Instructions for Use – MICTEC Talcum Sprayer

Item #: 20943-60 – 5mm Ø, 300mm working length

⚠ Basic Warnings and Precautions

In order to keep risks to patients and users as low as possible, we ask you to carefully follow these operating instructions. The use, disinfection, cleaning, and sterilization of the instruments may only be carried out by trained specialists.

Do not overload the instruments. Overloading due to excessive force can lead to fractures, bending, and malfunctions of the medical device and injuries to the patient or user. Do not bend bent instruments back to their original position, as this presents a danger of breakage.

Inspections:

Before using the instruments, they must be inspected for fractures, cracks, deformations, damage, and functionality. Particular care must be taken when checking areas such as edges and points. Worn, corroded, deformed, porous, or otherwise damaged instruments must be rejected. Do not use damaged products!

The products are NON-STERILE when delivered. The packaged products are marked accordingly.

After receiving the products, check to see whether they are accurate, complete, intact, and functional.

The attending physician and all other people involved in the handling of the products are responsible within their field of activity to have appropriate product knowledge based on the latest technology standard. This enables the correct handling of the products and prevents health or safety risks for patients, users, or third parties.

If Creutzfeldt-Jakob disease or an HIV infection is suspected or diagnosed, measures must be taken to prevent its possible transmission to other patients, users, and third parties. If the instruments are used on patients with Creutzfeldt-Jakob disease or HIV infection, we do not accept any responsibility for their reuse. If Creutzfeldt-Jacob Disease (CJD) or its variant (vCJD) is used, patients or suspects must be treated separately or the instrument disposed of.

The use of the instrument on the heart and central nervous or circulatory system is **not** allowed!

⚠ Intended Use

Spray nozzles are used to perform pleurodesis, a surgical procedure in which the lung pelt is bonded/glued to the pleura. By introducing talc into the pleural cavity, inflammation is artificially induced, which causes the pleura to grow into the lungs. Thus, no gap between the pleura and lungs should form. A renewed occurrence of an accumulation of air or fluid should be prevented.

Preparation Onsite

The instruments/products should be disinfected and cleaned immediately, but no later than one hour after use. Immediately after use, remove coarse dirt from the instruments with a lint-free cloth. The impurities should not dry on the objects in order to not complicate the disinfection and cleaning processes. Wet disposal is recommended. During wet disposal, the instruments are preferably placed in a solution of a cleaning agent or a combined cleaning and disinfecting agent, which has no protein fixing effect. Disinfectants containing aldehydes or hot water (>40°C) should be avoided, as they have a fixing effect and can influence the success of cleaning. Under no circumstances should instruments be placed in physiological saline, as prolonged contact may lead to pitting and rust.

When selecting a cleaning agent system, it must be ensured that – if thermal disinfection is not used – a suitable disinfectant with tested effectiveness (e.g., VAH/DGHM or FDA approval or CE marking) is used instead, that it is compatible with the cleaning agent used, and that both chemicals are compatible with the instruments.

The concentrations specified by the manufacturer of the cleaning agent and disinfectant must be strictly adhered to.

7248 S. Tucson Way, Centennial, Colorado 80112, USA / Toll free: 800.821.7496 / Local: 303.790.9411 / Fax: 303.792.2606
info@sontecinstruments.com / SontecInstruments.com

Material Resistance

When selecting cleaning agents and disinfectants, please make sure that the following components are **not** included:

- Organic, mineral, and oxidizing acids
- Stronger alkalis (pH>11 not permitted; mild alkaline cleaners are recommended)
- Organic solvents (alcohol, acetone, etc.), gasolines
- Halogenated hydrocarbons, chlorine, iodine
- Ammonia

If elevated levels of chloride are present in the water, pitting corrosion and stress corrosion may cause cracking to occur on the instrumentation. By using mild alkaline enzymatic cleaners or demineralized/deionized water, such corrosion can be minimized.

Transport

The safe storage and transport of instruments to the place of preparation must be carried out in a closed container to prevent damage to the instruments and contamination of the environment.

Preparation for Decontamination

The instruments must be disassembled or opened for reprocessing, if possible.

MICASEPT instruments cannot be dismantled! In the case of MICASEPT instruments, never use brushes or other objects in the area of the internal channel sealing system, which could damage the MICASEPT seal in the slot of the jaw. MICASEPT instruments should **never** be rinsed in the jaw part in the direction of the handle with a manual or machine water pressure hose! For MICASEPT instruments, it may only be flushed transversely to the instrument axis to avoid damage to the inner seal.

MICTEC instruments are partially dismantled. Flush MICTEC instruments with rinsing connection for at least 10 seconds with a water gun inside (pulsed procedure). Flush instruments with cavities, holes, and threads with a water gun for at least 10 seconds (pulsed procedure).

Pre-Cleaning

Place instruments in cold water for at least 10 minutes. If necessary, clean the instruments under cold water with a soft brush until no residues are visible. Rinse the instruments for at least 10 seconds with a water pressure gun, paying attention to the joints, then rinse carefully under cold tap water. Please consider the above-mentioned limitations of the MICASEPT and MICTEC instruments.

Cleaning Manually

Machine cleaning is preferred. Should the instrument be cleaned manually, the following steps must be followed:

1. Rinse products under cold tap water (<40°C) until all visible contamination has been removed. Stubborn dirt should be removed with a soft brush.
2. Prepare the cleaning bath according to the manufacturer's instructions (validated method: Neodisher Mediclean forte 0.5% (v/v)).
3. Immerse the instruments completely in the cleaning solution for 15 minutes and sonicate in an ultrasonic bath at 35 kHz. All surfaces must be wet, and acoustic shadows must be avoided.
4. Manually clean the inserted instrument in the solution with a soft brush. All surfaces must be brushed several times.
5. Moving parts must be moved in the cleaning solution.
6. For channels and internal pipe surfaces only: Drive the brush into and out of the pipes at least six times, then rinse the channels with tap water (water gun) and repeat this procedure.
7. Rinse instruments completely under running tap water, while moving the moving parts.
8. Drain the remaining water well.

Disinfection Manually

Place the instruments in disinfectant solution for 15 minutes (validated method: Bomix® plus 1% (v/v)) and then rinse thoroughly with demineralized water. Since there is no "general" material compatibility (this is always dependent on the water quality used, dosage, exposure time, temperature, and any effects by mixing with other means), the information of the disinfectant manufacturer must be strictly observed. Residues of disinfectants can attack the material during subsequent sterilization. Therefore, make sure that the disinfectants are removed without leaving any residue.

7248 S. Tucson Way, Centennial, Colorado 80112, USA / Toll free: 800.821.7496 / Local: 303.790.9411 / Fax: 303.792.2606
info@sontecinstruments.com / SontecInstruments.com

Drying with Manual Processing

Manual drying can be achieved by using a lint-free cloth. Dry cavities of instruments with oil-free compressed air according to ISO 8573-1. If residual moisture is still present, post-drying can be performed in a drying cabinet at 60°C. The drying time depends on the load as well as the design of the instruments (e.g., cavities, material, etc.).

Cleaning / Disinfection by Machine (RDG)

When selecting the RDG, it is important to ensure that:

- The RDG has proven effectiveness (e.g., DGHM or FDA approval or CE marking according to DIN EN ISO 15883).
- If possible, a tested program for thermal disinfection (at least 5 minutes at 90°C or A0 value >3000) is used. (Chemical disinfection poses a danger of disinfectant residues on the instruments.)
- The program used is suitable for the instruments and contains sufficient rinsing cycles.
- Suitable water is used for rinsing (e.g., Aqua purificata / Aqua purificata valde), and the air used for drying is filtered and thus they do not reduce the hygiene status at this point.
- The RDG is regularly maintained and reviewed.

Rinse-friendly loading of sieve trays, inserts, holders, etc.:

- Sieve trays must not be overloaded.
- Instruments with cavities must also be completely rinsed inside.

For dismountable instruments: Place instruments in disassembled condition on the inserts of the MIC wagon. Do not lay down instruments that cannot be dismantled or hinged (articulated) instruments while open in a sieve tray on the insertion trolley.

1. 1 min. pre-rinse with cold tap water
2. Emptying
3. 3 min. pre-rinse with cold tap water
4. Emptying
5. 5 min. wash at 55°C with 0.5% alkaline/enzymatic cleaner
6. Emptying
7. 3 min. neutralization with cold demineralized water and neutralizer
8. Emptying
9. 2 min. intermediate rinse with cold demineralized water
10. Emptying

Machine thermal disinfection must be carried out at 93°C +/- 2°C during machine cleaning, taking into account the national requirements regarding the A0 value (see ISO 15883). The exposure time is 300 seconds.

If elevated levels of chloride are present in the water, pitting corrosion and stress corrosion may cause cracking to occur on the instrumentation. By using alkaline cleaners or deionized water, such corrosion can be minimized.

The cleaning result should be checked by visual inspection. The instruments must be visually clean; if necessary, the process must be repeated.

Desiccation

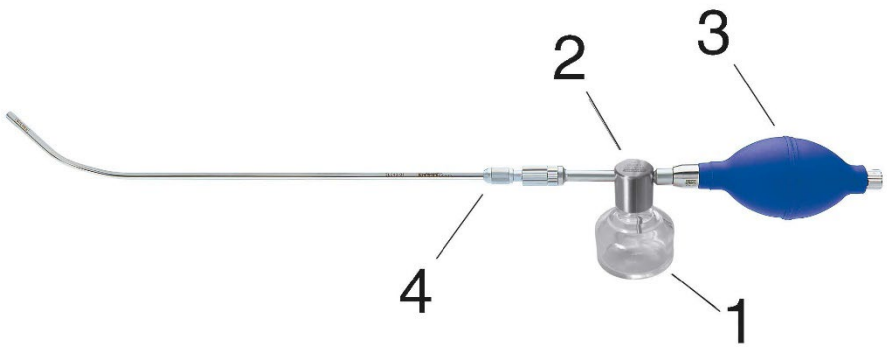
Dry the instruments/products through the drying cycle of the washer-disinfector at 100°C for 20 minutes. If necessary, manual drying can also be achieved using a lint-free cloth. Dry the cavities of instruments with oil-free compressed air in accordance with ISO 8573-1. If there is still residual moisture, it can be dried in a drying cabinet at 60°C. However, the drying time depends on the load and the items to be washed.

Instruction

1. Preparation of talc glass (Part 1)
   - The filling is sterile either in the pharmacy or via direct filling onsite with a sterile metal funnel on the operating table – Recommended filling quantity: 3 - 5 gr.
   - Remove the stainless-steel cap or sterile seal (not necessary for direct filling).
   - Screw on the atomizer main body (Part 2), observing the correct positioning of the red ring gasket.
   - We recommend replacing this seal if cracks or other damage are visible.

7248 S. Tucson Way, Centennial, Colorado 80112, USA / Toll free: 800.821.7496 / Local: 303.790.9411 / Fax: 303.792.2606
info@sontecinstruments.com / SontecInstruments.com

2. Connecting the bellows (Part 3) or the adapter piece (not shown) for the compressed air supply to the atomizer main body (Part 2)
3. Connecting the distributor pipe (Part 4) to the rotatable attachment of the atomizer main body (Part 2)



Functional Test

After drying is complete, perform the following:

- A visual inspection for cleanliness and damage
- The assembly of the instruments
- The care of the moving steel parts before sterilization with steam-permeable care oil (e.g., paraffins according to Ph.Eur.)
- A functional test

If necessary, repeat the reprocessing procedure until the instrument is optically clean.

- Important: Insulated instruments with electrosurgical connections (for example: electrodes, electrosurgical forceps, or electrosurgical scissors) and their insulation are to be checked for pressure marks or damage such as cracks, rough surface, warping, chipping, or discoloration. Instruments with such changes and damage may no longer be used and must be discarded!
- Defective products may only be repaired by DUFNER Instrumente GmbH. Unauthorized modifications and repairs are strictly prohibited and will void the manufacturer's warranty. Before being returned for repair, defective products must have first undergone the entire reprocessing procedure. Contact Sontec customer service for repair inquiries, and a Certificate of Sterilization will be provided with which to confirm the processing / decontamination status.
- MICASEPT instruments must be returned no later than 24 months after the first use to check the MICASEPT Sealing System. If the MICASEPT instruments are not used under CO2 pressure, the majority of which are in the fields of VATS / thoracoscopy, the inspection of the MICASEPT sealing system must be carried out no later than 36 months after usage.
- Suction irrigation instruments are to be greased with a sterilizable care grease prior to assembly.

Packaging

Sort the cleaned and disinfected instruments into the sterilization trays and package them in disposable containers (single or double) and/or sterilization containers that meet the following requirements:

- Accordance with DIN EN ISO 11607 and EN 868-2 to -10.
- Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F) with sufficient vapor permeability).
- Adequate protection of instruments or sterilization packaging from mechanical damage.
- Regularly maintained according to the sterilization container manufacturer's instructions.

[Validated method: Hospital-typical packaging (paper / foil packaging)]

Sterilization

The recommended steam sterilization of the products is carried out using a fractionated pre-vacuum method (according to ISO 13060 / ISO 17665), taking into account the respective national requirements (3 pre-vacuum phases with at least 60 millibar pressure).

7248 S. Tucson Way, Centennial, Colorado 80112, USA / Toll free: 800.821.7496 / Local: 303.790.9411 / Fax: 303.792.2606
info@sontecinstruments.com / SontecInstruments.com

Sterilization parameters by region/country (standard):

Europe: Temperature 134°C, holding time minimum 4 minutes.

USA: Temperature 132°C, holding time minimum 4 minutes.

Others: Temperature 132-137°C, holding time minimum 4 minutes.

[The validation was performed on the worst case in the half-cycle process at 132°C for 2 minutes.]

Drying time: At least 20 minutes. Plasma sterilization is **not** possible because of the plastic parts present!

Information About the Validation of the Treatment

The following test instructions, materials, and machines were used in the validation by CleanControlling GmbH Project No. 7923A, 7924A, 7925:

- Detergent: Neodisher Mediclean Forte 0.5%; Dr. Weigert (alkaline).
- Disinfectants: Bomix plus 1%, Bode.
- Neutralizer: Neodisher Z 0.1%; Dr. Weigert.
- Cleaning disinfection device: Miele PG 8535.
- Sterilization: Pre-vacuum procedure in half cycle.

If the chemicals and machinery described above are not available, it is up to the user to validate their procedure accordingly. It is the responsibility of the user to ensure that the reprocessing procedure, including resources, materials, and personnel, is adequate to achieve the required results. The state-of-the-art and national laws require compliance with validated processes. The use of a washer-disinfector in accordance with the ISO 15883 series of standards is required.

Storage

The sterilized instruments must be stored as directed by the sterile packaging manufacturer to maintain an effective sterile barrier.

- Temperature: -20°C - +50°C
- Relative humidity: 0 - 75%, non-condensing
- Air pressure: 500 - 1600 hPa

Useful Life/Max Treatment Cycles

Due to the product design and the materials used, no defined limit can be set for the maximum number of reprocessing cycles that can be performed. The service life of medical devices is determined by their function and gentle handling. The user can determine the end of life of the product themselves by visual and functional inspection during each reprocessing.

Disposal

If cleaning is not possible, the instrument must be separated and excluded from further use, then properly disposed of. If the instrument can no longer be used due to wear or damage, it must be properly disposed of. This means that the instruments must be dismantled (if possible), the impurities removed, and the instruments sterilized again before disposal.

Repairs

If a repair of the instrument is necessary, please send it to us for an optimal result. MICASEPT and CLICASEPT instruments in particular can only be repaired correctly by DUFNER. Instruments will only be accepted for repair or service if they have been cleaned, disinfected, and sterilized in accordance with the preparation instructions described above. A corresponding Certificate of Sterilization must be enclosed with the return shipment. Contact Sontec customer service with all repair-related inquiries.

Warranty

The products are manufactured from high-quality materials and are subjected to quality control before delivery. However, should problems occur, please contact our service department. We cannot provide a guarantee that the products are suitable for every respective procedure in which they are to be applied. This must be determined by the user. Sontec Instruments, Inc. assumes no liability if it can be proven that these operating instructions have been violated.

7248 S. Tucson Way, Centennial, Colorado 80112, USA / Toll free: 800.821.7496 / Local: 303.790.9411 / Fax: 303.792.2606
info@sontecinstruments.com / SontecInstruments.com

SYMBOLS USED ON LABELING		
Manufacturer	Date of Manufacture	Consult Instructions for Use
REF Reference Number	LOT Lot Number	QTY Quantity
Caution! See Warnings and Precautions.	NON STERILE Packaged Non-Sterile	Rx Only U.S. Federal law restricts this device to sale by or on the order of a physician.
Handling & storage only in a dry location.	1°C 35°C Handling & storage only between 1°C – 35°C.	

Sontec Instruments Inc.
7248 South Tucson Way
Centennial, CO 80112 USA
Phone: (800) 821-7496
Fax: (303) 792-2606
www.sontecinstruments.com