

Swirler Aerosol System

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Instructions for Use

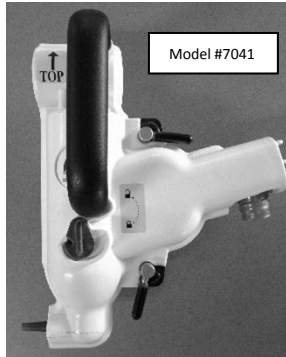
Swirler Aerosol System

Intended Use: Aerosol Delivery and Trapping System

CONTRAINDICATIONS: Hypersensitivity to any component of this product.
CAUTION: Federal law restricts this device to sale by or on the order of a physician.
CAUTION: Patient shall be constantly monitored by a trained Nuclear Medicine Technologist.
CAUTION: For Single Patient Use only. Re-use could result in patient cross-contamination.
CAUTION: Read DTPA package insert prior to use.

ASSEMBLY INSTRUCTIONS

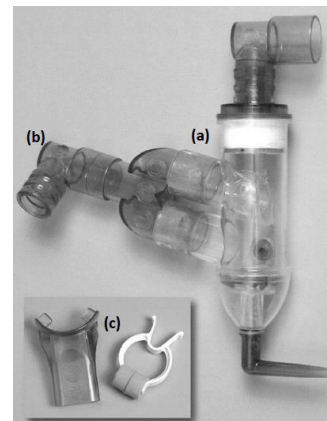
1. Remove the *Swirler* Aerosol System components from its packaging. **Swirler Aerosol System includes:** (a) Aerosol System and (b) patient "L" Connector. **Swirler Aerosol System includes:** (a) Aerosol System, (b) patient "L" Connector and (c) Tru-Fit Mouthpiece and Noseclip.
2. Attach O₂ tubing to the *Swirler* O₂ stem by holding the stem at its elbow with the opposite hand and pushing firmly.
3. Connect the loose end of the O₂ tubing to the O₂/air source.



4. Attach the required *Swirler* Ultra Shield (Swirler Aerosol System) to an IV pole or table surface.

CAUTION: The Shield must be mounted in the upright position.

5. Attach the *Swirler* Aerosol System assembly to the retaining clips on the front of the Shield cover. When the injection stopper aligns with the injection access site in the front Shield cover, snap the assembly securely in place.
 6. Align the front Shield assembly, complete with the *Swirler* Aerosol System and attached O₂ tubing, with the back Shield (mounted in Step 4) and securely latch, as indicated, into the locked position.
- CAUTION:** The Shield must be securely latched.
7. Check for proper O₂/air flow by slowly adjusting the O₂/air flow to 8 liters per minute at 50 psi (.34 MPa). Place hand over the exhaust of the *Swirler* Aerosol System to ensure a steady O₂/air flow.
- NOTE:** If a water bottle or humidifier is attached to the O₂/air source, it must be detached for the system to operate properly.
8. Turn off the O₂/air source.
 9. Read the DTPA package insert. Prepare and store the Tc99m DTPA pharmaceutical according to the manufacturer's instructions. **Suggested Protocols:** A typical patient dose is in the range of 15mCi (555MBq) per cc (ml) for pre-perfusion and twice that for post-perfusion imaging with 2cc (2ml) as a usual volume.
 10. Inject the pharmaceutical into the *Swirler* Aerosol System through the injection site.



PATIENT SETUP

1. Secure the mouthpiece to the patient “L” connector.
2. Position IV pole with the Shield assembly on the patient’s right side, close enough for the mouthpiece connection to the patient.
3. Align the mouthpiece and patient “L” connector to the patient and secure “L” to the *Swirler* Aerosol System.
4. Place the mouthpiece in the patient’s mouth.



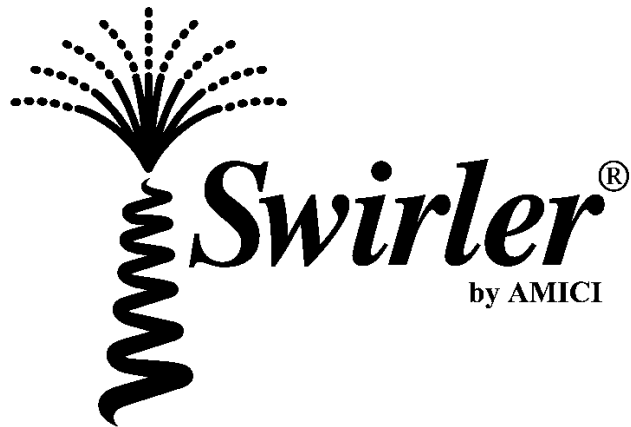
- NOTE:** For a good seal, make sure the tongue is under the mouthpiece (not occluding the opening), the bite bars separate the teeth, and the lips are over the mouthpiece flange.
5. Remove skin oils from the patient’s nose with an alcohol swab before applying Noseclip.
NOTE: The coordination of a respiratory technician is recommended for a ventilator-assisted patient. The patient “L” connector may be connected directly to the patient’s trach tube; no adapter is required.

OPERATING INSTRUCTIONS

1. To ensure that the O₂/air flow is unimpeded and the patient is familiar with the breathing techniques, instruct the patient to take several test breaths (normal tidal breathing) from the system before the O₂/air flow is turned on.
CAUTION: In order to reduce the risk of pharmaceutical leakage into the environment, ensure that all connections are secure before initiating O₂/air flow.
2. Gradually turn on the O₂/air flow (taking two to four seconds, maximum) to attain a flow rate of 8 liters per minute at 50 psi (.34 MPa). **CAUTION:** Abruptly turning the flow rate to a higher setting may detach O₂ tubing from the *Swirler* Aerosol System.
3. Instruct the patient to breathe normally, through the system, until the desired amount of pharmaceutical is delivered to the lungs. Breath holding is unnecessary.
NOTE: Be prepared throughout the procedure to shut off O₂/air flow immediately if the patient disconnects from the system.
4. At the completion of the prescribed inhalation period, turn off the O₂/air flow.
5. Detach the system from the patient after three or four additional breaths to purge the system of residual aerosol.

DISPOSAL INSTRUCTIONS

1. Prior to removing the *Swirler* Aerosol System from the Shield, label disposal bag appropriately.
CAUTION: Adhere to hospital protocol for the disposal of radioactive and biohazardous materials. After using the *Swirler* Aerosol System one time, it must be disposed of, along with the mouthpiece and Noseclip.
2. Disconnect O₂ tubing from the O₂ stem.
3. Unlock the front Shield assembly from the back Shield with the *Swirler* Aerosol System still attached.
NOTE: The cover assembly shields from radiation exposure.
4. While holding the detached front Shield assembly upright, slide the disposal bag up over the complete assembly. Place pressure against the *Swirler* Aerosol System to dislodge it from the cover assembly into the disposal bag.
5. Upright bag, draw tie and place in decay storage.



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