Records processed under FOIA Request 2014-1543; Released 11/12/14

K062385

SEP 27 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Replacement Prostheses

Trade Name:	Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes
Common Name:	Tympanostomy Tubes
Classification Name:	Tympanostomy Tubes (CFR 21 § 874.3880)
Official Contact:	Jeff Cobb Vice President of Regulatory Affairs & Quality Grace Medical, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis, TN 38133
Telephone:	(901) 380-7000
Telefax:	(901) 380-7001
Date Prepared:	August 14, 2006

Predicate Devices – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are substantially equivalent to the predicate devices listed below.

Predicate Device	Manufacturer	510(k) Number (if known)
Fluoroplastic Ventilation Tubes	Gyrus ENT	K992222
Tympanostomy Tubes	Grace Medical Inc.	K943325

Intended Use – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes have the same primary intended use as the predicate devices which consist of:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

Materials – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are manufactured from the same materials as the Gyrus ENT Fluoroplastic Ventilation Tubes.

Design Features – Various designs of Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are available to meet physician preference. The design features of the Grace Medical PTFE Ventilation Tubes should not raise new safety or effectiveness issues.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comparison Charts

	GRACE MEDICAL BLUE PTFE (FLUOROPLASTIC) VENTILATION TUBES	GRACE MEDICAL VENTILATION TUBES (K943325)	GYRUS ENT FLUOROPLASTIC VENTILATION TUBES (K992222)
Intended Use	• Chronic otitis media with effusion (serous, mucoid, or purulent) • Recurrent episodes of acute otitis media despite conventional medical treatment • A record of persistent high negative middle ear pressure associated with one or more of the following system: 1. Conductive hearing loss that is symptomatic 2. Persistent or recurrent otalgia 3. Persistent or recurrent vertigo, tinnitus, or both • Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.	Same	Same
Primary Material(s)	Blue (PTFE) Fluoroplastic (Same as Gyrus ENT)	Fluoroplastic	Blue (PTFE) Fluoroplastic
How Supplied	Sterile	Sterile	Sterile

Differences between the Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes and the predicate devices should not raise new issues regarding safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Grace Medical, Inc.
c/o Jeff Cobb
Vice President
Regulatory Affairs & Quality
8500 Wolf Lake Drive, Suite 110
Memphis, TN 38133

SEP 27 2006

Re: K062385
Trade/Device Name: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy tube
Regulatory Class: Class II
Product Code: ETD
Dated: August 14, 2006
Received: August 15, 2006

Dear Mr. Cobb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

510(k) Number: K062385

Device Name: Blue PTFE (Fluoroplastic) Ventilation Tubes

Indications for Use:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2/96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K062385

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Grace Medical, Inc.
c/o Jeff Cobb
Vice President
Regulatory Affairs & Quality
8500 Wolf Lake Drive, Suite 110
Memphis, TN 38133

SEP 27 2006

Re: K062385
Trade/Device Name: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy tube
Regulatory Class: Class II
Product Code: ETD
Dated: August 14, 2006
Received: August 15, 2006

Dear Mr. Cobb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

510(k) Number: K062385

Device Name: Blue PTFE (Fluoroplastic) Ventilation Tubes

Indications for Use:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2/96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K062385

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 16, 2006

GRACE MEDICAL, INC.
8500 WOLF LAKE DR., STE. 110
MEMPHIS, TN 38133
ATTN: JEFF COBB

510(k) Number: K062385
Received: 15-AUG-2006
Product: BLUE PTFE (FLUOROPLASTIC) VENTILATION TUBES

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

K062385

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Process
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

GRACE MEDICAL INC
8500 Wolf Lake Drive, Suite 110
Memphis TN 38133
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
621607535

2. CONTACT NAME
Jeff Cobb

2.1 E-MAIL ADDRESS
jeff@eaglevis.com

2.2 TELEPHONE NUMBER (include Area code)
901-380-7029

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) Trade 11-Aug-2006

Form FDA 3601 (08/2003)

Close Window

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
Supplement	Supplement			
	Report			
	Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Grace Medical, Inc.	Establishment Registration Number *(if known)*: 1057421		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (901) 380-7000		
Street Address: 8500 Wolf Lake Drive, Suite 110	FAX Number *(including area code)*: (901) 380-7001		
City: Memphis	State / Province: TN	ZIP/Postal Code: 38133	Country: USA
Contact Name: Jeff Cobb			
Contact Title: Vice President, Regulatory Affairs & Quality	Contact E-mail Address: jeff@eaglevis.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Media Arts (301) 443-1090 EF

22

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other *(specify below)*

- [ ] Response to FDA correspondence:

- [ ] Change in design, component, or specification:
  - Software / Hardware
  - Color Additive
  - Material
  - Specifications
  - Other *(specify below)*

- [ ] Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other *(specify below)*

- [ ] Location change:
  - Manufacturer
  - Sterilizer
  - Packager

- [ ] Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - Correspondent / Applicant
  - Design / Device
  - Informed Consent
  - Manufacturer
  - Manufacturing Process
  - Protocol - Feasibility
  - Protocol - Other
  - Sponsor

- [ ] Report submission:
  - Current Investigator
  - Annual Progress Report
  - Site Waiver Report
  - Final

- [ ] Repose to FDA Letter Concerning:
  - Conditional Approval
  - Deemed Approved
  - Deficient Final Report
  - Deficient Progress Report
  - Deficient Investigator Report
  - Disapproval
  - Request Extension of Time to Respond to FDA
  - Request Meeting
  - Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

Change in materials from natural PTFE to blue PTFE. Proposed material has been cleared via 510(k) K992222.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1 ETD	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K992222	1	Fluoroplastic Ventilation Tubes	1	Gyrus ENT LLC
2	K943325	2	Tympanostomy Tubes	2	Grace Medical, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Tympanostomy Tubes

	Trade or Proprietary or Model Name for This Device		Model Number
1	Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes	1	various
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K992222	2 K943325	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
ETD	21 § 874.3880	[ ] Class I [x] Class II
Classification Panel: Ear, Nose, and Throat		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

* Chronic otitis media with effusion (serous, mucoid, or purulent)
* Recurrent episodes of acute otitis media despite conventional medical treatment
* A record of persistent high negative middle ear pressure associated with one or more of the following system:

1. Conductive hearing loss that is symptomatic
2. Persistent or recurrent otalgia
3. Persistent or recurrent vertigo, tinnitus, or both

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 1057421	☑ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name: Grace Medical, Inc.		Establishment Registration Number: 1057421		
Division Name *(if applicable)*		Phone Number *(including area code)*: (901) 380-7000		
Street Address: 8500 Wolf Lake Drive, Suite 110		FAX Number *(including area code)*: (901) 380-7001		
City: Memphis		State / Province: TN	ZIP/Postal Code: 38133	Country: USA
Contact Name: Jeff Cobb	Contact Title: Vice President, Regulatory Affairs & Quailty		Contact E-mail Address: jeff@eaglevis.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )		
Street Address		FAX Number *(including area code)*: ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )		
Street Address		FAX Number *(including area code)*: ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F754	ASTM	PTFE Polymer		
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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GRACE MEDICAL
CREATIVE MICROTECHNOLOGY FOR ENT

August 14, 2006

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Notification – Blue PTFE (Fluoroplastic) Ventilation Tubes

Dear Sir/Madam:

Please accept this letter as our intent to market the above referenced products. This Premarket Notification is being submitted in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807.

In response to the requirements addressed by the SMDA of 1990, I am enclosing a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

To the best of our knowledge, all of the accompanying information is truthful and accurate and no material fact(s) has been omitted.

Sincerely,

Grace Medical, Inc.

Jeff Cobb
Vice President
Regulatory Affairs & Quality

Submitted in Duplicate

27

EN II
KB

8500 Wolf Lake Dr., Suite 110 • Memphis, TN 38133 USA • 1-866-472-2363 • 901-386-0990 • Fax 901-380-7001
www.gracemedical.com • info@gracemedical.com

ISO 13485 CERTIFIED COMPANY

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required By 21 CFR 807.87 (j))

I certify that, in my capacity as Vice President of Regulatory Affairs and Quality for Grace Medical, Inc., I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Jeff Cobb

8/14/06

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Number: K062385

Device Name: Blue PTFE (Fluoroplastic) Ventilation Tubes

Indications for Use:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2/96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices
510(k) Number K062385

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(Grace Medical Inc.) (K943325)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I. Device Identification

A) Device Name

1) Proprietary Name(s)

The family of Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes consists of a variety of sizes and shapes of ventilation tubes manufactured from PTFE.

2) Common Name(s)

Tympanostomy Tubes

3) Classification Name(s)

Tympanostomy Tube (CFR 21 § 874.3880)

4) Classification

Class II

5) Classification Panel

Ear, Nose and Throat

6) Device Product Code(s)

77 ETD

B) Predicate Device Names

The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are substantially equivalent to the predicate devices listed below.

Predicate Device	Manufacturer	510(k) Number (if known)	Exhibit
Fluoroplastic Ventilation Tubes	Gyrus ENT	K992222	2
Tympanostomy Tubes	Grace Medical Inc.	K943325	3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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II. Administrative Information

A) Manufacturer Identification

GRACE MEDICAL, INC.
8500 Wolf Lake Drive, Suite 110
Memphis, TN 38133

B) Establishment Registration Number

Registration Number: 1057421

C) Official Contact

Jeff Cobb, Vice President, Regulatory Affairs & Quality

III. Classification

A) Classification Name(s)

Tympanostomy Tube (CFR 21 § 874.3880)

B) Classification

Class II

C) Classification Panel

Ear, Nose and Throat

D) Device Product Code(s)

77 ETD

IV. Special Controls

A) Special Controls under §514 of the Act have not been developed for these devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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V. Information Required for Substantial Equivalence Determination

A) INTENDED USE

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

B) DEVICE DESCRIPTIVE INFORMATION

The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are intended to ventilate the middle ear subsequent to otitis media. The placement of the tube in the tympanic membrane provides the means for eliminating any fluid buildup in the middle ear while creating an avenue of the passage of air to equalize pressure on either side of the drum. These ventilation tubes will be machined from blue PTFE (fluoroplastic) Rod. PTFE has been used as a material for ventilation tubes and other middle ear applications for many years.

- Grace Medical PTFE Ventilation Tubes were cleared via 510(k) No. K943325.
- Gyrus ENT (blue) Fluoroplastic (PTFE) Ventilation Tubes manufactured from the same material were cleared via 510(k) No. K992222.

This material will be purchased from the vendor as blue colored PTFE (fluoroplastic) rod stock. PTFE (fluoroplastic) from this vendor meets USP Class VI for plastics, ASTM D 1710, and ASTM F-754. The colorant meets 21 CFR Part 73.2725. Analysis of this colorant used by the vendor is supplied as **Exhibit 1**. This blue colored PTFE rod stock is the same material cleared via 510(k) No. K992222.

The procedure for placement is the same as current ventilation tubes.

1) Schematics and Diagrams

The Grace Medical Blue Ventilation Tubes may be offered in a variety of sizes and shapes including the following:

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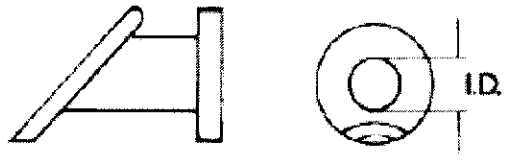
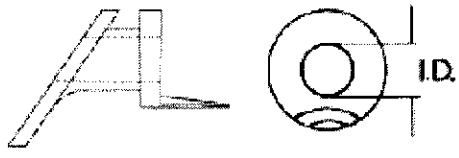
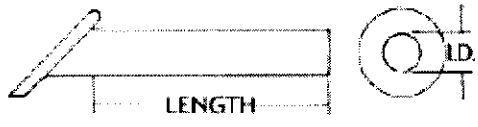
(a) Armstrong Beveled Grommet – 1.14mm ID



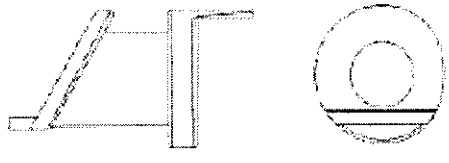
(b) Armstrong Beveled Grommet with Tab – 1.14mm ID



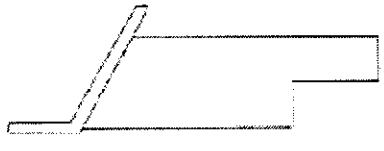
(c) Armstrong Beveled Plain End Tube – 1.14mm ID, Length 7.6mm



(d) Armstrong V Beveled Grommets – 1.14mm ID



(e) Armstrong V Straight Ventilation Tube – 1.14mm ID, Length 4.5mm to 7.5mm



(f) Baxter Beveled Bobbin – 0.97mm to 1.27mm ID

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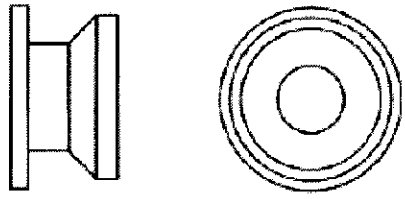
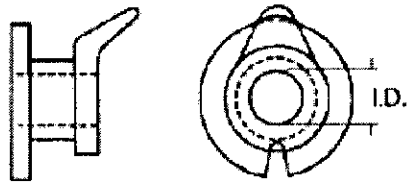
(g) Berger V Bobbin Ventilation Tube – 1.27mm ID

(h) Bevel Bobbin Ventilation Tube – 1.14mm ID



(i) Canale Ventilation Tube – 1.14mm ID



(j) Collar Button Ventilation Tube – 1.27mm ID

(k) Collar Bobbin Ventilation Tube – 0.75mm – 1.27mm ID

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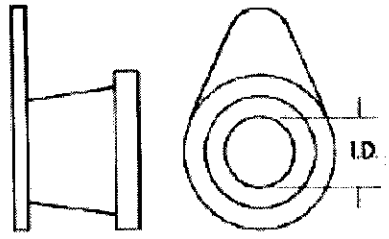
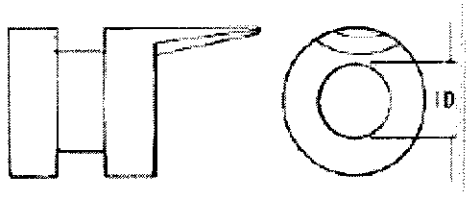
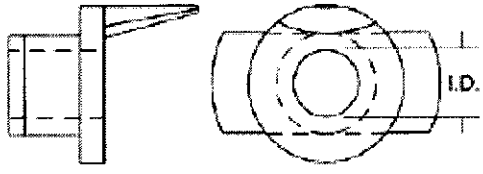


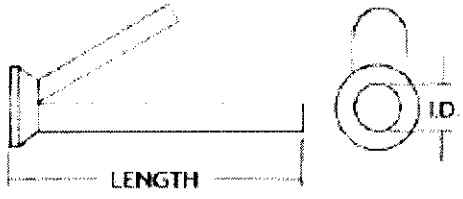
(l) Donaldson Ventilation Tube – 1.14mm ID



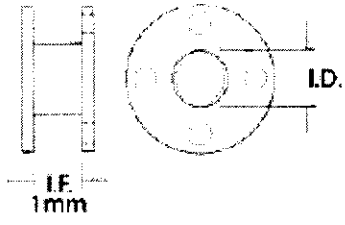
(m) Dutcher Ventilation Tube – 1.27mm ID



(n) Feuerstein Split Ventilation Tube – 1.02mm ID



(o) Fluoroplastic/Titanium Ventilation Tube – 1.00mm to 1.5mm ID



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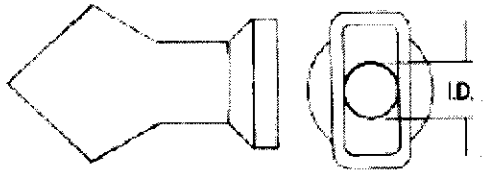
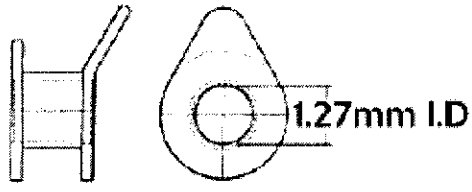
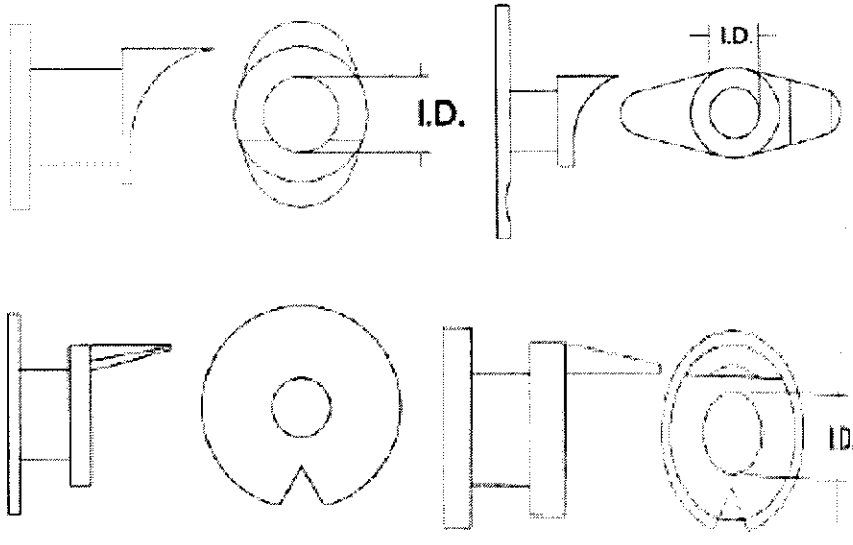
(p) Lindeman-Silverstein Arrow Ventilation Tube – 1.14mm ID



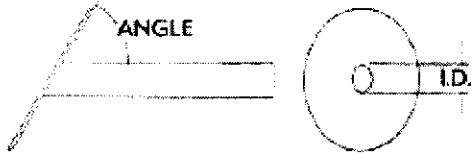
(q) Moretz-Type Ventilation Tube – 1.27mm ID



(r) Paparella-Type Ventilation Tube – 1.02mm to 1.50mm ID



(s) Per-Lee Ventilation Tube – 1.57mm ID



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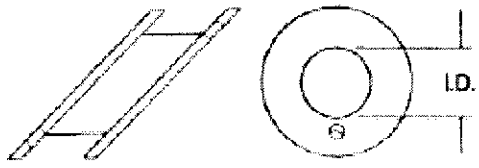
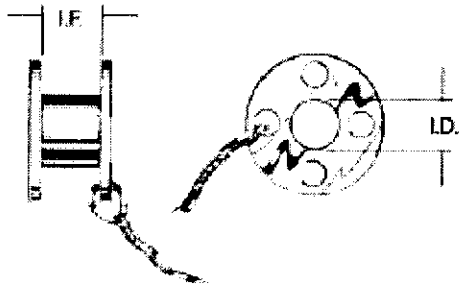
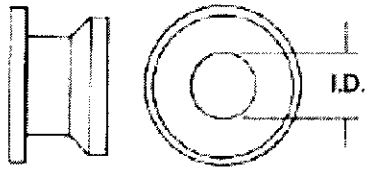
(t) Pope Beveled Grommet Ventilation Tube – 1.14mm ID



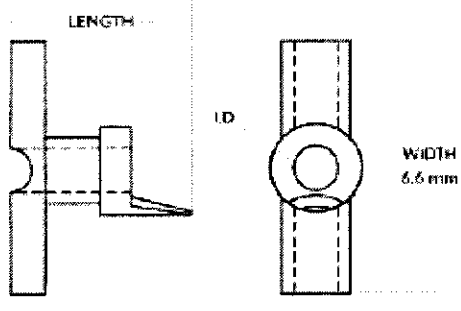
(u) Reuter Bobbin Ventilation Tube – 1.00mm to 1.27mm ID



(v) Rock Pediatric Ventilation Tube – 1.02mm ID



(w) Rube Ventilation Tube – 1.14mm ID



(x) Shah Long-Term Ventilation Tube – 1.00mm ID

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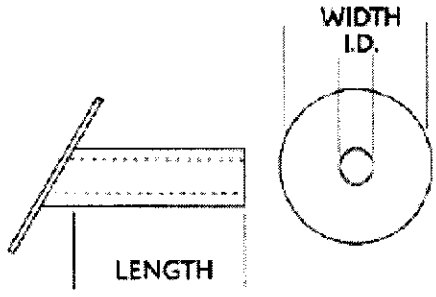
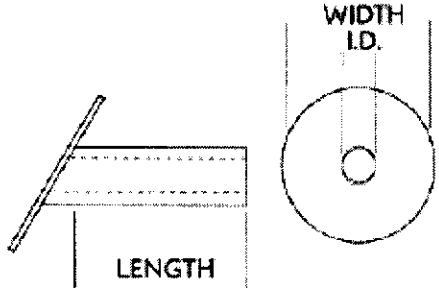
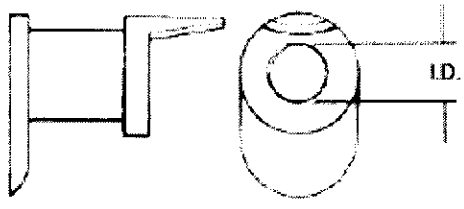


(y) Shah Ventilation Tube – 0.76mm to 1.14mm ID



(z) Shea Parasol Ventilation Tube – 1.02mm to 1.52mm ID

(aa) Shea Ventilation Tube – 0.76mm ID



(bb) Sheehy Type Collar Button Ventilation Tube – 1.27mm ID

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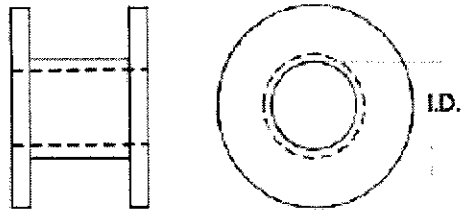
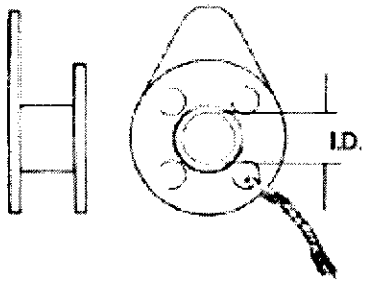
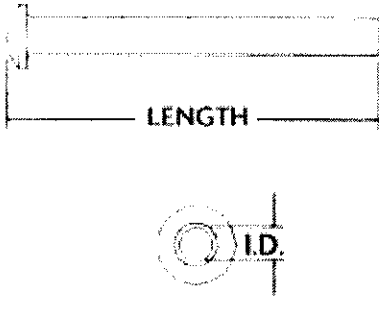


(cc) Shepard Grommet Ventilation Tube – 1.02mm to 1.14mm ID

(dd) Spoon Bobbin Ventilation Tube – 1.00mm to 1.27mm ID



(ee) Straight Ventilation Tube – 0.86mm to 1.14mm ID, Length 7mm to 12mm



(ff) Sultan Ventilation Tube – 1.27mm ID

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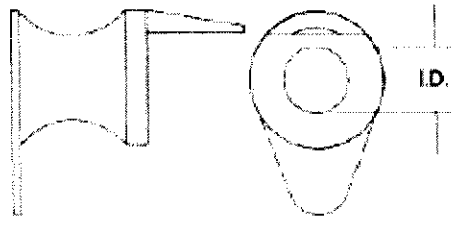
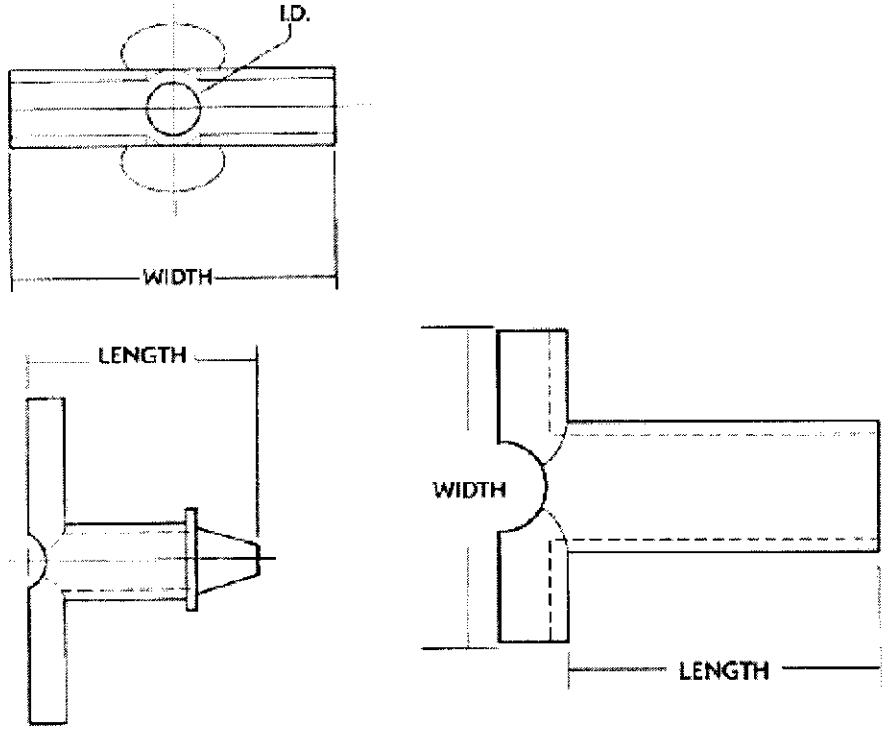


(gg) <u>T-TubeVentilation Tube – 1.14mm to 1.32mm ID, Length 4mm to 12mm, Width 4mm to 9.8mm</u>



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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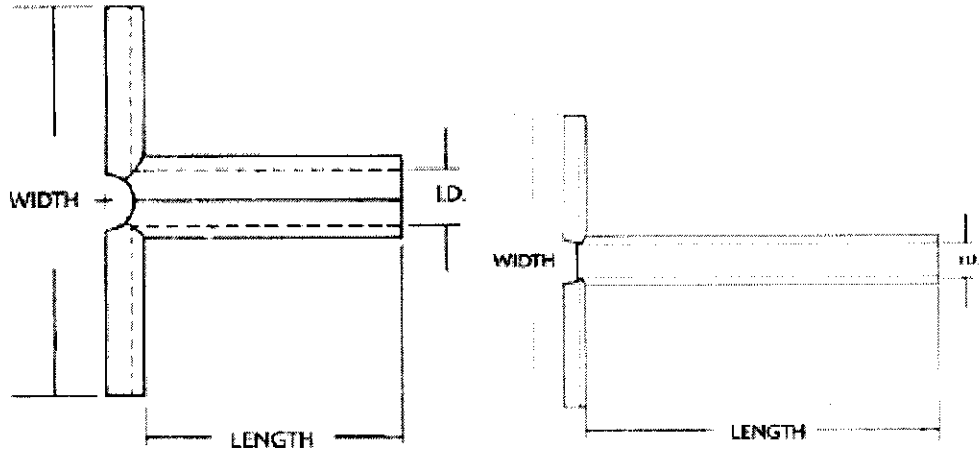

2) Materials: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are made of the same material used in the Gyrus ENT (blue) Fluoroplastic Ventilation Tubes cleared via K992222.

C) STERILITY INFORMATION

Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are provided sterile. This method of sterilization was referenced in and used on product cleared via Grace Medical 510(k) Nos. K060518, K981575, and K972815.

1) Sterilization Method: The devices are sterilized by exposure to H_2O_2 plasma.
2) Sterility Assurance Level: The sterility assurance level (SAL) is 10^{-6}.
3) Sterilization Validation Method: Validation of the sterilization cycle is performed in accordance with ANSI/AAMI/ISO 14937 – Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.
4) Packaging: The devices are packaged inside a molded polypropylene case specifically designed for otology implants with the exception of some of the adjustable length devices which may be packaged in an adjustor body which allows for ease of adjustment to length. The polypropylene case or adjustor body is heat sealed inside a Tyvek® and ionomer pouch, which is in turn placed inside a paperboard carton and shrink-wrapped.

These products ARE NOT labeled 'non-pyrogenic'.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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D) LABELING

1) Indications for Use

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

2) Package Labeling

Sample labeling is shown below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF 520-101 Qty: 5 / Box LOT 7333

FLUOROPLASTIC VENT TUBE-ARMSTRONG TYPE, 1.14 MM ID

STERILE H2O2

2011-01 0473

CAUTION: This device is restricted to sale by or on the order of a physician
ATTENTION: Ce dispositif ne peut être vendu que par un médecin ou sous prescription médicale
ATTENZIONE: Questo dispositivo può essere venduto solo da personale medico o dietro ricetta medica
CUIDADO: Este dispositivo sólo se puede vender por o bajo receta de un médico
VORSICHT: Dieses Gerät darf nur vom einem Arzt bzw. auf dessen Anordnung verkauft werden

GRACE MEDICAL
CREATIVE MICROTECHNOLOGY FOR ENT

7731 Hwy 70, Suite 107, Bartlett, TN 38133, USA
Toll Free 866-472-2363 • Phone 1-901-386-0990 • Fax 1-901-386-0950
Email: info@gracemedical.com • www.gracemedical.com

©2001 Grace Medical, Inc.

Not returnable if box seal is broken

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3) Package Insert

A sample of the Instructions for Use is provided below.

IMPORTANT MEDICAL INFORMATION

PURPOSE
The purpose of the Tympanostomy tube insertion procedure is to aspirate or ventilate the middle ear subsequent to acute otitis media. The placement of the tube in the tympanic membrane provides the means for drainage of any fluid buildup in the middle ear while creating an avenue for the passage of air to equalize pressure on either side of the tympanic membrane

DESCRIPTION
Grace Medical, Inc's tympanostomy (myringotomy) tubes are produced from a variety of biocompatible materials which include silicone elastomer, polytetrafluoroethylene, stainless steel, and Titanium. Various configurations are available to suit the physician's preference for short or long term ventilation.

INDICATIONS
1. Chronic otitis media with effusion characterized as either serous, mucoid, or purulent
2. Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies
3. A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss that is symptomatic, persistent or recurrent otalgia, persistent or recurrent vertigo and/or tinnitus
4. Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction

CONTRAINDICATIONS
1. Cases where drug treatment will suffice
2. Cases where myringotomy will, in the opinion of the surgeon, alleviate the patient's condition
3. Contraindications may be relative or absolute and must be weighed against the patient's entire condition.

POSSIBLE ADVERSE EFFECTS
Known potential adverse reactions include:
1. Ventilation tube could become clogged and cease to function properly
2. Early extrusion of the ventilation tube may occur
3. Additional infection from airborne or aqueous contaminants entering through the tube may occur.
4. Persistent or permanent perforation may occur which may require a grafting procedure to close.
5. Patient allergy or sensitivity to certain materials may result in tissue irritation.
6. Longer term tubes, such as T-tubes, and tubes with larger flanges may require a second surgical procedure to remove the tube.

PRECAUTIONS
Once a myringotomy tube is inserted into the tympanic membrane, care should be taken to avoid environments which could cause contamination of the middle ear.

RE-STERILIZATION
Grace Medical, Inc. assumes no liability for products which have been resterilized by health care facilities..

* Metallic components which may be used in Grace Medical implants are unaffected by the magnetic fields produced by MRI units

GRACE MEDICAL
CREATIVE MICROTECHNOLOGY FOR EAR

Product Information for Tympanostomy Tubes
Informations techniques pour les drains transtympaniques
Informazioni sul prodotto per tubi per miringotomia
Información de producto para tubos de timpanostomía
Produktinformationen über Tronmelfellschnittröhren

CAUTION: This device is restricted to sale by or on the order of a physician
ATTENTION : Ce dispositif ne peut être vendu que par un médecin ou sous prescription médicale
ATTENZIONE: Questo dispositivo può essere venduto solo da personale medico o dietro ricetta medica
CUIDADO: Este dispositivo sólo se puede vender por o bajo receta de un médico
VORSICHT: Dieses Gerät darf nur von einem Arzt bzw. auf dessen Anordnung verkauft werden

Refer to product label for sterilization method used
Référez-vous à l'étiquette de produit pour la méthode de stérilisation employée
Per il metodo di sterilizzazione impiegato, consultare l'etichetta del prodotto
Consulte la etiqueta del producto para información sobre el método de esterilización utilizado.
Siehe Produktetikett für Informationen über anzuwendende Sterilisationsmethode

STERILE H2O2 Sterilized by hydrogen peroxide plasma
Stérilisé par plasma de peroxyde d'hydrogène
Sterilizzato con plasma con perossido di idrogeno
Esterilizado por plasma de peróxido de hidrógeno.
Sterilisiert mit Wasserstoffperoxidplasma

STERILE EO Sterilized by ethylene oxide
Stérilisé par l'oxyde d'éthylène
Sterilizzato con ossido di etilene
Esterilizado por óxido de etileno.
Sterilisiert mit Äthylenoxid

STERILE R Sterilized by gamma irradiation
Stérilisé par irradiation gamma
Sterilizzato con radiazioni gamma
Esterilizado por irradiación gamma.
Sterilisiert mit Bestrahlung durch Gamma strahlen

Do not use if peel pouch is opened or damaged
N'employez pas si l'emballage scaple est ouvert ou endommagé
Non utilizzare se il sacchetto è aperto o danneggiato
No use este producto si la bolsa ha sido abierta o dañada
Nicht verwenden, wenn die ablösbare Tasche geöffnet oder beschädigt wurde

CUSTOMER SERVICE
(For product ordering & information)
Grace Medical, Inc.
7731 Hwy 70, Suite 107, Bartlett, TN 38133, USA
Tel: 001-901-386-0990 Fax: 001-901-386-0950

AUTHORIZED REPRESENTIVE
(For EC regulatory affairs)
Genesis Medical Products Ltd
The coach House, Phoenix Business Centre,
Low Mill Road, RIPON, North Yorkshire, England HG4 1NS
Tel: +44(0)1765 605551 Fax: +44(0)1765 603201

Form: C00958 DCP# 354

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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VI. SUMMARY OF EQUIVALENCE

A) Indications for Use

The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes have the same intended use and general indications for use as the following predicate devices:

Predicate Device	Manufacturer	510(k) Number (if known)
Fluoroplastic Ventilation Tubes	Gyrus ENT	K992222
Tympanostomy Tubes	Grace Medical Inc.	K943325

B) Design Type

The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes have the same design type (including materials of construction and geometry) as the predicate devices.

C) Materials of Construction

The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are made of the same blue fluoroplastic as the Gyrus ENT Fluoroplastic Ventilation Tubes cleared via 510(k) No. K992222.

D) STATEMENT OF SIMILARITIES/DISSIMILARITIES

1) Predicate Devices – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are substantially equivalent to the above-referenced devices marketed by Grace Medical and Gyrus ENT.

2) Intended Use – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes have the same primary intended use as the predicate devices.

3) Materials – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are manufactured from the same materials as the Gyrus ENT Fluoroplastic Ventilation Tubes cleared via 510(k) No. K992222.

4) Design Features – Various designs of the Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are available to meet physician preference.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF SIMIILARITIES/DISSIMILARITIES

	GRACE MEDICAL BLUE PTFE (FLUOROPLASTIC) VENTILATION TUBES	GRACE MEDICAL VENTILATION TUBES (K943325)	GYRUS ENT FLUOROPLASTIC VENTILATION TUBES (K992222)
Intended Use	• Chronic otitis media with effusion (serous, mucoid, or purulent) • Recurrent episodes of acute otitis media despite conventional medical treatment • A record of persistent high negative middle ear pressure associated with one or more of the following system: 1. Conductive hearing loss that is symptomatic 2. Persistent or recurrent otalgia 3. Persistent or recurrent vertigo, tinnitus, or both • Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.	Same	Same
Primary Material(s)	Blue (PTFE) Fluoroplastic (Same as Gyrus ENT)	(PTFE) Fluoroplastic	Blue (PTFE) Fluoroplastic
How Supplied	Sterile	Sterile	Sterile

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K062385

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Replacement Prostheses

Trade Name:	Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes
Common Name:	Tympanostomy Tubes
Classification Name:	Tympanostomy Tubes (CFR 21 § 874.3880)
Official Contact:	Jeff Cobb Vice President of Regulatory Affairs & Quality Grace Medical, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis, TN 38133
Telephone:	(901) 380-7000
Telefax:	(901) 380-7001
Date Prepared:	August 14, 2006

Predicate Devices – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are substantially equivalent to the predicate devices listed below.

Predicate Device	Manufacturer	510(k) Number (if known)
Fluoroplastic Ventilation Tubes	Gyrus ENT	K992222
Tympanostomy Tubes	Grace Medical Inc.	K943325

Intended Use – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes have the same primary intended use as the predicate devices which consist of:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

Materials – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are manufactured from the same materials as the Gyrus ENT Fluoroplastic Ventilation Tubes.

Design Features – Various designs of Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are available to meet physician preference. The design features of the Grace Medical PTFE Ventilation Tubes should not raise new safety or effectiveness issues.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comparison Charts

	GRACE MEDICAL BLUE PTFE (FLUOROPLASTIC) VENTILATION TUBES	GRACE MEDICAL VENTILATION TUBES (K943325)	GYRUS ENT FLUOROPLASTIC VENTILATION TUBES (K992222)
Intended Use	• Chronic otitis media with effusion (serous, mucoid, or purulent) • Recurrent episodes of acute otitis media despite conventional medical treatment • A record of persistent high negative middle ear pressure associated with one or more of the following system: 1. Conductive hearing loss that is symptomatic 2. Persistent or recurrent otalgia 3. Persistent or recurrent vertigo, tinnitus, or both • Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.	Same	Same
Primary Material(s)	Blue (PTFE) Fluoroplastic (Same as Gyrus ENT)	Fluoroplastic	Blue (PTFE) Fluoroplastic
How Supplied	Sterile	Sterile	Sterile

Differences between the Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes and the predicate devices should not raise new issues regarding safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXHIBIT 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process

(b)(4) Trade Secret Process

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EXHIBIT 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K992222

Food and Drug Administration
510(k) Notification – Fluoroplastic Ventilation Tubes
June 30, 1999

510(k) Number: K992222
Device Name: Fluoroplastic Ventilation Tubes

Indications for Use:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Retraction pocket of the tympanic membrane

8/20/99

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992222

Prescription Use ✓
(Per 21 CFR 801.109)

Page 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AUG 26 1999

K 992222

510(k) Summary of Safety and Effectiveness

Trade Name:	Fluoroplastic Ventilation Tubes
Common Name:	Tympanostomy Tubes
Classification Name:	Tympanostomy Tubes (CFR 21 § 874.3880)
Official Contact:	Alicia E. Farage Senior Regulatory Affairs Specialist Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Telefax:	(901) 373-0242
Date Prepared:	July 2, 1999

The Fluoroplastic Ventilation Tubes are substantially equivalent to the current fluoroplastic tubes marketed by Smith & Nephew, Inc., ENT Division, and the fluoroplastic tubes marketed by Xomed.

These devices have the same indications for use: to ventilate the middle ear subsequent to otitis media.

Differences between the Fluoroplastic Ventilation Tubes and the predicate devices should not affect the safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1999

Ms. Alicia E. Farage
Sr. Regulatory Affairs Specialist
Smith & Nephew, Inc.
ENT Division
2925 Appling Road
Barlett, TN 38133

Re: K992222
Trade Name: Fluoroplastic Ventilation Tubes
Regulatory Class: II
Product Code: 77 ETD
Dated: June 30, 1999
Received: July 1, 1999

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gyrus ENT Catalogue Pages

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Berger "V" Bobbin Ventilation Tube

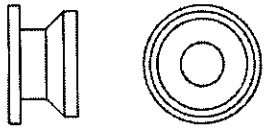
14-5282

Designed to help reduce the possibility of lumen clogging. Hourglass-shaped lumen widens on both sides of the tympanic membrane to shorten the interflange dimension. This helps to reduce the accumulation of residual draining, minimizing the potential for lumen clogging. "V"-shape facilitates insertion. Features Gyrus ENT's exclusive MICRON™ finish.

Catalog Number	Material	I.D.	Units per Package	Units per Box
14-5282	Titanium	1.27mm	1	6

Designed by Eric S. Berger, M.D., Aberdeen, WA. U.S. Patent No. 4,080,171

Bevel Bobbin Ventilation Tube

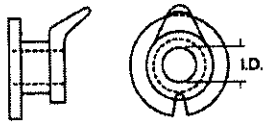


7014-3257

Catalog Number	Material	I.D.	Units per Package	Units per Box
7014-3257	Blue Fluoroplastic	1.14mm	1	6

Canale Ventilation Tube

Notched medial flange allows smaller myringotomy as the tube is screwed into the incision. Angled tab helps in easy insertion.

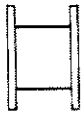


24-0080

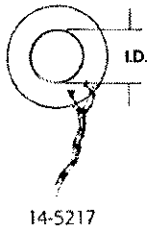
Catalog Number	Material	I.D.	Units per Package	Units per Box
24-0080	Blue Silicone	1.14mm	1	6

Collar Button Ventilation Tubes

A "collar button" shaped ventilation tube for treatment of chronic, serious otitis media.



14-5214



14-5217

Catalog Number	Material	I.D.	I.F.	Units per Package	Units per Box
14-5214	Fluoroplastic	1.27mm	1.5mm	1	6
7014-5062	Blue Fluoroplastic	1.27mm	1.5mm	1	6
14-5705	Fluoroplastic	1.27mm	1.5mm	2	60
14-5217	Fluoroplastic with Wire	1.27mm	1.5mm	1	6
14-5004	Fluoroplastic	1.27mm	1.5mm	1	30
7014-5060	Blue Fluoroplastic	1.27mm	1.5mm	2	60
7014-5314	PC Coated Fluoroplastic	1.27mm	1.5mm	1	6
7014-5316	PC Coated Fluoroplastic	1.27mm	1.5mm	1	30
7014-5317	PC Coated Fluoroplastic	1.27mm	1.5mm	2	60
24-0014	Blue Silicone	1.27mm	1.5mm	1	6
7024-1014	Blue Ultrasil™ Silicone	1.27mm	1.5mm	1	6
7024-1314	Blue Ultrasil™ Silicone	1.27mm	1.5mm	1	30
7024-1060	Blue Ultrasil™ Silicone	1.27mm	1.5mm	2	60

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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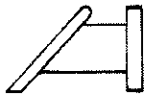
Armstrong Beveled Grommets # 1



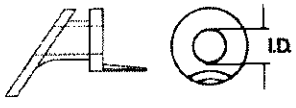
14-0242

Beveled inner flange corresponds to the angle of the tympanic membrane, resists premature extrusion.

Catalog Number	Material	I.D.	Units per Package	Units per Box
14-0242	Fluoroplastic	1.14mm	1	6
14-5700	Fluoroplastic	1.14mm	2	60
7014-5061	Blue Fluoroplastic	1.14mm	1	6
7014-3061	Blue Fluoroplastic	1.14mm	1	30
7014-5761	Blue Fluoroplastic	1.14mm	2	60
7014-0267	PC Coated Fluoroplastic	1.14mm	1	6
7014-3067	PC Coated Fluoroplastic	1.14mm	1	30
7014-6067	PC Coated Fluoroplastic	1.14mm	2	60

Designed by B.W. Armstrong, M.D., Charlotte, NC.

Armstrong Beveled Grommets # 2



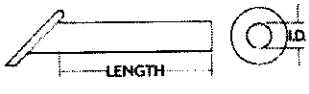
24-0050

Beveled inner flange corresponds to the angle of the tympanic membrane, resists premature extrusion. Tab permits easy removal.

Catalog Number	Material	I.D.	Units per Package	Units per Box
24-0050	Blue Silicone, with Tab	1.14mm	1	6
7024-1050	Blue Ultrasil™ Silicone, with Tab	1.14mm	1	6
7024-1350	Blue Ultrasil™ Silicone, with Tab	1.14mm	1	30
7024-5755	Blue Ultrasil™ Silicone, with Tab	1.14mm	2	60

Designed by B.W. Armstrong, M.D., Charlotte, NC.

Armstrong Beveled Plain End Ventilation Tubes



14-0244

Beveled inner flange corresponds to the angle of the tympanic membrane, resists premature extrusion.

Catalog Number	Material	I.D.	Length	Units per Package	Units per Box
14-0244	Fluoroplastic	1.14mm	7.6mm	1	6
14-5706	Fluoroplastic	1.14mm	7.6mm	2	60
24-0052	Blue Silicone	1.14mm	7.6mm	1	6
7024-1052	Blue Ultrasil™ Silicone	1.14mm	7.6mm	1	6
7014-0345	PC Coated Fluoroplastic	1.14mm	7.6mm	1	6
7014-0346	PC Coated Fluoroplastic	1.14mm	7.6mm	1	30
7014-0347	PC Coated Fluoroplastic	1.14mm	7.6mm	2	60

Designed by B.W. Armstrong, M.D., Charlotte, NC.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Armstrong V Beveled Grommets

The Armstrong V grouping of ventilation tubes provides easy insertion and clear visualization of the incision. All tubes are blue, in color, and are PacifiC™ coated to help prevent biofilm formation.

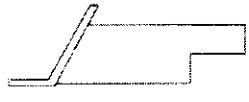
7014-0395

Catalog Number	Material	I.D.	Units per Package	Units per Box
7014-0395	PC Coated Blue Fluoroplastic	1.14mm	1	6
7014-0396	PC Coated Blue Fluoroplastic	1.14mm	1	30
7014-0397	PC Coated Blue Fluoroplastic	1.14mm	2	60

Designed by B.W. Armstrong, M.D., Charlotte, NC.

Armstrong V Straight Ventilation Tubes

The Armstrong V grouping of ventilation tubes provides easy insertion and clear visualization of the incision. All tubes are blue and are PacifiC™ coated to help prevent biofilm formation.



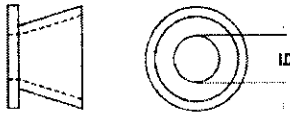
7014-0398

Catalog Number	Material	I.D.	Length	Units per Package	Units per Box
7014-0398	PC Coated Blue Fluoroplastic	1.14mm	4.5mm	1	6
7014-0399	PC Coated Blue Fluoroplastic	1.14mm	4.5mm	1	30
7014-0400	PC Coated Blue Fluoroplastic	1.14mm	4.5mm	2	60
7014-0401	PC Coated Blue Fluoroplastic	1.14mm	7.5mm	1	6
7014-0402	PC Coated Blue Fluoroplastic	1.14mm	7.5mm	1	30
7014-0403	PC Coated Blue Fluoroplastic	1.14mm	7.5mm	2	60

Designed by B.W. Armstrong, M.D., Charlotte, NC.

Baxter Beveled Bobbin

Designed to enhance retention and aeration. The tapered lumen assists the surgeon in cleaning if necessary.



7014-0271

Catalog Number	Material	I.D.	Units per Package	Units per Box
7014-0271	PC Coated Blue Fluoroplastic	0.97mm	1	6
7014-0273	PC Coated Blue Fluoroplastic	0.97mm	1	6
7014-0275	PC Coated Blue Fluoroplastic	0.97mm	2	60
7014-0270	PC Coated Blue Fluoroplastic	1.27mm	1	6
7014-0272	PC Coated Blue Fluoroplastic	1.27mm	1	30
7014-0274	PC Coated Blue Fluoroplastic	1.27mm	2	60

Designed by Dave Baxter, R.N., Boston, MA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

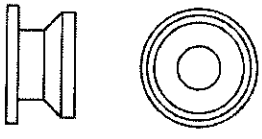
14-5282

Berger "V" Bobbin Ventilation Tube

Designed to help reduce the possibility of lumen clogging. Hourglass-shaped lumen widens on both sides of the tympanic membrane to shorten the interflange dimension. This helps to reduce the accumulation of residual draining, minimizing the potential for lumen clogging. "V"-shape facilitates insertion. Features Gyrus ENT's exclusive MICRON™ finish.

Catalog Number	Material	I.D.	Units per Package	Units per Box
14-5282	Titanium	1.27mm	1	6

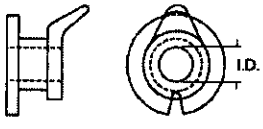
Designed by Eric S. Berger, M.D., Aberdeen, WA. U.S. Patent No. 4,080,171



7014-3257

Bevel Bobbin Ventilation Tube

Catalog Number	Material	I.D.	Units per Package	Units per Box
7014-3257	Blue Fluoroplastic	1.14mm	1	6



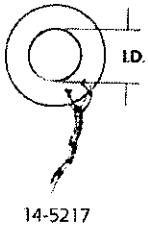
24-0080

Canale Ventilation Tube

Notched medial flange allows smaller myringotomy as the tube is screwed into the incision. Angled tab helps in easy insertion.

Catalog Number	Material	I.D.	Units per Package	Units per Box
24-0080	Blue Silicone	1.14mm	1	6

14-5214



14-5217

Collar Button Ventilation Tubes

A "collar button" shaped ventilation tube for treatment of chronic, serious otitis media.

Catalog Number	Material	I.D.	I.F.	Units per Package	Units per Box
14-5214	Fluoroplastic	1.27mm	1.5mm	1	6
7014-5062	Blue Fluoroplastic	1.27mm	1.5mm	1	6
14-5705	Fluoroplastic	1.27mm	1.5mm	2	60
14-5217	Fluoroplastic with Wire	1.27mm	1.5mm	1	6
14-5004	Fluoroplastic	1.27mm	1.5mm	1	30
7014-5060	Blue Fluoroplastic	1.27mm	1.5mm	2	60
7014-5314	PC Coated Fluoroplastic	1.27mm	1.5mm	1	6
7014-5316	PC Coated Fluoroplastic	1.27mm	1.5mm	1	30
7014-5317	PC Coated Fluoroplastic	1.27mm	1.5mm	2	60
24-0014	Blue Silicone	1.27mm	1.5mm	1	6
7024-1014	Blue Ultrasil™ Silicone	1.27mm	1.5mm	1	6
7024-1314	Blue Ultrasil™ Silicone	1.27mm	1.5mm	1	30
7024-1060	Blue Ultrasil™ Silicone	1.27mm	1.5mm	2	60

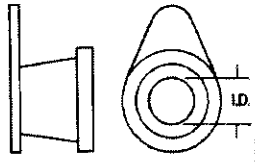
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Collar Bobbin® Ventilation Tubes

Unique thicker collar permits grasping from different angles while the tapered lumen resists clogging with a minimal TM incision.

Catalog Number	Material	I.D.	I.F.	Units per Package	Units per Box
14-5287	Titanium	1.14mm	1.5mm	1	6
14-5297	Titanium	1.27mm	1.5mm	1	6
14-5288	Fluoroplastic	0.75mm	1.5mm	1	6
14-5289	Fluoroplastic	1.14mm	1.5mm	1	6
14-5298	Fluoroplastic	1.27mm	1.5mm	1	6



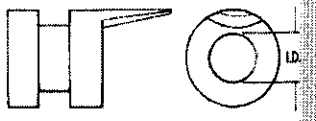
14-5288

Donaldson Ventilation Tubes

Flanges resist migration and extrusion. Large lumen promotes good ventilation.

Catalog Number	Material	I.D.	Units per Package	Units per Box
24-0015	Blue Silicone	1.14mm	1	6
24-5702	Blue Silicone	1.14mm	2	60
24-0060	Blue Soft Silicone	1.14mm	1	6
24-0016	Blue Silicone with Tab	1.14mm	1	6
7024-5012	Blue Silicone with Tab	1.14mm	1	30
24-5707	Blue Silicone with Tab	1.14mm	2	60
7024-1015	Blue Ultrasil™ Silicone	1.14mm	1	6
14-6043	Fluoroplastic	1.14mm	1	60

Designed for James A. Donaldson, M.D., Seattle, WA



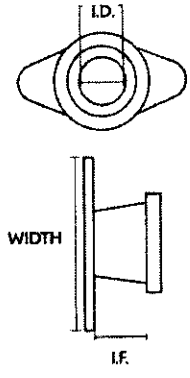
24-0016

DuraVent™ Tubes

Designed for long-term ventilation, the DuraVent™ combines a tapered lumen for increased ventilation with thin tapered flanges providing reduced mass behind the tympanic membrane. The thin, collapsible flanges allow easier insertion and removal with no special instrumentation requirements.

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
24-0075	Blue Silicone	1.37mm I.F., 4.5mm Width	1.27mm	1	6
24-5775	Blue Silicone	1.37mm I.F., 4.5mm Width	1.27mm	2	60
7024-1075	Blue Ultrasil™ Silicone	1.37mm I.F.	1.27mm	1	6
7024-1375	Blue Ultrasil™ Silicone	1.37mm I.F.	1.27mm	1	30

As developed in conjunction with Bruce Black, M.D., Brisbane, Australia.



24-0075

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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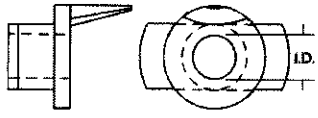
Dutcher Ventilation Tube with Tab



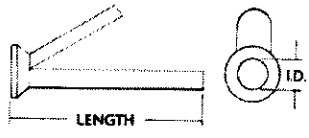
7024-0054

Catalog Number	Material	Description	I.D.	Dimensions	Units per Package	Units per Box
7024-0054	Blue Silicone Ultrasil	With Tab	1.27mm	Medial Flange - 4.3mm, Internal Flange - 3mm	1	5

Designed for Paul Dutcher, M.D., Rochester, NY.

Feuerstein Split Ventilation Tube

Resists both extrusion and migration.



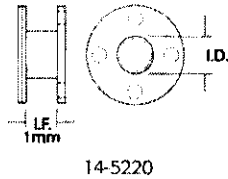
14-0248

Catalog Number	Material	I.D.	Length	Units per Package	Units per Box
14-0248	Fluoroplastic	1.02mm	9mm	1	6

Designed for Sidney S. Feuerstein, M.D., New York, NY.

Fluoroplastic/Titanium Ventilation Tubes

Combines the advantages of biocompatible titanium and "clog" resistant properties of fluoroplastic. The tube features a fluoroplastic lumen insert and medial flange resists clogging. Only titanium contacts the tympanic membrane. Ideal for long-term ventilation.

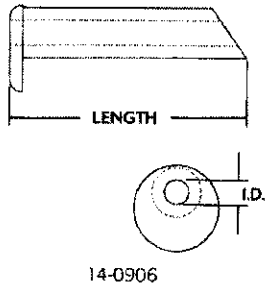


14-5220

Catalog Number	Material	Description	I.D.	I.F.	Units per Package	Units per Box
14-5220	Fluoroplastic/Titanium	With Flange Holes	1mm	1mm	1	6
14-5271	Fluoroplastic/Titanium	Without Holes	1.27mm	1mm	1	6
14-5272	Fluoroplastic/Titanium	Without Holes	1.5mm	1mm	1	6

Jahn HydroxylVent® Tubes

Highly biocompatible dense hydroxylapatite tube designed for subannular placement. Intended for use only when long-term ventilation is indicated.



14-0906

Catalog Number	Material	I.D.	Overall Length	Units per Package	Units per Box
14-0906	Hydroxylapatite	1mm	9.5mm	1	6
14-0926	Hydroxylapatite	1.27mm	9.5mm	1	6
14-0927	Hydroxylapatite, with Fluoroplastic Liner	1mm	9.5mm	1	6

Designed by Anthony F. Jahn, M.D., Newark, NJ.

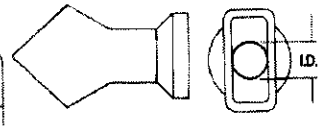
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Lindeman-Silverstein Arrow Ventilation Tube

Designed to be rotated after insertion to lock in place.

Catalog Number	Material	I.D.	Units per Package	Units per Box
14-0240	Fluoroplastic	1.14mm	1	6

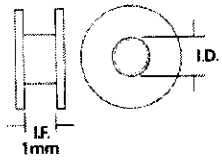


14-0240

Designed for Roger Lindeman, M.D., Seattle, WA and Herbert Silverstein, M.D., Sarasota, FL.

Micron™ Bobbin Ventilation Tubes

Two standard bobbin designed titanium tubes featuring Gyrus ENT's exclusive MICRON™ finish that provides the necessary ultra-smoothness without the glare or reflection of ordinary polished finishes. The smooth finish of the lumen surface reduces the potential for clogging and unwanted tissue ingrowth. Design and biocompatibility of this tube make it well-suited for long-term ventilation.



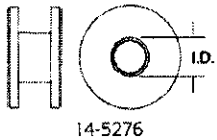
14-5281

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-5221	Titanium	"Mini" Version	0.76mm	1	6
14-5279	Titanium	No Flange Holes	1.14mm	1	6
14-5280	Titanium	No Flange Holes	1mm	1	6
14-5281	Titanium	No Flange Holes	1.27mm	1	6
14-5781	Titanium	Twin Pack No Flange Holes	1.27mm	2	60
14-5273	Titanium	With Spoon Flange	1.27mm	1	6
14-5215	Titanium	With Flange Holes	1mm	1	6
14-5219	Titanium	"Unibobbin" (Flange Holes on One Flange Only)	1mm	1	6
7014-5881	Blue Titanium	No Flange Holes	1.27mm	1	12
7014-5381	Blue Titanium	No Flange Holes	1.27mm	1	6

U.S. Patent No. 4,744,792

Micron™ + Plus Ventilation Tubes

This bobbin-style ventilation tube features the innovative Hydromer™ coating on the lumen and outer surfaces of each flange, providing a "slicker" surface than Teflon™ (fluoroplastic) material. Only titanium contacts the tympanic membrane, making the tube well-suited for long-term ventilation.

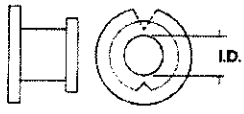


14-5276

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-5276	Titanium	+ Hydromer™ Coated	1.27mm	1	6
7014-5776	Titanium	+ Hydromer™ Coated	1.27mm	2	60

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14



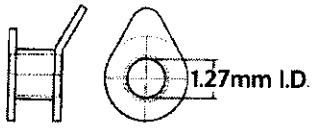
24-0042

Mini-Reversible Ventilation Tube

This ventilation tube is characterized by its reversible insertion feature. The tube is notched on both flanges, in a style similar to Paparella-type tubes, for atraumatic insertion. The small flange (1.78mm) may be inserted in the tympanic membrane to encourage early extrusion. When longer term ventilation is desired, the larger flange (2.16mm) may be inserted to help delay extrusion. Each "V" notch is positioned 180° from the other to help the surgeon conceptualize the location of the inserted flange and notch behind the tympanic membrane.

Catalog Number	Material	I.D.	Description	Units per Pkg.	Units per Box
24-0042	Silicone	0.89mm	Reversible	1	6

Designed for Burton J. Cohen, M.D., Louisville, KY.



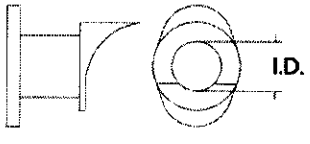
14-5265

Moretz-Type Ventilation Tubes

Familiar bobbin-style ventilation tube is enhanced with an angled lateral tab. The angled tab not only provides an improved grasp with alligator forceps, but also improved visualization during insertion procedure.

Catalog Number	Material	Description	I.D.	I.F.	Units per Package	Units per Box
14-5265	Titanium	Angled Tab	1.27mm	1mm	1	6
7014-5498	Blue Polyethylene	–	1.27mm	1mm	1	6
7014-3498	Blue Polyethylene	–	1.27mm	1mm	1	30
7014-5798	Blue Polyethylene	–	1.27mm	1mm	2	60
7014-2043	PC Coated Fluoroplastic	–	1.27mm	1.29mm	1	6

As developed by William Moretz, M.D., Augusta, GA.



7014-0257

Paparella 2000 - Type 1 Ventilation Tubes

This tube has been designed for moderate to long-term ventilation using the proven "T" flange. The lateral aspect of one of the medial wings has been notched to cradle the long arm of the malleus, giving the tube added stability and retention. The tabbed lateral flange helps in insertion and easy removal. The choice of silicone or soft silicone Ultrasil™ gives the surgeon more flexibility in choosing just the right tube for the millennium.

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
7014-0257	Blue Soft Silicone Ultrasil	Without Tab	1.14mm	1	6
7014-0357	Blue Soft Silicone Ultrasil	Without Tab	1.14mm	1	30
7014-5757	Blue Soft Silicone Ultrasil	Without Tab	1.14mm	2	60

Designed for Michael Paparella, M.D., Minneapolis, MN.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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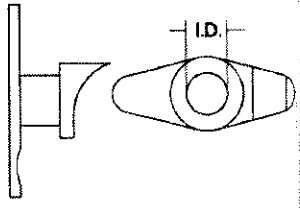
Paparella 2000 - Type 2 Ventilation Tubes

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
7014-0255	Blue Silicone	With Tab	1.14mm	1	6
7014-0256	Blue Soft Silicone Ultrasil™	With Tab	1.14mm	1	6
7024-1356	Blue Soft Silicone Ultrasil™	Without Tab	1.14mm	1	30
7024-5756	Blue Soft Silicone Ultrasil™	Without Tab	1.14mm	2	60

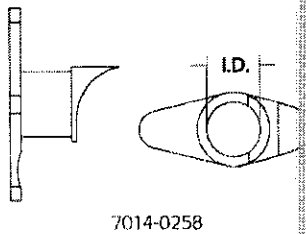


7014-0256

Designed for Michael Paparella, M.D., Minneapolis, MN.

Paparella 2000 - Type 3 Ventilation Tubes

Catalog Number	Material	I.D.	Units per Package	Units per Box
7014-0258	Blue Soft Silicone Ultrasil™	1.5mm	1	6
7014-0358	Blue Soft Silicone Ultrasil™	1.5mm	1	30
7014-5758	Blue Soft Silicone Ultrasil™	1.5mm	2	60



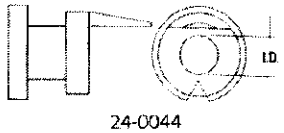
7014-0258

Designed for Michael Paparella, M.D., Minneapolis, MN.

Paparella-Type Type # 1 Ventilation Tubes

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

Catalog Number	Description	Material	I.D.	Units per Package	Units per Box
14-0252	With Tab	Fluoroplastic	1.02mm	1	6
24-0043	Without Tab	Blue Silicone	1.02mm	1	6
24-0044	With Tab	Blue Silicone	1.02mm	1	6
24-5701	With Tab	Blue Silicone	1.02mm	2	60
24-0058	With Tab	Blue Soft Silicone	1.02mm	1	6
7024-1044	With Tab	Blue Ultrasil™ Silicone	1.02mm	1	6
7024-1344	With Tab	Blue Ultrasil™ Silicone	1.02mm	1	30
7024-5016	With Tab	Blue Silicone	1.02mm	1	30
7014-0280	With Tab	Blue Silicone	1.14mm	1	6
7024-0280	With Tab	Blue Ultrasil™ Silicone	1.14mm	1	6
7024-0281	With Tab	Blue Ultrasil™ Silicone	1.14mm	1	30
7024-0282	With Tab	Blue Ultrasil™ Silicone	1.14mm	2	60
7014-0281	With Tab	Blue Ultrasil™ Soft Silicone	1.14mm	1	6
7024-1380	With Tab	Blue Ultrasil™ Soft Silicone	1.14mm	1	30
7024-5780	With Tab	Blue Ultrasil™ Soft Silicone	1.14mm	2	60



24-0044

Designed for Michael Paparella, M.D., Minneapolis, MN.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

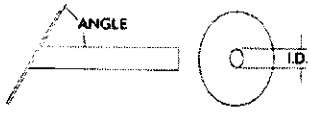
Paparella-Type Type # 2 Ventilation Tubes

24-0046

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-0254	Fluoroplastic	With Tab	1.27mm	1	6
24-0046	Blue Silicone	With Tab	1.27mm	1	6
7024-3046	Blue Silicone	With Tab	1.27mm	1	30
7024-5746	Blue Silicone	With Tab	1.27mm	2	60
7024-1046	Blue Ultrasil™ Silicone	With Tab	1.27mm	1	6
24-0048	Blue Silicone	With Tab	2.03mm	1	6

Designed for Michael Paparella, M.D., Minneapolis, MN.

Per-Lee Ventilation Tubes



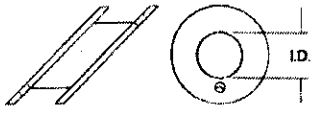
24-0026

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

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
24-0026	Blue Silicone	60°, 15mm Long	1.57mm	1	6

Designed for John H. Per-Lee, M.D., Emory University, Atlanta, GA.

Pope Beveled Grommet Ventilation Tubes



14-5250

This ventilation tube offers advantages during insertion and for postoperative inspection. Easily introduced with alligator forceps, the grommet will pass through a very small speculum. The elongated flanges and length of the tube help to prevent premature extrusion. The 45° bevel on the flange approximates the angle of the tympanic membrane, allowing the physician to see straight through the lumen. Such problems as fluid reoccurrence and plugging of the lumen are easily recognized and corrected. The good visibility also makes postoperative evaluation of middle ear aeration much easier.

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-5250	Polyethylene	Blue	1.14mm	1	6
7014-3250	Polyethylene	Blue	1.14mm	1	30
7014-5750	Polyethylene	Blue	1.14mm	2	60
7014-2047	Fluoroplastic Blue, PC	Blue	1.14mm	1	6

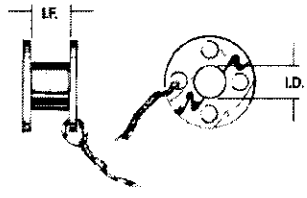
Designed for T.H. Pope, Indianapolis, IN.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Reuter Bobbin Ventilation Tubes

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



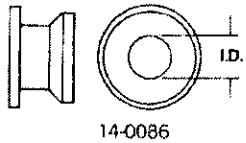
14-5211

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-5212	Fluoroplastic	1mm I.F., Without Holes	1mm	1	6
7014-3255	Blue Fluoroplastic	1mm I.F., Without Holes	1mm	1	6
14-5709	Fluoroplastic	1mm I.F., Without Holes	1mm	2	60
7014-5319	PC Coated Fluoroplastic	1mm I.F., Without Holes	1mm	1	6
7014-5320	PC Coated Fluoroplastic	1mm I.F., Without Holes	1mm	1	30
7014-5321	PC Coated Fluoroplastic	1mm I.F., Without Holes	1mm	2	60
14-5213	Fluoroplastic	1mm I.F., Without Holes	1.14mm	1	6
14-5224	Fluoroplastic	1mm I.F., With Wire	1.14mm	1	6
14-5225	Fluoroplastic	1mm I.F.	1.14mm	1	6
14-5019	Fluoroplastic	1mm I.F., Without Holes	1.14mm	1	30
14-5710	Fluoroplastic	1mm I.F.	1.14mm	2	60
7014-5326	PC Coated Fluoroplastic	1mm I.F.	1.14mm	1	6
7014-5327	PC Coated Fluoroplastic	1mm I.F.	1.14mm	1	30
7014-5328	PC Coated Fluoroplastic	1mm I.F.	1.14mm	2	60
14-5227	Fluoroplastic	0.5mm I.F.	1.27mm	1	6
14-5208	Stainless Steel	1mm I.F.	1.14mm	1	6
14-5209	Stainless Steel	1mm I.F.	1.27mm	1	6
14-5210	Stainless Steel	1mm I.F.	1mm	1	6
14-5701	Stainless Steel	1mm I.F.	1mm	2	60
14-5211	Stainless Steel	1mm I.F., With Wire	1mm	1	6
14-5216	Stainless Steel (Satin Finish)	1mm I.F., With Wire	1mm	1	6
14-5218	Stainless Steel (Satin Finish)	1mm I.F.	1mm	1	6
14-5215	Titanium (Micron™ Finish)	1mm I.F.	1mm	1	6

Designed for S. Harold Reuter, M.D., Houston, TX.

Rock Pediatric Ventilation Tube

A simple, short-term fluoroplastic "bobbin" tube for children. The larger flange 2.41mm (0.095") diameter is inserted through an incision in the tympanic membrane.



14-0086

Catalog Number	Material	I.D.	I.F.	Units per Package	Units per Box
14-0086	Fluoroplastic	1.02mm	0.89mm	1	6

Designed for Erwin H. Rock, M.D., Yonkers, NY.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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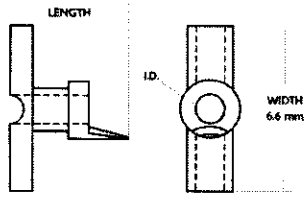
Rube Ventilation Tube



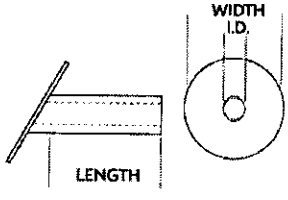
7014-0260

Based on the T-Tube design, the Rube Tube has the unique advantage of a shorter flange width which allows easier insertion.

Catalog Number	Material	I.D.	Length	Width	Units per Package	Units per Box
7014-0260	Blue Silicone with Tab	1.14mm	4.5mm	6.6mm	1	6

Designed by William Rubenstein, M.D., Houston, TX.

Shah Long-Term Ventilation Tubes



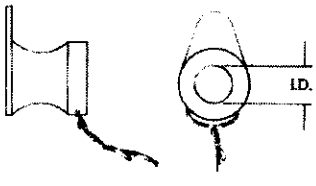
24-0012

Designed for long-term ventilation. Can be trimmed to length.

Catalog Number	Material	I.D.	Dimensions	Overall Length	Units per Package	Units per Box
24-0012	Blue Silicone	1mm	5.1 x 5.1mm	5.1mm	1	6
7024-5000	Blue Silicone	1mm	6 x 4.25mm	6.8mm	1	30

As developed in conjunction with Mr. N. Shah, F.R.C.S., D.L.O., London, England.

Shah Ventilation Tubes



14-0005

"Shoehorn" flange enables smaller incision and easy insertion.

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-0005	Fluoroplastic	With Wire	1.14mm	1	6
14-5015	Fluoroplastic	With Wire	1.14mm	1	30
14-6044	Fluoroplastic	Without Wire	1.14mm	1	6
14-5001	Fluoroplastic	Without Wire	1.14mm	1	30
14-2230	Fluoroplastic	Without Wire	0.76mm	1	6
14-5020	Fluoroplastic	Without Wire	0.76mm	1	30

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

Shea Parasol Ventilation Tubes

24-0036

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

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
24-0035	Blue Silicone	With Tab, Small Flange	1.02mm	1	6
24-0036	Blue Silicone	With Tab	1.02mm	1	6
24-5703	Blue Silicone	With Tab	1.02mm	2	60
7024-1036	Blue Ultrasil™ Silicone	With Tab	1.02mm	1	6
24-0038	Blue Silicone	With Tab	1.52mm	1	6

Designed for John J. Shea, M.D., Memphis, TN.
U.S. Patent No. 3,871,380.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

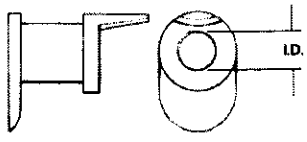
Records processed under FOIA Request 2014-1543; Released 11/12/14

GYRUS ENT

Shea Ventilation Tube

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
24-0034	Blue Silicone	With Tab	0.76mm	1	6

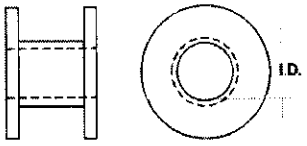
Designed for John J. Shea, M.D., Memphis, TN. US Patent No. 0239,330



24-0034

Sheehy Type Collar Button

Catalog Number	Material	I.D.	Units per Package	Units per Box
7014-5971	Fluoroplastic	1.27mm	1	6
7014-3071	Fluoroplastic	1.27mm	1	30
7014-5771	Fluoroplastic	1.27mm	2	60
7014-1080	PC Coated Fluoroplastic	1.27mm	1	6
7014-3075	PC Coated Fluoroplastic	1.27mm	1	30
7014-5780	PC Coated Fluoroplastic	1.27mm	2	60
7024-5781	Blue Silicone	1.27mm	1	6
7024-5782	Blue Silicone	1.27mm	2	60
7024-1000	Ultrasil™ Blue Silicone	1.27mm	1	6
7024-1001	Ultrasil™ Blue Silicone	1.27mm	2	60



7014-5971

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14-0030

Shepard Grommet Ventilation Tubes

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

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-0007	Fluoroplastic	With Tab	1.02mm	1	6
14-0008	Fluoroplastic	With Tab	1.14mm	1	6
14-0027	Fluoroplastic	–	1.14mm	1	6
7014-3256	Blue Fluoroplastic	–	1.14mm	1	6
14-0028	Fluoroplastic	With Wire	1.02mm	1	6
14-5702	Fluoroplastic	With Wire	1.02mm	2	60
14-0029	Fluoroplastic	–	1.02mm	1	6
14-5711	Fluoroplastic	–	1.02mm	2	60
7014-1030	Fluoroplastic	–	1.02mm	1	6
7014-1031	Fluoroplastic	–	1.02mm	1	30
7014-1032	Fluoroplastic	–	1.02mm	2	60
14-0030	Fluoroplastic	With Wire	1.14mm	1	6
14-5704	Fluoroplastic	With Tab and Wire	1.14mm	2	60
24-0020	Blue Silicone	With Tab	1.02mm	1	6
14-6028	Blue Polyethylene	With Tab and Wire	1.02mm	1	6
14-6029	Blue Polyethylene	With Tab	1.02mm	1	6
14-6030	Blue Polyethylene	With Tab and Wire	1.14mm	1	6
14-6031	Blue Polyethylene	With Tab	1.14mm	1	6
14-5003	Fluoroplastic	–	1.14mm	1	30
14-5009	Fluoroplastic	With Wire	1.02mm	1	30
14-5002	Fluoroplastic	–	1.02mm	1	30
14-5010	Fluoroplastic	With Tab and Wire	1.14mm	1	30
7024-5008	Blue Silicone	With Tab	1.02mm	1	30
7024-1020	Blue Ultrasil™ Silicone	–	1.02mm	1	6

Designed for Marvin G. Shepard, M.D., Dallas, TX.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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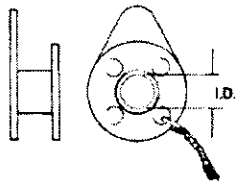
Spoon Bobbin Ventilation Tubes

This is the popular bobbin-style ventilation tube with the addition of an insertion flange. The spoon-shaped flange, inserted through the incision first, eases introduction and positioning of the tube.

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
7014-5224	Fluoroplastic	Without Wire, Without Holes	1mm	1	12
14-5240	Stainless Steel	Without Wire	1mm	1	6
14-5241	Stainless Steel	With Wire	1mm	1	6
7014-5225	Stainless Steel	With Wire	1mm	1	30
14-5273	Titanium	With Wire, Without Holes	1.27mm	1	6



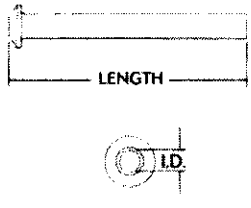
14-5241

Designed for Baldev K. Devgan, M.D., Malibu, CA

Straight Ventilation Tubes

Small flange for easy insertion through small incision in the drum. May be cut to length.

Catalog Number	Material	I.D.	Overall Length	Units per Package	Units per Box
14-0032	Fluoroplastic	0.89mm	12mm	1	6
14-0033	Fluoroplastic	1.14mm	12mm	1	6
14-5703	Fluoroplastic	1.14mm	12mm	2	60
14-0034	Fluoroplastic	0.89mm	7mm	1	6
14-5707	Fluoroplastic	0.89mm	7mm	2	60
7014-1035	PC Coated Fluoroplastic	0.89mm	7mm	1	6
7014-1036	PC Coated Fluoroplastic	0.89mm	7mm	1	30
7014-1037	PC Coated Fluoroplastic	0.89mm	7mm	2	60
14-0035	Fluoroplastic	1.14mm	7mm	1	6
14-5708	Fluoroplastic	1.14mm	7mm	2	60
14-6033	Blue Polyethylene	1.14mm	12mm	1	6
14-5713	Clear Polyethylene	0.86mm	7mm	2	60
14-0016	Clear Polyethylene	0.86mm	7mm	1	6
14-6035	Blue Polyethylene	1.14mm	7mm	1	6
14-5007	Fluoroplastic	1.14mm	12mm	1	30
14-5011	Fluoroplastic	1.14mm	7mm	1	30
7014-1039	PC Coated Fluoroplastic	1.14mm	7mm	1	6
7014-1040	PC Coated Fluoroplastic	1.14mm	7mm	1	30
7014-1041	PC Coated Fluoroplastic	1.14mm	7mm	2	60



14-0035

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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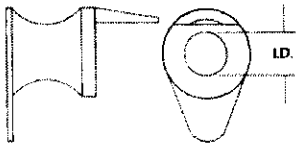
Sultan Ventilation Tubes



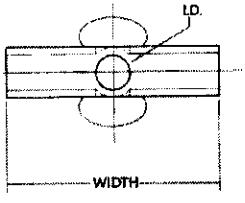
14-5230

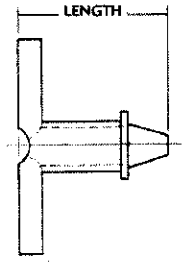
"Shoehorn" flange permits easy insertion into a smaller incision. Integral tab for removal.

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
14-5230	Fluoroplastic	With Tab	1.27mm	1	6
14-5005	Fluoroplastic	With Tab	1.27mm	1	30

Designed for Andre A. Sultan, M.D., France.

T-Tubes, Butterfly



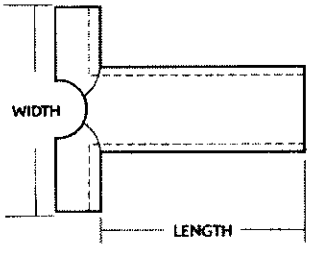


24-0073

This modified T-Tube design is for the surgeon who prefers a grommet-style flange on the lateral end. The grommet is notched in a "butterfly" shape for added visibility during insertion. The flexible medial flanges are easily inserted through a small incision and permit long-term ventilation. The lumen features an 11% larger I.D. than the standard T-Tube.

Catalog Number	Material	I.D.	Dimensions	Units per Package	Units per Box
24-0073	Blue Silicone	1.27mm	5.3mm L x 7.6mm W	1	6
7024-5018	Blue Silicone	1.27mm	5.3mm L x 7.6mm W	1	30
7024-1073	Blue Ultrasil™ Silicone	1.27mm	5.3mm L x 7.6mm W	1	6

T-Tubes, Tiny



7024-0076

Catalog Number	Material	I.D.	Dimensions	Units per Package	Units per Box
7024-0076	Blue Silicone	1.32mm	4mm L x 4mm W	1	6
7024-1076	Blue Ultrasil™ Silicone	1.32mm	4mm L x 4mm W	1	6

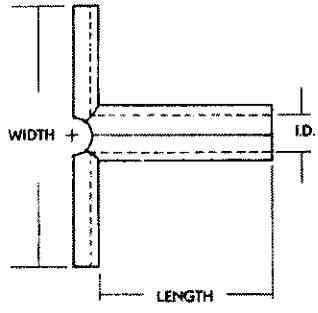
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

T-Tubes, Modified

This modification of the Gyrus ENT T-Tube features shorter flanges to lessen the possibility of trauma to the tympanic membrane. Overall length is also reduced to eliminate need for trimming. The I.D. has been increased to facilitate ventilation with less clogging. O.D. is the same as the original design.

Catalog Number	Material	I.D.	Length	Units per Package	Units per Box
24-0072	Blue Silicone	1.32mm	4.8mm	1	6
7024-5017	Blue Silicone	1.32mm	4.8mm	1	30
24-5704	Blue Silicone	1.32mm	4.8mm	2	60
24-0074	Blue Soft Silicone	1.32mm	4.8mm	1	6
7024-1072	Blue Ultrasil™ Silicone	1.32mm	4.8mm	1	6

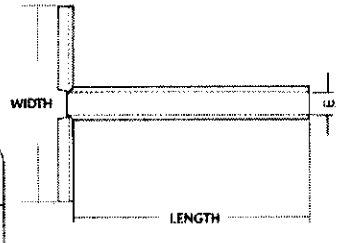


24-0072

T-Tubes, Richards

Richards T-Tubes offer the surgeon a long-term ventilation tube that is easily inserted through 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 blue silicone and is easily trimmed to adapt to the surgeon's needs.

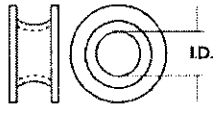
Catalog Number	Material	I.D.	Dimensions	Units per Package	Units per Box
24-0071	Blue Silicone	1.14mm	12mm L x 9.8mm W	1	6
7024-5014	Blue Silicone	1.14mm	12mm L x 9.8mm W	1	30
24-0059	Blue Soft Silicone	1.14mm	12mm L x 9.8mm W	1	6
24-5706	Blue Silicone	1.14mm	12mm L x 9.8mm W	2	60
7024-1071	Blue Ultrasil™ Silicone	1.14mm	12mm L x 9.8mm W	1	6



24-0071

Venturi + Plus Ventilation Tube

Catalog Number	Material	Description	I.D.	Units per Package	Units per Box
7014-5278	Titanium	+ Hydromer™ Coated	1.27mm	1	6



7014-5278

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

EXHIBIT 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

LEXAN® 8040 Film
For Medical Packaging

General Information

Product Description

LEXAN® 8040 film is an amorphous engineering thermoplastic. Inherent physical properties include high heat resistance, exceptional optical clarity and gloss, physical strength and ease of thermoforming and processability. LEXAN 8040 film is in compliance with FDA regulations and meets USP-VI criteria. Available gauges are .005" to .030" in roll web, sheets from .040" to .500" through authorized conversion locations.

Medical Application

LEXAN film may be used for medical packaging in flat pouches or thermoformed blisters and trays. Steam autoclave and some dry heat sterilization processes are possible with LEXAN film. LEXAN 8040 film will retain its clarity and structural integrity/shape through controlled high temperature cycling.

Listed below are typical product packaging examples using LEXAN film and steam/dry heat:

- Ophthalmic solutions (bottle delivery)
- Parenteral drugs
- Implants
- Instrument tray sets
- Woven products
- Diagnostics
- Specialty products
- Hot-fill delivery systems*

* Applies to OTC markets

Processing

GE Structured Products has introduced LEXAN 8040 film to the medical packaging supplier community, custom thermoformers, contract packagers and packaging machinery manufacturers. A processing tips publication for continuous web thermoforming of LEXAN film can be obtained from GE Structured Products. Also available is a comprehensive listing of LEXAN film package suppliers. Please call (800) 451-3147 to obtain further information.

GE Structured Products will also provide technical assistance to OEM's or contract suppliers as needed to achieve optimum efficiencies and finished part quality. Our technical staff has over 50 years of processing and thermoforming expertise in engineering plastics.

Cost

The diversity of products, manufacturing processes, sterilization and distribution in the burgeoning medical device and pharmaceutical industry precludes a standard packaging formula for computing "finished" cost. Each individual or company must determine the suitability of LEXAN 8040 film for packaging based on specific product/company advantages.

Package Design/Application Development

GE Structured Products can offer package design review, production technical assistance and limited prototype generation to visualize package concepts using LEXAN film. Sterile sample packages highlighting LEXAN capabilities are available upon request.

Lidding

High-heat sterilization processes require specialized lid stock/adhesive. TYVEK† and paper lidding have been developed to meet the stringent requirements of autoclave and selected dry-heat procedures. A listing of recommended manufacturers of lid stock is available by calling (800) 451-3147.

Benefits

- Steam or dry heat (to 265°F) sterilizable
- Exceptional clarity and gloss
- Pinhole resistant
- Dimensionally stable (-40°F to 265°F)
- Will not stress-whiten when folded
- High modulus allows downgauging
- Deep draw thermoformable (up to 2:1 depth/draw)
- Can be processed by EtO, gamma*, or E-beam sterilization.

* Use of gamma radiation will impart slight material yellowing without change in or loss of physical properties characteristics.

Regulatory Compliance

LEXAN 8040 film is in compliance with FDA regulations and meets USP-V criteria. DMF information may be obtained by written inquiry to:

GE Plastics
Highway 69 South, Bldg. 1
Mt. Vernon, IN 47620
Att: Mr. Howard Munro

Lot traceability with written certification is available through authorized GE Structured Products conversion locations.

Inasmuch as General Electric Company has no control over the use to which others may put this material, it does not guarantee that the same results as those described herein will be obtained. Nor does General Electric Company guarantee the effectiveness or safety of any possible or suggested design for articles of manufacture as illustrated herein by any photograph, technical drawings and the like. Each user of the material or design or both should make his own tests to determine the suitability of the material or any material for the design as well as the suitability of the material or design or both for his own particular use. Statements concerning possible or suggested uses of the materials or designs described herein are not to be construed as constituting a license under any General Electric patent covering such use or as recommendations for use of such materials or designs in the infringement of any patent.

Structured Products Department
General Electric Company
One Plastics Avenue
Pittsfield, MA 01201

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SP-1000 (7/88) RTB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

OCT 11 1994

Anthony D. Prescott
Grace Medical Company, Inc.
8624 North Lake Cove
Arlington, Tennessee 38002

Re: K943325/S1
Tympanostomy Tubes
Dated: September 6, 1994
Received: September 7, 1994
Regulatory class: II
21 CFR 874.3880/Procode: 77 ETD

Dear Mr. Prescott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

OCT - 5 1994

Re: Temporary Deferral of Activities Relating to Medical Device Submissions

Dear Submitters of Premarket Notification (510(k)), Premarket Approval (PMA), and Investigational Device Exemption (IDE) Applications:

FDA is moving ODE and certain other CDRH offices from their present Rockville, Maryland location to another facility in Rockville, Maryland. This move will occur in October 1994. Because the move affects ODE's Document Mail Center and most ODE review staff, equipment, and files, the office's capacity to conduct reviews of submissions will be substantially reduced until the move is completed. Therefore, the statutory review peric for new and existing submissions affected by the move will be adjusted accordingly. Submitters of IDE applications affected by the move should not consider their applicatior deemed approved at the conclusion of the normal 30-day review period. FDA anticipates that the move will take 7 calendar days but notes that the maximum adjustment for any particular submission may be 14 days, depending on the circumstances of the move and the timing of the submission. The statutory review periods on submissions pending when the move begins will be suspended during the relocation period. ODE will continue to accept mail during the move but will not officially log it in until the relocation is completed. When ODE functions resume, submissions received during and immediately following the move will then be officially logged in, but on a staggered basis to preserve equity in the order of receipt and manageability of the accumulated workload. Statutory review periods will begin when submissions are officially logged in. ODE will, of course, attempt to minimize the period during which regular procedures are suspended. Following the move, DA will publish a notice identifying the exact period during which action on new and existing submissions was temporarily deferred. All premarket approval, premarket notification, and investigation device exemption application submissions should now be addressed as follows:

Office of Device Evaluation (PMA, 510(k), or IDE as appropriate)
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

Please use the above address on all future mailing to ensure proper delivery. Persons who may be affected by this temporary deferral should contact FDA with any questions they may have regarding ODE's move to the new Rockville, Maryland location. These persons should call CDRH's Division of Small Manufacturers Assistance at 800-638-2041, or 301-443-6597 (in Maryland).

Sincerely yours,

Robert I. Chissler
Acting Director
Program Operations Staff
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Food and Drug Administration Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD

Dear Madam/Sir,

Enclosed is Grace Medical Company Inc.'s 510(k) notification for tympanostomy tubes. If you have any questions please contact me by phone at (901) 794-8829 , fax at (901) 794-8960, or by mail at the address listed below.

Sincerely,

Anthony D. Prescott
Grace Medical Company, Inc.
8624 North Lake Cove
Arlington, TN 38002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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July 8, 1994

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification

Attention: Document Mail Clerk,

This is a pre-production 510(k) notification of Grace Medical Co., Inc's intent to market the following device:

Classification Name: Tube, Tympanostomy

Classification Number: 77ETD

Common/Usual Name: Tympanostomy Tube

Proprietary Name:

Establishment Registration Number: 1057421

Classification: Class II

Performance Standard: None established- Materials standards listed in exhibit C

Promotional Material: Promotional literature is included as exhibit B.

Substantial Equivalence: These tympanostomy tubes are similar in design, materials (316 stainless steel (ASTM F-138), titanium (ASTM F-67, ASTM F-136) and fluoroplastic (ASTM F-754), and function to those marketed by Smith & Nephew Richards. Product information sheets from this company are included as exhibit A. Sample specifications and labeling for Grace Medical Co., Inc. 's products are listed as exhibit B. Please refer to Rationale for Equivalency on page 2 of this document.

In response to the requirements addressed by the SMDA of 1990, I am enclosing a summary of the safety and effectiveness information upon which the substantial equivalence determination is based as exhibit D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Rationale For Equivalency

Does New Device Have Same Intended Use? - **YES**

Ventilation Tubes Manufactured By Grace Medical Company, Inc. are to be used only by registered physicians for the surgical treatment and prevention of recurrent middle ear infection. Identical devices have been marketed for identical purposes by Smith & Nephew Richards, Xomed-Treace, Microtek Medical, River Medical, and others.

Does New Device have Technological Characteristics That Raise New Types of Safety or Effectiveness Questions? - **NO**

Ventilation Tubes Manufactured by Grace Medical Company, Inc. utilize the same materials : 316 stainless steel (ASTM F-138), titanium (ASTM F-67, ASTM F-136) and fluoroplastic (ASTM F-754), as those marketed by the firms mentioned above. (see exhibit C for ASTM specifications). The physical characteristics of Grace Medical Company, Inc.'s ventilation tubes are identical to those currently being marketed. Examples of GMCI's products are shown in exhibit B. Examples of similar products currently being marketed by other companies are shown in exhibit A. Packaging and sterilization are according to accepted standards within the medical industry and are described in more detail on page 3 of this document.

Does Descriptive or Performance Information Demonstrate Equivalence? - **YES**

"Tympanostomy tube placement has clearly been shown to be an efficacious treatment for recurrent bouts of acute otitis media or chronic otitis media with effusion."**

**Weigel, MT; Parker, MY; Goldsmith MM; Postma DS; Pillsbury HC, A prospective randomized study of four commonly used tympanostomy tubes., Laryngoscope (UNITED STATES) Mar 1989, 99 (3) p252-256.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Packaging:

Products will be packaged in a plastic inner product container approved for medical packaging. This container will be placed in a peel pouch and sealed. The peel pouch will then be placed into a dispenser carton in quantities of six. The dispenser carton will then be shrink wrapped for distribution.

Sterilization will be according to either of two methods:

General Information:

Contract medical product sterilizers will be used to sterilize product for Grace Medical Company, Inc. The following sterilization techniques will be employed.

Method 1: ETO gas
Standard to be used for validation and compliance: AAMI ST-27: ST-34
Sterility assurance level: 10-6

Method 2: Steam sterilization
Standard to be used for validation and compliance: AAMI ST-25-113 : ST-34
Sterility assurance level: 10-6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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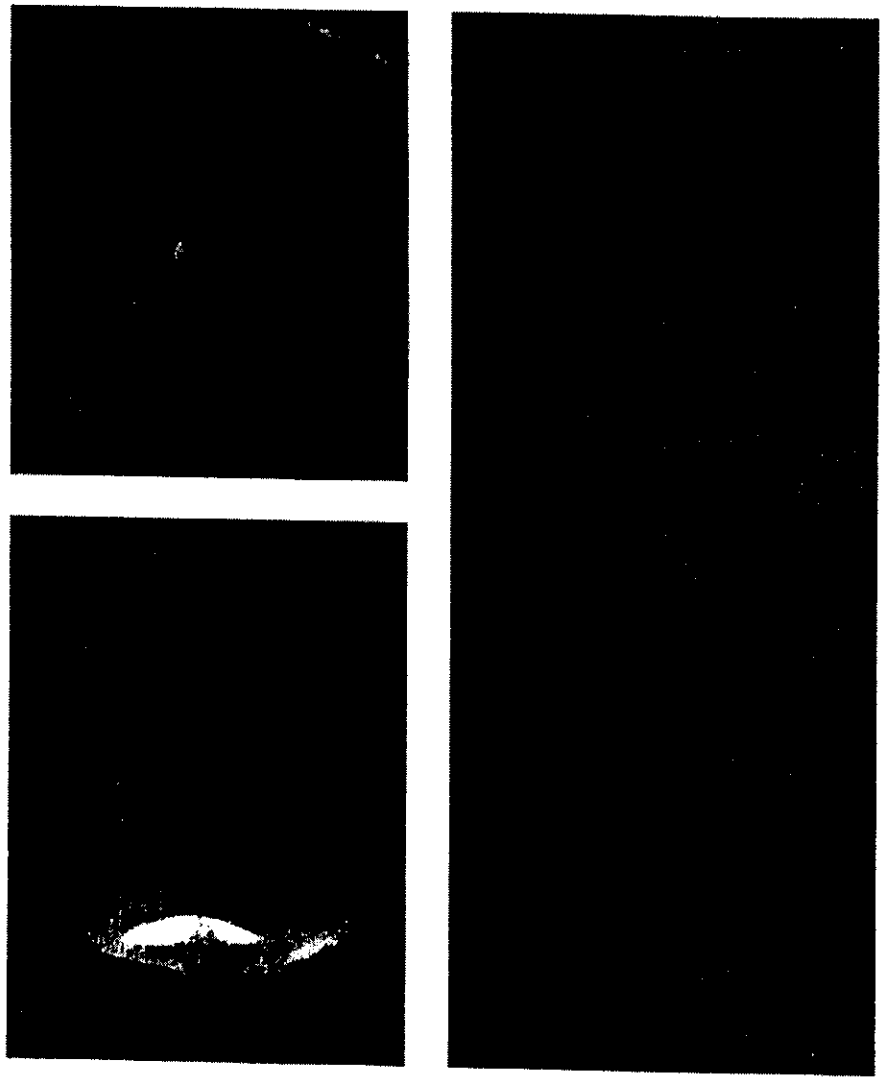
exhibit A-1

S M I T H & N E P H E W R I C H A R D



ENT MICROSURGERY CATALOG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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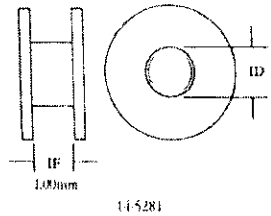
exhibit A-2

IMPLANTS

VENTILATION TUBES



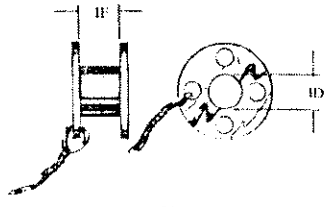
14-5281

MICRON BOBBIN VENTILATION TUBES

Two standard bobbin design titanium tubes featuring Ivehards' exclusive MICRON finish that provides the necessary ultra smoothness without the glare or reflection of ordinary polished finishes. The smooth finish of the lumen surface reduces the potential for clogging and unwanted tissue ingrowth. Design and biocompatibility of this tube make it well suited for long term ventilation.

Material	Cat. No.	ID (mm)	Description	Units per Pkg.	Units per Box
Titanium	14-5221	0.76	"Mini" Version	1	6
Titanium	14-5279	1.16	No Flange Holes	1	6
Titanium	14-5280	1.00	No Flange Holes	1	6
Titanium	14-5281	1.27	No Flange Holes	1	6
Titanium	14-5781	1.27	Twin Pack No Flange Holes	2	60
Titanium	14-5275	1.27	w/Spoon Flange	1	6
Titanium	14-5215	1.00	w/Flange Holes	1	6
Titanium	14-5219	1.00	"Tinybobbin" (Flange Holes on One Flange Only)	1	6

[illegible]



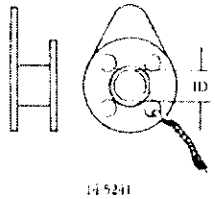
14-5211

REUTER BOBBIN VENTILATION TUBES*

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

Material	Cat. No.	ID (mm)	Description	Units per Pkg.	Units per Box
Fluoroplastic	14-5212	1.00	1mm IF, w/o holes	1	6
Fluoroplastic	14-5709	1.00	1mm IF, w/o holes	2	60
Fluoroplastic	14-5213	1.14	1mm IF, w/o holes	1	6
Fluoroplastic	14-5224	1.14	1mm IF, w/wire	1	6
Fluoroplastic	14-5225	1.14	1mm IF	1	6
Fluoroplastic	14-5710	1.14	1mm IF	2	60
Fluoroplastic	14-5227	1.27	0.5mm IF	1	6
Stainless Steel	14-5208	1.14	1mm IF	1	6
Stainless Steel	14-5209	1.27	1mm IF	1	6
Stainless Steel	14-5210	1.00	1mm IF	1	6
Stainless Steel	14-5703	1.00	1mm IF	2	60
Stainless Steel	14-5211	1.00	1mm IF, w/wire	1	6
Stainless Steel (Satin Finish)	14-5216	1.00	1mm IF, w/wire	1	6
Stainless Steel (Satin Finish)	14-5218	1.00	1mm IF	1	6
Titanium	14-5215	1.00	1mm IF	1	6

*Designed for Donald Reuter, M.D., Houston, TX



14-5241

SPOON BOBBIN VENTILATION TUBES*

This is the popular bobbin style ventilation tube with the addition of an inserted flange. The spoon shaped flange, inserted through the incision first, eases introduction and positioning of the tube.

Material	Cat. No.	ID (mm)	Description	Units per Pkg.	Units per Box
Stainless Steel	14-5240	1.00	w/Wire	1	6
Stainless Steel	14-5241	1.00	w/Wire	1	6
Titanium	14-5273	1.27	w/Wire	1	6

*Designed for Robert S. Dempsey, M.D., Malibu, CA

8

85

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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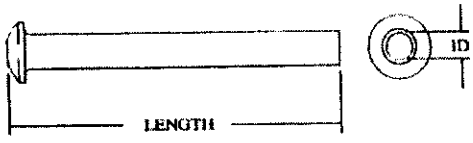
exhibit A-2

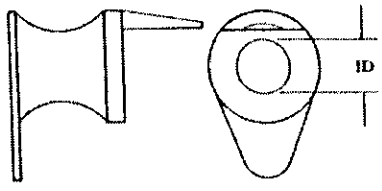
IMPLANTS
VENTILATION TUBES



STRAIGHT VENTILATION TUBES

Small flange for easy insertion through small incision in the drum. May be cut to length.

Material	Cat. No.	I.D. (mm)	Length (mm)	Units per Pkg.	Bu
Fluoroplastic	14-0032	0.89	12	1	6
Fluoroplastic	14-5712	0.89	12	2	6
Fluoroplastic	14-0033	1.14	12	1	6
Fluoroplastic	14-5703	1.14	12	2	6
Fluoroplastic	14-0034	0.89	7	1	6
Fluoroplastic	14-5707	0.89	7	2	6
Fluoroplastic	14-0035	1.14	7	1	6
Fluoroplastic	14-5708	1.14	7	2	6
Polyethylene	14-6033	1.14	12	1	
Polyethylene	14-5713	0.86	7, Clear	2	6
Polyethylene	14-0016	0.86	7, Clear	1	
Polyethylene	14-6035	1.14	7, Blue	1	

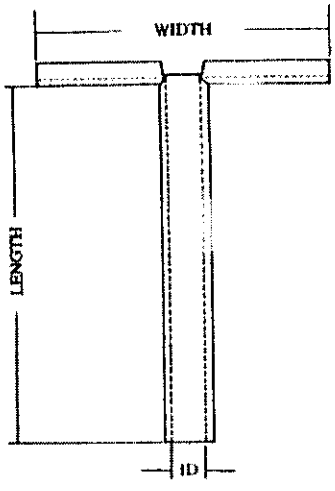


SULTAN VENTILATION TUBE*

"Shoehorn" flange permits easy insertion into a smaller incision. Integral tab for removal.

Material	Cat. No.	ID	Description	Units per Pkg.	I
Fluoroplastic	14-5230	1.27mm	w/tab	1	

*Designed for Andre A. Sultan, M.D., France



RICHARDS T-TUBES

Richards T-Tube offers the otology surgeon a long term ventilation tube that is easily inserted thro 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-T made of blue silicone rubber and is easily trimmed to adapt to the surgeon's needs.

Material	Cat. No.	ID (mm)	Description: Length (mm)	Description: Width (mm)	Units p Pkg.
Silicone	24-0071	1.14	12	9.8	1
Soft Silicone	24-0059	1.14	12	9.8	1
Silicone	24-5706	1.14	12	9.8	2
Silicone (Modified T-Tube)	24-0072	1.32	4.8	7.6	1
Soft Silicone (Modified T-Tube)	24-0074	1.32	4.8	7.6	1
Silicone (Modified T-Tube)	24-5704	1.32	4.8	7.6	2
Silicone (Butterfly Vent. Tube)	24-0073	1.27	5.3	7.6	1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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exhibit A-4

IMPLANTS

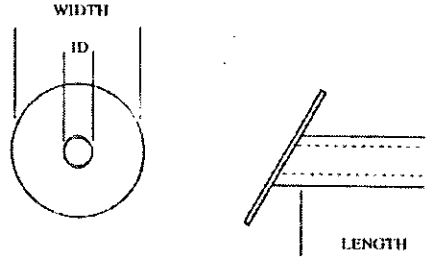
VENTILATION TUBES

[illegible] VENTILATION TUBE*

[illegible] for long term ventilation. Can be trimmed to length.

Material	Cat. No.	I.D.	Description		Units per	
			Length	Width	Pkg.	Box
Silicone	24-0012	1.00	5.1mm	5.1mm	1	6

[illegible] in conjunction with Mr. N. Shah, F.R.C.S. D.L.O., London, England



[illegible] PARASOL VENTILATION TUBES*

[illegible] design of the "folding" or collapsible flap allows easy insertion. Tube flap opens like an umbrella [illegible] placed through incision. A simple pull on the removal tab inverts umbrella for easy removal.

Material	Cat. No.	ID (mm)	Description	Units per	
				Pkg.	Box
Silicone	24-0035	1.02	w/tab, sm. flange	1	6
Silicone	24-0036	1.02	w/tab	1	6
Silicone	24-5703	1.02	w/tab	2	60
Silicone	24-0038	1.52	w/tab	1	6
Silicone	24-0040	2.03	w/tab	1	6

[illegible] John J. Shea, M.D., Memphis, TN
[illegible] No. [illegible]

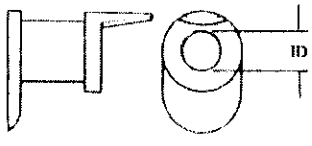
24-0036

[illegible] VENTILATION TUBE*

[illegible] flange enables easy insertion; integral tab for removal.

Material	Cat. No.	ID	Description	Units per	
				Pkg.	Box
Silicone	24-0034	0.76mm	w/tab	1	6

[illegible] John J. Shea, M.D., Memphis, TN
[illegible] No. [illegible]



[illegible] GUARD GROMMET VENTILATION TUBES*

[illegible] styles, colors, and sizes available. All are easily inserted with forceps or tube inserter through [illegible] in drum.

Material	Cat. No.	I.D. (mm)	Description	Units per	
				Box	Pkg.
Thermoplastic	14-0007	1.02	w/tab	1	6
Thermoplastic	14-0008	1.14	w/tab	1	6
Thermoplastic	14-0027	1.14		1	6
Thermoplastic	14-0028	1.02	w/wire	1	6
Thermoplastic	14-5702	1.02	w/wire	2	60
Thermoplastic	14-0029	1.02		1	6
Thermoplastic	14-5711	1.02		2	60
Thermoplastic	14-0030	1.14	w/wire	1	6
Thermoplastic	14-5704	1.14	w/wire	2	60
Silicone	24-0020	1.02	w/tab	1	6
Polyethylene	14-6028	1.02	w/tab & wire	1	6
Polyethylene	14-6029	1.02	w/tab	1	6
Polyethylene	14-6030	1.14	w/tab & wire	1	6
Polyethylene	14-6031	1.14	w/tab	1	6

[illegible] Marvin G. Shepard, M.D., Dallas, TX

14-0030

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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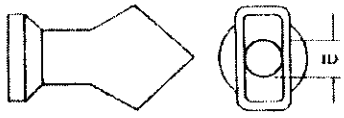
exhibit A-5

IMPLANTS

VENTILATION TUBES



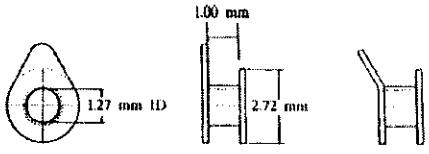
14-0240

LINDEMAN-SILVERSTEIN ARROW VENTILATION TUBE*

Designed to be rotated after insertion to lock in place.

Material	Cat. No.	ID (mm)	Description	Units per	
				Pkg.	Box
Fluoroplastic	14-0240	1.14	—	1	6

*Designed for Roger Lindeman, M.D., Seattle, WA and Herbert Silverstein, Sarasota, FL

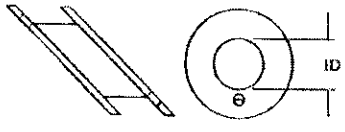


MORETZ-TYPE VENTILATION TUBE*

Familiar bobbin style ventilation tube is enhanced with an angled lateral tab. The angled tab not only provides an improved grasp with an alligator forceps, but also improved visualization during insertion procedure.

Material	Cat. No.	ID (mm)	Description	Units	
				Pkg.	Box
Titanium	14-5265	1.27	Angled Tab	1	6

*As Developed by William Moretz, M.D., Augusta, Ga



POPE BEVELED GROMMET VENTILATION TUBES*

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

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

Material	Cat. No.	ID	Description	Units per	
				Pkg.	Box
Polyethylene	14-5250	1.14mm	Blue	1	6
Fluoroplastic	14-5400	1.14mm	Blue	1	6

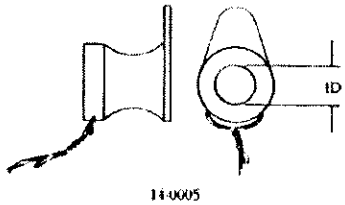
*Designed for T. B. Pope, Crawfordsville, IN

ROCK PEDIATRIC VENTILATION TUBE*

A simple short term fluoroplastic "bobbin" tube for children. The larger flange 2.41mm (0.095") diam. is inserted through an incision in the tympanic membrane.

Material	Cat. No.	ID	Description	Units per	
				Pkg.	Box
Fluoroplastic	14-0086	1.02mm	0.89mm IF	1	6

*Designed for Irwin H. Rock, Yonkers, NY



14-0005

SHAH VENTILATION TUBES*

"Shoehorn" flange enables smaller incision and easy insertion.

Material	Cat. No.	ID (mm)	Description	Units per	
				Pkg.	Box
Fluoroplastic	14-0005	1.14	w/Wire	1	6
Fluoroplastic	14-2230	0.76		1	6
Fluoroplastic	14-6044	1.14	w/o Wire	1	6

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

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exhibit A-6

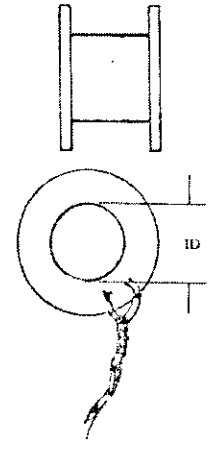
IMPLANTS

VENTILATION TUBES

BUTTON VENTILATION TUBES

"Button" shaped ventilation tube for treatment of chronic serous otitis media.

Material	Cat. No.	ID (mm)	Description	Units per Pkg.	Units per Box
Fluoroplastic	14-5214	1.27	1.65mm IF	1	6
Fluoroplastic	14-5059	1.27	1.65mm IF, Blue	1	6
Fluoroplastic	14-5705	1.27	1.65mm IF	2	60
Fluoroplastic	14-5217	1.27	1.65mm IF w/Wire	1	6
Silicone	24-0014	1.27	1.65mm IF	1	6

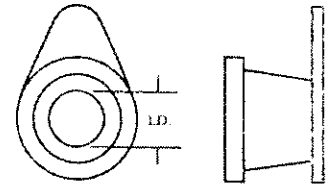


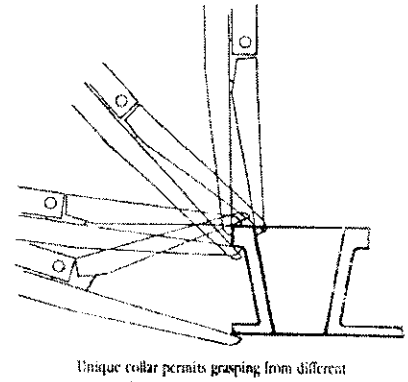
EAR BOBBIN VENT TUBES*

"Collared" flange permits grasping from different angles to suit surgeon preference. "Tapered" lumen ventilation, and "Spoon" flange eases insertion.

Material	Cat. No.	Description	Units per Pkg.	Units per Box
Titanium	14-5286	0.75mm I.D.	1	6
Titanium	14-5287	1.14mm I.D.	1	6
Titanium	14-5297	1.27mm I.D.	1	6
Fluoroplastic	14-5288	0.75mm I.D.	1	6
Fluoroplastic	14-5289	1.14mm I.D.	1	6
Fluoroplastic	14-5298	1.27mm I.D.	1	6

* Available in compatible soft Shore Black, KD-1 BCS





Unique collar permits grasping from different angles, to suit surgeon preferences

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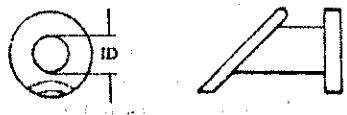
exhibit A-7

IMPLANTS

VENTILATION TUBES

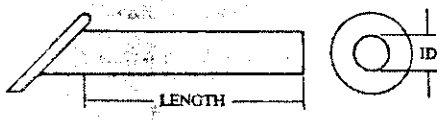


ARMSTRONG BEVELED GROMMETS*

Beveled inner flange corresponds to the angle of the tympanic membrane, resists premature extrusion. Tab permits easy removal.

Material	Cat. No.	ID (mm)	Description	Units per	
				Pkg.	Box
Fluoroplastic	14-0242	1.14		1	6
Fluoroplastic	14-6040	1.14	Blue Fluoro.	1	6
Fluoroplastic	14-5700	1.14		2	60
Silicone	24-0050	1.14	w/tab	1	6

*Designed by B.W. Armstrong, M.D., Charlotte, NC

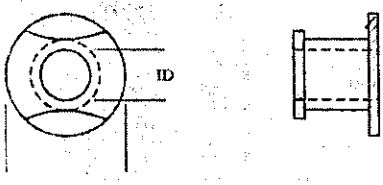


ARMSTRONG BEVELED PLAIN END VENTILATION TUBES*

Beveled inner flange corresponds to the angle of the tympanic membrane, resists premature extrusion.

Material	Cat. No.	I.D. (mm)	Description Length (mm)	Units per	
				Pkg.	Box
Fluoroplastic	14-0244	1.14	7.6	1	6
Fluoroplastic	14-5706	1.14	7.6	2	60
Silicone	24-0052	1.14	7.6	1	6

*Designed by B. W. Armstrong, M.D., Charlotte, NC

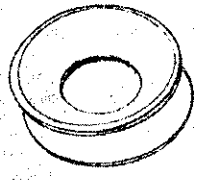


BALDWIN BUTTERFLY VENTILATION TUBES*

The hourglass shape of the lateral flange facilitates insertion and allows greater vizualization of the tympanic membrane incision. Fluoroplastic material resists clogging.

Material	Cat. No.	ID
Blue Fluoroplastic	14-5401	1.27mm ID
Blue Fluoroplastic	14-5402	1.00mm ID

*As developed by Robert L. Baldwin, M.D., Birmingham, AL



BERGER "V" BOBBIN VENTILATION TUBE*

Designed to help reduce the possibility of lumen clogging. Hourglass shaped lumen widens on both sides of the tympanic membrane to shorten the interflange dimension. This helps to reduce the accumulation of residual draining, minimizing the potential for lumen clogging. "V" shape facilitates insertion. Features Richards' exclusive MICRON Finish.

Material	Cat. No.	ID (mm)	Description	Units per	
				Pkg.	Box
Titanium	14-5282	1.27		1	6

*Designed by Eric S. Berger, M.D., Aberdeen, WA
Patents Pending

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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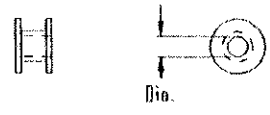
exhibit B

Grace Medical Company, Inc.

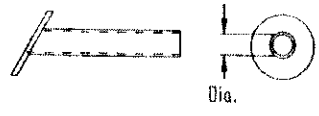
Material	Inner Diameter (m.m.)	Catalog Number	Styles Available
Stainless Steel	.8" 1.0" 1.15" 1.27"	xx-xxxx xx-xxxx xx-xxxx xx-xxxx	A,B
Titanium	8" 1.0" 1.15" 1.27"	xx-xxxx xx-xxxx xx-xxxx xx-xxxx	A,B
Fluoroplastic	8" 1.0" 1.15" 1.27"	xx-xxxx xx-xxxx xx-xxxx xx-xxxx	A,B,C,D

Style A:



Style B:

Style C:



Style D:

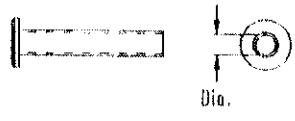


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exhibit C-1

Designation: F 138 – 86

Standard Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[1]

This standard is issued under the fixed designation F 138; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This specification has been approved for use by agencies of the Department of Defense and for listing in the DoD Index of Specifications and Standards.

1. Scope

1.1 This specification covers the requirements for two compositions of special quality stainless steel bar and wire, except suture wire, used for the manufacture of surgical implants.

NOTE 1—Exposure to temperatures above 800°F (425°C) during fabrication may impair corrosion resistance unless such exposure is followed by a solution-annealing treatment.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels[2]

A 484/A 484M Specification for General Requirements for Stainless and Heat-Resisting Bars, Billets and Forgings[3]

A 555/A 555M Specification for General Requirements for Stainless and Heat-Resisting Steel Wire and Wire Rods[2]

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[2]

E 45 Practice for Determining the Inclusion Content of Steel[4]

E 112 Test Methods for Determining Average Grain Size[4]

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue[5]

2.2 *American Society for Quality Control (ASQC) Standard:*

C1-1968 Specification of General Requirements for a Quality Program[6]

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 484/A 484M and A 555/A 555M shall apply.

3.2 In the case where a conflict exists between this standard and those listed in 2.1 and 2.2, this standard shall take precedence.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 Grade (1 or 2),

4.1.3 ASTM designation,

4.1.4 Form (bar, wire, fine wire),

4.1.5 Condition (see 5.1),

4.1.6 Mechanical properties (if applicable, for special conditions),

4.1.7 Finish (see 5.2),

4.1.8 Applicable dimensions including size, thickness, width, and length (exact, random or multiples) or print number, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 *Condition:*

5.1.1 Bar and wire shall be furnished to the implant manufacturer, as specified, in the hot-worked, annealed, or cold-worked condition (see Table 1).

5.1.2 Fine wire shall be furnished to the implant manufacturer, as specified, in the annealed, or cold-drawn condition (see Table 2).

5.2 *Finish:*

5.2.1 Types of finish available in bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

5.2.2 Types of finish available for fine wire products are cold-drawn, bright-annealed, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

6. Chemical Composition

6.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 3.

6.2 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A 751.

7. Metallurgical Requirements

7.1 The material shall contain no free ferrite phase when

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Sept. 26, 1986. Published November 1986. Originally published as F 138 – 71. Last previous edition F 138 – 82.

[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 01.05.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] *Discontinued—See 1986 Annual Book of ASTM Standards*, Vol 13.01.

[6] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

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exhibit C-2

Designation: F 136 – 84

Standard Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[1]

This standard is issued under the fixed designation F 136; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed Ti-6A1-4V E.L.I. (extra low interstitial) titanium alloy to be used in the manufacture of surgical implants.

1.2 The material in this specification has been subjected to testing in laboratory animals.[2,3] The results of these studies and the clinical history indicate a well characterized level of local biological response.[4,5]

1.3 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents in parentheses are provided for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate[4]

B 348 Specification for Titanium and Titanium Alloy Bars and Billets[4]

B 381 Specification for Titanium and Titanium Alloy Forgings[4]

E 8 Test Methods of Tension Testing of Metallic Materials[5]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[6]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[7]

F 620 Specification for Titanium 6A1-4V ELI Alloy Forgings for Surgical Implants[8]

2.2 C1-1968 Specifications of General Requirements for a Quality Control Program[9]

3. Product Classification

3.1 *Strip*—Any product under 0.1875 in. (4.75 mm) in thickness and under 24 in. (610 mm) wide.

3.2 *Sheet*—Any product under 0.1875 in. (4.75 mm) in thickness and 24 in. (610 mm) or more in width.

3.3 *Plate*—Any product 0.1875 in. (4.75 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 1.75 in. (44.45 mm), thick inclusive is covered by this specification.

3.4 *Bar*—Rounds from 3/16 in. (7.9 mm) to 1.75 in. (44.45 mm) in diameter. (Other sizes by special order.)

3.5 *Forging bar*—Bar as described in 3.4, used for production of forgings, may be furnished in the hot rolled condition.

3.6 *Wire*—Rounds less than 3/16 in. (4.8 mm) in diameter.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 Applicable ASTM designation,

4.1.3 Form (sheet, strip, plate, wire, bar, or forging),

4.1.4 Condition (See 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (see 5.2),

4.1.7 Applicable dimensions including size, thickness, width, or print number,

4.1.8 Special tests, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 The various titanium mill products covered in this specification are normally formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The ingot metal for such mill operations is usually melted in arc furnaces of a type conventionally used for reactive metals.

5.2 *Finish*—Annealed material may be furnished to the implant manufacturer as descaled or pickled, sandblasted, ground, or combinations of these operations.

6. Chemical Requirements

6.1 The heat analysis shall conform to the chemical composition of Table 1. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product.

6.2 The product analysis tolerances shall conform to the check tolerances of Table 2.

6.3 For referee purposes, Methods E 120 shall be used.

6.4 Samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved June 29, 1984. Published September 1984.

[2] Laing, P. G., Ferguson, Jr., A. B., and Hodge, E. S., "Tissue Reaction in Rabbit Muscle Exposed to Metallic Implants," J. Biomed Materials Research, Vol. 1, 1967, pp. 135–149.

[3] Laing, P. G., "Compatibility of Biomaterials," Orthopedic Clinics of North America, Vol. 4, No. 2, April, 1973, pp. 249–273.

[4] *Annual Book of ASTM Standards*, Vol 02.04.

[5] *Annual Book of ASTM Standards*, Vol 03.01.

[6] *Annual Book of ASTM Standards*, Vol 03.05.

[7] *Annual Book of ASTM Standards*, Vol 03.01.

[8] *Annual Book of ASTM Standards*, Vol 13.01.

[9] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

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exhibit C-3

Designation: F 67 – 89

Standard Specification for Unalloyed Titanium for Surgical Implant Applications[1]

This standard is issued under the fixed designation F 67; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for four grades of unalloyed titanium used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate[2]

B 348 Specification for Titanium and Titanium Alloy Bars and Billets[2]

B 381 Specification for Titanium and Titanium Alloy Forgings[2]

E 8 Test Methods of Tension Testing of Metallic Materials[3]

E 16 Methods of Free Bend Test for Ductility of Welds[4]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[5]

E 190 Test Method for Guided Bend Test for Ductility of Welds[3]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[3]

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]

2.2 *Aerospace Material Specification:*

AMS 2249C Chemical Check Analysis Limits, Titanium and Titanium Alloys[7]

2.3 *American Society for Quality Control (ASQC) Standard:*

C1-1968 Specifications of General Requirements for a Quality Program[8]

3. General Requirements for Delivery

3.1 Material furnished to this specification shall conform to the requirements of the latest issues of Specifications B 265, B 348, and B 381.

3.2 In the case where a conflict exists between this specification and those listed in 3.1, this specification shall take precedence.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 Grade (1, 2, 3, or 4),

4.1.3 ASTM designation,

4.1.4 Form (sheet, strip, plate, bar, billet or forging),

4.1.5 Condition (5.1),

4.1.6 Mechanical properties (if applicable, for special conditions),

4.1.7 Finish (5.2),

4.1.8 Applicable dimensions including size, thickness, width, and length (exact, random, multiples) or print number,

4.1.9 Special tests, and

4.1.10 Special requirements.

5. Manufacture

5.1 *Condition*—Material shall be furnished to the implant manufacturer in the hot-rolled, cold-worked, forged, or annealed, condition.

5.2 *Finish*—Unalloyed titanium material shall be free of injurious external and internal imperfections of a nature that will interfere with the purpose for which it is intended. Annealed material may be furnished as descaled, as sandblasted, or as ground, or both sandblasted and ground. If shipped as hot rolled, descaled, sandblasted, or ground, the manufacturer shall be permitted to remove minor surface imperfections by spot grinding if such grinding does not reduce the thickness of the material below the minimum permitted by the tolerance for the thickness ordered.

6. Chemical Composition

6.1 The heat analysis shall conform to the requirements as to chemical composition prescribed in Table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, samples of which shall be taken from the finished product.

6.2 *Product Analysis*—Product analysis tolerances do not broaden the specified heat analysis requirements, but cover variations between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1 for applicable grade. Product analysis limits shall be as specified in Table 2.

6.2.1 The product analysis is either for the purpose of

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of subcommittee F04.02 on Resources.

Current edition approved Nov. 24, 1989. Published January 1990. Originally published as F 67 - 66. Last previous edition F 67 - 88.

[2] *Annual Book of ASTM Standards*, Vol 02.04.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] Discontinued—See 1977 *Annual Book of ASTM Standards*, Part 10.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

[6] *Annual Book of ASTM Standards*, Vol 13.01.

[7] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[8] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

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In Response To the Safe Medical Devices Act of 1990, The Following is a Summary of Safety and Effectiveness Information.

ARTICLE SUMMARIES

General

Various articles beginning in 1968 discuss the use of ventilation tubes for disease prevention and control, specifically to successfully treat glue ear (serous otitis media with effusion). This method of surgical treatment is generally recommended if repeated rounds of the appropriate antibiotics fail to clear up the infection or if the infection recurs on a frequent basis. Ventilation tubes made from Polyethylene, Fluoroplastic, Silicone, Stainless Steel, Titanium, and Nylon are discussed in these articles. [1,3,5,6,7,8]

Problem Reports

An incidence of postoperative infection of up to 15 percent has been reported following middle ear ventilation tube surgery according to one article. This is reported to be an unacceptably high rate of infection for a typical surgery. Another author felt that there was no demonstrable advantage of a titanium ventilation tube over tubes made of less expensive materials.[2,4]

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1. Armstrong BW, Role of ventilating tubes in tympanoplasty. Arch Otolaryngol (UNITED STATES) Jan 1973, 97 (1) p13-4

2. Balkany TJ; Barkin RM; Suzuki BH; Watson WJ, A prospective study of infection following tympanostomy and tube insertion. , Am J Otol (UNITED STATES) Apr 1983, 4 (4) p288-91

3. Goode RL, T-tube for middle ear ventilation , Arch Otolaryngol (UNITED STATES) May 1973, 97 (5) p402-3

4. Graham JK, Serous otitis media: complication of polyethylene tube insertion. , Eye Ear Nose Throat Mon (UNITED STATES) Sep 1971, 50 (9) p327-8

5. Pappas JJ, Middle ear ventilation tubes., Laryngoscope (UNITED STATES) Jul 1974, 84 (7) p1098-117

6. Shone GR; Griffith IP, Titanium grommets: a trial to assess function and extrusion rates. , J Laryngol Otol (ENGLAND) Mar 1990, 104 (3) p197-9

7. Weigel, MT; Parker, MY; Goldsmith MM; Postma DS; Pillsbury HC, A prospective randomized study of four commonly used tympanostomy tubes., Laryngoscope (UNITED STATES) Mar 1989, 99 (3) p252-256.

8. Wilson HL, Polyethylene tube with nylon whisker for serous otitis media. , Arch Otolaryngol (UNITED STATES) Aug 1969, 90 (2) p226-7

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPLICABLE SAFETY AND PERFORMANCE STANDARDS

ASTM STANDARDS FOR MATERIALS DEEMED SUITABLE FOR IMPLANTABLE DEVICES

The following standards have been developed based upon years of experience and successful use of these materials in implantable devices. Materials used in the manufacture of ventilation tubes for Grace Medical Company, Inc. does comply with these standards.

F 67 - 89 Standard Specification for Unalloyed Titanium for Surgical Implant Applications.

F 136 - 84 Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

F 138 - 86 Standard Specification for Stainless Steel Bar and Wire for Surgical Implants

F 754 - 88 Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes.

AAMI STANDARDS FOR STERILIZATION

Grace Medical Company's sterile products will be sterilized using the following industry standard guidelines to assure sterility.

AAMI ST-27-113 Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices.

AAMI ST-25-113 Guideline for Industrial Moist Heat Sterilization of Medical Products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA DATABASE FOR REPORTS OF SERIOUS INJURY

Seven reports have been logged in the MDR for patient injury from ventilation tubes. Six of the seven incidents deal with silicone ventilation tubes. The problems can be broken down as follows:

2 Reports - Residual perforation after ventilation tube removal. One physician reported a 20% occurrence of this problem.

1 Report - Jahn Hydroxylapatite Ventilation tube was occluded by soft tissue overgrowth and had to be explanted.

1 Report - Failure of silicone Parasol ventilation tube to extrude.

3 Reports - silicone ventilation tube broke during removal.

MDR REPORTS (as of 6/21/94)
DIALOG(R)File 158:Diogenes(R)
(c) 1994 DIOGENES. All rts. reserv.

03720977 1280865
MDR REPORT - PRELIMINARY : SMITH AND NEPHEW RICHARDS, INC., JAHN HYDROXYLVENT TUBE MODEL NA CATALOG UNK SERIOUS INJURY
FDA NO.: M399540
DEVICE CLASSIFICATION: (ETD) Tube, Tympanostomy. CLASS: 2. 874-3880.
874.3880.
COMPANY NAME: SMITH AND NEPHEW RICHARDS, INC (SMITNEPHRICH)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: APRIL 1994.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 930727
NOTE:
THE DEVICE WAS IMPLANTED IN A 29-YR-OLD MALE PT ON 9/16/92 TO TREAT LONG STANDING LEFT-SIDED CHRONIC EUSTACHIAN TUBE DYSFUNCTION. THE PT HEALED UNEVENTFULLY. THE PT DEVELOPED SOFT TISSUE OVERGROWTH OF THE MEDIAL SURFACE AND LUMEN OF THE TUBE. THE DEVICE WAS SUBSEQUENTLY EXPLANTED. SEE DISCLAIMER STATEMENT.

03669027 1228915
MDR REPORT - FINAL : SMITH AND NEPHEW RICHARDS, INC., VENTILATION TUBE MODEL NA CATALOG 24-0036 SERIOUS INJURY
FDA NO.: M361753
DEVICE CLASSIFICATION: (ETD) Tube, Tympanostomy. CLASS: 2. 874-3880.
874.3880.
COMPANY NAME: SMITH AND NEPHEW RICHARDS, INC (SMITNEPHRICH)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: APRIL 1994.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 930113
NOTE:
PT HAD A MYRINGOTOMY WITH INSERTION OF VENT TUBE IN 1989. RECENTLY PT HAS DEVELOPED FREQUENT EAR INFECTIONS IN RIGHT EAR BECAUSE THE PARASOL VENT TUBE DID NOT EXTRUDE. ADMITTED FOR REMOVAL OF VENT TUBE. THE PT WAS A 7-YR-OLD MALE. THE DEVICE WAS IMPLANTED ON 8/7/92. SEE DISCLAIMER STATEMENT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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03132423 1097069
MDR REPORT - FINAL : SMITH & NEPHEW RICHARDS, INC.. ARMSTRONG BEVELED PLAIN END VENTILATION TUBE MODEL NA CATALOG 240052 SERIOUS INJURY
FDA NO.: M202906
DEVICE CLASSIFICATION: (LBL) Tube, Tympanostomy, Porous Polyethylene.
CLASS: 2. 874-3880. 874.3880.
COMPANY NAME: SMITH & NEPHEW RICHARDS, INC (SMITNEPHRICH)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: JUNE 1993.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 900713
NOTE:
THE DEVICE BROKE DURING A ROUTINE SURGICAL PROCEDURE TO REMOVE THE DEVICE. REVISION SURGERY WAS NECESSARY TO REMOVE MULTIPLE PIECES OF DEVICE FROM PT'S MIDDLE EAR. THE PT IS A 2-YR-OLD FEMALE. NO ADD'L INFO IS ANTICIPATED. THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT TO A REDESIGNED DATABASE. SEE DISCLAIMER STATEMENT.

03090389 1055035
MDR REPORT - FINAL : RICHARDS MICROSURGERY DIV.. RICHARDS T-TUBE (FOR EAR) CATALOG 24-0071 SERIOUS INJURY
FDA NO.: M150788
DEVICE CLASSIFICATION: (ETD) Tube, Tympanostomy. CLASS: 2. 874-3880.
874.3880.
COMPANY NAME: RICHARDS MICROSURGERY DIV (RICHMEDI)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: JUNE 1993.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 880226
NOTE:
ONE OF TWO HORIZONTAL FLANGES BROKE OFF DURING REMOVAL OF DEVICE. THE CAUSE OF THIS PROBLEM HAS NOT BEEN DETERMINED. THIS IS A RECOGNIZED ADVERSE AFFECT ASSOCIATED WITH THE DEVICE OR ITS USE AS STATED IN LABELING AND/OR REPORTED IN THE MEDICAL LITERATURE. BOTH THE FREQUENCY AND THE SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED. SEE DISCLAIMER STATEMENT.

03070653 1035299
MDR REPORT - FINAL : RICHARDS MEDICAL CO. RICHARDS T-TUBE CATALOG 24-007 SERIOUS INJURY
FDA NO.: M134233
DEVICE CLASSIFICATION: (ETD) Tube, Tympanostomy. CLASS: 2. 874-3880.
874.3880.
COMPANY NAME: RICHARDS MEDICAL CO (RICHMEDI)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: JUNE 1993.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 861211
NOTE:
THE DOCTOR REPORTED SEVERAL PERSISTANT PERFORATIONS IN THE TYMPANIC MEMBRANE AFTER REMOVAL OF THE DEVICE. THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE CAUSE ASSOCIATED WITH THIS TYPE OF EVENT IS USUALLY ATTRIBUTED TO PHYSIOLOGICAL OR PROCEDURAL FACTORS. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED. SEE DISCLAIMER STATEMENT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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03069166 1033812
MDR REPORT - FINAL : RICHARDS MEDICAL CO. MODIFIED T-TUBE CATALOG 24-0072 SERIOUS INJURY
FDA NO.: M127090
DEVICE CLASSIFICATION: (LBL) Tube, Tympanostomy, Porous Polyethylene
CLASS: 2. 874-3880, 874.3880.
COMPANY NAME: RICHARDS MEDICAL CO (RICHMEDI)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: JUNE 1993.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 861114
NOTE:
THE SURGEON REPORTS THAT AFTER USING THE MODIFIED T-TUBE OVER A PERIOD OF 1-1/2 YEARS, HE HAS REPORTEDLY EXPERIENCED AN APPROXIMATE 20% RATE OF PERFORATION OF THE TYMPANIC MEMBRANE. THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE CAUSE ASSOCIATED WITH THIS TYPE OF EVENT IS USUALLY ATTRIBUTED TO PHYSIOLOGICAL OR PROCEDURAL FACTORS. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED. SEE DISCLAIMER STATEMENT.

03050927 1015573
MDR REPORT - FINAL : RICHARDS MEDICAL CO., ARMSTRONG PLAIN END VENTILATION TUBE CATALOG 24-0152 SERIOUS INJURY
FDA NO.: M116832
DEVICE CLASSIFICATION: (ETD) Tube, Tympanostomy. CLASS: 2. 874-3880. 874.3880.
COMPANY NAME: RICHARDS MEDICAL CO (RICHMEDI)
ADVISORY COMMITTEE: EAR, NOSE AND THROAT DEVICE PANEL (DVEAR).
SOURCE: FDA MDR LIST (MDR). LIST EDITION: JUNE 1993.
DOCUMENT TYPE: DEVICE (DEV).
PUBLICATION DATE: 851220
NOTE:
THE IMPLANT WAS REPORTED TO HAVE BROKEN INTO SEVERAL PIECES DURING THE ROUTINE REMOVAL OF THE DEVICE IN DECEMBER 1985. THE DR REPORTEDLY OPENED THE EAR DRUM FOR REMOVAL FROM MIDDLE EAR. THE PT IS A THREE-YEAR-OLD MALE. THE VENTILATION TUBE IN THE OPPOSITE EAR DRUM WAS RMOVED INTACT AND WITHOUT DIFFICULTY. THIS DEVICE IS COMPOSED OF A RELATIVELY SOFT AND PLIABLE SILICONE RUBBER IN A CONFIGURATION WHICH INCORPORATES THIN WALL SECTIONS. SPECIFIC DETAILS REGARDING THE ROUTINE REMOVAL OF THIS SPECIFIC DEVICE ARE NOT KNOWN, BUT THE PROCEDURE IS NORMALLY PERFORMED USING FORCEPS CAPABLE OF GRASPING WITH CONSIDERABLE FORCE. THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT TO A REDESIGNED DATABASE. SEE DISCLAIMER STATEMENT.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

AUG 8 1994

Anthony D. Prescott
Grace Medical Company, Inc.
8624 North Lake Cove
Arlington, Tennessee 38002

Re: K943325
Tympanostomy Tube
Dated: July 8, 1994
Received: July 11, 1994

Dear Mr. Prescott:

(b)(4) Trade Secret Process

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Trade Secret Process

[redacted]

Sincerely yours,

Harry R. Sauberman, P.E.
Chief, Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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September 6, 1994

Miriam Provost, Ph.D.
Food and Drug Administration Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD

Subj.: K943325

Dear Dr. Provost,

Per the letter I received from the FDA dated August 8th, 1994 I have enclosed the following information:

(b)(4) Trade Secret Process

[redacted]

If you have any questions please contact me by phone at (901) 794-8829 , fax at (901) 794-8960, or by mail at the address listed below.

Sincerely,

Anthony D. Prescott
Grace Medical Company, Inc.
8624 North Lake Cove
Arlington, TN 38002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Draft Labels

(b)(4) Trade Secret Process - Draft Labels

(b)(4) Trade Secret Process - Product Data

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(1)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Vasant G Malshet

Subject: 510(k) Number K062385

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) √

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

ETD/77/II/21 CFR 874.3880

Review: JSeverta for Emann (initial) (check sheet) EMB 9/27/06
(Branch Chief) (Branch Code) (Date)

Final Review: JS for DRS 9/27/06
(Division Director) (Date)

Revised:4/2/03

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	✓	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(4)

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K062385

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard**, which is posted with the 510(k) boilers on the H drive.]		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose	✓	
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No

Reviewer: [signature]

Concurrence by Review Branch: [signature]

Date: 9/25/12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K043375 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Date : September 20, 2006
Reviewer : Vasant G. Malshet **Division/Branch**: DOED/ENTB
Trade Name : Blue PTFE (Fluoroplastic) Ventilation Tubes
Common Name : Tympanostomy Tubes
Classification : ETD/77/II/ 21 CFR 874.3880
510(K) Number : K060518
Applicant : Grace Medical
Contact : Jeff Cobb
Phone : (866) 472-2363

Ms. Baker and I reviewed this submission.

		YES	NO	
1.	IS PRODUCT A DEVICE?	x	_	IF NO STOP
2.	DEVICE SUBJECT TO 510(k)?	x	_	IF NO STOP
3.	SAME INDICATION STATEMENT?	x	_	IF YES GO TO 5
4.	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	NA	_	IF YES STOP ->
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	x	_	IF YES GO TO 7
6.	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	_	_	IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	x	_	IF YES STOP -> SE IF NO GO TO 10
8.	NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	_	_	IF YES STOP -> NE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?	_	_	IF NO STOP -> NE
10.	PERFORMANCE DATA AVAILABLE?	_	_	IF NO REQUEST DATA
11.	DATA DEMONSTRATE EQUIVALENCE	_	_	YES SE; NO NE

"yes" responses to 4, 6, 8, 11, and every "no" response requires an explanation

NARRATIVE DEVICE DESCRIPTION

1. **Intended Use**:

- Chronic Otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute Otitis media despite conventional medical treatment
- A record of persistent high negative ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomic
  2. Persistent or recurrent otalgia

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. Persistant or recurrent vertigo, tinnitus or both
- Atelectasis resultant from retraction pocket of tympanic membrane or eustachian tube dysfunction

Product to Which Compared to: The submissions states that the Blue PTFE (Fluoroplastic) Ventilation Tubes are substantially equivalent to Flouroplastic Ventilation Tubes, K990000 and Tympanostomy Tubes, K943325. These tympanostomy tubes also are commonly used by ENT surgeons world wide. The design and indications for use for the subject devices are substantially equivalent to previously cleared tympanostomy tubes.

2. **Device Description**: The submission states that the Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are intended to ventilate the middle ear subsequent to otitis media. The placement of the tube in the tympanic membrane provides the means for eliminating any fluid buildup in the middle ear while creating an avenue of the passage of air to equalize pressure on either side of the drum. These ventilation tubes will be machined from blue PTFE (fluoroplastic) Rod. PTFE has been used as a material for ventilation tubes and other middle ear applications for many years.
   - Grace Medical PTFE Ventilation Tubes were cleared via 510(k) No. K943325. •Gyrus ENT (blue) Fluoroplastic (PTFE) Ventilation Tubes manufactured from the same material were cleared via 510(k) No. K992222.

The submission states that this material will be purchased from the vendor as blue colored PTFE (fluoroplastic) rod stock. PTFE (fluoroplastic) from this vendor meets USP Class VI for plastics, ASTM D 1710, and ASTM F-754. The colorant meets 21 CFR Part 73.2725. Analysis of this colorant used by the vendor is supplied as Exhibit 1. This blue colored PTFE rod stock is the same material cleared via 510(k) No. K992222.

The procedure for placement is the same as current ventilation tubes. The company intends to market the following tympanostomy tubes:

(a) Armstrong Beveled Grommet - 1.14mm ID
(b) Armstrong Beveled Grommet with Tab - 1.14mm ID
(c) Armstrong Beveled Plain End Tube - 1.14mm ID, Length 7.6mm
(d) Armstrong V Beveled Grommets - 1.14mm ID
(e) Armstrong V Straight Ventilation Tube - 1.14mm ID, Length 4.5mm to 7.5mm
(f) Baxter Beveled Bobbin - 0.97mm to 1.27mm ID
(g) Berger V Bobbin Ventilation Tube - 1.27mm ID
(h) Bevel Bobbin Ventilation Tube - 1.14mm ID
(i) Canale Ventilation Tube - 1.14mm ID
(j) Collar Button Ventilation Tube - 1.27mm ID
(k) Collar Bobbin Ventilation Tube - 0.75mm - 1.27mm ID
(l) Donaldson Ventilation Tube - 1.14mm ID
(m) Dutcher Ventilation Tube - 1.27mm ID
(n) Feuerstein Split Ventilation Tube -1.02mm ID

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(o) Fluoroplastic/Titanium Ventilation Tube - 1.00mm to 1.Smm ID
(p) Lindeman-Silverstein Arrow Ventilation Tube - 1.14mm ID
(q) Moretz-Type Ventilation Tube - 1.27mm ID
(r) Paparella-Type Ventilation Tube -1.02mm to 1.50mm ID
(s) Per-Lee Ventilation Tube - 1.57mm ID
(t) Pope Beveled Grommet Ventilation Tube - 1.14mm ID
(u) Reuter Bobbin Ventilation Tube - 1.00mm to 1.27mm ID
(v) Rock Pediatric Ventilation Tube - 1.02mm ID
(w) Rube Ventilation Tube - 1.14mm ID
(x) Shah Long-Term Ventilation Tube - 1.00mm ID
(y) Shah Ventilation Tube - 0.76mm to 1.14mm ID IDIH
(z) Shea Parasol Ventilation Tube - 1.02mm to 1.52mm ID
(aa) Shea Ventilation Tube - 0.76mm ID
(bb) Sheehy Type Collar Button Ventilation Tube - 1.27mm ID
(cc) Shepard Grommet Ventilation Tube – 1.02mm to 1.14mm ID
(dd) Spoon Bobbin Ventilation Tube – 1.00mm to1.27mm ID
(ee) Straight Ventilation Tube – 0.86mm to 1.14mm ID, Length 7mm to 12mm
(ff) Sultan Ventilation Tube – 1.27mm ID
(gg) T-TubeVentilation tube-1.14mm to 1.32mm ID, Length 4mm to 12 mm, Width 4mm to 9.8mm

4. **Biocompatibility:** The sponsor states that Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are made of the same material used in the Gyrus ENT (blue) Fluoroplastic Ventilation Tubes cleared via K992222. Therefore, I conclude that further biocompatibility testing is unnecessary.

5. **Clinical:** These tympanostomy tubes are commonly used by ENT surgeons world wide. The design and indications for use for the subject devices are substantially equivalent to previously cleared tympanostomy tubes.

6 **Labeling**: The sponsor has provided adequate labeling information. The labeling contains the "CAUTION" statement as outlined in 21 CFR 801.109 (b)(1).

7 **Sterilization method**: The devices are sterilized by exposure to H_2O_2 plasma. The sterility assurance level (SAL) is 10^{-6}. Validation of the sterilization cycle is performed in accordance with ANSI/AAMI/ISO 14937 – Sterilization of health care products- General requirements for characterization of a sterilizing agent and the development validation, and routine control of a sterilization process for medical devices.

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8 **Packaging**: The submission (revised via fax, see attached) states that the devices are packaged inside a molded polypropylene case designed for otology implants with the exception of some of the adjustable length devices which may be packaged in an adjustor body. The polypropylene case or adjustor body is heat sealed inside a Tyvek and ionomer pouch which is placed inside a paperboard carton and shrink-wrapped.

The submission contains 510(k) summery of safety and effectiveness (which includes a table of comparison) and indication for use statement via fax (see attached).

	YES	NO
Is the device life-supporting or life sustaining?	_	x
Is the device implanted (short-term or long-term)?	x	_
Does the device design use software?	_	x
Is the device sterile?	x	_
Is the device home use?	_	x
Is the device for prescription?	x	
Does the device contain a drug or biological product as a component?	_	x
Is this device a kit?	_	x

RECOMMENDATION: Substantially Equivalent to the other Class II devices found in 21 CFR 874.3880 for Tympanostomy Tubes

Vasant G. Malshet, Ph.D., DABT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Date: August 23, 2006
To: Vasant Malshet, PhD
From: Karen Baker

Subject: K062385 Sterilization Review

Device: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes

Indication for use:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following:
    1. Conductive hearing loss that is symptomatic
    2. Persistent or recurrent otalgia
    3. Persistent or recurrent vertigo, tinnitus, or both
- Atalectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction

Device description: Grace Medic al PTFE Ventilation Tubes are placed in the tympanic membrane to provide a means for eliminating any fluid buildup in the middle ear while creating an avenue for the passage of air to equalize pressure on either side of the ear drum. The devices are of various configurations and designs.

Sterilization method: The devices are sterilized by exposure to H_2O_2 plasma. The sterility assurance level (SAL) is 10^{-6}. Validation of the sterilization cycle is performed in accordance with ANSI/AAMI/ISO 14937 – Sterilization of health care products-General requirements for characterization of a sterilizing agent and the development validation, and routine control of a sterilization process for medical devices.

Packaging: The submission states that the devices are packaged inside a molded polypropylene case designed for otology implants. The polypropylene case is heat sealed inside a Tyvek and ionomer pouch which is placed inside a paperboard carton and shrink-wrapped.

In the original submission the sponsor used the packaging notation from an earlier submission and erroneously kept the sentence about adjustable length devices. Following a telephone call from Dr. Malshet an e-mail with a correction was sent.

Labeling: The sample labeling provides the required information: sterile condition, lot number, expiration dating, etc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Summary: The sponsor sent in the correct information regarding the device packaging. I have no questions regarding the sterilization of these devices.

Thank you for the opportunity to review this submission.

Karen Baker, MSN, RN
Nurse Consultant/ENTB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Malshet, Vasant

[redacted] (b) (4) [redacted]

Sincerely,

JC

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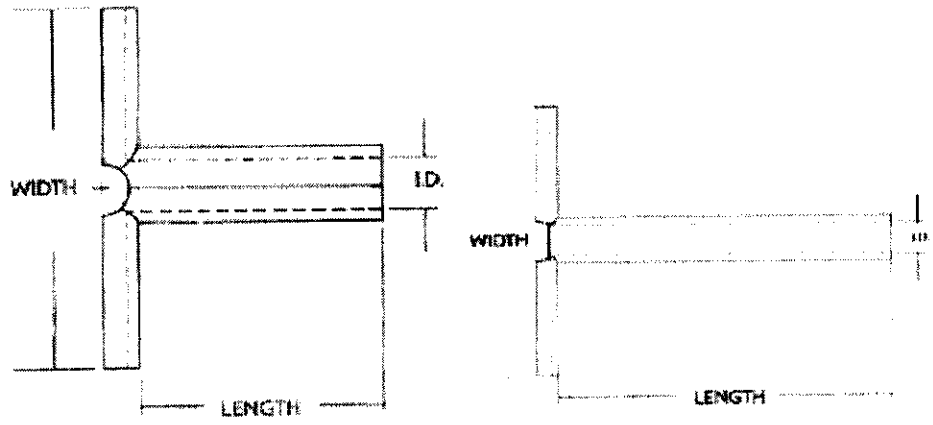

2) Materials: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are made of the same material used in the Gyrus ENT (blue) Fluoroplastic Ventilation Tubes cleared via K992222.

C) STERILITY INFORMATION

Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are provided sterile. This method of sterilization was referenced in and used on product cleared via Grace Medical 510(k) Nos. K060518, K981575, and K972815.

1) Sterilization Method: The devices are sterilized by exposure to H_2O_2 plasma.
2) Sterility Assurance Level: The sterility assurance level (SAL) is 10^{-6}.
3) Sterilization Validation Method: Validation of the sterilization cycle is performed in accordance with ANSI/AAMI/ISO 14937 – Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.
4) Packaging: The devices are packaged inside a molded polypropylene case specifically designed for otology implants. The polypropylene case is heat sealed inside a Tyvek® and ionomer pouch, which is in turn placed inside a paperboard carton and shrink-wrapped.

These products ARE NOT labeled 'non-pyrogenic'.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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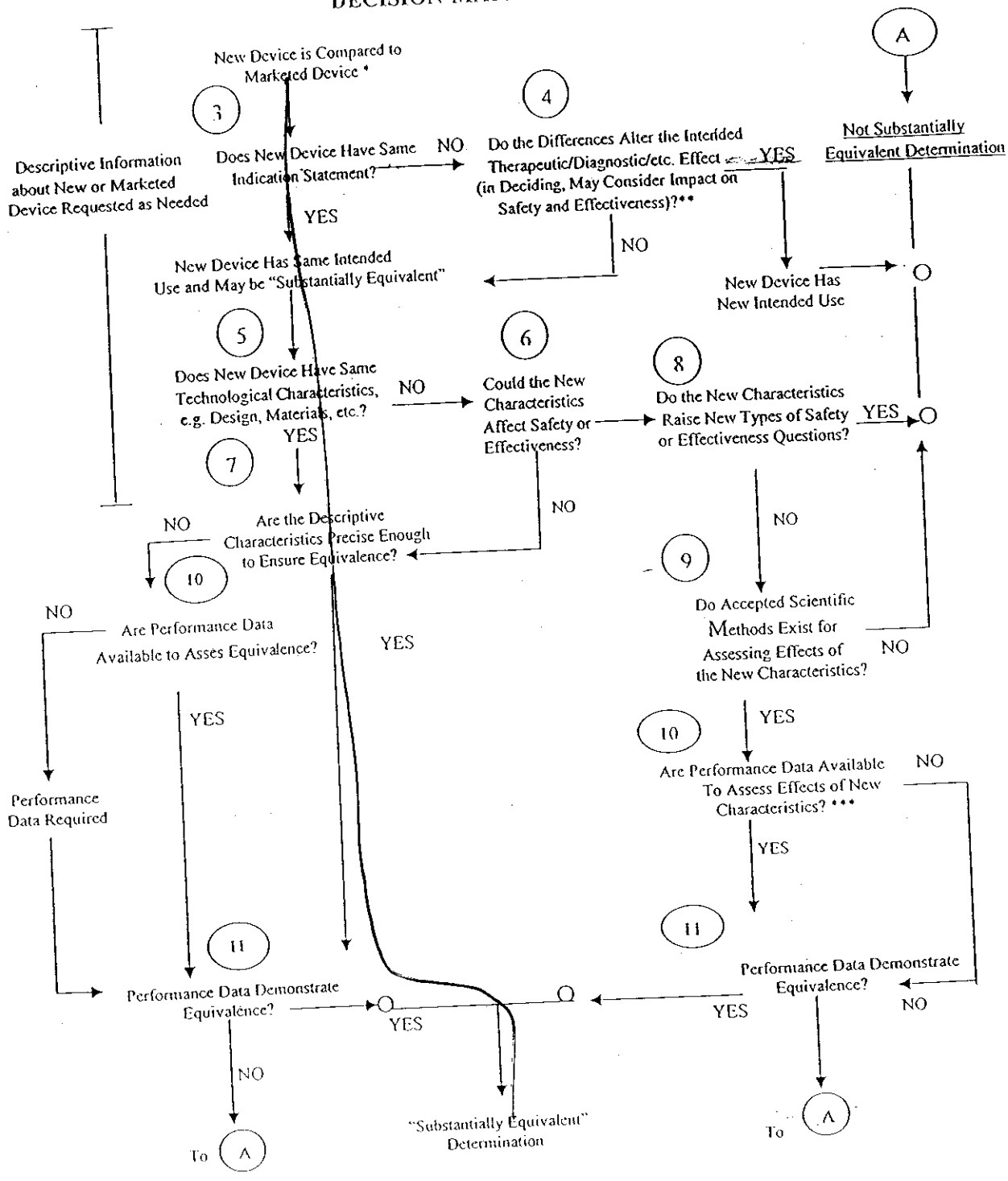
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118