Flexible Nasopharyngoscope

Operator Manual

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Distributed by Anthony Products, Inc.

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1. Introduction

- The flexible nasopharyngoscope is sold in unsterile condition as a reusable endoscope.
- The delivery must be checked for transport damages after receipt. The complete endoscope and, in particular, the insertion tube, must be checked for wear and damage before each use.
- This nasopharyngoscope has been specially developed for use between the upper respiratory tracts of the nasal passage and the vocal chords, and may only be used for this purpose. For the patient's well-being and safety, the doctor should select a method which seems suitable to him/her on the basis of his/her experience.
- These documents are intended as reference for the operation and correct functioning of the instrument and are not to be used as instructions for endoscopic examinations or operations.

Note: The glass fibre bundles and optical components contained in the flexible endoscope are very sensitive and require very careful handling. They can be damaged by high atmospheric humidity, the penetration of liquids, extreme temperatures or impacts. The same naturally also applies for all other optical components. It is particularly important to avoid any impacts on the distal end. The insertion tube must not be excessively kinked, pulled, pressed or twisted. The nasopharyngoscope must also be protected from direct sunlight and X-rays.

2. Structure of the Nasopharyngoscope

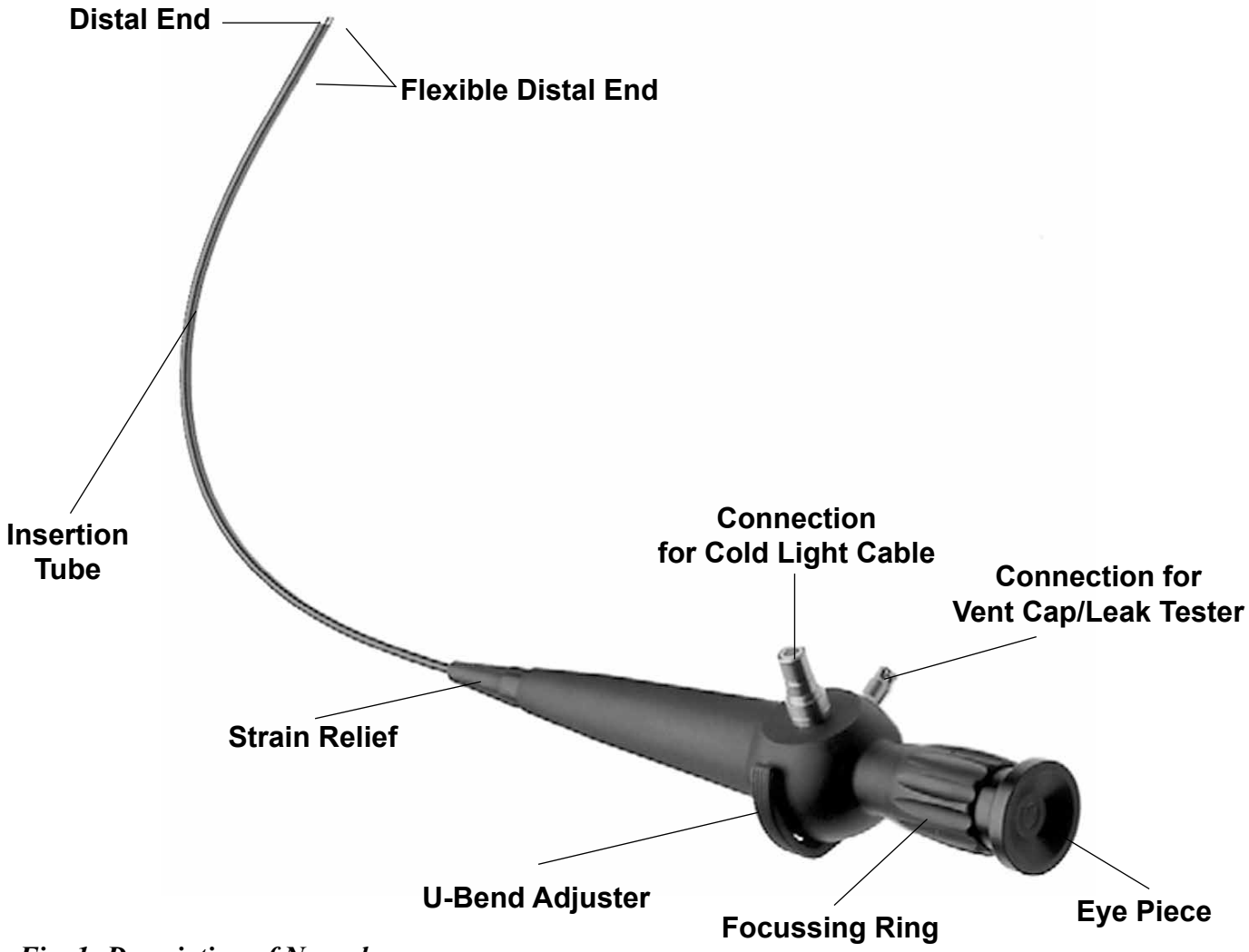

Fig. 1: Description of Nasopharyngoscope

2. Structure of the Nasopharyngoscope (continued)

A video camera can be connected to the eye piece. You can, of course, also view the image directly with your eye.

The sharpness of the image is adjusted on the focussing ring, by turning the ring to the left or right. The dioptric markings permit individual adjustment to different users. If a transmission device is connected, the white dioptric marking on the focussing ring should be located opposite the white line on the endoscope body (see Fig. 2).

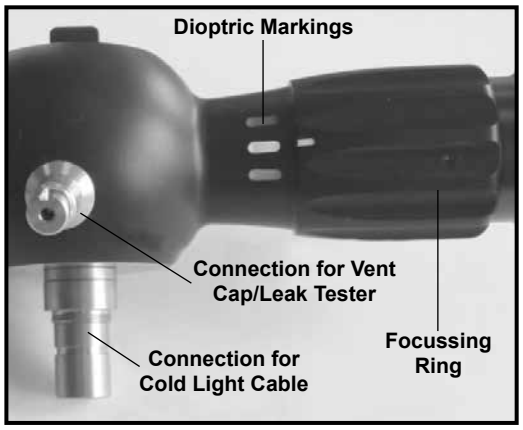

Fig 2: Connections/Dioptric Markings

The U-bend adjuster (see Fig. 3) is used to control the flexible distal end. When the U-bend adjuster is moved in direction D (down), the distal end is moved downwards (provided that the U-bend adjuster of the endoscope is pointing down). When moved in direction U (up), the distal end is moved upwards.

Note: If the endoscope is held differently, e.g. with the U-bend adjuster pointing upwards, the distal end will move in the same direction when the U-bend adjuster is moved.

The connection for the leak tester or vent cap and the cold light cable connection are also located on the endoscope body (see Fig. 2).

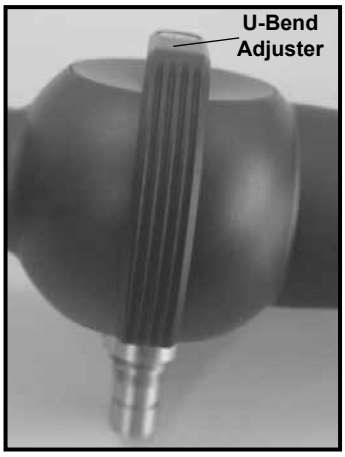

Fig. 3 U-bend Adjuster

Warning: A vent valve is located on the endoscope body. The vent cap (see Fig. 4) must be connected before ETO gas sterilization, before dispatch and before ventilation, as the endoscope may otherwise be damaged by pressure changes.

The vent cap must be removed before use on patients, cleaning, disinfecting and immersing in fluids, as the endoscope can otherwise be damaged by penetrating moisture.

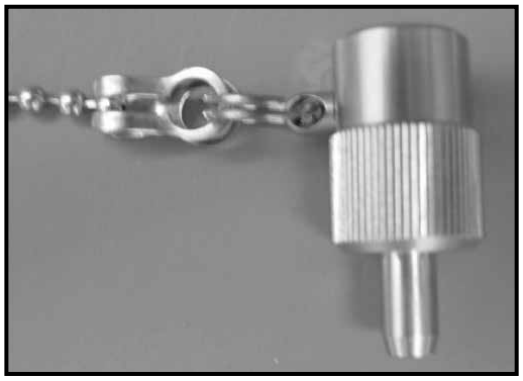

Fig. 4: Vent Cap

3. Technical data

Field of view: 85º

Depth of field: .....2.5 – 50 mm

Outer diameter insertion tube: .....3.4 mm

Working length: .....300 mm

Bending range of distal tip: .....125º up/125° down

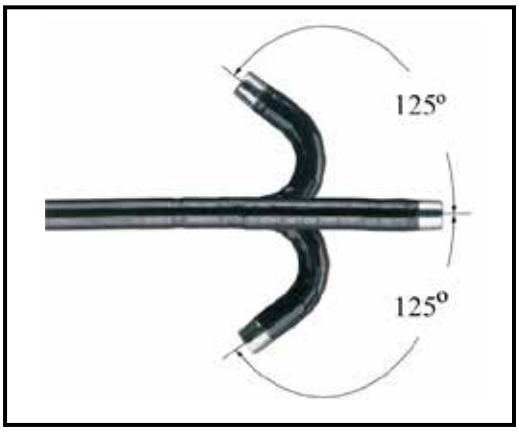

Fig. 5: U-bend Range

4. Operation

Hold the endoscope in your hand in so that the U-bend adjuster can be easily moved, using the other hand to guide the insertion tube.

Warning: Only use water-based lubricant, in order to prevent wear of the insertion tube material.

The distal end of the endoscope can become very hot as a result of intensive illumination. These surface temperatures can cause burns to the mucous membrane.

After completing the examination, take care to manipulate the U-bend adjuster so that the flexible distal end is moved back without causing injuries to the patient. The doctor should observe and take account of anatomical factors when removing the insertion tube.

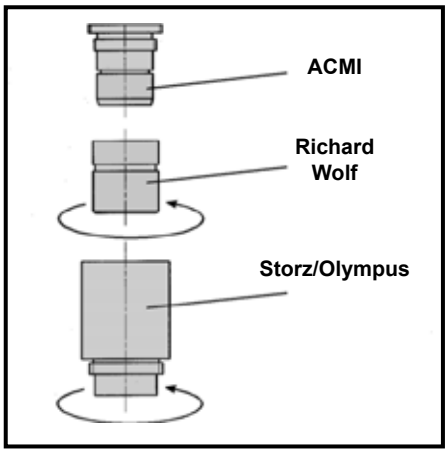

Fig. 6 Fitting the Glass Fiber-optic Connection

5. Functional Testing of the Endoscope

A functional test must be performed before disinfecting/sterilizing the endoscope. The functional elements should naturally also be checked before the operation, ensuring that the disinfected or sterilized endoscope is not soiled or contaminated.

The endoscope must be prepared following the individual steps in Section 7, Preparation.

The insertion tube must be checked for wear and damage before each use, by carefully moving your finger tips along the tube.

Warning: Do not pull on the tube. The functioning of the flexible distal end must also be checked by operating the U-bend adjuster.

Both the eyepiece and the lens on the distal end must be cleaned.

The endoscope can be used with almost all common glass fibre optic cables by screwing on the relevant adapter (see Fig. 6).

Fig. 8 Leak Tester

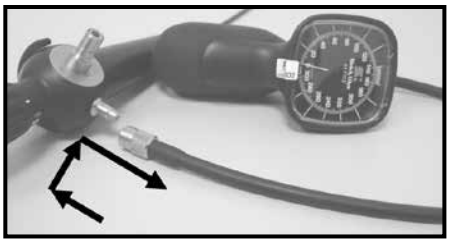

Fig 9. Connection mechanism of leak tester

6. Leak Test

Warning: A leak test must be performed before each immersion in fluid, during cleaning and disinfecting. If the leak test is positive (detected perforation, i.e. the instrument leaks), the endoscope must not be further prepared. The test should be repeated if necessary. The outer casing must be wiped with instrument disinfectant or 70% isopropanol. The endoscope is enclosed in a protective film sheathing, packed in the shipping crate and passed to the service workshop with the remark "leaky, not disinfected".

Before fitting the leak tester (see Fig. 8) to the relevant connection, make sure that the two connecting parts are completely dry. **Never connect or remove the leak tester under water.** To connect the leak tester correctly (see Fig. 9), guide the connector centrally onto the connection, aligning the pin located on the side of the connector (also visible from the outside) with the groove located on the connection. Then press the connector towards the endoscope and rotate sideways approx. 90º, until it reengages effortlessly at the top. The plug-in connection must not now be removed. The leak tester is pumped up to a range between 140-160 mmHg and observed for approximately 20 seconds. If the pressure drops continuously, the leak tester may not be correctly connected. If the compressed air pressure drops despite correct connection, then the endoscope is leaky and must not be immersed in fluid.

The imperviousness meter is then removed and the endoscope completely immersed in water.
Attention: The imperviousness meter is not immersed with the endoscope.
If a leaky point exists (detectable through constantly rising air bubbles), the endoscope should be removed from the water immediately. In order to detect any holes on the flexible distal end, it should be moved up and down with the U-bend adjuster.

If small air bubbles have formed on the indentations on the outside of the endoscope, these can be eliminated by light knocking. If air bubbles still rise continuously, the endoscope is not tight and must be removed from the water immediately.

If the leak test on the endoscope has a negative result (no perforation detected), remove the endoscope from the water and unscrew the leak tester. The endoscope can then be immersed in the cleaning liquid or disinfectant.

7. Preparation

- **The flexible nasopharyngoscope is not autoclavable and must also not be cleaned with ultrasound.**
- **Clean medical products are a prerequisite for reliable and effective disinfecting or sterilization. Particular importance is therefore attached to cleaning in the general preparation procedure.**
- **Do not use excessive pressure when cleaning the insertion tube, so as to avoid causing any damage. The endoscope must not be immersed for longer than the maximum time indicated by the cleaning liquid manufacturer, as the outer surface and optics may otherwise be damaged, resulting in the penetration of fluids.**
- **The endoscope should be cleaned and disinfected before each use. The leak test should also be carried out as specified.**
- **Cleaning and disinfectant solutions must be carefully removed by intensive rinsing with sterile distilled water, as they can cause chemical irritations and allergic reactions in the patient's mucous membrane.**
- **It is important not to use any aldehyde-containing agents for preliminary cleaning, as these cause fixing of albumen.**
- **In the event of inadequate cleaning, the effectiveness of the following disinfecting procedure and the functioning of the endoscope cannot be guaranteed.**
- **Use gloves and protective goggles for all cleaning and disinfecting measures.**

Chemical disinfection must be carried out at 55°C and for at least 5 minutes. This process has been validated by the company Schülke & Mayr using Thermosept ED 1% disinfectant.

7.1. Manual cleaning

7.1.1 Preliminary cleaning:
Preliminary cleaning must be carried out immediately after the examination. As soon as the endoscope is removed after the examination, the insertion tube must be wiped with a soft, lint-free disposable cloth in order to remove coarse impurities.

The endoscope must then be disconnected from the cold light cable and from any connected transmission devices (e.g. camera system). Any adapters screwed onto the cold light cable connection should be unscrewed and included in the preparation process.

7.1.2 Manual cleaning:
Prepare the cleaning solution according to the manufacturer's instructions and completely immerse the endoscope in this solution after the leak test (see Chapter 6). Carry out all cleaning steps beneath the surface of the liquid, in order to avoid sprays of contaminated fluid. Clean the outer casing of the endoscope with a lint-free disposable cloth. Clean connections/valve openings, distal end and control elements carefully with a soft brush. Then clean the cleaning brushes and disinfect with the endoscope.

7.1.3 Rinsing off the cleaning solution:
Place the endoscope and accessories (valves, adapters and cleaning brushes) in a bowl with clean tap water, in order to rinse off the cleaning agent.

7.1.4 Disinfection:
Completely immerse the cleaned endoscope in the disinfectant with all accessories and cover the basin with a tightly closing cover. Follow the manufacturer's instructions exactly with regard to concentration and action time. The date on which the disinfectant solution is prepared must be marked on the basin. When the solution is changed, the disinfection basins must be subjected to thorough mechanical and disinfectant cleaning.

7.1.5 Final rinsing:
Remove the endoscope and accessories from the disinfectant solution with sterile disposable gloves. Place the disinfected endoscope and accessories in a basin or bowl with microbiologically perfect/sterile distilled water. Fresh water must be used for each instrument. Thoroughly rinse the outside of the endoscope with microbiologically perfect and, if required, with sterile distilled water.

7.1.6 Drying and storage:
Carefully blow dry ducts with compressed air if required. Dry the outer casing of the endoscope with a lint-free disposable cloth and carry out a functional check of the endoscope. The endoscope can then once again be used for examining patients.

Warning: Care must be taken not to contaminate the endoscope after the cleaning process.
For storage or preservation, the endoscope must be stored completely dry, protected from dust, and preferably hanging in a special endoscope cabinet. The box is not suitable for long-term storage of the endoscope. Store adapters dry and dust-free where applicable. Do not insert the vent cap when storing the endoscope (see 7.3.5).

7.2. Semi-mechanical Cleaning

7.2.1 Preliminary cleaning (see 7.1.1)

7.2.2 Manual cleaning (see 7.1.2)

7.2.3 Rinsing off the cleaning solution (see 7.1.3)

7.2.4 Preparing the disinfection device:
Place the cleaned endoscope in a disinfection basin with all accessories, cover with the lid and start the program sequence. The manufacturer's instructions regarding concentration and action time must be precisely complied with. The date and time of preparation of the disinfectant should be marked on the basin, for example. In certain disinfection devices, final rinsing and drying can also be carried out in addition to the disinfection procedure.

7.2.5 Final rinsing (see 7.1.5)

7.2.6 Drying and storage (see 7.1.6)

7.2.7 Disinfection equipment:
Clean, disinfect and, if possible, dry the basin and hose daily after use. Renew the disinfectant solution in the instrument tank according to the manufacturer's instructions (depending on the number of disinfection procedures, service life or contamination). Empty the water tank and water canister after use. Dry carefully at the end of the day's work and avoid standing residual water. If present, replace sterile water filter in accordance with manufacturer's instructions. Have regular servicing carried out by the equipment service department as per the manufacturer's instructions.

7.3 Mechanical Endoscope Preparation in the Cleaning and Disinfection Device

7.3.1 Preliminary cleaning (see 7.1.1)

7.3.2 Manual cleaning (see 7.1.2)

7.3.3 Rinsing off the cleaning solution (see 7.1.3)

7.3.4 Preparing the cleaning and disinfecting device for endoscopes:
Place the cleaned endoscope in the basket of the cleaning and disinfecting device for endoscopes in accordance with the manufacturer's instructions and connect the endoscope to the relevant system if required. Place the accessories (e.g. valves, cleaning brushes) in the accessories compartment. Then push the basket into the cleaning and disinfecting device for endoscopes, close the door, select the program and start it.

7.3.5 Removing the endoscope from the cleaning and disinfecting device for endoscopes:
Remove the endoscope with disinfected hands or sterile disposable gloves and carry out a functional test (see 5.). The endoscope can then be used for patient examinations once more.
For storage or preservation, the endoscope must be stored completely dry, protected from dust, and preferably hanging in a special endoscope cabinet. Store the vent cap dust-free and dry and do **not** insert it into the endoscope during storage.

8. Steris

Successful germ elimination has been proven in the full cycle (Steris System 1).

9. ETO gas Sterilization

ETO gas sterilization is suitable for the nasopharyngoscope in respect of material compatibility. The process parameters must be performed in accordance with the information of the ETO gas sterilization manufacturer. Desorption times prescribed according to the gas concentration must be observed.

10. Electrical safety

The degree of electrical insulation is fixed by the manufacturer of the equipment used with the endoscope and its accessories. Many years of experience have shown that instruments exclusively manufactured and repaired by API do not give rise to any safety risks.

11. Service

API does not supply their optical and mechanical parts to any outside company, therefore only API, or its subsidiaries are able to repair API medical endoscopes with original parts and **to guarantee the original technical specification and safety of the product.**
Additionally, the API warranty for the medical endoscope is void if a repair is done by an unauthorized repair shop. Then API is no longer responsible for the original specification and for the safety standards of the product.
The vent cap must be connected during transport in the crate, as otherwise the endoscope may be damaged by pressure changes.