

INSTRUCTIONS FOR USE

Important ⚠

Before using these products, please read the following information thoroughly!

Warning ⚠

Reusable products are delivered unsterile, indicated on the device label by the following symbol:



Prior to their first use and before each subsequent use, the devices need to be cleaned and sterilized as described in the reprocessing section of this document.

Warning ⚠

The packaging cannot withstand the high temperatures of autoclaving and should be disposed of before sterilization.

Warning ⚠

The instruments may only be used by trained and, if applicable, instructed physicians. Disinfection, cleaning and sterilization may only be performed by specially trained medical personal.

INTENDED USE

The stent placement kit enables the insertion and placement of silicone tracheobronchial tubular stents. This prosthesis introduction system, which is connected to the bronchoscope sheaths, is equipped with a distal safety stop and a channel that allows visibility through an endoscope when inserting a prosthesis.

Domains of Application

- Bronchoscopic stent placement

Patient Target Group

Patients undergoing bronchoscopic surgery. Children, adolescents, adults, seniors; all gender.

INDICATIONS

The bronchoscope system is indicated for use in interventional bronchoscopy:

- Tracheobronchial stent placement

CONTRAINDICATIONS

Non fixed fracture of the cervical vertebral column, aortal aneurysm (absolute); malformations of the mouth, maxillary or larynx, fracture of lower or upper maxillary (relative).

RESIDUAL RISKS & SIDE EFFECTS

Transitory laryngal pains on awakening (rare).

SCOPE OF DELIVERY

Stent Placement Kit

A stent placement kit consists of the following three part: stent introducer tube, stent pusher and stent loader. It is especially designed for deploying silicone stents.

- Stent placement kits are colour-coded to correspond with the tracheal and bronchial tubes.
- The recommended stent sizes for each kit are etched on each introducer tube. (Please note, the orange stent introducer can accommodate large stents up to 20 mm in addition to all Y-stents).
- In the event of complaints, contact the distributor

/ See distributor's address

Warning ⚠

- After unpacking, check all parts for any damage caused during transit.

DEVICE DESCRIPTION & VARIANTS

Pusher

This instrumentation allows introduction and placement of tracheobronchial silicone stents by pushing the stent through the Introducer Tube. Used in combination with the bronchoscope, it features a distal safety stop along with a vision channel (only adult) providing visual observation by an endoscope of the stent placement procedure.

Note: The yellow coded tube does not have the safety stop features.

Variants

Universal/ Adult/ Jumbo	
Pediatric	

Introducer Tubes

This instrumentation allows introduction and placement of tracheobronchial silicone stents. Stents are inserted into the tube by the stent loader.

Stent Loaders

Telescopic Stent Loaders allow tracheobronchial silicone stents to be inserted into the Introducer Tube.

- Single-action loader: Optimized for placement of standard and large straight stents.
- Double-action loader: Optimized for placement of both large straight and Y-stents.

Variants

Single-action loader	
Double-action loader	

Silicone cap for Axial Ports

Connectable to the axial port, colour-coded silicone caps guarantee the airtightness of the system and provide endoscope and instrument support.

STENT LOADING & DEPLOYING

Loading a Stent with single-action Loader

- Select the desired size of your silicone stent.
- Pick up the stent loader (two pieces) and remove the cap. Place the loader on a flat surface with the round tube opening facing up.



- Lubricate the stent with medical grade silicone or other appropriate lubricant. Lubricants may also applied to the stent loader itself. Take the lubricated silicone stent and fold it lengthwise. Feed the folded stent into the stent loader.



- Remove the stent pusher from the stent introducer tube and lubricate the tip and inside the barrel of the stent introducer tube with medical grade silicone or other appropriate lubricant. Take the stent introducer in one hand and the stent loader in the other.



- Put on the cap to the stent loader and gently insert the stent introducer tube. Push the loader straight toward the introducer using your hand or use the sterilized table until you feel a slight resistance and hear a click from the stent introducer tube tip touching the bottom of the stent loader.



- DO NOT push using the handles of the stent introducer as you may bend the tube. Instead, hold the top part of the introducer tube where the hole is, or put the introducer on the sterilized table and push down the loader vertically downward.



- Remove the stent introducer tube from the loader. Insert the stent pusher into the stent introducer tube. DO NOT push all the way otherwise you will deploy the stent.



- The stent is now ready to be deployed.



Deploying a Stent

- To deploy the stent, remove the bronchoscope from the sheath system together with the silince cap that covers the axial main port.
- Insert the stent introducer into the sheath system all the way to the end. It is possible to view the stent deployment by inserting the telescope into the stent pusher. If desired, you may use a specific silicone cap on the axial main port of the universal base, or on the proximal end of the stent pusher to prevent air leak.
- To deploy the stent, push the stent pusher all the way down the stent introducer using a firm, smooth motion. The stent will slide into the airway. Use the fluoroscopy to confirm that you are deploying the stent at the right place.
- Remove the bronchoscope from the stent pusher and remove the stent introducer and the stent pusher together from the sheath system. Insert the bronchoscope back into the sheath system (with silicone cap, if needed) and manipulate the stent with forceps, if necessary.



Loading a Y-Stent with double-action Loader

- Remove lid and pusher from loader assembly.



- Lubricate the groove of the stent loader with medical grade silicone or other appropriate. Make sure the part in which stent will pass is well lubricated.



- Follow the direction of the Y stent engraved on the stent loader. Starting from one extremity with stent studs facing up fold stent into a V and insert in groove.



- Push stent completely into the cavity. Re-position lid, then slide it for locking onto loader.



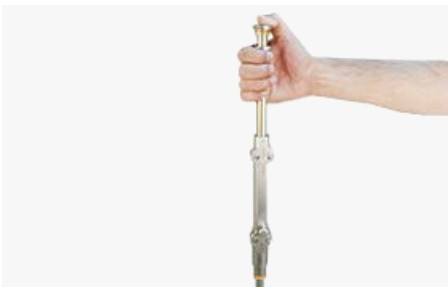
- Confirm that the stent is fully stored in the stent loader.



- Well lubricate the inside of the Orange or Yellow or White coded stent loader with medical grade silicone or other appropriate.



- Insert the introducer tube into end of loader. Align the arrow engraved on the introducer tube with the arrow engraved on the loader lid. Place introducer tube and loader vertically against a surface.



STENT PLACEMENT KITS

8. Lock upwards internal part of double-action pusher.



9. Push the double-action pusher gently toward the introducer so that the stent slides smoothly. DO NOT twist the pusher while this process. If you feel the resistance, stop pushing to allow stent to position itself, then push again. Repeat this action if necessary to assure complete loading.



10. Unlock internal part of double-action pusher and progressively continue pushing stent.



11. A visual marking on the introducer tube serves as an indicator of stent position.



Deploying a Y-Stent

- Once the stent is in the introducer tube, remove the stent loader and insert the stent pusher into the stent introducer.
- Before deploying the stent through the sheath system, rotate the introducer tube so the marking of “Y” faces up. This way the stent will deploy into the right position.



GENERAL TESTING & INSPECTION

Visually check for damage, bend, and wear. Long and narrow instruments should be particularly checked for damages. If instruments are part of a larger set, they are to be checked together with all associated components.

PERFORM FUNCTIONAL TEST

The functional test shows whether the proper functioning of the instrument and its components is guaranteed. Perform the functional test before each use.

- Check that your instrument is in good condition by inspecting the tubes for damage or obstruction. Make sure the handles of the pusher rotates 360°.
- Select the corresponding loader and pusher.



- If a closed system is used, select the appropriate silicone caps according to your instrument configuration (optics, suction catheter, laser fibers, etc.). Connect the

- silicone caps to the metallic ports.
- The Y-Stent loader is compatible with the orange, yellow and white stent placement kits.
- The Y-stent loader is designed to accommodate Y-shaped and straight stents up to 20 mm in diameter.

Warning

Equipment needs to be cleaned and sterilized before each procedure.

LABELING

Warning

Please pay attention to the symbols on the product label and in this instruction for use. Care must be taken to ensure that the instruments are fully traceable at all times.

STORAGE

The storage area must be dust-free, low in microbiological contamination, dark and free from temperature fluctuations.

PRODUCT LIFE

Only use the instrument within the product's service life if its labeling is clearly legible, if it is not damaged and if it functions properly.

No maximum number of uses for these reusable medical devices is defined. Given the design of the medical device and the stability of the materials used, a careful visual inspection and functional check of the device before use allows the user to detect signs of material degradation that would prevent its use. These checks are the best method to monitor the useful life of this medical device and allow its reuse / See „Perform functional test“.

Warning

In case of present or suspected damage to the devices, do not try to repair the instrument. Avoid any further use of damaged instruments!

GUIDELINES FOR CARE, MAINTENANCE & CLEANING

REPROCESSING

Warning

Be following instructions only apply to reusable products. Please note that any deviation from these instructions, including the use of cleaners / detergents not specifically indicated in these instructions will require an evaluation of device-specific efficacy and suitability of the actually

performed cycle. Respective evaluation usually requires equipment qualification and device specific performance qualification / validation.

LIMITATIONS ON REPROCESSING

The reusable surgical instruments are designed for repeated use. The service life of the instruments results from reprocessing and handling. Therefore, a limit for the number of reprocessing cycles cannot be specified. Before each use, the product must be checked for function and damage. Damaged products must be disposed of.

Warning

If the instruments are used on patients infected with prion-based diseases (e.g. CJD) the instrument must not be reused. Even after reprocessing and sterilization, the risk of cross-contamination cannot be eliminated and the instrument must be destroyed.

REPROCESSING INSTRUCTIONS

Warning

Always ensure that the products are used and reprocessed by qualified personnel with appropriate experience in hospital hygiene and sterilization techniques. To ensure safe and effective reprocessing of the products, the following instructions have been validated by the manufacturer for effectiveness and compatibility with the instruments. It is the responsibility of the end user to ensure that cleaning and sterilization is indeed performed with appropriate equipment, materials and personnel to achieve the desired result. Any deviation from these instructions should be evaluated for effectiveness and possible adverse consequences.

Warning

All reusable products must be subjected to reprocessing as described in the following sections before being used for the first time. Follow the instructions and warnings of the manufacturers of the decontamination, disinfection and cleaning agents to be used.

CLEANING

Warning

Improper cleaning, rinsing, and drying can result in potentially hazardous residues or inadequate sterilization.

Pre-Cleaning

Instruments, or fully disassembled instruments if applicable, must be brushed under cold water until all visible contamination is removed. If the instrument has a flushing port, the lumen of the

shaft must be flushed for at least 10 seconds through the flushing port with a water jet gun (static pressure greater than 4 bar) after manual brushing. The instruments are then treated in a 0.5% alkaline enzymatic (e.g. Neodisher® Mediclean forte) ultrasonic bath for 10 minutes. Finally, rinse again for 30 seconds with a water jet gun.

AUTOMATED CLEANING¹

The automated cleaning was validated with Neodisher® Mediclean forte (alkaline-enzymatic: pH-value 10.4 – 10.8) for cleaning and Neodisher® Z (acidic: pH-value 3.0 – 2.6) for neutralization.

Step	Parameter	
Pre-rinse	Rinsing temperature	Cold tap water
	Exposure time	180 secs. / 3 mins.
Cleaning	Cleaning temperature	55°C
	Exposure time	600 secs. / 10 mins.
	Detergent	Alkaline-enzymatic (e.g. Neodisher® Mediclean forte)
	Concentration	0.50%
Neutralization	Rinsing temperature	Cold DI water
	Exposure time	60 secs. / 1 min.
	Neutralizing agent	acidic (e.g. Neodisher® Z)
	Concentration	0.10%
Rinse	Rinsing temperature	Cold DI water
	Exposure time	120 secs. / 2 mins.
Thermal disinfection	Disinfection temperature	90 °C(A0 3000)
	Exposure time	300 secs. / 5 mins.
Drying	Drying	60 mins. / 1 hour

STEAM STERILIZATION²

Parameter	
Procedure	Triple fractionated pre-vacuum
Temperature	min. 132°C
Duration	min. 3 mins.
Drying time	min. 20 mins.

The instructions provided above have been validated as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

¹ Validated with washer-disinfector Miele PG 8535
² Validated with steam autoclave Lautenschläger ZentraCert

ADDITIONAL INFORMATION

Do not exceed maximum loading capacity of the sterilizer when processing multiple instruments in one sterilization cycle.

PACKAGING

Packaging suitable for steam sterilization must comply with the requirements according to ISO 11607 / ANSI / AAMI ST79 / AAMI TIR12, for example, disposable sterilization packs (single or double packs) temperature resistant up to at least 137°C (279°F) and sufficient steam permeability, which provide sufficient protection against mechanical damage, or sterilization containers which need to be maintained according to the manufacturer's instructions.

MAINTENANCE

Sort out all blunt or damaged instruments. Clearly damaged instruments (breakage, brittle silicone parts) are NOT to be reused but repaired or disposed of.

WARRANTY

A guarantee of two years from the manufacturing date is given for material and manufacturing defects. Transport costs and shipping risk are not assumed. In addition, the warranty stated in the General Terms and Conditions applies. This warranty does not apply to instruments that have been repaired, modified or improperly handled by unauthorised persons. In this case, no liability is assumed for the operational safety of the instrument either. In addition, the warranty becomes null and void.

Warning

- Risk of infection due to non-sterile instruments.
 - Prepare the instrument before returning it to the distributor.
 - Return the reconditioned instrument in its original packaging to the distributor.
- / See distributor's address



REPAIRS

Risk of injury due to improper repair.

- Repairs may only be carried out by the manufacturer or by persons authorised by the distributor.

Warning

Risk of infection due to non-sterile instruments.

- Prepare the instrument before returning it to the distributor.
- Return the reconditioned instrument in its original packaging to the distributor.

/ See distributor's address

DISPOSAL

Environmentally friendly disposal enables the reuse of valuable raw materials.

Dispose of the product in accordance with the applicable country-specific regulations and laws for the disposal of medical devices.

RELEVANTE NOTE

All serious incidents that have occurred in relation to the product must be reported to the manufacturer and the competent national authority of the country in which the incident occurred.

/ See manufacturer's address

COMPATIBILITY

Combination products for the products listed in the Appendix:

Bronchosopes

24-3202	/	38101-542	/	BX-3000
24-3205	/	38101-543	/	BX-4000-SA
24-3209	/	38101-544	/	BX-5500-CA
24-3210	/	38101-545	/	BX-5500-FA

Bases

24-1301	/	38101-500	/	BS-2301-3
24-1401	/	38101-501	/	BS-2410-3
24-1501	/	38101-502	/	BS-2501-3

Tubes

24-2101	/	38101-510	/	BT-2000-3
24-2102	/	38101-511	/	BT-2101-3
24-2103	/	38101-512	/	BT-2103-3
24-2104	/	38101-513	/	BT-2105-3
24-2105	/	38101-514	/	BT-2106-3
24-2201	/	38101-515	/	BT-2201-3
24-2202	/	38101-516	/	BT-2203-3
24-2203	/	38101-517	/	BT-2205-3
24-2204	/	38101-518	/	BT-2210-3
24-2301	/	38101-519	/	BT-2402-3
24-2302	/	38101-520	/	BT-2403-3
24-2303	/	38101-521	/	BT-2404-3
24-2401	/	38101-522	/	BT-2601-3
24-2402	/	38101-523	/	BT-2602-3
24-2403	/	38101-524	/	BT-2603-3
24-2404	/	38101-525	/	BT-2701-3
24-2405	/	38101-526	/	BT-2800-3

APPENDIX

All products covered by these instructions are listed below:

Introducer Tubes

24-4001	/	38101-560	/	BR-2000-3
24-4002	/	38101-561	/	BR-2101-3
24-4003	/	38101-562	/	BR-2103-3
24-4004	/	38101-563	/	BR-2200-3
24-4005	/	38101-564	/	BR-2402-3
24-4006	/	38101-565	/	BR-2403-3
24-4007	/	38101-566	/	BR-2601-3
24-4008	/	38101-567	/	BR-2701-3

Pusher

24-4020	/	38101-570	/	BP-2000-3
24-4021	/	38101-571	/	BP-2101-3
24-4022	/	38101-572	/	BP-2103-3
24-4023	/	38101-573	/	BP-2200-3
24-4024	/	38101-574	/	BP-2402-3
24-4025	/	38101-575	/	BP-2403-3
24-4026	/	38101-576	/	BP-2601-3
24-4027	/	38101-577	/	BP-2701-3

Stent Loaders

24-4040	/	38101-580	/	BI-2000-3
24-4041	/	38101-581	/	BI-2101-3
24-4042	/	38101-582	/	BI-2103-3
24-4043	/	38101-583	/	BI-2200-3
24-4044	/	38101-584	/	BI-2402-3
24-4045	/	38101-585	/	BI-2403-3
24-4046	/	38101-586	/	BI-2001-3
24-4047	/	38101-587	/	BI-2701-3

Silicone Caps

24-1903	/	38101-592	/	BS-2300-3
24-1904	/	38101-593	/	BS-2301-3
24-1905	/	38101-594	/	BS-2302-3
24-1906	/	38101-595	/	BS-2303-3
24-1907	/	38101-596	/	BS-2304-3
24-1908	/	38101-597	/	BS-2305-3

SYMBOLS USED ON LABELING (ACC. DIN EN ISO 15223-1)

- Legal manufacturer
- Manufacturing date
- Consult instructions for use
- Batch code
- Product number
- Caution, consult accompanying documents
- Do not use if package is opened or damaged
- Non-sterile
- Keep out of direct sunlight
- Protect against moisture
- Prescription use only
- Medical Device
- Distributor

CE-Marking

CONTACT DETAILS

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