Instructions for use

Rhino Laryngoscope

Type FS2

1. Connection for light guide
2. Connection for pressure tester
3. focusing
4. angling lever

Content

1 Risks and hazard warnings

1. Please first check the packaging, the Rhino Laryngoscope and the accessories for completeness and shipping damage. In case of damage, make a note of the damage and notify your dealer or the manufacturer.

2. Use the Rhino Laryngoscope only for its intended purpose, in accordance with the regulations of the MDR or MPDG, in accordance with the generally recognised rules of technology, and in accordance with the valid occupational safety and accident prevention regulations.

3. In particular, only use medically approved light sources for connection to the Rhino Laryngoscope.

4. Before using the Rhino Laryngoscope, visually inspect it to ensure that it is in good working order and condition. The Rhino Laryngoscope is a high-quality precision-mechanical-optical instrument; handle it with care.

Caution:
Do not use the Rhino Laryngoscope if it has any defects that could endanger patients, users or third parties, e.g. sharp edges or burrs caused by damage.

Caution:
Do not use the Rhino Laryngoscope if it is leaking. (See chapter
Cleaning, care and disinfection). Serious infections may otherwise occur.

Caution:
Handle pointed or sharp objects such as scalpels or needles with care in the vicinity of the Rhino Laryngoscope so that no mechanical damage could be caused to the endoscope or the insertion tube.
This applies in particular to insertion into a disinfection bath.

Caution:
Do not look directly into the light exit at the distal end. The energy of connected light sources can cause eye damage. In particular, the laryngoscope must not be used for eye examinations contrary to its intended use.

Attention:
Likewise, do not look into the light emission of a suitable light source, the radiation is even higher.

Caution:
The Rhino Laryngoscope may only be used by persons who, on the basis of their training or knowledge and practical experience, can guarantee proper handling.

Attention:
In case of prolonged or improper use (sharp bending of the flexible insertion tube), damage to the light guides and image guides (breakage) can lead to a reduction in illumination and a reduction in the transmitted pixels in the observation room.

Caution: Avoid direct sunlight, sudden strong temperature fluctuations or mechanical stress such as hard impacts and kinking of the insertion tube.

Attention:
The operational safety and usability of the medical device depend not only on your skills, but also on the care of the device. Regular cleaning and care are therefore necessary (see chapter Cleaning, care and disinfection).

Attention:
Qualified service and the use of original spare parts guarantee that the operational safety, usability and value of your medical device are maintained.

Attention:
Before using the laryngoscope, make sure that it is working properly, especially that the images are transmitted correctly without too many missing parts.

2 Intended use

The Rhino Laryngoscope FS2 is used for human oto-rhino laryngology.
The flexible Rhino Laryngoscopes can be used to examine the nose, pharynx and larynx, nasal cavities and nasopharynx.

The Rhino Laryngoscope is not intended for examination of the paranasal sinuses and the lower larynx. larynx area.

It is used exclusively in medical practices and clinics by staff specially trained in handling endoscopes. trained in handling endoscopes.

Caution:
The Rhino Laryngoscope FS2 may only be used on persons who have a sufficiently large body opening for the insertion of the insertion tube. This is especially important for nasal examinations in children.

The optical quality of the endoscope is only guaranteed in the image plane area. If you focus outside the sharp image plane area, it is possible to detect foreign particles within the optical system.

This is not a quality defect, but a design-related optical effect.

3 Symbols used

The symbols used have the following meaning

	On the type plate: Attention, follow instructions for use
	Symbol for separate collection of electrical and electronic equipment
	In the instructions for use: Caution, general danger area
IP 68	Unit is dust-tight and protected against permanent submersion
MD	Device is a medical device

4 Functionality and application

4.1 Application

The flexible Rhino Laryngoscopes FS2 of **orlvision** GmbH (hereinafter referred to as orlvision) are high-quality medical products. They are used for endoscopic examination in human ear, nose and throat medicine. The flexible Rhino Laryngoscopes can be used to examine the nasopharynx.

4.2 How it works

The Rhino Laryngoscope is a fibre-optic endoscope and has an optical focusing and imaging unit as well as an image guide. The image is captured at the distal end, guided via the image guide into the optical unit (multiple lens system) and can be viewed through the eyepiece. The image is focused at the focal point. At the distal end of the Rhino Laryngoscope is the exit of a light guide that illuminates the observation region.

The light for illuminating the observation region is supplied by a light guide via the light guide plug from an external light source. The distal end of the insertion tube can be angled within a range of± 130° by operating the angulation lever.

4.3 Notes on use

The instructions for use explain how to operate the medical device safely, properly and effectively. Please read the instructions for use before putting the device into operation, starting with the chapter on risks and hazard warnings. Keep the instructions close to the device. Observe the ambient conditions specified in the technical data.

The instructions for use do not replace the corresponding basic medical and technical knowledge. The user may have to acquire such knowledge in special advanced training courses.

orlvision accepts no liability for diagnoses and interpretations of findings made with the aid of medical products acquired from **orlvision. The** acquisition of medical expertise and its diagnostic and therapeutic consequences are the sole responsibility of the user of the medical product.

Before each use, test the direction of movement of the bailing unit by operating the bailing lever to avoid an incorrect bailing direction.

We recommend the use of a lubricant on the shaft before inserting the shaft into the nasal cavity to be examined.

4.4 Scope of delivery

The scope of delivery for the flexible Rhino Laryngoscope is as follows:

- The Rhino Laryngoscope: Handpiece with insertion tube and the connection sockets for the light guide to the cold light source and for connection to the pressure tester.

- A hand air pump (pressure tester; item no. M-860-00003-0057) for carrying out the leak test.
- These instructions for use or a note on downloading from the homepage

5 Technical data, manufacturer and accessories

5.1 Technical data Rhino Laryngoscope FS2

Parameter	Data
Focus area	3 mm ± 1 to 50mm -5 / +10
Field of view (FOV)	90° ± 5
Diameter distal end	2.9 mm + 0 / -0.1
Diameter insertion tube	2.9 mm ± 0.1
Distal angulation up / down	130° ± 5
Working length	300 mm ± 5
Total length	540 mm
Weight in g	310g ± 10
Risk class according to MDR	1
Transport and storage temperature in ° Celsius	- 10°C to + 60°C
Operating temperature in ° Celsius The distal end can warm up to 9°C above room temperature.	0° to + 35°
Relative humidity	0 to 100 %
Air pressure	950 to 1050 hPa
Protection class against environmental influences	IP 68
Operating mode	Continuous operation

6 Manufacturer

The manufacturer of the Rhino laryngoscope FS2 is:
orlvision GmbH
Industrial Road 17
D-35633 Lahnau

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7 Swiss Representative

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UK Responsible Person

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The Nucleus, Chesterford Research Park,
Little Chesterford, Essex CB10 1XL

Tel +44 (0) 1799 542716
enquiries@liteoptics.com

9 Recommended accessories

Only use a medically approved cold light source.

Attention:
The light source must meet the requirements of the DIN EN ISO 60601-1 standard!
The connection on the Rhino laryngoscope is compatible for light guides with ACMI / Storz / Wolf endoscope connection.
Possibilities:

- Lighthandle Firefly ES201, 5W LED
- Light source orlLED 180, ILO

Caution:
If a high-power cold light source is used and there is dirt at the outlet of the light guide or the light inlet plug on the laryngoscope, strong heat may be generated due to light absorption. There is a risk of burns.

On request, we are also happy to offer you a wide range of adaptation options to light sources and endoscopes of other makes and also to LED hand-held light sources.

10 Use of the Rhino Laryngoscope

10.1 Insert, angle and retract the insertion tube.

Carefully insert the insertion tube into the regions to be examined (nasal and pharyngeal cavities). If necessary, the distal end can be adjusted by 130° with the angling lever (see illustration)± . The level of adjustment should be tested in a free trial. The examining doctor holds the laryngoscope in his hand to check the adjustment of the distal end.

After the examination, return the angling lever to the rest position and carefully withdraw the insertion tube.

10.2 Finishing the examination

After use, the laryngoscope must be cleaned and disinfected, see chapter 11.

11 Cleaning, care and disinfection

11.1 Manual procedures

In accordance with KRINKO/BfArM recommendations, the machine method is always the preferred method for reprocessing.

11.1.1. Cleaning

The laryngoscope must be carefully cleaned after each use. To do this, wipe it with a clean disposable cloth soaked in an appropriate disinfectant on all accessible external parts.

We recommend for cleaning: 2% Sekusept® aktiv (manufacturer Ecolab). Leave on for 5 minutes. Make sure that the surfaces remain moist. Wipe with a dry disposable cloth afterwards.

Attention:
Please do not exert large mechanical forces on the flexible end of the endoscope when wiping it, the light and image guides inside could be damaged (breakage).

11.1.2. Disinfection

Disinfection may only be carried out by trained personnel and in accordance with the specifications of the Robert Koch Institute.

Attention:
Before each disinfection / insertion, a leak test (see chapter 11.3) must be carried out. In case of leakage, the laryngoscope must be discarded immediately and sent to the manufacturer for repair. In case of leakage, the immersion disinfection becomes ineffective!

We recommend the following disinfection: Immersion disinfection with 2% Sekusept® active. (manufacturer Ecolab). Immersion time 30 minutes.

Caution:
Permanent immersion of the laryngoscope in concentrated alcohol will cause irreversible damage. If necessary, perform a short wipe disinfection. However, make absolutely sure that the alcohol can evaporate immediately after the wipe disinfection.

11.1.3. Final rinse

Remove the laryngoscope and accessories from the disinfectant solution with fresh disposable gloves. Place the disinfected laryngoscope in a basin/tub with microbiologically safe water (drinking water quality). Use fresh water for each instrument. Thoroughly rinse the outer surfaces of the laryngoscope with microbiologically safe water.

11.2 Machine processes

We recommend the following procedures using the BHT INNOVA® E3 CMS DC washer-disinfector from CANTEL GmbH or an equivalent machine with the settings given below.

11.2.1. Cleaning

Cleaning agent: 0.5 % Dr. Weigert neodisher Mediclean forte®
Automatic cleaning process with programme no. 24 with the following settings:

- Step Pre-cleaning for 4 minutes
- Step Emptying
- Step Cleaning 0.5% at 37°C for 6 minutes
- Step Cleaning 0.5% at 43°C for 6 minutes
- Step Emptying
- Step Intermediate rinse for 2 minutes

Attention:
Before each cleaning or disinfection / insertion, a leak test (see chapter 11.3) must be carried out. In case of leakage, the Rhino laryngoscope must be discarded immediately and sent to the manufacturer for repair. In case of leakage, the disinfection will be ineffective!

- **Pre-cleaning**:
  Pre-cleaning with pre-soaked wipes with 0.5 % Dr. Weigert neodisher Mediclean forte® until the instrument is visually clean.

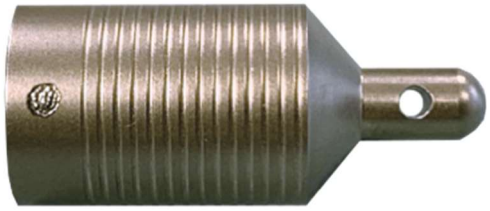
Attention:
Please do not exert large mechanical forces on the flexible end of the endoscope when wiping it, the light guides inside could be damaged (breakage).

- **Cleaning**
  Detergent: 0.5 % Dr. Weigert neodisher Mediclean forte®

- **Disinfection**
  Disinfectant: 1.0 % Dr. Weigert neodisher endo SEPT PAC

  Automatic cleaning and disinfection process with programme no. 22 NORMAL-PAA with the following settings:
  - Step Pre-cleaning for 4 minutes
  - Step Emptying
  - Step Cleaning 0.5% at 37°C for 6 minutes
  - Step Cleaning 0.5% at 43°C for 6 minutes
  - Step Emptying
  - Step Intermediate rinse for 2 minutes
  - Step chemical disinfection with 1% disinfectant at 25°C for 10 minutes.
  - Step Emptying
  - Step Final cleaning at 20°C for 4 minutes

Attention:
Usually the laryngoscope is connected to the automatic pressure monitoring system during machine cleaning. If this is not done, the cover cap M-860-0003-0086-P must be used to protect the valve connection.
It is also recommended to use this cover cap for manual cleaning.



Cover cap Article number M-860-00003-0086-P

Valve cover cap fitted

11.3 Leak test

Attention:
The leak test must be carried out before **each reprocessing**! The light guide may be removed for the leak test.

Connection Leak Tester

Attention:
The connection tube of the pressure tester and the connection of the pressure tester to the laryngoscope must be dry!

Place the valve adapter firmly on the connection of the pressure tester and turn them a quarter turn clockwise. The pressure tester is now firmly connected to the laryngoscope and cannot be pulled off.

Close the drain plug on the pressure tester. Create a test pressure of 160 (±10) mmHg by pumping the leak tester.

Caution:
If the manometer reading drops by more than 10 mmHg within one minute, do not immerse the laryngoscope in liquid. In this case, wipe the outer sheath with the recommended disinfectant or isopropanol 70 %, wrap the laryngoscope in a protective foil cover, pack it in the original packaging and label it "leaking, not disinfected". Then hand it over to the service workshop or the manufacturer.

Attention:
Never connect or disconnect the tester under water, otherwise moisture may enter the unit and repair may be necessary.

After completing the leak test, open the valve on the leak tester to release the excess pressure. Then turn the tester connection cap to the left and pull off the tester connection.

11.4 Care

The Rhino Laryngoscope is easy to care for. Apart from thorough cleaning and regular checking for damage, no special care is required. The Rhino Laryngoscope should be stored in a dry place, safe from dust.

12 Maintenance and repairs

12.1 Maintenance

The components of the Rhino Laryngoscope are maintenance-free for their users. Repairs and maintenance work may only be carried out by **orlvision** or by specialist companies authorised by orlvision. The company orlvision provides the authorised companies with all necessary product documentation.

Attention:
Unauthorised opening, repairs and modifications to the laryngoscope release **orlvision** from any liability for operational safety. This will void any warranty claims during the warranty period.

12.2 Return

In order to avoid damage due to transport and shipping in the event of a return, please use only the original shipping packaging.

13 Disposal

Environmentally friendly disposal according to EU Directive 2012/19/EU. The appliance contains electronic components. To prevent environmental risks or hazards due to improper disposal, the product, including accessories, must be disposed of in accordance with the applicable EU directives 2012/19/EU. Disposal can be carried out via the manufacturer

For this purpose, please send to the manufacturer at:
Orlvision GmbH, Gewerbestraße 17, D-35633 Lahnau.
Disposal in household waste is prohibited.

14 Reporting of serious incidents

All serious incidents related to this product shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

Notes

Notes

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