Distributor:
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INSTRUCTIONS FOR USE AND PREPARATION
RIGID ENDOSCOPES

1. Table of Content

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2. Intended Purpose and Scope of Application

Endoscopes are instruments that provide the insight at various parts of the human body. They serve for visualisation diagnostics and / or therapy with minimally invasive operations. Endoscopes are either inserted through a natural orifice or through an operationally made orifice.
Endoscopes are exclusively designed for surgical use and must not be used for any other purposes. Inappropriate handling and maintenance as well as alienated use may cause premature wear.
The products must be only used for their intended applications in medical sectors by correspondingly trained and qualified expert staff.
Responsibility for the choice of the instrumentarium according to the application resp. indication rests on the treating doctor resp. user. Sufficient instruction and training of the medical staff and information transfer of all necessary information must be guaranteed.

Indications:
The use of rigid endoscopes is indicated with endoscopic operations and other methods of minimally invasive surgery.

Contraindications:
The use of rigid endoscopes is contraindicated when endoscopic operations are contraindicated.

Groups of patients:
Patients of any age without limitation with limitation with whom an endoscopic standard examination is indicated.

3. Products

The rigid endoscopes are characterized by a rigid shaft.
Rigid medical endoscopes are used for visualisation of body orifices. Each endoscope has been exclusively developed for diagnostic and operative surgery in a specific field of application.
Furthermore, the different endoscopes designs vary in length, diameter and lens angle as well as compatible accessories.
These instructions for use apply for all rigid endoscopes of Dimeda, with or without working channel or rinsing channels as well as the accessories included in the extent of delivery.
The endoscopes have different names according to their fields of application.

Endoscope	medical field of application (examples)
Rigid Endoscope	Umbrella term for all versions
Arthroscope	Orthopedy
Resectoscope, Nephoscope, Ureteroscope	Urology
Hysteroscope	Gynaecology
Cystoscope	Urology und Gynaecology.
Laparoscope	Visceral surgery
Laryngoscope, Otoscope, Rhinoscope/ Sinoscope	ENT
Thoracoscope	Thoracic surgery
Bronchoscope	Pneumology
Vertebroscope	Spine surgery: Has, in addition to the optical system, 2 rinsing channels and 1 working channel for the insertion of instruments.

Table: Overview of endoscopes and their fields of application

4. Symbols (Instruction for use / Packaging / Label)

Symbol	Explanation	Symbol	Explanation
	Observe instruction manual		Manufacturer
	Attention!		Serial No.
	CE symbol		Product is non-sterile
	Article No.		

CE marking confirms the compliance of the product with the Medical Devices Directive 93/41/EEC resp. the Medical Devices Act (MPG [Germany]).


An *Instruction for Use and Preparation* is enclosed to each endoscope. Read this carefully and store it for easy access for the user resp. the medical expert staff.


Read carefully the warning notices marked by this symbol.
Inappropriate application of the products may result in serious injuries of patient, user and third parties.

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5. Precautions and important Instructions

Prior to any application of the endoscopes and instruments, they are to be checked for breaks, cracks, bending, damage and operational reliability. The areas working end, jacket tube, lens and all movable parts must be especially carefully checked. Worn, corroded, deformed, porose or otherwise damaged products must absolutely be sorted out.
Before initial use, brand-new endoscopes need to run through the complete treatment process once.
Delivery always happens in unsterile condition.
Endoscopes must never be cleaned in ultrasonic bath. As a result, the optical system might be damaged.

Functional Impairment:
Endoscopes corrode and are impaired in their function when they get in contact with aggressive substances or wire brushes or similar are used for preliminary cleaning. Therefore, it is absolutely essential to observe the preparation and sterilization instruction.
Operating Conditions:
Correct maintenance and care are inevitable for the warranty of safe operation of the aforementioned products. Furthermore, a functional and visual check ought to be executed before any application. We therefore refer to the corresponding paragraphs in this instruction manual.

Reprocessing of Endoscopes after Use with highly infectious Patients:
Regarding the preparation of medical devices that were used with patients suffering or being suspect to be suffering from the Creutzfeldt-Jacob disease (CJD) or its variant (vCJ), the requirements stated in the corresponding annex for hospital hygiene and infection prevention and by publications in the Bundesgesundheitsblatt (Federal Health Bulletin) must be observed. The medical devices applied with this group of patients must be safely eliminated by combustion (Kat. IB - European Waste Catalogue EWC 180103). Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing, but no inactivating effect upon TSE agents.
From the available sterilizing methods, a limited effect could only be proven for only steam sterilization (especially 134°C, 18 minutes).
Storage:
The products ought to be stored in a clean, dry environment and single in their packaging or in a protecting container with single compartments. Protect areas such as working end and ocular with corresponding tubes, protecting caps, gauze or fabric. Especially consider that no chemicals are stored in immediate near to the storage place.
Delivery Condition:
The medical devices are delivered in unsterile condition and have to be prepared and sterilized by the user according to the following instruction before initial and any further application.

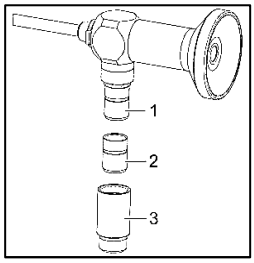
6. Intended Use

Instructions for Use with Camera Systems:
For intended use, endoscopes are always connected to a camera light system. Non-compatible and incorrectly combined products may menace or injure the patient. The connection between camera and endoscope happens by a cable via which illumination as well as picture transmission take place.
Compatibility Data for the Light Source:
Cold-light source:

- Max. 240 Watt,
- Colour index CRI > 70
- Colour temperature 3.000 – 6.000 K (Kelvin)

Available connections for optical fibre cable types:

(1) ACMI
(2) Wolf
(3) Storz



Instructions for Use with Rinsing Pumps:
Only compatible hose sets may be connected to the rinsing connections of the endoscopes. Rinsing may only be executed with rinsing solutions suitable for the endoscopic surgery.
Instructions for Use of further medical Equipment in Combination with Endoscopes:
(Shaver, HF equipment, insufflators, lasers, a.s.o.)
Use only equipment that is suitable with the endoscopes resp. indicated for the application. Refer to the instructions for use of the respective equipment for handling information and safety instructions.
Special care must be given to the use of equipment and instruments that might get in direct contact with the endoscope tip and especially the camera lens.
Dimeda is not liable for any damages of endoscopes caused by lasers, shavers or the like.
Dimeda endoscopes are not MRT- compatible.

7. Limitation of Preparation and Disposal

Independent from their sterilization procedure, endoscopes can be re-used very often in case of corresponding care and in as much as they are undamaged and unpolluted. Check the endoscopes for damages prior to any preparation.
Frequent restoration has little effect upon the endoscopes. The product service life is normally determined by wear and damages in use. Please introduce the endoscopes to expert disposal or a recycling system after completion of their product lifetimes. National regulations and disposal guidelines must be observed!
For further information we recommend the Red Brochure of the AKI (Value-preserving Prepar4ation of instruments).
It is available as free download Rote Broschüre | AKI Arbeitskreis Instrumentenaufbereitung (a-k-i.org)

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8. Preparation

⚠ Warning Notices

- Urban water in use must correspond to drinking water quality.
- Demineralised water should be low-germ (<100 CFU/ml) and have an electr. Conductivity <10 µS/cm.
- Disassemble products before cleaning.
- Reassemble disassembled products before sterilization.
- No use of chloride-containing detergents in order to avoid affection of the passive layer

⚠ Application Site

Rough pollution, residuals of e.g., haemostasis, skin disinfection agents and lubricants as well as caustic remedies shall, if possible, be removed before depositing of the instruments.
Wherever possible, dry disposal (moisturised, closed system) is to be favoured. Surface drying of residuals must be avoided!
Long waiting periods before preparation, e.g., overnight or over the weekend, must be avoided for both methods of disposal (<6 hours).

⚠ Transportation

The products must be dry disposed immediately after use. This means that the products have to be transported moistly in a closed container from the application site to preparation in order to avoid surface drying at the endoscopes.

Preparation for Decontamination

The endoscopes shall, if possible, be disassembled before the following preparation steps resp. introduced to the following preparations steps in opened condition. Unwashed areas must be avoided. The endoscopes must be prepared in suitable screen baskets or drainage bowls (determine size according to endoscope). the endoscopes shall be fixed in the cleaning basket with a minimum distance (1cm) to each other. Any overlapping shall be avoided in order to exclude damage of the endoscopes by the cleaning process. Quantity and kind of loading into the instrument trays chosen for the cleaning has to be done in a way that no impairment of the cleaning result has to be expected. The endoscopes shall be arranged in a way that water can drain off from cannulas, blind holes and hollow bodies.

Manual Preliminary Cleaning

Rinse the products under cold urban water (drinking quality, <40°C) as long until all visible pollution has been removed. Adhering dirt has to be removed with a soft brush (natural bristles or plastic bristles, **never use metal bristles or metal sponges**). Movable parts at the instrument have to be moved. Hollow bodies, lumens, columns and slots have to be rinsed intensively (>60 sec) by means of a water pistol or similar with cold urban water (drinking quality, <40°C).

Dip subsequently into immersion bath with urban water (40 - 45°C) with a ***pH-neutral cleaning agent (e.g., neodisher® MediZym 0,5% - 2% solution)*** for 20-30 min. Then rinse instruments under flowing, cold water (<40°C) for 15 sec.

⚠ Ultrasonic Treatment: (accessories only, no optics!!!)

Dip accessories into an ultrasonic bath (<40°C) with an alkaline cleaner (0,5% neodisher® MediClean forte), sonication period of 5 min. and a frequency of approx. 35 kHz. While doing so, observe the cleaning agent manufacturer's instructions. Place accessories in a way that all surfaces, hollow bodies, lumens and openings are covered.
Subsequently shortly rinse accessories under cold water (<15 sec.). Movable parts must be moved. Rinse again hollow bodies, lumens, columns and slots by means of a water pistol (or similar) (>30 sec.) with cold urban water (<40°C).

Cleaning / Disinfection

Automatic Cleaning / Disinfection Process

(RDG according to EN ISO 15883-1,-2;):

- 1 minute preliminary cleaning with cold urban water (drinking water quality <40°C)
- Water drainage
- 3 minutes preliminary cleaning with cold urban water <40°C
- Water drainage
- 5 minutes cleaning at 45°C ±5°C with a pH-neutral cleaning agent ***(neodisher® MediZym 0,5% - 2% solution)***
- Water drainage
- 3 minutes rinsing with cold urban water <40°C
- Water drainage
- 2 minutes rinsing with demineralised water <40°C,

The specific instructions of the manufacturer of the cleaning equipment must be observed.

Automatic Disinfection

Automatic thermal disinfection in cleaning and disinfection device under consideration of the national requirements to the A0 value; e.g. A0- Wert 3000: >5 minutes at 92°C±2°C with demineralised water.

Automatic Drying

Automatic drying according to automatic drying process of the cleaning and disinfection device for at least 30 minutes (device setting: 90°C).
If need be, subsequent manual drying with lint-free towel and blowing out of lumens by means of sterile, oil-free pressurised air.

Checks

The endoscopes must be macroscopically clean, i.e., free of visible pollution after each cleaning.

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- Stained instruments have to be sorted out immediately and to be introduced to a special treatment.
- All movable parts (e.g., blades and working tips) have to be checked extra carefully.
- In case of appearance of failures or damages the instruments have to be sorted out immediately.

Care of Equipment

Let endoscopes and accessories cool down to ambient temperature. „Care" means application of instrument oil or instrument milk (emulsion of white oil in water). Products with joints or closure (forceps, clamps, a.s.o.) or with metallical sliding surfaces (punches a.s.o.) must be treated with steam sterilisable care products on paraffin oil basis. The paraffin oil must correspond to the respectively applicable pharmacopoeia and be physiologically harmless according to the "Deutsches Arzneibuch", resp. "European Pharmacopeia (Ph. Eur.)" or "American Pharmacopoeia", "United States Pharmacopeia (USP)". The care products prevent friction of metal upon metal and keep the products smooth-running. Laser labelled products may fade during treatment with basic cleaners containing phosphoric and hydrofluoric acid. Thus, the coding function may be affected or get lost. Basically, endoscopes and their accessories must be undergone permanent care before function test. Care products operate in a way that even after permanent repeated use any „clogging" by accumulating effect is excluded.

Packaging

The endoscopes are packed into a suitable standard-conforming packaging for sterilisation according to DIN EN ISO 11607 resp. DIN EN 868 and sealed.

Sterilization

Sterilization of the products by means of the pre-vacuum process (acc. to DIN EN ISO 17665-1) in consideration of the respective national requirements. Sterilisation of the endoscopes has to occur in suitable sterilisation packaging (endoscope in tray, this one wrapped in a fleece and then packaged in the sterilisation container. Sterilisation has to be executed by means of a fractionated pre-vacuum process, with the following parameters:

- 132°C / 269,6°F,
- ≥4 minutes hold time,
- 3 pre-vacuum cycles,
- Drying in vacuum for at least 20 minutes

Observe the autoclave manufacturer's instructions for use and the recommended guidelines for maximum loading with sterilisation items. The autoclave must be properly installed, maintained, validated and calibrated.

⚠ Additional Information

The preparator is responsible that the actually performed preparation with utilized equipment, materials and staff in the processing facility obtains the requested results. Normally this requires validation and routine monitoring of the process and the utilized equipment.

9. Clean Utility Storage

Use adequate approved sterilization packaging (e.g., acc. to DIN EN 868, ISO 11607) for sterilization, subsequent transport and storage.
The endoscopes incl. accessories:

- Have to be stored dry.
- Have to be protected against mechanical damage.
- Have to be stored and moved in safe containers / packaging's.
- Must nor be thrown neither dropped.

Inspection prior to next Application:

Prior to any application, the endoscopes have to be examined for breaks, cracks, deformations, damages and functioning. Areas like tips, closures, locks, detents and all movable parts must be examined extra carefully. Worn, corroded, deformed, porous or otherwise damaged endoscopes must be sorted out. Due to their alloys, the special steels utilized for endoscope manufacturing („stainless") form specific passive layer as protective layers. These steels are only limitedly resistant against the attack of chloride ions and aggressive media and liquids! In addition to the efforts made by the manufacturer in the choice of the correct materials and their careful processing, the user must ensure appropriate and continuous care of the endoscopes.

- The glass surfaces of the endoscopes (distal and proximal) must be clean and free of deposits.
- Only completely cooled down endoscopes must be utilized, since otherwise condensate may form in the optics.

10. Service, Repair and Return Transport

Service and Repair:

Do not independently execute any repair or modifications of the product. Exclusively authorized manufacturer's staff is responsible and intended to do so. In case of complaints, claims or references, we would ask you to get in contact with us.

Return Transport:

For protection of your staff and the Dimeda employees, clean thoroughly and sterilize the endoscope (and corresponding accessories, if applicable) prior to shipping. If this should not be possible for urgent reasons, the endoscope has to be prepared as well as possible and labelled correspondingly.
On behalf of quick processing of inquiries, we would plead you to send the product with the following declarations:

- article number (REF)
- serial number (SN) or (LOT)
- as precise description of error as possible
- proof of sterility

11. Liability and Warranty

Dimeda as distributor of the products rejects any responsibility for immediate damage or secondary damage caused by inappropriate use, handling or by inappropriate sterilization and maintenance. Repair of the instruments by companies or persons that are not authorized to repair by **Dimeda Instrumente GmbH**, will cause the expiration of the warranty.

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