

# USER MANUAL



30864-03125325



Erbe Swiss AG  
Fröschenweidstrasse 10  
8404 Winterthur

# USER MANUAL

## Urethrotomy Instruments



All rights to this User Manual, in particular rights of duplication, dissemination and translation, are reserved. No part of this User Manual may be reproduced in any form (by photocopying, microfilming or other methods) or processed, duplicated or disseminated by the use of electronic systems without the written consent of Erbe Vision GmbH.

The information contained in this User Manual can be changed or expanded without prior notice and without obligation on the part of Erbe Vision GmbH.

The illustrations in this User Manual may differ in some details from your product.

Printed by Erbe Vision

Printed in Germany

Copyright © Erbe Vision GmbH

# Table of Contents

<b>1</b>	<b>Safety instructions</b> .....	<b>7</b>
	Safety instructions and levels of danger.....	7
<b>2</b>	<b>General information</b> .....	<b>8</b>
	This user manual is for following article no.....	8
	Symbols .....	9
<b>3</b>	<b>Device Description</b> .....	<b>10</b>
	Intended use .....	10
	Sheaths .....	10
	Knives.....	10
	Obturers .....	10
	Intendend User .....	10
	Contraindication .....	10
<b>4</b>	<b>Available Models and Combination Products</b> .....	<b>11</b>
<b>5</b>	<b>Reprocessing Instructions - Sheaths</b> .....	<b>12</b>
	Automated cleaning .....	12
	Automated wash.....	13
	Maintenance, inspection and testing.....	13
	Sterilization .....	14
	Steam.....	14
	Packaging .....	14
<b>6</b>	<b>Reprocessing Instructions - Knives</b> .....	<b>15</b>
	Warning and Precautions .....	15
	Cleaning – Automatic.....	15
	Manual Pre-Cleaning .....	15
	Automated wash.....	15
	Disinfection .....	16
	Sterilization .....	16
	Steam.....	16
	Packaging .....	16
	Control and Testing.....	17
<b>7</b>	<b>Assembling – Disassembling Instructions</b> .....	<b>18</b>
	Knives.....	18
	Obturator .....	18
	Sheaths with Stopcock .....	19
	Assembly .....	19
	Disassembly.....	19
<b>8</b>	<b>Visual and Functional Inspection-Check</b> .....	<b>20</b>

Table of Contents

9	<b>Storage</b> .....	21
10	<b>Repairs</b> .....	22
11	<b>Warranty</b> .....	23
12	<b>Attached Document</b> .....	24
	Combination Chart .....	24
	Combination Product .....	24

# Chapter 1

## Safety instructions

---

### Safety instructions and levels 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.**











---

Sheaths	Knives	Obturators
20864-048	20864-052	20864-049
20864-050	20864-053	
20864-051	20864-054	
	20864-055	

---

**Symbols**


---

Symbols	Description
	Manufacturer
	Symbol for "Catalog Number"
<b>Qty</b>	Symbol for "Quantity"
	Symbol for "Batch Code"
	Symbol for "Consult the Instruction for Use"
	Conformity to the essential requirements
	CE mark and identification number of the notified body: mdc medical device certification GmbH Kriegerstraße 6 70191 Stuttgart
	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 urethrotomy instruments for use during urology procedures. The urethrotomy instruments include sheaths, obturators, knives and guides

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

---

### Intended use

---

**Sheaths** The sheaths are endoscopic components. They are element shaped as a thin metal tube through which other elements are introduced and assembled to create the complete operative endoscopic unit.

**Knives** The knives are medical device used for cutting and dissection of body tissue during surgical intervention.

**Obturators** The obturators endoscopic components. They are devices with a distally rounded head or end that are placed into the sheaths of a rigid endoscope in order to fill out the sheath's lumen (open end), thereby assisting their insertion into the body and protecting against adverse damage to the patient.

**Intendend User** The products must be used only in medical facilities by trained and skilled medical personnel. The products must not be used whether 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:

- Urinary tract infection
- Coagulation disorder

**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 section “Attached Document” 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 - Sheaths

### 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 ( $\leq 23^{\circ}\text{C}$ ) 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<sup>1</sup> in an ultrasonic cleaner<sup>2</sup> 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 ( $\leq 23^{\circ}\text{C}$ , 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).

---

<sup>1</sup> The detergent Neodisher® MediClean forte of Dr. Weigert was used for the validation.

<sup>2</sup> The ultrasonic cleaning was validated with Branson 8800 ultrasonic cleaner.

---

### Automated wash

---

- Place the instrument in an automated washer<sup>3</sup> 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 ( $\leq 23^{\circ}\text{C}$ )	N/A
Wash 1	min. 2 minutes	55°C	Enzymatic Detergent <sup>a</sup>
Rinse 1	min. 1 minutes	43°C	N/A
Thermal Rinse (optional)	min. 5 minutes	90°C	N/A

<sup>a</sup> 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.

---

<sup>3</sup> 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 Sheaths with Stopcock on page 19.

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

---

## Steam

---

	US Cycle	EU Cycle	WHO Cycle
Phase <sup>a</sup>	Pre-vacuum	Pre-vacuum	Pre-vacuum
Wrapping	Double <sup>b</sup>	Double <sup>b</sup>	Double <sup>c</sup>
Temperature	132°C (270°F)	134°C (273°F)	134°C (273°F)
Time <sup>d</sup>	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

<sup>a</sup> The sterilization validation was validated with the STERIS Amsco® Lab 250 sterilizer.

<sup>b</sup> The Halyard Health H300-510(k) K082554 wrap was used for the validation.

<sup>c</sup> The Halyard Health H600-510(k) K082554 wrap was used for the validation.

<sup>d</sup> 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 Sheaths with Stopcock on page 19 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

## Reprocessing Instructions - Knives

**WARNING!** || Products are delivered in a Non-Sterile State and must be cleaned, disinfected and sterilized before the first and any other subsequent use

### Warning and Precautions

Country-specific regulations and laws for cleaning medical products have to be observed.

- For patients with Creutzfeld-Jakob-Disease, CJK-on-spec or its possible variants, Bovine Spongiform Encephalopathy or Transmissible Spongiform Encephalopathy country-specific regulations and laws concerning cleaning of instruments have to be observed
- Do not use metal brushes, sponges, abrasive cleanser, hard or sharp tools to clean electrodes
- Do not bend or deform the electrode or the cutting wire

### Cleaning – Automatic

- **Reprocess the knives as soon as reasonably practical following use.**
- Manual Pre-Cleaning**
- Rinse the knives for at least 5 minutes under cold tap water.
  - Brush the knives until no debris is detectable with the naked-eye.
  - Rinse the knives under cold tap water.
- Automated wash**
- Place the instrument in an automated washer<sup>4</sup> 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. 2 minutes	Cold tap water ( $\leq 23^{\circ}\text{C}$ )	N/A
Wash 1	min. 2 minutes	55°C	Enzymatic Detergent <sup>a</sup>
Neutralization	min. 3 minutes	Cold DI water ( $\leq 23^{\circ}\text{C}$ )	N/A
Rinse 1	min. 2 minutes	Cold DI water ( $\leq 23^{\circ}\text{C}$ )	N/A

<sup>a</sup> The detergent neodisher® MediClean forte of Dr. Weigert was used for the validation with a concentration of 0.5 %.

<sup>4</sup> The automated cleaning was validated with the washer/disinfector "Miele PG 8535". For use with another washer/disinfector make sure that it is also in compliance with EN ISO 15883-2

---

### Disinfection

---

Thermal disinfection has been validated using the following parameters:

Time	Temperature
Min. 300 sec	Min. 93°C

**CAUTION!** || Do not immerse knives in chemical disinfectant. Disinfectant residues can cause adverse effects in function

---

### Sterilization

---

Product Sterilization with fractional pre-vacuum procedure, in accordance with ISO 17665 has been validated using the following parameters:

**Steam**

	US Cycle	EU Cycle	WHO Cycle
	Pre-vacuum <sup>a</sup>	Pre-vacuum <sup>a</sup>	Pre-vacuum <sup>a</sup>
Wrapping	Paper/film packaging <sup>b</sup>	Paper/film packaging <sup>b</sup>	Paper/film packaging <sup>b</sup>
Temperature	132°C (270°F)	134°C (273°F)	134°C (273°F)
Time	4 minutes	3 minutes	18 minutes
Dry time	45 minutes	45 minutes	45 minutes
<p>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.</p> <p>Users must verify that drying time set in their autoclave yields dry surgical equipment.</p>			
Open door time	45 minutes	45 minutes	45 minutes

<sup>a</sup> The sterilization validation was validated with the sterilizer "Lautenschläger ZentraCert".

<sup>b</sup> The paper/film packaging „EA 1940“ from E.Line S.r.l. was used for the validation.

**Packaging** The products are delivered non-sterile in sealed plastic or in a protective box/ foam packaging.

Transport packaging is not suitable for sterilization. Devices have to be packed into suitable sterilization packaging systems (e.g. STERICLIN pouch used during sterilization validation) acc. to ISO 11607 and/or AAMI / ANSI ST77:2006 in order to be sterilized.

**WARNING!** || *As knives are made out of thin metallic components sterilization wrap made out of paper should not be used as the knives could perforate the paper seal.*

---

### **Control and Testing**

---

The knives have to be visually examined for cleanliness after every cleaning and disinfection. They have to be macroscopically clean from visual residual and soil.

- If residue, liquids, impurities are visible, repeat cleaning process.
- Ensure that the knife is faultless prior to each application
- The insulation and HF connector must be intact
- Plastic components should be checked before sterilisation. Knife must be replaced if plastic components are brittle, cracked or worn

# Chapter 7

## Assembling – Disassembling Instructions

---

### Knives

---

Touch the knife just with a cloth or similar. The knives can break easily if they get lateral force. Put the knife into the guide-tube until it snaps into the locking position. To proof if the knife is locked in, pull carefully on the guide tube (see next figure). Don't touch the knife!

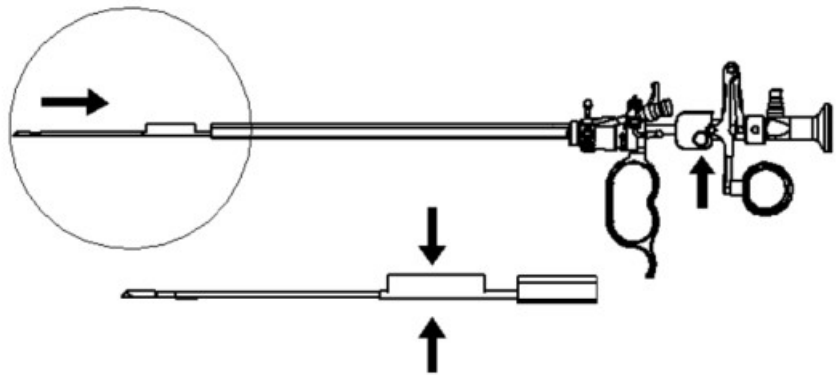


Fig. 7-1

To unlock the knife, push the button in the side of the guide and pull it carefully out of the guide-tube.

---

### Obturator

---

To remove an obturator from the sheath with the Quick-Lock-Device:

- 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



Fig. 7-2

To remove the obturator from the sheath with the locking-device:

- Turn the lever anti-clockwise
- Insert the obturator, lining-up the arrow markings on the sheath and the obturator
- Lock in by turning the lever clockwise.

---

### Sheaths with Stopcock

---

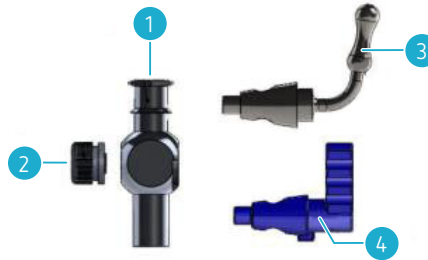


Fig. 7-3

#### Assembly

**NOTE!** || In order to ensure sterility, only use grease<sup>a</sup>, which is suitable for medical instruments for the stopcock.

- <sup>a</sup> 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)

# Chapter 8

## 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 9

## Storage

The urethrotomy 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 10

## 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 11

## 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 12

## Attached Document

---

### Combination Chart

---

Sheaths	Knives	Obturator
		

---

### Combination Product

---

Sheaths	Knives	Obturator
20864-048	20864-052	20864-049
20864-050	20864-053	
20864-051	20864-054	
	20864-055	









Manufactured by

**Erbe Vision GmbH**

Eisenbahnstraße 102, 78573 Wurmlingen, Germany

Website: [www.erbe-med.com](http://www.erbe-med.com)

Service address:

**Erbe Elektromedizin GmbH**

Waldhörnlestraße 17, 72072 Tübingen, Germany E-

Mail: [techservice@erbe-med.com](mailto:techservice@erbe-med.com)

Tel.: +49 7071 755 - 437