by the manufacturer must be observed.

Caution! Plastic components of the CAMLOG® or the CONELOG® Implant System must not be sterilized (only cleaned and disinfected), except for the plastic components made out of PEEK. Plastic components made out of PEEK can be sterilized.

Prosthetic components connected with a non-sterilizable material cannot be sterilized (just cleaned and disinfected).

### 2.1 Mechanical cleaning and disinfection

**2.1.1 Initial disinfection:** Immediately after use in the patient's mouth, immerse all prosthetic components in a bath with combined cleaning and disinfecting agent. This serves for user safety and prevents the contaminants from drying. The cleaning and disinfecting agent used for pre-treatment is only for personal protection and may not take the place of the disinfection step to be performed after cleaning.

**2.1.2 Preliminary cleaning**

Remove coarse contaminants from the prosthetic components (after use in the patient's mouth or contamination in the dental laboratory) within a maximum of 2 hours after use.

- **2.1.2.1 Remove contaminants from the prosthetic components under running water using a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only. Brush until no visible contaminants remain. Some prosthetic components have cavities. Remove all residues in these. Contamination should no longer be visible.**

- **2.1.2.2 Full rinse of the prosthetic components for one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml).**

**2.1.3 Disinfection of the pre-cleaned products in the thermal disinfector:**

**2.1.3.1 Thermal disinfector (cleaning and disinfection device)**

When choosing the thermal disinfector, care should be taken that:

- In general, the thermal disinfector has a proven efficacy (CE marking, conforming to EN ISO 15883 in Europe or FDA clearance in the U.S.) and is validated specifically for the equipment and product.
- A proven program for thermal disinfection is used (A0 value > 3000 or – for older devices – at least 5 min. at 90°C / 194°F).
- The program used is suitable for the prosthetic components and includes sufficient rinsing cycles.
- Only deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml) is used for rinsing.
- The air used for drying is filtered.
- The thermal disinfector is regularly checked and serviced.

Use only thermal disinfection that requires no disinfecting agent. Avoid using any rinse aids. There is a risk of disinfectant residues on the prosthetic components when chemical disinfection is used.
2.1.3.2 Cleaning agents
When using cleaning agents, care should be taken that:

- in general, the cleaning agents are suitable for cleaning prosthetic components made of metals and plastics.
- the chemicals used are compatible with the prosthetic components.

We recommend the use of cleaning agents that require no neutralizing agents.

2.1.3.3 Worksteps
1. Place the pre-treated prosthetic components in the thermal disinfector using a small parts basket. The prosthetic components are not to come into contact with one another.
2. Start the program.
3. Remove the prosthetic components from the thermal disinfector after program end.
4. Dry the prosthetic components if necessary. Use compressed dry air, free of oil and with a low bacterial count. We also recommend the use of a sterile filter.
5. Inspect the prosthetic components for signs of corrosion, surface damage, chipping or contamination. Remove prosthetic components from use. Re-clean and disinfect prosthetic components which are still contaminated.
6. Packaging: Pack prosthetic components for sterilization promptly. We recommend using disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S. It must be ensured that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C / 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.

General note
The proof of general suitability for effective mechanical cleaning and disinfection was provided by an independent accredited testing laboratory taking into account the above-described procedure. A thermal disinfector (cleaning and disinfecting device) G 7836 CD (Manufacturer: Miele & Cie. GmbH & Co., Gütersloh) and neodisher medizym as the cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) were used. The procedure described above was taken into account.

2.2 Manual cleaning and disinfection
2.2.1 Initial disinfection: Immediately after use in the patient's mouth, immerse all prosthetic components in a bath with combined cleaning and disinfecting agent. This serves for user safety and prevents the contaminants from drying.

The cleaning and disinfecting agent used for pretreatment is only for personal protection and may not take the place of the disinfection step to be performed later after cleaning.

2.2.2 Preliminary cleaning: Remove coarse contaminants from the prosthetic components (after use in the patient's mouth or following contamination in the dental laboratory) within a maximum of 2 hours after use.

2.2.2.1 Remove contaminants from the prosthetic components under running water using a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only. Brush until no visible contaminants remain. Some prosthetic components have cavities. Remove all residues in these. Contamination should no longer be visible.

2.2.2.2 Full rinse of the prosthetic components for at least one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml).
2.2.3 Combined cleaning and disinfection: Place the prosthetic components for cleaning and disinfection in the fresh combined cleaning and disinfecting solution for the scheduled application time making sure they are completely covered. The prosthetic components are not to come into contact with one another. In case of persistent contamination use an ultrasonic unit. Brush off the prosthetic components using a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only. Remove all residues completely. Remove all debris contained in the areas with limited access. Observe the concentrations and application times and the guidelines for rinsing specified by the manufacturer of the combined cleaning and disinfecting agent, as well as the instructions for post-rinsing.

2.2.4 Rinsing: Remove the prosthetic components, rinse them for at least one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ ml). Take particular care in rinsing the area that have limited access.

2.2.5 Drying: Dry the prosthetic components. Use a loose lint free disposable cloth and compressed dry air, free of oil and with a low bacterial count. We also recommend the use of a sterile filter.

2.2.6 Inspection: Inspect the prosthetic components for signs of corrosion, surface damage, chipping or contamination. Damaged prosthetic components cannot be used. Re-clean and disinfect prosthetic components which are still contaminated.

2.2.7 Packaging: Pack prosthetic components for sterilization promptly. We recommend using disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S. It must be ensured that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C / 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.

2.3 Sterilization

- The sterilization time (exposure time at sterilization temperature) is at least 20 minutes at a minimum of 121°C / 250°F or at least 4 minutes at a minimum of 132°C / 270°F. Permissible steam sterilization procedures are fractionated vacuum procedures (with sufficient product drying) and gravitation procedures. Other sterilization procedures are not allowed (not valid for U.S.).

- For U.S.: Permissible steam sterilization procedures are fractionated vacuum procedures (with sufficient product drying). Other sterilization procedures are not allowed. The sterilization time (exposure time at sterilization temperature) is at least 4 minutes at a minimum of 132°C / 270°F.

- A minimum drying time of 30 minutes is recommended for each of the cycles described above.

Care should be taken that:

- the maximum steam sterilization temperature is 138°C / 280°F.
- the steam sterilizers used have CE marking and meet the requirements of EN 13060 or EN 285 (Europe) or have FDA clearance (U.S.).

In general, use only adequately validated methods specific to the equipment and product for sterilization according to ISO 17665.

- Regularly check and service the sterilizers used.
- Observe the validated parameters in each cycle.

Warning! All non-sterile packed CAMLOG® and CONELOG® products must not be sterilized in the CAMLOG original packaging!
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