K830228

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 28 1983

Mr. Curtis H. Miller
Vice President of Operations
Micromedics, Inc.
320 Chester Street
St. Paul, Minnesota 55107

Ref: K830228
Various Otological Ventilation Tubes
Dated: January 15, 1983
Received: January 24, 1983

Dear Mr. Miller:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Standards) or class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Office of Medical Devices, Division of Compliance Operations (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G Britain

Robert G. Britain
Associate Director for
Device Evaluation
Office of Medical Devices
National Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date 2/14/83

From Reviewer(s)- Name(s) Mija Browne

Subject 510(K) Notification K830228

To The Record

It is my recommendation that the subject 510(K) Notification;

✓ (A) Is substantially equivalent to marketed devices.

___ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

___ (C) Requires more data.

___ (D) Is an incomplete submission. (See Submission Sheet)

Additional Comments:

Class Code w/ Panel: ETD

Otological Ventilation Tubes ~~&~~ by Micromedics are substantially equivalent to other ENT Tympanostomy tubes such as those by Richards Manufacturing. They are equivalent in materials, design, safety & efficacy.

REVIEW: _____ BRANCH CHIEF DATE

HLS 2/23/83

FINAL REVIEW: _____ DIVISION DIRECTOR 2/23/83 DATE

OPTIONAL REVIEW: _____ ASSOC. DIRECTOR FOR DEVICE EVAL. DATE

K830228

micromedics, inc.
320 Chester Street
St. Paul, Minnesota 55107
(612) 227-0770

January 15, 1983

Food and Drug Administration
Bureau of Medical Devices
HFK-20
8757 Georgia Avenue
Silver Spring, Maryland 20910

RE: 510 (K) Notification

Gentlemen:

Enclosed please find two copies of our 510 (K) Notification for otological ventilation tubes for your review. If you have further questions please contact the writer.

Thank vou for your attention to this matter.

Yours truly,

Curtis H. Miller
Vice President of Operations

CHM:nls

encl

micromedics, inc.
320 Chester Street
St. Paul, Minnesota 55107
(612) 227-0770

510 (K) Pre-Market Notification

for

Otological Ventilation Tubes

Prepared by:

Curtis H. Miller
Vice President of Operations

MICROMEDICS, Inc.
320 Chester Street
St. Paul, Minnesota 55107

612-227-0770

JANUARY 15, 1983

CONTENTS

PRODUCT NAMES

I. Common (Generic) Name: Tympanostomy Tubes

II. Other Common Names:

Eustachian Tubes
Myringotomy Tubes
Otological Ventilation Tubes
Otological Drain Tubes

III. Specific Product Names:

A. Ventilation Tube, Donaldson Design, Silicone
B. Ventilation Tube, Shepard Design, with tab, Silicone
C. Ventilation Tube, Shepard Design, with wire, Teflon
D. Ventilation Tube, Shepard Design, without wire, Teflon
E. Ventilation Tube, Paparella Design, Type I, Silicone
F. Ventilation Tube, Paparella Design, Type II, Silicone
G. Ventilation Tube, T-Tube Design, Silicone
H. Ventilation Tube, Armstrong Design, Silicone
I. Ventilation Tube, Per-Lee Design, 50 Degree, Silicone
J. Ventilation Tube, Per-Lee Design, 60 Degree, Silicone
K. Ventilation Tube, Umbrella Design, Type I, Silicone
L. Ventilation Tube, Umbrella Design, Type II, Silicone
M. Ventilation Tube, Straight Shank Design, 12mm, Teflon
N. Ventilation Tube, Straight Shank Design, 7mm, Teflon
O. Ventilation Tube, Sheehy Design, with wire, Teflon
P. Ventilation Tube, Sheehy Design, without wire, Teflon
Q. Ventilation Tube, Reuter Design, with wire, Stainless Steel
R. Ventilation Tube, Reuter Design, without wire, Stainless Steel
S. Ventilation Tube, Reuter Design, with wire, Teflon
T. Ventilation Tube, Reuter Design, without wire, Teflon

REGISTRATION NUMBERS

MICROMEDICS has completed and filed form FD-2891 for registration of medical device establishments.

As of this date we have not received notification of registration or a registration number.

CLASSIFICATION

These products have been classified as a Class II product.

PERFORMANCE STANDARDS

No specific performance standards have been promulgated for these devices.

Silicone tubes will be manufactured using medical grade materials purchased from (b) (4) [redacted] Incoming material will be certified and tested to meet manufacturer's specification for chemical purity and toxicity. Material will be compounded and molded under strict controls. Molded material will be further tested to assure correct physical properties and non-toxicity.

Teflon tubes will be manufactured using virgin material from (b) (4) [redacted]. This material is commonly used in a variety of implanted devices.

Stainless Steel tubes and wires will be manufactured using a 316L alloy of stainless steel. This material is extremely corrosion resistant and is non-magnetic. This material is widely used in the manufacture of surgical instruments and implants because of its bio-compatability.

The primary package for all tubes will be molded from polypropylene. Only (b)(4) [redacted] material will be used in the molding process.

PERFORMANCE STANDARDS (Continued)

Cleaning and packaging of all tubes will be done under strict controls in a "clean room" environment.

Finished product will be sterilized and tested for sterility in accordance with the United States Pharmacopoeia.

PACKAGING & LABELING

Ventilation tubes will be packaged individually, or in pairs, in a molded container. The container will be labeled as shown in figure 1.

The container will subsequently be packaged in a tyvek peel-pouch for sterilization. The pouch will be printed as shown in figure 2.

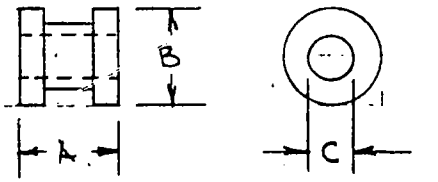
The sterilizable pouch will also contain a set of three patient record labels. These labels are to be affixed by the physician to the patients record, providing product traceability. A sample of these labels is shown in figure 3.

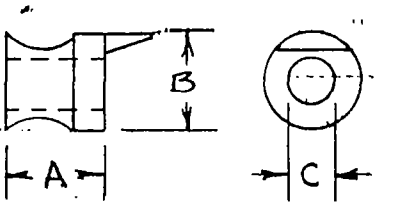
The sterilizable pouches will be packaged in a chipborad box. Each box will contain six pouches. A sample of the box label is shown in figure 4.

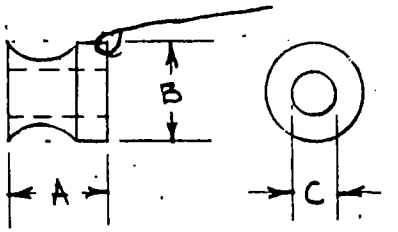
Each box will also contain a printed insert. A sample of this insert is shown in figure 5.

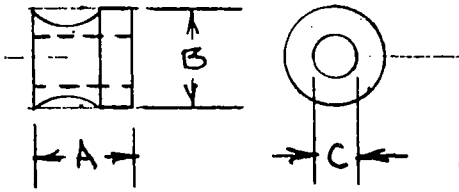
MICROMEDICS, INC.
510 (K) Pre-Market Notification
Ventilation Tubes
January 15, 1983

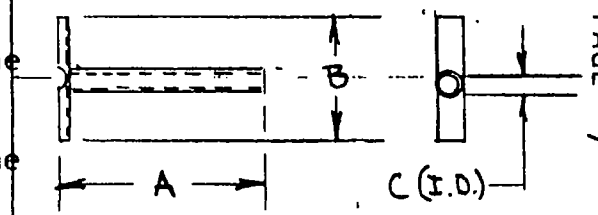
CATALOG NUMBER	DESCRIPTION	DIMENSIONS A	B	C	D	MAT'L
VT-0100-01	Donaldson Design 1 tube/pkg.	.090	.090	.045	-	Silicone
VT-0100-02	Donaldson Design 2 tubes/pkg.	.090	.090	.045	-	Silicone
VT-0200-01	Shepard Design with tab 1 tube/pkg.	.090	.063	.045	-	Silicone
VT-0200-02	Shepard Design with tab 2 tubes/pkg.	.090	.063	.045	-	Silicone
VT-0201-01	Shepard Design with wire 1 tube/pkg.	.090	.063	.045	-	Teflon
VT-0201-02	Shepard Design with wire 2 tubes/pkg.	.090	.063	.045	-	Teflon
VT-0202-01	Shepard Design without wire 1 tube/pkg.	.090	.063	.045	-	Teflon
VT-0202-02	Shepard Design without wire 2 tubes/pkg.	.090	.063	.045	-	Teflon
VT-0400-01	T-Tube Design 1 tube/pkg.	.500	.387	.045	-	Silicone
VT-0400-02	T-Tube Design 2 tubes/pkg.	.500	.387	.045	-	Silicone





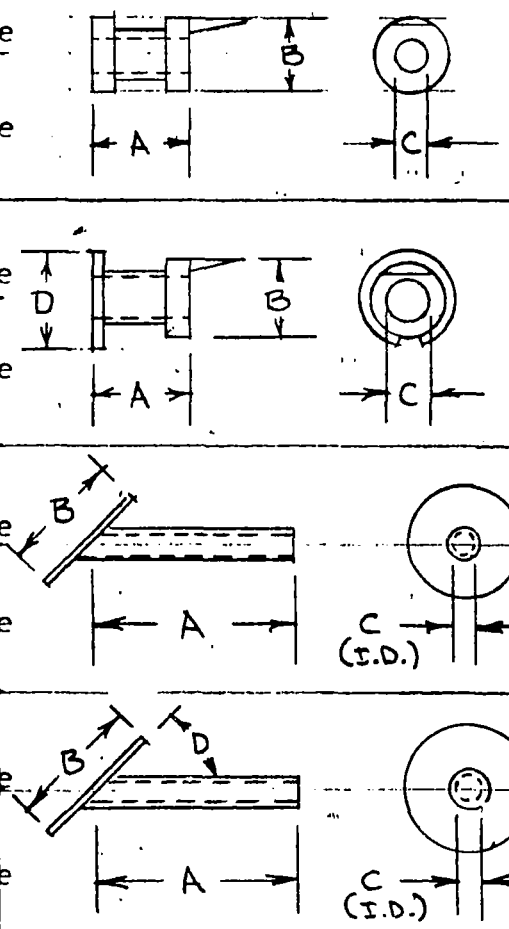






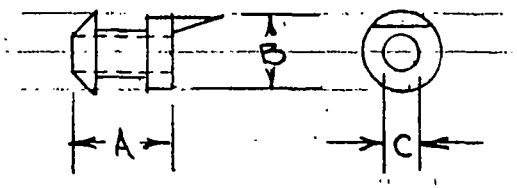
MICROMEDICS, INC.
510 (K) Pre-Market Notification
Ventilation Tubes
Januarv 15, 1983

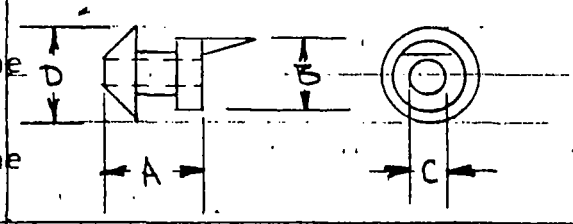
CATALOG NUMBER	DESCRIPTION	DIMENSIONS A	B	C	D	MAT'L
VT-0300-01	Paparella Design Tvpe I 1 tube/pkg.	.090	.090	.045	-	Silicone
VT-0300-02	Paparella Design Tvpe I 2 tubes/pkg.	.090	.090	.045	-	Silicone
VT-0301-01	Paparella Design Type II 1 tube/pkg.	.080	.110	.060	.173	Silicone
VT-0301-02	Paparella Design Type II 2 tubes/pkg.	.080	.110	.060	.173	Silicone
VT-0500-01	Armstrong Design 1 tube/pkg.	.275	.160	.045	-	Silicone
VT-0500-02	Armstrong Design 2 tubes/pkg.	.275	.160	.045	-	Silicone
VT-0600-01	Per-Lee Design 50 Degree 1 tube/pkg.	.470	.315	.060	-	Silicone
VT-0601-01	Per-Lee Design 60 Degree 1 tube/pkg.	.470	.315	.060	-	Silicone

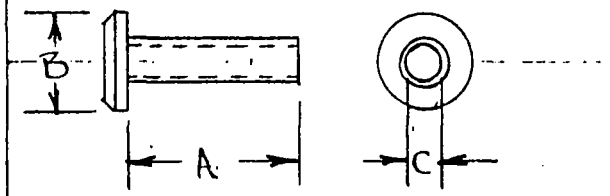


MICROMEDICS, INC.
510 (K) Pre-Market Notification
Ventilation Tubes
January 15, 1983

CATALOG NUMBER	DESCRIPTION	DIMENSIONS A	B	C	D	MAT'L
VT-0700-01	Umbrella Design Type I 1 tube/pkg.	.095	.090	.040	.100	Silicone
VT-0700-02	Umbrella Design Type I 2 tubes/pkg.	.095	.090	.040	.100	Silicone
VT-0701-01	Umbrella Design Type II 1 tube/ pkg.	.095	.125	.060	.188	Silicone
VT-0701-02	Umbrella Design Type II 2 tubes/pkg.	.095	.125	.060	.188	Silicone
VT-0900-01	Straight Shank Design 12mm 1 tube/pkg.	.470	.100	.045	-	Teflon
VT-0900-02	Straight Shank Design 12mm 2 tubes/pkg.	.470	.100	.045	-	Teflon
VT-0901-01	Straight Shank Design 7mm 1 tube/pkg.	.275	.100	.045	-	Teflon
VT-0901-02	Straight Shank Design 7mm 2 tubes/pkg.	.275	.100	.045	-	Teflon

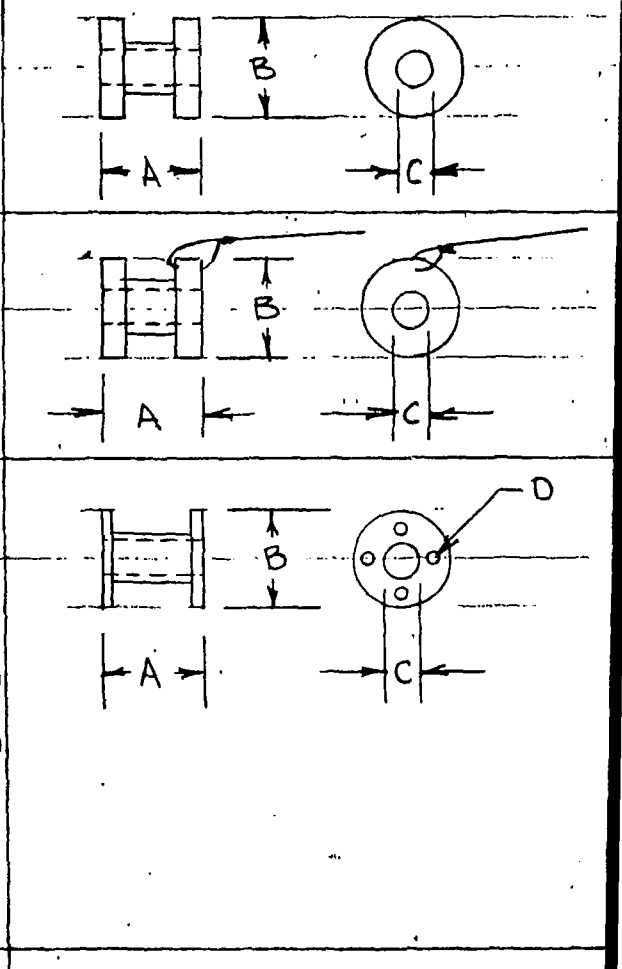






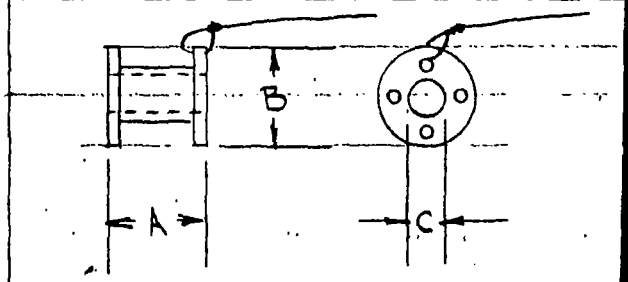
MICROMEDICS, INC.
510 (K) Pre-Market Notification
Ventilation Tubes
Januarv 15, 1983

CATALOG NUMBER	DESCRIPTION	DIMENSIONS A	B	C	D	MAT'L
VT-1001-01	Sheehy Design without wire 1 tube/pkg.	.080	.120	.050	-	Teflon
VT-1001-02	Sheehy Design without wire 2 tubes/pkg.	.080	.120	.050	-	Teflon
VT-1000-01	Sheehy Design with wire 1 tube/pkg.	.080	.120	.050	-	Teflon
VT-1000-02	Sheehy Design with wire 2 tubes/pkg.	.080	.120	.050	-	Teflon
VT-1201-01	Reuter Design without wire 1 tube/pkg.	.056	.112	.045	.014	SS
VT-1201-02	Reuter Design without wire 2 tubes/pkg.	.056	.112	.045	.014	SS
VT-1203-01	Reuter Design without wire 1 tube/pkg.	.056	.112	.045	.014	Teflon
VT-1203-02	Reuter Design without wire 2 tubes/pkg.	.056	.11[illegible]	.045	.014	Teflon



MICROMEDICS, INC.
510 (K) Pre-Market Notification
Ventilation Tubes
January 15, 1983

CATALOG NUMBER	DESCRIPTION	DIMENSIONS A	B	C	D	MAT'L
VT-1200-01	Reuter Design with wire 1 tube/pkg.	.056	.112	.045	-	SS
VT-1200-02	Reuter Design with wire 2 tubes/pkg.	.056	.112	.045	-	SS
VT-1202-01	Reuter Design with wire 1 tube/pkg.	.056	.112	.045	-	Teflon
VT-1202-02	Reuter Design with wire 2 tubes/pkg.	.056	.112	.045	-	Teflon



EQUIVALENT PRODUCTS

This product line was acquired by MICROMEDICS, Inc. from McGhan Medical Division of 3M Company. McGhan had been marketing the products, with FDA approval, since 1978.

In the transaction, MICROMEDICS acquired all of the inventory, equipment, tooling and documentation related to this line.

Initially, therefore, MICROMEDICS manufacturing will consist of completing and packaging products which were already being manufactured by McGhan.

We will subsequently be manufacturing our own products. We will use the tooling and documentation acquired from McGhan where possible.

In addition to having been marketed previously by McGhan/3M, MICROMEDICS ventilation tubes are substantially equivalent to other products marketed by the following companies:

Richards Manufacturing Company, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

EQUIVALENT PRODUCTS (Continued)

Storz Instrument Company
3365 Tree Court Industrial Blvd.
St. Louis, Missouri 63122

Xomed, Inc.
8641 Baypine Road
Jacksonville, Florida 32216

Copies of McGhan, Richards, Storz and Xomed catalogs are attached for reference.

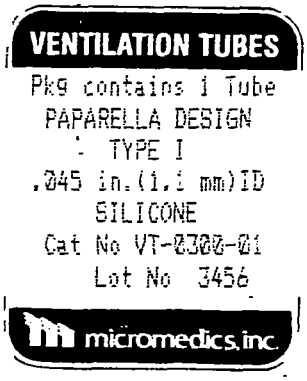


Fig 1 - Container Label (Typical)

PEEL

Contents sterile unless package opened or damaged

micromedics, inc.
ST. PAUL, MN.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

PEEL

Contents sterile unless package opened or damaged

micromedics, inc.
ST. PAUL, MN.

CAUTION: U.S. Federal law restricts this device to sale by or on the order *of a licensed physician.*

FIG 2 - Pouch Label (Typical)

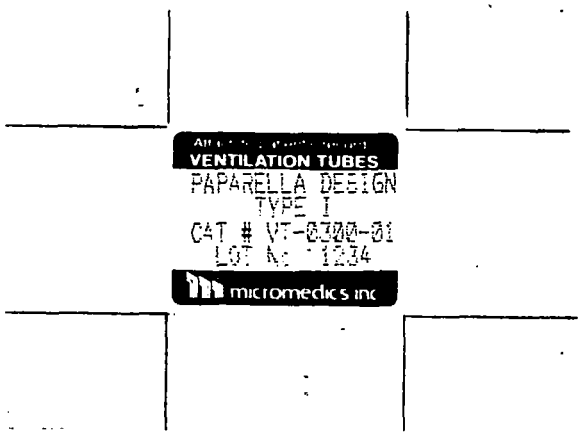


FIG 3 - Patient Record Label (Typical)

micromedics, inc.

320 Chester Street
St Paul Minnesota 55107
(612) 227-0770

Contents sterile unless
package opened
or damaged

VENTILATION TUBES

CONTENTS: 6 PACKAGES OF 1 TUBE
PAPARELLA DESIGN: TYPE I
.045 IN.(1.1 MM)ID: SILICONE
CATALOG NUMBER VT-0300-01
LOT NUMBER 1234
Sterility not g'nteed after 01/ 85

micromedics, inc.

CAUTION: U.S. Federal
law restricts this device to
sale by or on the order of
a licensed physician.

FIG 4 - Box Label (Typical)

Contraindications

There are no known contraindications to the use of an otological ventilation tube.

Precautions

Water should be prevented from entering an ear in which a ventilation tube has been inserted. Water could possibly cause contamination, or create a "stinging" sensation in the middle ear. Measures should be taken to prevent entry of water by providing the patient with ear molds or protective ear devices.

Product Is Supplied Sterile

These products are sterile in the sealed, unopened, undamaged secondary package. Do not implant any product which is not sterile.

Sterility

Sterilization of these products is by ethylene oxide gas under a tested, controlled cycle. Each lot is tested for sterilization according to United States Pharmacopeia standards. Sterility of the product is maintained only if the secondary package is sealed and undamaged. Sterility is not guaranteed after the expiration date marked on the package.

Package

Ventilation tubes are supplied in a sterile package with product identification marked on both primary and secondary packages. The primary package consists of a specially designed polypropylene case incorporating a positive closing lid. The secondary package is a sealed pouch made from uncoated Tyvek paper and poly mylar film. These packages are stored and shipped in a small box designed to accommodate and protect 6 packages.

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Lindeman, R.C. and H. Silverstein. "The Arrow Tube." *Archives of Otolaryngology*, 80 (Oct. 1964), 473.

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micromedics, inc.

320 Chester Street
St. Paul, Minnesota 55107
(612) 227-0770

Otological Ventilation Tubes

Description

Micromedics Otological Ventilation Tubes are designed for placement through the tympanic membrane to ventilate the middle ear space and, if present, drain fluid from the middle ear.

These tubes act as ventilation devices, allowing free exchange of air between the outer ear and middle ear space, equalizing the pressure on both sides of the tympanic membrane. When fluid is present the tube can also act as a drainage device, allowing fluid to drain from the middle ear space to the external auditory canal.

These tubes are available in a variety of materials, the choice of material being a matter of surgeon preference. The materials used by Micromedics to manufacture ventilation tubes, Teflon, Polyethylene, Silicone, and Stainless Steel. These materials have a long history of use as implanted medical devices and are well tolerated by body tissue for both long and short-term durations.

Indications

Where chronic eustachian tube dysfunction fails to respond to conventional therapy.

FIG 5a - Box Insert

To Open

1. Remove secondary package from box and peel open package under clean aseptic conditions by accepted sterile technique. Remove inner, primary package.
2. Working in a sterile field, carefully snap open lid of primary package.
3. Remove tube from primary package using a sterile instrument.

To Reclean

If the product becomes contaminated, wash thoroughly in a hot water and mild, non-oily soap solution. Do not use synthetic detergents or oil based soaps. Rinse thoroughly in hot water followed by distilled water and sterilize by one of the following methods.

To Resterilize

Place tube in a sterilizable case such as the original package supplied by miromedics, and place in a lint free pouch.

High speed (Flash) Instrument Sterilization: Sterilize a minimum of 3 minutes at 270°F, 30 psi (132°C, Kg/cm)

Standard Gravity Sterilization: Sterilize a minimum of 30 minutes at 250°F, 15 psi (121°C, 1kg/cm²)

Surgical Procedure

Proper surgical procedures and techniques are the responsibility of the medical profession. Each surgeon must evaluate the appropriateness of the procedure based upon current accepted techniques, medical judgement and experience. The following surgical procedure by Joseph R. DiBartolomeo, M.D. is provided for the purpose of general information only.

The surgical procedure is usually carried out under a local anesthesia in adults and cooperative children, or under brief general anesthesia. The ear canal is prepped and the largest speculum that can be accommodated by the ear canal is inserted. Too large a speculum or forceful insertion of the speculum may result in bleeding which will interfere with the surgeon's view. A conventional myringotomy is performed using either a flap or slit incision. Middle ear fluid, if present, is removed using suction techniques. This fluid is diluted by instilling normal saline from a syringe with a blunt tip needle through the myringotomy incision. After the fluid has been diluted by the saline, the middle ear is again suctioned clear of its fluid. The length of the slit incision should be kept to a minimum.

Tube Insertion

Ventilation tubes may be inserted using either a conventional tube inserter or small alligator type forceps. Grommet-type silicone tubes may be inserted using forceps, squeezing together the outer flange, thus enabling the surgeon to more easily visualize placement of the inner-flange through the myringotomy site. In addition, the compression of the tube into a flatter shape allows the tube to be inserted through an incision smaller than the outside diameter of the inner flange. On releasing the tube, the outer flange springs into place lateral to the tympanic membrane. Teflon, polyethylene, and stainless steel tubes can be inserted using either small forceps or a tube inserter. The insertion/removal tabs provided on certain tube styles can also act as an aid in insertion and positioning of the tube in the tympanic membrane. Current literature suggests that the ventilation tube be left in place until the eustachian tube regains its normal function. Depending on the etiology, the eustachian tube may no a few days or remain indefinitely imp condition has normalized, the tube r removed by the surgeon, or left until If extruded before the eustachian tu patent, a new ventilation tube may b Based on physician experience and ear should be examined periodically condition reappraised as to removal of the tube.

Tube Removal

It is seldom necessary to remove a a postoperative infection or prolong occur, a culture of the drainage and the organism should be obtained. If therapy is not effective in eradicatin or eliminating the drainage, removal considered. Grommet-type tubes ca by grasping the outer flange with sm pulling the tube straight out. Tubes integral removal tabs assist graspin of the tube. Attachment wires, provi tube designs, lie in the external aud provide an excellent removal aid.

Caution

United States Federal Law restricts sale by or on the order of a licensed

Warranty

Micromedics warrants that reasona used in the manufacture of this pro replace at no charge any product th feels was defective at the time of s

FIG 5b - Box Insert

MEDICS, INC.
K) Pre-Market
lation Tubes
ry 15, 1983

ry package from box and peel
der clean aseptic conditions by
echnique. Remove inner,

ile field, carefully snap open lid
ge.

m primary package using a

nes contaminated, wash
water and mild, non-oily soap
synthetic detergents or oil
thoroughly in hot water
water and sterilize by one of the

izable case such as the original
miromedics, and place in a lint

h) Instrument Sterilization:
um of 3 minutes at 270°F, 30 psi

Sterilization: Sterilize a
inutes at 250°F, 15 psi (121°C,

edure

cedures and techniques are the
medical profession. Each
uate the appropriateness of the
on current accepted
l judgement and experience.
cal procedure by Joseph R.
. is provided for the purpose
ion only.

The surgical procedure is usually carried out under a local anesthesia in adults and cooperative children, or under brief general anesthesia. The ear canal is prepped and the largest speculum that can be accommodated by the ear canal is inserted. Too large a speculum or forceful insertion of the speculum may result in bleeding which will interfere with the surgeon's view. A conventional myringotomy is performed using either a flap or slit incision. Middle ear fluid, if present, is removed using suction techniques. This fluid is diluted by instilling normal saline from a syringe with a blunt tip needle through the myringotomy incision. After the fluid has been diluted by the saline, the middle ear is again suctioned clear of its fluid. The length of the slit incision should be kept to a minimum.

Tube Insertion

Ventilation tubes may be inserted using either a conventional tube inserter or small alligator type forceps. Grommet-type silicone tubes may be inserted using forceps, squeezing together the outer flange, thus enabling the surgeon to more easily visualize placement of the inner-flange through the myringotomy site. In addition, the compression of the tube into a flatter shape allows the tube to be inserted through an incision smaller than the outside diameter of the inner flange. On releasing the tube, the outer flange springs into place lateral to the tympanic membrane. Teflon, polyethylene, and stainless steel tubes can be inserted using either small forceps or a tube inserter. The insertion/removal tabs provided on certain tube styles can also act as an aid in insertion and positioning of the tube in the tympanic membrane. Current literature suggests that the ventilation tube be left in place until the eustachian tube regains its normal function. Depending on the etiology, the eustachian tube may normalize within a few days or remain indefinitely impaired. If the condition has normalized, the tube may be removed by the surgeon, or left until self-extruded. If extruded before the eustachian tube becomes patent, a new ventilation tube may be reinserted. Based on physician experience and training, the ear should be examined periodically and the condition reappraised as to removal or reinsertion of the tube.

Tube Removal

It is seldom necessary to remove a tube. Should a postoperative infection or prolonged drainage occur, a culture of the drainage and sensitivity of the organism should be obtained. If conservative therapy is not effective in eradicating the infections or eliminating the drainage, removal should be considered. Grommet-type tubes can be removed by grasping the outer flange with small forceps and pulling the tube straight out. Tubes supplied with integral removal tabs assist grasping and removal of the tube. Attachment wires, provided on certain tube designs, lie in the external auditory canal and provide an excellent removal aid.

Caution

United States Federal Law restricts this device to sale by or on the order of a licensed physician.

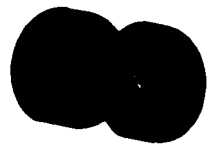
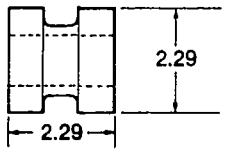
Warranty

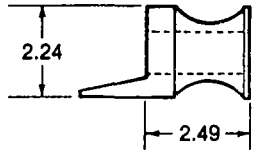
Micromedics warrants that reasonable care was used in the manufacture of this product, and will replace at no charge any product that Micromedics feels was defective at the time of shipment.

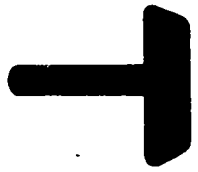
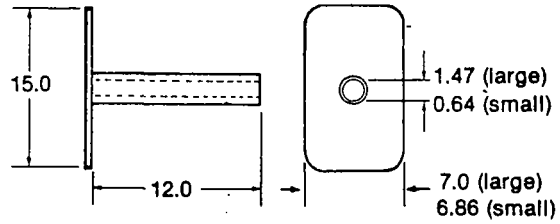
FIG 5b - Box Insert

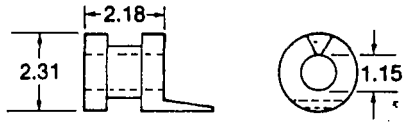
Silicone Ventilation Tubes

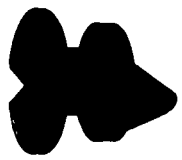
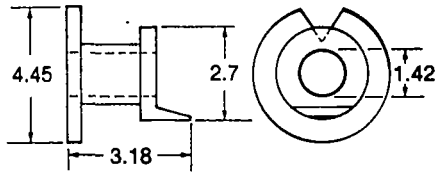
Cat. No.	Product Information	Quantity Per Box
		Dimensions Given In Millimeters
55-10001	**Donaldson design**[1] 1 tube/package, 5 packages/box	5
55-10002	**Donaldson design** 2 tubes/package, 5 packages/box	10
55-09001	**Shepard design**[2] **with tab,** 1 tube/package, 5 packages/box	5
55-09002	***Shepard design with tab,*** 2 tubes/package, 5 packages/box	10
55-11101	**Mesh, large**[3]**,** 1 tube/package, 5 packages/box	5
55-11601	**Mesh, small**[3] 1 tube/package, 5 packages/box	5
55-12101	**Paparella design**[4]**, Type 1,** 1 tube/package, 5 packages/box	5
55-12102	**Paparella design, Type 1,** 2 tubes/package, 5 packages/box	10
55-12601	**Paparella design**[4]**, Type II,** 1 tube/package, 5 packages/box	5
55-12602	**Paparella design, Type II,** 2 tubes/package, 5 packages/box	10
55-13001	**Armstrong design**[5]**,** 1 tube/package, 5 packages/box	5
55-13002	**Armstrong design,** 2 tubes/package, 5 packages/box	10
55-14501	**Per-Lee design**[6] **50°,** 1 tube/package, 5 packages/box	5
55-14601	**Per-Lee design 60°,** 1 tube/package, 5 packages/box	5
55-14701	**Per-Lee design 70°,** 1 tube/package, 5 packages/box	5

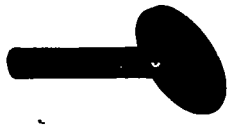
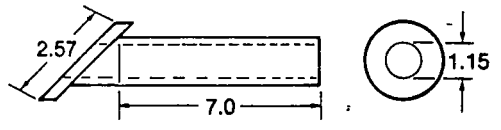



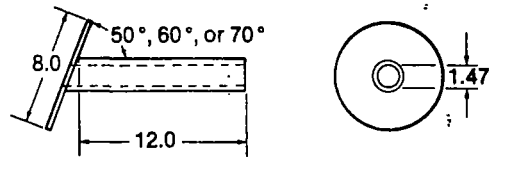



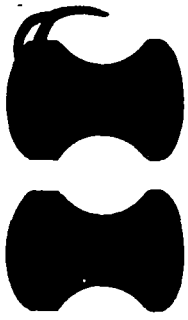



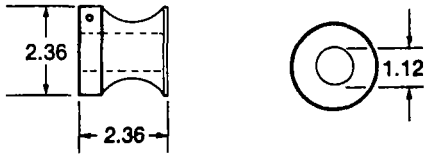



Teflon®* Ventilation Tubes

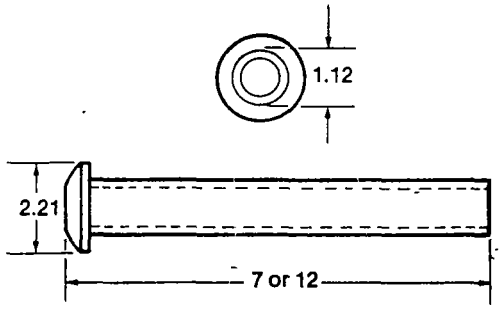
Cat. No.	Product Information	Quantity Per Box
55-20101	**Shepard design[2] with wire,** 1 tube/package, 5 packages/box	5
55-20102	**Shepard design with wire,** 2 tubes/package, 5 packages/box	10
55-20601	**Shepard design[2] without wire,** 1 tube/package, 5 packages/box	5
55-20602	**Shepard design without wire,** 2 tubes/package, 5 packages/box	10



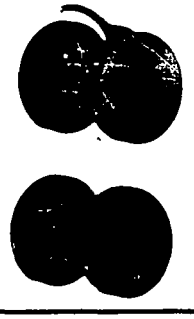
Dimensions Given In Millimeters

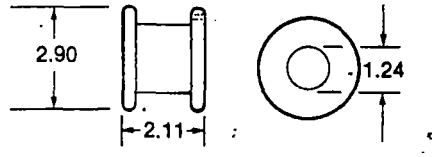


55-21101	**Straight shank, 12 mm,** 1 tube/package, 5 packages/box	5
55-21102	**Straight shank, 12 mm,** 2 tubes/package, 5 packages/box	10
55-21601	**Straight shank, 7mm,** 1 tube/package, 5 packages/box	5
55-21602	**Straight shank, 7mm,** 2 tubes/package, 5 packages/box	10



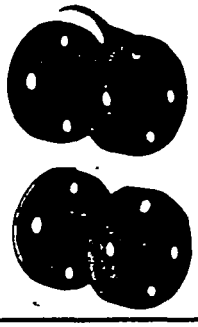
55-22101	**Sheehy design[7] with wire,** 1 tube/package, 5 packages/box	5
55-22102	**Sheehy design with wire,** 2 tubes/package, 5 packages/box	10
55-22601	**Sheehy design[7] without wire,** 1 tube/package, 5 packages/box	5
55-22602	**Sheehy design without wire,** 2 tubes/package, 5 packages/box	10

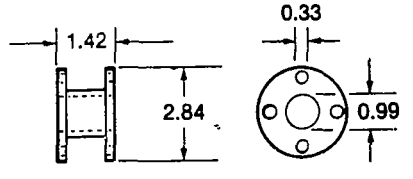




Stainless Steel Ventilation Tubes

55-30101	**Reuter design[8] with wire,** 1 tube/package, 5 packages/box	5
55-30102	**Reuter design with wire,** 2 tubes/package, 5 packages/box	10
55-30601	**Reuter design[8] without wire,** 1 tube/package, 5 packages/box	5
55-30602	**Reuter design without wire,** 2 tubes/package, 5 packages/box	10





Designs by:

[1]James A. Donaldson, M.D., Seattle, Washington
[2]Marvin C. Shepard, M.D., Dallas, Texas
[3]James A. Crabtree, M.D., Los Angeles, California
[4]Michael Paparella, M.D., Minneapolis, Minnesota
[5]B.W. Armstrong, M.D., Charlotte, North Carolina
[6]John H. Per-Lee, M.D., Atlanta, Georgia
[7]James L. Sheehy, M.D., Los Angeles, California
[8]S. Harold Reuter, M.D., Houston, Texas

*Registered Trademark of E.I. DuPont Company

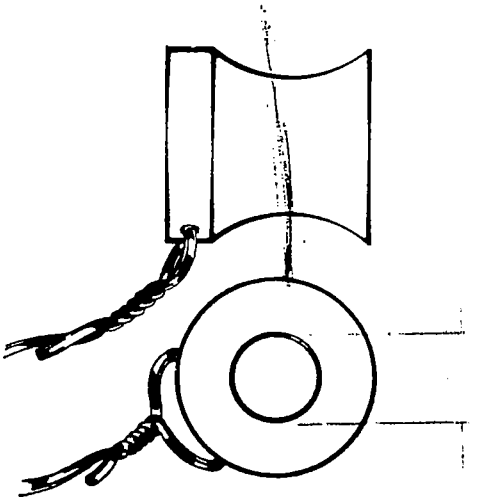
Teflon Drain Tubes

Teflon, with its friction-free surface and non-wettable property, discourages clogging. It is extremely well-tolerated by body tissues for long-term ventilation.

Blue tinted Teflon available in selected tube styles.

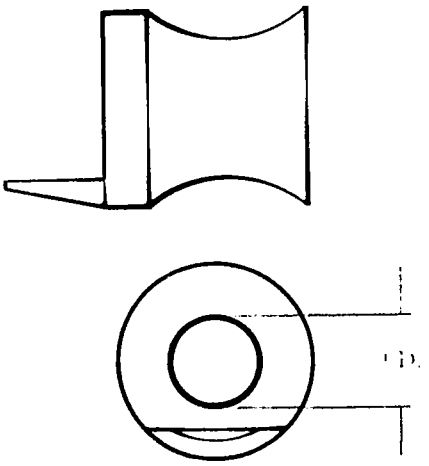
May be resterilized, if necessary, by low heat steam autoclave (not flashed), or ETO gas.

Shepard Teflon Grommet Drain Tube

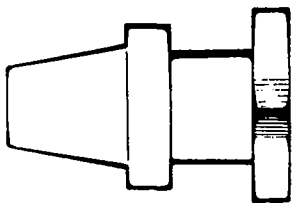


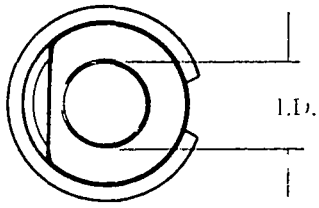
Various styles, colors or sizes available. See chart below. All are easily inserted with forceps or tube inserter through flap incision in drum.

CAT. NO.	MATERIAL	LUMEN I.D.	STYLE
14-0007. . .	White Teflon	.040" (1mm)	Integral Tab
14-0008. . .	White Teflon	.045" (1.15mm). . .	Integral Tab
14-0028. . .	White Teflon	.040" (1mm)	Wire Only
14-0029. . .	White Teflon	.040" (1mm)	Without Wire . . . . . Without Tab
14-0030. . .	White Teflon	.045" (1.15mm)	Wire
14-6028.	Blue-tint Teflon	.040" (1mm)	Wire and Tab
14-6029.	Blue-tint Teflon	.040" (1mm)	Tab Only
14-6030.	Blue-tint Teflon	.045" (1.15mm) . . .	Wire and Tab
14-6031.	Blue-tint Teflon	.045" (1.15mm)	Tab Only



[1] Designed for Marvin G. Shepard, M.D., Dallas, Texas. Presented before the Dallas Academy of Ophthalmology and Otolaryngology, April, 1963, at the Shea Micro-Aural Surgical Course held at the Southwestern Medical School of the University of Texas.

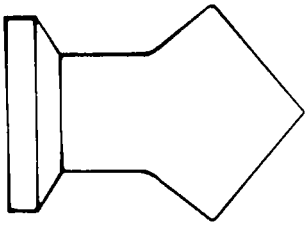


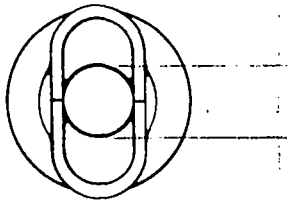


Teflon Drain Tubes

Simple "twist-in" insertion, integral removal tab. Three lumen sizes available.

CAT. NO.	I.D.
14-0252	.040" (1mm)
14-0254	.050" (1.27mm)
14-0256	.080" (2mm)

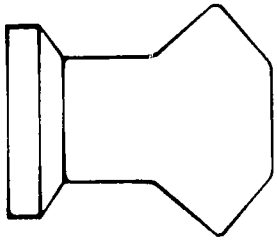


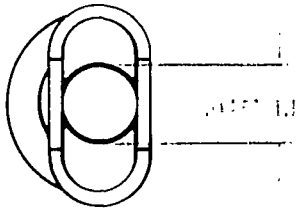


Lindeman - Silverstein Teflon Arrow Drain Tube

May be rotated 90° after insertion to lock in place. Large lumen to resist clogging, insure good drainage.

CATALOG NO. 14-0240 . . .045" (1.15mm) I.D.





Teflon Gross[2] Drain Tube

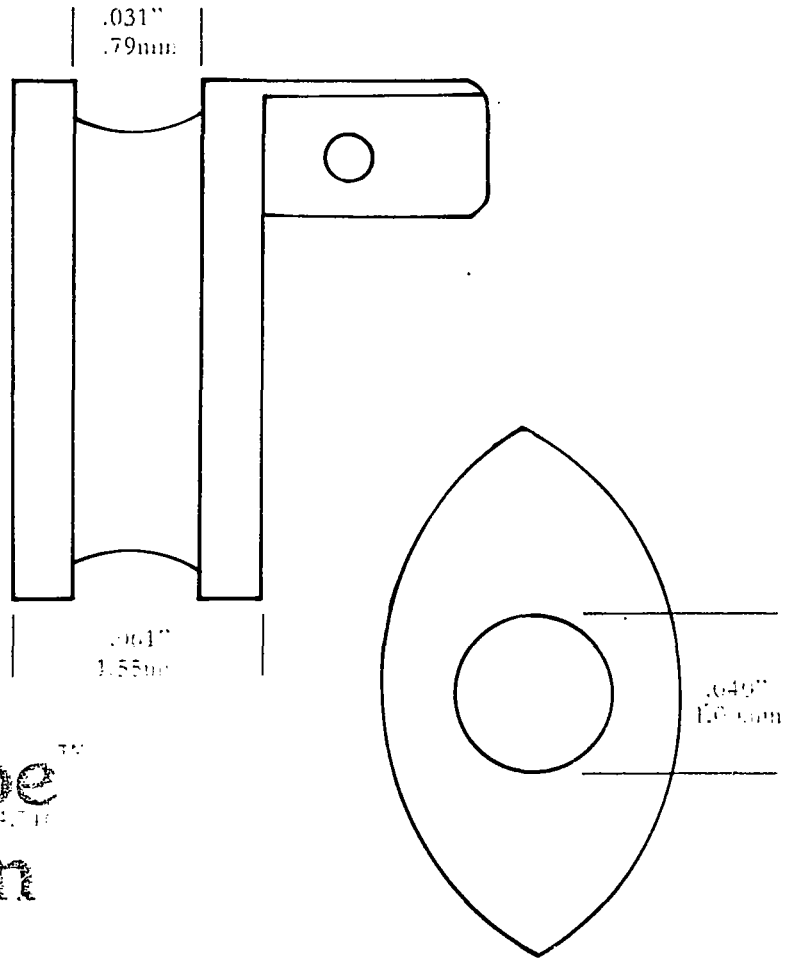
Blunt arrow lessens possibility of impingement against promontory. Flat side of flange shows orientation of arrow.

CATALOG NO. 14-0235 . . .045" (1.15mm) I.D.

[1] Lindeman, R.C., and Silverstein, H.: "The Arrow Tube." Archives of Otolaryngology, 80:473, Oct., 1964.

[2] Designed for Charles W. Gross, M.D., Memphis, Tenn.

® Registered trademark of the du Pont Company



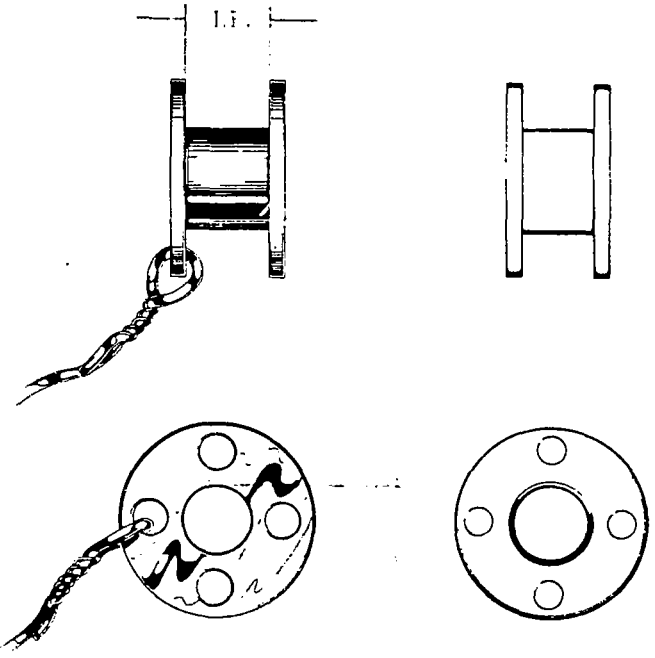
The Canoe™ Ventilation Tube

This middle ear ventilation tube is designed to reduce the possibility of premature extrusion, and to make insertion easier. The canoe shape allows tissue growth around the tube, reducing much of the extrusion pressure of tissue that occurs with other devices. The shape also facilitates insertion. The tab on the anterior flange permits grasping with alligator forceps. The tab also offers a .012" (.30mm) horizontal cannulation for easy handling with a right-angle pick. The Canoe Ventilation Tube has an inside diameter of .040"(1.00mm). It is available in blue or white Teflon®and in silicone.

CAT. NO.	MATERIAL
14-6025	Teflon, Blue
14-5255	Teflon, White
24-0070	Silicone

Designed for Gordon Smyth, M.D., Belfast, Northern Ireland

®Registered trademark of the du Pont Company



Reuter "Bobbin" Drain Tubes

The Reuter Bobbin Tube features wide flange to help resist extrusion. Large lumen diameters for long-term ventilation available in various sizes, styles, and materials. See chart below.

Available styles and sizes of Reuter tubes:

CAT. NO.	MATERIAL	LUMEN I.D.	TUBE I/F DISTANCE	FINISH	STYLE
14-5208	316L Stainless Steel (ASTM F-138)	1.15mm	1mm	Bright	Without Wire
14-5209	316L Stainless Steel (ASTM F-138)	1.25mm	1mm	Bright	Without Wire
14-5210	316L Stainless Steel (ASTM F-138)	1mm	1mm	Bright	Without Wire
14-5211	316L Stainless Steel (ASTM F-138)	1mm	1mm	Bright	With Wire
14-5212	Teflon®	1mm	1mm	White	Without Wire, Without Flange Holes
14-5213	Teflon	1.15mm	1mm	White	Without Wire, Without Flange Holes
14-5216	316L Stainless Steel (ASTM F-138)	1mm	1mm	Satin	With Wire
14-5218	316L Stainless Steel (ASTM F-138)	1mm	1mm	Satin	Without Wire
14-5224	Teflon	1.15mm	1mm	White	With Wire
14-5225	Teflon	1.15mm	1mm	White	Without Wire
14-5226	Teflon	1.25mm	.5mm	White	With Wire
14-5227	Teflon	1.25mm	.5mm	White	Without Wire
14-5228	316L Stainless Steel (ASTM F-138)	1mm	.5mm	Bright	Without Wire

[1] Designed for S. Harold Reuter, M.D., Houston, Texas

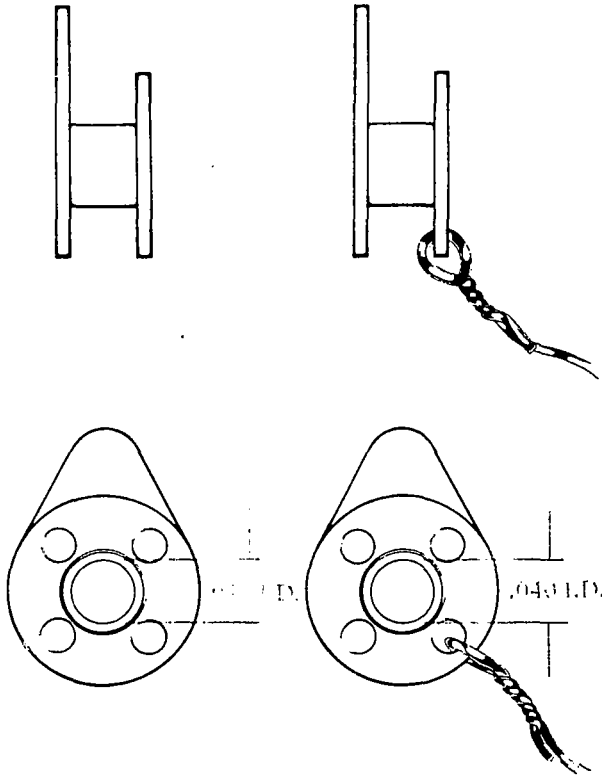
®Teflon is a registered trademark of the E. I. du Pont Company

Spoon - Bobbin Drain Tube*

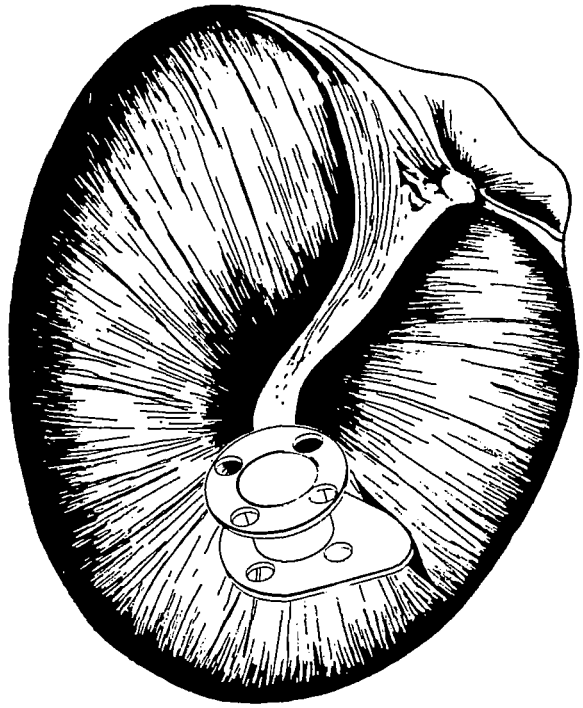
This is the popular bobbin-style drain tube with the addition of an insert flange.

The spoon-shaped flange, inserted through the incision first, eases introduction and positioning of the tube.

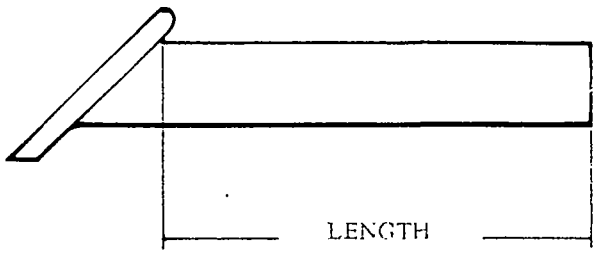
Inside lumen diameter is .040" (1mm); available with or without removal-wire. Richards Certified Stainless Steel (ASTM F-138). Individually sterile packaged.

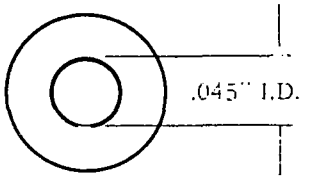


CAT. NO.	DESCRIPTION
14-5240	Without wire
14-5241	With wire



*As developed for Baldev K. Devgan, M.D., University of Tennessee, Memphis, Tennessee



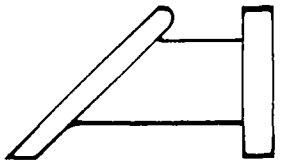


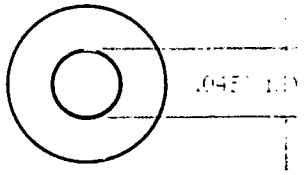
Armstrong[1] Beveled Drain Tube, Teflon®

PLAIN END

Flange resists premature extrusion.
(7.5mm) long.

CATALOG NO. 14-0244 . . . .045" (1.15mm) I.D.



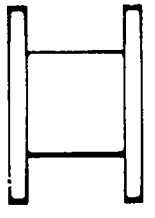


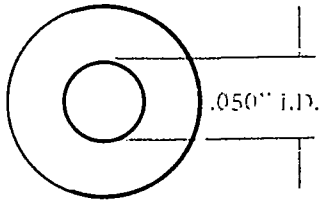
Armstrong Beveled Drain Tube, Teflon

GROMMET TYPE

Inner flange angled to fit tympanum. Outer flange helps prevent migration into middle ear. For long-term ventilation.

CATALOG NO. 14-0242 . . . .045" (1.15mm) I.D.





Teflon "Collar Button" Drain Tube[2]

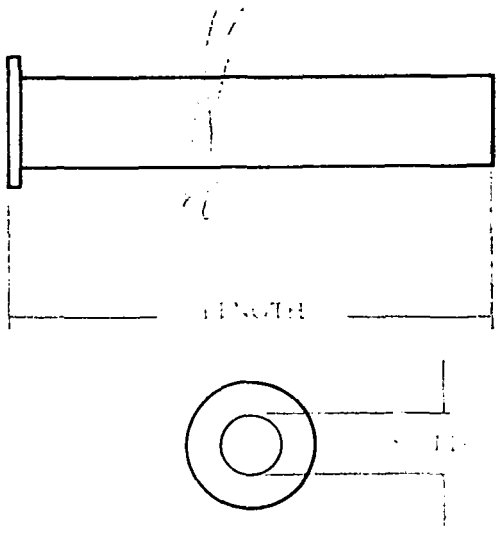
A "collar button" shaped drain tube for treatment of chronic serious otitis media. Permits prolonged aeration of the middle ear to allow mucosal edema in the tubotympanum to subside. Pressure on either side of tympanic membrane is equalized.

CATALOG NO. 14-5214. . . .050" (1.25mm) I.D.

[1] Designed for B.W. Armstrong, M.D., Charlotte, N.C.

[2] Sheehy, James L., M.D.: "Collar Button Tube for Chronic Serous Otitis" Trans. American Academy of Ophthalmology and Otolaryngology, 68:888-889, Sep.-Oct., 1964.

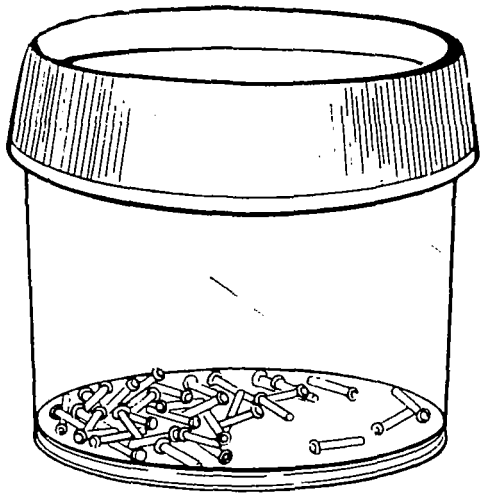
®Registered trademark of the E. I. Du Pont Company



Polyethylene Drain Tubes

Flanged polyethylene tubing. Easily inserted through small incision in the drum. 7mm long, may be cut to length.

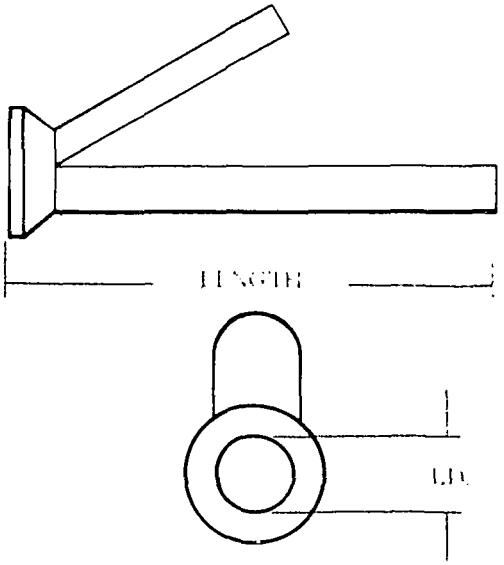
CATALOG NO. 14-0016 . . . . .034" (.85mm) I.D.



Bulk-Pack Polyethylene Drain Tubes

- 50 Tubes - Non-sterile
- Packed in sterilizing Jar

CATALOG NO. 14-0022 . . . . .034" (.85mm) I.D.



Feuerstein[1] Teflon[2] Split Tubes

Resists both extrusion and migration. Three sizes available.

CAT. NO.	I.D.	LENGTH
14-0246	.045" (1.15mm)	14mm
14-0248	.040" (1mm)	9mm
14-0250	.035" (.9mm).	9mm

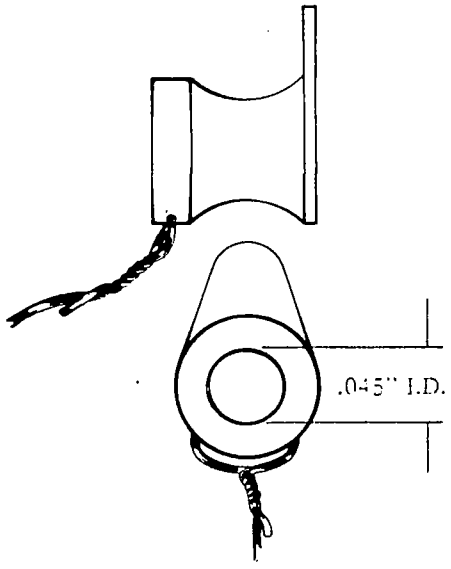
[1] Designed for Sidney S. Feuerstein, M.D., New York, N.Y.

[2] ®Registered trademark of the du Pont Company

Shah[1] Drain Tube, Teflon

"Shoehorn" flange enables smaller incision and easy insertion. Richards Certified Stainless Steel (ASTM F-138) wire for removal.

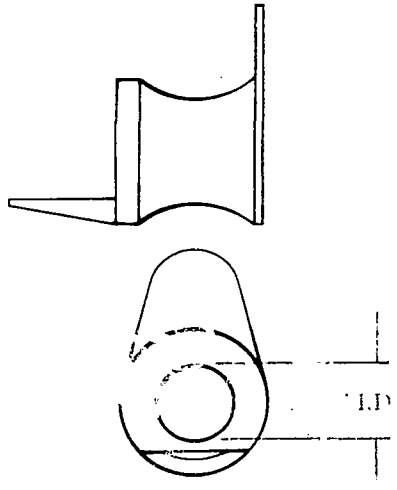
CATALOG NO. 14-0005 . . .045" (1.15mm) I.D.



Sultan Drain Tube, Teflon

Same features as the Shah Tube, but with integral tab for removal.

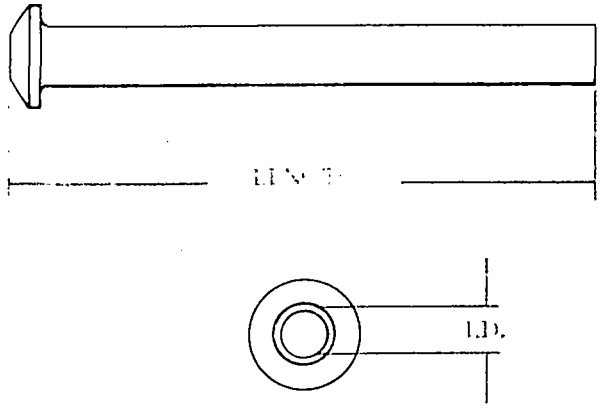
CATALOG NO. 14-5230 . . .045" (1.15mm) I.D.



Teflon Drain Tubes

Small flange for easy insertion, indicated for relief to pressure in the middle ear. 7mm or 12mm long, may be cut to length.

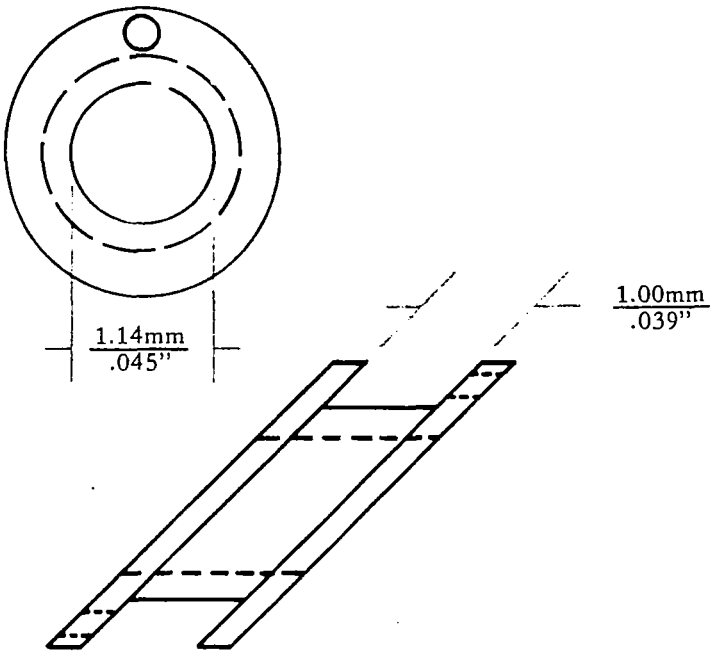
CAT. NO.	MATERIAL	LUMEN I.D.	LENGTH
14-0032	White Teflon	.035" (.9mm)	12mm
14-0033	White Teflon	.045" (1.15mm)	12mm
14-0034	White Teflon	.035" (.9mm)	7mm
14-0035	White Teflon	.045" (1.15mm)	7mm
14-6032	Blue-tint Teflon	.035" (.9mm)	12mm
14-6033	Blue-tint Teflon	.045" (1.15mm)	12mm
14-6034	Blue-tint Teflon	.035" (.9mm)	7mm
14-6035	Blue-tint Teflon	.045" (1.15mm)	7mm

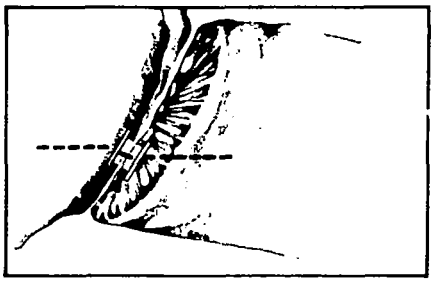


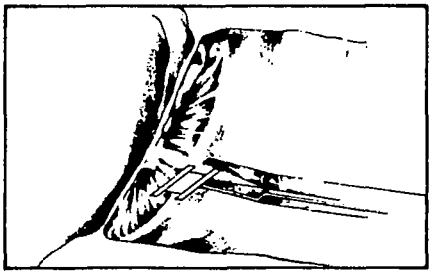
[1] Designed for Mr. N. Shah, F.R.C.S., D.L.O., London England

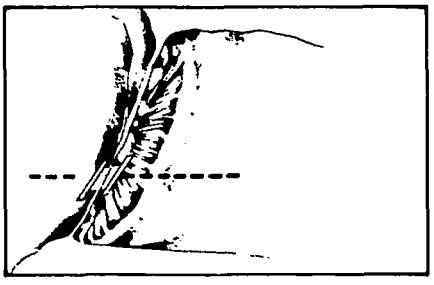
®Teflon is a registered trademark of the du Pont Company

Pope* Beveled Grommet Drain Tube









This new ventilation tube offers advantages during insertion and for postoperative inspection. Easily introduced with alligator forceps, the grommet will pass through a very small speculum (2.25mm x 1.1mm). The elongated flanges and length of the tube (1.4mm) help to prevent premature extrusion.

The 45° bevel on the flange approximates the angle of the tympanic membrane, allowing the otoscopist to see straight through the lumen. Such problems as fluid recurrence and plugging of the lumen are easily recognized and corrected. The visibility factor also makes postoperative evaluation of middle ear aeration much easier.

Made of blue polyethylene. Inside diameter of .045" (1.14mm).

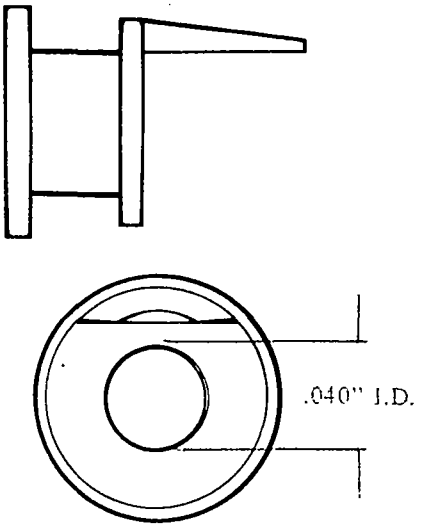
CAT. NO. 14-5250

*T. H. Pope, Jr., M.D., Durham, N.C.

Rock[1] Pediatric Ventilating Tube

A simple short-term Teflon® "bobbin" tube for children. The larger flange (.095" or 2.4mm dia.) is inserted through incision in the tympanic membrane, decreasing possibility of extrusion. The smaller flange (.085" or 2.2mm dia.) has the integral tab for ease in extraction. Lumen diameter is .040" (1mm); interflangeal distance is .035" (0.9mm).

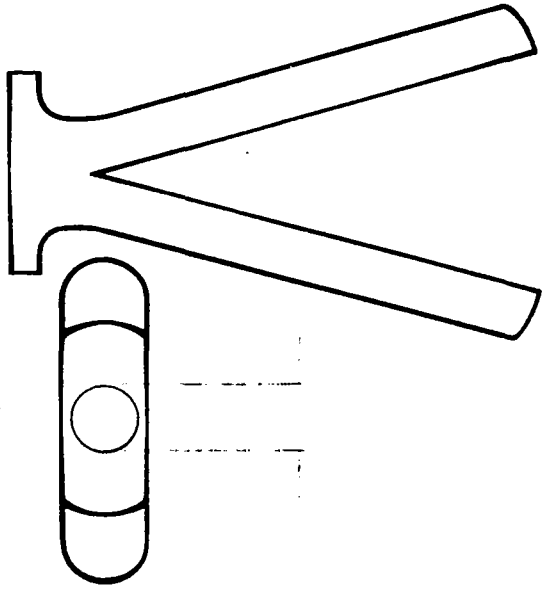
CATALOG NO. 14-0086 . . . . . .040" (1mm) I.D.



JSK[2] Teflon Split Drain Tube

Stays in place for long-term drainage. 7mm long, may be trimmed to proper length.

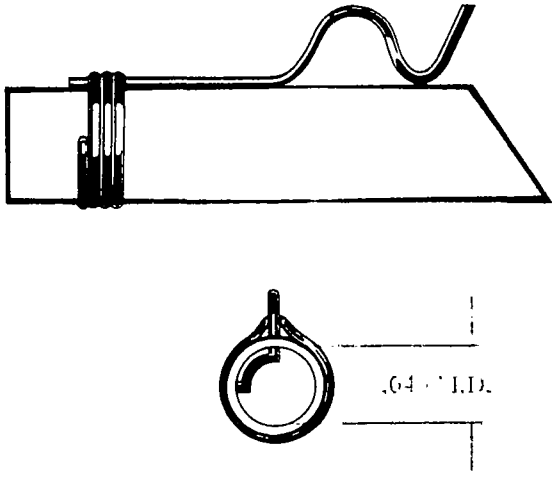
CATALOG NO. 14-0026 . . . . .033" (.84mm) I.D.



Silverstein Malleus[3] Clip Tube

The Teflon® and Richards Certified Stainless Steel (ASTM F-138) tube clips to the malleus, providing a firm hold for long-term ventilation. Especially useful in the treatment of persistent secretory otitis media. 7mm long.

CATALOG NO. 14-0018 . . . . . .040" (1mm) I.D.



[1] Designed for Erwin H. Rock, M.D., Yonkers, New York

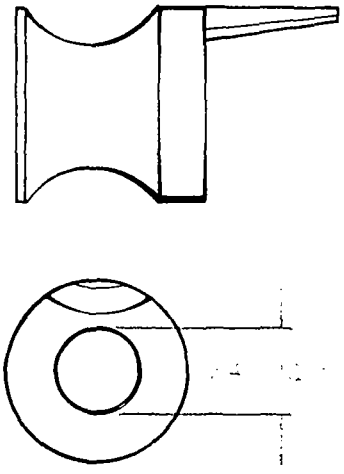
[2] Designed for John S. Knight, M.D., Kansas City, Mo.

® Registered trademark of the du Pont Company.

[3] Designed for Herbert Silverstein, M.D., Sarasota, Fl.

Richards Silicone Drain Tubes

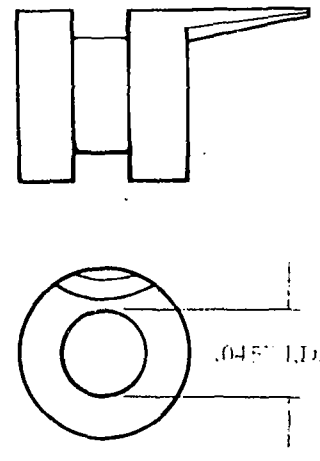
The soft, compressible silicone elastomer is well tolerated by tissue and is thus suitable for both long-term and short-term ventilation. Blue opaque color makes the tubes easy to see for both insertion and removal. May be inserted with standard sizes of tube inserters or compressed with forceps through a smaller incision, as the silicone "springs back" to its original configuration. May be resterilized, if necessary, by steam autoclave or ETO gas.



Shepard Silicone Drain Tube

With Integral Removal Tab

CAT. NO. 24-0020 . . . . . .040" (1mm) I.D.



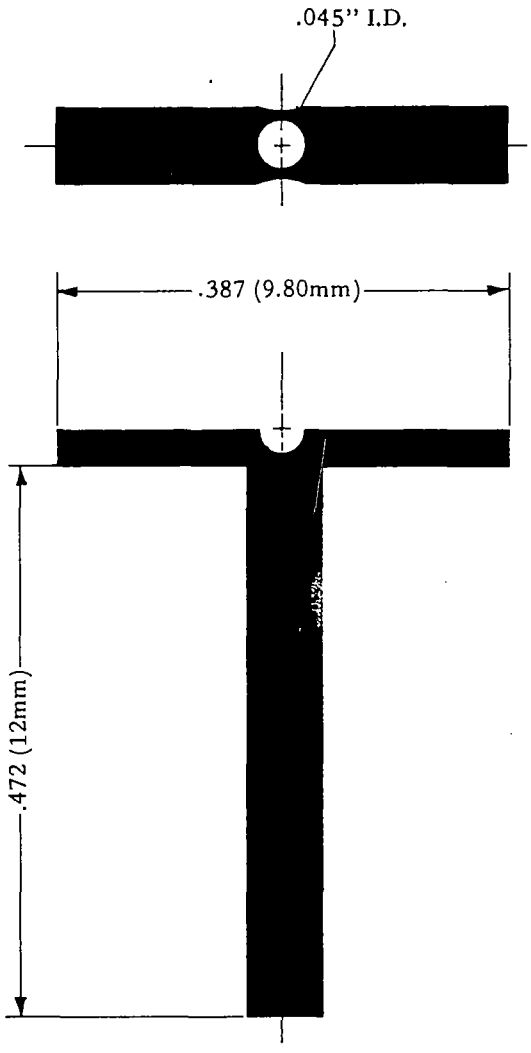
Donaldson Drain Tube, Silicone

Flanges resist migration and extrusion. Large lumen promotes good drainage. Features unique integral tab. Inside diameter is .045" (1.15mm).

CAT. NO. 24-0015 . . . . . .without tab
24-0016 . . . . . .with tab

[1] As designed for Marvin G. Shepard, M.D., Dallas, Texas.

[2] James A. Donaldson, M.D., University of Washington, Seattle, Wash.



Richards T-Tube

Richards T-Tube offers the otology surgeon a long term ventilation tube that is easily inserted with a smaller incision and is designed to remain firmly positioned in the tympanic membrane.
Because the T-Tube is designed with a long shaft and flexible flanges, it is easily extracted. The T-Tube is made of silicone and is easily trimmed to adapt to the surgeon's needs.

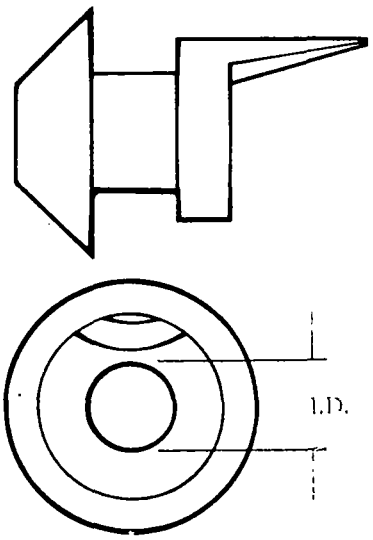
Catalog No. 24-0071 . . . . . Richards T-Tube ventilation tube.
.045" (1.1mm) I.D.
.472" (12mm) length

Shea[1] 'Parasol' Drain Tubes, Silicone

U. S. Pat. No. 3,871,380

Unique design of the "folding" or collapsible flap allows easy insertion. Tube flap opens like an umbrella when placed thru incision. Simple pull on removal tab "inverts" umbrella for easy removal.

CAT. NO.	I.D.
24-0036	.040" (1mm)
24-0038	.060" (1.5mm)
24-0040	.080" (2mm)

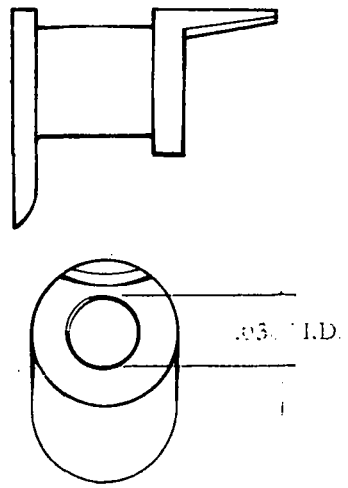


Shea[2] Ventilation Tube, Silicone

U.S. Pat. No. D239,330

"Shoehorn" flange enables easy insertion; integral tab for removal.

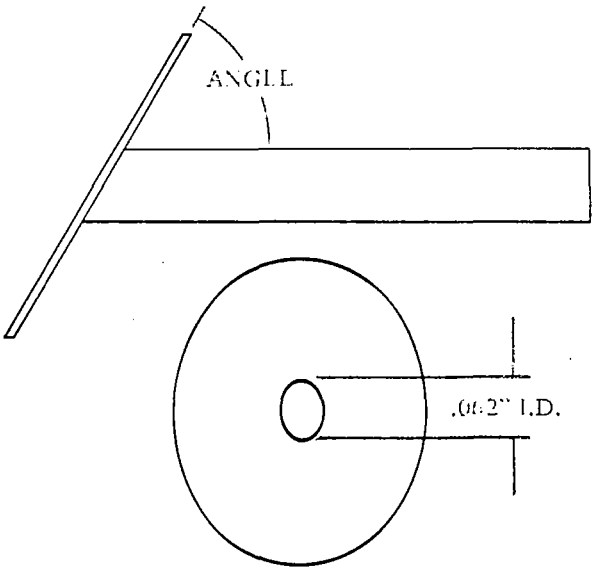
CATALOG NO. 24-0034 . . . . .030" (.76mm) I.D.



Per-Lee[3] Drain Tubes, Silicone

Extra-large flange prevents extrusion, angled to align with ear canal for long-term drainage. Large lumen for superior drainage.

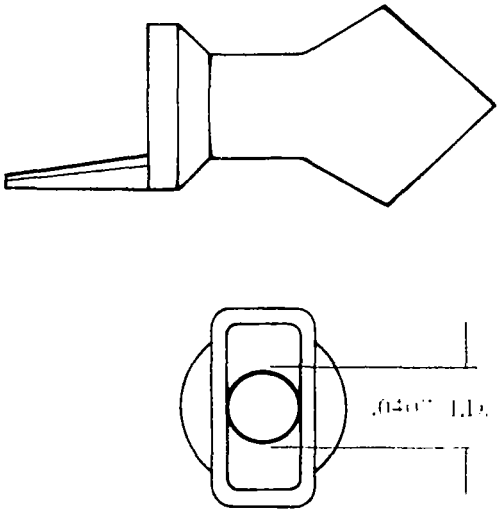
CAT. NO.	FLANGE ANGLE
24-0026	60°
24-0028	70°



[1] Designed for John J. Shea, M.D., Memphis, Tenn.

[2] Designed for John J. Shea, M. D., Memphis, Tenn.

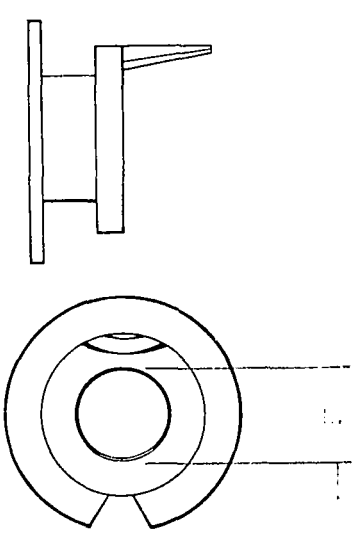
[3] Designed for John H. Per-Lee, M.D., Emory University Clinic, Atlanta, Ga.



Lindeman - Silverstein[1] Arrow Drain Tube, Silicone

Rotate after insertion to lock in place, with integral tab.

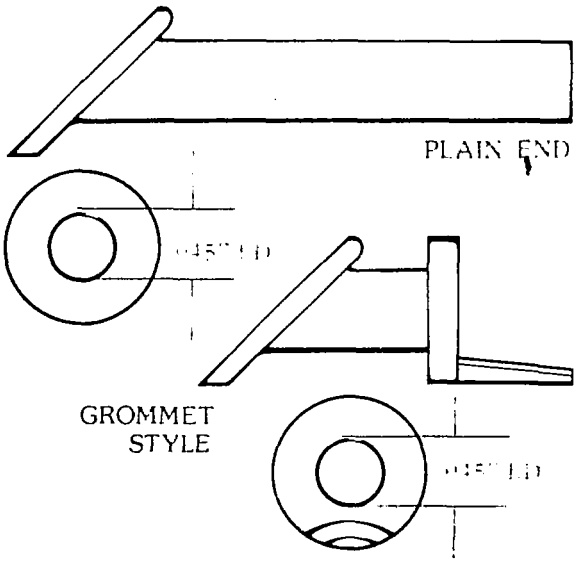
CATALOG NO. 24-0023 . . . . .040" (1mm) I.D.



Drain Tubes, Silicone

Notched inner flange for "twist-in" insertion. Very stable for long-term implantation.

CAT. NO.	I.D.
24-0044	.040" (1mm)
24-0046	.050" (1.27mm)
24-0048	.080" (2mm)



Armstrong[2] Silicone Drain Tubes

Choice of 2 Popular Styles

- Grommet
- Plain End

Both styles are of blue-tinted Silicone for ease of insertion and removal. Beveled interior end corresponds to the angle of the tympanic membrane, resists premature extrusion. Inside diameter is .045" (1.15mm).

CAT. NO.	DESCRIPTION
24-0050.	.Grommet Style with Tab
24-0052.	.Plain End

[1] Lindeman, R.C., and Silverstein, H.: "The Arrow Tube." Archives of Otolaryngology, 80:473, Oct., 1964.

[2] Designed for B.W. Armstrong, M.D., Charlotte, North Carolina

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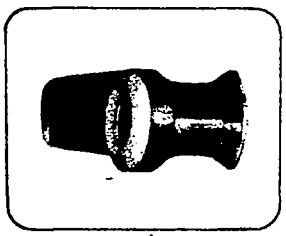
INSTRUMENT COMPANY

storz®

OTOLOGICAL VENTILATION TUBES

Storz Otological Ventilation Tubes are designed for easy placement through the tympanic membrane to ventilate the middle ear space, and, if present, drain accumulations of fluid from the middle ear. These tubes are available in a variety of designs, sizes and materials. The materials used to manufacture ventilation tubes are silicone, Teflon®, polyethylene and stainless steel.

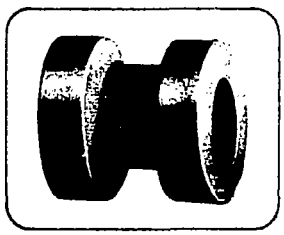
Ventilation tubes are supplied sterile in either one or two tubes per package. These are stored and shipped in an outer box containing five packages. Catalog numbers ending in -1 are packaged one tube per package, five tubes per box. Catalog numbers ending in a -2 are packaged two tubes per package, ten tubes per box.



Shepard Design, Silicone, with Integral Tab, 1.1 mm I.D.

One Tube Per Package **T5000-1**

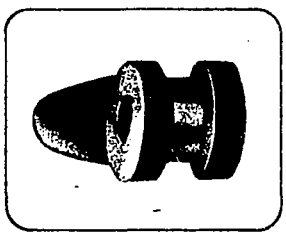
Two Tubes Per Package **T5000-2**



Donaldson Design, Silicone, without Tab, 1.1 mm I.D.

One Tube Per Package **T5010-1**

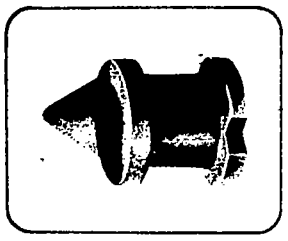
Two Tubes Per Package **T5010-2**



Donaldson Design, Silicone, with Integral Tab, 1.1 mm I.D.

One Tube Per Package **T5011-1**

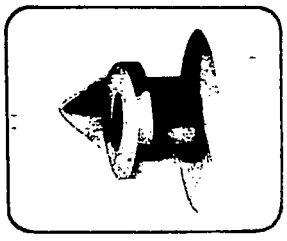
Two Tubes Per Package **T5011-2**



Paparella Design,
Silicone, Type I, 1.2 mm I.D.

One Tube Per Package **T5020-1**

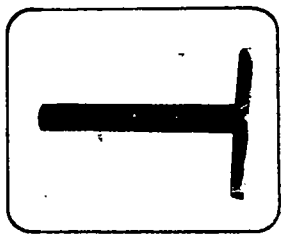
Two Tubes Per Package **T5020-2**



Paparella Design,
Silicone, Type II, 1.5 mm I.D.

One Tube Per Package **T5021-1**

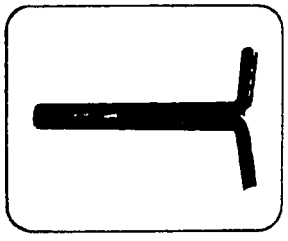
Two Tubes Per Package **T5021-2**



T-Tube Design,
Silicone, Soft, 12 mm Length, 1.1 mm I.D.

One Tube Per Package **T5030-1**

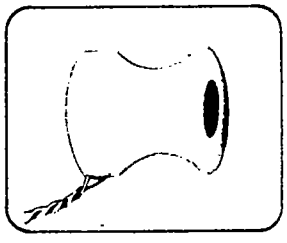
Two Tubes Per Package **T5030-2**



T-Tube Design,
Silicone, Firm, 12 mm Length, 1.0 mm I.D.

One Tube Per Package **T5031-1**

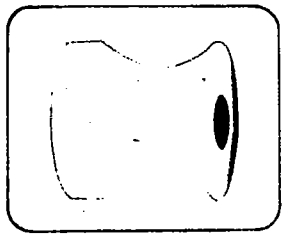
Two Tubes Per Package **T5031-2**



Shepard Design,
Teflon*, with Wire, 1.0 mm I.D.

One Tube Per Package **T5100-1**

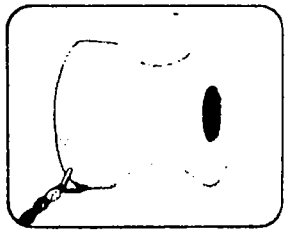
Two Tubes Per Package **T5100-2**



Shepard Design,
Teflon, without Wire, 1.0 mm I.D.

One Tube Per Package **T5101-1**

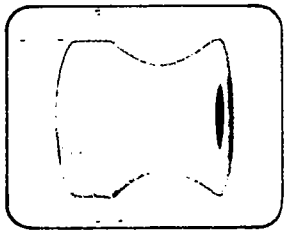
Two Tubes Per Package **T5101-2**



Shepard Design,
Teflon, with Wire, 1.1 mm I.D.

One Tube Per Package **T5102-1**

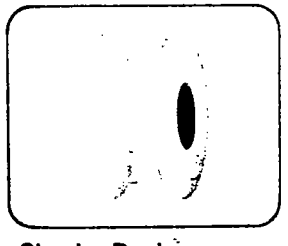
Two Tubes Per Package **T5102-2**



Shepard Design,
Teflon, without Wire, 1.1 mm I.D.

One Tube Per Package **T5103-1**

Two Tubes Per Package **T5103-2**



Sheehy Design,
Teflon, without Wire, 1.28 mm I.D.

One Tube Per Package **T5110-1**

Two Tubes Per Package **T5110-2**

* Teflon is a Registered Trademark of the duPont Company

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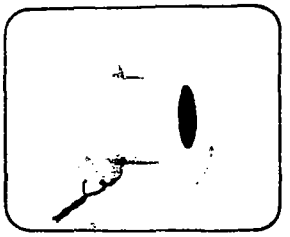
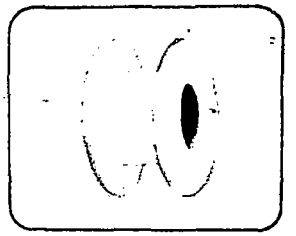
INSTRUMENT COMPANY



Sheehy Design, Teflon, with Wire, 1.28 mm I.D.

One Tube Per Package **T5111-1**

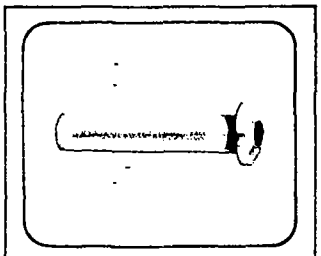
Two Tubes Per Package **T5111-2**



Reuter Design, Teflon, without Wire, 1.1 mm I.D.

without Flange Holes,
One Tube Per Pkg. **T5120-1**
Two Tubes Per Pkg. **T5120-2**

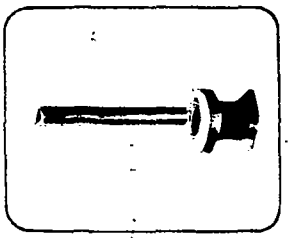
with Flange Holes,
One Tube Per Pkg. **T5121-1**
Two Tubes Per Pkg. **T5121-2**



Straight Shank Design, Teflon, 2.2 mm Flange Diameter, .9 mm I.D.

7 mm Length,
One Tube Per Pkg. **T5130-1**
Two Tubes Per Pkg. **T5130-2**

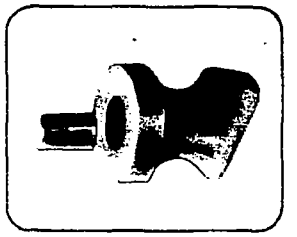
12 mm Length,
One Tube Per Pkg. **T5134-1**
Two Tubes Per Pkg. **T5134-2**



Shepard Design, Polyethylene, with Integral Tail, 1.0 mm I.D.

One Tube Per Package **T5200-1**

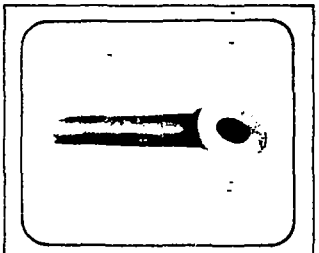
Two Tubes Per Package **T5200-2**



Shah Design, Polyethylene, with Integral Tab, 1.1 mm I.D.

One Tube Per Package **T5210-1**

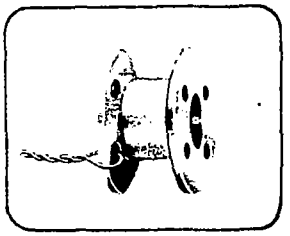
Two Tubes Per Package **T5210-2**



Armstrong Design, Polyethylene, Straight Shank, 7 mm Length, 1.1 mm I.D.

One Tube Per Package **T5220-1**

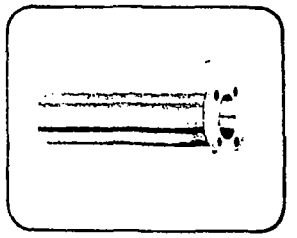
Two Tubes Per Package **T5220-2**



Reuter Design, Stainless Steel, with Flange Holes, with Wire, 1.0 mm I.D.

One Tube Per Package **T5301-1**

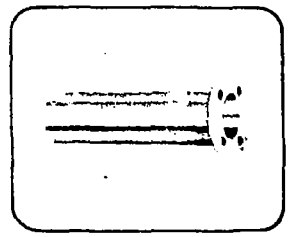
Two Tubes Per Package **T5301-2**



Robinson® Design, Stainless Steel, Four Hole, Extra Small

One Tube Per Package **T5310-1**

Two Tubes Per Package **T5310-2**

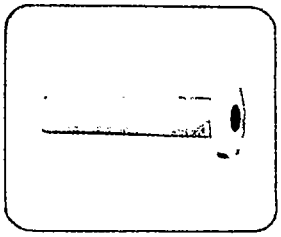


Robinson® Design, Stainless Steel, Four Hole, Small

One Tube Per Package **T5311-1**

Two Tubes Per Package **T5311-2**

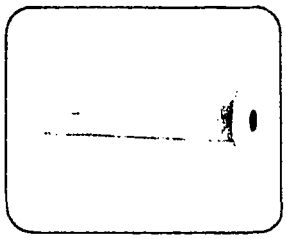
* Teflon is a Registered Trademark of the duPont Company



Straight Shank Design, Teflon, 7 mm Length, 2.75 mm Flange Diameter, .9 mm I.D.

One Tube Per Package **T5131-1**

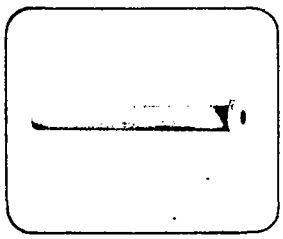
Two Tubes Per Package **T5131-2**



Straight Shank Design, Teflon, 7 mm Length, 2.2 mm Flange Diameter, 1.1 mm I.D.

One Tube Per Package **T5132-1**

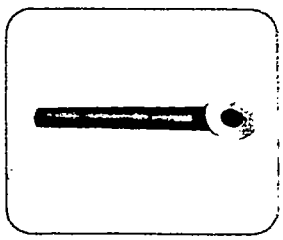
Two Tubes Per Package **T5132-2**



Straight Shank Design, Teflon, 12 mm Length, 2.2 mm Flange Diameter, 1.1 mm I.D.

One Tube Per Package **T5133-1**

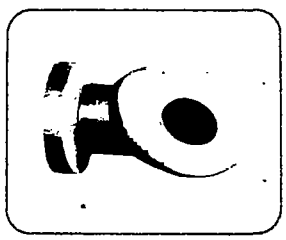
Two Tubes Per Package **T5133-2**



Armstrong Design, Polyethylene, Straight Shank, 12 mm Length, 1.1 mm I.D.

One Tube Per Package **T5221-1**

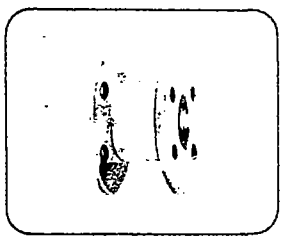
Two Tubes Per Package **T5221-2**



Armstrong Design, Polyethylene, Grommet Type, 1.1 mm I.D.

One Tube Per Package **T5222-1**

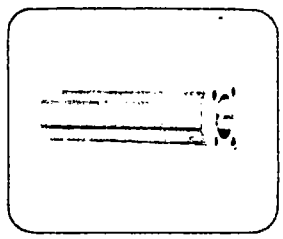
Two Tubes Per Package **T5222-2**



Reuter Design, Stainless Steel, with Flange Holes, without Wire, 1.0 mm I.D.

One Tube Per Package **T5300-1**

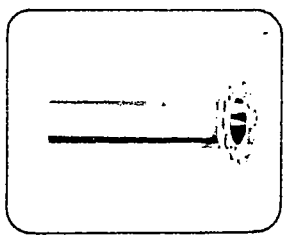
Two Tubes Per Package **T5300-2**



Robinson® Design, Stainless Steel, Four Hole, Standard

One Tube Per Package **T5312-1**

Two Tubes Per Package **T5312-2**



Robinson® Design, Stainless Steel, Twelve-Hole, Standard

One Tube Per Package **T5313-1**

Two Tubes Per Package **T5313-2**

Inside Diameter Metric Scale

1.0mm = .040"
1.1mm = .043"
1.2mm = .047"
1.3mm = .051"
1.4mm = .055"
1.5mm = .059"

All dimensions are nominal.
All Teflon® tubes are white.
All silicone and polyethylene tubes are blue.

storzstorz
INSTRUMENT COMPANY

Xomed®

Myringotomy—Ventilation Tubes (Short Term)

Armstrong Beveled Grommet

1.1 mm I.D. (.045")

XO-1056	Teflon®
XO-1057	Teflon® w/s.s. wire
XO-1066	Silicone

Armstrong Beveled Straight Shank

1.1 mm I.D. (.045")

XO-1050	Teflon® (7 mm length)
XO-1051	Teflon® (8 mm length)
XO-1052	Teflon® (9 mm length)
XO-1053	Teflon® (10 mm length)
XO-1054	Teflon® (11 mm length)
XO-1055	Teflon® (12 mm length)
XO-1060	Silicone (7 mm length)
XO-1063	Silicone (10 mm length)
XO-1065	Silicone (12 mm length)

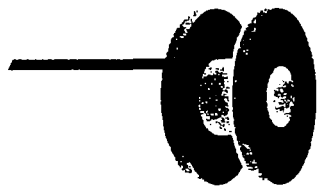
Armstrong tubes are designed with the flange angled to the shank so they will slide into place without need to tilt or twist them. Thus, they require a smaller incision in the tympanic membrane than would otherwise be necessary. Due to the angle of the flange, the tube is parallel to the wall of the ear canal when in place in the tympanic membrane. Particularly in the case of the Straight Shank design, this eliminates the chance of obstruction due to interference between the end of the tube and the canal wall. In short, Armstrong tubes take into consideration the anatomy of the tympanic membrane and external auditory canal.

Reference:
1. "What Your Colleagues Think of Tympanostomy Tubes", The Laryngoscope, Vol. 78, No. 8, August, 1968, pp. 1303-1313.

*Designed by Beverly W. Armstrong, M.D., Charlotte, North Carolina

Collar Button

1.1 mm I.D. (.045") 2.5 mm O.D. (.100")



XO-1084	Polyethylene w/integral tail, 1.0 mm between flanges
XO-1085	Polyethylene w/integral tail, .5 mm between flanges

Donaldson* Type

1.1 mm I.D. (.045") 2.2 mm O.D. (.090")

XO-1020	Teflon®
XO-1021	Teflon® w/s.s. wire
XO-1024	Silicone w/tab
XO-1025	Silicone

The Donaldson type ventilation tube is of a pure grommet design. The internal and external flanges are identical in size. Incorporated in the design are sharp tube to flange angles to ensure secure placement in the tympanic membrane. The silicone elastomer version can be compressed for easy insertion, allowing it to be placed through a smaller incision.

References:
1. "Myringotomy—When and How", GP, 29:68, 1964
2. "The Role of the Artificial Eustachian Tube in Cleft Palate Patients", Cleft Palate Journal, 3:61, 1966

*Designed by James A. Donaldson, M.D., Seattle, Washington

Feuerstein* Split Tubes

1.1 mm I.D. (.045"), 12 mm length

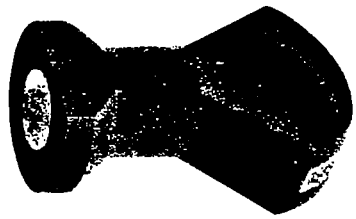
XO-1046	Teflon®

The flanged end extends into the middle ear, and is held in position by the myringotomy opening to help eliminate the chance of premature extrusion. The split tube shank prevents displacement into the middle ear, and keeps secretions from plugging the lumen.

*Designed by Sidney S. Feuerstein, M.D., New York, N.Y.

Gross*

1.1 mm I.D. (.045")



XO-1001	Teflon®
XO-1003	Teflon® w/s.s. wire

The Gross ventilation tube is similar to the Lindeman-Silverstein Arrow but has a rounded end which prevents it from being positioned against the promontory and, thus, occluding the lumen. A flat surface on the outer flange is aligned with the rounded end which protrudes through the tympanic membrane. This flat portion eliminates springing of forceps and provides easy manipulation for insertion. The tube is inserted through the tympanic membrane and rotated 90°, thus locking it into position. The flat portion on the flange serves as a guide for final positioning of the tube since it is aligned with the rounded end.

*Designed by Charles W. Gross, M.D., Memphis, Tennessee

J.S.K.* Split Tube

1.1 mm I.D. (.045"), 7 mm length

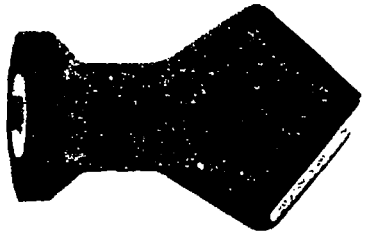
XO-1047	Teflon®

The flange is inserted inside the middle ear space to prevent premature extrusion. The split tube shank prevents migration of the tube into the middle ear. The flange is rotated 90° after insertion to help retain the tube in the tympanic membrane.

*Designed by J. S. Knight, Kansas City, Missouri

Lindeman-Silverstein* Arrow

1.1 mm I.D. (.045")



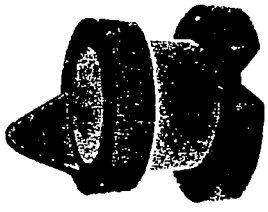
XO-1000	Teflon®
XO-1002	Teflon® w/s.s. wire
XO-1005	Silicone

The portion of the tube which enters the middle ear cavity is flared into the shape of an arrow. The wide flange serves to retain the tube in place while implanted, thus preventing premature extrusion into the ear canal. The slotted effect of the lumen created by this flare is intended to recess the lumen entrance. In the event the tube comes into contact, with the promontory when inserted, two channels to the lumen will remain unobstructed, with the arrow point in contact with the promontory. Insertion of the Lindeman-Silverstein Arrow tube is made with the flat axis of the arrow in the same plane as the incision. Once in, the tube is rotated 90° to bring the flared tapers to a position of butting the area adjacent to the incision.

*Designed by Roger C. Lindeman, M.D., Seattle, Washington and Herbert Silverstein, M.D., Sarasota, Florida

Paparella Type 1*

1.1 mm I.D. (.045"), 2.5 mm inner flange diameter



XO-1026	Silicone

This tube is indicated for routine use, and generally remains in the tympanic membrane 4-8 months or longer. It is inserted by introducing the lead corner of the flange into the myringotomy. The tube is then rotated until the entire flange is behind the tympanic membrane. This technique allows a smaller incision and more secure tube retention. The soft silicone permits easy insertion by the popping or semi-twist pop methods.

*Designed by Michael M. Paparella, M.D., Minneapolis, Minnesota

Pope* Beveled Grommet

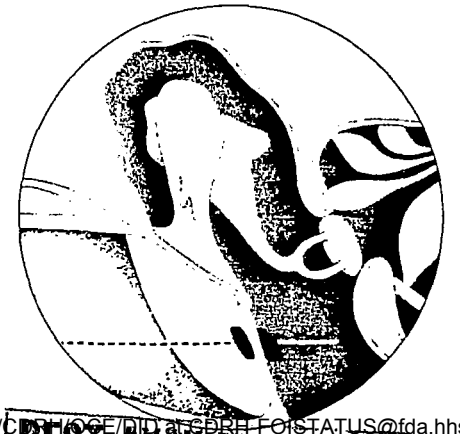
1.1 mm I.D. (.045")

XO-1018	Polyethylene
XO-1019	Polyethylene w/s.s. wire

The Pope Beveled Grommet Ventilation Tube is designed to make the surgeon's line of vision parallel to the lumen of the tube. The 45 degree bevel on the flange approximates the angle of the tympanic membrane, thus allowing the otoscopist to see straight through the lumen. If the fluid recurs, or if the lumen becomes plugged, such problems may be recognized quickly and corrected easily. Postoperatively, evaluation of middle ear aeration is much easier, particularly when faced with the red tympanic membrane of the crying child.

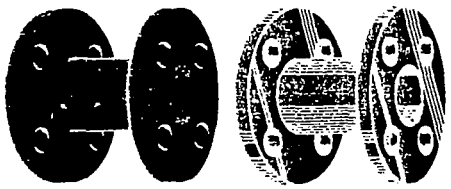
The flanges are one (1) mm apart and elongated to prevent early extrusion. The length of the tube is 1.4 mm. The Pope Beveled Grommet is introduced easily with Alligator forceps. Its size allows it to pass through a very small speculum (2.25 mm x 1.1 mm). There is a hole in the flange that allows the surgeon to rotate the grommet to an optimal position with a straight pick.

*Designed by T. Pope, M.D., Durham, North Carolina



Reuter* Bobbins

1.1 mm I.D. (.045"), 2.5 mm O.D. (.100")
1.0 mm between flanges



XO-1030	Teflon® w/flange holes
XO-1031	Teflon® w/o flange holes
XO-1033	Stainless Steel w/flange holes
XO-1035	Teflon® w/flange holes, w/s.s. wire
XO-1036	Teflon® w/o flange holes, w/s.s wire
XO-1038	Stainless Steel w/flange holes, w/s.s. wire

1.25 mm I.D. (.050"), 2.5 mm O.D. (.100")
.50 mm between flanges

XO-1032	Stainless Steel w/flange holes
XO-1034	Teflon® w/flange holes
XO-1037	Stainless Steel w/flange holes, w/s.s. wire
XO-1039	Teflon® w/flange holes, w/s.s. wire

Our Reuter Bobbins are available in a variety of sizes and materials, while retaining the same basic design features. The square flange to tube configuration is employed in this family of ventilation tubes. The wide double flanges prevent premature extrusion from the tympanic membrane or inadvertent loss into the middle ear. The four equally spaced holes (.381 mm diameter) in each flange provide easy manipulation for insertion or removal, by gripping the tube between a flange hole and outer flange surface with a very small alligator forceps. The holes are also intended to encourage nipple-

(Continued next page)

Xomed

Myringotomy—Ventilation Tubes (Short Term)

like membranous ingrowth to enhance tenacity of fixation. Designed especially for patients with chronic secretory otitis media, Reuter Bobbins are easily inserted into an anterior-inferior myringotomy using one of the flange holes as previously described.

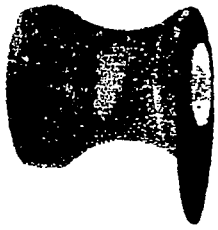
*Designed by S. Harold Reuter, M.D., Houston, Texas

Suggested myringotomy and tube placement procedure:

1. Make anterior-inferior myringotomy incision
2. Insert tube into myringotomy with a very small alligator forceps, utilizing one of the flange holes to manipulate
3. Tube is now in place for extended middle ear ventilation

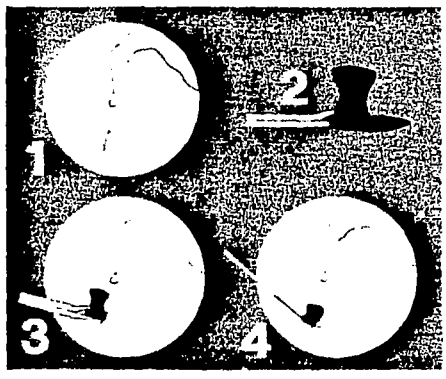
Shah Type

1.1 mm I.D. (.045"), 2.3 mm O.D. (.090")



XO-1016	Teflon®
XO-1017	Teflon® w/s.s. wire

The Shah type ventilation tube incorporates a longer and larger inner flange for ease of introduction, which enables the surgeon to make a smaller myringotomy. The flange also serves as a means of retarding early extrusion.

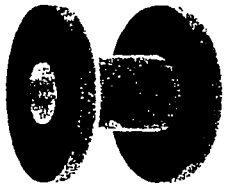


Suggested myringotomy and tube placement procedure:

1. Make a small myringotomy incision.
2. Hold tube on the rounded edge with a very small alligator forceps.
3. Introduce the longer pointed flange through the myringotomy.
4. Gently press the rounded edge with a blunt needle to complete the procedure.

Sheehy* Type Collar Button

1.25 mm I.D. (.050"), 3 mm O.D. (.120")

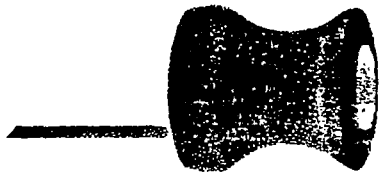


XO-1022	Teflon®
XO-1023	Teflon® w/s.s. wire

*Designed by James L. Sheehy, M.D., Los Angeles, California

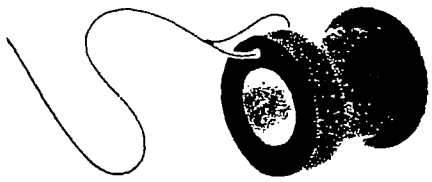
Shepard* Grommet

1.1 mm I.D. (.045"), 2.36 mm O.D. (.093")



XO-1010	Teflon® w/integral Teflon® tail
XO-1011	Teflon® w/welded s.s. wire
XO-1012	Teflon® w/tab
XO-1014	Teflon® w/o s.s. wire
XO-1015	Silicone w/integral silicone tail

1.0 mm I.D. (.040"), 2.46 mm O.D. (.097")



XO-1007	Teflon® w/welded s.s. wire
XO-1008	Teflon® w/o s.s. wire

One of the most popular ventilation tubes is the Shepard Grommet. This is due to the ease of insertion and removal accomplished with the tube. Our Shepard Grommets are available in a variety of lumen sizes and materials as indicated above. As with all Xomed tubes with attached stainless steel wires, the wires on our Shepards are welded rather than twisted to ensure them against detachment from the tube. This often occurs when a twisted wire is trimmed too short prior to placement of the tube. With a welded wire, the wire can be trimmed to within a very short distance from the tube to minimize the chance of the wire piercing the ear canal. Another unique Xomed innovation is the Shepard Grommet tube with an integral tail of the same material as the tube. These tubes, available in Teflon® and silicone, further eliminate the problems associated with stainless steel wires, such as blood flow resulting from a pierced external auditory canal wall.

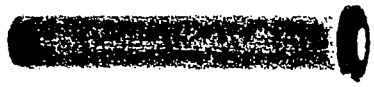
*Designed by Marvin C. Shepard, M.D., Dallas, Texas

Suggested myringotomy and tube placement procedure:

1. Make sharply curved myringotomy incision, creating a superior flap.
2. Insert tube through incision by grasping lower lip of tube with very small alligator forceps. (Suggest bending of barrel to a slightly downward curve for better visualization).
3. Make sure superior flap is everted to ensure healing of the myringotomy incision when the tube is removed. Stainless steel wire or integral tail aids removal, and can also be utilized should the tube inadvertently drop into the middle ear (Silicone tail should not be used for removal from the t.m.).

Straight Shank

1.1 mm I.D. (.045")

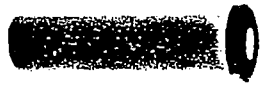


Teflon®	Polyethylene	Length	Flange O.D.
XO-1040	**XO-1090**	7 mm	2.75 mm
XO-1043		10 mm	2.75 mm
XO-1045		12 mm	2.75 mm

1.1 mm I.D. (.045")

Teflon®	Length	Flange O.D.
XO-1093	7 mm	2.2 mm
XO-1094	12 mm	2.2 mm

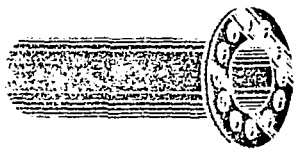
.9 mm I.D. (.035"), 7 mm length



Teflon®	Polyethylene	Flange O.D.
XO-1087	**XO-1080**	2.2 mm
XO-1088	**XO-1081**	2.75 mm
XO-1089	**XO-1082**	3.25 mm

Xomed

Stainless Steel—6 mm length



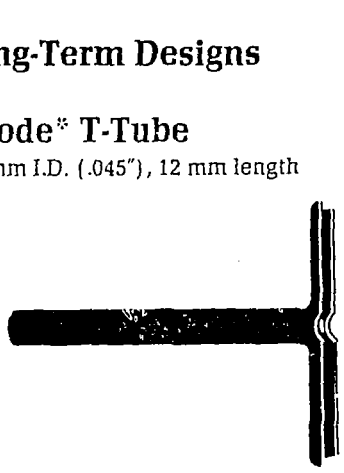
XO-1048	Standard	1.25 mm I.D. (.050") 3 mm O.D. (.120")
XO-1049	Small	1.1 mm I.D. (.045") 1.7 mm O.D. (.065")
XO-1095	Extra Small	.8 mm I.D. (.032") 1.0 mm O.D. (.041")

The Xomed stainless steel ventilation tubes are of the popular straight shank design to minimize the chance of loss in the middle ear. Like the Reuter Bobbins there are holes in the flange for ease of insertion and to encourage mucosal ingrowth to enhance retention in the tympanic membrane. Because the shank of the tube is stainless steel rather than plastic or silicone, a larger lumen size can be achieved without increasing the outside diameter. The rigidity of the tube makes for easy insertion in a small tympanic membrane opening.

Long-Term Designs

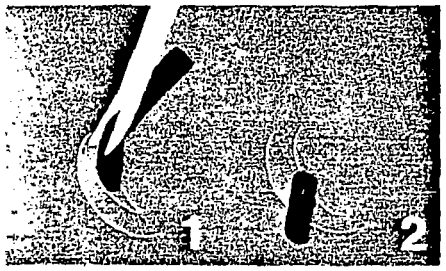
Goode* T-Tube

1.1 mm I.D. (.045"), 12 mm length



XO-1092 Silicone

The Goode T-Tube is a logical alternative to the Per-Lee ventilation tube when a similar design is desired but the surgeon does not wish to make a myringotomy incision to remove the tube from the tympanic membrane. The Goode T-Tube offers versatility since it can be used for either short or long term ventilation. It is easy to insert and remove, and the extrusion rate has been shown to be as low as 2.5%. The Goode T-Tube may be used not only for treatment of chronic serous otitis media, but also for middle ear ventilation immediately after tympanoplastic surgery when indicated. The tube is made in one piece of medical-grade silicone elastomer. The "T" portion of the tube (or flange) collapses readily on insertion and removal through a myringotomy, and its curved wall prevents the tube opening from obstructing against the promontory. The shaft (or shank) of the tube can be trimmed to the proper length desired before or after insertion.



Suggested myringotomy and tube placement procedure:

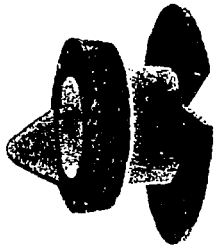
1. Cut tube shaft length to about 8 mm prior to insertion.
2. After adequate anesthesia, make a curved myringotomy incision in the inferior portion of the tympanic membrane, parallel to and about 2 mm from the annulus.
3. Grasp tube at junction of "T" with alligator forceps folding the two sides of the "T" forward alongside the shaft (Fig. 1). Insert tube through the myringotomy so that the "T" expands in the anterior-posterior plane parallel to the middle ear (Fig. 2). Tube shaft may be further trimmed to an optimal length after insertion using House-Bellucci scissors.

Reference:
1. "T-Tube for Middle Ear Ventilation", Arch. Otolaryngology, Vol. 97, May, 1973, pp. 402-403

*Designed by Richard L. Goode, M.D., Stanford, California

Paparella* Type 2

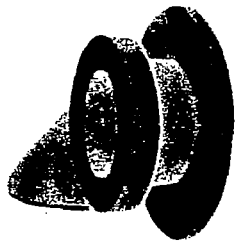
1.5 mm I.D. (.060"),
4.4 mm Inner Flange Diameter



XO-1076 Silicone

Paparella* Type 3

2.0 mm I.D. (.080"),
5.0 mm Inner Flange Diameter

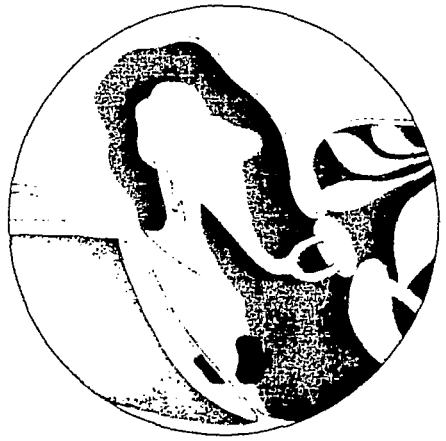


XO-1077 Silicone

*The Paparella Types 2 and 3 are designed for difficult cases and are intended to remain in the tympanic membrane for prolonged periods of time. These soft, silicone elastomer tubes are easily placed through a small myringotomy incision.

The Paparella Type 2 is inserted by introducing the lead corner of the V-shaped notch, on the inner flange, into the myringotomy. The tube is then rotated until the entire flange is behind the tympanic membrane. For many physicians, the Paparella Type 2 has become a standard or routine ventilation tube, since premature extrusion is virtually eliminated. The tube generally remains 1-2 years or longer.

*Designed by Michael M. Paparella, M.D., Minneapolis, Minnesota



Xomed®

Myringotomy—Ventilation Tubes (Long Term)

Pappas* Tri-Flange

1.25 mm I.D. (.050″), 2.75 mm O.D. (.108″)
.5 mm and 1.0 mm between flanges

XO-1028	Teflon®

The Pappas Tri-Flange tube is inserted in the anterior-inferior portion of the tympanic membrane, where the distance from the latter to the middle wall of the middle ear is greatest. The medial portion of the tube must not touch the middle ear mucosa. This situation seems to be a source of blockage from dried secretion.

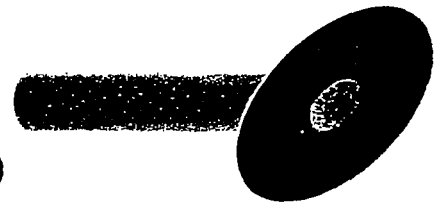
To insert the tube, a myringotomy incision is made (larger than that for a regular collar button tube) and the middle ear is evacuated. A flange is grasped on edge with an alligator forceps and the opposite end of the flange is gently pushed through the incision. The tube is then positioned with a right angle hook. It is then palpated with the hook to observe mobility. If it is immobile because of touching the medial wall of the tympanum, then it is removed and repositioned.

At present, this tube is used routinely. It offers, by its versatility, 6 month, 1 year and 1 + year toleration in the tympanic membrane. In 54 ears, the Pappas Tri-Flange tubes are in place and functioning in 93% after 14 months. In 74 ears, 92% are in place and functioning after 12 months. Six months after insertion in 198 ears, 97% were functioning and intact.

*Designed by Dennis G. Pappas, M.D., Birmingham, Alabama

Per-Lee*

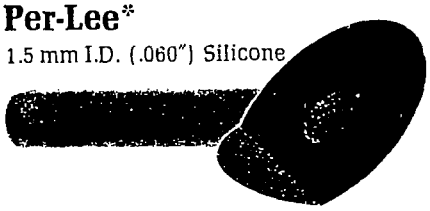
1.5 mm I.D. (.060″) Silicone



Posterior-Inferior Placement	
XO-1070	50° Flange Angle
XO-1071	60° Flange Angle

Per-Lee*

1.5 mm I.D. (.060″) Silicone



Anterior-Superior Placement	
XO-1073	50° Flange Angle
XO-1074	60° Flange Angle
XO-1075	70° Flange Angle

The Per-Lee ventilation tubes are manufactured of medical-grade silicone elastomer. They are intended for long-term use in patients with refractory serous otitis media. The tubes have an integral wide flange placed at an angle to the lumen. The variety of angles available (50°, 60°, 70°) enables the surgeon to select the correct product to accommodate the obtuse angle that the drum makes with the trajectory of the bony ear canal. They also facilitate parallel alignment with the back side of the tympanic membrane. (The most popular angle is the 60°.) The flange diameter and tube length are trimmed to custom fit to the given anatomical situation. Success requires that part of the flange lie medial to the malleus or bony annulus, usually the former.

Reference:
Per-Lee, J. H.: Experience with a "Permanent" Wide Flange Middle Ear Ventilation Tube. The Laryngoscope, Vol. LXXIX, No. 4, April, 1969, pp. 581-591

*Designed by John H. Per-Lee, M.D., Atlanta, Georgia

Silverstein* Permanent Aeration

1.1 mm I.D. (.045″), 3.5 mm Flange Diameter

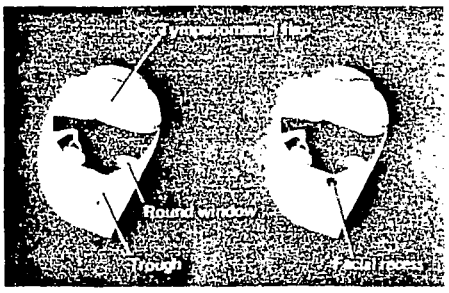
XO-1078	Silicone, 12 mm Length.
XO-1079	Silicone, 7 mm Length. No stylet (Green)

The Silverstein Permanent Aeration Tube (SPAT) is a flanged silicone elastomer tube for chronic secretory otitis media. It is particularly useful in cleft palate patients and others where permanent middle ear aeration is indicated. Specifications of the tube are as described above, and a stylet is also provided with each SPAT to prevent obstruction in the early post-operative period.

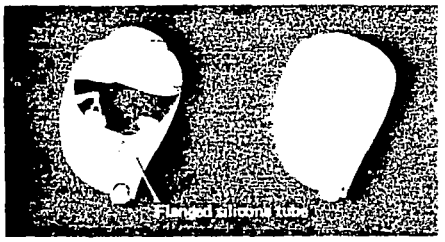
Reference:
Silverstein, Herbert: Permanent Middle Ear Aeration. Archives of Otolaryngology, Vol. 91, April, 1970

*Designed by Herbert Silverstein, M.D., Sarasota, Florida

Instructions for Use:



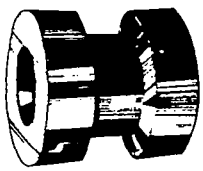
Left, a tympanomeatal flap is elevated, exposing the middle ear structures. Right, area where hole is drilled into facial recess.



Left, SPAT inserted through hole. Bridge sutured to tendon to hold tube in place. Right, permanent silicone-rubber tube in place with tympanomeatal flap over tube.

Biolite®-coated Silicone Donaldson type Vent Tube

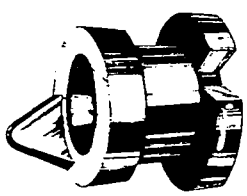
1.1 mm I.D. (.045")



XO-1125

Biolite®-coated Silicone Paparella type 1 Vent Tube

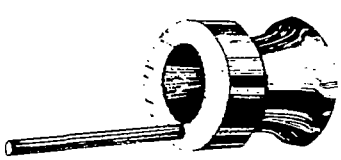
1.1 mm I.D. (.045")



XO-1126

Biolite®-coated Teflon® Shepard Vent Tube w/tail

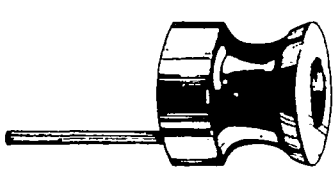
1.1 mm I.D. (.045")



XO-1110

Biolite®-coated Silicone Shepard Vent Tube w/tail

1.1 mm I.D. (.045")



XO-1115

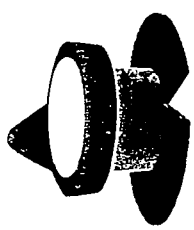
Biolite® is an ultra-thin carbon coating which is applied by a special process to the vent tubes listed above. Biolite (and other similar materials) has been used extensively in such highly critical areas of implantation as artificial heart valves, dental implants, and transcutaneous leads. The excellent success of these applications indicates that Biolite® coating is uniquely suited for use in otologic procedures.

The Biolite® coating does not alter the physical characteristics of the Teflon® or Silicone materials used to fabricate the vent tubes, nor does it measurably change the dimensions of the tubes. The Shepard, Donaldson, or Paparella style tube that you select may be handled the same with Biolite® coating as the standard tube without Biolite®.

Biolite® is a registered trademark of the Medical Products Division of the General Atomic Company. Teflon® is a registered trademark of DuPont Company.

Extensive bibliography available on request.

Castelli Vent Tube



XO-1200 Paparella design
1.1 mm. I.D. (.060")

XO-1201 Donaldson design
1.1 mm. I.D. (.045")

- Allows air to penetrate, but not water.
- In experimental animal tests, middle ear infections due to water entering were prevented.
- Patients can participate in water sports to a limited degree, or shower in a normal manner.
- Made of soft silicone.
- Each design has a tab on the external flange to facilitate insertion and removal.

A porous membrane is bonded to the external flange of a ventilation tube. The unique properties of the membrane are such that it allows the flow of air across the membrane at very low pressures while restricting the entry of water except at very high pressures. Thus, the patient with this ventilation tube in place can participate in water sports, and shower in a normal manner. The necessity for ear plugs is eliminated, thus saving the patient money.

Indications

The Castelli Membrane Vent Tube is designed for use exclusively as a ventilation tube, not as a drainage tube. It is indicated for children over four years of age, or adult patients who require the use of a ventilation tube for the purpose of aerating the middle ear and preventing the recurrence of middle ear effusions. It may also be used for those patients who require the use of a ventilation tube which is placed to correct the condition of middle ear atelectasis due to tympanic membrane retraction and eustachian tube dysfunction. It may be used with thin or serous type effusions at the discretion of the physician.

Contraindications

Under certain circumstances the membrane could clog, stopping the flow of air. Therefore, the Castelli Membrane Tube should not be used when:

- the patient has a thick, glue-like or mucoid effusion, or for the purpose of providing drainage
- the patient is four years old or younger
- antibiotic drops are used
- the middle ear has not been thoroughly aspirated

Insertion

Thoroughly aspirate the middle ear. Make sure the field is free from blood, or this could clog the membrane. Grasp the tab on the external flange with forceps, and place it in the myringotomy incision. A blunt middle ear pick can then be used to manipulate the tube into place. Do not use a Morgan type or similar tube inserter or it will puncture the membrane.

Reference:
Castelli, J. B., M.D., et al; "A Semipermeable Membrane For Tympanic Ventilation Tubes"; Transactions of the American Academy of Ophthalmology and Otolaryngology, April, 1976