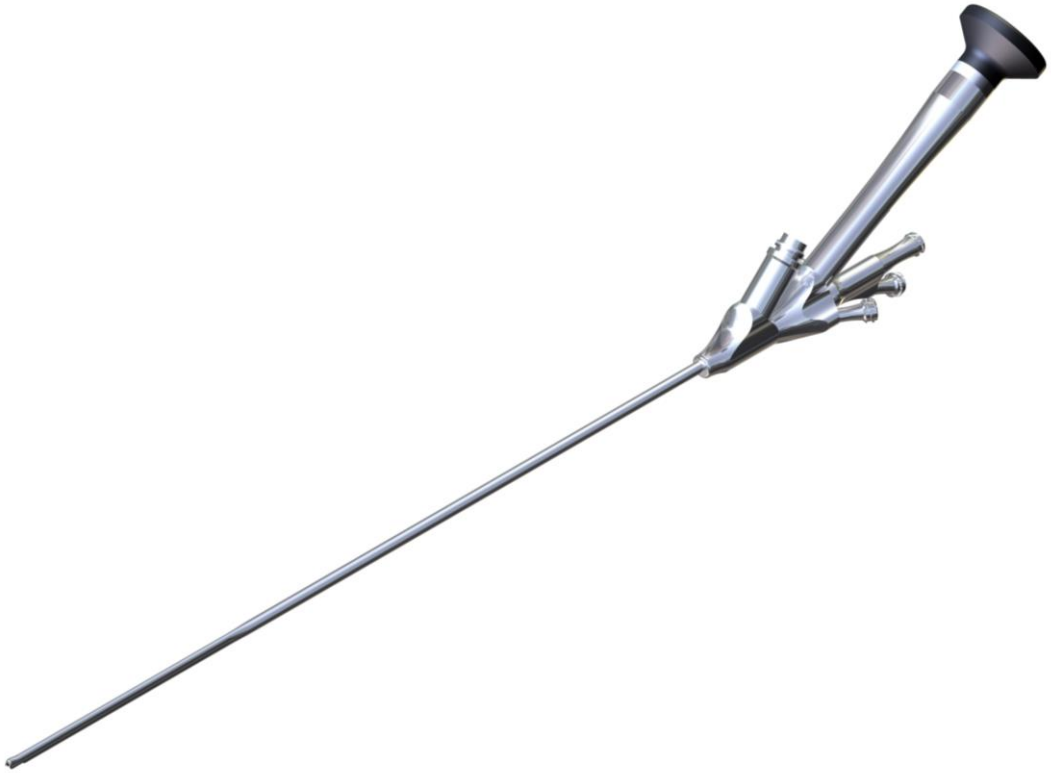
Rigid endoscopes with working channel for invasive applications



REDA Instrumente GmbH
Gänsäcker 34
D-78532 Tuttlingen / Germany

Tel: +49(0)7462 / 9445-0
Fax: +49(0)7642 / 9445-20

www.reda-instrumente.de
info@reda-instrumente.de

1. Content

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

2. Legal advices

This technical manual contents ownership protected information, which underlay copyright conditions. All rights are protected. This technical manual must not be copied, neither by photocopies, microfilms or other procedures and must not be distributed or saved, neither complete nor in extract without explicit written authorization of Blazejewski MEDI-TECH GmbH.

Nomenclature which is at the same time a registered trade mark is not especially marked. In absence of trademark declaration it may not be gathered that a designation will be a free trademark.

Blazejewski MEDI-TECH GmbH would greatly appreciate being informed about any errors or omissions that may be found in the content of this instruction manual.

With regard to continuous development and improvement of our products we reserve the right to alter technical features without written notice.

Dealer:

Manufacturer:

Reda Instrumente GmbH
Gänsäcker 34
D-78532 Tuttlingen
Tel.: +49 (0) 7462 9445-0
Fax.: +49 (0) 7462 9445-20
email.: info@reda-instrumente.de
www.reda-instrumente.de

CE 0297

3. Signs and Symbols

Please take notice.

Warning: Indicates to possible dangerous situations. No observance can lead to dead or serious injuries.

Attention: Indicates to possible dangerous situations. No observance could cause injuries or product damages

Attention! / Caution!
Please consider the accompanying documents.

Please consider the technical manual.
Please read technical manual before use.

CE 0297

CE-Marking according to Council Directive 93/42/EEC.

CE-Marking
By CE-Marking the conformity of the medical device with the following directives is indicated:

Rigid Endoscopes with working channel for invasive applications are produced according to the requirements of

Council Directive 93/42/EEC
DIN EN ISO 13485

CE0297

4. Introduction

We thank you that you have decided to purchase a rigid endoscope with working channel of Blazejewski MEDI-TECH GmbH.

Endoscopes are medical devices that are manufactured at the highest technical level and require careful handling, care and storage. Under the circumstances they will satisfy the high demands which are asked to them and will be usable over a long period to complete satisfaction.

Blazejewski MEDI-TECH GmbH products are precision devices.

Please keep your endoscopes always with the utmost care, so you will enjoy them over a long period.

Read this manual carefully before using your new product. Thereby you keep yourself, the patient and any third parties from damage, which could occur by incorrect installation or by improper operation.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

5. Security advices / warnings

Improper use of this device and non-observance of the given instructions, warnings and precautions can lead to serious risks and consequences of the surgery or to injury, damage and even death of the patient, user and any third parties or damage to the endoscope!

This manual is designed to get familiar with the equipment and its intended capabilities in detail and use. The manual has to be enclosed with the device therefore always.

The instruction manual contains important information needed for safe, proper and efficient operation of the device.

We reserve the right to alter technical features, so that deviations of the content or pictorial representation are possible.

This manual should help to make the use of rigid endoscopes with working channels of Blazejewski MEDI-TECH GmbH easier, but it is not designed as a guidance for endoscopic procedures and does not contain detailed description of endoscopy, and is not suitable for beginners' introduction to this surgical technique!

This device may only be used by technically competent and trained persons who are instructed to handle the instrument.

All persons using the devices have to read these instructions carefully first.

Handling of the device has to be carried out in accordance with these instructions.

Use the endoscope for endoscopic purposes only!

Inspect the endoscope, the appropriate endoscopic accessories and all devices connected to optical and mechanical parts for all possible damages to exclude the risk of injury before every use! Defective and loose parts affect the function and safety and have to be removed immediately! Endoscopes with damaged or defective parts must not be used any longer. The full function and intended use of the medical device has to be ensured and verified by the user when using accessories and other components before use.

In case of doubt, contact your dealer or the manufacturer.

The device is not intended for use in potentially explosive areas!

Mechanical stress due to falling off, strong buckling, bending in a narrow winding, strong shocks and torsion, tensile load or compressive stresses can result in damage or destruction of the endoscope and thus lead to malfunction!

We are not responsible for damages caused by misuse of the endoscope, no liability!

Endoscopic procedures should be performed by trained professionals (e.g. physicians) with appropriate training and experiences in performing endoscopic procedures only. It is within the responsibility of the user to consult information about indications, contraindications, potential complications, risks and the development of endoscopic methods continuously.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Notes on combinations with other medical devices

The connection of other equipment or supplies (such as TV adapter, light sources, optical fibre cables, cameras, monitors, printers, video recorder, image processing systems, filing systems, pumps, shavers, insufflator, RF devices, work items, laser devices, pneumatic or electro hydraulic lithotripters etc.) opens up a variety of therapeutic applications.
Follow the instructions and security advices of the used devices and accessories. Make sure that users are adequately trained.
In case of doubt, contact your dealer or the manufacturer.

Protective measures for RF applications, including laser application, high-energy applications are not integrated in the Blazejewski MEDI-TECH GmbH device. Note that only the devices which are permitted for medical purposes may be adapted!

A thorough understanding of procedures used for endoscopic laser and electrosurgical treatment, applied principles and methods is needed to avoid shock and burn risks for patients and users as well as damage to other equipment and instruments. Liability claims arising from improper use or combination with other devices and instruments are excluded.
Make sure when joint operation of an endoscope with electronic medical devices is performed, that the BF conditions (isolated, floating applied part) are observed.

If endoscopes should be used with electronic medical devices and / or energy-powered endoscopic usable accessories, leakage currents may added up.

Notes for use with light sources

Blazejewski MEDI-TECH rigid endoscopes can be adapted to all common light sources for medical endoscopy. The malfunction of a used light source might lead to hazards. Keep an operational replacement light source available, or use light sources that have a spare bulb. If bulb change is necessary during endoscopic application do not move the endoscope during the bulb change. Only if it is possible pull out the endoscope carefully for bulb change. Remember that light is an energy source that can heat each endoscope optics. The application time is limited by the selection of the light source.

In combination with high intensity light sources, both the light source side and the instrumental side optical fibre end can achieve temperatures that can cause burns. In addition, light of high energy radiation can lead to a temperature increase in tissue. During invasive application temperatures above +41 °C should be avoided, as this can cause tissue damage!

Therefore, avoid direct tissue contact and if applicable, pay attention to adequate irrigation of the operative field and the respective device-specific instructions and safety precautions.

Notes for use with high frequency surgical equipment

Prior to application of endoscopic high frequency treatment, surgical patients should be prepared in a suitable manner for the intended intervention. This includes activities to eliminate and to prevent the formation of ignitable gases in particular. In contrast to conventional high-frequency surgery inappropriate (particularly to low) power settings in high-frequency endoscopic surgery can cause a distinctive depth effect in the surrounding tissue.

The power adjustment should be made according to the users experience with respect to appropriate clinical references and / or appropriate training.

To avoid burns and / or unwanted depth effects in the surrounding tissue and to avoid endoscope damage, the high-frequency current should be switched on only if the appropriate application part (electrode) can be seen through the endoscope. The corresponding manuals, specifications and security advices should be respected.
Never touch the endoscope while operating with an active electrode.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Notes for use with lasers

If endoscopes or endoscopic accessories are used with laser devices, suitable protective glasses have to be worn to avoid potential damage to the eyes.

To avoid burns and / or unwanted depth effects in the surrounding tissue or damage of the endoscope, the laser power should be activated only if the tip of the laser fibre can be seen through the endoscope. The respective device-specific instructions and safety precautions have to be observed.
Never touch the endoscope while operating with an activated laser fibre.

Notes for use with lithotripters

To avoid danger and in relation to possible restrictions on use of ultrasonic, electro-hydraulic, pneumatic and mechanical lithotripsy device-specific instructions and safety precautions have to be observed.
Appropriate surgery sheaths may be used for stone extraction with stone forceps. The required dimensions of suitable instrument can be gathered from technical specifications of the respective single devices.
Never touch the endoscope while operating with an activated **Lithotripsy unit.**

CT (Computer tomography)

Certain metals of the endoscope can be dangerous due to heating during the application, so that an X-ray examination may be contraindicated in such patients. Due to X-radiation, optical components can discolour and thus can lead to endoscope damage. Concomitant use of CT (computed tomography) / X-ray and endoscopes can lead to hazards. Note therefore appropriate manufacturers and safety instructions.

MRT (Magnetic resonance tomography)

Due to magnetic field induced movements / relocations or heating some metals of the endoscope can be dangerous during the investigation, so that an MRI scan may be contraindicated in such patients.
The optical and electrical medical devices for endoscopy may be damaged by magnets. Metals of the endoscope can cause side effects and visual disturbances. Concomitant use of MRI / magnetic resonance imaging and endoscopes can lead to hazards.
Note therefore appropriate manufacturers and safety instructions.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

6. Intended use

MEDI-TECH GmbH Blazejewski rigid endoscopes are optical devices which allow inspecting the body's interior through natural body openings or artificial cavities and the visualization of organs, tissues and structures.
To the human eye such insights remain hidden without the aid of an endoscope.

The following parameters of rigid endoscope optics without working channel can be varied:
Sizes, working length, probe diameter, direction of view and field of view.

Rigid endoscopes without working channel might be used for diagnostic purposes or in combination with surgical instruments (e.g. ureterorenoscopy) for surgical purposes.

Endoscopic procedures performed both diagnostic and therapeutic way, are useful and far less stressful for the patient than traditional methods.

Indications:
The use of rigid endoscopes of Blazejewski MEDI-TECH GmbH is indicated for endoscopic procedures and other procedures in minimally invasive surgery.

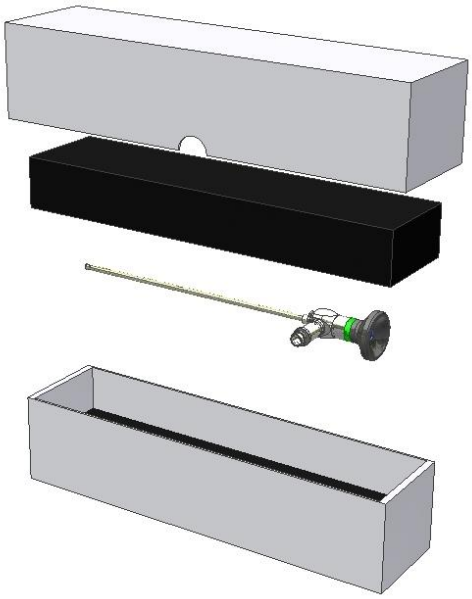
Contraindications:
The use of rigid endoscopes of Blazejewski MEDI-TECH GmbH is contra-indicated if endoscopic procedures are contraindicated.

Please read carefully the instruction manual prior to operation.
These instructions have to be kept in a prominent position in proximity to the medical device.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

7. Initial operation

Remove the Blazejewski MEDI-TECH GmbH rigid endoscope and its accessories from the packaging and carefully remove all packing materials.



The delivery includes:	1 piece	Rigid Endoscope
	1 piece	Wolf-Adaptor
	1 piece	Storz-Adaptor

Rigid endoscope and accessories have to be checked promptly for completeness and obvious damage after unpacking. Damage can be claimed only if the supplier is notified immediately (within 24 hours).
Please use for any necessary return of equipment or accessories the original packaging. Describe the problem, identify the malfunction and designate a contact person for possible inquiries.

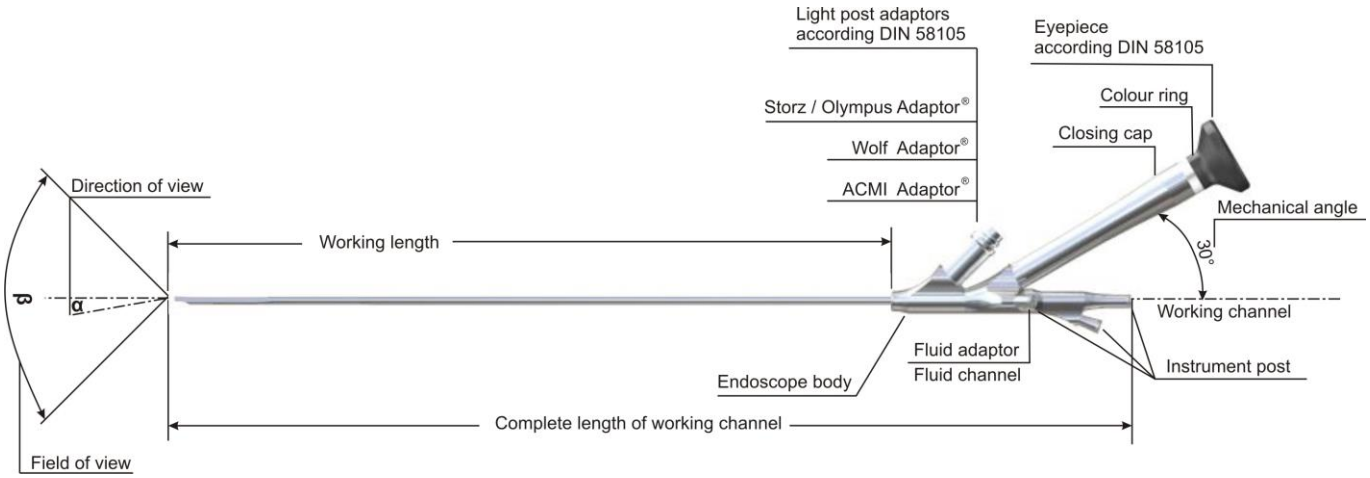
Caution:
Please note the references made in section 5 (combinations with other medical devices) if equipment or other medical devices are connected to the endoscope.

Follow the instructions and safety advices of the used devices and the accessories strictly.

Blazejewski MEDI-TECH GmbH rigid endoscopes are supplied non-sterile and have to be cleaned before first use according to the reprocessing instructions. Rigid endoscopes have to be disinfected or sterilized according to the medical indication (please note section 10, cleaning, disinfection, sterilization).

8. Device description / sketch / part description

8.1 Endoscope with working channel (e.g. ureterorenoscope)



Compatibility	
• **Instrument connection**	Storz®-, Wolf®
• **Fibre optics connection**	ACMI®-, Wolf®-, Storz®/Olympus®
• **Eyepiece**	Eyepiece according to DIN 58105, screwable
Objective	CAD-designed tension-free composed-objective for optimal sharpness, colour sync and resolution,
Image transmission	CAD-designed rod lens system for optimal sharpness, colour rendering and resolution
Light-guiding system	High quality light fibres
Optical glass	Distal and proximal sapphire
Biocompatibility	All materials which come in direct contact with the body (stainless steel, glass, epoxy adhesives) are biocompatible. All outside metal parts are made of high quality “stainless steel” and are approved for medical equipment manufacturing. We do not use additional materials and manufacturing processes that have a negative impact on the biocompatibility.
Sterilization	Autoclavable, max. 134° C / 2,2 bar / 5 min
Certificates	Council Directive of 93/42/EEC (CE-mark) DIN EN ISO 13485

Working length		in mm	
Diameter		in mm	
Direction of view α		0°	Colour code green
		6° 12° 15°	Colour code white
Field of view β		in degree	

9. Operation

Setup of minimum configuration in endoscopy (due to different combination of units this may vary)

TV-Adapter connection to a Camera

TV-Adapter connection to an endoscope

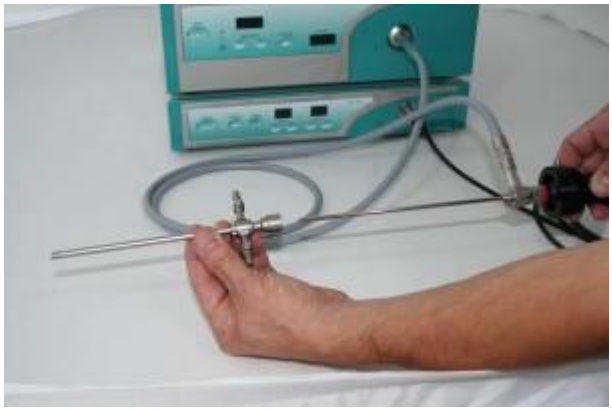
Pay attention to the eyepiece adjustment!

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Fibre optics connection

Pay attention to fibre optics adjustment!

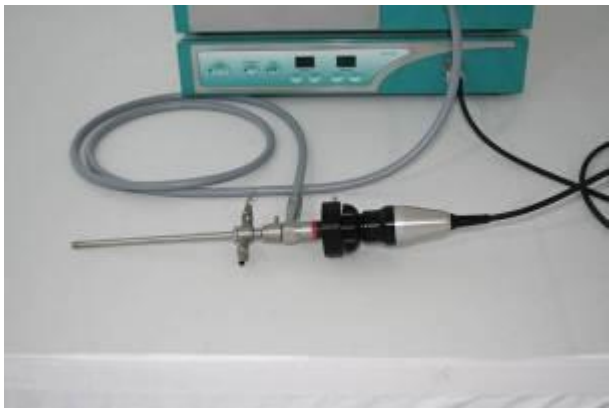
Instrument connection



Pay attention to the correct positioning of the instrument to the optics!

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Pay attention to instrument adjustment!



Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

10. Cleaning, disinfection, sterilization

General Principles / Introductory Remarks
Note also that the manner of treatment can have significant impact on the life of endoscopes.
Check your endoscope optics function (such as adequate lighting of the fibres, clear, sharp, bright and round picture) and check your endoscope for possible damage (such as sharp edges, loose parts or visible deformation of materials) before each use.

All Blazejewski MEDI-TECH endoscope optics have to be cleaned before each use, disinfected and sterilized, and this is especially true for first-time use after delivery, because all instruments are supplied non-sterile (cleaning and disinfection after removal of the protective packaging; sterilization after packaging). An effective cleaning and disinfection is an essential prerequisite for effective sterilization.

As part of your responsibility for the sterility of the instruments / devices in use always ensure:

- that adequate equipment and product-specific validated procedures for cleaning / disinfection and sterilization are used in principle only,

- that used equipment (disinfector, sterilizer) is serviced and checked regularly and

- that validated parameters are strictly adhered to in each cycle.

During the application please pay special attention to the collection and separation of soiled / contaminated instruments. Keep them separated and do not place them back on the instrument tray in order to avoid higher contamination of the assembled instrument tray. Clean / disinfect contaminated instruments. Place them back on the instrument tray and sterilize the instrument tray fully stocked afterwards.

The endoscope optics should be cleaned immediately after each use. To avoid adverse effects on the components of the endoscope lens use demineralised water for cleaning if possible only.
An effective cleaning and disinfection is an essential prerequisite for effective sterilization.
Before each use, the endoscope optics has to be cleaned, disinfected and sterilized. Please observe the applicable regulations of your country as well as the hygiene directives applicable to medical practices/hospitals.

This especially applies to the different guidelines / requirements for effective prion inactivation.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Procedure according to DIN EN ISO 17664 Sterilization of medical devices - reprocessing of resterilizable medical devices

10.1. Instructions for reprocessing

A mechanical process (disinfector) should be used for cleaning and disinfection wherever possible. A manual method should be used in case non-availability of an automated procedure only due to the significantly lower efficacy and reproducibility. The pre-treatment is carried out in both cases.
As endoscope optics are provided with irrigation and aspiration stopcocks, these should be disassembled for sterilization. We recommend a **steam sterilization / autoclave process**.

10.2. Limitations and restrictions on reprocessing, durability

Frequent reprocessing of rigid endoscope optics has an impact on their usability. The end of product lifetime is usually determined by wear and damage caused by use.

Please note:
If appropriate care is used and if the rigid endoscopes are undamaged and clean they can be used up to 100 times. Any further re-use or the use of damaged and / or contaminated instruments is the responsibility of the user.
If you are unsure, however, if your endoscope optics is ready for use, we recommend to return the rigid endoscope for inspection or for replacement to our service-address.

10.3. Preparation at the site of use

In clinical practise used endoscope optics get sometimes in contact with corrosive etching agents and drugs. Endoscopes have to be removed from other equipment after use immediately. Surface contamination should be cleaned with a lint-free soft coarse cloth / paper towel.

Please note:
"Dropping" of instruments (optics) during surgery in a collecting container will inevitably lead to damage. Please pay special attention to place back the device gentle after use.

10.4. Preparation before purification

In clinical practise used endoscope optics get sometimes in contact with corrosive etching agents and drugs. Coarse impurities on the instruments have to be removed directly after use (within 2 h).

A wet clean up should be performed immediately after surgery in order to avoid drying out of blood, protein and other substances on the endoscope and to protect personnel. Dried protein complicates the cleaning, disinfection and sterilization.

Use running water or a disinfectant solution. The disinfectant should be free of aldehyde (otherwise fixation of blood smears), exhibit proven efficacy (e.g. VAH/DGHM - or FDA approval or CE mark) and suitable for the disinfection of instruments.

For manual removal of impurities use a soft brush or a clean soft cloth only, which is used for this purpose only. Never use metal brushes or steel wool or other sharp objects.

Rinse all lumens of the instruments five times using a disposable syringe (minimum volume of 10-50 ml, according to the instrument size).
Degrease the irrigation/aspiration stopcocks.

Please note:
The disinfectant used in the pre-treatment serves for personal security only. It does not replace the next disinfection step carried out after cleaning.

Caution:
Endoscopes must not be cleaned in an ultrasonic bath.

Caution:
Use approved cleaning agents only. Do not put the endoscope in alcohol or other corrosive liquids.

Procedure:

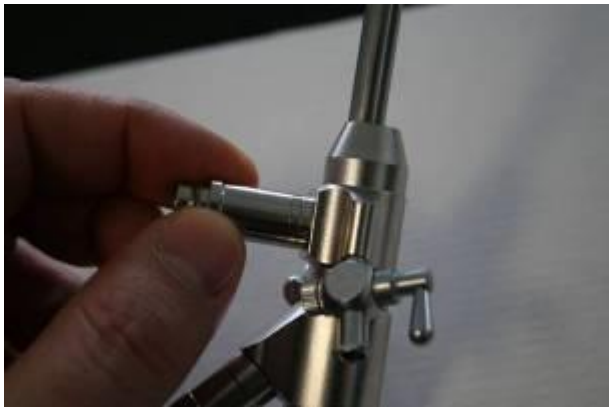
• Remove all sealing caps, valves, bushing grommets from the endoscope (discard disposable items immediately)

Picture 1

Picture 2

- Remove all adaptors, stopcocks from the endoscope (discard disposable items immediately)

Picture 3



Picture 4

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Picture 5

Picture 6

Picture 7

Picture 8

• Preclean working and irrigation channels with brushes, blow through with air and rinse with sterile water afterwards. Dry all channels with compressed air.

Picture 9

Picture 10

• Rinse the endoscope with sufficient deionized water.

Please do not forget to screw the adapter, the flow valves again after sterilization. Fat the flow valves after sterilization always. Use fats approved for medical devices only.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

10.5. Cleaning and disinfection

Please note!
A mechanical process (disinfector) should be used for cleaning and disinfection whenever possible. Because of the significantly lower efficacy and reproducibility a manual method should be used in case non-availability of an automated procedure only.

The pre-treatment has to be carried out in both cases.

Separate the endoscope from connections (flushing and suction hose, fibre optics cable, and camera head). If endoscopes are equipped with an optical bridge or one-way cock, they have to be removed.
Light guide adapters and screw caps of stopcocks, plug valves, protecting caps of valves and bridges must be removed. Clean coarse contamination of the surface with a damp, soft lint-free cloth.

Cleaning is necessary for hygienic reasons.

Caution:
Endoscopes must not be decontaminated and cleaned in an ultrasonic bath.

Caution:
Use approved cleaning agents. Do not put the endoscope in alcohol.

10.5.1 Mechanical cleaning / disinfection (disinfector / RDG (cleaning and disinfection of equipment))

When selecting the disinfector ensure:

- that the disinfector has been tested for efficacy (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883),
- that if possible a tested program for thermal disinfection is used (A0-value> 3000 or - for older machines - at least 5 min at 90 ° C) (the use of chemical disinfection harbours the risk of disinfectant residues on the instruments),
- that the program used is suitable for the instruments and contains sufficient rinse cycles,
- that only sterile or germ-poor (max. 10 bacteria / ml) and endotoxin-poor (max. 0.25 endotoxin units / ml) water (e.g. purified water / highly purified water) is used,
- that the air used for drying is filtered,
- that the disinfector is maintained and checked regularly.

When choosing the cleaning agents ensure:

- that this is basically suitable for the cleaning of instruments made of metals and plastics,
- that - if thermal disinfection is used - in addition a suitable disinfectant with proven efficacy (e.g. VAH/DGHM- or FDA approval or CE marking) is used which is compatible with the cleaning agent ,
- that chemicals used are compatible with the instruments (see "material resistance")
- the declared concentrations of the cleaning, and if indicated, disinfection agent must be strictly adhered.

Procedure:

1. Disassemble the endoscopes as far as possible (light-guide, handle, irrigation stopcocks).
2. Place the disassembled instruments in the disinfector. Make sure that the instruments do not touch each other.
3. If applicable: Connect all lumens of the instruments using the existing connection of the Luer lock flush port to an appropriate irrigation adaptor of the disinfector.
4. Start the program.
5. Remove the instruments from the disinfector at the end of the program.
6. Check and pack the instruments after removal from the disinfector as soon as possible (see sections "control", "maintenance" and "packaging"), possibly after additional drying in a clean place.

The evidence for the suitability of the instruments/devices for an effective automated cleaning and disinfection has been provided by an independent accredited test laboratory using a disinfector G 7836 CD (thermal disinfection, Miele Cie. GmbH & Co., Gütersloh) and the detergent Neodisher mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above has been considered.

10.5.2 Manual cleaning and disinfection

When choosing the cleaning agent and disinfectant ensure:

- that these are basically suitable for the cleaning and disinfection of instruments made of metals and plastics,
- that the cleaning agent - is suitable for ultrasonic cleaning (no foam) - if applicable,
- that a disinfectant with proven efficacy (e.g. VAH/DGHM- or FDA approval or CE mark) is used and that it is compatible with the cleaning agent,
- that chemicals used are compatible with the instruments (see "material resistance").

Combined cleaning / disinfecting agents should not be used if possible. Only in cases of very low contamination (no visible impurities) can combine cleaning / disinfecting agents are used.

Cleaning and disinfectant concentrations and contact times which are specified by the manufacturer must be strictly adhered.

Use freshly prepared solutions only. Use sterile or germ-poor (up to 10 bacteria / ml) and endotoxin-poor (max. 0.25 endotoxin units / ml) water (e.g. purified water / highly purified water) only. Use filtered air for drying only.

Procedure:

Cleaning

1. Disassemble the instruments as far as possible (fibre optic light-guide, handle, irrigation stopcocks)
2. Place the disassembled instruments in the cleaning bath for a predefined exposure time. Make sure that the instruments covered adequately (possible carefully brushing with a soft brush). Pay attention that the instruments do not touch. Move movable parts several times back and forth. If applicable: Rinse all lumens of the instruments five times at the beginning or the end of the exposure using a disposable syringe (minimum volume of 10-50ml (according to the instrument size)) and the existing Luer lock connector and an appropriate irrigation adaptor.
3. Remove the instruments from the cleaning bath and rinse them thoroughly at least three times with water.
4. Check the instruments (see chapter "Control" and "maintenance").

Disinfection

5. Place the disassembled, cleaned and inspected instruments for specified contact time in the disinfectant, so that the instruments are sufficiently covered.
6. Place the disassembled instruments for a prescribed contact time in the cleaning bath, so that the instruments are adequately covered
   If applicable: Rinse all lumens of the instruments five times at the beginning or the end of the exposure using a disposable syringe (minimum volume of 10-50 ml (according to the size of the instrument)) and the existing Luer lock connector and an appropriate irrigation adaptor.
7. Remove the instruments from the cleaning bath and rinse them thoroughly at least five times with water.
8. Dry the instruments by using filtered compressed air.
9. Pack the instrument as soon as possible after removal (see Chapter "Packaging", possibly after additional drying in a clean place).

The evidence of the general suitability of the instruments/devices for effective manual cleaning and disinfection has been provided by an independent accredited test laboratory using the detergent Cidezyme / Enzol and the disinfectant Cidex Opa (Johnson & Johnson GmbH, Norderstedt). The method described above has been considered.

10.6. Drying
Endoscopes and its working and irrigation channels or cavities have to be dried completely and then stored in appropriate containers.

10.7. Inspection, maintenance and testing
Check all instruments after cleaning respectively cleaning / disinfection for corrosion, damaged surfaces, chips and contamination. Exclude damaged instruments (limited number of reuse, please see section "reuse"). Adherent contaminations of the optics glass surface and mechanic parts might remain even after careful cleaning and disinfection. Still contaminated instruments have to be cleaned and disinfected again.

Inspection of the mechanics and endoscope surface
• The endoscope surfaces have to be undamaged and in particular free of sharp edges. Check for dents, bends, mechanical / thermal damage caused by radiofrequency or laser surgery equipment as well as for cracks and spalling**.**

Inspection of the fibre optics
• Hold the distal endoscope end toward a lighted window or a bright ceiling light.

Caution:
Do not use a cold-light source for this test. Direct view into the radiated light from a cold light sources can cause eye damage**.**

Look at the light guide connector. The individual fibres now appear bright. Move the bright ceiling light facing side slightly up and down. The brightness of the fibres changes a bit. It is uncritical if individual fibres remain dark. A fracture rate of about 20 to 30% impedes the endoscopic procedures strongly.

• The surfaces of the light entry and exit surfaces should be smooth and clean.
Rough surfaces with deposits, tangible or withdrawn individual fibres may lead to insufficient lighting. Further application and processing may result in progressive endoscope damage.

Caution:
Endoscopes with damaged fibre optics should be sent in to the manufacturer or an authorized service specialist for checking.

Verification of the proximal and distal areas of glass

• Glass surfaces have to be clean and debris-free. Persistent encrustation, observed during visual examination, should be removed with appropriate cleaning pastes or alcohol-soaked cotton swab or toothpick. Inadequate rinsing of the optics after cleaning and disinfection is often the cause of precipitates.

• Corresponding to the indications appropriate working distance the image has to be sharp and clear. A fuzzy, non-circular, cloudy, foggy, image points out to damage.

Caution:
Endoscopes with indelible persistent encrustations should be sent in to the manufacturer or an authorized service specialist for checking.

Caution:
Endoscopes with damaged glass surfaces (e.g. chips), impaired image quality or striking surface damage and deformation may no longer be used. They should be discarded or sent in to the manufacturer or an authorized service specialist for checking.

Maintenance:
Put the disassembled endoscopes (fibre optic light guide, handles) together again.

Caution:
Irrigation stopcocks must not be installed on the endoscope prior to sterilization of the endoscope.

Instrument oils may not be used prior to sterilization of the endoscopes.
Greasing the rinsing taps is only permitted after sterilization and using sterile fat that has a proven biocompatibility

Please note:
Endoscopes do not require regular maintenance carried out by the manufacturer.

10.8. Packaging

Pack the endoscope immediately after cleaning, disinfection and maintenance.
The packaging of the sterile device protects the content and serves the sterile transport. The packaging material has to match legally required features.
The durability of the material to saturated steam, temperature differences and pressure changes has to be guaranteed.

Sort and place the cleaned and disinfected instruments on the corresponding sterilization tray.

Please pack the corresponding instruments or sterilization trays in disposable sterilization packaging (single or double pack) and / or sterilization containers, which meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- Suitability for steam sterilization (temperature stability up to at least 141 ° C (286 ° F) sufficient vapour permeability)
- Adequate protection of instruments and sterilization packaging against mechanical damage
- Regular maintenance according to the manufacturer's instructions (sterilization container)

The packaging has to be labelled with the date of sterilization, the batch number and expiration date.

10.9. Sterilization
Since the success of sterilization depends on the previous state of cleaning unclean endoscope optics should never be sterilized! Prior to sterilization convince yourself that the endoscope, the optical surfaces in particular are clean. Make sure that the examination according to section 10.7 does not indicate to usability limitations of the endoscope.

It is the user's responsibility to implement the listed sterilization processes in order to achieve the desired and required sterilization effects. Prior to thermal sterilization the optical lenses have to be cleaned with pure alcohol. It is essential to ensure that optical components are not in contact with hot metal surfaces during thermal sterilization as thermal bridges might lead to destruction of materials and leakage of the entire system.

Steam sterilization / autoclaving
The following sterilization procedures should be applied only; other sterilization methods are not permitted:

Steam sterilization
- Fractionated vacuum procedure[1] (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- according to DIN EN ISO 17665 (until now: DIN EN ISO 11134 554/ANSI AAMI) validation (valid IQ / OQ (picking) and product-specific performance (PQ))
- maximum sterilization temperature 138 ° C (280 ° F, plus tolerance according to DIN EN ISO 17665 (formerly DIN EN ISO 11134 554/ANSI AAMI))
- Sterilization time (exposure time at sterilization temperature) at least 20 min at 121 ° C (250 ° F) and at least 3[2] min at 132 ° C (270 ° F) / 134 ° C (273 ° F).

[1] The use of less effective gravitational method is permitted for non-availability of the fractionated vacuum method only ,can have significantly longer exposure times and has to be validated by the user as to suitability and effectiveness.

[2] and 18 min (for prion inactivation)

The evidence of the general suitability of the instruments/devices for effective steam sterilization has been provided by an independent accredited test laboratory using the steam sterilizer Systec V-150 (System GmbH Labor Systemtechnik, Wettenberg) and the fractionated vacuum procedure. At this, typical conditions in clinics and medical practices as well as the method described above has been considered.

Caution:
Flash sterilization is not permitted.

Caution:
Do not apply hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide, or plasma sterilization.

Caution:
Other settings of autoclave and autoclave cycles might have negative effects on the device or its components.

Caution:
Weight and load of the sterilization material must not be exceeded as it may cause excessive condensate and result in rust damage.

Caution:
When sterilizing multiple instruments in a sterilization cycle, do not exceed the maximum load of the sterilizer.

Caution:
Please note that with increasing number of instruments in a sterilization cycle the success of sterilization will be decreased.
Please refer to the manufacturer's instructions.

Caution:
The dryness of the optics has be achieved after cooling to room temperature.

Caution:
Please follow the sterilizer manufacturer's instructions, especially the ventilation times after sterilization. The relevant national legal regulations have to be observed.

Hint:
It is the user's responsibility to implement the listed sterilization processes in order to achieve the desired and required sterilization effects.

The instructions of the sterilizer manufacturer have to be strictly adhered to.

Note:
Please do not forget to attach the adapter, the one-way cocks and other accessories after sterilization again. The one-way cocks have to be greased after sterilization always. Use approved medical sterile fats only.

10.10. Storage
Optics need to be completely dried.
Store sterilized endoscopes in sterile and suitable containers always. Store closed containers in a sterile area or cabinet protected safely from heat, radiation, dust, moisture, temperature fluctuations and contamination.

10.11. Material resistance
Be careful in the selection of cleaning and disinfecting agents. Ensure that the following components are not included:

Substances that are:
- organic, mineral and oxidizing acids (minimum admissible value pH 5.5)
- strong alkalis (maximum admissible value pH 11, neutral / enzymatic or slightly alkaline detergent recommended)
- organic solvents (for example: alcohols, ethers, ketones, benzenes)
  oxidizing agents (for example: hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic / halogenated hydrocarbons
- oils

Clean all instruments, sterilization trays and sterilization containers with metal brushes or steel wool.

All instruments, sterilization containers and sterilization trays must not be exposed to temperatures higher than 141 ° C (286 ° F)!

10.12. Reusability
The rigid endoscopes can - with appropriate care and, if undamaged and unpolluted – be used up to 100 times.
Any further reuse or the use of damaged and / or contaminated instruments/devices is the responsibility of the user.
In case of non-observance any liability is excluded.

10.13. Exceptions
Please observe the processing instructions for the following list:
The following rigid endoscopes or parts thereof are, for technical reasons, partly made of chrome-plated parts. Therefore, please do not place them into the thermal disinfector or ultrasonic bath. Use appropriate cleaning and disinfection agents only.
• Interchangeable one-way cocks

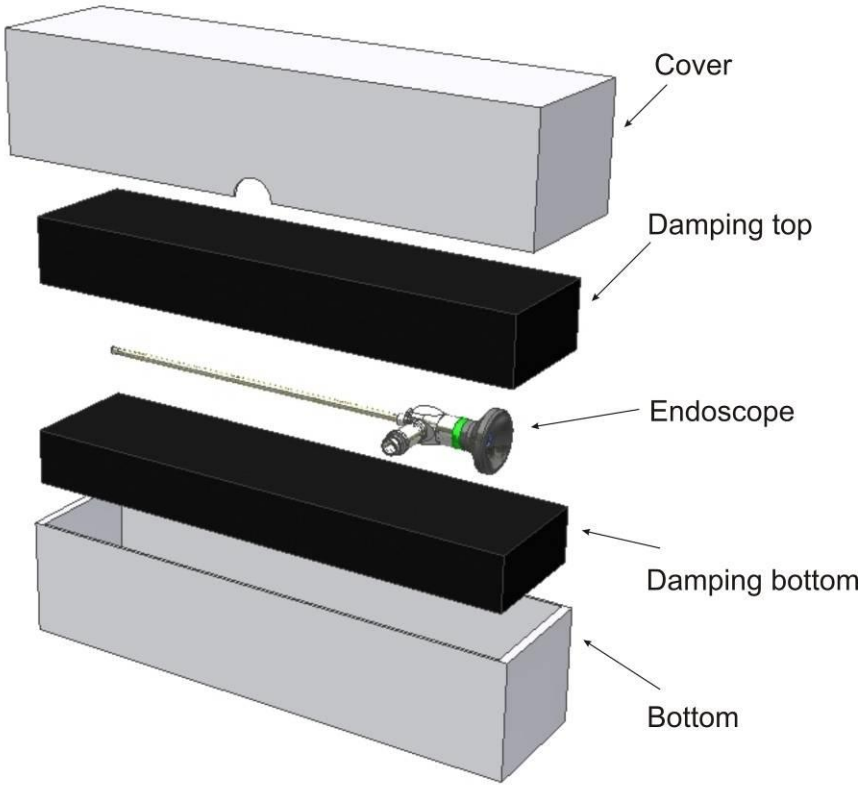
Be careful when selecting cleaning and disinfecting agents. Ensure that components described in **"10.11. Material resistance"** are not included.

10.14. Additional information
The above listed instructions have been validated by the manufacturer of medical devices for the preparation of a medical device whose reuse is deemed suitable. It is the responsibility of the processor to ensure that the effective reprocessing of instruments/devices is carried out with appropriate equipment, materials and personnel in a reprocessing facility in order to achieve the desired results.
Therefor validation and routine monitoring of the process is required normally. Any deviation from the instructions provided by the processor should be carefully evaluated for their effectiveness and possible adverse consequences likewise.

11. Packaging / storage / transport

Caution!
Blazejewski MEDI-TECH GmbH rigid endoscopes are supplied non-sterile

The original package includes:	1 piece	Cover topside made of cardboard
	1 piece	Damping-top part made of foam
	1 piece	Damping-bottom made of foam
	1 piece	Bottom-lower shell made of cardboard



Please use for any necessary return of endoscopes or accessories the original packaging.

Make sure that sterile endoscopes are returned only.

Store non-sterilized endoscopes protected against heat, radiation, dust, moisture and temperature fluctuations always.

Store sterilized endoscopes in sterile and suitable containers always. Store closed containers in a sterile area or cabinet protected safely from heat, radiation, dust, moisture, temperature fluctuations and contamination.

12. Trouble shooting

Problem	Possible cause	Remedying of defect
Picture cloudy, foggy	- Glass surfaces contaminated	- Cleaning of glass surfaces according to section 10.5 (manual cleaning)
	- Deposits, coarse encrustations of glass surfaces	- Remove deposits according to section 10.5, check water quality
	- Leaky, defective lens system	- Send in the endoscope for repair
Picture too dark, too small illumination	- Glass surfaces contaminated	- Cleaning of glass surfaces according to section 10.5 (manual cleaning)
	- Deposits, coarse encrustations of glass surfaces	- Remove deposits according to section 10.5, check water quality
	- Wrong light conducting cable connector	- Check light conducting cable connector, replace if necessary
	- Fibre optics defect	- Check fibre optics according to section 10.8
	- Defect light conducting cable, light source	- Check light conducting cable, light source
Yellowish lighting	- Dirty fibre optics	- Cleaning of glass surfaces according to section 10.5 (manual cleaning) If necessary send in the endoscope for service.
	- Dirty, broken light conducting cable	- Check light conducting cable (for example, shine on white surface), replace if necessary
Staining, discoloration	- Inadequate cleaning (for example, remaining protein residues)	- Clean up, possibly with thorough scrubbing
	- Inadequate rinsing of endoscope between treatment phases (especially before sterilization)	- Ensure thorough rinsing between the treatment phases (see section 10.5 and 10.6)
	- Contaminated, too often used disinfectants and cleaning solutions	- Replace disinfection and cleaning solutions regularly

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de

Problem	Possible cause	Remedying of defect
Leakage	- Leaking connections	- Check connections between sealing cap and irrigation stopcock
	- Defect irrigation stopcocks	- Send in the endoscope for repair

13. Warranty, service and repair

The Blazejewski MEDI-TECH GmbH provides 12 months warranty of the rigid endoscope without working channel function.
The duration of this warranty is limited to claims that are submitted within the specified warranty period from date of purchase of the endoscope, possibly related to repairs, stating the invoice number.
This warranty applies to defects only that are not normal wear and tear, misuse, mishandling, improper or inadequate treatment or due to force majeure. In cases of maintenance or repair, please contact the Blazejewski MEDI-TECH service or an authorized repair specialists:

Blazejewski MEDI-TECH GmbH
Elzstraße 2
DE 79350 Sexau
Tel.:+49 (0) 7641 / 93067 – 0
Fax: +49 (0) 7641 / 93067 – 29
www.Blazejewski.de
Email: info@Blazejewski.de

In the interest of rapid processing of service requests, we ask you to send in the product with the following information:
• Item number (REF)
• Serial number (SN)
• Detailed fault description

Caution:
To protect your personnel and Blazejewski MEDI-TECH staff, please clean and sterilize the endoscope (possibly related accessories) thoroughly before sending in.
Is it for compelling reasons not possible the endoscope should be reprocessed as far as possible and labelled appropriate.
For safety reasons Blazejewski MEDI-TECH GmbH service can decline the repair of soiled or contaminated products.
If the user does repair the endoscope himself or hand it out to an unauthorized repair/service facility all warranty and guarantee claims will be lost.

Unauthorized opening, repair and modifications of the device relieve the manufacturer from any liability for the reliability of the system. During warranty period therefore all warranty will void.

The manufacturer is obliged to warrant the function of the device for a period of 12 month. This warranty is limited to claims made within the warranty period, which begins with the date of purchase**.** This warranty applies to defects only that are not normal wear and tear, misuse or mishandling, lack of care or force majeure. This warranty excludes wear parts. For inquiries or ordering of spare parts, the type and serial number should be specified always.

Your distributor:

Your service address:

Blazejewski MEDI-TECH GmbH
Elzstrasse 2
D-79350 Sexau
Tel.: +49 (0) 7641 93067-0
Fax: +49 (0) 7641 93067-29
Email.: info@blazejewski.de
www.blazejewski.de

CE 0483

If you have further questions, we will be pleased to answer them.

You can contact us from 8:00 - 16:30 daily.

14. Waste management

The implementation of European legislation into national laws and regulations obliges you to dispose medical devices appropriately.
The symbol below indicates that medical devices have to be disposed separately from household/consumer waste. Please dispose medical device waste according to national and local regulations.

Dispose used and contaminated medical equipment at a collection point of a suitable waste authority.
Medical waste is classified according to dangerous goods legislation (for transportation) to the UN number UN 3291 (Medical Waste).
Please attach the symbol below at the waste container.
Please dispose medical waste according to national and local regulations.

Packaging material, as long as not contaminated, dispose according to relevant national and local regulations.

Reda Instrumente GmbH• Gänsäcker 34 • D-78532 Tuttlingen • Tel.:+49 (0) 7462 / 9445 - 0 • Fax.: +49 (0) 7462 / 9445 - 20
www.reda-instrumente.de • email: info@reda-instrumente.de