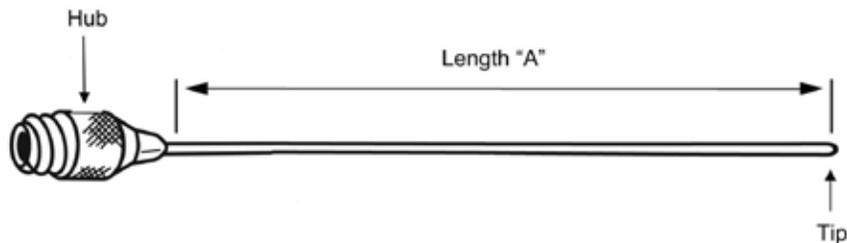


Guide to measuring a straight, custom-length MicroSprayer - Model IA-1B



All Penn-Century aerosol drug delivery devices are available in custom lengths for intratracheal or other uses in larger species, in other locations of the body, or in *in-vitro*, *ex-vivo*, or other experimental laboratory set-ups. The intratracheal portion (Length A) may be straight, or have a bend.

For optimal intratracheal aerosol deposition in the lung and to avoid injury to the animal, the device must be measured correctly to assure that the portion inserted into the trachea is long enough to reach near to but not touching the carina (first bifurcation). In larger animals it may also be possible to insert the device in one lung, if desired. **It is the responsibility of the user to determine the correct measurement for their particular use.**

Methods of measuring the delivery tube for *in vivo* intratracheal use

If the custom MicroSprayer® Aerosolizer – Model IA-1B will be inserted in the trachea directly, or via an endotracheal tube in a large animal, or used in a custom in-vitro lab set-up, it will require several steps to determine the correct length. Various methods have been used for determining the correct measurement for intratracheal use in larger animals, including:

- Dissecting an animal of similar size
- Using radio-opaque imaging agents to visualize the trachea
- In a primate, measuring the distance from the mouth to the teat (which is parallel to the carina) and adding an additional amount to assure sufficient length
- Ordering a Tubing Sample Kit from Penn-Century

Location of intratracheal portion is important to results

In prior published studies, optimal lung deposition is achieved when the very tip of the MicroSprayer® Aerosolizer is positioned near to, but not touching the carina. If the user plans to insert the device via an endotracheal tube, the tip of MicroSprayer® but emerge slightly past the end of the endotracheal tube. In this way, the aerosol can pass freely forward into the lungs, and not be forced into inner walls of the trachea or endotracheal tube.

General information: MicroSprayer® Aerosolizer – Model IA-1B

- The MicroSprayer® Aerosolizer – Model IA-1B is made of rigid stainless steel 19-gauge tubing with rounded tip. It has an outer diameter of .042" (1.1 mm) except at tip which is .048" (1.2 mm)
- Particle size range of the Model IA-1B: Mass Median Diameter of 25-30 µm (microns).
NOTE: Particle size was analyzed with water using laser defraction method. Results may vary depending on the drug or material being administered, the method of particle size analysis used, the length of the sprayer tip or the manner of use.
- The tip of the device contains small aerosolizing components that contribute to formation of the aerosol. The passages through there are approximately 140 microns in diameter.
- The device has a luer-type hub. It can be operated with 1-ml polycarbonate syringe (provided), or 0.5 ml glass, gas-tight syringe.
- For best results, all Penn-Century devices are designed so that the user must push the plunger of the syringe rapidly and with sufficient force to produce an aerosol spray.
- The MicroSprayer® Aerosolizer – Model IA-1B can be operated with a commercial 1ml polycarbonate syringe (provided) or an optional 0.5ml glass syringe (available for purchase). It is intended to be filled with one dose at a time. It cannot be loaded with multiple doses.
- The MicroSprayer® Aerosolizer is patented, and is the only air-free intratracheal device. Air must be eliminated from the syringe for the device to work as it is intended.
- Our glass or plastic syringes are clear. You can see inside and push out any air bubble that remains after it is filled. Both syringes have standard measurement marks on the outside. The can only be filled and used to administer one dose at a time.
- The Model IA-1B can be used with liquids or particles in liquid suspension (solutions) in a wide range of formulations from small molecules to bioactive compounds. It is the responsibility of the user to test their formulation with the MicroSprayer® and determine the feasibility of use at the dose intended.

Please select and read the section that applies to you:

___ **The MicroSprayer® Aerosolizer will be inserted directly into the trachea or elsewhere:**

- The user must pre-determine the correct length to assure that the portion inserted into the trachea reaches a point close to, but not touching the carina. The user may need to make this measurement by means of dissection or other means to establish the best length.

___ **The MicroSprayer® Aerosolizer will be inserted into the trachea via an endotracheal tube:**

- The MicroSprayer® Aerosolizer – Model IA-1B has an outer diameter of .042" (1.1 mm) except at tip which is .048" (1.2 mm)
- The inner diameter of the endotracheal tube must be large enough for the MicroSprayer® to pass through it easily.
- The MicroSprayer® Aerosolizer – Model IA-1B is not flexible . The user must take into consideration the anatomy of the animal they will be using. They must be able to insert the device straight down trachea of the anesthetized animal without needing to bend it.
- The user must pre-determine the correct length and placement of the endotracheal tube so that it reaches a point close to, but not touching the carina. The user may need to make this measurement by means of dissection or other means to establish the best length for the endotracheal tube.
- The MicroSprayer® measurement must be long enough to pass through the endotracheal tube AND emerge very slightly from the far end of it – so that the aerosol spray is not trapped inside the ET tube and can flow freely into the lungs.
- Marking the insertion point: The user can place some tape on the MicroSprayer® or a mark to indicate how far they will need to insert the MicroSprayer® into the endotracheal tube, once the animal has been intubated, to assure that the tip of the MicroSprayer® is emerging from the end of the endotracheal tube.
- Administering large dose volumes: The MicroSprayer® Aerosolizer – Model IA-1B can only be operated with a commercial 1ml polycarbonate syringe, provided by Penn-Century, or a 0.5ml glass Hamilton syringe, as specified by Penn-Century. Administration of dose volumes larger than 1ml may require the user to detach and refill the syringe provided multiple times, while maintaining the MicroSprayer® in position in the trachea. The user may also purchase additional plastic syringes at a nominal cost. These can be filled in advance to more easily administer doses larger than 1ml.
- Sterilizable and reusable: The MicroSprayer® Aerosolizer – Model IA-1B is made of stainless steel and other resistant components that can be re-used, sterilized, sonicated, autoclaved and/or flushed with any organic solvent.

___ **The MicroSprayer® Aerosolizer will be used in a custom, in-vitro lab set-up:**

- The MicroSprayer® Aerosolizer – Model IA-1B is made of rigid stainless steel 19-gauge tubing with rounded tip. It has an outer diameter of .042" (1.1 mm) except at tip which is .048" (1.2 mm)
- Particle size range of the Model IA-1B: Mass Median Diameter of 25-30 µm (microns).
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- The tip of the device contains small aerosolizing components that contribute to formation of the aerosol. The passages through there are approximately 140 microns in diameter.
- The device has a luer-type hub. It can be operated with 1-ml polycarbonate syringe (provided), or 0.5 ml glass, gas-tight syringe.
- For best results, all Penn-Century devices are designed so that the user must push the plunger of the syringe rapidly and with sufficient force to produce an aerosol spray.
- The device is intended to be filled with one dose at a time. It cannot be loaded with multiple doses.
- If the device is to be used to deposit liquid aerosol particles onto a surface such as a cell culture medium, it is the user's responsibility to determine the rate and concentration of deposition of material, based on their own unique drug formulation.

For any additional questions, please contact Penn-Century, Inc. at: info@penncentury.com, or call us at 215-753-6540.