GEBRAUCHANWEISUNG

Omni K-Feile / Omni K-Bohrer / Omni Hedsrtömfeile

Hersteller: Micro-Mega SA

Omni K-Feile / Omni K-Bohrer / Omni Hedströmfeile

Reference: 30006234-A

Gebrauchsanweisung DE

1. **Indikation**

Die Medizinprodukte (K-Feile, Hedströmfeile, K-Bohrer) werden im Rahmen einer nicht operativen Wurzelkanalbehandlung zur Katheterisierung (Nr. 006 bis 015) und zur Formgebung des Wurzelkanals (alle anderen Durchmesser) eingesetzt. Die K-Feile 008 und 010 werden auch zur Exploration, einer ersten Penetration und zur Permeabilisierung des Wurzelkanals eingesetzt. Nur für den zahnärztlichen Gebrauch.

2. **Kontraindikationen**

Außer bei Kindern bis zu 2 Jahren (Verwendung von Ethylenoxid im Sterilisationsprozess) bestehen keine Kontraindikationen für die Verwendung bei einer orthograden endodontischen Behandlung.

3. **Komplikationen**

In Fällen mit komplexer Kanalanatomie könnten perioperative Risiken (Instrumentenbruch, Stufenbildung, laterale Perforation (Stripping), apikale Trichterbildung, Via falsa, Perforation usw.) eintreten, die in der Folge zu einem Risiko für infektiöse Prozesse führen könnten.

4. **Merkmale und Warnhinweise**

ø	Maximal empfohlene Anzahl der Verwendungen (sofern die Feile nicht sichtbar beschädigt ist)
< 020	2
≥ 020	5

- Vor dem Gebrauch den Zustand der Schneide des Instruments kontrollieren und sicherstellen, dass das Instrument fest mit dem Griff verbunden ist. Das Instrument nicht verwenden, wenn es beschädigt ist oder Anzeichen von Verschleiß aufweist.
- Informieren Sie den Hersteller und die zuständige nationale Aufsichtsbehörde über jedes schwerwiegende Ereignis, zu dem es in Zusammenhang mit der Verwendung des Instruments kommt.

Medizinprodukt-Klasse gemäß Richtlinie 93/42/EWG und Verordnung (EU) 2017/745 über Medizinprodukte: Is.

Symbol auf Verpackung	STERILE EO	Mit Ethylenoxid sterilisiert.

5. **Klinische Leistungen**

Über das in Absatz 1 genannte Anwendungsgebiet hinaus werden keine weitergehenden Aussagen zu den klinischen Leistungen des Produkts getroffen.

6. **Aufbereitungsanleitung**

Allgemeine Empfehlungen	• Für sämtliche Instrumente aus Metall wird die Verwendung von Desinfektions- und Reinigungsmitteln mit Korrosionsschutz empfohlen. • Zur eigenen Sicherheit sollten Sie eine persönliche Schutzausrüstung tragen (Handschuhe, Schutzbrille und -maske). • Keine Reinigungs- oder Desinfektionsmittel verwenden, die Phenol oder Aldehyd enthalten und/oder alkalisch sind. • Befolgen Sie immer die Gebrauchsanweisung, die vom Hersteller des jeweiligen Produkts bereitgestellt wird.
Einschränkungen bei der Aufbereitung	• Aufgrund des Produktdesigns und der verwendeten Materialien kann kein definiertes Limit von max. durchführbaren Aufbereitungszyklen festgelegt werden. Die Lebensdauer der Medizinprodukte wird durch deren Funktion und den schonenden Umgang bestimmt. Die mehrfache Anwendung von Desinfektions- und Resterilisationszyklen kann das Risiko für eine Abtrennung der Feile erhöhen. • Der Anwender hat sicherzustellen, dass die verwendete Aufbereitungsmethode, einschließlich Ressourcen, Materialien und Personal, geeignet ist und die geltenden Anforderungen erfüllt. • Der Stand der Technik und nationale Gesetze erfordern, dass validierte Prozesse angewendet werden.
Benötigte Materialien	• Handschuhe, Masken, Kittel wie vom Hersteller des Reinigungsmittels bzw. der Reinigungslösung empfohlen • Leitungs- oder entionisiertes Wasser • Desinfektionsmittel (neodisher® Septo Active) • Reinigungslösung (neodisher® MediZym) • Kleine Bürsten mit weichen Borsten • Sterilisationsschale (Behälter) • Ultraschallbad oder Reinigungs-Desinfektionsgerät • Sterilisator der Klasse B *Anmerkung: Alle Materialien sollten regelmäßig gereinigt und ersetzt werden. Kennzeichnen Sie die für jeden Prozessschritt verwendeten Materialien (Erstbehandlung, Reinigung oder Spülung).*

1		**Erstbehandlung** Die gebrauchten Produkte in einen Behälter einlegen oder mit einem Wischtuch mit Leitungswasser bei 20–40 °C und mit 1,0 % neodisher® Septo Active zwischen 5 und 15 min spülen. Die Produkte mit Leitungswasser bei 20–40 °C für 1 min abspülen. Falls eine Wartezeit bis zum nächsten Schritt anfällt, ist sicherzustellen, dass das Instrument durch Einpacken in ein nasses Wischtuch feucht bleibt. Eine Wartezeit von 1 Stunde darf nicht überschritten werden. *Anmerkungen:* • *Keine fixierenden Mittel oder heißes Wasser (> 40 °C) benutzen, da dies zur Fixierung von Rückständen führt und den Reinigungserfolg beeinflussen kann.* • *Die Anweisungen sowie die Konzentrationsangaben und Eintauchzeiten des Desinfektionsmittelherstellers befolgen bzw. einhalten (eine zu starke Konzentration kann Korrosion oder andere Schädigungen an den Instrumenten hervorrufen).*
2		**Vorbereitung vor der Reinigung** Falls die Instrumente sichtbare Verunreinigungen aufweisen, wird empfohlen, sie von Hand vorzureinigen, und zwar mit einer weichborstigen Bürste unter Leitungswasser bei 20–40 °C für mindestens 1 min, bis alle Verunreinigungen entfernt sind. *Anmerkung: Die Anweisungen sowie die Konzentrationsangaben und Eintauchzeiten des Herstellers befolgen bzw. einhalten (eine zu starke Konzentration kann Korrosion oder andere Schädigungen an den Instrumenten hervorrufen).*
3		**Sichtprüfung** Überprüfen Sie die gebrauchten Produkte und entsorgen Sie die beschädigten (defekten, entspiralisierten oder anormal gebogenen) Produkte.
manuell	**4**	**Reinigen** Geben Sie die Produkte in das Becherglas des Ultraschall-Reinigungsgeräts. Das Ultraschallgerät mit Leitungswasser und 0,5–2,0 % neodisher® MediZym für 10–30 min laufen lassen. *Anmerkungen: Befolgen Sie die Anweisungen und halten Sie die Angaben des Herstellers der Reinigungslösung hinsichtlich der Wasserqualität, Konzentrationen und Reinigungszeiten ein.*
	5	**Spülen** Die Produkte mit Leitungswasser bei 20–40 °C für 1 min abspülen. *Anmerkung: Die Verwendung von entionisiertem Wasser wird empfohlen.*
	6	**Trocknen** Die Produkte mit Druckluft trocknen, bis sie sichtbar getrocknet sind.
automatisch	**4** **5** **6**	**Reinigen/Spülen/Trocknen** Die Instrumente in die Schale des Einschubwagens in das Reinigungs-Desinfektionsgerät legen. Den Reinigungszyklus mit 0,2–1,0 % neodisher® MediZym durchführen. Trocknung durchführen. *Anmerkungen:* • *Eine Desinfektion (thermisch oder chemisch-thermisch) ist nicht erforderlich, da die Produkte nach der Reinigung sterilisiert sind.* • *Befolgen Sie die Anweisungen und halten Sie die Angaben des Herstellers der Reinigungslösung hinsichtlich der Konzentrationen ein.* • *Befolgen Sie die Anweisungen des Herstellers des Reinigungs-Desinfektionsgeräts und bestätigen Sie nach jedem Zyklus, dass die Kriterien für einen erfolgreichen Abschluss gemäß den Angaben des Herstellers erfüllt wurden.* • *Der abschließende Spülschritt sollte mit entionisiertem Wasser erfolgen. Halten Sie bei den anderen Schritten die vom Hersteller vorgegebene Wasserqualität ein.* • *Verwenden Sie ausschließlich ein Reinigungs-Desinfektionsgerät nach EN ISO 15883, das regelmäßig gewartet und validiert wird.*
	7	**Sichtprüfung** Kontrollieren Sie die gebrauchten Produkte durch Sichtprüfung. Wiederholen Sie die Schritte 4, 5 und 6, wenn das Produkt erkennbar nicht sauber ist bzw. entsorgen Sie die beschädigten Produkte.
	8	**Verpackung** Überführen Sie die Instrumente für die Dampfsterilisation in einen Papier-Kunststoff-Beutel, der mit ISO 11607 und EN 868 konform ist. *Anmerkungen*: • *Im Falle von scharfen Instrumenten, die nicht in einen Behälter gelegt werden, sollten Silikonschlauchstücke um sie platziert werden, um ein Durchstechen der Verpackung zu verhindern.* • *Die Sterilisationsbeutel gemäß den Empfehlungen des Beutelherstellers dicht verschließen. Falls dazu ein Folienschweißgerät o. Ä. verwendet wird, muss dieser Prozess validiert und das Folienschweißgerät kalibriert und qualifiziert sein.*
	9	**Sterilisation** Die Produkte mit heißem Wasserdampf sterilisieren: • Sterilisator: Klasse B • Mindesttemperatur: 132 °C • Mindestzeit: 3 min • Absoluter Druck: 2,2 bar • Mindest-Trocknungszeit: 20 min Kontrollieren Sie die physikalisch-chemischen Indikatoren und Zyklusparameter. Gemäß den gesetzlichen Regelungen in Frankreich sind zur Inaktivierung von Prionen als Geräteeinstellung eine Temperatur von 134 °C und eine Dauer von 18 min vorgeschrieben. *Anmerkungen:* • *Wenn mehrere Instrumente in einem Autoklavierzyklus sterilisiert werden, ist sicherzustellen, dass die Maximalbeladung des Autoklavs nicht überschritten wird.* • *Die Sterilisationsbeutel gemäß den Empfehlungen des Sterilisatorherstellers in den Dampfsterilisator geben.* • *Verwenden Sie ausschließlich Dampfsterilisatoren mit Vorvakuum-Luftverdrängung, die die Anforderungen der Normen EN 13060 (Klasse B, Klein-Sterilisatoren) und EN 285 (Groß-Sterilisatoren) erfüllen, mit gesättigtem Dampf.*
	10	**Lagerung** Lagern Sie die Produkte in einer trockenen, sauberen und staubfreien Umgebung bei einer Temperatur, die den Vorgaben des Herstellers der Papier-Kunststoff-Beutel für die Dampfsterilisation entspricht. *Anmerkung: Kontrollieren Sie die Verpackung und die Medizinprodukte vor ihrem Gebrauch (Unversehrtheit der Verpackung, keine Feuchtigkeit und Verfalldatum). Im Fall einer Beschädigung ist der gesamte Prozess zu wiederholen.*

7. **Lager- und Transportbedingungen**

Entsorgung

Nach Gebrauch müssen die Instrumente in einem sicheren Behältnis abgelegt werden, das gemäß den Grundsätzen der guten zahnmedizinischen Praxis zum Sammeln von Schneid- und Stichinstrumenten (wie z. B. Nadeln oder Einmalskalpelle) verwendet wird.

8. **Symbole**

	Edelstahl-Material		Wurzelkanalaufbereitung
	Menge		Bei der angegebenen Temperatur in einem Dampfsterilisator (Autoklav) sterilisierbar
	K-Feile		Sortiment
	K-Bohrer		Bei beschädigter Verpackung nicht verwenden
	Hedström-feile		Medizinprodukt

Jahr der CE-Kennzeichnung: 2020

Omni K-Feile / Omni K-Bohrer / Omni Hedströmfeile

Instructions for use EN

1. **Indication**

The medical devices (K-Feile, Hedströmfeile, K-Bohrer) are used for catheterisation (n°006 to 015) and root canal shaping (all other diameters) during a non-surgical endodontic treatment. K-Feile 008 and 010 are also used in the exploration, initial penetration and root canal permeabilisation.
For use by dental professionals only.

2. **Contraindications**

Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there are no contraindications to the use for endodontically treating a tooth by orthograde route.

3. **Complications**

In cases of complex canal anatomy, per-operative risks (instrumental breakage, ledge, stripping, zipping, false path, perforation, etc.) could occur and lead to a risk of infectious processes.

4. **Characteristics and warnings**

ø	Maximum recommended number of uses (if the file is not visually damaged)
< 020	2
≥ 020	5

- Check the condition of the instrument's blade and its fit with the handle before use. If the instrument is damaged or shows signs of wear, do not use it.
- Inform the manufacturer and the national regulatory authority of any serious incident relating to the instrument.

Medical device class according to Directive 93/42/EEC and MDR 2017/745: Is.

Packaging symbol	STERILE EO	Sterilised using Ethylene Oxide.

5. **Clinical claims**

There are no specific clinical claims for the devices other than the achievement of the indication for use that corresponds to paragraph 1.

6. **Reprocessing instructions**

General recommendations	• For all metal devices, the use of anticorrosion disinfecting and cleaning agents is recommended. • For your own safety, please wear personal protective equipment (gloves, glasses and mask). • Do not use cleaning or disinfecting agents containing phenol, aldehyde and alkaline composition. • Always respect the instructions for use provided by the manufacturer of the products.
Limitations on reprocessing	• Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. The service life of the medical devices is determined by their function and careful handling. Multiple use disinfection and re-sterilisation cycles may lead to increased risk of file separation. • The user must ensure that the processing method used, including re-sources, materials and personnel, is appropriate and meets the applica-ble requirements. • The state of the art and national laws require that validated procedures be followed.
Material needed	• Gloves, masks, gown as recommended by the manufacturer of cleaning agent and detergent • Tap or deionized water • Disinfectant (neodisher® Septo Active) • Detergent (neodisher® MediZym) • Small soft brushes • Container • Ultrasonic tub or washer-disinfector • Class B sterilisation apparatus *Remark: All material used should be cleaned and replaced regularly. Identify material used for each step of the process (initial treatment, cleaning or rinsing).*

1	**Initial treatment** Place used products in a container or a wipe with tap water at 20-40 °C and 1.0 % neodisher® Septo Active for 5 to 15 min. Rinse the products with tap water at 20-40 °C for 1 min. If there is waiting time before the next step, make sure the device stays moist by placing it in a wet wipe. Do not exceed 1 hour waiting time. *Remarks:* • *Do not use fixing agents or hot water (> 40 °C), as this causes fixation of residues and can impair successful cleaning.* • *Follow instructions and respect concentrations and immersion times specified by the manufacturer (an excessive concentration may cause corrosion or other defects on devices).*
2	**Preparation before cleaning** If the devices have visible impurities, it is recommended to manually pre-clean by brushing under tap water at 20-40°C for at least 1 min with a soft brush until all impurities have been removed. *Remark: Follow instructions and respect concentrations and immersion times specified by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).*
3	**Visual inspection** Inspect the used products and discard damaged products (broken, untwisted or abnormally bent).
manual 4	**Cleaning** Insert the products into an ultrasound apparatus beaker. Run ultrasound apparatus for 10-30 min with tap water and 0.5-2.0% neodisher® MediZym. *Remarks: Follow instructions, observe water quality, concentrations and cleaning time specified by the manufacturer of the cleaning solution.*
manual 5	**Rinsing** Rinse the products with tap water at 20-40°C for 1 min. *Remark: It is recommended to use deionized water.*
manual 6	**Drying** Dry the products with compressed air until products are visibly dry.
automatic 4 5 6	**Cleaning/Rinsing/Drying** Place the instruments in the tray of the washer/ disinfector's sliding trolley. Perform cleaning cycle with 0.2-1.0% neodisher® MediZym. Perform drying. *Remarks:* • *Disinfection (thermal or chemical-thermal) is not required since the products are sterilised after cleaning.* • *Follow instructions and concentrations specified by the manufacturer of the detergent solution.* • *Follow the instructions of the washer-disinfector and verify that the success criteria have been met after each cycle as specified by the manufacturer.* • *The final rinse step should be with deionized water. For other steps, follow the water quality defined by the manufacturer.* • *Use only approved washers-disinfectors that comply with EN ISO 15883, and are maintained and validated regularly.*
7	**Visual inspection** Inspect the used products. Re-do steps 4-5-6 if the product is visibly not clean or discard any damaged products.
8	**Packaging** Place the instruments in a paper-plastic pouch for steam sterilisation in compliance with ISO 11607 and EN 868 standards. *Remarks*: • *For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent the packaging from being pierced.* • *Seal the pouches as recommended by of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermo-sealer must be calibrated and qualified.*
9	**Sterilisation** Sterilise the products using steam: • Apparatus: class B • Minimum temperature: 132°C • Minimum time: 3 min • Absolute pressure: 2.2 bar • Minimum drying: 20 min Control the physico-chemical indicators and cycle parameters. The temperature settings at 134°C and duration of 18 min are mandatory for prion inactivation according to French regulations. *Remarks:* • *When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser's maximum load is not exceeded.* • *Place the pouches in the steam steriliser according to the recommendations given by the steriliser manufacturer.* • *Use only a pre-vacuum air removal steam steriliser that meets the requirements of EN 13060 (class B, small steriliser) and EN 285 (full-size steriliser), with saturated steam.*
10	**Storage** Store the products in a dry, clean and dust-free environment at the temperature specified by the paper-plastic pouch by the steam steriliser manufacturer. *Remark: Check the packaging and the medical devices before using them (packaging integrity, no humidity and use-by date). In case of damage, a complete rerun should be performed.*

7. **Storage and transport conditions**

8. **Disposal**

After use, instruments must be placed in a secure container, used to collect cutting or sticking instruments (like needles or disposable bistouries) as per good dentistry practices.

9. **Symbols**

SSt	Stainless steel material		Root canal preparation
	Quantity	134°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
■	K-Feile		Assortment
●	K-Bohrer		Do not use if packaged is damaged
▲	Hedströmfeile	MD	Medical device

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CE 0459

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OMNIDENT

GEBRAUCHANWEISUNG

Omni K-Feile / Omni K-Bohrer / Omni Hedsrtömfeile

Hersteller: NOVAPEX

Processing of OMNIDENT Products

Instructions For Use

www.omnindent.de

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

EN

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)

EN

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.

EN

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.

⚠ 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)

EN

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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