

# Instructions for use

## Naso-pharyngo-laryngoscope

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Version:

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## 1 Important note



Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant specialist personnel.



Read the warnings marked by this symbol carefully. Improper use of the products may result in serious injury to the patient, users or third parties.

## 2 Scope of application

These instructions for use apply to the product group of Naso-Pharyngo-Laryngoscopes from Dimededa Instrumente GmbH. These instructions for use contain important information on the safe and effective use of these instruments. Before use, read the instructions for use for all instruments used in the procedure and use them accordingly. If you have any questions or comments about the contents of these instructions for use, please contact Dimededa Instrumente GmbH. These instructions for use also contain reprocessing instructions for Naso-Pharyngo-Laryngoscopes.

## 3 Intended patient population

With regard to the flexible Naso-Pharyngo-Laryngoscopes, there are no restrictions and limitations to the patient population, unless there is at least one contraindication. The attending physician or the user/operator is responsible for the selection of the instrument set for specific applications or surgical use, the adequate training and information and the sufficient experience for the handling of the instrument set.

## 4 Products / Purpose

Flexible Naso-Pharyngo-Laryngoscopes are used in diagnostic endoscopy. They are used for examination and diagnosis within the scope of the product-specific purposes listed below. (use < 60min). They correspond to risk class I.

| Naso-pharyngo-laryngoscope product family  |   |
|--|---|
| (Basis UDI-DI)   | Purpose   |
| Flexible fibre optic nasopharyngolaryngoscope<br>404279644715B6  | Endoscope with a flexible inserted part for visual examination and treatment of the structures inside the nasal passages. |
| Indication   |   |
| Flexible Naso-Pharyngo-Laryngoscopes are indicated as an aid in examinations and visualisation of the upper respiratory tract, including diagnosis of respiratory diseases, laryngeal disorders, sore throats or swallowing difficulties, diagnosis of structural anomalies and possibly defective functions of the various structures, or for therapeutic purposes, microsurgery or biopsies. |   |

## 5 Contraindications

### General contraindications

The use of flexible Naso-Pharyngo-Laryngoscopes is generally contraindicated when the use of other surgical techniques is indicated.

In addition, there are generally contraindications,

- if the patient is not willing,
- if the technical requirements are not met.
- not for use on the central circulatory and nervous system within the meaning of the Regulation.

### Product-specific contraindications

- Acute epiglottitis
- Pseudocroup
- Coagulopathies

## 6 Performance features

| Endoscope type                 | Flexible Naso-pharyngo-laryngoscope |           |           |
|--------------------------------|-------------------------------------|-----------|-----------|
| Article                        | 92.561.28                           | 92.561.32 | 92.561.34 |
| Insertion tube                 | Ø 2.8 mm                            | Ø 3.2 mm  | Ø 3.4 mm  |
| Useful length (working length) | 300 mm                              | 300 mm    | 300 mm    |
| Viewpoint                      | 85°                                 | 85°       | 85°       |
| Angle up/down                  | 160°/160°                           | 160°/160° | 160°/160° |

## 7 General instructions for use

The instructions for use contain important information on the operation and correct functioning of the flexible Naso-Pharyngo-Laryngoscopes.

⚠ This instruction is not intended to instruct or explain relevant surgical and/or examination techniques.

⚠ Each individual Dimededa Naso-Pharyngo-Laryngoscope has been developed for a specific field of application and may only be used in this field of application.

⚠ The Naso-Pharyngo-Laryngoscopes are to be used exclusively as intended and by trained and qualified personnel. The surgeon is responsible for the selection and proper use of the Naso-Pharyngo-Laryngoscopes.

⚠ This instruction cannot replace the training, care and state of the art of the user. If training in the safe use of the Naso-Pharyngo-Laryngoscope is required, this can be provided by Dimededa.

⚠ The use of Dimededa Naso-Pharyngo-Laryngoscopes must be in accordance with the recognised medical rules and procedures for naso-pharyngo-laryngoscopic procedures. We therefore assume that the relevant legal regulations, standards and recommendations (e.g. of the RKI or also the AKI) are known. The applicable country-specific laws and regulations must always be observed.

⚠ Dimededa Naso-Pharyngo-Laryngoscopes are precision devices. All metal parts are made of stainless steel. In the case of patients with hypersensitivity to components of high-alloy steels, it is the responsibility of the attending physician to clarify the patient's possible allergies in an explanatory discussion before their use and to assess the residual risk or find alternatives.

⚠ The flexible instruments must not be used if, in the opinion of a responsible physician, such use could cause danger to the patient.

⚠ Please always handle your Naso-Pharyngo-Laryngoscope with the utmost care.

⚠ After each cleaning/disinfection and before each use, the Naso-Pharyngo-Laryngoscopes must be checked for cleanliness, function and damage (see chapter 12).

⚠ No damaged or defective Naso-Pharyngo-Laryngoscope may be used. Damaged individual parts must be replaced immediately with original spare parts. Damaged Naso-Pharyngo-Laryngoscopes must be sorted out immediately.

If a malfunction should occur during an application on the patient, the application must be interrupted immediately.

⚠ Protect the Naso-Pharyngo-Laryngoscope from direct sunlight.

⚠ Protect the Naso-Pharyngo-Laryngoscope from X-rays.

⚠ Protect the Naso-Pharyngo-Laryngoscope from vibration.

⚠ Always handle the naso-pharyngo-laryngoscope with the greatest possible care (impact).

⚠ Do not hit the distal tip on hard objects.

⚠ Do not bend the insertion tube (max. steering radius of 25 mm).

⚠ Do not use Naso-Pharyngo-Laryngoscopes while discharging a defibrillator.

⚠ If Creutzfeld-Jacob syndrome (CJD or vCJD) is suspected or diagnosed, measures must be taken immediately to prevent transmission to other patients, users or third parties. The Naso-Pharyngo-Laryngoscopes must not be reused and must be

disposed of after thorough reprocessing and sterilisation.

⚠ For infection prevention reasons, the shipment of contaminated medical devices must be strictly rejected. The medical devices must therefore be decontaminated directly on site in order to avoid contact and aerogenic infections among staff.

⚠ Dimededa, as the distributor of these products, accepts no liability for direct or consequential damage caused by improper use or handling, in particular by failure to observe the enclosed instructions for use or by improper care or maintenance.

## 8 Precautions and warnings

The instructions for use and reprocessing as well as the specifications of accessories or medical devices used in combination must be carefully read, observed and kept.

⚠ The Naso-Pharyngo-Laryngoscopes are not supplied sterile and must be cleaned, disinfected and sterilised before first use and before each subsequent use.

⚠ Naso-Pharyngo-Laryngoscopes must not be cleaned in an ultrasonic bath.

⚠ Naso-Pharyngo-Laryngoscopes must not be exposed to gamma radiation.

⚠ Naso-Pharyngo-Laryngoscopes Flexible must not be autoclaved/steam sterilised. Temperatures of > 60 °C must not be exceeded.

⚠ If there are signs of damage, the Naso-Pharyngo-Laryngoscope must not be used under any circumstances.

⚠ If an unsuitable light source is chosen, it is possible that light with high radiant energy escapes from the light window and increases the temperature in the tissue (> 41 °C). Only light sources with max. 300 W (xenon) or 250 W (halogen) may be used. Overheated Naso-Pharyngoscopes may only be used after sufficient cooling.

Failure to do so may result in death or serious injury to the patient or irreparable damage to the product.

## 9 Combination products & accessories

In combinations with energetically operated naso-pharyngo-laryngoscopic accessories, there is a possible risk of excessive voltages and currents.

Ensure that patient leakage currents are minimised in combinations.

To avoid electrical coupling between patient and device, we recommend the use of Dimededa devices and accessories.

Combine flexible Naso-Pharyngo-Laryngoscopes with other medical devices only if:

- the intended use in the operating or operating instructions permits this;
- the technical data in the operating instructions allow this;
- the standard of the TV lenses or cameras corresponds to the general standard.

### Accessories / Spare parts

| Article number          | Designation   |
|-------------------------|---|
| 92.562.01               | Rooster bridge  |
| 92.562.02               | Adjustable one-way Y-flush tap                            |
| 92.562.00               | Leakage tester complete with adapter, incl. silicone hose |
| 97.345.00               | Mobile light source                                       |
| 91.925.xx-<br>91.951.xx | Light guide cable (various)                               |
| 91.900.xx               | Light guide adapter                                       |

All accessories and spare parts must be obtained exclusively from the manufacturer. Only accessories recommended by Dimededa may be used with the flexible Naso-Pharyngo-Laryngoscopes, ureterorenoscopes, bronchoscopes and cystoscopes.

## 10 Assembly/disassembly

Mount or dismount the light guide connection according to the illustration.

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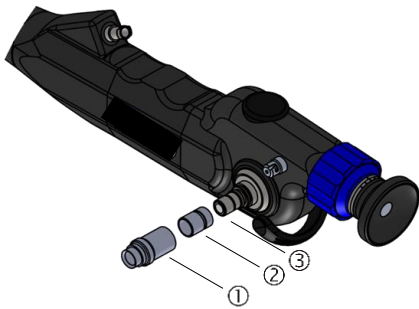
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1. Storz® / Aesculap® / Olympus® adapter
2. Wolf® adapter
3. ACMI® connection fixed to the unit

| Disassembly            | Assembly                |
|------------------------|-------------------------|
| Unscrew adapter 1 or 2 | Screw on adapter 1 or 2 |

- Ensure that the adapters of the fibre optic cables match the adapters of the flexible Naso-Pharyngo-Laryngoscopes (see illustration). Corresponding connection systems only fit into intended adapters.
- Adapters for fibre optic connection Storz®/Aesculap®/Olympus® (1) and Wolf® (2) are included as standard.
- To avoid fogging of the Naso-Pharyngo-Laryngoscope during the operation, the proximal end of the optic must be completely dry before adapting the camera or camera adapter. To ensure a firm and secure connection of the individual components, the closure of the Naso-Pharyngo-Laryngoscope and that of the adapter must not be dirty or damaged.
- Always hold the flexible Naso-Pharyngo-Laryngoscope by the main part or the eye funnel. Handle the insertion tube carefully, i.e. do not press or squeeze it.
- Ensure that glass surfaces are not touched with other instruments.

⚠ There is a risk of infection when disassembling contaminated Naso-Pharyngo-Laryngoscopes.

### 11 Control and maintenance

Allow flexible Naso-Pharyngoscopes and accessories to cool to room temperature before any inspection or maintenance. Assemble disassembled Naso-Pharyngo-Laryngoscopes and accessories.

#### General inspection (visual inspection)

- After each cleaning and disinfection, check flexible Naso-Pharyngo-Laryngoscopes and accessories for protein residues and contamination. Re-clean contaminated Naso-Pharyngo-Laryngoscope and accessories. The flexible Naso-Pharyngo-Laryngoscopes must not show any residues of cleaning agents and disinfectants.
- Before each sterilisation and before each use, the flexible Naso-Pharyngo-Laryngoscopes must be checked for cleanliness, function and damage.
- There must be no damage to the entire Naso-Pharyngo-Laryngoscope such as loose, bent, deformed, broken, cracked, rough, chipped parts, worn surfaces, sharp edges, defective insulations, etc.
- Sort out and replace damaged, defective, stained or cloudy Naso-Pharyngoscopes and accessories. Defective cables must be replaced immediately.
- Make sure that no parts are missing or have come loose (e.g. sealing rings) and that the connecting elements between the instruments function correctly.
- Visual inspection of the glass surfaces: The surfaces must be clean and smooth.
- Do not use product with damaged fibre optics, damaged glass surfaces or stubborn deposits that cannot be removed by cleaning.
- If any of the aforementioned deviations occur, the flexible Naso-Pharyngo-Laryngoscope must not be used any longer and must be sent to the manufacturer or an authorised service centre for repair (s. ch. 14) or disposed of properly (s. ch. 14).

#### (Manual) leak test

- A leak test is absolutely essential before each use, cleaning, disinfection and sterilisation or other immersion procedure. It is carried out by means of a leak tester with pressure gauge.
- Provide container with clean water or cleaning solution.
- Test connection and test connection hose must be dry.
- Place the connection cap firmly on the valve and turn it 90° counterclockwise. The tester is then firmly connected to the Naso-Pharyngo-Laryngoscope and cannot be pulled off.
- Generate a test pressure of max. 160 mm/hg by pumping at the leak tester, visible by slight inflation of the bend rubber at the distal bend part.
- If the pressure gauge indicator drops continuously, do not place the Naso-Pharyngo-Laryngoscope in liquid as the device is leaking. Please return the device for repair.
- If there is a leak, it must still be connected to the Naso-Pharyngo-Laryngoscope. The leak tester must not be placed in water. Immerse the Naso-Pharyngo-Laryngoscope in liquid and observe the bubbles rising. If bubbles (or streams of bubbles) rise steadily over a period of more than 1 minute, this is a sign of leakage. Please return the Naso-Pharyngo-Laryngoscope for repair.
- Initial bubble formation arises from external niches and is of no significance.
- Always pay attention to the pressure gauge of the leak tester. If the pressure drops, pressurise again if necessary, otherwise there is a risk of water damage.
- After successful testing, remove the Naso-Pharyngo-Laryngoscope from the water, bleed the system and disconnect the leak tester.
- If the leak test is positive (= proven perforation):
  - Remove the unit from the solution under pressure.
  - Wipe the outer sheath with disinfectant solution (microzide wipes).
  - Dry the duct systems and contacts with compressed air.
  - Wrap the Naso-Pharyngo-Laryngoscope in a protective foil cover, pack it in the shipping box and send it for repair with the note "leaking, not disinfected".
- ⚠ Never connect or disconnect the tester under water!
- ⚠ Never immerse the Naso-Pharyngo-Laryngoscope in liquids if there is a pressure drop!



#### Testing of the deviation mechanism

- Slowly operate the angling lever to test the function.
- Check whether the full angle is achieved.
- ⚠ Any restrictions of the angulation possibilities may indicate a defect of the Naso-Pharyngo-Laryngoscope. To avoid major damage to the Naso-Pharyngo-Laryngoscope in this case, use the Naso-Pharyngo-Laryngoscope only when the angulation is smooth.
- **Testing the fibre optics**
  - Before each use, check image quality (clear and distortion-free) and light transmission through the glass fibres.
  - Point the distal Naso-Pharyngo-Laryngoscope end against glare-free light, e.g. in front of a bright ceiling light (no cold light source), hold the light guide connector eyes close (10 cm distance) and move it back and forth.
  - The brightness of the fibres changes. If the glass fibres appear as dark spots at the distal end, glass fibres are broken and sufficient illumination may no longer be ensured. If individual fibres remain dark, this is harmless. From a breakage rate of

approx. 10-20 %, it is recommended that the nasopharyngo-laryngoscope be sent in for repair.

#### Maintenance and servicing

Flexible Naso-Pharyngo laryngoscopes and accessories are maintenance-free. There are no components included that require maintenance by the user or manufacturer.

### 12 Preparation

#### ⚠ Warnings

- The flexible Naso-Pharyngo-Laryngoscopes are not supplied sterile and must be cleaned, disinfected and sterilised before first use and before each subsequent use.
- Flexible Naso-Pharyngo-Laryngoscopes must not be cleaned in an ultrasonic bath.
- Flexible Naso-Pharyngo-Laryngoscopes must not be exposed to gamma radiation.
- Flexible Naso-Pharyngo-Laryngoscopes must not be autoclaved/steam sterilised. Temperatures of > 60 °C must not be exceeded.

#### General instructions for safe reprocessing

- After each cleaning/disinfection and before each use, the Naso-Pharyngo-Laryngoscopes must be checked for cleanliness, function and damage (see chapter 12). No damaged or defective Naso-Pharyngo-Laryngoscopes may be used. Damaged parts must be replaced immediately with original spare parts. Damaged Naso-Pharyngo-Laryngoscopes must be sorted out immediately.
- Reprocess contaminated Naso-Pharyngo-Laryngoscope and accessories as soon as possible.
- Manual or mechanical (automatic) cleaning and disinfection must be carried out after each use. Follow the manufacturer's instructions (e.g. dosage).
- Do not apply strong pressure by hand.
- Ensure that Naso-Pharyngo-Laryngoscopes and accessories do not touch each other during cleaning.
- Only use detergents to completely dissolve proteins.
- Avoid any fixation of proteins before and during reprocessing.
- Do not use abrasive cleaning agents or metal brushes.
- The parameters specified by the manufacturer of the detergent and disinfectant for concentration, temperature, duration of use and contact time must be observed and automatic dosing devices must be controllable.
- If there are increased chloride concentrations in the water, pitting and stress corrosion cracking can occur on the instruments. Such corrosion can be minimised by using fully demineralised water or alkaline cleaning agents.
- Steam sterilise only Naso-Pharyngo-Laryngoscopes and accessories marked "autoclave".
- The choice of detergent and disinfectant depends on the characteristics of the instruments and national guidelines and recommendations.
- The applicable country-specific laws and regulations must always be observed.
- Follow instructions for reprocessing and sterilisation.
- In case of contact with corrosive agents, clean immediately with water. If possible, use fully demineralised water (deionised water).
- Incorrect cleaning can lead to damage to property.
- ⚠ Always clean mechanically (automatically) after contact with:
  - Blood
  - Wounds
  - Internal tissue
  - Organs

#### Preparation of the instruments and pre-cleaning

##### Preparation of the instruments at the point of use

- Remove visible surgical residues and surface soiling as completely as possible with a clean, damp, lint-free cloth.
- Always carry out a leak test before immersing in liquids (see chapter 11).



# Instructions for use

## Naso-pharyngo-laryngoscope

|                    |                   |                 |           |
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- Do not use warm water (> 40 °C) or fixing disinfectants, as this can lead to fixation of the residues on the product (risk of protein coagulation or denaturation), which can influence the success of the subsequent reprocessing steps.

### Transport

- The instruments can be transported to the respective reprocessing rooms either wet or dry.
- We recommend using designated storage systems (e.g. disposal containers) for safe and smooth transport for reprocessing.
- Avoid drying of residues in any case.

### Manual pre-cleaning

Pre-cleaning must always be carried out before both manual and mechanical (automatic) cleaning.

- Disassemble the Naso-Pharyngo-Laryngoscope and accessories into individual parts. Disassemble the flexible Naso-Pharyngoscope as far as possible (see chapter 10). Remove all light guide adapters before reprocessing.
- To remove stubborn dirt, soak the product in cold water (< 40 °C) for at least 5 minutes.
- Using a soft cleaning brush (natural bristles), clean the product under running cold city water (< 40°C) until all visible dirt has been removed.
- Cavities, lumens, narrow crevices and slits must be flushed intensively (> 30 seconds) with cold city water using a water pressure gun (or syringe).
- Clean the optical surfaces (proximal eye funnel (eyepiece), distal tip, light guide cable connector) with a lint-free cleaning cloth and clean them carefully under cold running city water (< 40°C). Do not use a cleaning brush as scratches may occur. Impurities and scratches that affect the optical quality can be made visible by light reflections on the optical surface.
- If there are still residues on the surface of the optical fibres after cleaning, these residues can burn onto the surface when using a light source and thus impair the fibre transmission (light transmission).

### Manual preparation

#### Manual cleaning

(Validated with the alkaline cleaning agent neodisher® MediClean forte)

- Place the instruments completely in the alkaline cleaning bath (e.g. 0.5 % neodisher® MediClean forte for 5 min). Observe the exposure time according to the manufacturer's instructions.
- It must be ensured that the cleaning solution reaches all areas of the instrument. Moving parts on the instrument must be moved several times (min. 3 x) in the cleaning bath. Rinse cavities, lumens, narrow gaps and slits in the cleaning bath several times (min. 3 x 20 ml) with a syringe (without cannula).
- After the required exposure time, the instruments are re-cleaned under cold running water (< 40 °C) with a soft brush. Cavities, lumens, narrow crevices and slits are rinsed around and through again with the water pressure gun (or syringe) (> 30 sec.).
- Then rinse the Naso-Pharyngo-Laryngoscopes again under cold running city water and re-clean with a brush for complete removal of the cleaning agent (> 30 sec). Flush the cavity and lumen using a water pressure gun for at least 30 seconds.

#### Manual disinfection

(Validated with the aldehyde-free disinfectant Korsolex® plus)

- Immerse instruments in an RKI or VAH-listed disinfectant (e.g. 3 % Korsolex plus for 15 min). Follow the instructions of the disinfectant manufacturer.
- It must be ensured that the disinfectant reaches all areas of the instrument. Moving parts on the instrument must be moved several times (min. 3 x) in the disinfectant bath. Rinse cavities, lumens, narrow gaps and slits in the disinfectant bath several times (min. 3 x 20 ml) with a syringe (without cannula).
- After the exposure time, rinse the instrument thoroughly with cold deionised water (min. 3 min). Cavities and lumens must be rinsed several times

(min. 3 x 20 ml) with deionised water using a syringe (without cannula).

Manual drying is carried out using a lint-free disposable cloth. To avoid water residues in cavities as far as possible, it is recommended to blow them out using sterile, oil-free compressed air.

### Mechanical reprocessing (automatic cleaning and chemo-thermal disinfection)

- It is recommended to use a washer-disinfector RDG-E according to the requirements of the ISO 15883 series of standards.
- Instruments must be placed on machine-safe instrument holders in a way that is suitable for rinsing.
- The instrument trays (e.g. sieve trays) must be such that the subsequent cleaning in the washer-disinfector is not obstructed by rinsing shadows.
- The instruments should be fixed in the cleaning basket with a minimum distance between them.
- Overlapping should be avoided in order to prevent damage to the instruments during the cleaning process.
- Temperatures of 60 °C must not be exceeded to avoid damage to the flexible Naso-Pharyngo-Laryngoscope.
- Always follow the instructions of the appliance and detergent manufacturers.

Suitable pH-neutral or alkaline cleaners should be used for mechanical cleaning. We recommend the cleaning solution THERMOSHIELD® NR (formerly: THERMOTON® NR) from Dr. Schumacher GmbH with a dosage of 0.5 %, according to the manufacturer's instructions for Naso-Pharyngo-Laryngoscope reprocessing.

For chemical disinfection, we recommend the disinfectant THERMOSHIELD® DESINFJEKTANT (formerly: THERMOTON® DESINFJEKTANT) from Dr. Schumacher GmbH.

Automatic reprocessing validated with washer-disinfector Belimed WD 425, pH-neutral cleaning agent THERMOTON® NR (identical composition and formulation as THERMOSHIELD® NR), disinfectant THERMOTON® DESINFJEKTANT (identical composition and formulation as THERMOSHIELD® DESINFJEKTANT):

- Manual pre-cleaning (according to chapter 12.2)
- Automatic leak test in the RDG-E (if necessary also manually, see chap. 12.2)
- 3 minutes pre-cleaning with cold city water (< 40 °C)
- 5 minutes Cleaning at 55 °C ± 2 °C 0.6 % pH neutral cleaning agent (e.g. THERMOSHIELD® NR)
- 1 minute intermediate rinsing with deionised water (< 40 °C)
- 5 minutes chemical disinfection with e.g. 1 % THERMOSHIELD® DESINFJEKTANT at 55 °C ± 2 °C, deionised water
- 1 minute final rinse with deionised water 55 °C ± 2 °C
- 15 minutes automatic drying according to the automatic drying process of the washer-disinfector at 55 °C ± 2 °C
- This can be followed by additional manual drying with a lint-free cloth or blowing out lumens using sterile, oil-free compressed air.
- After machine cleaning, remove the Naso-Pharyngo-Laryngoscopes immediately from the cleaning device to avoid corrosion.
- Avoid accelerated cooling of the instrument.

### 13 Sterilisation

The flexible Naso-Pharyngo-Laryngoscopes are not supplied sterile and must be cleaned, disinfected and sterilised before first use and before each subsequent use.

- Before each sterilisation, the flexible Naso-Pharyngo-Laryngoscopes must be thoroughly cleaned (manually or mechanically) and disinfected (see chapter 12).
- Before each sterilisation, check flexible Naso-Pharyngo-Laryngoscopes for cleanliness, function and damage (see chapter 12).
- Sterilise Naso-Pharyngo-Laryngoscopes individually wrapped in suitable sterilisation containers.

- Ensure that the entire surface is in contact with the sterilisation medium.
- Ensure that the fasteners securely hold the Naso-Pharyngo Laryngoscopes.
- The Naso-Pharyngo-Laryngoscopes must not be subjected to mechanical stress as this could damage the sensitive lens systems.
- After completion of the sterilisation process, the Naso-Pharyngo-Laryngoscopes should be cooled slowly to room temperature. The Naso-Pharyngo-Laryngoscope must not be rinsed with cold water or other liquids for cooling, as this may damage the optics.

### Sterilisation process

Only special processes for thermolabile optics that have been tested and approved for this purpose may be used.

⚠ Flexible Naso-Pharyngo-Laryngoscopes must not be exposed to gamma radiation.

⚠ Flexible Naso-Pharyngo-Laryngoscopes must not be steam sterilised or autoclaved. Temperatures of 60 °C must not be exceeded.

### Recommended sterilisation methods:

- Gas sterilisation with EtO (validated parameters, see chap. 13)
- Gas sterilisation with hydrogen peroxide in the STERIS® V-PRO® process (see chap. 13)

Select the appropriate sterilisation procedure for thermally labile instruments according to national legal requirements and recommendations.

It is possible that sterilisation procedures not listed in these instructions are also compatible with the Naso-Pharyngo-Laryngoscopes.

When using procedures other than those listed as validated in this manual, the responsibility for sterility rests with the operator.

### Sterilisation with ethylene oxide (gas sterilisation)

Perform sterilisation with ethylene oxide (gas sterilisation) according to DIN EN ISO 11135. Take relevant national requirements into account. EtO equipment operating under a validated procedure according to EN 1422 ensures safe sterilisation and desorption according to the manufacturer's instructions. When sterilising with ethylene oxide gas, follow all reprocessing protocols from national authorities, health authorities, professional associations and from your facility, as well as the instructions of the manufacturer of your sterilisation equipment.

The sterilisation result depends on various factors, for example also on how the sterilised instrument is packed or stored or how the instrument is arranged in the steriliser. Check the degree of sterilisation using biological or chemical indicators.

⚠ Ethylene oxide gas is toxic and may be hazardous to health. Follow the applicable health protection regulations to determine the suitability of the process.

- Clean and dry the instruments thoroughly before gas sterilisation. Water residues may prevent sterilisation or cause damage to the naso-pharyngo-laryngoscope.
- Allow the instruments to outgas sufficiently after sterilisation and dry properly after sterilisation to remove toxic residues of ethylene oxide gas.

|                         |                                   |   |
|-------------------------|-----------------------------------|---|
| EtO sterilisation       | Temperature                       | 55 °C ± 3 °C  |
|                         | Chamber pressure                  | 1.7 bar (0.17 MPa)  |
|                         | Relative humidity                 | 40 - 100 %  |
|                         | Exposure time (exposure duration) | 120 min (2 hours)   |
|                         | EtO concentration                 | 7 - 8.5 % EtO (≥ 260 mg/l)<br>91.5 - 93 % CO <sub>2</sub> |
| Outgassing (desorption) | Minimum duration                  | ≥ 6 hours at 52 - 58 °C                                   |

When the specified desorption conditions are observed in conjunction with the listed sterilisation parameters, the flexible Naso-Pharyngo-Laryngoscopes are free of residual gas within the meaning of the limits specified in DIN EN ISO 10993-7.

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### Sterilisation with hydrogen peroxide in the STERIS® V-PRO® process

Gas sterilisation with hydrogen peroxide is another alternative method for sterilising thermolabile flexible Naso-Pharyngo-Laryngoscopes. For this procedure, the efficacy has been validated and the material compatibility tested over 30 cycles.

The validation of Dimeda's flexible Naso-Pharyngo-Laryngoscopes is valid for the following STERIS® V-PRO® low temperature sterilisation system:

| Sterilizer (Low Temperature Sterilization System) | Flexible cycle |
|---|----------------|
| V-PRO® maX  | ✓              |
| V-PRO® maX 2                                      | ✓              |
| V-PRO® 60   | ✓              |
| V-PRO® s2   | ✓              |

The suitability of the flexible Naso-Pharyngo-Laryngoscopes for effective sterilisation was demonstrated by an independent accredited testing laboratory. Sterilisation is considered sufficiently effective when a reduction of viable microorganisms by at least a factor of 10<sup>6</sup> is achieved (sterility assurance level (SAL): 10<sup>-6</sup>).

For information on packaging and weight restrictions, refer to the steriliser manufacturer's information.

### 14 Storage and packaging

- Flexible Naso-Pharyngo-Laryngoscopes sterilised with gas or equivalent methods must be stored in a closed cabinet, protected from contamination, after appropriate desorption (see chapter 13).
- Before storage, flexible Naso-Pharyngo-Laryngoscopes must be completely dry.
- Store and pack flexible Naso-Pharyngo-Laryngoscopes individually only.
- Store flexible Naso-Pharyngoscopes in a dry, clean, dust-free and well-ventilated environment and in a sheltered place at room temperature (free from corrosive vapours). To avoid the formation of condensation, major temperature fluctuations should be avoided.
- Flexible Naso-Pharyngo-Laryngoscopes should preferably be stored hanging on suitable holders in a special closed Naso-Pharyngo-Laryngoscope cabinet.
- The transport packaging of the flexible Naso-Pharyngo-Laryngoscopes is not intended for cleaning, sterilisation and storage, therefore do not store flexible Naso-Pharyngo-Laryngoscopes in the transport packaging.
- The flexible Naso-Pharyngo-Laryngoscopes must be reprocessed after a storage period of 7 days at the latest.
- Before use, after storage, rub outer sheath with microzide cloth and flush channels with 20 ml alcohol 70 %.

### Transport

- For transport, the flexible Naso-Pharyngo-Laryngoscope must be transported protected from contamination in suitable closed containers to avoid recontamination.
- Transport of Naso-Pharyngo-Laryngoscopes for evaluative examinations in the transport packaging is not permitted. The transport packaging may only be used to send a defective unit to the manufacturer for repair (see below).

### Service and repair

To ensure the operational safety of the flexible Naso-Pharyngo-Laryngoscopes:

- Repairs must only be carried out by the respective dealer or a qualified Dimeda authorised service centre.
- Only use original spare parts for repairs.
- The guarantee and warranty claim expires in the event of repairs that are not carried out by authorised service centres.
- Information about repairs and warranties is available from Dimeda representatives or authorised service centre.

### Shipping

Return of used medical devices only permitted in cleaned and sterilised condition with written proof.

- Always use the original transport packaging for returns. The packaging must ensure optimum protection of the flexible Naso-Pharyngo-Laryngoscopes during transport.

### Lifetime

- Flexible Naso-Pharyngo-Laryngoscopes are reusable instruments.
- The service life of the flexible Naso-Pharyngo-Laryngoscopes depends on the frequency of use as well as care and careful handling.
- When used as intended, the flexible Naso-Pharyngo-Laryngoscopes can be used and reprocessed for 30 cycles without maintenance/breakage.
- Before each use, check the flexible Naso-Pharyngo-Laryngoscope for cleanliness, function and damage (see chapter 12).
- At the end of its life cycle, dispose of the flexible Naso-pharyngo-laryngoscope properly, if necessary (see below).

### Disposal

- The following must be observed during disposal:
- Thoroughly clean and sterilise flexible Naso-Pharyngo-Laryngoscopes before disposal.
- Dispose of packaging and used parts in accordance with country-specific regulations.
- Protect flexible Naso-Pharyngo-Laryngoscopes from access by unauthorised persons.












### Incident reporting

- In the event of a serious incident occurring in relation to the device, the user and/or the patient shall immediately report it to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### Compliance with regulations

- This medical device is CE marked in accordance with the Medical Device Regulation (MDR) 2017/745.

### 15 Description of symbols used

|   |  |
|---|--|
|  | Attention!   |
|  | Follow the instructions for use                                      |
|  | Article number   |
|  | Lot designation  |
|  | CE mark, if applicable m identification number of the notified body. |
|  | Indication for non-sterile product                                   |
|  | Name and address of the manufacturer                                 |
|  | Date of manufacture  |
|  | Medical device   |
|  | Unique Device Identification, code for identifying a product         |
|  | Registration number of the manufacturer in the EUDAMED database      |