Designation: F 1573 – 95 (Reapproved 2000)

Standard Specification for Anesthetic Equipment—Oropharyngeal and Nasopharyngeal Airways[1]

This standard is issued under the fixed designation F 1573; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers minimum performance and safety requirements for oropharyngeal and nasopharyngeal airways for human use.

1.2 Size designations, dimensions, and tolerances; material compatibility; product marking and labeling; and packaging are considered.

1.3 Because of the wide variation in size and configuration of the human airway, various conditions of use, user preferences, and cost, this specification cannot cover all types of oropharyngeal and nasopharyngeal airways.

1.4 Standards for the types of airways not specifically addressed by this specification may be developed in the future.

1.5 This specification is not intended to limit the development of the other devices so long as the minimum safety and performance requirements stated herein are met.

2. Referenced Documents

2.1 *ASTM Standards:*

ANSI Z79.3-1983 Anesthetic Equipment—Oropharyngeal and Nasopharyngeal Airways[2]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *buccal end (flanged end)*—the end of the airway that is flanged and is expected to fit between the teeth or gums or against the external nares.

3.1.2 *nasopharyngeal airway*—a device intended to maintain the patency of respiratory passages through the nasal cavity into the pharynx.

3.1.3 *oropharyngeal airway*—a device intended to maintain the patency of respiratory passages through the oral cavity into the pharynx.

3.1.4 *pharyngeal end*—the end of the airway that is intended to be inserted into the patient's pharynx.

3.1.5 *shall*—the word "shall," as used in this specification, is to be understood as denoting a mandatory requirement.

3.1.6 *should*—the word "should," as used in this specification, is to be understood as denoting a recommendation that is a sound safety practice: it does not denote a mandatory requirement.

4. Size Designation

4.1 *Measurement System*—The metric system shall be the standard of measurement used. Other units of measure may be provided as supplemental information.

4.2 *Size*:

4.2.1 *Oropharyngeal Airways*—The size of oropharyngeal airways shall be designated by a number giving the nominal length in centimetres in accordance with Table 1[3,4] and Fig. 1(*a*) and (*b*).

4.2.2 *Nasopharyngeal Airways*—The size of nasopharyngeal airways shall be designated by a number expressing the inside diameter in millimetres as the primary dimension, in accordance with tolerances given in Table 2[3,4,5] and Fig. 1(*c*).

5. Materials and Manufacture

5.1 Airways shall be fabricated from plastics, or elastomeric materials, or from combinations of these materials.

5.1.1 Airways shall be nontoxic and compatible with the human tissue with which they are intended to be used, as determined by the implantation test in the *U.S. Pharmacopeia*.[6]

NOTE 1—The designs shown in Fig. 1 and Fig. 2 are intended to illustrate typical common types of airways for the purpose of size designation and marking, but are not otherwise intended to form a part of this specification.

5.1.2 All material should be resistant to changes or deterioration from normal concentrations of substances encountered during routine use.

5.2 Reusable airways shall be made of material capable of being sterilized. The manufacturer shall supply recommended methods of sterilization.

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[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.12 on Airways.

Current edition approved Jan. 15, 1995. Published April 1995.

[2] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

[3] Table 1 and Table 2 are intended to relate nominal size to the length (or diameter) of the airway. Clinical practice neither suggests nor requires the availability of all nominal sizes given in the tables.

[4] Sizes not shown may be added by interpolation.

[5] For nasopharyngeal airways, the actual outside diameter shall be designated on the product or the package label within ±0.5 mm (see X1.1.2).

[6] See *U.S. Pharmacopeia*, 12601 Twinbrook Pkwy., Rockville, MD 20852.

TABLE 1 Dimensions and Tolerances of Oropharyngeal Airways

Nominal Size of Airway	Length (L), mm	Tolerance, Length (L), mm
3	30	±2.5
3.5	35	±2.5
4	40	±2.5
4.5	45	±2.5
5	50	±2.5
5.5	55	±2.5
6	60	±2.5
6.5	65	±2.5
7	70	+5.0
...	...	−2.5
8	80	±5.0
9	90	±5.0
10	100	±5.0
11	110	±5.0
12	120	±5.0

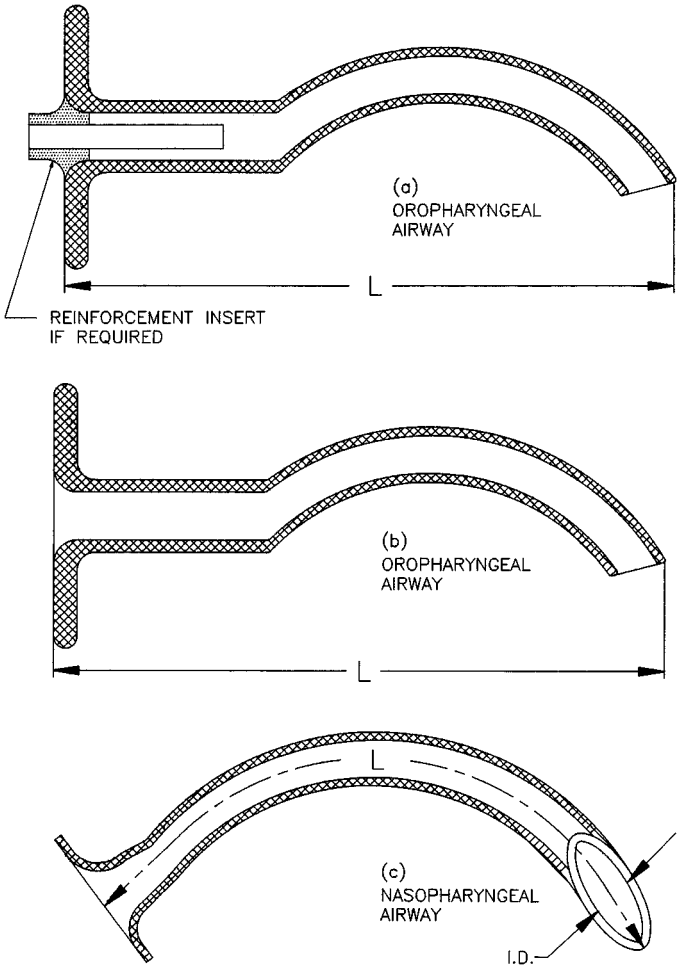

FIG. 1 Airway Length

5.3 Airways intended for single use or packages containing such airways shall be marked "Single Use Only" or "Do Not Reuse" (see 8.4 and 9.4).

6. Design

6.1 *Oropharyngeal Airways*:

6.1.1 Oropharyngeal airways should have sufficient rigidity to keep the base of the tongue in a forward position while the airway is in use.

TABLE 2 Dimensions and Tolerances of Nasopharyngeal Airways

Nominal Size of Airway	Inside Diameter, mm	Suggested Length, mm
5.0	5.0 ± 0.2	90
5.5	5.5 ± 0.2	100
6.0	6.0 ± 0.2	110
6.5	6.5 ± 0.2	120
7.0	7.0 ± 0.2	130
7.5	7.5 ± 0.2	140
8.0	8.0 ± 0.2	150
8.5	8.5 ± 0.2	160
9.0	9.0 ± 0.2	170

6.1.2 Oropharyngeal airways shall have sufficient rigidity at the buccal (flanged) end (by use of an insert, if necessary) to prevent collapse when bitten by the patient. Collapse shall have occurred when the airway has narrowed to the point of interfering with the passage of a correctly sized suction catheter or to a 25 % reduction in available airflow under incisor bite of 225 *N*. (See X1.1.5.1 and X2.1.2).

6.1.3 Edges and corners that may come in contact with the patient's tissues should have a minimum radius of curvature of 0.5 mm.

6.1.4 The oropharyngeal airway (or its package or package insert) should be clearly marked with the designation, " *DO NOT USE AS A BITE BLOCK*" to prevent incisor luxation that is a common sequel to such use of oropharyngeal airways.

6.2 *Nasopharyngeal Airways*:

6.2.1 The nasopharyngeal airway shall be constructed to prevent kinking in use. Kinking shall have occurred when the airway, bent into the same curvature as the human nasopharynx, has flattened to the point of interfering with the passage of a steel ball that is 50 % of the diameter of the airway lumen. (See X1.1.5.1 and X2.1.2)

6.2.2 Nasopharyngeal airways that have been preformed into the correct anatomical curvature shall be straightened for testing and shall not kink or interfere with the passage of the steel ball described in 6.2.1.

6.2.3 The diameter of the flange shall be at least twice the outside diameter of the tube.

7. Workmanship, Finish, and Appearance

7.1 Mismatch of surfaces produced by molds shall not cause a depression of one surface relative to another by more than 0.15 mm, if the surfaces were designed to produce a continuous surface. All surfaces shall be generally smooth and free of flash.

8. Product Marking

8.1 Each oropharyngeal airway shall be permanently and clearly marked with nominal size and name or trademark of the manufacturer as shown in Fig. 2(*a*) and 2(*b*). The nominal size should be further suffixed by the abbreviation," cm" (centimetres).

8.2 Each nasopharyngeal airway shall be permanently and clearly marked with the nominal size as shown in Fig. 2(*c*). The manufacturer's name or trademark shall also be marked on the

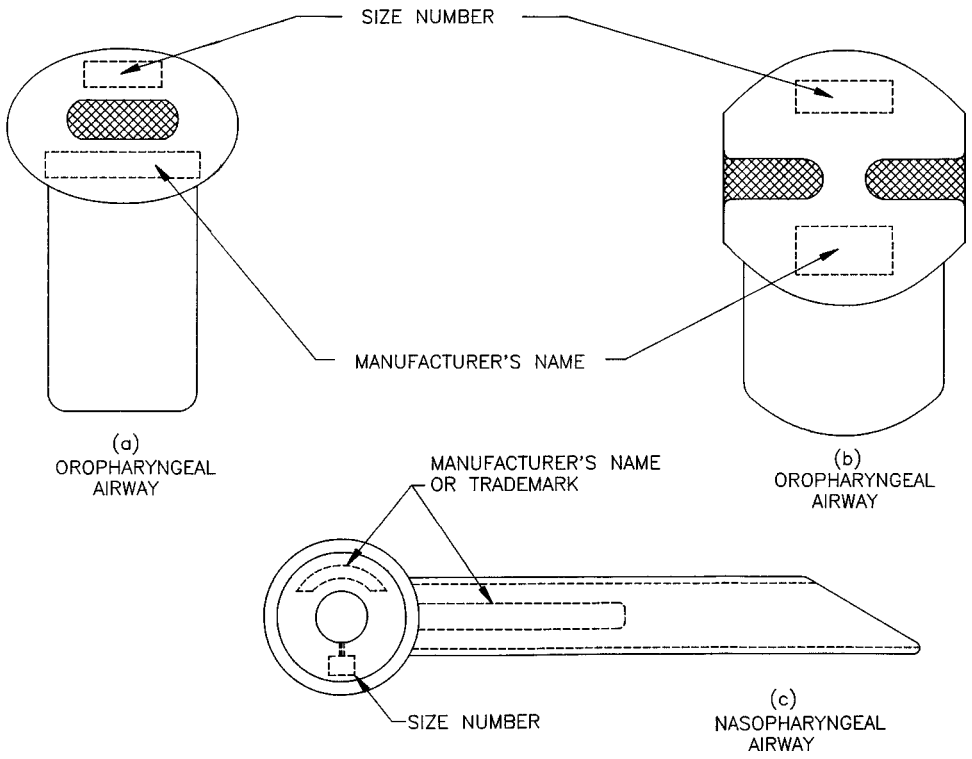

FIG. 2 Airway Marking

airway as shown in Fig. 2(*c*). The actual outside diameter to within ±0.5 mm, shall be included in the package label or on the product itself.

8.3 All required markings shall be clearly legible to the normal unaided eye.

8.4 All airways should be marked to differentiate those intended for single use from those that are intended to be reusable (see 5.3).

8.5 Airways shall be marked (or the package or package insert will record) either the date of manufacture, or a code that allows traceability to the date of manufacture.

9. Packaging and Package Marking

9.1 Airways may be marketed in a sterile or a nonsterile condition.

9.2 Airways marketed as sterile shall be in properly sealed packages capable of maintaining the sterile integrity of the airways under normal conditions of shipping and storage. The manufacturer shall disclose, upon request, the test method used to verify package integrity.

9.3 For airways supplied in sterile form, the word *"STERILE"* and the lot or batch number shall be readily apparent on examination of the package.

9.4 The packages containing airways intended for single use shall be clearly marked "Single Use Only" or "Do Not Reuse."

9.5 If individually packaged, the size of the airway shall be readily apparent on examination of the package. The size should be marked on the package label in bold print for ease of identification.

10. Precision and Bias

10.1 No statement is made about either the precision or bias of test methods of X2.1.2.1 or X2.1.3.2, since the results merely state whether there is conformance to the specification as described.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The following rationale is provided for the requirements in this specification. The section and subsection numbers given in parentheses refer to the correspondingly numbered sections and subsections in the text.

X1.1.1 *Size of Oropharyngeal Airways*—A nominal number is assigned to airways falling within certain dimensions. This size designation provides the user with a rapid means of determination for the proper airway and also for an equivalent product. The marking of oropharyngeal airways only by millimetre length, for instance, might prove to be confusing because the actual measured dimension would not be immediately familiar to the user. (See 3.1.3.)

X1.1.2 *Nasopharyngeal Airways*—Both inside and outside diameter are important dimensions when considering what airways to use. The passage of the airway will be influenced by the outside diameter, and passage of a suction catheter through the lumen of the airway must also be considered. Although materials are specified in this specification, it is possible that, in the future, manufacturing processes and new materials will result in significant changes in the wall thickness of the airway. If only one dimension is provided, the user will have insufficient data for comparison. (See 3.1.2.)

X1.1.2.1 Tolerances must be specified so that in the worst case, the nearest possible size of suction catheter may be passed through the nasopharyngeal airway. For example, it should be possible to pass a 16 French (5.3 ± 0.15 mm) through a 6-mm airway. The tolerance of ±0.2 mm, that is possible under current manufacturing practice, would allow this passage to occur without reaching the point of an interference fit.

X1.1.2.2 The outside diameter is less critical than the inside diameter, and a tolerance of ±0.5 mm would be allowable if the airway conforms to the sizing given in Table 2.

X1.1.3 The nasal airway must flex and compress as it is passed through the nares. Metal is not sufficiently pliable for this purpose. (See 4.1.)

X1.1.3.1 Both oropharyngeal and nasopharyngeal airways will be in contact with the mucosa for prolonged periods and shall be compatible with these tissues. (See 4.2.1.)

X1.1.3.2 Anesthetic gases, water soluble lubricants, topical anesthetics, and other agents are commonly used with airways. To test all possible combinations of all possible substances would be prohibitively expensive. The committee has not been presented with sufficient data to justify such extensive testing. (See 4.2.2.)

X1.1.4 Manufacturers supply recommended methods of sterilization for reusable devices, as required by Food and Drug Administration regulations. (See 4.2.)

X1.1.4.1 Disposable airways are marked to differentiate them from reusable airways. These markings are important as a reprocessed disposable device may fail to perform adequately. (See 5.3)

X1.1.5 One of the primary purposes of the oropharyngeal airway is to prevent soft tissue obstruction of the human airway by the tongue. If the oropharyngeal airway were to collapse (for example, when heated to body temperature), this purpose would be defeated. (See 5.1.1.)

X1.1.5.1 Oropharyngeal airways are often used to maintain an air passage or as a route for suctioning patients who are unconscious or suffering from seizure disorders. In these cases, patients may bite down on the airway. The airway should not collapse and occlude the air passage. The biting force of the incisor of an adult male has been determined to be an average of 225 *N*. No data was available for biting force of a patient under seizure. (See 5.1.2.)

X1.1.5.2 Any sharp corners or edges on the device may cause tissue damage to the surrounding mucosa. (See 6.1.3.)

X1.1.5.3 A radius of curvature has not been specified for the human nasopharynx due to wide anatomic variation. A suggested guideline for test purposes is 5 cm. The manufacturer should specify in the product labeling any limitations regarding radius of curvature. (See 6.1.3.)

X1.1.5.4 It is important that the flange diameter be twice the tube diameter, to minimize the possibility that the airway may slip into the patient's posterior pharynx. (See 6.2.3.)

X1.2 *Finish*—Flash and other rough surfaces may cause mucosal damage during airway use. (See Section 6.)

X1.2.1 Several reports have indicated that the semirigid Guedel-type oropharyngeal airway (among other types) does not adequately distribute the force of jaw closure, and that it prevents the upper and lower incisors from gliding past each other during biting. As a result, the forward luxation of the upper and lower incisors commonly results. An acceptable bite block is one which distributes force of biting to one or both sets of molars that are in direct opposition. (See 6.1.4.)

X1.2.2 These permanent markings provide the only means of size identification and product traceability. (See 9.1 and 9.2.)

X1.2.3 Unless the markings of "Do Not Reuse" or "Single Use Only" is on the device, the user cannot differentiate between reusable and disposable devices of similar appearance. Often, the individual who removes the airway is not the person who initially put the device in place and package information is of no value under these circumstances. (See 9.4.)

X1.2.4 No standardized test method for this requirement is possible, given the variety of packaging types and numerous test methods available. (See 8.2.)

X1.2.5 Materials used in the manufacture of oropharyngeal and nasopharyngeal airways may become less compliant and more susceptible to breakage with age. It has been noted, however, that only in rare circumstances will age affect the characteristics of airways, and a manufacturer's code will adequately identify airways.

X2. TEST METHODS

X2.1 The following test methods are provided for the requirements in this specification. The section and subsection numbers given in parentheses refer to the correspondingly numbered sections and subsections in the text.

X2.1.1 *Visual and Dimensional Inspection* (see 3.1.2):

X2.1.1.1 For reusable devices, read the instructions and sterilize or disinfect accordingly. Then perform the tests in accordance with X2.1.2 or X2.1.3, as applicable. (See 4.2.)

X2.1.1.2 For disposable devices, visually inspect the package or device for proper labeling. (See 5.3.)

X2.1.2 *Test Method for Collapse at Bit Block Area (Oropharyngeal Airways) (see* 5.1.2*)*:

X2.1.2.1 *Apparatus*—A compression tester similar to that shown in Fig. X2.1 should be used. A tensile testing machine, with compression fixture, may be substituted.

X2.1.2.2 *Procedure*—Precondition test samples in accordance with applicable tests in *Plastics—General Test Methods, Nomenclature*, ASTM Part 35,[7] for the material being tested. Before insertion into the test fixture, bring the test unit to a temperature of ±1°C. Apply a force of 225 N to the bite block area of the airway for 3 min. The airflow through the airway, while holding constant pressure as measured on the flowmeter, shall be at least 75 % of the original value as measured before the force was applied. An initial flow of 10 L/min is suggested.

X2.1.2.3 Using radius gage, measure correct radius of curvature. (See 6.1.3.)

NOTE X2.1—The above procedure in X2.1.2.2 is feasible, though technically difficult, as a means of testing oropharyngeal airways of the Guedel, Connell, and Waters types. It is not feasible as a test for the Berman airway. It has been suggested that a steel ball test (see X2.1.3) be used as an alternative test for all oropharyngeal airways, including the Berman airway. (For descriptions of the various airway types, see Footnote 8.[8] (See 6.1.4.)

X2.1.3 *Test for Kinking (Nasopharyngeal Airways) (See* 6.2.1*)*:

X2.1.3.1 *Apparatus*—A test fixture similar to that shown in Fig. X2.2 should be used.

X2.1.3.2 *Procedure*—Precondition test samples in accordance with applicable tests in *Plastics—General Test Methods, Nomenclature*, ASTM, Part 35,[7] for the material being tested. Prior to insertion into the test fixture, bring the test specimen to a temperature of 37 ± 1°C. Position the test specimen in the fixture so its inside radius of curvature is placed on the 5-cm scribed line of the test fixture. Anchor the distal end of the test

[7] Available from ASTM International, 100 Barr Harbor Dr., PO Box C700, West Conshohocken, PA 19428.

[8] Dorsch, J. A., and Dorsch, S. E., *Understanding Anesthesia Equipment*, Second Edition, Wiliams and Wilkins, Baltimore, MD, 1984, pp. 332–333.

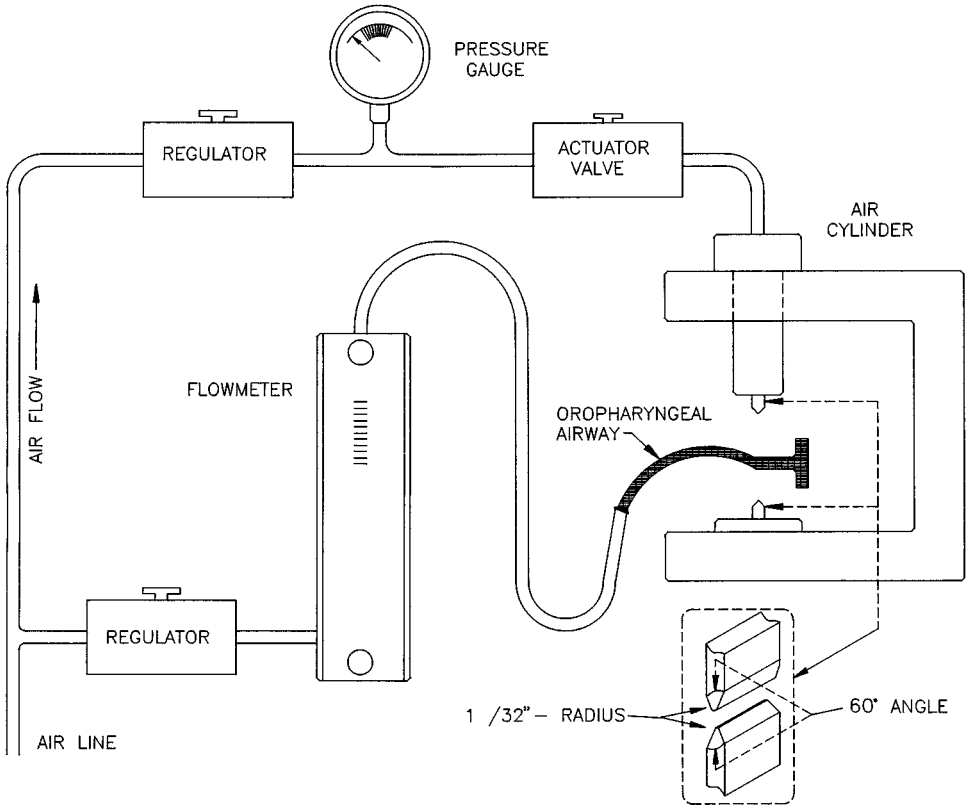

FIG. X2.1 Compression Tester

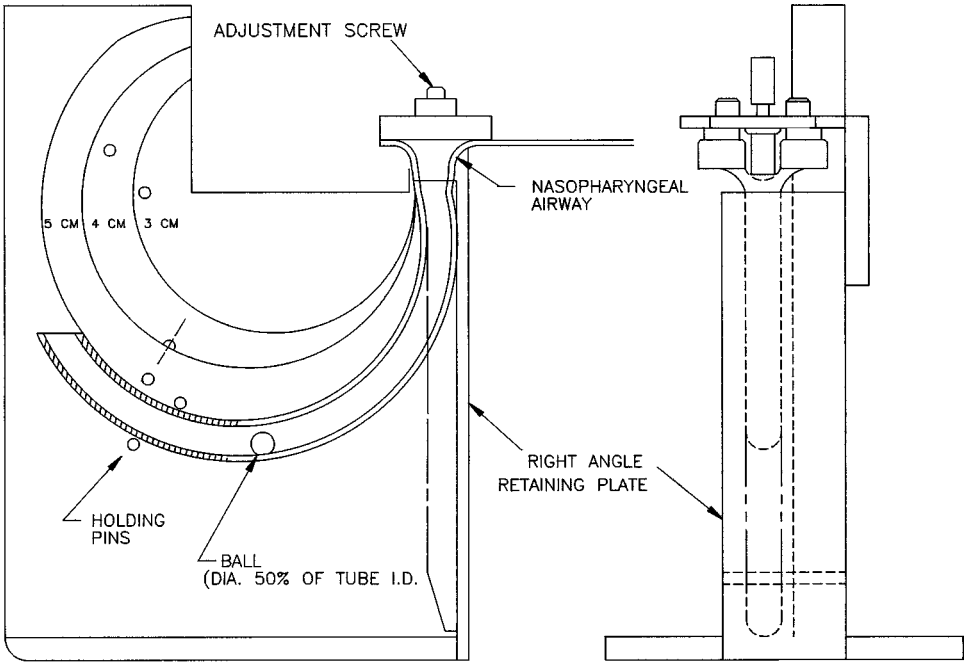

FIG. X2.2 Kinking Test Fixture

specimen between the pins provided on thescribed line. Drop a steel ball that is 50 % of the diameter of the airway lumen into the flanged end of the test specimen. The ball should pass through the lumen of the airway without interference. After the ball is removed, return the curved airway to the straight vertical position and anchor the distal end between the pin and right-angle retaining plate. Drop the steel ball into the flange of the test specimen. If the ball passes all the way through to the pinned areas at the distal end without interference, the airway passes the test.

X2.1.3.3 Using vernier calipers or optical comparator, measure the diameter of flange compared to the outside diameter of the airway tube. (See 6.2.3.)

X2.2 *Finish*—Using calipers or micrometer, measure adjacent surfaces for mismatch resulting in sharp edges. (See Section 6.)

X2.2.1 For reusable devices, after processing in accordance with the manufacturer's instructions, visually inspect for deterioration of markings. (See 8.1 and 8.2.)

X2.2.2 Visual inspection. (See 8.3, 8.4, and 8.5.)