ONE STOP SHOWROOM FOR HOSPITAL & HEALTHCARE PRODUCTS.

Instructions For Use

Rigid Endoscopes

USER MANUAL

WESTERN SURGICAL®

Western Surgical

AN ISO 9001 : 2008 & ISO 13485 : 2015 AC 2012 CERTIFIED COMPANY

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1 User Instructions

1.1 General Instructions

The Instructions For Use contain important information which is essential to ensure a safe and correct operation of the product.

The Instructions For Use are part of the product. Therefore, it must be permanently available during the entire life-cycle of the product at the site of operation.

The product may only be used by persons who have the needed training, knowledge and experience. All persons, who are handling this product must read the Instructions For Use carefully before use.

The Instructions For Use must be passed on to the successive owner or user of this product.

All information regarding specifications and design in this document is subject to change without notice. Variations between the product and its representation in the Instructions For Use are possible.

1.2 Signs and Symbols

	**Warning** Indicates a hazard. If not avoided, the hazard can result in death or serious injury.
	**Caution** Indicates a potential hazard. If not avoided, this hazard may result in personal injury or product/property damage.
	Observe Instructions For Use!
	Applied part of type BF according EN 60601-1
CE XXXX	CE-mark in accordance with Medical Device Directive 93/42 EEC. Products with CE-mark without notified body number (CE) are class I products. Products with CE-mark and notified body number (CE xxxx) are products higher than class I.

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	Indication that the product may be autoclaved, resp. steam sterilized
	Manufacturer
	Date of manufacture
	Indicates the tolerable temperature
	Indicates the tolerable air humidity
	Indicates the tolerable air pressure
	Magnetic resonance unsafe
	Sterilize prior to each use
 only	Federal Law (USA) restricts this device to sale by or on the order of a physician
	Indication that the product does not contain natural rubber latex

2 Safety Instructions

WARNING:

The product may only be used observing the guidelines of this Instructions For Use. If instructions, warnings and precautions are not observed, this may lead to risks and serious consequences during use.

Check and guarantee unrestricted function, completeness and integrity of the product and/or accessories before use.

CAUTION:

Keep the original packaging for possible returns in case of service.

WARNING:

Make sure that all devices operated nearby comply with the relevant EMC requirements.

WARNING:

The image quality can be affected by the electromagnetic emissions of peripheral equipment (e. g. monitor, video equipment) which is connected. In case of extreme electromagnetic interferences, the image quality may be influenced (e. g. slight stripes, color changes on the monitor).

WARNING:

Use in combination with MR

The product is MR unsafe - in areas with magnetic resonance imaging, the product is unsafe

WARNING:

Accessories and/or peripheral devices, which are connected to the interfaces of the product must comply verifiably to the relevant specifications (e. g. IEC 60601-1). Furthermore, all configurations of the system standard IEC 60601-1-1 have to be fulfilled.

WARNING:

Unsterile parts – danger of infection

Parts, which are delivered unsterile, have to be processed before use.

WARNING:

Improper use and maintenance, as well as application in deviance to its intended use may lead to risks for patient and user or early wear and tear of the product.

WARNING:

Ensure that the product has cooled down sufficiently after reprocessing. The use in hot condition is not allowed.

WARNING:

Endoscopic procedures may only be carried out by specialists who have corresponding training, knowledge and experience.

CAUTION:

The product is susceptible in regard to bending, heavy kinking, torsion, draft or pressure load. This may damage the optical components and thus lead to operating failure.

CAUTION:

Only operate the product within the specified environmental conditions.

2.1 Instructions for Combination with other Medical Products

WARNING:

The simultaneous use of NMR (Nuclear Magnetic Resonance), endoscopes and endoscopic accessory can be dangerous and can lead to artefacts; observe manufacturer's instructions and safety notes.

WARNING:

There is a variety of therapeutic fields of applications in connection with laser and high-frequency surgery, as well as pneumatic or electro-hydraulic endoscopic accessories. Observe Instructions For Use and safety notes of the used product and accessories.

WARNING:

Multiplication of leakage current - risk for patients

If the product is used with electro medical devices and/or power-driven endoscopic accessories, the leakage currents can multiply.

If the product or endoscopic accessories are used with products of different manufacturers and in combination with medical electrical products, ensure that the BF conditions (insulated, earth-free applied part) are fulfilled.

Products marked with this symbol fulfil the BF regulations.

WARNING:

Ensure that the corresponding Interconnection Conditions are kept. Also, the relevant standards and the respective national deviations must be followed.

Do not touch the endoscope and the metal enclosure of the light source at the same time

WARNING:

Excessive temperatures in combination with light sources

Light sources, especially high-power light sources, emit large amounts of light energy and thermal energy

Result: The light guide connector and the endoscope's distal end may become extremely hot.

Risks during use of light sources:

- Irreversible tissue injury or unwanted coagulation to the patient, resp.
- Burns or thermal damage to surgical equipment (e.g. surgical drapes, plastic materials, etc.)
- If the light source fails during use, this may endanger the patient. Therefore hold ready an operable second light source or use a light source which comes with spare lamp.

Safety measures:

- Avoid exceeding use of intensive light.
- Use the minimum level of illumination necessary to satisfactorily view the target area.
- Do not put in touch the endoscope's distal end or the light guide connector with patient's tissue, flammable materials or heat-sensitive materials.
- Do not touch the endoscope's distal end or the light guide connector.
- Avoid contamination of the distal end face, resp. light emission face.

3 Intended Use

WARNING:

The product may only be used for the described purpose.

This Instruction For Use is applicable for all rigid endoscopes with working channel:

Arthroscopes are used to display joints.

Cystoscopes are used to display urinary bladder and urethra.

Hysteroscopes are used to display uterine cavity, uterine tube and neck of the uterus.

Laparoscopes are used to display abdominal cavity and its inner organs.

OR-Laparoscopes are used to display abdominal cavity and its inner organs and to insert instruments into abdominal cavity.

Sinuscopes are used to display frontal sinus, maxillary sinus and paranasal sinuses.

Otoscopes are used to display outer ear canal and eardrum.

Laryngo-Pharyngoscopes are used to display the structure of the pharyngeal and laryngeal zone.

Indications

The use of Arthroscopes, Hysteroscopes, Laparoscopes and OR-Laparoscopes is indicated for minimal-invasive surgery.

The use of Sinuscopes, Otoscopes and Laryngo-Pharyngoscopes is indicated for invasive endoscopic procedures.

Contraindications

The use of endoscopes is contraindicated if endoscopic procedures are contraindicated.

4 Product Description

Serial number as well as item number for identification of the product can be found on the product label.

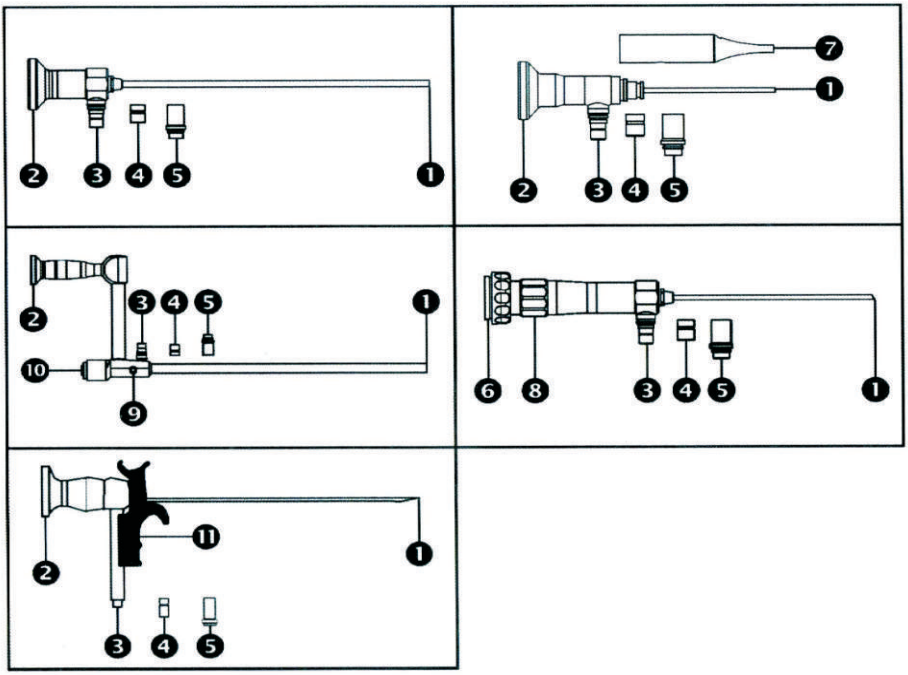

Figure: 1

1	*Objective*	7	*Speculum adapter*
2	*Ocular*	8	*Focussing ring*
3	*Light guide connection system ACMI*	9	*Luer Lock connection*
4	*Adapter for light guide connection system Wolf*	10	*Working channel*
5	*Adapter for light guide connection system Storz*	11	*Handpiece*
6	*C-Mount camera connection*		

Scope of delivery

- Endoscope
- Instructions For Use

5 Start of Operation

5.1 Assembly/First Installation

- If applicable screw on adapters.

5.2 Tests

CAUTION:

The glass surfaces must be clean and free from deposits for corresponding working distances (see Technical Data).

Carry out the following steps for testing before reprocessing and immediately before use:

Testing the fiberoptic

- Move distal end of endoscope in different directions in front of a bright ceiling lamp (no cold light source) and hold the end of the light guide connection close to the eye.
- The brightness of fibers will change. If single fibers stay dark, this is harmless. From a breakage rate of approx. 10 - 20 % on it is recommended to send the endoscope for repair.

Testing the glass surfaces

- Visual inspection of glass surfaces. The surfaces have to be clean and smooth.
- If damages are discovered during inspection observe chapter Trouble Shooting.

WARNING:

Risk for patients

Risks for patients due to the use of products with sharp edges or damaged surfaces.

- Do not use these products.

CAUTION:

Damaged products

- Do not use products with damaged fiberoptic, damaged glass surfaces or stubborn deposits, which cannot be removed by cleaning.

Send damaged products to the manufacturer or authorized repair center. Authorized repair centers can be inquired from the manufacturer.

5.3 Disassembly

- Screw off all adapters.

6 Cleaning and Disinfection

6.1 General Instructions

Adhere to national legal regulations, national and international standards and regulations as well as internal hygiene regulations for processing.

Machine cleaning provides better and safer results and should therefore be preferred over manual cleaning.

Successful processing of this medical product can only be ensured if processing is performed through a validated processing procedure. The user/processor is responsible for the validation.

To prevent contamination of a loaded instrument tray during the procedure, be careful not to put contaminated instruments back into this tray, rather collect them separately.

Encrusted or fixated residues from surgery can make the cleaning process more difficult or ineffective, and can cause corrosion of stainless steels. To avoid this, the time interval between procedure and processing must not exceed 6 h. Furthermore do not use any pre-cleaning temperature > 45°C or cleaning or disinfection agents (active ingredients: aldehyde, alcohol) which will fixate the residues even further.

Excessive doses of neutralizers or basic detergents can cause chemical degradation and/or fading of laser inscriptions on stainless steel surfaces.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfecting and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. To remove such residues, the products must be rinsed sufficiently with fully desalinated water and dried thoroughly.

Only use process chemicals that have been tested and approved (e.g. VAH/DGHM or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations.

All process parameters specified by the chemical's manufacturer, such as temperature, concentration and exposure times, must be strictly observed. Failure to do so can result in the following problems:

- Optical deterioration of materials, e.g. fading or discoloration of titanium or aluminium surfaces. For aluminium, pH > 8 in the application/process solution can already cause visible surface changes.
- Material damage, e.g. corrosion, cracks, fracturing, premature aging or swelling.

- Do not use process chemicals which may cause tension cracks at synthetics or which could lead to embrittlement.
- Clean product directly after use.
  Excessive contaminations can be removed manually with a soft cloth or a soft cleaning brush.
  Further detailed information regarding a reprocessing method that is hygienically safe and safe for the materials can be found under: www.a-k-i.org

Immediately following each examination

- If existing, remove adapters and sealing cap (e. g. Luer Lock).
- Completely remove visible residues from operations with a moist, lint-free disposable cloth.
- Put the dry product into a closed disposal container and have it transferred to cleaning and disinfection within 6 h.

CAUTION:

The product must not be cleaned and/or disinfected in an ultrasonic bath.

Use detergents and disinfectants which are approved for the present product. Observe manufacturer's instructions.

Observe concentration, temperature, duration of impact and duration of use according to manufacturer's instructions.

6.2 Manual Cleaning and Disinfection

Validated method

Inspect visible surfaces for residual contamination after manual cleaning/disinfection. Repeat the cleaning process if necessary.

Optical surfaces must not be cleaned with a brush. Remove residues on optical surfaces with a pad moistened with alcohol (70 % ethanol) or neutral cleaning agent.

Manual cleaning with immersion disinfection and cleaning with brush

Stage	Step	T (°C/°F)	t (min)	Conc. (%)	Water quality	Chemical
I	Cleaning	35-45/ 95-113	5	0.8	D-W	Enzymatic cleaning agent, e. g. Cidezyme/Enzol
II	Intermediate rinse	RT (cold)	3 x 1	---	D-W	---
III	Disinfection	20-25/ 68-77	12	---	D-W	0.55 % orthophtalaldehyde solution, e. g. Cidex OPA
IV	Final rinse	RT (cold)	3 x 2	---	FD-W sterile	

Stage	Step	T (°C/°F)	t (min)	Conc. (%)	Water quality	Chemical
V	Drying	RT	---	---	---	

D-W Drinking water
RT Room temperature
FD-W Fully desalinated water (demineralized, low microbiological contamination, max. 10 germs/ml and low in endotoxins value, max. 0.25 Endotoxin units/ml)

Stage I

- Fully immerse the product in the cleaning solution. Ensure that all accessible surfaces are moistened.
- Clean the product while it is lying in the cleaning solution, using a lint free tissue or a suitable cleaning brush, until all visible residues have been removed from the surfaces.
- Brush off all surfaces, eventually by turning the brush, that are not accessible to visual inspection, such as hidden crevices, lumens or complex geometry at least 1 minutes until no more residues can be removed. Mobilize non-fixed components during cleaning 3 times in each direction as far as it will go.
- Thoroughly rinse these components with the cleaning solution (at least five times), using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Stage II

- Rinse the product 3 times completely (all accessible surfaces) for at least 1 minute. Mobilize non-fixed components during cleaning 3 times in each direction as far as it will go. Use unused water for every rinse cycle.
- Rinse all surfaces that are not accessible to visual inspection, such as hidden crevices, lumens (e. g. working channel) or complex geometry with a disposable syringe (20 ml) thoroughly, but at least 5 times.
- Allow water to drip off for a sufficient length of time.

Stage III

- Fully immerse the product in the disinfecting solution. Ensure that all accessible surfaces are moistened.
- Mobilize non-fixed components such as adjusting screws, joints, sliedes, etc. during cleaning 3 times in each direction as far as it will go.
- Rinse all surfaces that are not accessible to visual inspection, such as hidden crevices, lumens (e. g. working channel) or complex geometry with a disposable syringe (20 ml) thoroughly, but at least 5 times.

Stage IV

- Rinse the product after disinfection 3 times completely (all accessible surfaces) for at least 2 minutes. Mobilize non-fixed components such as adjusting screws, joints, sliedes, etc. during cleaning 3 times in each direction as far as it will go. Use unused water for every rinse cycle.
- Rinse all surfaces that are not accessible to visual inspection, such as hidden crevices, lumens (e. g. working channel) or complex geometry with a disposable syringe (20 ml) thoroughly, but at least 5 times.
- Allow water to drip off for a sufficient length of time.

Stage V

- Dry the product with lint-free tissue.
- Areas, which cannot be reached with the lint-free tissue, can be dried with medical-quality filtered compressed air (p max. = 0.5 bar).

Material compatibility releases exist for:

- Gigasept FF (Schülke & Mayr GmbH)
- Lysetol FF (Schülke & Mayr GmbH)
- Helipur HplusN (B. Braun Medical AG)
- Cidex OPA (Johnson & Johnson)
- Cidezyme/Enzol (Johnson & Johnson)
- Neodisher MediClean forte (Chem. Fabrik Dr. Weigert GmbH & Co. KG)

6.3 Mechanical Cleaning and Disinfection

CAUTION:

- Only products marked as autoclavable may be thermally disinfected.

Hints for mechanical cleaning and disinfection

Inspect visible surfaces for residual contamination after mechanical cleaning/disinfection. Repeat the cleaning process if necessary.

The automatic endoscope reprocessors has to be validated (e. g. DGHM- or FDA-approval, resp. CE mark according to DIN EN ISO 15883).

For thermal disinfection, fully desalinated water (demineralized) must be used and a Ao-value of >3 000 must be achieved.

The used automatic endoscope reprocessors must be maintained and checked regularly.

Place the product in a perforated tray (avoid areas that cannot be reached during rinsing).

Connect single parts with lumens and channels directly to the special connection of the injector cart.

Validated method

Mechanical alkaline cleaning and thermic disinfection

Device type: one-chamber cleaning/disinfection device without ultrasonic

Stage	Step	T (°C/°F)	t (min)	Water quality	Chemical/Note
I	prerinse	< 25/77	2	D-W	-
II	cleaning	55/131	10	D-W	alkaline cleaner pH > 10 (e. g. neodisher MediClean forte 0.5%)
III	rinse I	> 10/50	1	D-W	-
IV	rinse II	> 10/50	1	FD-W	-
V	thermal disinfection	90/194	5	FD-W	-
VI	drying				according to disinfector program

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination: max. 10 microorganisms/ml, low endotoxin: max. 0.25 endotoxin units/ml)

Color anodized parts or plastic components (e. g. serial rings, ocular) may bleach out during mechanical cleaning.

7 Sterilization

7.1 General Instructions

Before sterilization ensure that the endoscope has no restrictions in use. See chapter Start of Operation (section Tests).

Ensure that the sterilization agent can reach all surfaces.

The implementation of the sterilization lies within the responsibility of the user in order to attain the required degree of sterilization.

7.2 Sterilization Methods

WARNING:

For USA only.

STERIS SYSTEM 1® must not be used in the USA!

STERIS SYSTEM 1E™ has been cleared by the FDA (U.S. Food and Drug Administration) as an effective liquid chemical sterilant processing system that can be used to process reusable heat-sensitive devices that cannot be sterilized by other legally marketed sterilization methods validated for that type of device.

Validated methods

Steam sterilization (fractionated vacuum)

AUTOCLAVE	Indication that the product may be autoclaved, resp. steam sterilized

Steam sterilizer according DIN EN 285 and validated according DIN EN ISO 17665.

Sterilization in fractionated vacuum at 134 °C/exposure time 5 min.

CAUTION:

Heated products are very shock-sensitive.

- Avoid shocks and vibrations.

CAUTION:

Sudden changes in temperature can damage the product.

- Do not quench the product after autoclavation but let it cool down to room temperature without additional cooling.

CAUTION:

If manufacturer's instructions regarding steam sterilization methods and steam quality are not observed this may lead to defects, subsequent damages or shortened life-span of the product.

- Observe manufacturer's instructions.

Material compatibility exists for:

Gas sterilization (EtO)

- Ethylenoxid (Sterivit method)

Low temperature plasma sterilization

- STERRAD® 50 (Advanced Sterilization Products)
- STERRAD® 100S (Advanced Sterilization Products)
- STERRAD® 200 (Advanced Sterilization Products)

Low temperature sterilization

- SYSTEM 1® (Steris Corporation)
- SYSTEM 1E™ (Steris Corporation)

Observe manufacturer's instructions for all named methods.

The use of different sterilization methods by turns can lead to shortened life-span of the product. Do only use one of the released methods.

8 Troubleshooting

Problem	Possible cause	Solution
Cloudy image	▪ Glass surfaces are dirty	▪ Clean glass surfaces according chapter Cleaning and Disinfection
	▪ Stubborn residue on the glass surfaces	▪ Remove residue according chapter Cleaning and Disinfection; check water quality
	▪ Lens system defective or not sealed	▪ Send endoscope system in for repair
Image too dark, too little illumination	▪ Glass surfaces dirty	▪ Clean glass surfaces according chapter Cleaning and Disinfection
	▪ Stubborn residue on the glass surfaces	▪ Remove residues according chapter Cleaning and Disinfection; check water quality
	▪ Wrong light guide	▪ Use suitable light guide
	▪ Light guide not attached to scope correctly	▪ Check position of light guide
	▪ Fiberoptic defect	▪ Check fiber optic according chapter Start of Operation (Tests)

Problem	Possible cause	Solution
	▪ Light guide, light source defect	▪ Replace light guide, change lamp. Warning: risk of burnings! See Instructions For Use 300 W Xenon Light Source
Illumination has yellow tint	▪ Fiberoptic dirty	▪ Clean glass surfaces according chapter Cleaning and Disinfection
	▪ Light guide dirty, defective	• Check light guide (e. g. illuminate onto a white surface).
Formation of patches, discolouring	▪ Inadequate cleaning (e.g. protein residues)	▪ Clean again, if required by thorough rubbing
	▪ Inadequate rinsing of the endoscope between processing phases (esp. before sterilization)	▪ Ensure adequate rinsing between the processing phases
	▪ Chloride concentration too high	▪ Check water quality
	▪ Heavy metal ions and/or silicates, increased content of iron, copper, manganese in water or sterilization steam	▪ Check water quality; if applicable, only use distilled (deionised) water

Problem	Possible cause	Solution
	▪ Contaminated or too frequently used disinfection or cleaning solutions	▪ Regularly replace the disinfection and cleaning solutions
	▪ Outside rust (e.g. through steam or preparation along with damaged or rust-prone instruments)	▪ Check maintenance systems; in case of common processing, check material compatibility, existing damages and avoid mutual contact
	▪ Contact corrosion	▪ Avoid contact with other products
	▪ Too high concentration of mineral substances (e.g. calcium) or organic substances	▪ Check water quality; if applicable, only use distilled (deionised) water

9 Maintenance and Repair

Maintenance

The present product is maintenance-free. It does not contain components which have to be maintained by the user or manufacturer.

Repair

For repairs contact the manufacturer or authorized repair center. Authorized repair centers can be inquired at the manufacturer.

For a fast processing of your service requests, return the product indicating:

- Item number (REF)
- Serial number (SN)
- Detailed description of defects

WARNING:

For the protection of your staff, as well as the staff of the repair center, thoroughly clean, disinfect and sterilize the product (and, if applicable, accessories) before shipment. If this should, due to pressing reasons, not be possible, process product as good as possible and mark it accordingly. The repair center can refuse the repair of polluted or decontaminated products due to safety reasons. Pack the product in such a way that the packaging cannot be contaminated.

CAUTION:

Choose a suitable and secure packaging (preferably original packaging).

The manufacturer reserves the right to return contaminated products to the sender.

10 Warranty

The manufacturer commits to a 12 months guarantee on the function of the product. This guarantee is restricted to claims, which are immediately risen in written form within the guarantee period starting from the date of the invoice, resp. with reference to repairs, indicating the invoice number. Legal guarantee claims are not restricted by this warranty.

This guarantee is only applicable to defects that cannot be attributed to normal wear and tear, misuse or wrong handling, lack of proper care or Acts of God.

Guarantee and warranty claims will not be accepted if the user himself or a non-authorized repair center will perform maintenance or repair work. In case a product has to be maintained the same applies for maintenances, which are not permitted explicitely.

Liability claims which arise from improper handling or combination with other devices or accessories cannot be claimed.

11 Disposal

Always observe national regulations when disposing of or recycling the product or its components.

12 Technical Data and Storing

Storing and transport

Temperature:	- 20 °C to + 70 °C
Relative air humidity:	5 % to 95 %
Air pressure:	700 hPa to 1,060 hPa

Store processed products in germ-tight packaging and dustproof in a dry, dark and well-tempered room.

Operation

Temperature:	+15 °C to +40 °C

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7.3 WARRANTY CERTIFICATE

western surgical product is warranted to be free from electrical and mechanical defects in material and workmanship, under normal use. The western surgical product must not have been moved from the site of original installation. A new or remanufactured part to replace the defective part will be provided without charge for the part itself, through an authorized western surgical service dealer. The replacement part assumes the unused portion of the warranty.

WESTERN SURGICAL WILL NOT BE RESPONSIBLE FOR:

1. Damage or repairs required as a consequence of faulty installation or application by others.
2. Damage or repairs needed as a consequence of any misapplication, negligent handling, improper servicing, unauthorized alteration, or improper operations.
3. Failure to start due to voltage conditions, blown fuses, open circuit breakers or other damages due to the inadequacy or interruption of electrical service.
4. Damage as a result of floods, winds, fires, lightning, accidents, corrosive atmosphere, or other conditions beyond the control of western surgical
5. Parts not supplied or designated by western surgical.

Date of Installation	**Installed By**
Model No.	**Serial No.**
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :

1) Any Defect Througut Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

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Dt. 4-6-2018

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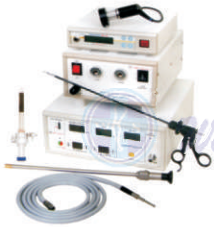
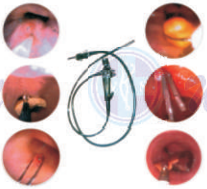
OUR OTHER PRODUCTS RANGE









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