



Instructions for Use

Endoscopy Instruments & Accessories



Strauss Surgical
3020 NW 82nd Avenue
Miami, FL 33122
United States of America


IFU Endoscopy Instruments & Accessories			
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STS-URO-2435-30-BP-PI
STS-URO-2435-30-BP
STS-URO-2435-33-BP
STS-URO-2435-20B-BP
STS-URO-2435-36-BP
STS-URO-2430-209-SL
STS-URO-2430-209-SL/KK
STS-URO-2430-211-SL-KK
STS-URO-100-126-QL-BP
STS-URO-100-127-QL-BP
STS-URO-215-24-BP
STS-URO-230-24-BP-SL
STS-URO-215-24-BP-TL
STS-URO-235-60-BP-SL
STS-URO-235-60-BP-SL/BL
STS-HFBP-534-06-VL
STS-HFBP-261-MT
STS-HYS-175-03-BP
STS-HYS-175-30-BP
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STS-HYS-340-00-BP
STS-HYS-340-02-BP
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STS-ART-270-00
STS-ART-190-60-OB
STS-ART-190-60-OT
STS-ART-216-40
STS-ART-216-40/Y
STS-ART-216-28
STS-ART-216-28K
STS-ART-223-27K
STS-ART-115-00
STS-ART-IC
STS-URO-078-QL
STS-URO-079-QL
STS-URO-081-QL
STS-URO-080-QL
STS-URO-076-QL
STS-URO-077-QL
STS-URO-GRA-43-OPT
STS-URO-BIO-43-OPT

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1. Device Description

Strauss' devices are used during endoscopic procedures embracing several field such as arthroscopy, cystoscopy, hysteroscopy, lithotripsy, nephroscopy, resectoscopy, urethroscopy, urology and urethrotomy.



Carefully read these instructions before using Strauss Surgical Instruments. Keep them in a safe place for future reference.

1.1. Intended Use

1.1.1. Obturators

The obturators are 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.

1.1.2. Guides

The guides are endoscopic components. They are elements used to assist the entry of the endoscopic devices into an appropriate rigid endoscope.

1.1.3. Adapters

The adapters are connecting devices, used to join two or more pieces of apparatus or device components, or make them compatible so that they mate together.

1.1.4. Cables

The cables are devices that function as conductors between the electrosurgical unit and the electrodes.

1.1.5. Evacuators

The evacuators are devices used in conjunction with and assist the use of an endoscope. The evacuator is connected to an endoscope and used to remove tissue, residues and concretions.

1.1.6. Syringes

The syringes are used to withdraw fluids during surgical procedures.

1.1.7. Syringe Adaptors

The syringe adaptors are used to connect components to syringes.

1.2. 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.

1.3. Contraindications

The devices are contraindicated for all the intended uses, other than the ones claimed by manufacturer. The devices are to be neither used in contact with central circulatory system nor with central nervous system.

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

- Acute inflammation of the abdominal area
- Urinary tract infection
- Coagulation disorder



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.




Improper use can lead to hazardous situations

2. Available Models and Combination Products



Please refer to section "Attached Document" for further information

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

3. 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 ($\leq 23^{\circ}\text{C}$) 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 detergent¹ in an ultrasonic cleaner² 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).


Automated wash

- Place the instrument in an automated washer³ 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 ⁴
Rinse 1	min. 1 minute	43°C	N/A

Drying

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

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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.

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.

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.

⁴ The detergent neodisher® MediClean forte of Dr. Weigert was used for the validation.

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.

Sterilization

i In order to ensure the sterility, disassemble the stopcocks of the sheaths and Albarran’s before autoclaving. For disassembly of the stopcocks prior to sterilization refer to Section 4.2 “Assembly of Stopcock”.

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

Steam

	Pre-vacuum⁵
Wrapping	Double
Temperature	Min. 132°C (min. 270°F)
Time	min. 3 minutes*
Dry Time	50 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.


*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 Section 4.2 “Assembly of Stopcock” 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.

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4. Assembling – Disassembling Instructions

4.1. 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

⁵ The sterilization validation was validated with the STERIS Amsco® Lab 250 sterilizer.



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.

4.2. Sheaths and Obturators




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



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

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5. Visual and Functional Inspection-Check



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

6. Storage

Strauss Surgical instruments and accessories 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.

7. 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.

8. 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 unauthorized personnel renders the guarantee invalid.

9. Disposal












Observe country-specific regulations and laws for the disposal of medical products.


10. Safety Information

The user and/or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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11. Used Symbols


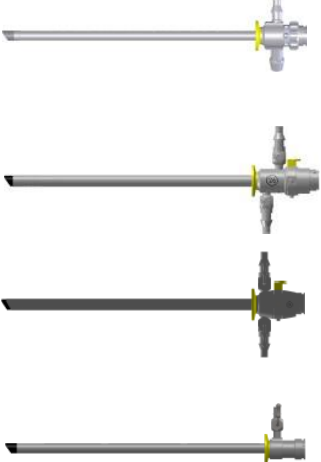
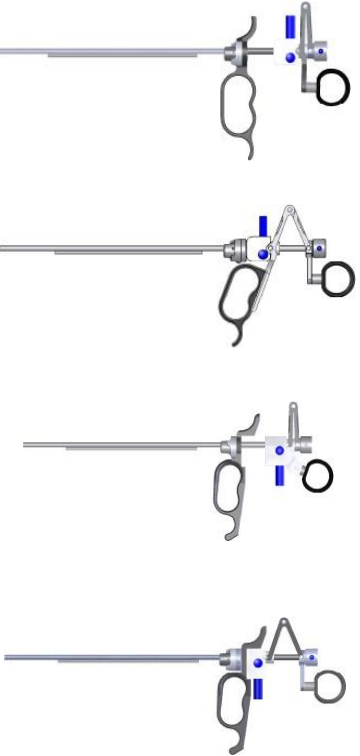
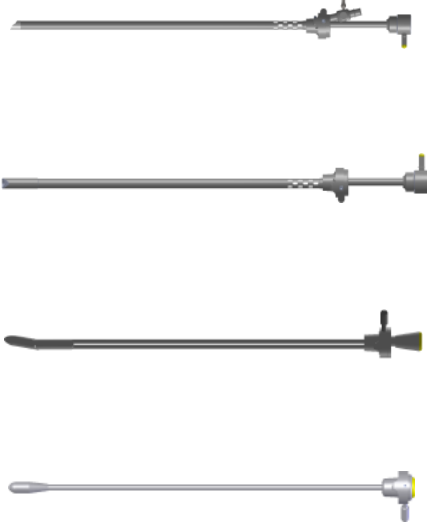

Symbol	Description		
	Symbol for "Manufacturer"	Legal Manufacturer: Strauss Surgical 3020 NW 82n Avenue Miami, FL 33122 United States of America	Tel.: +1 (305) 436 0599 Fax: +1 (305) 436 0399 Email: sales@straussurgical.com <u>Website:</u> www.straussurgical.com
	German Product Description		
	Symbol for "Catalog Number"		
Qty	Symbol for "Quantity"		
	Symbol for "Batch Code"		
	Symbol for "Consult the Instruction for Use"		
			
	Symbol for "Non-Sterile"		
	Symbol for "Caution, consult accompanying documents"		
	Symbol for "Keep dry"		
	Symbol for "Keep away from sunlight"		
	Symbol for "Medical Device"		

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12. Attached Document

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12.1 Combinations – Rigid HF Monopolar Bipolar Electrodes and Resectoscope System

Electrodes	Sheaths	Working Elements	Obturators	Cables
				

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12.1.1 Combination Product SL-SR Saline/Bipolar 24 FR


Electrodes	Sheath and Obturator		Working Element	Cable
Bipolar 24/26Fr STS-URO-2435-30-BP-PI STS-URO-2435-30-BP STS-URO-2435-33-BP STS-URO-2435-20B-BP STS-URO-2435-36-BP STS-URO-2430-209-SL STS-URO-2430-209-SL/KK STS-URO-2430-211-SL-KK	STS-URO-100-126-QL-BP STS-URO-100-127-QL-BP	STS-URO-215-24-BP STS-URO-230-24-BP-SL STS-URO-215-24-BP-TL	STS-URO-235-60-BP-SL STS-URO-235-60-BP-SL/BL	STS-HFBP-534-06-VL STS-HFBP-261-MT

12.1.2 Combination Product SL-SR Saline/Bipolar 19Fr and 17.5 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
Bipolar 17.5/18Fr STS-HYS-175-03-BP STS-HYS-175-30-BP STS-HYS-175-20-BP Bipolar 19/22Fr STS-HYS-340-00-BP STS-HYS-340-02-BP STS-HYS-340-03-BP STS-HYS-340-10-BP STS-HYS-340-20-BP	17.5/18Fr STS-HYS-175-26-BP STS-HYS-175-24-BP STS-HYS-175-23-BP STS-HYS-175-60-BP-SL 19/22Fr STS-HYS-310-21 STS-HYS-309-01 STS-HYS-315-19 STS-HYS-325-19	Bipolar 17.5/18Fr STS-HYS-175-60 Bipolar 19/22Fr STS-HYS-335-60-BP	STS-HFBP-534-06-VL STS-HFBP-261-MT

12.1.3 Monopolar Product 19 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
Monopolar 19/22Fr STS-HYS-340-00 STS-HYS-340-03 STS-HYS-340-10 STS-HYS-340-20	STS-HYS-310-21 STS-HYS-309-01 STS-HYS-315-19 STS-HYS-325-19	STS-HYS-335-60D	STS-HF-533-04 STS-HF-531-02 STS-HF-532-03

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12.1.4 Monopolar Product 24 Fr

Electrodes	Sheath and Obturator		Working Element	Cable
Monopolar 24/26Fr STS-URO-240-00 STS-URO-240-10 STS-URO-240-20 STS-URO-240-15 STS-URO-240-25 STS-URO-240-35 STS-URO-240-40 STS-URO-240-50 STS-URO-240-55 STS-URO-240-65	STS-URO-209-26 STS-URO-209-06	STS-URO-320-10 STS-URO-320-10-TL STS-URO-225-24	STS-URO-235-60	STS-HF-533-04 STS-HF-531-02 STS-HF-532-03

12.1.5 Laser Guiding Working Instrument

Sheath, Obturators and Accessories			Working Elements and Guide
Sheaths 23FR: STS-URO-045-23 Sheath 17.5/18FR: STS-HYS-175-26-BP STS-HYS-175-24-BP Sheaths 19/22FR: STS-HYS-309-01 STS-HYS-310-21 Sheaths 24/26FR: STS-URO-209-26 STS-URO-209-06	Obturators 23FR: STS-URO-045-30 Visual Obturator 23FR: STS-URO-045-35 Obturator 17.5/18FR: STS-HYS-175-23-BP Obturator 19/22FR: STS-HYS-315-19 Obturator 24/26FR: STS-URO-320-10	Bridge 23FR: STS-URO-045-40 Adaptor 23FR: STS-URO-047-26	Working Element 17.5/18FR STS-HYS-047-08 Working Element 19/22FR STS-HYS-048-22 Working Element 24/26FR STS-URO-047-08 STS-URO-047-10

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1223. Combinations Products – Flexible HF Bipolar Electrodes

Sheath	Electrodes	Obturators	
			

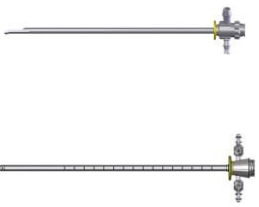





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12.3.

Sheaths		Electrodes	Obturators
<p>Outer Sheaths: STS-HYS-010-43 STS-HYS-010-40 STS-HYS-084-05 STS-HYS-025-41 STS-HYS-010-33 STS-HYS-010-30 Compact Operating sheath STS-HYS-022-33</p>	<p>Inner Sheaths: STS-HYS-082-15 STS-HYS-025-42</p>	<p>STS-HYS-515-05 STS-HYS-516-05 STS-HYS-516-05/90 STS-HYS-517-05</p>	<p>STS-HYS-010-45 STS-HYS-010-35</p>

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12.3 Combination Products – Cysto-Urethroscopy System

Sheaths	Obturators	Forceps and Working Units	Bridges and Adaptors	Flexible Electrodes, Baskets	Cables
					

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Sheaths, Bridge Adaptors	Obturator, Accessories	Forceps	Basket	Forceps Adaptors	*Cable
<p>Sheaths:</p> <p>STS-URO-001-17 STS-URO-001-19 STS-URO-001-21 STS-URO-001-23 STS-URO-001-25 STS-URO-042-01 STS-URO-045-23 STS-URO-730-01 STS-HYS-010-40 STS-HYS-010-33</p> <p>Bridge Adaptors:</p> <p>STS-URO-045-40 STS-URO-030-01 STS-URO-050-02 STS-URO-035-40 STS-URO-047-26 STS-URO-047-25</p>	<p>Obturator:</p> <p>STS-URO-020-17 STS-URO-020-19 STS-URO-020-21 STS-URO-020-23 STS-URO-020-25 STS-URO-042-02 STS-URO-045-30 STS-URO-045-35 STS-URO-150-001-QL STS-URO-150-003-QL STS-URO-730-70 STS-HYS-010-45 STS-HYS-035-45 STS-HYS-010-35 STS-HYS-200-102</p> <p>Accessories:</p> <p>STS-URO-011-90 STS-URO-011-92 STS-URO-011-80 STS-URO-011-82 STS-URO-198-00 STS-URO-199-00 STS-URO-940-01 STS-URO-940-02</p>	<p>STS-URO-076-QL STS-URO-082-00 STS-URO-BIO-43-OPT STS-URO-GRA-43-OPT</p> <hr/> <p align="center">Working Elements</p> <hr/> <p>STS-URO-235-60</p> <p>Laser-Cysto-Urethroscope Working Element</p> <p>STS-URO-047-08 STS-URO-047-10 STS-HYS-047-08</p>	<p>Basket:</p> <p>STS-URO-30-70-B10 STS-URO-30-70-B15 STS-URO-25-70</p>	<p>STS-URO-035-25 STS-URO-082-90 STS-URO-400-10 STS-URO-400-10-QL STS-URO-730-02</p>	<p>STS-HF-531-02 STS-HF-532-03 STS-HF-533-04</p>

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12.4 Combination Products – Hysteroscopy System

Sheath	Obturators	Adaptors
		

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Sheaths	Working Element	Obturator	Adaptos
STS-HYS-010-33 STS-HYS-010-30 STS-HYS-084-05 STS-HYS-082-15 STS-HYS-022-33 STS-HYS-010-40 STS-HYS-010-43 STS-HYS-025-41 STS-HYS-025-42	STS-HYS-046-12 STS-HYS-047-08 STS-HYS-047-12 STS-HYS-335-60	STS-HYS-010-35 STS-HYS-010-45	STS-HYS-200-377 STS-HYS-200-378

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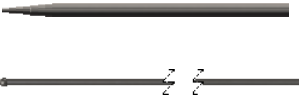

Issue Date:


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Revision:


08.25.2022

12.5 Combination Products – Nephroscopy System

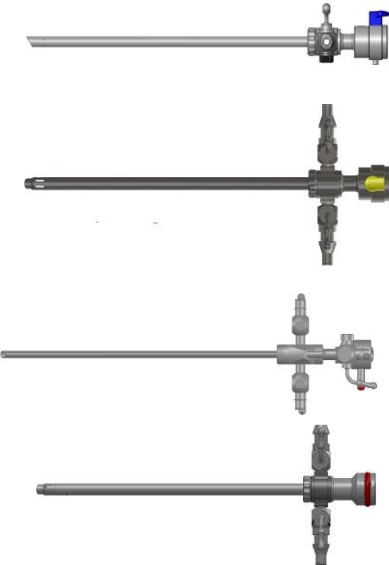



Sheaths	Obturator	Forceps	Probes	Adaptors
				


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Sheaths	Obturator	Forceps	Probes	Adaptors
STS-NEP-420-14	STS-NEP-420-14T			

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Issue Date:	30.04.2021	Revision:	

12.6 Combination Products – Arthroscopy System

Sheaths	Obturators	Trocars	Adaptors
			

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Issue Date:	30.04.2021	Revision:	08.25.2022	

Sheaths	Obturator	Trocars	Adaptors
STS-ART-116-40	STS-ART-190-60-OB	STS-ART-216-40	STS-ART-115-00
STS-ART-116-40/Y	STS-ART-190-60-OT	STS-ART-216-40/Y	STS-ART-IC
STS-ART-113-28		STS-ART-216-28	
STS-ART-113-28K		STS-ART-216-28K	
STS-ART-190-60		STS-ART-223-27K	
STS-ART-201-27			
STS-ART-115-40D			
STS-ART-260-00			
STS-ART-270-00			

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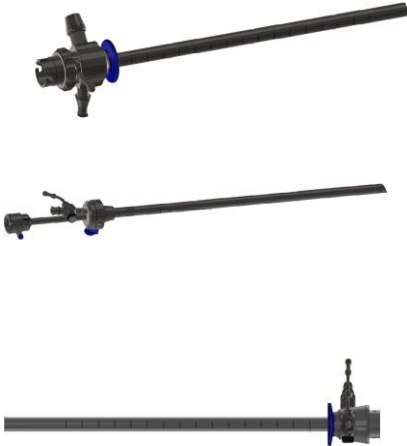


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Revision:

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12.7 Combination Products – Lithotripsy System

Sheath	Obturator	Forceps
		

IFU Endoscopy Instruments & Accessories				
Issue Date:	30.04.2021	Revision:	08.25.2022	

Sheaths	Obturator	Force ps
STS-URO-078-QL STS-URO-079-QL STS-URO-081-QL	STS-URO-080-QL	STS-URO-076-QL STS-URO-077-QL