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USER MANUAL

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USER MANUAL

Lithotripsy Instruments

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Chapter 1
Safety instructions

Safety instructions and level of danger	
WARNING!	Failure to observe can result in death or severe injury
CAUTION!	Failure to observe can result in slight injury or damage to the product.
IMPORTANT!	Failure to observe can result in damage to the product or surrounding.
NOTE!	Tips for optimum use and other useful information.

Chapter 2
General information

This user manual is for following article no.
20864-032
20864-033
20864-034
20864-036
20864-037

Used Symbols

Symbols	Description
	Symbol for “Manufacturer”
	Symbol for “Catalog Number”
	Symbol for “Quantity”
	Symbol for “Batch Code”
	Symbol for “Consult the Instruction for Use”
	This symbol on a product means: Conformity to EU essential requirements with the notified body number of: mdc medical device certification GmbH, Kriegerstrasse 6, D-70191 Stuttgart, Germany
	Symbol for “Non-Sterile”
	Symbol for "Caution, consult accompanying documents”
	Symbol for “Keep dry”
	Symbol for “Keep away from sunlight”

Chapter 3
Device Description

Erbe Vision GmbH has a range of lithotripsy instruments for use during urology procedures. The lithotripsy instruments include lithotripsy sheaths, obturators, stone forceps and adaptors.

IMPORTANT! *Carefully read these instructions before using Erbe ILithotripsy Instruments. Keep them in a safe place for future reference.*

Intended use

These products are intended for the endoscopic diagnosis and treatment of the lower urinary tract including:

- Inspection, localizing and treatment of bladder stones and/or tumors

Intended User

The products must be used only in medical facilities by trained and skilled medical personnel. The products must not be used if according to a qualified physician, the general condition of the patient is not adequate or if the endoscopic methods are contraindicated.

Contraindication

Do not use the devices if one or more below reported conditions is present:

- Acute inflammation of the abdominal area
- The device has been already used to treat patients with suspected or verified BSE, CJK / vCJK diseases

WARNING! Surgical patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Therefore, devices that have been in use or suspected of use on a patient with CJD after surgery must be disposed according to current national recommendations.

WARNING! Improper use can lead to hazardous situations.

Chapter 4
Available Models and Combination Products

IMPORTANT! || Please refer to chapter "Attached Document on page 23" for further information

WARNING! || An incorrect combination of products can lead to injury for patients, users or third party as well as product damage.

Chapter 5
Reprocessing Instructions

Point of use

- ➢ Wipe excess soil from the instrument using disposable paper towels or lint free cloth.
- ➢ If an automated reprocessing method will be used, rinse any channels in the instrument with sterile distilled water immediately after use.

Containment and transportation

- ➢ Reprocess the instrument as soon as reasonably practical following use.

Automated cleaning

Brush/Rinse

- Thoroughly rinse the instruments under cold running tap water (≤ 23°C) and use a soft- bristled brush and an appropriately sized lumen brush to remove all visible soil.
- While rinsing and brushing, actuate all moveable parts to ensure contact with all areas.

Ultrasonic cleaning

- Prepare an enzymatic detergent[1] in an ultrasonic cleaner[2] according to the manufacturer's recommendations.
- Fully immerse the instruments into the prepared detergent, flush each lumen with the detergent solution and actuate all moveable parts (e.g. lever of the stopcocks, locking lever/button, grip of the optical forceps and the turning wheels of the Albarran).
- Allow the instruments to sonicate for a minimum of 10 minutes.

Brush/Rinse

- Thoroughly rinse the instruments under cold running tap water (≤ 23°C, 60 ml per lumen) and use a soft-bristled brush and an appropriately sized lumen brush to aid in rinsing.
- While rinsing and brushing, actuate all moveable parts (e.g. lever of the stopcocks, locking lever/button, grip of the optical forceps and the turning wheels of the Albarran) and flush each lumen with a syringe filled with tap water (120 ml per article or 60 ml per lumen).

1 The detergent Neodisher® MediClean forte of Dr. Weigert was used for the validation.
2 The ultrasonic cleaning was validated with Branson 8800 ultrasonic cleaner.

Automated wash

- Place the instrument in an automated washer[3] on an incline to facilitate drainage.
- Program the washer with the following parameters, then activate the wash:

Phase	Recirculation time	Water temperature	Detergent type
Pre Wash	min. 3 minutes	Cold tap water (≤ 23°C)	N/A
Wash 1	min. 2 minutes	55°C	Enzymatic Detergent[a]
Rinse 1	min. 1 minutes	43°C	N/A
Thermal Rinse (optional)	min. 5 minutes	90°C	N/A

[a] The detergent neodisher® MediClean forte of Dr. Weigert was used for the validation.

Drying

- Dry the instruments completely with lint free cloths and filtered pressurized air (20 psi / 1400 hPa) prior to sterilization.

Inspecting

➢ Visually inspect the instrument, including all internal surfaces, for remaining soil.
➢ If soil remains, repeat manual or automated cleaning procedure, focusing on those areas.

Maintenance, inspection and testing

➢ Inspect the instrument on a continual basis. If a problem is observed or suspected, the instrument should be returned for repair.
➢ Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures.

[3] The automated cleaning was validated with the STERIS® Reliance® Genfore™ washer/disinfector. For use with another washer/disinfector make sure that it is also in compliance with EN ISO 15883-2.

Sterilization

CAUTION! In order to ensure the sterility, disassemble the stopcocks of the sheaths and Albarrans before autoclaving.

For disassembly of the stopcocks prior to sterilization refer to Assembly of Stopcock on page 15.

After performing the cleaning instructions specified above, perform the following sterilization cycle:

Steam

	US Cycle	EU Cycle	WHO Cycle
Phase[a]	Pre-vacuum	Pre-vacuum	Pre-vacuum
Wrapping	Double[b]	Double[b]	Double[c]
Temperature	132°C (270°F)	134°C (273°F)	134°C (273°F)
Time[d]	4 minutes	3 minutes	18 minutes
Dry time	45 minutes	45 minutes	45 minutes
Warning: Drying time depends on several variables, including altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Users must verify that drying time set in their autoclave yields dry surgical equipment			
Open door time	45 minutes	45 minutes	45 minutes

[a] The sterilization validation was validated with the STERIS Amsco® Lab 250 sterilizer.
[b] The Halyard Health H300-510(k) K082554 wrap was used for the validation.
[c] The Halyard Health H600-510(k) K082554 wrap was used for the validation.
[d] 18 minutes is the maximum time that should be used for the pre-vacuum cycle.

NOTE! Rapid cooling, or "quenching," the instruments after autoclaving will result in product damage.

After sterilization, re-assemble the stopcocks as described in Assembly of Stopcock on page 15 under sterile conditions.

Packaging

The instruments are delivered non-sterile in sealed plastic or in a protective box/foam packaging. Transport packaging is not suitable for sterilization.

Chapter 6
Assembling – Disassembling Instructions

Sheaths and Obturators

Fig. 6-1

Lithotripsy sheaths and corresponding obturators are color coded blue. To remove the obturator from the sheath:

- Press the button to release the quick-lock device
- Insert the obturator, lining-up the arrow markings on the sheath and the obturator
- Lock in gently by pushing until the locking device clicks in

WARNING! *Never use force to insert obturator, it should glide in easily, otherwise check for correct size or that it is correctly aligned.*

- Adaptor can be attached using the same technique with the alignment arrows.

Optical Stone Forceps

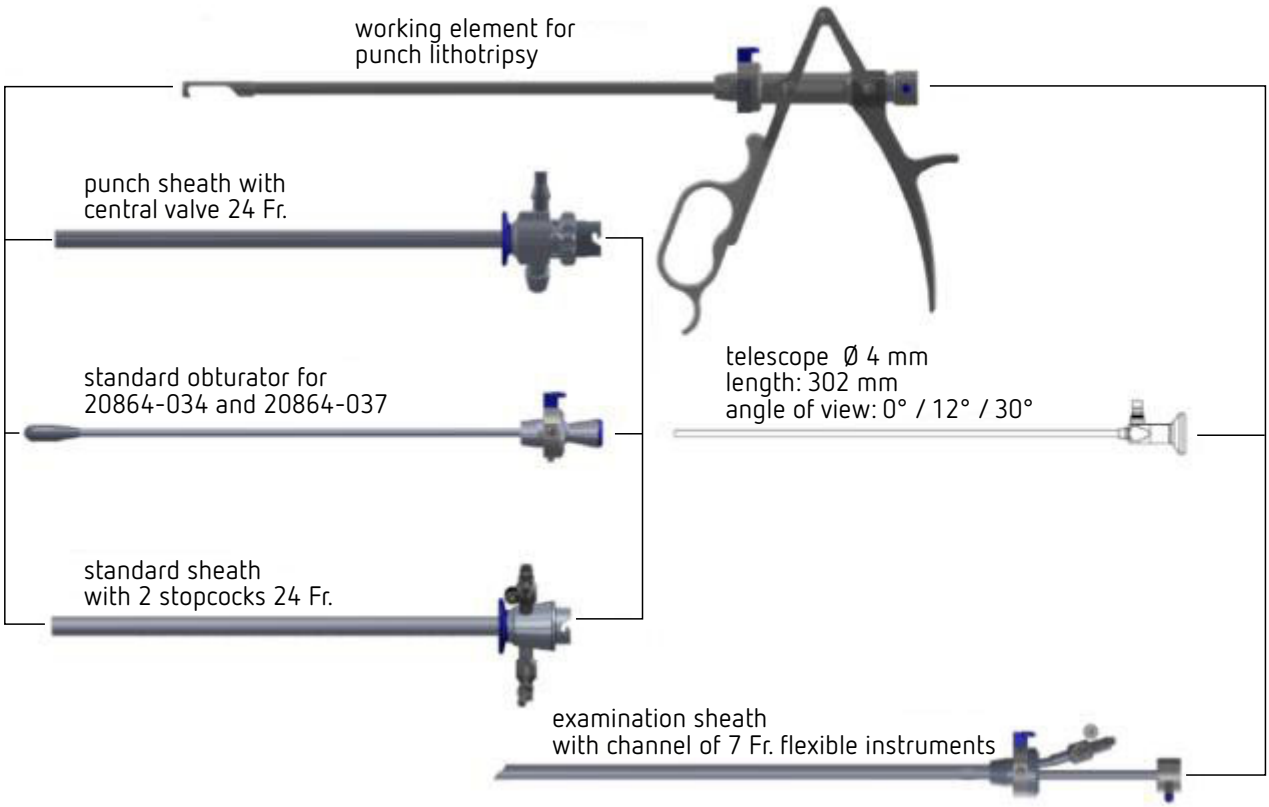


Fig. 6-2

The lithotripsy punch and the examination sheath can be introduced into either of the sheaths, by aligning the arrows markings. Flexible instruments or catheters with a minimum length of 340mm can be introduced in the working channels of the instruments. The gauge of the instrument channel opening is marked on the instrument and determines which size of flexible instrument or catheter is compatible.

Assembly of Stopcock

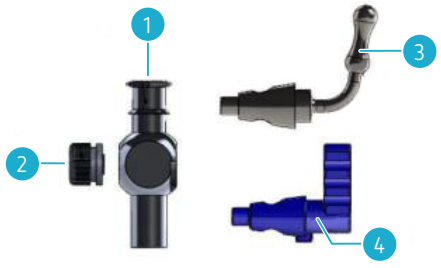


Fig. 6-3

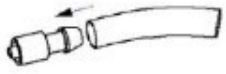
NOTE! **In order to ensure sterility, only use grease[a], which is suitable for medical instruments for the stopcock.**

[a] The HSW standard lubricant for stopcocks (P/N 8300022404) was used for the sterilization validation.

- ➢ Lubricate stopcock (3 or 4) on the running surfaces with a thin layer of grease (3 → Stainless steel, → 4 plastic).
- ➢ Mount stopcock and fix with stopcock nut (2).
- ➢ Remove excess grease.
- ➢ For sterilization disassemble stopcock
- ➢ Put each parts (1, 2, 3 or 4) into the sterilization tray.

Disassembly

- ➢ Loosen stopcock nut (2).
- ➢ Disassemble stopcock (3 or 4)



Irrigation tubing can be applied directly to the stopcocks or use a luerlock connector with tubing spout as in illustration above.

Forceps and Working Unit

Disassembling Instructions

Fig. 6-4 – Removing inner sheath

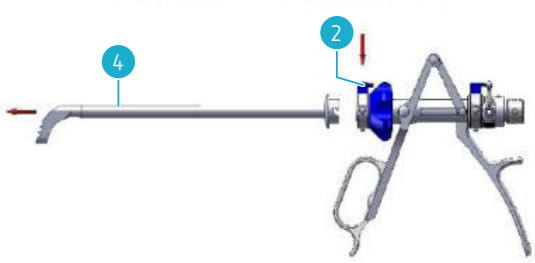


Fig. 6-5 – Removing outer sheath

- Release the inner sheath, by pressing the proximal quick-lock button (1) (see Fig. 6-4).
- Remove the inner tube (3) by grasping the forward jaw and pulling away from the handle. (see Fig. 6-4)
- Release the outer sheath (4) by pressing the distal quick-lock button (2) (see Fig. 6-5).
- Remove outer sheath (see Fig. 6-5)

Assembling Instructions

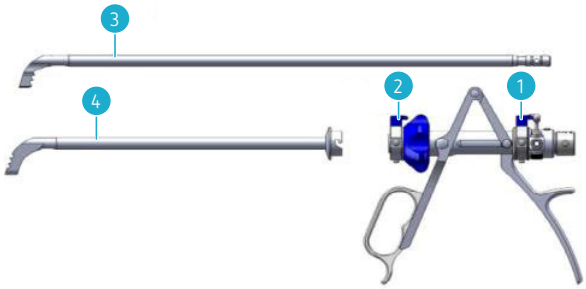


Fig. 6-6

- Insert the Outer sheath (4) into the distal quick lock (2), aligning the arrow with the click button, the quick lock will click into place (see Fig. 6-5)
- Insert the inner sheath (3) distally through the outer sheath aligning the jaws until it clicks into the proximal quick locking device (see Fig. 6-4)
- Introduce a compatible 4mm telescope into the scope channel of the lithotripter. Turn the locking device clockwise to lock in.
- Attach tubing's to the stopcocks according to use.
- The lithotripter is a safe and easy to use instrument for stone crushing. Using the screw mechanism, the strength of the jaws can be increased to crush especially hard stones.
- The jaws of the lithotripter should be closed when introducing or removing the instrument into or from the opening to insure an atraumatic procedure.
- Use the handle action to grasp or crush stones. Should more strength be required to crush the stone, first grasping the stone using the handle action then slowly continuously turning the screw mechanism sufficient pressure will be generated to crush the stone.

CAUTION! When introducing and removing these instruments from any sheath, the jaws should be closed, and the deflecting ramp should be in resting position.

Chapter 7
Visual and Functional Inspection-Check

WARNING! New medical products have to be inspected thoroughly visually and functionally after delivery and prior to each use

- Prior to subsequent use, products should be visually examined for bent, broken or loose parts, damaged insulation, fissures, scratches as well as worn out or cracked parts
- Check that function is as described in the instructions.
- Damaged or faulty products should not be used and should be taken out of circulation immediately.
- Damaged parts should be immediately replaced by original manufacturer parts.

Chapter 8
Storage

The lithotripsy instruments must be stored until subsequent use in a suitable sterilization container for steam sterilization according to the standards.

	Keep away from sunlight
	Keep dry
	Read carefully the reprocessing instructions

The storage room has to be dust-free, of low microbiological contamination, dark and free of temperature fluctuations.

Chapter 9
Repairs

In spite of application in compliance with intended use, medical products are subject to variable wear and tear depending on the intensity of the application. Wear is technically inevitable.

- Do not repair. Service and repairs must be carried out by the manufacturer or by authorized personnel
- Medical products have to be cleaned, disinfected and sterilized prior to sending for repair. Soiled or contaminated medical products should not be shipped.

Chapter 10
Warranty

This product is guaranteed against defects in workmanship and material. In the event of defects under guarantee, the product will be repaired, replaced or the charges refunded at the manufacturer's discretion.

Repairs, attempted repairs, alterations or other tampering of this product carried out by unauthorised personnel renders the guarantee invalid.

Chapter 11
Relevant Note

In these IFUs have been reported info concerning to Class I devices. However, Class I devices are not under Notified Body responsibility. The Class I devices have been reported for descriptive information only.

Chapter 12
Attached Document

Sheaths	Obturator	Forceps
		

Combination Product

Sheaths	Obturator	Forceps
20864-034	20864-035	20864-032
20864-036		20864-033
20864-037		

CE 0483

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