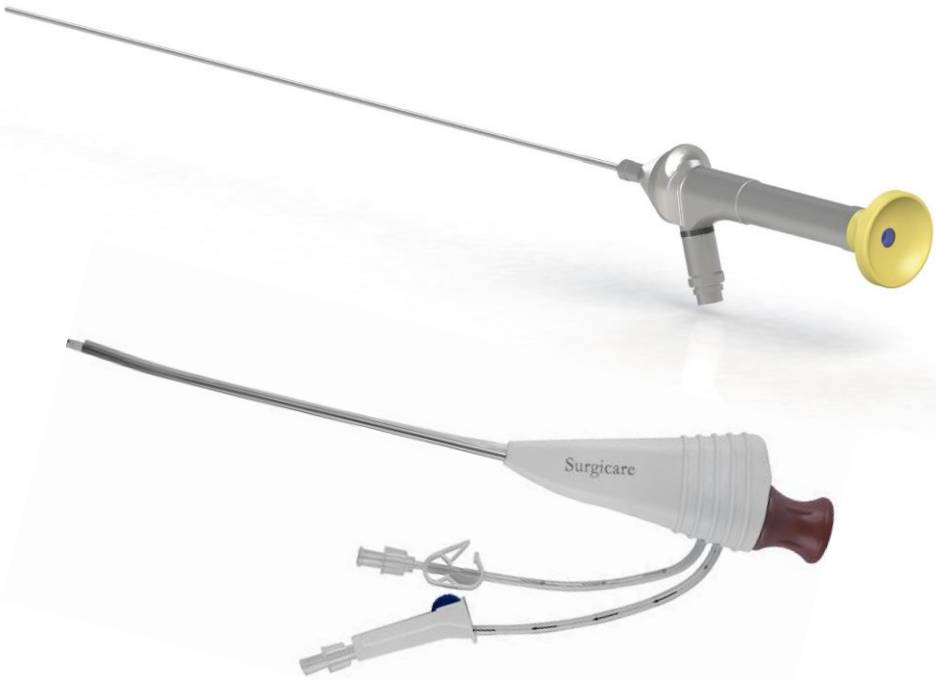
BERGER SURGICAL
MEDICAL PRODUCTS GMBH

english

FlexEye – Hysteroscope



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1 Target group

This manual is intended exclusively for trained and qualified personnel. Hysteroscopes are to be used exclusively by qualified personnel for clinical purposes.

Intended use and Indications

Hysteroscope are used as visual tools to access the uterine cavity. They are not, in and of themselves, a method of surgery.
The Berger FlexEye-Hysteroscope is used only in connection with the Hysteoroscope Sheath SUR 100 to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and minimal invasive interventional procedures. The scope is used in connection with an external light-source allowing direct viewing of the inner surface of the uterus or a connection to a standard endoscopic camera.

Diagnostic Hysteroscopy:

- Abnormal Uterine Bleeding
- Infertility & Pregnancy Wastage
- Evaluation of Abnormal Hysterosalpingogram
- Intrauterine Foreign Body
- Amenorrhea
- Pelvic Pain

Operative Hysteroscopy:

- Directed Biopsy
- Removal of Submucous Fibroids and Polyps
- Submucous Myomectomy
- Transection of Intrauterine Adhesions
- Transection of Intrauterine Septa
- Endometrial Ablation

3 Symbols

2.1 Warning notices

The following signal words distinguish between warning notices according to the type of danger:

- NOTICE warns against material damage.
- Caution warns against minor injuries.
- Warning warns against serious injuries.
- Danger warns against danger to life.

2.2 Symbols

	Observe user manual	WL	Working length
	Note on proper handling of hysteroscopes		Non-sterile
	Date of manufacture		Protect from sunlight
	Manufacturer		Store dry
LOT	Lot number		Warning!
SN	Serial number	CE	European approval mark (only for testing)
REF	Order number		

2.3 Product number range

These operating instructions apply to the following item numbers: 55-043-00

(BergerScope)

4 General description

During examination, diagnosis and/or (in combination with the Hysteroscope sheath SUR 100 and other accessories) treatment, hysteroscopes serve exclusively to visualize the uterus.

The hysteroscopes conform to the directives 93/42/EWG class I, rule 5. All class I products are marked with a CE

3 Product description/contents

Designation	Illustration	Item number
Hysteroscope		55-043-00
Adapter Wolf		55-152-03
Berger / Storz adapter		55-152-02
Verpackung / Karton		VERSURG01_A
Gebrauchsanweisung	IFU	IFU-FlexEye
Hysteroscope sheath, sterile (disposable)		SUR 100

4 Accessories/replacement parts

All accessories and spare parts must be procured from the manufacturer.

- 55-152-03 Wolf adapter
- 55-152-02 Berger /Storz adapter

5 Contraindications

Absolute contraindication to hysteroscopy is acute pelvic inflammatory disease (PID). Relative contraindications include the following conditions:

- Inability to distend the uterus
- Cervical/Vaginal Infection
- Known Pregnancy
- Recent Uterine Perforation
- Cervical Stenosis
- Uterine Bleeding or Menses
- Invasive Carcinoma of the Cervix
- Medical Contraindication or Intolerance to Anesthesia
- General surgical risks

5.1 Complications:

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation.

The following are clinical conditions that can significantly complicate Hysteroscopic endometrial ablation:

- Adenomatous Endometrial Hyperplasia
- Severe Adenomyosis
- Uterine Anomalies
- Uterine Leiomyoma
- Pelvic Pain (Subtle PID)
- General surgical risks

5.2 Contraindications to Hysteroscopic Myomectomy

Hysteroscopic myomectomy should not be undertaken without adequate training, Preceptorship, and clinical experience.

The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- Severe Anemia
- Inability to circumnavigate a myoma due to myoma size (e.g, predominantly intramural myomas with small submucous components)

WARNINGS

Suspicion of pregnancy should suggest a pregnancy test prior to the performance of diagnostic hysteroscopy. Only persons having adequate training with and familiarity with hysteroscopy should preform hysteroscopic procedures.

Consult medical literature relative to techniques, complications, and hazards prior to performance of any hysteroscopic procedure.

When hysteroscopic instruments and accessories from different manufactures are employed together in a procedure, verify compatibility prior to initiation of the procedure. When using a fluid distension medium, strict fluid intake and output monitoring is required. Excessive intravasation of distension fluid can lead to fluid overload.

Potential complications of Continuous Flow Hysteroscopy are: Hyponatremia /ypothermia / Pulmonary edema / Cerebral edema and Uterine perforation resulting in possible injury to bowel, bladder, major blood ves- sels, and ureter.

Failure to follow all applicable instructions may result in serious surgical consequen- ces.

Refer to appropriate electrosurgical system user manual indications and instructions to ensure that all safety precautions are taken.

A thorough understanding of the principles and techniques involved in laser, Electrosurgical and ultrasonic procedures is essential to avoid shock and born ha- zards

To both patient and medical personnel and damage to the device and other Medical instruments. Ensure that insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid, unless the instruments are specifically designed and labeled to function in liquid.

PRECAUTIONS

Vaginal ultrasonography prior to hysteroscopy may identify clinical conditions that will alter patient management. Intrauterine distention can usually be accomplished with pressures in the range of 35 – 75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressure greater than 75 – 80 mmHg.

6 Safe usage and preparation prior to use

The BergerScope – Hysteroscope is supplied non-sterile and must be cleaned and sterilized prior to first and each following use!

WARNING:

This device should be cleaned and sterilized immediately prior to each use according to the procedure provided below.
Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.


Read and keep the user manual.


Read and keep the user manuals for accessories and medical devices used in combination with the device.


Use hysteroscopes exclusively as intended, see chapter 3: “Intended use“


Ensure that hysteroscopes are used exclusively by trained and qualified personnel.


Make sure that the surgeon is proficient, theoretically and practically, in the approved surgical techniques. The surgeon is responsible for the correct execution of the operation.


Before the first sterilization, clean hysteroscopes thoroughly (preferably by automated cleaning/disinfection).


Before and after every use, clean, disinfect and sterilize hysteroscopes (see chapter 9: “Cleaning/disinfection“).


Store new or unused hysteroscopes in a dry, clean and safe place at room temperature.


Store and package hysteroscopes individually.

Store hysteroscopes dry at room temperature.


After every cleaning/disinfection and before every use, check hysteroscopes for: *cleanliness, proper functioning, and damage, e.g. insulation, loose, bent, rough, broken,* cracked, worn, missing parts etc.


Do not use damaged or defective hysteroscopes. Replace damaged parts with original spare parts immediately.


Reject damaged hysteroscopes immediately.

To prevent damage to the working end: Carefully insert hysteroscopes through a trocar.

Do not bend hysteroscopes.

It is possible for light with a high radiation energy to escape from the light window and increase the temperature of the tissue.

Ensure that the surface temperature of the main body does not exceed does not exceed 41 °C.

During longer applications, allow main body to cool down if necessary.

Use light sources with max. 300 W (xenon) or the same type LED light source and adjust the light to the minimum level for sufficient illumination.

Check image quality (clear and free of distortion) and light transmission through glass fibers.

-> Hold light guide connector against non-glare light. If the glass fibers appear as black spots (broken glass fibers) on the distal end, it is possible that the light output is insufficient.

To maintain the optical quality, make sure that hysteroscopes are not exposed to gamma rays.

In case of suspected or diagnosed Creutzfeld-Jacob Disease,
EMOS Technology GmbH advises against reusing the hysteroscopes and recommends disposing of them instead.

In case of suspected or diagnosed Creutzfeld-Jacob Disease, take immediate measures to protect other patients, users, or third parties from becoming infected.

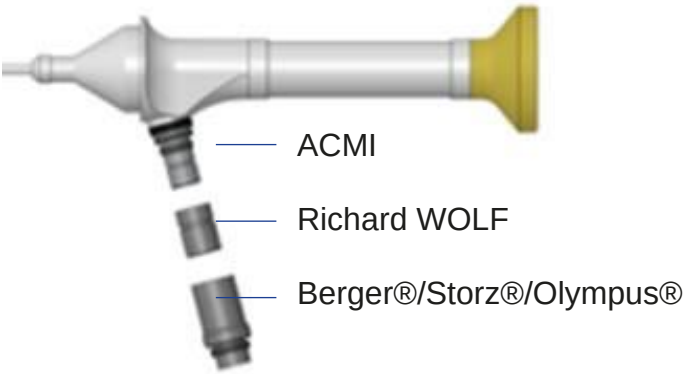
Observe country-specific laws and specifications.

7 Assembly/disassembly

The BergerScope – Hysteroscope should be evaluated prior to each use to ensure adequate optical performance. Inspect the image quality using direct visualization or through connection to a video camera.
Any sings of foggy or cloudy images indicate that the proximal or distal optics require cleaning. The instrument should be inspected closely for foreign materials, scratches, cracks, or other sings of damage to the distal tip, semi-flex sleeve or eyepiece. If required, the distal lens may be gently cleaned with a cotton swab moistened with isopropyl alcohol or with the Berger Proteins-Cleaning-Paste.

WARNING

Only 3.5mm light cables with Berger® / Storz® / Olympus® / Wolf® or ACMI connection connectors should be used to connect the hysteroscope to the endoscopic light source.



WARNING

Use of light cables larger than 3.5mm could result in extreme heating of the Hysteroscope in the vicinity of the light post.
Extreme heating could cause a tissue burn to the user or patient!

Attach/detach light guide connector as follows (see image 1).

7.1 Layout

(1) Objective lens distal window
(2) Tube
(3) Main Body
(4) Eyepiece
(5) Adapter for light guides, removable (Berger/Storz/Olympus)
(6) Adapter for light guides, removable (Wolf)
(7) Connecting piece for light guides (ACMI)

Adapter for Berger/Storz/Olympus (6) and Wolf (7) light guide connector is included as standard.

For safe assembly:

Always hold hysteroscope by main body or eyepiece.

Ensure that light guide connector safely connects to one of the hysteroscope light adapters (see illustration 6, 7).

Ensure that other instruments do not come in contact with the glass surfaces.

7.2 Combinations

DANGER!
Danger to life due to high voltages and currents!

Ensure that patient leakage currents are minimized for combinations.

Combinations with medical devices with energetically operated accessories suitable for endoscopic applications:

Combine hysteroscopes with other medical devices if:

- allowed according to intended use in user or operating manual.
- allowed according to technical data in user or operating manual.
- standard for TV lenses or cameras complies with general standard.

8 Cleaning/disinfection

The Berger FlexEye-Hysteroscope must be thoroughly cleaned immediately after each use to remove blood or other foreign material. Dismantle the hysteroscope prior to cleaning.
Unscrew the light cable adapters and optional coupler as applicable.
Please note that the automated cleaning and disinfection process along with the steam sterilization is considered the preferred method of reprocessing

MANUAL CLEANING:

Rinse the device for a minimum of 2 minutes under cold running water to remove visible soil.
ENZOL® Enzymatic Detergent or other enzymatic detergent solutions is recommeded for cleaning. The instructions provided with the enzymatic cleaner should be closely followed to ensure proper cleaning. Using a soft-bristled, non-metal brush, thoroughly clean device paying Particular attention to hard to reach areas. Thoroug- hly rinse the device for a minimum of one minute with demineralized (DM)-water to remove all detergent residues. Dry with a soft towel or gauze surgical sponge. Visual- ly inspect each device paying particular attention to hard to each areas. If visible soil remains, repeat cleaning procedure again.

AUTOMED CLEANING:

Rinse the device for a minimum of two minutes under cold running tap water to remove visible soil. Put the hysteroscope in a disassembled state on an endoscope tray. We recommended to use a special suitable tray system for scopes. Put the tray on an instrument rack in the washer disinfector and select the instrument cycle ensuring the following validated parameters.

Instrument cycle:

PHASE	MIN. RECIRCULATION TIME (MINUTES)	WATER / TEMPARATURE	DETERGENT TYPE AND CONCENTRATION
Pre-rinsing 1	02:00	Cold tap water (<40 °C)	N/A
Pre-rinsing 2	03:00	Cold tap water (<40 °C)	N/A
Cleaning Cycle	05:00	Hot Tap Water 60 ° (Set Point)	Neodisher Mediclean Forte 0.50 %
Neutralization	03:00	Warm Tap Water 40 °C	Neodisher Z 0.10 %
Post-RinsiNG	02:00	Warm DM-Water 40 °C	N/A
Thermal disinfection	3:00	90 °C	N/A
Drying	10:00	100 °C	N/A

CAUTION:
Failure to promptly clean the hysteroscope after use (within two hours) may result in permanent damage to the Instrument and ineffective sterilization.

INSPECTION OF THE DEVICE AFTER CLEANING/DISINFECTION
Thoroughly inspect the endoscope under magnifying glasses concerning any remaining soil. Repeat the process until the device is completely clean. Check for any traces of surface corrosion or mechanical damage to the endoscope shaft. (see chapter 8.)

Check Endoscope for clear and crisp image (no fog, no humidity drapped)

Hold light guide connector against non-glare light. If the glass fibers appear as black spots (broken glass fibers) on the distal end, it is possible that the light output is insufficient.

GAS PLASMA STERILIZATION:
The hysteroscope may be prepared for clinical use as a semi-critical device by using the STERRAD®100S System. To achieve sterilization, refer to the instrument for Use document of the STERRAD® 100S System.
We recommended a special suitable tray system for scopes to be used during the processing.

STEAM STERILIZATION:
The hysteroscope may be prepared for clinical use as a semi-critical device by applying a fractionated pre-vacuum steam sterilization process according to ISO17665. We recommended a special suitable tray system for scopes to be used during the processing.

Ensure the following parameters are properly programmed:

Sterilization Type:	Pre-Vacuum
Sterilization Temperature:	Minimum: 132°-134°C Maximum: 137°C
Pressure:	2.0 – 2.3 bar
Minimum Holding time:	04:00 minutes
Minimum Drying time:	35:00 minutes

After completing the sterilization, the hysteroscope should be cooled down slowly to room temperature.

The Hysteroscope sterilization Instructions are compatible with the UK Standards HTM01-01 Part D and HTM01-01 Part C.
A Wash Disinfector Cycle (PH Level 12-14) for 1 minute at 90 degrees C.
Together with Steam Sterilization for a minimum of 3.5 minutes at 134-137 degrees C

Do not clean hysteroscopes in an ultrasonic

bath. Do not gamma-sterilize

hysteroscopes.

NOTICE!

Handle the instrument with care, avoid material damage due to incorrect cleaning!

- Final Report Validation of automated processing no.: 11762
- Final Report Validation of steam sterilization, no.: 11763
- Both reports are available from Berger Surgical upon request.

END OF LIFE-CYCLE

The end of the product life cycle depends on the careful handling of the device rather than the number of uses or reprocessing cycles. The device should be replaced immediately if it shows a foggy image or mechanical damage-

9 Storage

Handle with care. This instrument should be stored in a protective container in a dry, clean and dust free environment at modest temperature of 5°C to 40°C. Protect the distal lens and provided proximal eyepiece from scratches and other physical damage.

10 Repair

Have device repaired exclusively by the respective retailer or a repair facility authorized by Berger Surgical Medical Products GmbH.

Use exclusively original spare parts for repairs.

Repairs carried out by service centers not authorized by Berger Surgical Medical Products- GmbH void all warranty claims.

11 Service

Repairs are to be exclusively carried out by qualified service personnel Authorized by Berger Surgical Medical Products GmbH.

Obtain information on repair or warranties from Berger Surgical Medical Products GmbH agent, or from an authorized customer Service center.

12 Before returning the scope

Clean and sterilize hysteroscopes.

Returning used medical devices is exclusively permitted when cleaned and sterilized/disinfected, and with written verification thereof.

Use origninal package.

13 Limited Warranty

This device is warranted to the original purchaser against defects in workmanship and material for one year from the data of original purchase to extent that Berger Surgical Medical Product GmbH will, at our option, replace, repair, of refund the purchase price of the device or any part thereof which examination discloses, to our satisfaction, is defective.
This warranty does not apply to any product, or part thereof, which has been repaired or altered by persons not authorized by Berger Surgical Medical Product, or which has been subjected to misuse, neglect or accident.

This warranty is in lieu of all other warranties, express or implied, including, without limitation, any warranties of mechanical nature, and fitness for a particular purpose and of all other obligations on the part of the manufacture or seller.
We shall not be liable for any anticipated or lost profits, incidental or consequential damage, costs, time charges, or other losses in connection with the device or any of its part.
The use of damaged and/or contaminated Hysteroscope is the responsibility of the user. Disregarding these instructions for use will void the guarantee or warranty claims. We accept no liability in the case of improper handling, incorrect or inade- quate preparation or unauthorized repairs.

We reserve the right to change or discontinue the equipment at any time without incurring any obligation to make the same or similar changes on equipment previ- ously built or sold by us.

14 Disposal

Observe the following when disposing of the device:

Clean and sterilize hysteroscopes thoroughly before disposal.

Dispose of packaging and used parts in accordance with country-specific regulations.

Keep hysteroscopes out of reach of unauthorized persons.

After end of life cycle:

Check hysteroscopes for: cleanliness, proper functioning, and damage, e.g. insulation, loose, bent, broken, cracked, worn, rough, missing parts etc.

If necessary, dispose of hysteroscopes correctly (see chapter 17: “Disposal “).

15 Technical Data

The semi-flex endoscopes are reusable instruments. The lifespan of the endoscope depends on frequency of use as well as maintenance and careful handling.
Berger Surgical Medical Products GmbH manufactures all hysteroscopes and accessories according to the following guidelines in the current edition of each of the following:

- Medical Devices Directive 93/42 in preparation
- EN ISO 13485
- Standard series ISO 8600

Berger Surgical medical Products GmbH would appreciate any comments from users regarding possible errors unclear passages in this

Notes

Manufacture

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