



# Instructions for Use

## **ALMIKRO MICRO ENDOSCOPE SYSTEM**

Micro endoscope for assisted osteosynthesis of mandibular fractures

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Reference numbers of the individual products can be found in the corresponding product brochure MODUS® OptoFix 2.0 by the company Medartis®.

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# Important System Information

## Introduction

These instructions for use refer to a product of the company Almikro GmbH & Co.KG, Löwenweg 1e, D-79189 Bad Krozingen, Germany. Almikro is the manufacturing company according to the medical device guideline.

The manufacturer Almikro GmbH & Co. KG bears the sole responsibility regarding the endoscope specific contents.

The distribution of the micro endoscope is done by the company MEDARTIS AG, Hochbergerstrasse 60E, CH-4057 Basel/Schweiz. Tel. +41 (0) 61 633 34 34, Fax +41 (0) 61 633 34 00, [www.medartis.com](http://www.medartis.com).

Any of the information and instruction mentioned here is to be absolutely considered and followed.

## Product description

The micro endoscope system is used for the assisted internal fixation of mandibular fractures. The micro endoscope system has been developed and produced according to the medical device guidelines, the guideline 93/42/MDD, DIN EN 13485, DIN EN ISO 9001/2000, DIN EN 58105-2 and all specific regulations regarding the medicinal products of Almikro GmbH Co. KG.

## Materials used

The material of the micro endoscope that gets directly in touch with a patient consist of quartz glass or stainless steel.

## Information to delivery conditions

The individual parts of the system are only to be accepted if product label and packaging of the manufacturer are undamaged and unopened at the time of delivery. In an opposite case the product subject to complaint has to be returned IMMEDIATELY within 10 working days to the distribution partner MEDARTIS AG, Basel, Switzerland or to the respective MEDARTIS subsidiary or distribution partner.

Any component is delivered NON-STERILE and has to be processed appropriately before first use. Remove any packaging material before proceeding with the preparation process.

## Intended use

The micro endoscope is indicated for temporary use as a supplementary method for the endoscopically assisted transbuccal osteosynthesis of fractures involving the condylar neck, condylar base and ramus region of the mandible. It supports the intraoral, retromandibular and accordingly submandibular/angular endoscopically assisted approach.

## Indications

Endoscopic transbuccal osteosynthesis of fractures involving the condylar neck, condylar base and ramus region of the mandible. It supports the intraoral, retromandibular and accordingly submandibular/angular endoscopically assisted approach.

The surgeon bears for each patient the sole responsibility for the indication as well as for the choice of the corresponding instrumentation.

## Contra-indications

- Active or suspected infections at or near the implant site
- Fever or leucocytosis
- Metal allergies or foreign body reactions
- Patients with insufficient blood supply
- Patients who due to their mental or neurological health state are not able to or unwilling to cooperate. Patients which are unwilling to or unable to comply with the postoperative instructions
- Patients with instable physical or mental health status
- Risk patients, e.g. pregnant female

## Possible complications

In most cases possible complications are rather clinical related than instrument related. Amongst these are:

- Metal sensitivity or allergic reactions
- Nerve damage due to surgical trauma
- Early or late superficial as well as deep infections
- Increased fibrous tissue response around the surgical site

## Warnings and precautions

- Before clinical practice all components have to be examined visually and checked on functionality.
- All system components are designed and manufactured to function together and therefore adapted precisely to fit to each other. None of the products shall be replaced by an instrument or product of another manufacturer, even if it looks similar or even equal in size or form (design) to the original product. Materials used by other manufacturers, any changes in structure due to the use of other products and/or material contamination as well as even small deviations or inaccuracy between the instrument may result in a risk for the patient, user or third parties.

- Any component has to be handled and stored carefully. Damages to or scratches at the endoscope may compromise the rigidity of the product considerably and result in early fatigue.
- The storage and transport suitcase must not be heavily shaken or even tilted as in this case the individual components may get damaged or dropped.
- If not otherwise mentioned on the product label, the individual parts of the endoscope may be re-used.

### Choice of the appropriate product

Essential for the choice of the appropriate product in accordance with the individual patient's necessities are the clinical evaluation and clinical experience of the surgeon in charge. The respective system components shall be chosen in line with the surgical proceeding.

The surgeon in charge shall familiarize himself in depth, e.g. by means of:

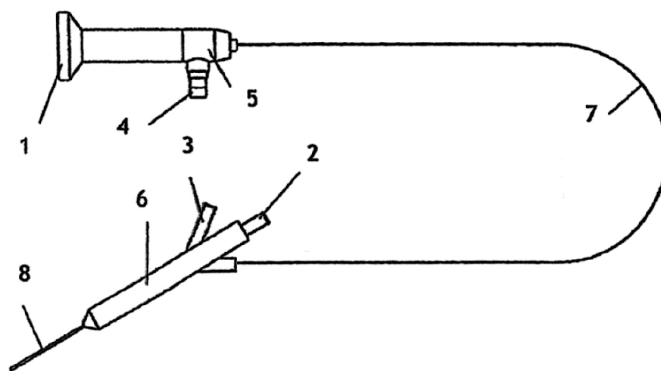
- Careful study of the entire product documentation
- Careful study of the current technical literature
- Conciliar consulting of surgeon colleagues experienced in this surgical field or in the use of the system
- Hands-on training with the system as well as the surgical proceeding

The decision for the surgical proceeding selected is based on an adequate therapy approach. The therapy concept is based on the following criteria amongst others:

- Patient's age
- Functional and aesthetic effects
- Psychological considerations
- Medical contra-indications.

### Special usage information for the micro endoscope system

#### Components



1. Ocular
2. Working channel
3. Irrigation channel
4. Light guide socket
5. Main body
6. Handle
7. Flexible optic cable
8. Endoscope probe

#### Functionality

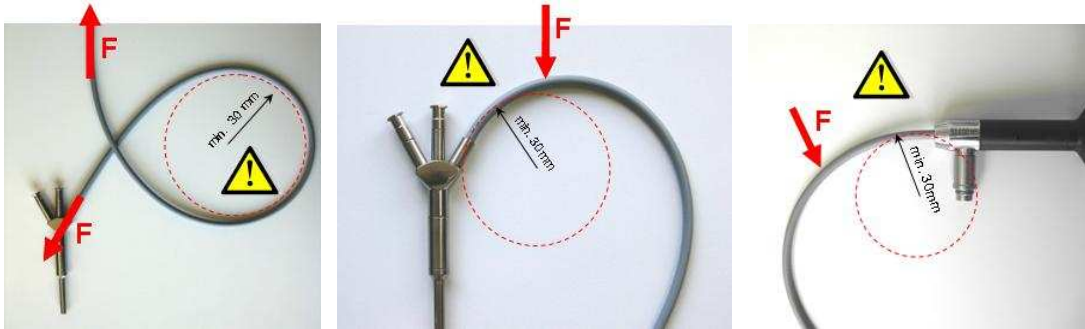
For endoscopy, the endoscope probe is introduced through the natural orifices or those prepared by the surgeon into the areas of the body to be endoscoped. Due to the construction of the ocular according to DIN EN 58105-2, the micro endoscope system can be adapted to all commercial medical cameras with C-Mount-adapters. The interchangeable light socket can be adapted to most light sources available on the market. If necessary, adapters are available.

#### Advice to protect the flexible optic cable

- The minimal bending radius of the flexible optic cable is 30 mm in action. If the optic cable is below this limit, there is the danger of irreversible breakage of the integrated glass fibres.
- The exit place of the flexible optic cable at the handle has to be protected from applying too much pressure and too much bending (the minimal bending radius is 30 mm).
- The entrance place of the flexible optic cable into the ocular has to be protected from applying too much pressure and too much bending (the minimal bending radius is 30 mm).
- During the sterilization process, observe that the diameter of the wound-up flexible part has to be no smaller than 120 mm (see also chapter „sterilization“).

#### Information for the adaption of medical cameras and light sources

Due to the design of the ocular according to DIN EN 58105-2, the micro endoscope system can be adapted to all commercial medical cameras with C-Mount-adapters. The interchangeable light socket can be adapted to most light sources available on the market. If necessary, adapters are available.



## Accessories

A variety of accessories is available for the micro-endoscope. Only original accessories are to be used. If you intend to use accessories from other manufacturers, please check beforehand their usability with Almikro. Almikro declines any liability for damages caused by the use of non Almikro accessories not authorized by Almikro.

## Information for the use of laser probes

When using laser probes, remember the dangers related to these. It is of utmost importance to observe the relevant safety instructions.

## Information for cleaning / disinfection and sterilization

### General Information for cleaning / disinfection and sterilization

- ① New products have to be carefully cleaned and disinfected prior to initial sterilization. Only trained personnel is allowed to carry through the cleaning/disinfection process (manual and/or automatic) including maintenance and mechanical inspection of the products prior to sterilization.
- ① Compliance with the appliance manufacturer's instructions is absolutely essential.
- ① Compliance with the manufacturer's recommendations of the chemical detergents is necessary. Almikro recommends to only use pH-neutral cleaning agents.
- ① It is the responsibility of the user facility to use appropriate cleaning and disinfection processes, if the processes recommended by Almikro are not followed.
- ① The indications of the system/product may implicit the contact to lymphatic tissue and thus the risk of a contamination by transmissible, elusive agents, e.g. vCJD. Products that either definitely or presumably came into contact with those agents need to be destroyed. Under no circumstances they are to be used/re-used.
- ① Metal brushes or steel wool are not to be used for the cleaning of Almikro products. The use of such may lead to visual and non visual surface changes which may influence the functionality and/or material resistance and thus the safe and effective use of the product.

### Manual pre-preparation for the cleaning process

- ① Immediately after use, the micro-endoscope has to be deposited in a container filled with water to avoid for blood, secretion and tissue residues to become touch dry. Afterwards, the micro-endoscope has to be rinsed under running water and the working and irrigation channel are to be pre-cleaned mechanically with a suitable fine brush. After this pre-cleaning process, no visible impurities have to be left on the micro-endoscope.
- ① After the pre-cleaning process, the main cleaning process has to be started immediately.
- ① Only use cleaning agents with documented evidence of efficacy (e.g. VAH/DGHM- or FDA, CE approved).
- ① Cleaning and disinfection agents shall be free of aldehyds to avoid a fixation of blood residues.
- ① Cleaning / disinfection agents are to be prepared according to the manufacturer's instructions.
- ① The working and irrigation channels are to be filled with cleaning solution by means of a syringe.
- ① Instruments / accessories are to be handled carefully and prevented from knocking against each other.
- ① The emerging phase shall not exceed 15 minutes as it may lead to corrosion of instrument/container.
- ① The working and irrigation channels have to be cleaned with a suitable fine brush.
- ① The irrigation channels of the endoscope have to be rinsed with water (aqua purificata) at a pressure of 3-10 bar.
- ① The other products have to be carefully rinsed with sterile or germfree (max. 10 germs/ml) water free of endotoxins (max. 0.25 endotoxins/ml), e.g. Aqua purificata until all cleaning residues are removed. The quality of this procedure influences all subsequent process steps.
- ① The cleaning solution has to be replaced daily or after visible impurities.
- ① After the cleaning process, the endoscope has to be checked visually. No visible impurities have to be left on the endoscope.
- ① The optical surfaces on the ocular and the objective as well as the light guide socket have to be dried.

## Manual disinfection

- ① Only use cleaning agents with documented evidence of efficacy (e.g. VAH/DGHM- or FDA, CE approved).
- ① The endoscope has to be deposited in a disinfection solution. The working and irrigation channels have to be filled by means of a syringe with a disinfectant. The immersion time depends on the instructions provided by the manufacturer of the disinfecting solution. Towards the end of the immersion time, the fine brushes have to be pulled several times through the working and irrigation channels.
- ① Never use the brushes from the cleaning process for the disinfection, as they may be contaminated from the cleaning process.
- ① Deposit the disinfected endoscope in a container filled with clean water (e.g. Aqua purificata) and irrigate the channels once more by means of a syringe.
- ① Rinse everything and repeat the step indicated above.
- ① The endoscope is only to be dried with medically cleaned compressed air.
- ① The rinsing and drying processes are to be done in conditions which exclude any recontamination.

## Automated cleaning and disinfection

In addition to the manual cleaning and disinfection process, and automated process can be applied. Make sure to attach the endoscope safely within the cleaning sieve with a suitable device to protect it from damage (e.g. MEDARTIS Instrument tray for micro endoscope M-6360).

When selecting the disinfectant, make sure:

- That the effectiveness of the disinfectant is proven (such as approval by VAH/DGHM or the FDA, or a CE mark).
- That the cleaning process includes the following phases in accordance with EN ISO 15883:

Phase	Temperature	Duration	Action
Cleaning	Heat to 93°C (199.4°F)	Device-specific	The cleanser is dispersed and suspended
Thermal disinfection (Ao value>3000)	93°C (199.4°F)	10 min.	Do not add additional cleaning agent
Rinsing	---	Device-specific	Rinse with demineralized water

## Information for packaging and transport before sterilization

- ① Filled containers, e. g. instrument trays have to be placed into suitable sterilization packages, e.g. sterilization containers, sterilization cloths.
- ① Almikro recommends carrying through the sterilization in the corresponding sterilization containers and instrument trays. Single-use sterilization pouches (single or double packaging) and/or other sterilization containers may also be used, provided they fulfil the following requirements:
- ① DIN EN ISO 11607/DIN EN 868-3 to 10 (so far DIN EN 868// ANSI/AAMI/ISO 11607)
- ① Suitable for steam sterilization (temperature resistant up to at least 141°C (286°F), sufficient steam transmissibility)
- ① Sufficient protection of the endoscope and accessories, the sterilization packaging against mechanical damages
- ① Continuous maintenance in accordance with the manufacturer's instructions.

## Sterilization

- ① If not otherwise marked as STERILE on the product label, the product is delivered NON STERILE.
- ① ALMIKRO as manufacturer recommends sterilizing in the provided sterilization containers, MEDARTIS MODUS instrument trays and implant containers.
- ① During the sterilization process, observe that the diameter of the wound-up flexible part has to be no smaller than 120 mm.
- ① Compliance with the manufacturer's instructions of the sterilizer is essential.
- ① Independently of the sterilization process the thermal load must not cross 140°C.
- ① In case the sterilization parameters recommended by Almikro are not followed, the user facility is responsible to make sure that the sterilization chamber, packaging method and loading configuration used are qualified and validated accordingly.
- ① The products must be stored dry after sterilization.

## Steam sterilization

- ① All **non-sterile** products can be sterilized in an autoclave (EN 13060 and EN 285). For both initial and subsequent sterilization, the following parameters were verified by the manufacturer in accordance with the requirements of the current sterilization standard.

Procedure	Fractionated vacuum method	Flow method
Duration of exposure	≥ 5 min.	≥ 15 min.
Temperature	134°C (273°F)	134°C (273°F)
Drying time	>20 min. - 30 min.	> 15 min. - 30 min.

- ① In principle, ALMIKRO recommends using the fractionated vacuum method for sterilization with an exposure time of  $\geq 18$  minutes.
- ① Steam sterilization with the gravitation method must be verified with additional validation for the specific product, sterilizer and procedure.
- ① In addition, do not use hot-air sterilization, irradiation sterilization and do not use a substitute procedure for sterilizing thermolabile items such as peroxide sterilization for ALMIKRO and MEDARTIS instruments, implant containers, instrument trays and sterilization containers.
- ① Flash sterilization is prohibited.

### Other sterilization methods

- ① The micro endoscope system is suitable for the routine sterilization with formaldehyde/ethylene oxide according to the validated process with parametrical release according to DIN 550, on the condition that further regulations (appropriate cleaning and disinfection after use, appropriate packaging through certified staff/service provider in packaging according to DIN 868 part 7 and 8) are followed. For the use of gas sterilization procedures, TRGS 513 has to be followed.
- ① If the gas sterilization unit does not have a de-aeration chamber, the endoscope and the accessories need to be stored and aired for seven days in a suitable room at room temperature.
- ① The micro endoscope system is apt to plasma sterilization with STERRAD® 100NX according to Johnson & Johnson requirements „How to determine what can be sterilized in the STERRAD® 100NX Sterilizer“.

### Storage after sterilization

Any component of the system is to be stored under dry and controlled conditions.

### Information for maintenance of the micro endoscope system

Regular inspection at the manufacturer or at the distribution partner authorized by the manufacturer is essential to assure the safe and effective use. Maintenance is only to be done by authorized personnel.

### Technical Data

#### Optical characteristics

Optical Resolution	15.000 pixel
Direction of view	0° direct view
Angle of view	70°
Illumination	integrated fiber optical illumination

#### Endoscope probe

Outer diameter	4.7 mm
Operating length	30 mm
Working channel	3.30 mm
Irrigation channel	0.70 mm
With LuerLock	access proximal end

### Distribution Information

Distributed by:  
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 www.medartis.com

The micro endoscope system is distributed directly by MEDARTIS® AG, Basel, by the corresponding MEDARTIS® subsidiary or the respective MEDARTIS® distribution partner in your country. Addresses of subsidiaries or distributors are listed on the MEDARTIS® homepage [www.medartis.com](http://www.medartis.com). Please also refer to the backside of these Instructions for Use.

MEDARTIS®, as distribution partner does not exercise medicine and does not recommend any specific surgical procedure. The surgeon in charge is responsible for the choice of the appropriate instrument, the surgical proceeding as well as the resulting surgical result.

The present Instructions for Use are not sufficient for the immediate use of the system/product. MEDARTIS®, as distributor recommends an introduction into the use of the system by an experienced user or trained MEDARTIS®/distribution partner staff.

If you still have questions to the content of these instructions please contact your representative or MEDARTIS® directly prior to the first use of the system/product. Correct assembly of the components as well as eventual consequences due to incorrect assembling is the responsibility of the user of the system/product.






### Information to Shipment and Materials Return

- ① Products which are delivered damaged in their transport and product packaging may eventually no longer fulfil their intended use and therefore need to be returned to the manufacturer.
- ① Products subject to complaint shall be returned within 10 working days either directly to MEDARTIS® or your respective distributor. Please state the reason for return.
- ① Any component of the system is delivered **NON STERILE** and are subject to cleaning/disinfection and sterilisation prior to the first use.

### Information to Packaging and Product Label

- ① Any component of the micro endoscope is delivered in the corresponding transport and storage suitcase.
- ① The label on the suitcase features the delivery "NON STERILE", as well as the product information, the information regarding the system identification and the tracking. Labelling is effected in the name and on behalf of the manufacturing company Almikro by MEDARTIS® AG in Basel, Switzerland.

### Symbols used in Instructions and on Product Label

	Caution: Consult the provided detailed documentation
	Lot number
	Non sterile
	EUROCAT Institute for Certification and Testing GmbH Quarat Center, Wittichstraße 2, D-64295 <b>Darmstadt</b>
	Mark identifying medical devices of risk class I, non-sterile and without measuring function

### Information to Expiration of these Instructions

With the release of these Instructions for Use all prior editions alter invalid. Please exchange prior editions of these instructions in your files against the present version.

### Information to Copyright and Trademarks

- ① Reprint and/or copy, also in extracts, is only allowed with written approval of Almikro. In case of disregard Almikro reserves the right to appeal legal remedies.
- ① Designated trademarks and brands are the property of their respective owners.



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