Processing of OMNIDENT Products

Instructions For Use

PROCESSING OF OMNIDENT PRODUCTS
IN LINE WITH DIN EN ISO 17664/AAMI ST81

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INSTRUCTIONS FOR USE

1. GENERAL PRINCIPALES

- Endodontic instruments are to be used only in a clinical or hospital environment, following good dental practice, by qualified dental professionals such as general practitioners as well as Endo specialists (Endodontist) and Dental Assistants.
- Please always inspect the packaging before each use that sterile packaging is undamaged. Do not use the instruments if the packaging is damaged.
- All instruments that are intended for re-use must be cleaned, disinfected and sterilized prior to each use, and to instruments delivered in a sterile condition that are intended for re-use. Thorough cleaning and disinfection are essential prerequisites for effective sterilization.
- As part of your responsibility for the sterility of instruments, always make sure that only validated methods for cleaning/disinfection and sterilization are used, that devices (washer-disinfector, thermal disinfector or sterilizer) are regularly serviced and inspected, and that the validated parameters are maintained during each cycle. For your own safety, always wear protective gloves, glasses and a mask when handling contaminated instruments.
- In addition, always observe all applicable national legal regulations (KRINKO/ RKI/BfArM Processing recommendations) and regulations on hygiene relating to your practice or the hospital. This applies in particular to the guidelines regarding prion inactivation (does not apply to the USA).
- Disclaimer: The instructions for processing products prior to use/re-use herein have been validated by OMNIDENT. Users are solely responsible for any deviation from these instructions, and/or the use of alternative methods for processing. OMNIDENT accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the instructions for use set forth below. The user shall observe safe and lawful practices including, but not limited to, those set forth in this document.

2. LIMITATIONS AND RESTRICTIONS ON PROCESSING

2.1. Re-use

- Instruments (only reusable instruments) can be re-used several times – with due care and if they are not damaged and contaminated (see Table 1). Each re-use or application of non-validated methods is the sole responsibility of the user.
- Certain applications may cause the instruments to prematurely reach the end of their useful life. The maximum number of processing cycles will not always be reached.
- All liability is disclaimed for failure to follow these instructions or use of non- validated methods for the re-use of instruments.
- Please always ensure that sterile packaging/wrapping is undamaged. Do not use the instruments if the packaging is damaged.
- For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:
  - Use a new file and discard it after the canal was treated (single canal use).
  - Use small size files (this will also enable canal transportation to be avoided).
  - Visually inspect the working part for all the defects listed in the former paragraph during use (i.e after each wave).
  - Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected life.

2.2. Overview

Processing prior each use (for reusable products)

Product designation	Material	Special/additional procedure			Packaging for sterilization	Maximum number of processing cycles*	Recommended classification**	Notes
		Pre-treatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection				
K-Reamer, K-File , Hedstroem File	Stainless steel, silicone rubber (only for instruments with stopper)	Procedure A	Procedure A in LavEndo® box with mini step module	Procedure A in LavEndo® box with mini step module	MiniBox with step module with autoclave paper and single-use sterilization packaging	8	Critical B	Cleaned and undamaged instruments can be used up to eight times depending on the degree of wear
Endo boxes	Temperature-resistant plastic	Procedure B	Procedure B	Procedure B	Single-use sterilization packaging	50	-	If the specified sterilization temperature and time are exceeded, this may result in plastic cracks or deformation Disassemble during pre-treatment; do not clean or disinfect when assembled
Interim stand		Procedure B after removing and disposing of the foam disc	Procedure B, storage in mesh tray	Procedure B, storage in mesh tray				If the specified sterilization temperature and time are exceeded, this may result in plastic cracks or deformation Disassemble and dispose of the foam disc during pre-treatment; do not clean or disinfect when assembled. The new foam disc can be sterilized at the same time The interim stand is only used for initial treatment prior to processing (see section 4. Initial treatment at the point of use)
Silicone stopper	Silicone rubber	Procedure A	Procedure A in small parts basket	Procedure A, fitted to instrument	Fitted to instrument	1	See corresponding instrument	The stopper used must be removed during pre-treatment and replaced with a new stopper either before or after automated cleaning/ disinfection

Table 1

* The maximum number of uses has been validated with the standard methods (automated cleaning and disinfection, fractionated vacuum method for steam sterilization).

** according to RKI/ BfArM/ KRINKO directive (Germany only, intended use)

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Processing prior use (for single use products)

Instrument/product	Material	Special notes on cleaning/ sterilization	Possible damage/risks if maintenance instructions are not followed
Foam discs for interim stand	Foam	Cleaning and disinfection not permitted. Foam disc autoclavable once before single use	Disintegration of the foam if used more than once; risk of contamination from dried-on residues
Silicone stopper	Silicone rubber	The stopper used must be removed during pre-treatment and replaced with a new stopper	Proper cleaning of the hole cannot be guaranteed

Table 2

2.3. Important Information on material resistance

When selecting cleaning and disinfecting agents, make sure that they do not contain any of the following substances:

- Phenol;
- Strong acids (ph<6) or strong alkalis (ph>8); neutral enzymatic cleaning agent recommended;
- Aldehydes;
- Anti-corrosive substances (especially di- or triethanolamine);
- Oxidants (hydrogen peroxide, sodium hypochlorite over 5% strength);
- Oils.

⚠ WARNING

Never clean the instruments, boxes, modules or the interim stand with metal brushes or wire wool

- Never subject any instruments, boxes, modules or the interim stand to temperatures above 142°C (288°F). It is particularly important to ensure that the products to be sterilized are not stored too close to the walls or floor of the steam sterilizer (risk of excessive temperature and deformation).
- The blue foam insert for the interim stand must only be used once and used blue foam inserts must not be either cleaned/disinfected or sterilized.

3. CLEANING AND DISINFECTING AGENTS

The following must be taken into account when selecting cleaning and disinfecting agents:

- They must be suitable for cleaning and disinfecting instruments made from metal and plastic;
- The disinfecting agent must be aldehyde-free (Cidex OPA is permitted due to its special recipe);
- It must be compatible with the instruments (see section 2.3. Important Information on material resistance);
- A disinfecting agent with verified effectiveness (VAH/DGHM approval, FDA clearance or CE mark) must be used and this must be compatible with the cleaning agent used;
- If a thermal disinfection process is not used, a suitable disinfecting agent with verified effectiveness (VAH/DGHM approval, FDA clearance or CE mark) must also be used and this must be compatible with the cleaning agent used;
- Neutralization must not be necessary (cleaning agent);
- The cleaning agent, if applicable, must be suitable for ultrasonic cleaning (no foaming);
- Combined cleaning agents/disinfecting agents must not be used.

The concentrations, temperatures and contact times specified by the manufacturer of the cleaning agent and disinfecting agent as well as the minimum specifications for subsequent rinsing must be strictly adhered to. Rinse aids must not be used.

Only use freshly prepared solutions and low-germ (<10 CFU/ml) water; tap water that is particularly hard (≥14°dH) is not suitable for this (risk of lime residue).

4. INITIAL TREATMENT AT THE POINT OF USE

We recommend an automated procedure to clean and disinfect the instruments (washer-disinfector). A manual method should only be used if it is not possible to use an automated method, as it is less effective and demonstrates lower reproducibility. Manual cleaning and disinfection is less effective in direct comparison to the automated method. However, it is effective according to the requirements for a processed instrument. All methods are validated and therefore they are efficient and safe for the processing of OMNIDENT instruments.

The pre-treatment process should be performed on used instruments in every case. If the manual method is used, the new stopper needs to be removed and processed separately.

Pre-Treatment at the place of use

Contaminants (particularly pulp and dentine remnants) must be removed immediately after the instrument has been used on a patient (within maximum 2 hours). All further steps in the preparation process must be performed on the same day.

The following procedures must be used to ensure that no contamination can dry on the instruments, and to make subsequent preparation more effective:

Procedure A: Instruments that fit in the interim stand (see Table 1)

1) A prepared interim stand with a new foam disc must be used for each patient. The interim stand must be filled at least two thirds of the way with disinfecting agent.
2) Place in the interim stand prior to pre- disinfection/cleaning and for transport (minimum storage time according to the disinfecting agent manufacturer's instructions for use: Max. two hours).

Procedure B: Boxes and modules (see Table 1)

1) Within two hours, clean to remove contamination under flowing water for at least 3x1 min. on the outside and particularly on the inside.
2) Then place in a pan (not together with the instruments).
3) The pan is also used to transport the boxes and modules.

Please note that the disinfecting agent used during pre-treatment is for personal protection only and is not a substitute for the disinfection stage required after cleaning.

⚠ WARNING

Under no circumstances may instruments that have already come into contact with disinfecting agent be used to treat a patient again

5. PREPARATION BEFORE CLEANING

Procedure A: Instruments that fit in the interim stand (see Table 1)

1) Remove the stopper from the instrument (if present, see Table 1) and dispose of the used stopper.
2) Then clean to remove contamination under flowing water for at least 3x1 minute; to remove contamination manually, use a soft, clean brush or soft, clean cloth that is only used for this purpose; never use metal brushes or wire wool.
3) Check that no visible contamination or remnants remain and repeat the pre-cleaning process if necessary.

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Procedure B: Boxes and modules (see Table 1)

1) Place in a pan containing cleaning agent for the prescribed contact time (but no less than 15 minutes) and brush at both the start and end of the contact time on the outside and particularly on the inside for at least one minute each (using a soft, clean brush; never use metal brushes or wire wool).
2) Check that no visible contamination or remnants remain and repeat the pre-cleaning process if necessary.

6. CLEANING AND DISINFECTION

6.1. Automated cleaning/disinfection (washer-disinfector)

The following must be taken into account when selecting a washer-disinfector:

- The effectiveness of the washer-disinfector must have been verified (DGHM approval, FDA clearance or CE mark according to EN ISO 15883);
- Where possible, a tested thermal disinfection program must be used (A0 value≥3000 or at least five minutes at 90°C, or for older equipment at least 10 min. at 93°C).

⚠ WARNING

In the case of chemical disinfection, there is a risk of disinfecting agent residues remaining on the instruments

- The program used must be suitable for the instruments and include the prescribed rinsing cycles;
- Only sterile or low-germ (<10 CFU/ml) and low-endotoxin (<0.25 EU/ml) water (ideally highly purified water HPW) must be used for subsequent rinsing;
- The washer-disinfector must be regularly maintained and inspected.

Procedure A: Instruments that fit in the interim stand (see Table 1)

1) If present (see Table 1): Fit new stoppers to the pre- cleaned instruments.
2) Sort the instruments into the endo modules (step modules for manual instruments).
3) Place the endo module in the black upper section (manual instruments, see Figure 1) or the blue lower section (nickel- titanium instruments, see Figure 2) of the LavEndo® box and close it (click into place).

Figure 1

Figure 2

Info

Preparation in the socket module is not permitted

4) Insert the LavEndo® box horizontally into the washer-disinfector.
5) Start the program.
6) After the program has finished, remove the LavEndo® box from the washer-disinfector.

7) Check and package the instruments as soon as possible after removing them (see section 7. Inspection and maintenance and 8. Packaging), after leaving them to dry further in a clean place if necessary.

Procedure B: Boxes and modules (see Table 1)

1) Place in a sufficiently large mesh basket with the openings facing down and insert into the washer- disinfector (using a securing net if necessary), ensuring that the instruments are not touching.
2) Start the program.
3) After the program has finished, remove the instruments from the washer-disinfector.
4) Check and package the instruments as soon as possible after removing them (see section 7. Inspection and maintenance and 8. Packaging), after leaving them to dry further in a clean place if necessary.

An independent, accredited, recognized test laboratory has demonstrated the intrinsic suitability of the instruments for effective automated cleaning and disinfection using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher Medizym cleaning agent (Dr. Weigert, Hamburg). The laboratory used program D-V-MEDIZYM (based on the program DES-VAR-TD (Miele) under worst-case conditions) according to the procedure described above to demonstrate this effectiveness. The Cidex OPA disinfecting agent and the Cidezyme cleaning agent (both Johnson & Johnson GmbH, Norderstedt) were used for pre-treatment. Cleaning and disinfection validation were performed under worst-case conditions (low temperature, low concentration of agent, short soaking time and no drying).

6.2. Manual cleaning and disinfection

Procedure A: Instruments that fit in the interim stand (see Table 1)

1) Sort the instruments, without stoppers, into the endo modules (step modules for manual instruments).
2) Place the endo module in the black upper section (manual instruments, see Figure 3) or the blue lower section (nickel- titanium instruments, see Figure 4) of the LavEndo® box and close it (click into place).

Figure 3

Figure 4

Info

Preparation in the socket module is not permitted

3) If present (see Table 1): Place new stoppers in a small parts basket with a sufficiently small mesh size.
4) Insert the LavEndo® box horizontally and, if present, the small parts basket with the new stoppers into the cleaning bath for the prescribed contact time, ensuring that the instruments are sufficiently covered.
5) Then remove the LavEndo® box and, if present, the small parts basket with the stoppers from the cleaning bath and rinse thoroughly with water for at least 3x1 min.

6) Insert the LavEndo® box horizontally and, if present, the small parts basket with the new stoppers into the disinfection bath for the prescribed contact time, ensuring that the instruments are sufficiently covered.
7) Then remove the LavEndo® box and, if present, the small parts basket with the stoppers from the disinfection bath and rinse thoroughly with water for at least 5x1 min.
8) Dry the LavEndo® box and, if present, the small parts basket with the stoppers by blowing them with oil-free, filtered compressed air (or medical compressed air from a can) and then leaving them to dry further in a clean place.
9) Check and package the instruments as soon as possible (see section 7. Inspection and maintenance and 8. Packaging) and, if present (see Table 1), fit stoppers to the instruments.

Procedure B: Boxes and modules (see Table 1)

1) Place in a sufficiently large mesh basket with the openings facing down and insert into the ultrasonic bath filled with a sufficient amount of cleaning solution for the prescribed contact time (but no less than five minutes) and brush on the outside and particularly on the inside for at least one minute each (using a soft, clean brush; never use metal brushes or wire wool).
2) Then check that the instruments are not touching and activate the ultrasound for the prescribed contact time (but no less than five minutes).
3) Then remove the mesh basket from the cleaning bath and rinse thoroughly with water for at least 3x1 min.
4) Place in the disinfection bath in a sufficiently large mesh basket for the prescribed contact time, ensuring that the instruments are sufficiently covered but are not touching.
5) Then remove from the disinfection bath and rinse thoroughly with water for at least 5x1 min.
6) Dry by blowing them with oil-free, filtered compressed air (or medical compressed air from a can) and then leaving them to dry further in a clean place.
7) Check and package the instruments as soon as possible (see section 7. Inspection and maintenance and 8. Packaging).

An independent, accredited, recognized test laboratory has demonstrated the intrinsic suitability of the instruments for effective manual cleaning and disinfection using the cleaning agent Cidezyme/Enzol and disinfecting agent Cidex OPA (Johnson & Johnson GmbH, Norderstedt (Germany)). The laboratory used the procedure described above to demonstrate this. The Cidex OPA disinfecting agent and the Cidezyme cleaning agent (both Johnson & Johnson GmbH, Norderstedt) were used for pre-treatment.

7. INSPECTION AND MAINTENANCE

Open the LavEndo® boxes and remove the step modules. Check all instruments, modules and LavEndo® boxes after cleaning/disinfection. Defective instruments, boxes and modules should be discarded immediately.

These defects include:

- Plastic deformation (e.g. caused by an excessively high temperature during sterilization);
- Breakage;
- Loss of color coding or marking;
- Bent instrument;
- Untwisted threads;
- Damaged cutting surfaces;
- Dull cutting blades;
- Missing size marking;
- Corrosion.

Numerical restrictions on re-use are listed under “Maximum number of processing cycles”. Instruments that are still contaminated must be cleaned and disinfected again.

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⚠ WARNING

Instrument lubricants must not be used

8. PACKAGING

Place the Step module in the lower section of the black sterilization tray (see Figure 5) and close it with the matching cover. Then package the sterilization trays and instruments that do not fit in the interim stand (see Table 1) into disposable sterilization pouches (disposable packaging) that meet the following requirements:

- Compliance with DIN EN 11607/ANSI AAMI ISO 11607;
- Suitable for steam sterilization (withstands temperatures of up to 142°C (288°F) or more, sufficient vapor permeability).

Figure 5

⚠ WARNING

Sterilization in the sterilization trays without additional packaging is not permitted. The autoclave paper in the boxes is for added safety only

9. STERILIZATION

Only use the sterilization methods listed below; other sterilization methods are not permitted.

Steam sterilization

- Fractionated vacuum/pre-vacuum method (at least three vacuum cycles) or gravity displacement method[1] with sufficient product drying[2];
- Steam sterilizer in accordance with DIN EN 13060 or DIN EN 285, ANSI AAMI ST79;
- Validated in accordance with DIN EN ISO 17665 (valid IQ and OQ plus product-specific performance qualification (PQ));
- The maximum sterilization temperature of 138°C (280°F) must not be exceeded; the maximum sterilization temperature includes a tolerance according to DIN EN ISO 17665;
- See Table 3 for outside the USA, Table 4 for the USA only.

Sterilization procedure	Sterilization temperature	Minimum sterilization time Exposure time at sterilization temperature
Fractionated vacuum/pre-vacuum method	134°C (273°F)	3 minutes[3]
	121°C (250°F)	20 minutes
Gravity method	134°C (273°F)	15 minutes
	121°C (250°F)	60 minutes

Table 3 : (outside the USA)

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Sterilization procedure	Sterilization temperature	Minimum sterilization time Exposure time at sterilization temperature	Minimum drying time[2]
Fractionated vacuum/ pre-vacuum method	132°C (270°F)	4 minutes	20 minutes
	Not applicable at 121°C (250°F)		
Gravity method[4]	134°C (273°F)	15 minutes	20 minutes
	121°C (250°F)	60 minutes	20 minutes

Table 4 : (USA)

[1] The less effective gravity method should only be used if the fractionated vacuum method is not available. The gravity method is less effective in direct comparison to the fractionated vacuum method. However, it is effective according to the requirements for a processed instrument. All methods are validated and therefore they are efficient and safe for the processing of OMNIDENT instruments.

[2] The drying time that is actually required depends directly on parameters that are the sole responsibility of the user (loading configuration, how many items are loaded and how closely together they are loaded, condition of the sterilizer, etc.) and must therefore be established by the user. However, the drying time must never be less than 20 minutes.

[3] Or 18 min. (prion inactivation).

[4] Gravity method is not applicable for processing within the European Union.

Rapid sterilization method (USA: Immediate-use steam sterilization) and the sterilization method of unpackaged instruments (USA: Unwrapped sterilization) are not permitted.

Dry heat sterilization, radiation sterilization and sterilization using formaldehyde, ethylene oxide or plasma are also not permitted.

An independent, accredited, recognized test laboratory demonstrated the instruments' intrinsic suitability for effective steam sterilization using the HST 6x6x6 steam sterilizer (Zirbus Technology GmbH, Bad Grund) together with the fractionated vacuum method and the gravity method. The laboratory used typical conditions found in clinics and dental practices, as well as the procedure described above, to demonstrate this.

10. STORAGE AND TRANSPORT

- After sterilization, devices must be stored in the sterilization packaging and kept dry and dust-free. In case of damage to the packaging during storage or transport, the processing shall be repeated. Check the instructions for use given by the pouch manufacturer to determine the shelf life of the sterile packaging.

11. DISPOSAL

- Products shall be disposed of according to local regulations for the safe disposal of sharp and contaminated devices.

12. ADDITIONAL INFORMATION

- Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.
- Sterility cannot be guaranteed if packaging is open, damaged or wet.
- To get a free printed copy of IFU please see section "Order free by post" on website https://www.udm-dental.com/en/service/document- download/#instruction-for-use.
- Explanation of non-harmonized symbols for IFUs and labels, see IFU Symbols (https://www.udm-dental.com/en/service/document- download/#instruction-for-use).

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SYMBOL GLOSSARY

General information

Symbol	Title & Description & Source
	**Catalogue number:** Identifies the manufacturer's catalogue or SKU number, for example on a medical device or the corresponding packaging. The reference number shall be placed adjacent to the symbol. ISO 7000-2493; ISO 15223-1
	**Batch code:** Identifies the batch or lot number, for example on a medical device or the corresponding packaging. The lot number shall be placed adjacent to the symbol. ISO 7000-2492; ISO 15223-1
	**Assortment:** **Identifies the package includes an assortment of types or sizes.** **ISO 7000-2791; ISO 21531**
	**Expiration date:** Indicates that the device should not be used after the date accompanying the symbol in YYYY-MM-DD format. ISO 7000-2607; ISO 15223-1
	**Date of manufacturing:** Identifies the date on which a product was manufactured in YYYY-MM-DD format. ISO 7000-2497; ISO 15223-1
	**Manufacturer:** Identifies the manufacturer of a product. This symbol shall be used adjacent to the name and address of the manufacturer. ISO 7000-3082; ISO 15223-1
	**Country of manufacture:** To identify the country of manufacture of products. Draft 15223-1
	**Distributor:** Identifies the distributor of a product. This symbol shall be used adjacent to the name and address of the distributor. MDR Article 14
 Website URL	**Electronic instructions for use:** Indicates relevant information for use is available in electronic form on the manufacturer's URL (for IFUs). ISO 7000-1641; ISO 15223

Product handling

Symbol	Title & Description & Source
	**Medical device:** Indicates the item is a medical device. MDR Annex I, 23.2, b &q
	**Packaging unit:** Indicates the number of pieces in the package. ISO 7000-2794
	**Do not use if package is damaged:** Indicates a medical device should not be used if the package has been damaged or opened. ISO 7000-2606; ISO 15223-1
	**Keep away from sunlight:** Indicates a medical device that needs protection from light sources. ISO 7000-0624; ISO 15223-1
 0123	**CE:** Indicates requirements for accreditation and market surveillance relating to the marketing of products has been met and is a Medical Device Directive. Signifies European technical conformity. (Minimum Size: 5mm height) Defined in MDD and MDR

Warnings and precautions

Symbol	Title & Description & Source
	**Material:** Identifies a material or substance contained in a product or the material from which the product is made. XXX shown here and material listed is variable and should be changed accordingly. ISO 7000 - 2793; ISO 21531

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Symbol	Title & Description & Source
	**Caution:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself. IEC TIR 60878; ISO 7000-0434A; ISO 15223-1

Sterilization / cleaning

Symbol	Title & Description & Source
	**Sterilizable in a steam sterilizer (autoclave) at temperature specified:** To indicate that the instrument is sterilizable in a steam sterilizer(autoclave). ISO 7000-2868
	**Sterilized using Irradiation:** Indicates a medical device that has been sterilized using irradiation. ISO 7000-0534; ISO 15223-1
	**Single sterile barrier system:** Indicates a single sterile barrier system. MDR Annex I, 23.3 a

Related to instruments

Symbol	Title & Description & Source
	**File type H:** Indicates the type of instrument Based on ISO 3630-1; Rational existing at OMNIDENT, why filled symbols are used.
	**File type K:** Indicates the type of instrument Based on ISO 3630-1; Rational existing at OMNIDENT, why filled symbols are used.
	**Reamer type K:** Indicates the type of instrument Based on ISO 3630-1; Rational existing at OMNIDENT, why filled symbols are used.

13. ITEM LIST

OMNI K-BOHRER

Item Number	Customer Item name
210077	OMNI K-BOHRER 21MM STERIL ISO006 PA 6
210078	OMNI K-BOHRER 21MM STERIL ISO008 PA 6
210079	OMNI K-BOHRER 21MM STERIL ISO010 PA 6
210080	OMNI K-BOHRER 21MM STERIL ISO015 PA 6
210082	OMNI K-BOHRER 21MM STERIL ISO020 PA 6
210083	OMNI K-BOHRER 21MM STERIL ISO025 PA 6
210084	OMNI K-BOHRER 21MM STERIL ISO030 PA 6
210085	OMNI K-BOHRER 21MM STERIL ISO035 PA 6
210086	OMNI K-BOHRER 21MM STERIL ISO040 PA 6
210087	OMNI K-BOHRER 21MM STERIL ISO045 PA 6
210090	OMNI K-BOHRER 21MM STERIL ISO050 PA 6
210081	OMNI K-BOHRER 21MM STERIL ISO015-040 PA 6
210089	OMNI K-BOHRER 21MM STERIL ISO045-080 PA 6
210091	OMNI K-BOHRER 25MM STERIL ISO006 PA 6
210097	OMNI K-BOHRER 25MM STERIL ISO008 PA 6
210098	OMNI K-BOHRER 25MM STERIL ISO010 PA 6
210099	OMNI K-BOHRER 25MM STERIL ISO015 PA 6
210101	OMNI K-BOHRER 25MM STERIL ISO020 PA 6
210102	OMNI K-BOHRER 25MM STERIL ISO025 PA 6

Item Number	Customer Item name
210103	OMNI K-BOHRER 25MM STERIL ISO030 PA 6
210104	OMNI K-BOHRER 25MM STERIL ISO035 PA 6
210105	OMNI K-BOHRER 25MM STERIL ISO040 PA 6
210106	OMNI K-BOHRER 25MM STERIL ISO045 PA 6
210108	OMNI K-BOHRER 25MM STERIL ISO050 PA 6
210100	OMNI K-BOHRER 25MM STERIL ISO015-040 PA 6
210107	OMNI K-BOHRER 25MM STERIL ISO045-080 PA 6
210109	OMNI K-BOHRER 31MM STERIL ISO006 PA 6
210110	OMNI K-BOHRER 31MM STERIL ISO008 PA 6
210111	OMNI K-BOHRER 31MM STERIL ISO010 PA 6
210112	OMNI K-BOHRER 31MM STERIL ISO015 PA 6
210114	OMNI K-BOHRER 31MM STERIL ISO020 PA 6
210115	OMNI K-BOHRER 31MM STERIL ISO025 PA 6
210116	OMNI K-BOHRER 31MM STERIL ISO030 PA 6
210117	OMNI K-BOHRER 31MM STERIL ISO035 PA 6
210118	OMNI K-BOHRER 31MM STERIL ISO040 PA 6
210119	OMNI K-BOHRER 31MM STERIL ISO045 PA 6
210121	OMNI K-BOHRER 31MM STERIL ISO050 PA 6
210113	OMNI K-BOHRER 31MM STERIL ISO015-040 PA 6
210120	OMNI K-BOHRER 31MM STERIL ISO045-080 PA 6

OMNI K-FEILE

Item Number	Customer Item name
210122	OMNI K-FEILE 21MM STERIL ISO006 PA 6
210123	OMNI K-FEILE 21MM STERIL ISO08 PA 6
210124	OMNI K-FEILE 21MM STERIL ISO010 PA 6
210125	OMNI K-FEILE 21MM STERIL ISO015 PA 6
210127	OMNI K-FEILE 21MM STERIL ISO020 PA 6
210128	OMNI K-FEILE 21MM STERIL ISO025 PA 6
210129	OMNI K-FEILE 21MM STERIL ISO030 PA 6
210130	OMNI K-FEILE 21MM STERIL ISO035 PA 6
210131	OMNI K-FEILE 21MM STERIL ISO040 PA 6
210132	OMNI K-FEILE 21MM STERIL ISO045 PA 6
210134	OMNI K-FEILE 21MM STERIL ISO050 PA 6
210126	OMNI K-FEILE 21MM STERIL ISO015-040 PA 6
210133	OMNI K-FEILE 21MM STERIL ISO045-080 PA 6
210135	OMNI K-FEILE 25MM STERIL ISO006 PA 6
210136	OMNI K-FEILE 25MM STERIL ISO008 PA 6
210137	OMNI K-FEILE 25MM STERIL ISO010 PA 6
210138	OMNI K-FEILE 25MM STERIL ISO015 PA 6
210140	OMNI K-FEILE 25MM STERIL ISO020 PA 6
210141	OMNI K-FEILE 25MM STERIL ISO025 PA 6
210142	OMNI K-FEILE 25MM STERIL ISO030 PA 6
210143	OMNI K-FEILE 25MM STERIL ISO035 PA 6
210144	OMNI K-FEILE 25MM STERIL ISO040 PA 6
210145	OMNI K-FEILE 25MM STERIL ISO045 PA 6
210147	OMNI K-FEILE 25MM STERIL ISO050 PA 6
210139	OMNI K-FEILE 25MM STERIL ISO015-040 PA 6
210146	OMNI K-FEILE 25MM STERIL ISO045-080 PA 6
210148	OMNI K-FEILE 31MM STERIL ISO006 PA 6
210149	OMNI K-FEILE 31MM STERIL ISO008 PA 6
210150	OMNI K-FEILE 31MM STERIL ISO010 PA 6
210151	OMNI K-FEILE 31MM STERIL ISO015 PA 6
210153	OMNI K-FEILE 31MM STERIL ISO020 PA 6
210154	OMNI K-FEILE 31MM STERIL ISO025 PA 6

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Item Number	Customer Item name
210155	OMNI K-FEILE 31MM STERIL ISO030 PA 6
210156	OMNI K-FEILE 31MM STERIL ISO035 PA 6
210157	OMNI K-FEILE 31MM STERIL ISO040 PA 6
210158	OMNI K-FEILE 31MM STERIL ISO045 PA 6
210160	OMNI K-FEILE 31MM STERIL ISO050 PA 6
210152	OMNI K-FEILE 31MM STERIL ISO015-040 PA 6
210159	OMNI K-FEILE 31MM STERIL ISO045-080 PA 6

OMNI HEDSTRÖMFEILE

Item Number	Customer Item name
210040	OMNI HEDSTRÖMFEILE 21MM STERIL ISO008 PA 6
210041	OMNI HEDSTRÖMFEILE 21MM STERIL ISO010 PA 6
210042	OMNI HEDSTRÖMFEILE 21MM STERIL ISO015 PA 6
210044	OMNI HEDSTRÖMFEILE 21MM STERIL ISO020 PA 6
210045	OMNI HEDSTRÖMFEILE 21MM STERIL ISO025 PA 6
210046	OMNI HEDSTRÖMFEILE 21MM STERIL ISO030 PA 6
210047	OMNI HEDSTRÖMFEILE 21MM STERIL ISO035 PA 6
210048	OMNI HEDSTRÖMFEILE 21MM STERIL ISO040 PA 6
210050	OMNI HEDSTRÖMFEILE 21MM STERIL ISO045 PA 6
210052	OMNI HEDSTRÖMFEILE 21MM STERIL ISO050 PA 6
210043	OMNI HEDSTRÖMFEILE 21MM STERIL ISO015-040 PA 6
210051	OMNI HEDSTRÖMFEILE 21MM STERIL ISO045-080 PA 6
210053	OMNI HEDSTRÖMFEILE 25MM STERIL ISO008 PA 6
210054	OMNI HEDSTRÖMFEILE 25MM STERIL ISO010 PA 6
210055	OMNI HEDSTRÖMFEILE 25MM STERIL ISO015 PA 6
210057	OMNI HEDSTRÖMFEILE 25MM STERIL ISO020 PA 6
210058	OMNI HEDSTRÖMFEILE 25MM STERIL ISO025 PA 6
210059	OMNI HEDSTRÖMFEILE 25MM STERIL ISO030 PA 6
210060	OMNI HEDSTRÖMFEILE 25MM STERIL ISO035 PA 6
210061	OMNI HEDSTRÖMFEILE 25MM STERIL ISO040 PA 6
210062	OMNI HEDSTRÖMFEILE 25MM STERIL ISO045 PA 6
210064	OMNI HEDSTRÖMFEILE 25MM STERIL ISO050 PA 6
210056	OMNI HEDSTRÖMFEILE 25MM STERIL ISO015-040 PA 6
210063	OMNI HEDSTRÖMFEILE 25MM STERIL ISO045-080 PA 6
210065	OMNI HEDSTRÖMFEILE 31MM STERIL ISO008 PA 6
210066	OMNI HEDSTRÖMFEILE 31MM STERIL ISO010 PA 6
210067	OMNI HEDSTRÖMFEILE 31MM STERIL ISO015 PA 6
210068	OMNI HEDSTRÖMFEILE 31MM STERIL ISO020 PA 6
210070	OMNI HEDSTRÖMFEILE 31MM STERIL ISO025 PA 6
210071	OMNI HEDSTRÖMFEILE 31MM STERIL ISO030 PA 6
210072	OMNI HEDSTRÖMFEILE 31MM STERIL ISO035 PA 6
210073	OMNI HEDSTRÖMFEILE 31MM STERIL ISO040 PA 6
210074	OMNI HEDSTRÖMFEILE 31MM STERIL ISO045 PA 6
210076	OMNI HEDSTRÖMFEILE 31MM STERIL ISO050 PA 6
210069	OMNI HEDSTRÖMFEILE 31MM STERIL ISO015-040 PA 6

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CE* 0123

*CE is not applicable to the interim stand, stopper and all sterilization boxes

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