K992832

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-24-2016

SULZER MEDICA

NOV 19 1999

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

Phone (512) 435-3200
FAX (512) 435-3350
WATS (800) 648-1579 (US and Canada)

510(k) SUMMARY
SULZER VASCUTEK ePTFE VASCULAR PROSTHESIS

The Sulzer Vascutek expanded polytetrafluoroethylene (ePTFE) graft line is substantially equivalent to devices in commercial distribution by Impra, a division of C. R. Bard. All devices referenced under this application are 6mm in diameter or greater and are used to treat diseased or occluded systemic arteries and for A/V access. In addition, the application covers externally supported graft designs.

The device is composed of polytetrafluoroethylene, which has been fabricated in tubular form and expanded to impart porosity to the structure. Similar devices have been used clinically since the 1970's with few reported complications or material failures. ePTFE typically is used as a synthetic conduit to replace natural vessels or as a shunt for AV/dialysis access. The mechanical properties of Sulzer Vascutek ePTFE such as strength, suture retention, and handling are substantially equivalent to products currently in commercial distribution.

Sulzer Vascutek ePTFE grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

In vitro testing conducted on the Sulzer Vascutek ePTFE graft line shows it to be substantially equivalent to Impra commercial grafts. Results from animal studies demonstrate that the Sulzer Vascutek standard wall grafts to be equivalent to Impra standard wall grafts. Results from biomaterial testing demonstrate that the Sulzer Vascutek ePTFE grafts are biocompatible and non-toxic.

In summary, all testing demonstrates that the Sulzer Vascutek ePTFE graft line to be substantially equivalent to the grafts in commercial distribution by Impra, Division of C.R. Bard for the reconstruction and bypass of diseased or occluded systemic blood vessels and construction of subcutaneous a-v conduits for blood access.

Common name of the Device:	Vascular Graft
Trade name of Proprietary Name:	Sulzer Vascutek ePTFE Vascular Prosthesis
Submitter and Contact Person:	Edward E. Newton Regulatory Affairs Manager 1300 E. Anderson Lane, Austin, TX 78752 Phone: (512) 435-3407 Fax: (512) 435-3350
Submission Submitted on:	August 20, 1999

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Mr. Edward E. Newton
Regulatory Affairs Manager
Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K992832
Sulzer Vascutek ePTFE Vascular Prosthesis
Regulatory Class: II (Two)
Product Code: 74 DSY
Dated: August 20, 1999
Received: August 23, 1999

Dear Mr. Newton:

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 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). 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 call 301-796-8118.

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

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) 594-4648. 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" (21CFR 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/dsma/dsmamain.html."

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological 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 call 301-796-8118.

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

510(k) Number (if known): K992832

Device Name: Sulzer Vascutek ePTFE Vascular Prosthesis

Indications For Use: Sulzer Vascutek ePTFE grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992832

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Ms. Lisa Peterson
Regulatory Affairs Associate
Sulzer Carbomedics Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K992832/A1
Device Name: Sulzer Vascutek ePTFE Vascular Prosthesis
Dated: June 7, 2001
Received: June 13, 2001

Dear Ms. Peterson:

We have reviewed the information dated June 7, 2001, regarding the 510(k) notification K992832 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Department of Health & Human Services

Ms. Lisa Peterson
Regulatory Affairs Associate
Sulzer Carbomedics Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K992832/A1
Device Name: Sulzer Vascutek ePTFE Vascular Prosthesis
Dated: June 7, 2001
Received: June 13, 2001

Dear Ms. Peterson:

We have reviewed the information dated June 7, 2001, regarding the 510(k) notification K992832 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
~~Prepared by: lmk:LMK:8/8/01:P\DCRD\510(k)\PVDB 510k\K992832 A001-addtofile no new~~ 510K					
2450	[illegible]	8/15/01			

2

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

To: K993667/A2 and K992832/A1 for the Sulzer Carbomedics Inc. SealPTFE™ Vascular Prostheses
From: Lisa Kennell, microbiologist, DCRND Lisa Kennell 8/8/01
Subject: Summary of file and recommendation
Date: August 8, 2001

The sponsor submitted this information as an amendment to the previous 510(k)s, to incorporate additional sizes and configurations of the grafts. Previously, the grafts were available in straight configuration only (with and without support, thin and standard thickness walls), in diameters of 6, 7, 8, and 10 mm. The new configuration will be tapered and step-tapered, with and without support, in diameters 4-6, 4-7, and 5-8, and lengths of 25 to 50 cm. The submitter verified that the indications, operating principle, design, materials, shelf life, packaging, sterilization, manufacturing facilities, equipment, quality control processes and procedures, and gelatin impregnation process for these new configurations and sizes are identical to those in the cleared products. Furthermore, they have conducted and provided results of design verification tests identified in their FMEA analysis (relaxed internal diameter, balloon burst, DSC, longitudinal tensile strength, internodal distance, suture retention strength, wall thickness, water entry pressure, strength after repeated puncture, and peel testing (supported versions). Finally, they have included the mandatory Indications for Use statement, Summary Statement, and Truthful and Accuracy Statement in the submissions. I reviewed the proposed labeling/IFU and compared it to the one for the cleared devices. Although more detailed to cover the gamut of configurations, it does not appear to be markedly different with respect to indications, warnings, contraindications or precautions than the previously cleared labeling. The references included in the IFU are older, and appear to be descriptive only. I verified with Ms. Lisa Peterson that this is the case, and that the article relating to a new tapered graft does not relate to this one, but was included to cover the tapered configurations as a generic article.

RECOMMENDATION

These amendments do not appear to alter the design, components, method of manufacture, or intended use, and thus, the information can be added to the file, and the boilerplate letter for such additions issued.

Supervisor Signature 8/8/01
Date

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 6-13-01

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K992832/A1

To: Division Director: CU/DCRD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

✓ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____Additional information requires a new 510(k); please process [This information will be made into a new 510(k)

_____No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440_

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Lisa Kennell
Date: 8/8/01

Draft #2 : 9/8/99
Draft #3: 1/3/00

8/6

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

K 992832 / A1

SULZER MEDICA

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

Phone (512) 435-3200
FAX (512) 435-3350
WATS (800) 648-1579 (US and Canada)
www.sulzercarbomedics.com

Amended 510(k)

June 7, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Attention: Ms. Lisa Kennell

Subject: **Amendment to: K992832, Sulzer Vascutek ePTFE Vascular Prosthesis cleared November 19, 1999.**

Dear Ms. Kennell:

Sulzer Carbomedics Inc. is submitting this amendment to K992832 for the Sulzer Vascutek ePTFE Vascular Prosthesis in order to obtain clearance to market grafts in the same product line as approved via the referenced pre-market notification, but of different sizes and configurations.

Based on the Agency's recent determination that vascular grafts of less than 6mm are Class II devices, Sulzer Carbomedics proposes that a new 510 (k) is not required for this addition of new graft sizes and configurations to the ePTFE product line since the devices utilize the same materials and indications for use, and there is no change to the safety and effectiveness of the device.

For this reason, we request that the FDA utilize the attached information in a memo to file for premarket notification K992832 to allow the new sizes and configurations of the ePTFE graft to be distributed in the U.S.

5

5K24

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Sulzer Carbomedics considers the intent to market this device as confidential commercial information and request that the FDA consider it as such. We have not disclosed the intent to market this device to anyone in the United States except employees of our firm or others with a need to know, and we have taken precautions to protect its confidentiality. Thus, the protection afforded to such confidential information by 18 USC §1905, 21 USC §331(I), 5 USC §552, and other applicable laws is hereby claimed.

Please do not hesitate to contact me at (512) 435-3523, by fax at (512) 435-3350, or by e-mail at *lpeterson@carbomedics.com* if you have any questions regarding the enclosed submission.

Sincerely,

Lisa Peterson
Regulatory Affairs Associate

Enclosures

cc: Mairi MacFadyen, Sulzer Vascutek Ltd.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Amended 510(k)

for the

Sulzer Vascutek

ePTFE Vascular Prosthesis

SULZER CARBOMEDICS INC.
AUSTIN, TEXAS
JUNE 7, 2001

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Date of Submission:

FDA Document Number: K992832

Section A — Type of Submission

- ☐ 510(k)
- ☒ 510(k) add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission 510(k)s Only

- ☐ New Device
- ☐ Additional or expanded indications
- ☐ Change in Technology, design, materials, or manufacturing process
- ☒ Other reason (specify): Addition of grafts with different sizes and configurations.

Section B2 — Reason for Submission PMAs Only

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 — Reason For Submission IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Change in:
  - ☐ Correspondent
- ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol feasibility
  - ☐ Protocol other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response 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
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

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

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FDA Document Number: K992832

Section C — Product Classification

Product Code: 74 DYF

C.F.R. Section: 21 CFR §870.3460

Device class:
- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Classification panel: Cardiovascular Prosthetic Devices

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 74 DSY	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
- ☐ 510(k) summary attached
- ☒ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K992832	1 Sulzer Vascutek ePTFE Vascular Prosthesis	1 Sulzer Vascutek Ltd.
3	3	3
4	4	4
5	5	5
6	6	6

Section E — Product Information Applicable to All Applications

Common or usual name or classification name: vascular graft

Trade or proprietary or model name	Model Number
1 Sulzer Vascutek ePTFE Vascular Prosthesis	1 See Attachment A in attached amended 510(k)
3	3
4	4
5	5
6	6

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

1 K992832	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling): The Sulzer Vascutek ePTFE Graft is intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

FDA Document Number: K992832

Section F Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 9612515	☒ Manufacturer ☐ Contract manufacturer	☒ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Sulzer Vascutek Ltd.			
Division name (if applicable):		Phone number (include area code): 9011-441-41-812-5555	
Street address: Newmains Avenue		FAX number (include area code): 9011-441-41-812-7650	
City: Inchinnan	State / Province: Renfrewshire	Country: Scotland	ZIP / Postal Code: PA4 9RR
Contact name: Mairi MacFadyen			
Contact title: Manager, Regulatory Affairs			

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

FDA Document Number: K992832

Section G	Applicant or Sponsor		
Company / Institution name: Sulzer Carbomedics, Inc.		FDA establishment registration number: 1627803	
Division name (if applicable):		Phone number (include area code): (512) 435-3523	
Street address: 1300 East Anderson Lane		FAX number (include area code): (512) 435-3350	
City: Austin	State / Province: TX	Country: USA	ZIP / Postal Code: 78752
Signature:			
Name: Lisa Peterson			
Title: Regulatory Affairs Associate			

Section H	Submission correspondent (if different from above)		
Company / Institution name:		FDA establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Signature:			
Name:			
Title:			

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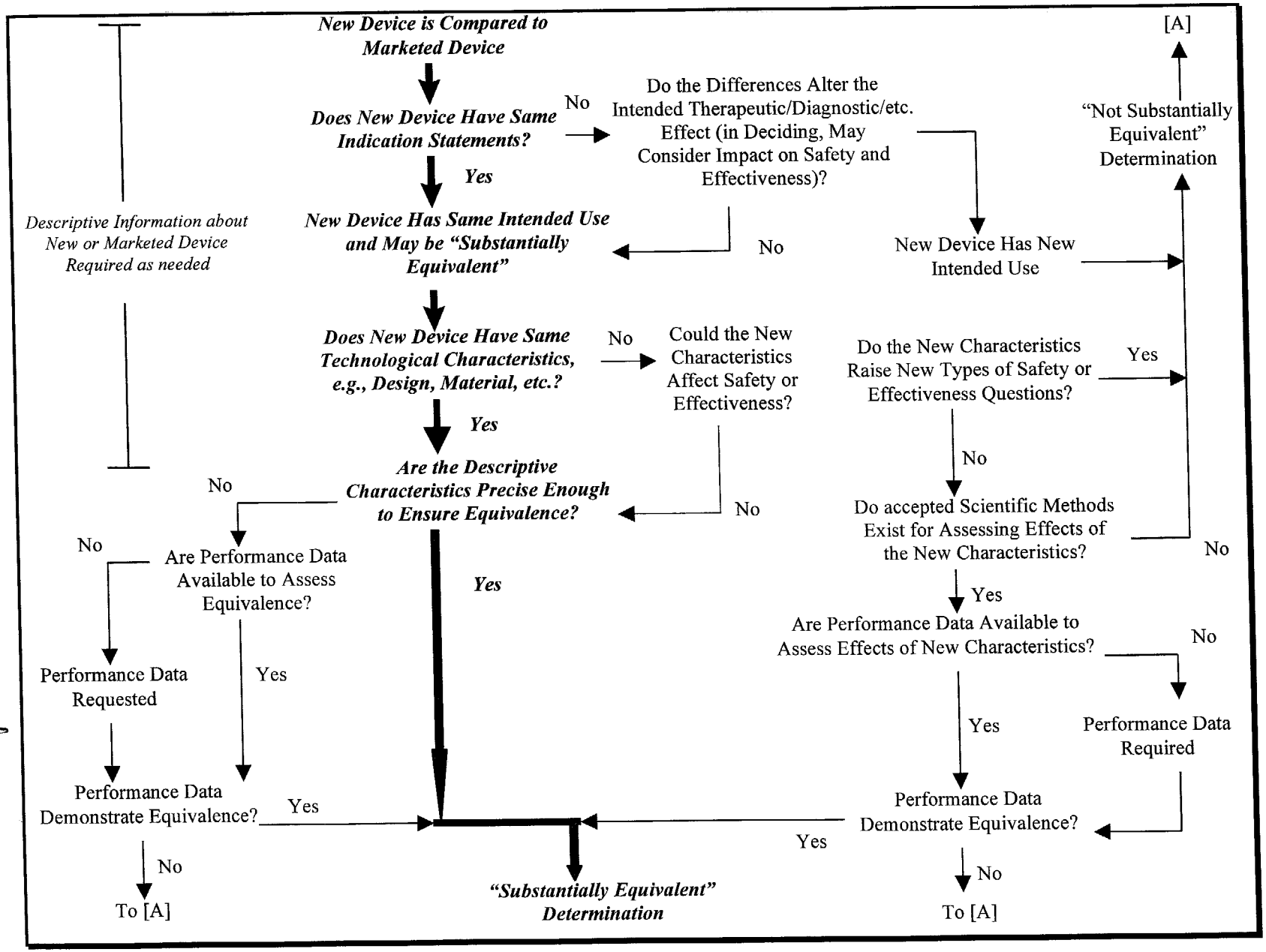
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

510(k) "Substantial Equivalence" Decision Tree



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

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Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

I. General Information

A. Sponsor Information

NAME AND ADDRESS

Sulzer Carbomedics Inc.
1300 East Anderson Lane
Austin, Texas 78752 USA

ESTABLISHMENT REGISTRATION NUMBER

1627803

OFFICIAL CONTACT

Lisa Peterson

Regulatory Affairs Associate
Sulzer Carbomedics Inc.

1300 East Anderson Lane

Austin, Texas 78752
Phone: 512-435-3523
Fax: 512-435-3350
E-mail:*lpeterson@carbomedics.com*

ALTERNATE CONTACT

Edward E. Newton

Regulatory Affairs Manager
Sulzer Carbomedics Inc.

1300 East Anderson Lane

Austin, Texas 78752
Phone: 512-435-3407
Fax: 512-435-3350
E-mail:*enewton@carbomedics.com*

B. Manufacturing and Sterilization Site

NAME AND ADDRESS

Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

ESTABLISHMENT REGISTRATION NUMBER

9612515

15

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

C. Device Distributor

Sulzer Vascutek USA Inc.
1300-C East Anderson Lane
Austin, Texas 78752 USA

D. Device Proprietary Name:

Sulzer Vascutek ePTFE Graft

E. Common/Classification Name: Vascular graft (prosthesis), less than 6mm

F. Classification

Vascular grafts containing diameters less than 6mm in size (Product Code 74DYF) are Class II cardiovascular prosthetic devices, per 21 CFR §870.3460.

G. Predicate Devices: 1. Sulzer Vascutek ePTFE Vascular Prosthesis, of 6mm or greater was cleared as K992832 on November 19, 1999.

H. Performance Standard

Testing for the Sulzer Vascutek ePTFE Graft containing diameters less than 6mm was performed in accordance with the FDA Draft Guidance Document entitled, *Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prosthesis* (December 1993), FDA blue book memorandum #G95-1 regarding the biological evaluation of medical devices, and the AAMI Vascular Prosthesis Standard (VP20, June 1994).

I. Intended Use

The Sulzer Vascutek ePTFE Graft containing diameters less than 6mm is indicated for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

A copy of the draft Instructions for Use and the Indications for Use statement are included in *Attachment A*.

J. Labeling

Draft labels for the Sulzer Vascutek ePTFE Graft containing diameters less than 6mm are included in *Attachment B*.

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

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K. Substantial Equivalence

The Sulzer Vascutek ePTFE grafts containing diameters less than 6mm are identical to those which previously received 510(k) concurrence as listed below:

- Same indications for use,
- Use the same operating principle,
- Incorporate the same basic graft design,
- Incorporate the same materials,
- Same shelf life, and
- Packaged and sterilized using the same materials and processes.

II. Device Details

A. Device Description and Comparison

The Sulzer Vascutek ePTFE grafts containing diameters less than 6mm are manufactured from virgin expanded polytetrafluoroethylene resin. This range of grafts will be supplied in short and stepped taper configurations. The taper configuration is created using a heat set process. Design verification testing performed to assess the risks associated with this range of grafts is provided in Table 2. Additionally, the ePTFE graft line containing diameters less than 6mm will be available in supported and unsupported configurations. The grafts are supplied sterile. The method of sterilization used is ethylene oxide. A shelf-life of five years has been established for the prosthesis.

With the exception of the diameter size and taper configuration, the Sulzer Vascutek ePTFE Graft containing diameters less than 6mm has the **identical** intended use, materials and function as the Sulzer Vascutek ePTFE Vascular Prosthesis of 6mm or greater which received marketing clearance on November 19, 1999 (K992832).

A description of the Sulzer Vascutek ePTFE Graft configurations containing diameters less than 6mm is provided in Table 1 below:

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TABLE 1

Graft Type	Description
Short Taper – Unsupported	The diameter at one end of the graft is different from the other end for implantation in the vasculature and to facilitate AV/dialysis access.
Short Taper – Central Supported	The supported graft has an external polypropylene support, which provides increased kink and compression resistance for implantation in areas such as axillo-femoral.
Stepped Taper – Unsupported	Similar to the short tapered graft, but the change in interval diameter is more of a distinct step rather than a gradual taper.
Stepped Taper – Central Supported	The supported graft has an external polypropylene support, which provides increased kink and compression resistance for implantation in areas such as axillo-femoral.

As noted above, the Sulzer Vascutek ePTFE grafts containing diameters less than 6mm are manufactured using proven technologies and materials. With the exception of the diameter size and taper configuration, the manufacturing facilities, equipment, quality control processes and procedures used for the ePTFE grafts containing diameters less than 6mm are **identical** to that used in the manufacture of the ePTFE Vascular Prostheses, of 6mm or greater, cleared via K992832. A listing of the sizes and configurations for the ePTFE grafts containing diameters less than 6mm is included in *Attachment C*.

B. Summary of Design Control Activities

The analysis method used to assess the risks associated with the use of the Sulzer Vascutek ePTFE grafts containing diameters less than 6 mm was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 2 below:

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TABLE 2

Configuration	Test Performed	Acceptance Criteria
(b)(4) Confidential and Proprietary Information - Testing		

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(b)(4) Confidential and Proprietary Information - Testing

[redacted]

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

(b)(4) Confidential and Proprietary Information - Testing

[redacted]

21

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

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The test methods used are the same as those submitted in K992832. The results indicate that the ePTFE grafts containing diameters less than 6mm are acceptable for clinical use.

A Declaration of Conformity with Design Controls is included in *Attachment D.*

C. 510(k) Statement

A 510(k) Statement for the Sulzer Vascutek ePTFE Graft containing diameters less than 6mm is included in *Attachment E.*

D. Truthful and Accuracy Statement

A certification of the truthfulness and accuracy of the Sulzer Vascutek ePTFE Graft containing diameters less than 6mm described in this amendment is provided in *Attachment F.*

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

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Attachment A

Instructions for Use and Indications for Use Statement

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

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DRAFT

INSTRUCTIONS FOR USE
UNSEALED ePTFE GRAFTS

Caution: - Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION

This range of Sulzer Vascutek grafts is manufactured from both supported and unsupported ePTFE (expanded polytetrafluoroethylene). The external support, where applicable, provides kink resistance and a smooth flow surface. Grafts with a central support are NOT designed to be removed. All grafts are supplied sterile and will remain so for the stated shelf life unless the packaging is opened or damaged.

INDICATIONS

Sulzer Vascutek ePTFE grafts are used for the creation of subcutaneous arteriovenous conduits for blood access, bypass or reconstruction of occluded or diseased arterial vessels.

Configuration	Graft Characteristic		Typical Applications
	Supported	Unsupported	
Short Taper – Unsupported		High Strength	The creation of arteriovenous conduits for blood access. Stepped taper and short taper configurations minimize the risk of steal syndrome and high cardiac output[3].
Short Taper – Central support	High Strength & Compression Resistant		The creation of arteriovenous conduits for blood access. Stepped taper and short taper configurations minimize the risk of steal syndrome and high cardiac output[3].
Step Taper – Unsupported		High Strength	The creation of arteriovenous conduits for blood access. Stepped taper and short taper configurations minimize the risk of steal syndrome and high cardiac output[3].
Step Taper – Central Support	High Strength & Compression Resistant		The creation of arteriovenous conduits for blood access. Stepped taper and short taper configurations minimize the risk of steal syndrome and high cardiac output[3].
External Spiral Reinforcement: - Central support grafts have approximately 6cm of external spiral support in the center of the graft. This spiral support is NOT designed to be removed.			

CONTRAINDICATIONS

1. Grafts only to be implanted by Vascular Prosthesis Consultant Surgeons who are experienced with the specific techniques required by these medical devices.
2. Unsupported grafts must not be implanted in such areas where total or partial occlusion can occur as a result of the movement of a patient's body.
3. These prostheses should not be implanted in patients who exhibit sensitivity to ePTFE materials.

WARNINGS

1. For blood access applications, do NOT cannulate the portion of the graft with central spiral support.
2. Do NOT remove central spiral support. Attempts to remove this support may damage the graft. If damage occurs, discard the graft.
3. Unsealed ePTFE grafts are neither elastic in a radial or longitudinal direction. Therefore care must be taken as follows:

   (i) *When using embolectomy or balloon angioplasty catheters within the lumen of a graft, the inflated balloon size must be carefully matched to the inside diameter of the graft. Failure to size the catheter correctly or the over-inflation of the balloon may result in rupture of either the graft or the balloon.*

   (ii) *Excessive tension on the unsealed ePTFE prosthesis must be avoided.*

   (iii) *Cut the graft long enough to ensure that no stress exists on the anastomoses. The patient's body mass and the likely extremes of their posture must be considered when determining the length of graft to be implanted, otherwise stress may be placed on the anastomosis during limb extension. Failure to consider these aspects may cause anastomotic disruption, resulting in excessive bleeding, loss of function or possible amputation of limb and in the worst case, death.*

   (iv) *The graft must not be filled with blood before it has been passed through the tunnel. Exerting pressure may cause blood components to be passed through the graft wall leading to the possible formation of seroma.*

4. **Never cut or open a graft to form a surgical patch**
5. Complications which may occur in conjunction with the use of any vascular prosthesis include but are not limited to: redundancy; infection; ultrafiltration or perigraft seroma; thrombosis; embolic events; occlusion; stenosis; mechanical disruption or tearing of the suture line, graft and/or host vessel; excessive suture hole bleeding; formation of pseudoaneurysms due to excessive, localized, or large needle punctures; or perigraft hematomas.

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

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INSTRUCTIONS FOR USE
UNSEALED ePTFE GRAFTS

DRAFT

PRECAUTIONS

1. **DO NOT PRECLOT.** No preclotting required.
2. **DO NOT USE BEYOND THE INDICATED EXPIRY DATE.**
3. **FOR SINGLE USE ONLY.**
4. **DO NOT RESTERILIZE.** This product must not be resterilized.
5. Clamping may damage any vascular prosthesis. Atraumatic clamps, ideally with soft shod jaws, should be used with a minimum application of force on the unsupported section of graft only. Excessive force must be avoided, as it will damage the external spiral support.
6. **Do not puncture grafts in the supported area.** Care must be taken not to puncture the opposite side of the graft when suturing.
7. Use a non-cutting tapered needle with non-absorbable monofilament polypropylene or PTFE suture stitched a suitable distance from the graft edge. To minimize suture line bleeding pull the suture at an angle of 90° to the graft.
8. Store in a clean, dry area, not less than 0°C (32°F) and not more than 50°C (122°F).
8. Exposure to oil, alcohol, aqueous solutions or any of these fluids when pressurized will affect the hydrophobic property of the material and may result in increased seroma formation[4].

THROMBECTOMY

Should a postoperative occlusion occur, declotting can be performed by carrying out a longitudinal incision with stay sutures for thrombectomy procedures. When a transverse incision is used, a horizontal mattress suture technique may be required to aid closure.

ANGIOACCESS

- When implanting a Sulzer Vascutek prosthesis care must be taken to ensure that a subcutaneous tunnel is created of similar size to the graft, such that a snug fit is achieved.
- To reduce the risk of hematoma formation it is suggested that the graft not be used for AV Access during the two weeks following implant.
- The blood access needle should be inserted at an angle of 45° (bevel upward) until the graft has been penetrated. Care must be taken not to puncture the opposite side of the graft.
- Do not cannulate at the same site. Rotate areas to reduce chance of graft damage and the possibility of perigraft hematoma or pseudoaneurysm formation. If using a supported graft do not cannulate near or within the supported portion.
- Do not cannulate within one inch of proximal and distal anastomosis.
- To minimize infection, strict adherence to aseptic techniques is recommended.
- Once the needle has been withdrawn, apply moderate digital compression to the cannulation site to assist haemostasis.

STERILIZATION

Sulzer Vascutek ePTFE grafts are sterilized in ethylene oxide, supplied sterile and must not be resterilized. The Tyvek® seal on both intermediate and inner trays must be intact. Any damage to the trays renders the prosthesis non-sterile. In the event of damage to the primary packaging, the product must not be used and should be returned immediately to the supplier.

PACKAGING

Only the innermost tray may be introduced into the sterile field.

ADDITIONAL LABELS

Additional labels are attached to this leaflet for inclusion in patient records to enable the tracking of this device.

Disclaimer of Warranties

Many factors are outside Sulzer Vascutek's supervision and control after sale of this device.

Sulzer Vascutek has no control over the conditions under which the device is used, the diagnosis of the patient or the methods or procedures used for implantation. Therefore, Sulzer Vascutek makes no warranty or guarantee of this device, expressed or implied.

SULZER VASCUTEK MAKES NO WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ANY WARRANTY OR REPRESENTATION BY ANY OTHER PERSON OR FIRM IS VOID. SULZER VASCUTEK NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH SALE OF THIS DEVICE. SULZER VASCUTEK WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THIS DEVICE.

Some jurisdictions do not allow the exclusion of or limitations on an implied warranty. Similarly, some jurisdictions do not allow the exclusion or limitations of incidental or consequential damages. Therefore, some of the above exclusions may not apply. This warranty gives specific legal rights. The patient may also have other rights which vary from jurisdiction to jurisdiction.

References

1. Rosental JJ *et al* **Prevention of high flow problems of arteriovenous grafts. Development of a new tapered graft.** Am J Surg. 1980 Aug;140(2):231-3.
2. Blumenberg RM *et al* **Perigraft seromas complicating arterial grafts** Surgery 1985, 97:2 194-204

Tyvek® Du Pont Registered Trade Mark

Manufactured by:

Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
SCOTLAND PA4 9RR

For USA orders:

Sulzer Vascutek USA Inc.
1300-C East Anderson Lane
Austin, Texas 78752
Toll Free: 1 (888) 758-8000

Part No.301-080

75

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Indications For Use

510(K) Number: K992832

Device Name: Sulzer Vascutek ePTFE Graft

Indications for Use: The Sulzer Vascutek ePTFE Graft is indicated for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

26

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

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Attachment B

Labeling for the Sulzer Vascutek ePTFE Graft

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DRAFT

Box Label

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE
0086

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

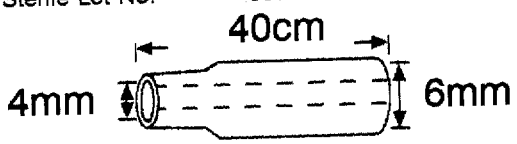
SERIAL NO 66353DD2

+H960S40ST040611

+S801066353DD21

USA

Cat No: S40ST0406
Batch No: 3522
Use by: 2006/05
Sterile Lot No: 6635



Step Taper

• ePTFE vascular prosthesis • Prothèses vasculaires ePTFE • ePTFE Gefäßprothese • ePTFE Vaatprothese • Protesi vascolare in ePTFE • Prótesis Vascular de ePTFE • Prótese Vascular de ePTFE • ePTFE kärlprotes • ePTFE karprotese • ePTFE karprotese • Αγγειακές Προσθέσεις από ePTFE • ePTFE人工血管

1 SMK

Diameter / Diamètre / Durchmesser / Diameter / Diametro / Diámetro / Diâmetro / Diameter / Diameter / Diameter / Διάμετρος / 直径	4-6mm
Usable Length/ Longueur utilisable / Länge / Bruikbare lengte / Lunghezza utilizzabile / Longitud utilizable / Comprimento utilizável Användbar längd / Brugbar længde / Brukslengde / Χρησιμοποιούμενο Μήκος / 使用可能長	40cm
Cat No. / Référence / Bestellnummer / Catalogusnummer / No. Catalogo / Referencia / Nr. Cat. / Artikel Nr / Kat. nr. / Kat. nr. / Αριθμός Καταλόγου / カタログ番号	S40ST0406
Use by / A utiliser avant / Verwendbar bis / Te gebruiken voor / Usare prima del / Usar antes de / Usar antes de / Förbrukas senast / Anvendes inden / Brukes innen / Χρήση πριν από / 使用期限	2006/05
Batch No. / No. de lot de fabrication / Ch.-Nr. / Batchnummer / No. Batch / Número de lote / Nr. Produção / Batch Nr / Batch nr. / Batch nr. / Αριθμός Παρτίδας / バッチ番号	3522
Sterile Lot No. / No. de lot de stérilisation / Sterile Lot-Nr. / Steriel Lotnummer / Lotto Sterile No / No lote de esterilización / Nr. Lote Esterilização / Steriliserings Lot Nr / Steriit lot. nr. / Ster. Lot. Nr. / Αριθμός Σειράς / 滅菌ロット番号	6635
Date of Manufacture / Date de fabrication / Herstellungsdatum / Datum van productie / Data di fabbricazione / Fecha de fabricación / Data de fabricação / Tillverkningsdatum / Fabrikationsdato / Produksjonsdato / Ημερομηνία Κατασκευής / 製造年月日	2001/05
Serial Number / Numéro de série / Seriennummer / Serienummer / Serie numero / Número de Serie / Número de Série / Serienummer / Serie nummer / Serienr / Σειριακός Αριθμός / シリアル番号	66353DD2

203-373

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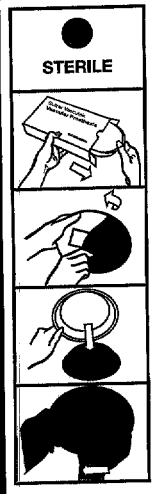
Tyvek Label

DRAFT

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE 0086

Step Taper



- **Please Read Instructions Before Use**
- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
- **Single Use Only**
- Do Not Preclot
- Sterilized in Ethylene Oxide
- Must Not be Used After Expiration Date
- Store in a Clean Dry Area at Between 0-50°C (32-122°F)

Diameter: 4-6mm

Usable Length: 40cm

Cat No: S40ST0406

Batch No: 3522

Sterile Lot No: 6635

Use by: 2006/05

Man. Date: 2001/05

Materials of Manufacture:
ePTFE

For ordering please contact:
Sulzer Vascutek USA, Inc
1300 East Anderson Lane
AUSTIN Tx, 78752
Toll Free (888) 758-8000

1 SMK

SULZER *MEDICA*

Manufactured by ~
Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

203-374

Patient Label

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

TYPE:
ePTFE

CONSTRUCTION:

Step Taper

MATERIAL OF MANUFACTURE:
ePTFE

DIAMETER 4-6mm

USABLE LENGTH 40cm

USE BY: 2006/05

CAT No. S40ST0406

BATCH No. 3522

STERILE LOT No. 6635

DATE: 2001/05

1 SMK

DRAFT

Part No. 203-026/1

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

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Box Label

DRAFT

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE 0086

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

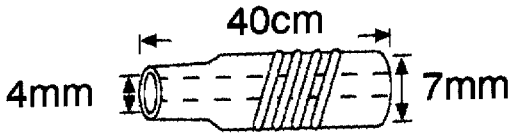
SERIAL NO 19673DD4

+H960S40ST0407CR1+

+$$01051967 3DD4+

USA

Cat No: S40ST0407CR
Batch No: 1888
Use by: 2006/05
Sterile Lot No: 1967



Step Taper Central Support

• ePTFE vascular prosthesis • Prothèses vasculaires ePTFE • ePTFE Gefäßprothese • ePTFE Vaatprothese • Protesi vascolare in ePTFE • Prótesis Vascular de ePTFE • Prótese Vascular de ePTFE • ePTFE kärlprotes • ePTFE karprotese • ePTFE karprotese • Αγγειακές Προσθέσεις από ePTFE • ePTFE人工血管

1 SMK

Diameter / Diamètre / Durchmesser / Diameter / Diametro / Diámetro / Diâmetro / Diameter / Diameter / Diameter / Διάμετρος / 直径	4-7mm
Usable Length/ Longueur utilisable / Länge / Bruikbare lengte / Lunghezza utilizzabile / Longitud utilizable / Comprimento utilizável Användbar längd / Brugbar længde / Brukslengde / Χρησιμοποιούμενο Μήκος / 使用可能長	40cm
Cat No. / Référence / Bestellnummer / Catalogusnummer / No. Catalogo / Referencia / Nr. Cat. / Artikel Nr / Kat. nr. / Kat. nr. / Αριθμός Καταλόγου / カタログ番号	S40ST0407CR
Use by / A utiliser avant / Verwendbar bis / Te gebruiken voor / Usare prima del / Usar antes de / Usar antes de / Förbrukas senast / Anvendes inden / Brukes innen / Χρήση πριν από / 使用期限	2006/05
Batch No. / No. de lot de fabrication / Ch.-Nr. / Batchnummer / No. Batch / Número de lote / Nr. Produção / Batch Nr / Batch nr. / Batch nr. / Αριθμός Παρτίδας / バッチ番号	1888
Sterile Lot No. / No. de lot de stérilisation / Sterile Lot-Nr. / Steriel Lotnummer / Lotto Sterile No / No lote de esterilización / Nr. Lote Esterilização / Steriliserings Lot Nr / Sterilt lot. nr. / Ster. Lot. Nr. / Αριθμός Σειράς / 滅菌ロット番号	1967
Date of Manufacture / Date de fabrication / Herstellungsdatum / Datum van productie / Data di fabbricazione / Fecha de fabricación / Data de fabricação / Tillverkningsdatum / Fabrikationsdato / Produksjonsdato / Ημερομηνία Κατασκευής / 製造年月日	2001/05
Serial Number / Numéro de série / Seriennummer / Serienummer / Serie numero / Número de Serie / Número de Série / Serienummer / Serie nummer / Serienr / Σειριακός Αριθμός / シリアル番号	19673DD4

203-373

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

30

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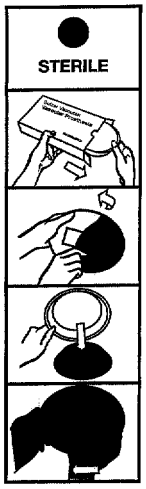
Tyvek Label

DRAFT

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE 0086

Step Taper Central Support



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- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
- **Single Use Only**
- Do Not Preclot
- Sterilized in Ethylene Oxide
- Must Not be Used After Expiration Date
- Store in a Clean Dry Area at Between 0-50°C (32-122°F)

Diameter: 4-7mm

Usable Length: 40cm

Cat No: S40ST0407CR

Batch No: 1888

Sterile Lot No: 1967

Use by: 2006/05

Man. Date: 2001/05

Materials of Manufacture:
ePTFE
POLYPROPYLENE

For ordering please contact:
Sulzer Vascutek USA, Inc
1300 East Anderson Lane
AUSTIN Tx, 78752
Toll Free (888) 758-8000

SULZER *MEDICA*

Manufactured by ~
Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

203-374

1 SMK

Patient Label

DRAFT

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

TYPE:
ePTFE

CONSTRUCTION: Step
Taper Central Support

MATERIAL OF MANUFACTURE:
ePTFE
POLYPROPYLENE

DIAMETER	4-7mm
USABLE LENGTH	40cm
USE BY: 2006/05	
CAT No.	S40ST0407CR
BATCH No.	1888
STERILE LOT No.	1967
DATE: 2001/05	

1 SMK

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

Part No. 203-026/1

31

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Box Label

DRAFT

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE 0086

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

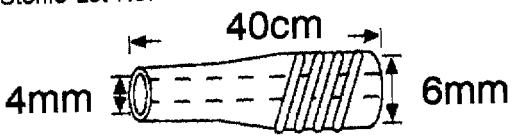
SERIAL NO 26673DD1

+H960B40T0406CR1C

+$$010526673DD1C

USA

Cat No: S40T0406CR
Batch No: 3522
Use by: 2006/05
Sterile Lot No: 2667



Short Taper Central Support

• ePTFE vascular prosthesis • Prothèses vasculaires ePTFE • ePTFE Gefäßprothese • ePTFE Vaatprothese • Protesi vascolare in ePTFE • Prótesis Vascular de ePTFE • Prótese Vascular de ePTFE • ePTFE kärlprotes • ePTFE karprotese • ePTFE karprotese • Αγγειακές Προσθέσεις από ePTFE • ePTFE人工血管

1 SMK

Diameter / Diamètre / Durchmesser / Diameter / Diametro / Diámetro / Diâmetro / Diameter / Diameter / Diameter / Διάμετρος / 直径	4-6mm
Usable Length/ Longueur utilisable / Länge / Bruikbare lengte / Lunghezza utilizzabile / Longitud utilizable / Comprimento utilizável Användbar längd / Brugbar længde / Brukslengde / Χρησιμοποιούμενο Μήκος / 使用可能長	40cm
Cat No. / Référence / Bestellnummer / Catalogusnummer / No. Catalogo / Referencia / Nr. Cat. / Artikel Nr / Kat. nr. / Kat. nr. / Αριθμός Καταλόγου / カタログ番号	S40T0406CR
Use by / A utiliser avant / Verwendbar bis / Te gebruiken voor / Usare prima del / Usar antes de / Usar antes de / Förbrukas senast / Anvendes inden / Brukes innen / Χρήση πριν από / 使用期限	2006/05
Batch No. / No. de lot de fabrication / Ch.-Nr. / Batchnummer / No. Batch / Número de lote / Nr. Produção / Batch Nr / Batch nr. / Batch nr. / Αριθμός Παρτίδας / バッチ番号	3522
Sterile Lot No. / No. de lot de stérilisation / Sterile Lot-Nr. / Steriel Lotnummer / Lotto Sterile No / No lote de esterilización / Nr. Lote Esterilização / Steriliserings Lot Nr / Sterilt lot. nr. / Ster. Lot. Nr. / Αριθμός Σειράς / 滅菌ロット番号	2667
Date of Manufacture / Date de fabrication / Herstellungsdatum / Datum van productie / Data di fabbricazione / Fecha de fabricación / Data de fabricação / Tillverkningsdatum / Fabrikationsdato / Produksjonsdato / Ημερομηνία Κατασκευής / 製造年月日	2001/05
Serial Number / Numéro de série / Seriennummer / Serienummer / Serie numero / Número de Serie / Número de Série / Serienummer / Serie nummer / Serienr / Σειριακός Αριθμός / シリアル番号	26673DD1

203-373

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

32

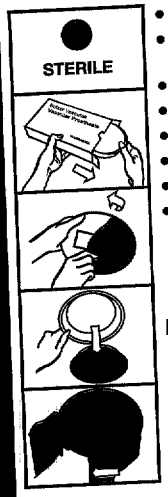
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Tyvek Label

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE 0086

Short Taper Central Support



- **Please Read Instructions Before Use**
- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
- **Single Use Only**
- Do Not Preclot
- Sterilized in Ethylene Oxide
- Must Not be Used After Expiration Date
- Store in a Clean Dry Area at Between 0-50°C (32-122°F)

Diameter: 4-6mm

Usable Length: 40cm

Cat No: S40T0406CR

Batch No: 3522

Sterile Lot No: 2667

Use by: 2006/05

Man. Date: 2001/05

Materials of Manufacture:
ePTFE
POLYPROPYLENE

DRAFT

For ordering please contact:
Sulzer Vascutek USA, Inc
1300 East Anderson Lane
AUSTIN Tx, 78752
Toll Free (888) 758-8000

SULZER *MEDICA*

Manufactured by ~
Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

203-374

1 SMK

Patient Label

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

TYPE:
ePTFE

CONSTRUCTION: Short
Taper Central Support

MATERIAL OF MANUFACTURE:
ePTFE
POLYPROPYLENE

DIAMETER	4-6mm
USABLE LENGTH	40cm
USE BY: 2006/05	
CAT No.	S40T0406CR
BATCH No.	3522
STERILE LOT No.	2667
DATE	2001/05

1 SMK

DRAFT

Part No. 203-026/1

Questions? Contact FDA/CDRH/OCE/DDD at 301-796-5693 or STATUS@fda.hhs.gov or call 301-796-8118.

33

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Box Label

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE
0086

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

SERIAL NO 43663DCF

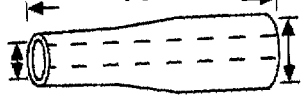
+H960S40T04061G

+$01054366 3DCFG

USA

Cat No: S40T0406
Batch No: 2355
Use by: 2006/05
Sterile Lot No: 4366

40cm

4mm  6mm

Short Taper

1 smk

• ePTFE vascular prosthesis • Prothèses vasculaires ePTFE • ePTFE Gefäßprothese • ePTFE Vaatprothese • Protesi vascolare in ePTFE • Prótesis Vascular de ePTFE • Prótese Vascular de ePTFE • ePTFE kärlprotes • ePTFE karprotese • ePTFE karprotese • Αγγειακές Προσθέσεις από ePTFE • ePTFE人工血管

Diameter / Diamètre / Durchmesser / Diameter / Diametro / Diámetro / Diâmetro / Diameter / Diameter / Diameter / Διάμετρος / 直径 4-6mm

Usable Length/ Longueur utilisable / Länge / Bruikbare lengte / Lunghezza utilizzabile / Longitud utilizable / Comprimento utilizável Användbar längd / Brugbar længde / Brukslengde / Χρησιμοποιούμενο Μήκος / 使用可能長 40cm

Cat No. / Référence / Bestellnummer / Catalogusnummer / No. Catalogo / Referencia / Nr. Cat. / Artikel Nr / Kat. nr. / Kat. nr. / Αριθμός Καταλόγου / カタログ番号 S40T0406

Use by / A utiliser avant / Verwendbar bis / Te gebruiken voor / Usare prima del / Usar antes de / Usar antes de / Förbrukas senast / Anvendes inden / Brukes innen / Χρήση πριν από / 使用期限 2006/05

Batch No. / No. de lot de fabrication / Ch.-Nr. / Batchnummer / No. Batch / Número de lote / Nr. Produção / Batch Nr / Batch nr. / Batch nr. / Αριθμός Παρτίδας / バッチ番号 2355

Sterile Lot No. / No. de lot de stérilisation / Sterile Lot-Nr. / Steriel Lotnummer / Lotto Sterile No / No lote de esterilización / Nr. Lote Esterilização / Steriliserings Lot Nr / Sterilt lot. nr. / Ster. Lot. Nr. / Αριθμός Σειράς / 滅菌ロット番号 4366

Date of Manufacture / Date de fabrication / Herstellungsdatum / Datum van productie / Data di fabbricazione / Fecha de fabricación / Data de fabricação / Tillverkningsdatum / Fabrikationsdato / Produksjonsdato / Ημερομηνία Κατασκευής / 製造年月日 2001/05

Serial Number / Numéro de série / Seriennummer / Serienummer / Serie numero / Número de Serie / Número de Série / Serienummer / Serie nummer / Serienr / Σειριακός Αριθμός / シリアル番号 43663DCF

203-373

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

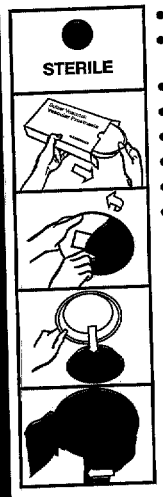
Tyvek Label

DRAFT

Sulzer Vascutek
Expanded PTFE
Vascular Prosthesis

CE 0086

Short Taper



- **Please Read Instructions Before Use**
- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
- **Single Use Only**
- Do Not Preclot
- Sterilized in Ethylene Oxide
- Must Not be Used After Expiration Date
- Store in a Clean Dry Area at Between 0-50°C (32-122°F)

Diameter: 4-6mm

Usable Length: 40cm

Cat No: S40T0406

Batch No: 2355

Sterile Lot No: 4366

Use by: 2006/05

Man. Date: 2001/05

Materials of Manufacture:
ePTFE

SULZER *MEDICA*

For ordering please contact:
Sulzer Vascutek USA, Inc
1300 East Anderson Lane
AUSTIN Tx, 78752
Toll Free (888) 758-8000

Manufactured by ~
Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

203-374

1 smk

Patient Label

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

TYPE:
ePTFE

CONSTRUCTION:

Short Taper

MATERIAL OF MANUFACTURE:
ePTFE

DIAMETER	4-6mm
USABLE LENGTH	40cm
USE BY: 2006/05	
CAT No.	S40T0406
BATCH No.	2355
STERILE LOT No.	4366
DATE: 2001/05	

1 smk

DRAFT

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

Part No. 203-026/1

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Attachment C

Listing of Sizes and Configurations

36

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Sulzer Vascutek ePTFE Vascular Graft (TaperFlo AV)	Length (cm)	Diameter (mm)	Model or catalogue number
Short Taper	30	4-7	S30T0407
Short Taper	40	4-6	S40T0406
Short Taper	40	4-7	S40T0407
Short Taper	45	4-6	S45T0406
Short Taper, Central Supported	40	4-6	S40T0406CR
Short Taper, Central Supported	40	4-7	S40T0407CR
Stepped Taper	20	4-6	S20ST0406
Stepped Taper	20	4-7	S20ST0407
Stepped Taper	25	4-6	S25ST0406
Stepped Taper	25	4-7	S25ST0407
Stepped Taper	30	4-6	S30ST0406
Stepped Taper	30	4-7	S30ST0407
Stepped Taper	35	4-6	S35ST0406
Stepped Taper	35	4-7	S35ST0407
Stepped Taper	35	5-8	S35ST0508
Stepped Taper	40	4-6	S40ST0406
Stepped Taper	40	4-7	S40ST0407
Stepped Taper	40	5-8	S40ST0508
Stepped Taper	45	4-6	S45ST0406
Stepped Taper	45	4-7	S45ST0407
Stepped Taper	45	5-8	S45ST0508
Stepped Taper	50	4-6	S50ST0406
Stepped Taper	50	4-7	S50ST0407
Stepped Taper	50	5-8	S50ST0508
Stepped Taper, Central Supported	40	4-7	S40ST0407CR
Stepped Taper, Central Supported	45	4-7	S45ST0407CR
Stepped Taper, Central Supported	45	5-8	S45ST0508CR
Stepped Taper, Central Supported	50	4-7	S50ST0407CR

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Attachment D

Declaration of Conformity with Design Control Statements

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 2016

SULZER MEDICA

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

Telephone: 0141-812 5555
Fax: 0141-812 7650

Declaration of Conformity with Design Controls for Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the additional sizes and configurations for eEPTE vascular prosthesis were performed by the designated individual (s) and the results demonstrated that the predetermined acceptance criteria were met.

Mairi MacFadyen

Name: Mairi MacFadyen
Title: Regulatory Affairs Manager
Sulzer Vascutek Ltd

31 May 2001
Date:

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SULZER MEDICA

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

Telephone: 0141-812 5555
Fax: 0141-812 7650

Declaration of Conformity with Design Controls for Manufacturing Facility

The Manufacturing Facility, Sulzer Vascutek Ltd, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Mairi MacFadyen

Name: Mairi MacFadyen
Title: Regulatory Affairs Manager
Sulzer Vascutek Ltd

31 May 2001
Date:

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Attachment E

510(k) Statement

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 2016

SULZER MEDICA

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

Telephone: 0141-812 5555
Fax: 0141-812 7650

510 (k) Statement

I certify that, in my capacity as Regulatory Affairs Manager for Sulzer Vascutek Ltd., I will make available all information included in this amended 510 (k) on safety and effectiveness, within 30 days of request, if the device described in the amended 510 (k) is awarded marketing clearance. The information I agree to make available will be duplicate of the amended 510 (k), including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Mairi MacFadyen

Name: Mairi MacFadyen
Title: Regulatory Affairs Manager
Sulzer Vascutek Ltd

June 6, 2001
Date:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8113

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Attachment F

Truthful and Accuracy Statement

43

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

Records processed under FOIA Request #2016-6076; Release Date: CDRH, [illegible] 2016

SULZER MEDICA

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

Telephone: 0141-812 5555
Fax: 0141-812 7650

Truthful and Accurate Statement

I certify that, in my capacity as Regulatory Affairs Manager for Sulzer Vascutek Ltd., I believe to the best of my knowledge that all data and information submitted in this amended premarket notification are truthful and accurate and that no material fact has been omitted.

Mairi MacFadyen

Name: Mairi MacFadyen
Title: Regulatory Affairs Manager
Sulzer Vascutek Ltd

June 6, 2001
Date:

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2004

Mr. Stewart Robertson
Regulatory Affairs Associate
Vascutek Ltd.
Newmains Avenue, Inchinnan
Renfrewshire, PA4 9RR
Scotland

Re: K952293
Vascutek Gelweave Vascular Graft
K955230
Vascutek Gelsoft PLUS Vascular Graft
K963611
Vascutek Cardiovascular Fabric
K964665
Vascutek Gelweave Vascular Graft (Bifurcated Configuration
K972201
Patch, pledget and intracardiac, PETP, PTFE, Polypropylene
K990503
Sulzer Vascutek Gelsoft Vascular Prosthesis
K992832 /A2
Sulzer Vascutek EPTFE Vascular Prosthesis
K993667
Sulzer Vascutek SEALPTFE Vascular Prosthesis
K002007
Sulzer Vascutek Gelsoft PLUS ERS Vascular Prosthesis
K013022
Sulzer Vascutek Gelweave Valsalva Vascular Prosthesis
K030999 (2 Amendments)
EPTFE Vascular Prosthesis; SEALPTFE
K034010
Vascutek Gelsoft PLUS ERS
Dated: March 26, 2004
Received: March 29, 2004

Dear Mr. Robertson:

We have reviewed the information dated March 26, 2004, regarding the 510(k) notifications previously submitted for the devices referenced above. Based solely on the change or modification that you have described, it does not appear that you have significantly changed or

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Additionally, we did not review any data submitted with this add to file. It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. The information you have supplied will be added to the file.

Sincerely yours,

Donna R. LaCourse

for Bram D. Zuckerman, M.D.
Director,
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 3/29/04

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K992832/A002

To: Division Director: CV/DCD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

X Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete: (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: MARIANNE GRUNWALDT

Date: 4/8/04

Draft #2 : 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

TO FILE

Date: April 7, 2004

File No: K992832/A002

Device: Sulzer Vascutek EPTFE Vascular Prosthesis

Reviewer: Marianne Grunwaldt

This amendment informs FDA of a change in packaging for all Vascutek product lines. The changes were made to package labels. However, all information previously cleared with the 510(K) is still included and no changes were made to any of the materials or packaging including the foil pouch or outer trays. Attached is an email from Karen Kelso the company's representative stating that the labeling changes are not different from those previously cleared and that all product lines are affected.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Grunwaldt, Marianne*

From: Kelso Karen [K.Kelso@vascutek.com]
Sent: Wednesday, April 07, 2004 10 00 AM
To: 'Grunwaldt, Marianne*'
Subject: RE: Your 510(K)s

Hi Marianne
this information is in the covering letter, which was in the front of the file. The list included each product range and it's relevant 510(k) or PMA reference. I have attached it for reference. Hope this helps clarify things.
Best wishes
Karen

-----Original Message-----
From: Grunwaldt, Marianne* [mailto:MXG8@CDRH.FDA.GOV]
Sent: 07 April 2004 14:31
To: 'Kelso Karen'
Subject: Your 510(K)s

Hello Karen, thanks so much for your response. We are now clear on the nature of the changes being made. However, could you please send me a list of all the products this affects? The list should include the product name and the 510(K) number related to it.
Best wishes,
Marianne

-----Original Message-----
From: Kelso Karen [mailto:K.Kelso@vascutek.com]
Sent: Wednesday, April 07, 2004 3:27 AM
To: 'Grunwaldt, Marianne*'
Subject: RE: K955230

Dear Marianne
there are no changes to any materials or packaging including the foil pouch or outer trays, only the label format has changed. This was done in line with Vascutek being purchased by Terumo and us having to abandon any reference to our old owner, Sulzer. It also takes into account the use of symbols in line with EN980 as well as new marketing demands for small product pictures and diameter indicators to make selection of the product easier in theatre. Everything else is identical to the approved packaging.
I hope this clears things up.
Best wishes
Karen

-----Original Message-----
From: Grunwaldt, Marianne* [mailto:MXG8@CDRH.FDA.GOV]
Sent: 06 April 2004 17:20
To: 'Kelso Karen'
Subject: K955230

Hello Karen, I am working on the 510(K)s you submitted regarding the new style of packaging and labeling for all your product lines. The question that I have is, are there any significant changes being made to the packaging? Specifically are the foil pouch or outer Tyvek trays being changed other than just the labels?

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

I look forward to your response.
Best regards,

Marianne

Marianne Grunwaldt
Biomedical Engineer
Peripheral Vascular Devices Branch
FDA Office of Device Evaluation
Phone: 301-443-8262 ext 112
Fax: 301-827-4351

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

K992832/A002

VASCUTEK
TERUMO

VASCUTEK Ltd.
a TERUMO Company
Newmains Avenue
Inchinnan
Renfrewshire, PA4 9RR
Scotland

Tel: +44 (0)141 812 5555
Fax: +44 (0)141 812 7650
www.vascutek.com

Submission: Update of Vascutek Labelling

(26th March 2004)

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

NOTIFICATION: FOR INFORMATION ONLY

FDA/CDRH/OCE/DMC
2004 MAR 29 A 10:35

Relevant Information:

GELWEAVE: K952293 (Straights) 19th December 1995, K964665 (Bifurcate) 19th February 1997, K013022 (Valsalva) 13th June 2002
GELSEAL: P890045 (Straights & Bifurcates) 11th January 1993
GELSOFT: P890045/S1 (Abdominal) 5th July 1995, K990503 (Peripheral) 9th December 2000, K002007 (Gelsoft ERS) 25th January 2001
GELSOFT PLUS: K955230 (Straights & Bifurcates) 9th February 1996, K034010 (Gelsoft Plus ERS) 19th February 2004
CARDIOVASCULAR FABRIC: K963611 (Gelseal, Gelsoft, Carotid Thin Wall) 21st November 1996, K972201 (Fluoropassiv CV Fabric) 14th April 1998
SEALPTFE: K993667 28th January 2000, K030999 (ePTFE Support) 9th March 2003
MAXIFLO: K992832 19th November 1999,K030999 (ePTFE Support) 9th March 2003

Dear Madam/Sir,

Vascutek hereby submit this document to update the FDA on our intent to shortly begin using a new style of packaging and labelling, which will concern the approved products detailed above. I have included a CDRH Submission Cover Sheet, which details the approved products concerned and details the contents of the attachments in this document. Please use this information to update your files where necessary. A random product sample from each product family has been chosen and the new labelling for it is attached.

Yours faithfully,

Stewart Robertson

Stewart Robertson
Regulatory Affairs Associate
Vascutek Ltd.

SK18

7

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Submission: Update of Vascutek Labelling for information only

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CDRH SUBMISSION COVER SHEET

Date of Submission: 26th March 2004 **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	**Other Submissi**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission: **Update of Vascutek labeling for all products**

Section B **Applicant or Sponsor**

Company/Institution Name: Vascutek Ltd		Establishment registration number: 9612515	
Division Name (if applicable): Cardiovascular		Phone number (include area code): +44 (0) 141 812 5555	
Street Address: Newmains Avenue, Inchinnan Industrial Estate		Fax number (include area code): +44 (0) 141 812 7650	
City: Renfrewshire	State/Province:	Zip code: PA4 9RR	Country: Scotland, United Kingdom
Contact Name: Karen Kelso			
Contact Title: Regulatory Affairs Manager		Contact e-mail address: k.kelso@vascutek.com	

Section C **Submission Correspondent (if different from above)**

Company/Institution Name: Terumo		Establishment registration number:	
Division name (if applicable) Cardiovascular Systems		Phone number (include area code): (734) 663 4145	
Street Address: 6200 Jackson Road		Fax number (include area code): (734) 741 6030	
City: Ann Arbor	State/Province: MI	Zip Code: 48103 -	Country USA
Contact Name: Steven Arick			

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

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Section D1 — Reason for Submission – PMA,PDP, or HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 — Reason for Submission - IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

- ☐ New Device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

☐ Change in technology
☐ Change in design

☐ Change in materials
☐ Change in manufacturing process

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ☐ 510(k) summary attached ☐ 510(k) statement
1	2	3	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name: Vascular Prostheses

Trade or proprietary or model name	Model Number
1 GELWEAVE, K952293 (Straights) 19/12/95, K964665 (Bifurcate) 9/02/97,K013022 (Valsalva) 13/06/02	1 See Attachment 1 for random sample of updated Gelweave labeling
2 GELSEAL, P890045 (Straights & Bifurcates) 11/01/93	2 See Attachment 2 for random sample of updated Gelseal labeling
3 GELSOFT, P890045/S1 (Abdominal) 05/07/95 K990503 (Peripheral) 09/12/00, K002007 (Gelsoft ERS) 25/01/01	3 See Attachment 3 for random sample of updated Gelsoft labeling
4 GELSOFT PLUS, K955230 (Straights & Bifurcates) 09/02/96 K034010 (Gelsoft Plus ERS) 19/02/04	4 See Attachment 4 for random sample of updated Gelsoft Plus labeling
5 CARDIOVASCULAR FABRIC, K963611 (Gelseal, Gelsoft, Carotid Thin Wall) 21/11/96, K972201 (Fluoropassiv CV Fabric) 14/04/98	5 See Attachment 5 for random sample of updated Cardiovascular Fabric labeling
6 SEALPTFE, K993667 28/01/00, K030999 (ePTFE Support) 09/03/03	6 See Attachment 6 for random sample of updated Sealptfe labeling
7 MAXIFLO, K992832 19/11/99, K030999 (ePTFE Support) 09/03/03	7 See Attachment 7 for random sample of updated Maxiflo labeling

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

1 AS ABOVE	2 AS ABOVE	3 AS ABOVE	4 AS ABOVE	5 AS ABOVE	6 AS ABOVE
7 AS ABOVE	8	9	10	11	12

Data included in submission: ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Section G	Product Classification – Applicable to All Applicants	
Product code: DSY DYF DXZ	C.F.R. Section 870.3450 870.3450 870.3470	Device Class: ☐ Class I X Class II ☐ Class III ☐ Unclassified
Classification Panel: Cardiovascular		
Indications (from labeling): No change to indications as approved in original submissions.		

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

Section H	Manufacturing/Packaging/Sterilization Sites Relating to a Submission		
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution name: SAME AS APPLICANT		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City	State/Province	Zip code:	Country
Contact name:			
Contact title:			
☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution Name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

City:	State/Province:	Zip 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 (include area code):		
Street address:	FAX number (include area code):		
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:	Contact e-mail address:		

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

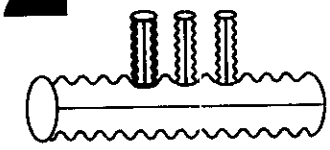
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELWEAVE - BOX LABEL

Gelweave™
Gelatin Impregnated
Woven Vascular Prosthesis

Gelweave™
Gelatin Impregnated
Woven Vascular Prosthesis

22/10/8/8mm



3 BRANCH PLEXUS
40cm + 3 @ 15cm

VASCUTEK
TERUMO

Catalogue No. カタログ番号 REF **73221088**

Lot No. ロット番号 LOT 74581/8 9862

Serial No. シリアル番号 SN 0000000006

製造年月日 Man. Date 2012/07

使用期限 Use By. 2017/07

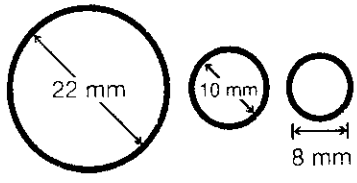
+H9607322108 81J

+SS17070000000006J9

Material of Manufacture: POLYESTER GELATIN

(01) 05037881106236(240)73221088

(17)170731(21) 0000000006



Diameter 直径 22/10/8/8mm
Usable Length 使用可能長 40cm + 3 @ 15cm
REF Catalogue No. カタログ番号 73221088
LOT Lot No. ロット番号 74581/8 9862
SN Serial No. シリアル番号 0000000006

Gelweave™ Gelatin Impregnated Woven Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 22/10/8/8mm
Usable Length 使用可能長 40cm + 3 @ 15cm
REF Catalogue No. カタログ番号 73221088
LOT Lot No. ロット番号 74581/8 9862
SN Serial No. シリアル番号 0000000006

Gelweave™ Gelatin Impregnated Woven Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 22/10/8/8mm
Usable Length 使用可能長 40cm + 3 @ 15cm
REF Catalogue No. カタログ番号 73221088
LOT Lot No. ロット番号 74581/8 9862
SN Serial No. シリアル番号 0000000006

Gelweave™ Gelatin Impregnated Woven Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 22/10/8/8mm
Usable Length 使用可能長 40cm + 3 @ 15cm
REF Catalogue No. カタログ番号 73221088
LOT Lot No. ロット番号 74581/8 9862
SN Serial No. シリアル番号 0000000006

Gelweave™ Gelatin Impregnated Woven Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Part No. 203-443 -C

14 6

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELWEAVE – OUTER TYVEK

Gelweave™
Gelatin Impregnated
Woven Vascular Prosthesis

3 BRANCH PLEXUS

REF Catalogue No. カタログ番号 73221088

Diameter 直径 22/10/8/8mm

Usable Length 使用可能長 40cm + 3 @ 15cm

LOT Lot No. ロット番号 74581/8 9862

Man. Date 製造年月日 2012/07

Use By 使用期限 2017/07

Do Not Preclot
プレクロッティング禁止

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

STERILE

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-443 -A

7/15

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELWEAVE – FOIL BAG LABEL

Gelweave™
Gelatin Impregnated
Woven Vascular Prosthesis

3 BRANCH PLEXUS

REF **Catalogue No.** カタログ番号
73221088

Diameter 直径
22/10/8/8mm

Usable Length 使用可能長
40cm + 3 @ 15cm

LOT Lot No. ロット番号
7458178 9862

Man. Date 製造年月日
2012/07

Use By 使用期限
2017/07

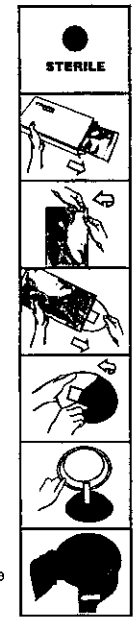
Do Not Preclot
プレクロッティング禁止

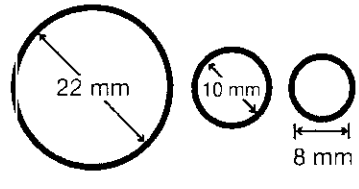
[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

STERILE





Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

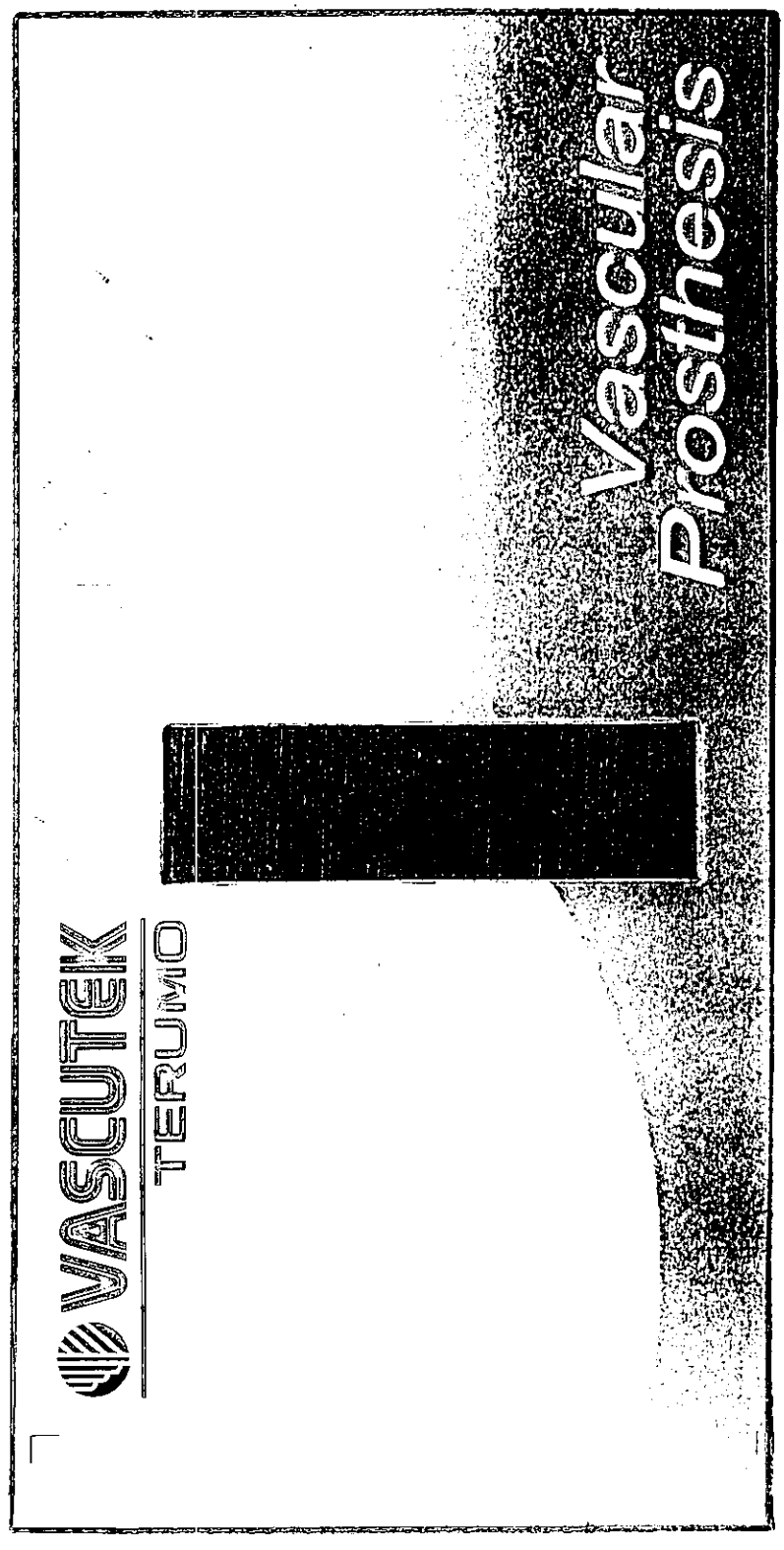
Part No. 203-443 -B

8
16

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – TOP PANEL



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – BOTTOM PANEL

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

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SEALED PRODUCT BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – SIDE PANELS

manufactured by ~
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue, Inchinnan,
Renfrewshire, PA4 9RR Scotland

Patent Nos: US5732572, US4747848, US6352554, US6368347, EP0691829, EP0183365

Gelsoft™, Gelseal™, Gelweave™, Gelweave Valsalva™, SEALPTFE™, Tapeflo™, Unilig™, Equi-Flo™ & Fluorocrassti™ are Trademarks of Vascutek Ltd.

CAUTION:
Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

200-155

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

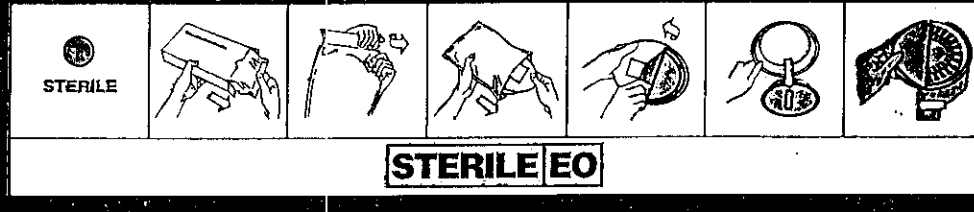
FOIL BAG – FRONT

WARNING

DO NOT OPEN FOIL POUCH
INTO STERILE FIELD

Read instructions before use

Foil pouch is protective cover only
Only the innermost pack may be
introduced to the sterile field

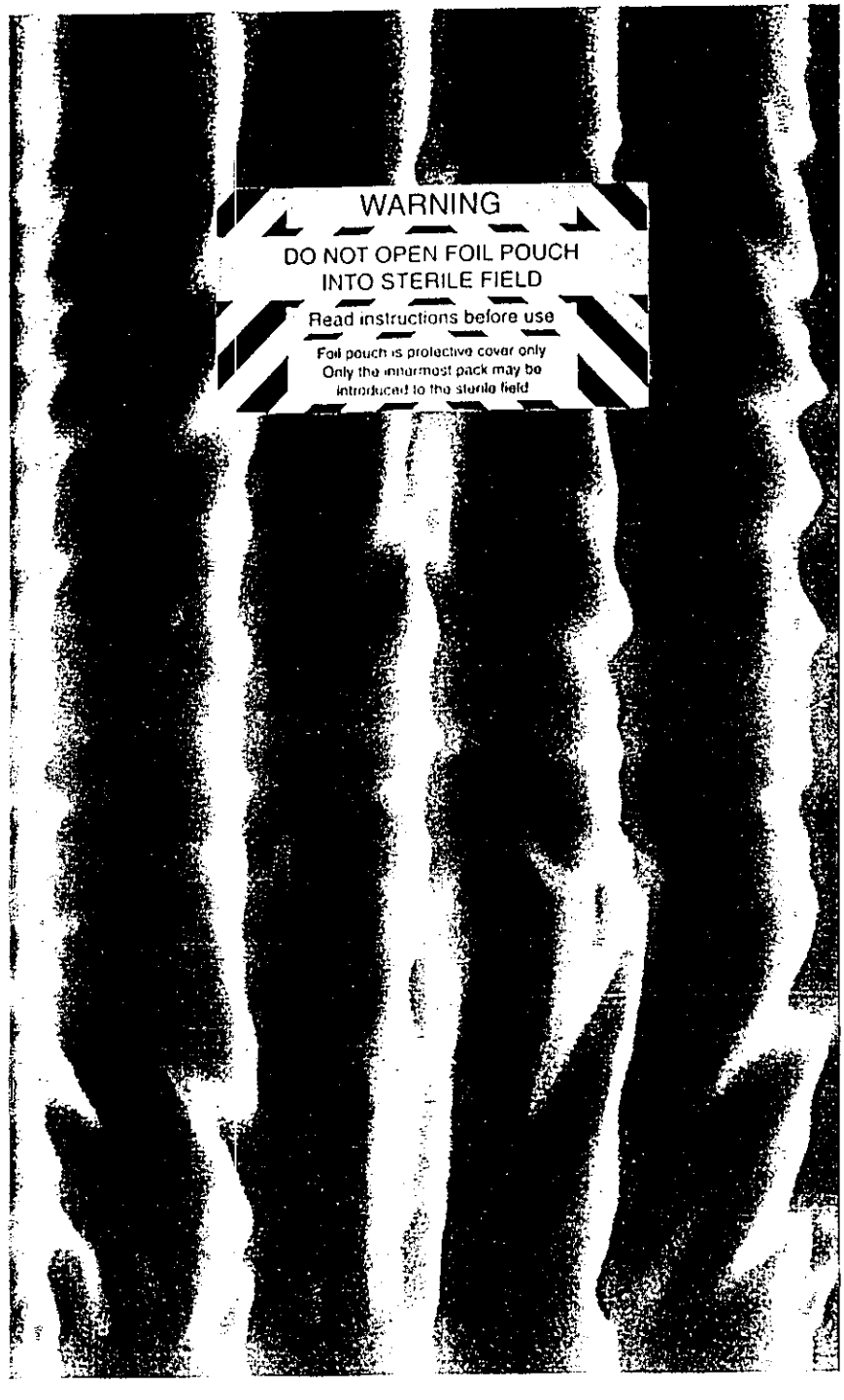


PLEASE READ
INSTRUCTIONS
BEFORE USE
STERILE DEVICE

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

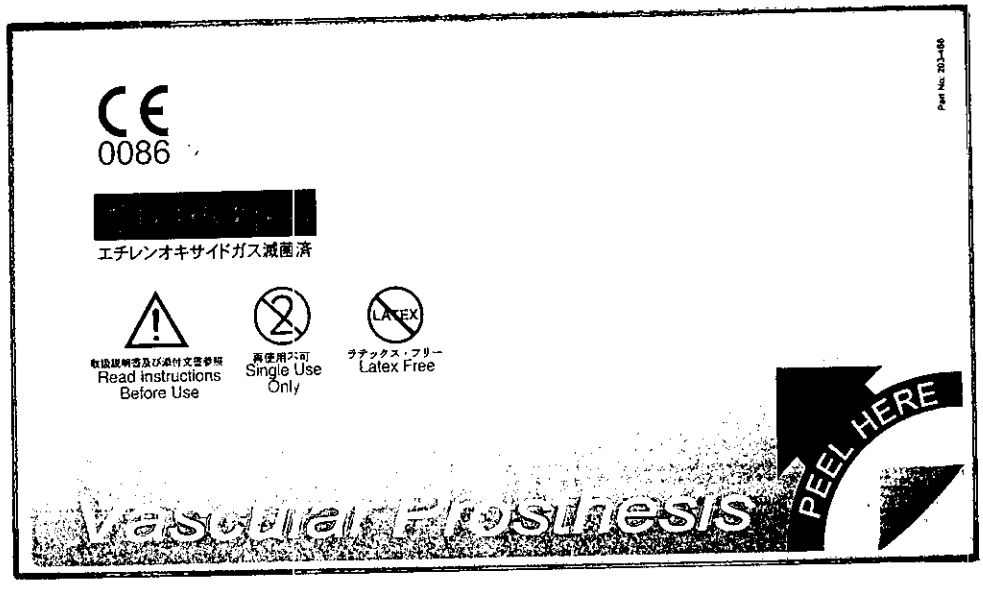
FOIL BAG – BACK



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – SEALED PRODUCT



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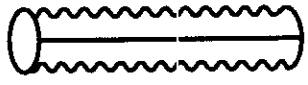
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSEAL - BOX LABEL

Gelseal™
Gelatin Impregnated
Knitted Vascular Prosthesis

Gelseal™
Gelatin Impregnated
Knitted Vascular Prosthesis

6mm



STRAIGHT
60cm

VASCUTEK
TERUMO

Catalogue No. カタログ番号 REF 436006

Lot No. ロット番号 LOT 99990/8 2110

Serial No. シリアル番号 SN 0000000043

製造年月日 Man. Date 2003/10

使用期限 Use By. 2008/10

+H96043600617

+SS0810000000004375

Material of Manufacture: POLYESTER GELATIN

(01) 05037881100012(240)436006

(17)081031(21) 0000000043

6 mm

Diameter 直径 6mm
Usable Length 使用可能長 60cm
REF Catalogue No. カタログ番号 436006
LOT Lot No. ロット番号 99990/8 2110
SN Serial No. シリアル番号 0000000043

Gelseal™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 6mm
Usable Length 使用可能長 60cm
REF Catalogue No. カタログ番号 436006
LOT Lot No. ロット番号 99990/8 2110
SN Serial No. シリアル番号 0000000043

Gelseal™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 6mm
Usable Length 使用可能長 60cm
REF Catalogue No. カタログ番号 436006
LOT Lot No. ロット番号 99990/8 2110
SN Serial No. シリアル番号 0000000043

Gelseal™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 6mm
Usable Length 使用可能長 60cm
REF Catalogue No. カタログ番号 436006
LOT Lot No. ロット番号 99990/8 2110
SN Serial No. シリアル番号 0000000043

Gelseal™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Part No. 203-440 -C

16
24

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSEAL – OUTER TYVEK

Gelseal™
Gelatin Impregnated
Knitted Vascular Prosthesis

STERILE

STRAIGHT

REF **Catalogue No.** カタログ番号
436006

Diameter 直径
6mm

Usable Length 使用可能長
60cm

LOT Lot No. ロット番号
99990/8 2110

Man. Date 製造年月日
2003/10

Use By 使用期限
2008/10

Do Not Preclot
プレクロッティング禁止

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-440 -A

17
25

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSEAL – FOIL BAG LABEL

Gelseal™
Gelatin Impregnated
Knitted Vascular Prosthesis

STRAIGHT

REF **Catalogue No.** カタログ番号
436006

Diameter 直径
6mm

Usable Length 使用可能長
60cm

LOT Lot No. ロット番号
99990/8 2110

Man. Date 製造年月日
2003/10

Use By 使用期限
2008/10

Do Not Preclot
ブレクロッティング禁止

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

STERILE

6 mm

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

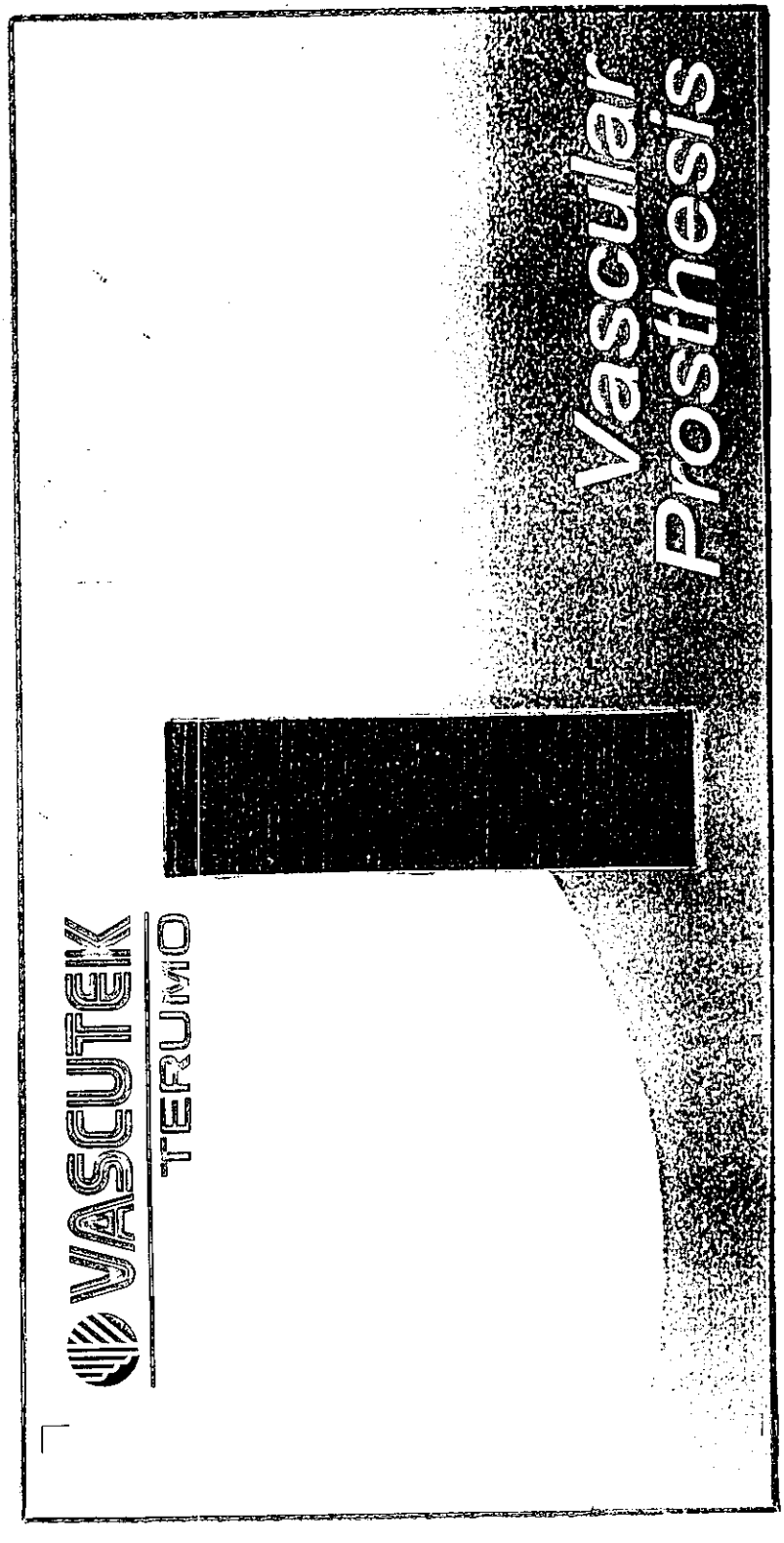
VASCUTEK
TERUMO

Part No. 203-440 -B

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – TOP PANEL



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – BOTTOM PANEL

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – SIDE PANELS

Manufactured by ~
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue, Inchinnan
Renfrewshire, PA4 9RR Scotland

Patent Nos: US5732572, US4747848, US6352554, US6368347, EP0691829, EP0183365

Getsoft™, Gelseal™, Gelweave™, Gelweave Valsalva™, SEALPTFE™, Taperflo™, Unity™, Equi-Flo™ & Fluoropassivo™ are Trademarks of Vascutek Ltd.

CAUTION:
Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

200-155

22

30

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

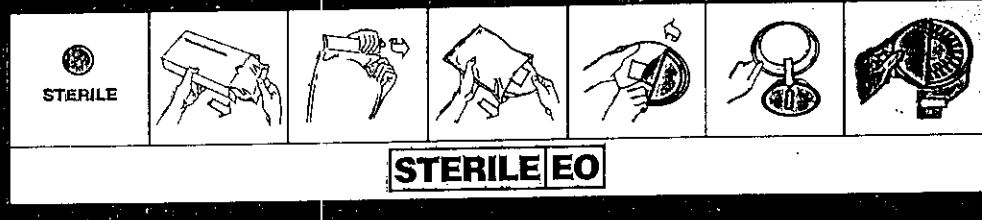
FOIL BAG – FRONT

WARNING

DO NOT OPEN FOIL POUCH
INTO STERILE FIELD

Read instructions before use

Foil pouch is protective cover only
Only the innermost pack may be
introduced to the sterile field



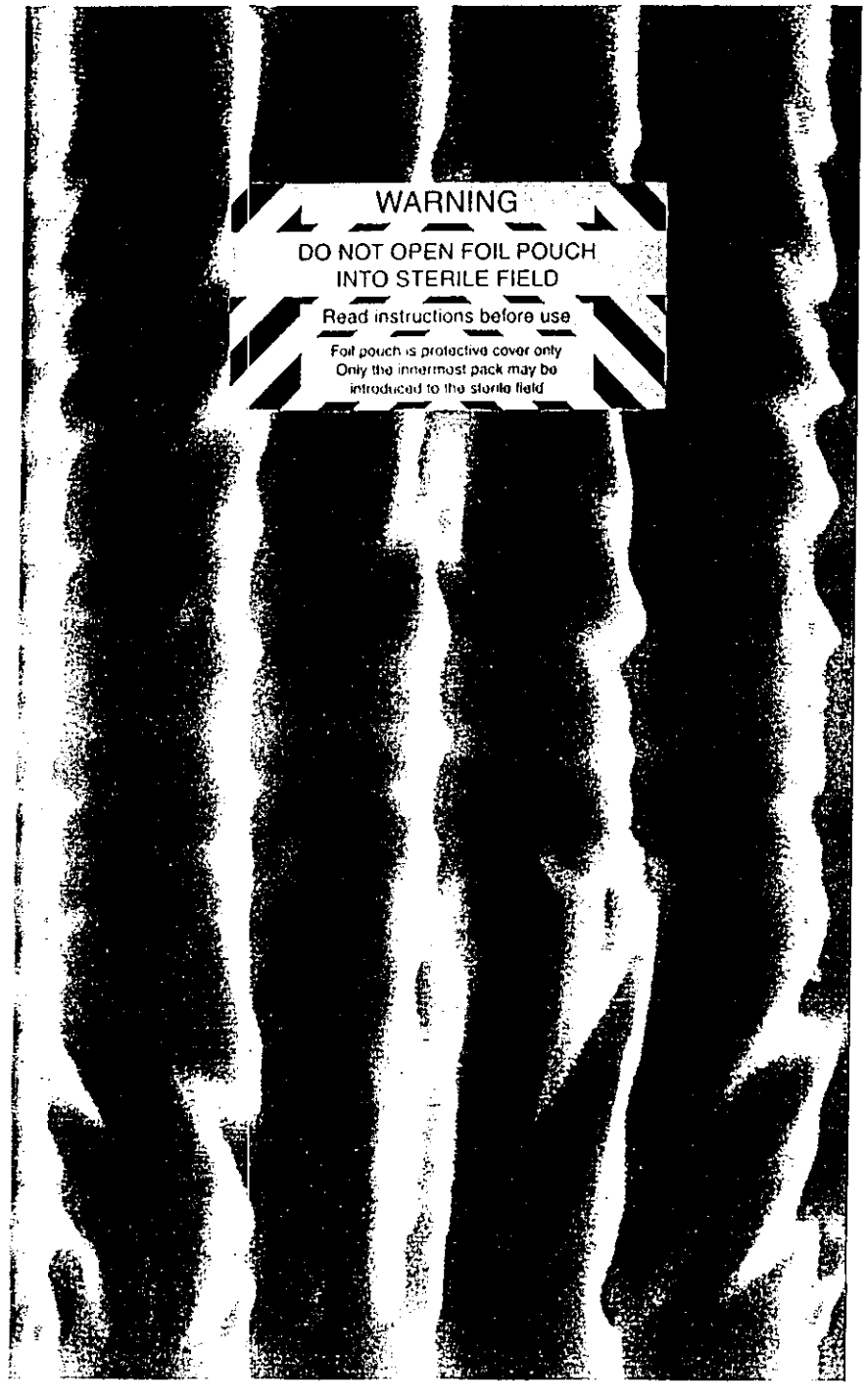
PLEASE READ
INSTRUCTIONS
BEFORE USE
STERILE DEVICE

23 31

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

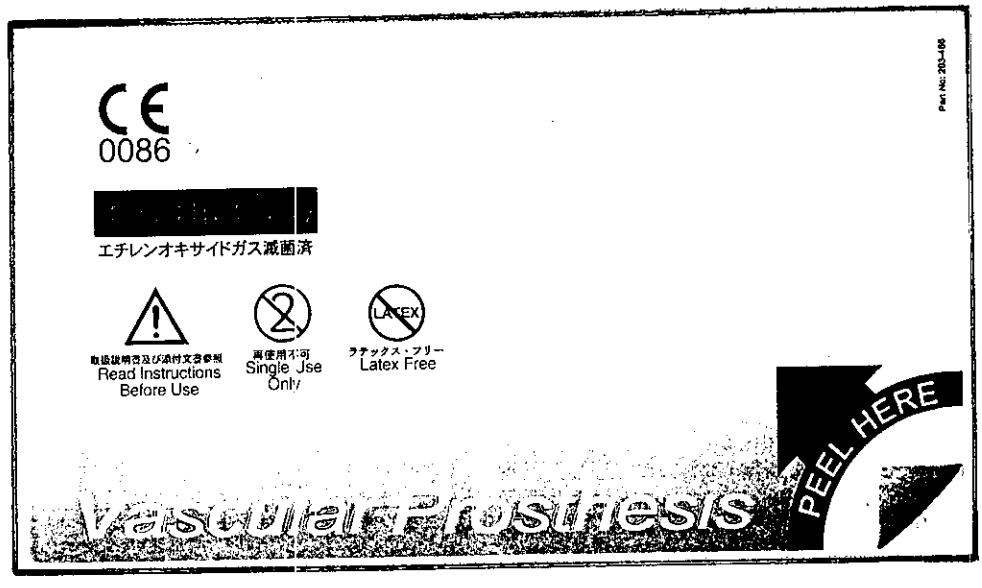
FOIL BAG – BACK



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – SEALED PRODUCT



25
33

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

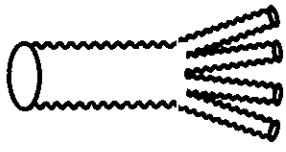
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSOFT - BOX LABEL

Gelsoft ™
Gelatin Impregnated
Knitted Vascular Prosthesis

Gelsoft ™
Gelatin Impregnated
Knitted Vascular Prosthesis

18x9x9mm



DOUBLE BIFURCATE
45cm

VASCUTEK
TERUMO

Catalogue No. カタログ番号 REF 631809DB

Lot No. ロット番号 LOT 19863 5619

Serial No. シリアル番号 SN 0000000022

製造年月日
Man. Date
2007/02

使用期限
Use By.
2012/02

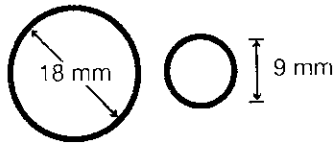
+H960631809DB1S

+SS12020000000022S9

Material of Manufacture: POLYESTER GELATIN

(01) 05037881110011(240)631809DB

(17)120229(21) 0000000022



Diameter 直径 18x9x9mm
Usable Length 使用可能長 45cm
REF Catalogue No. カタログ番号 631809DB
LOT Lot No. ロット番号 19863 5619
SN Serial No. シリアル番号 0000000022

Gelsoft ™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 18x9x9mm
Usable Length 使用可能長 45cm
REF Catalogue No. カタログ番号 631809DB
LOT Lot No. ロット番号 19863 5619
SN Serial No. シリアル番号 0000000022

Gelsoft ™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 18x9x9mm
Usable Length 使用可能長 45cm
REF Catalogue No. カタログ番号 631809DB
LOT Lot No. ロット番号 19863 5619
SN Serial No. シリアル番号 0000000022

Gelsoft ™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 18x9x9mm
Usable Length 使用可能長 45cm
REF Catalogue No. カタログ番号 631809DB
LOT Lot No. ロット番号 19863 5619
SN Serial No. シリアル番号 0000000022

Gelsoft ™ Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Part No. 203-441 -C

26

34

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSOFT – OUTER TYVEK

Gelsoft ™
Gelatin Impregnated
Knitted Vascular Prosthesis

DOUBLE BIFURCATE

STERILE

REF **Catalogue No.** カタログ番号
631809DB

Diameter 直径
18x9x9mm

Usable Length 使用可能長
45cm

LOT Lot No. ロット番号
19863 5619

Man. Date 製造年月日
2007/02

Use By 使用期限
2012/02

Do Not Preclot
プレクロッティング禁止

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions
Before use

再使用不可
Single Use
only

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-441 -A

27
35

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSOFT – FOIL BAG LABEL

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-441 -B

28
36

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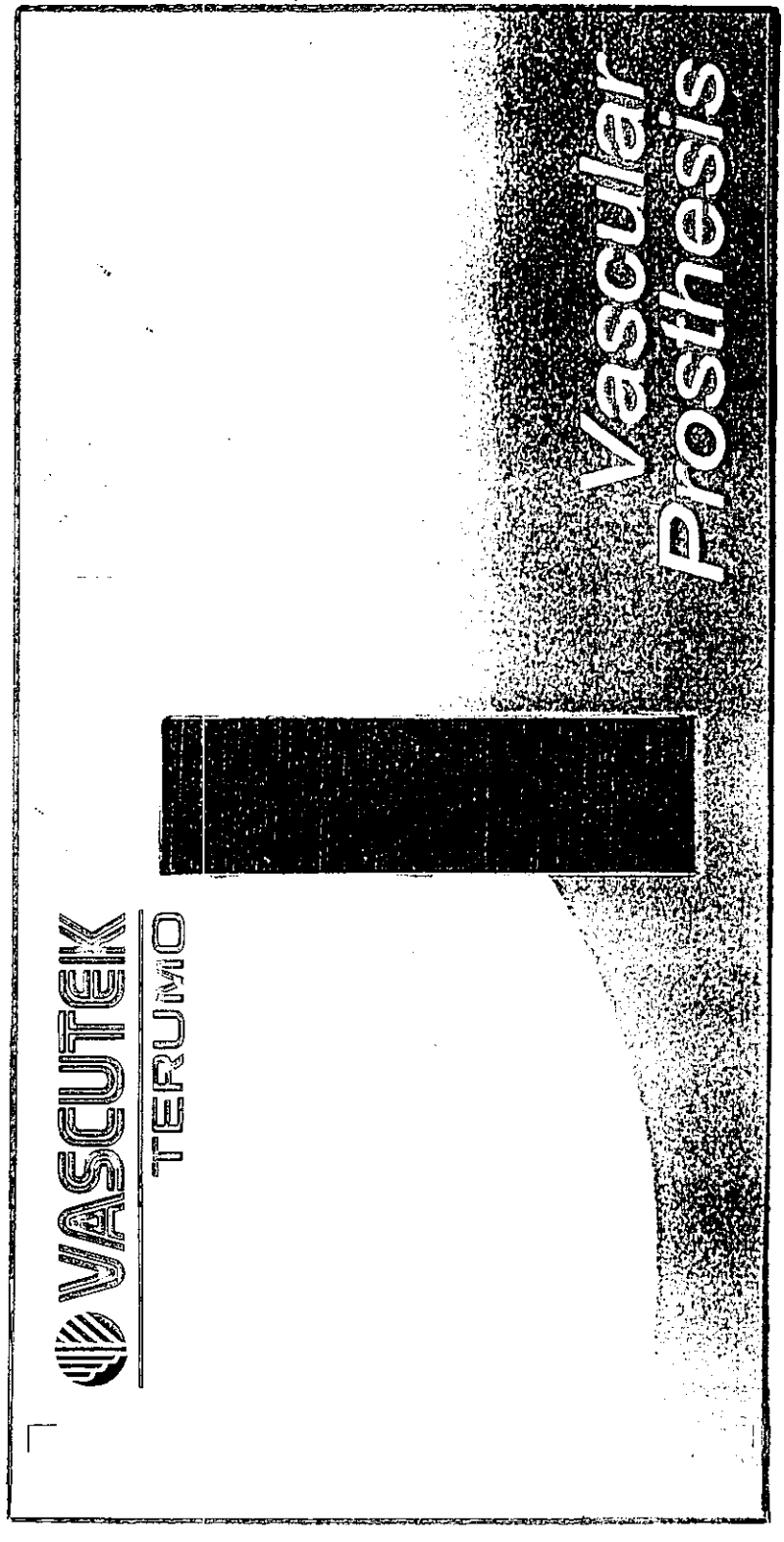
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – TOP PANEL



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – BOTTOM PANEL

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – SIDE PANELS

Manufactured by ~
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue Inchinnan
Renfrewshire, PA4 9RR Scotland

Patent Nos: US5732572, US4747848, US6352554, US6368347, EP0691829, EP0183365

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200-155

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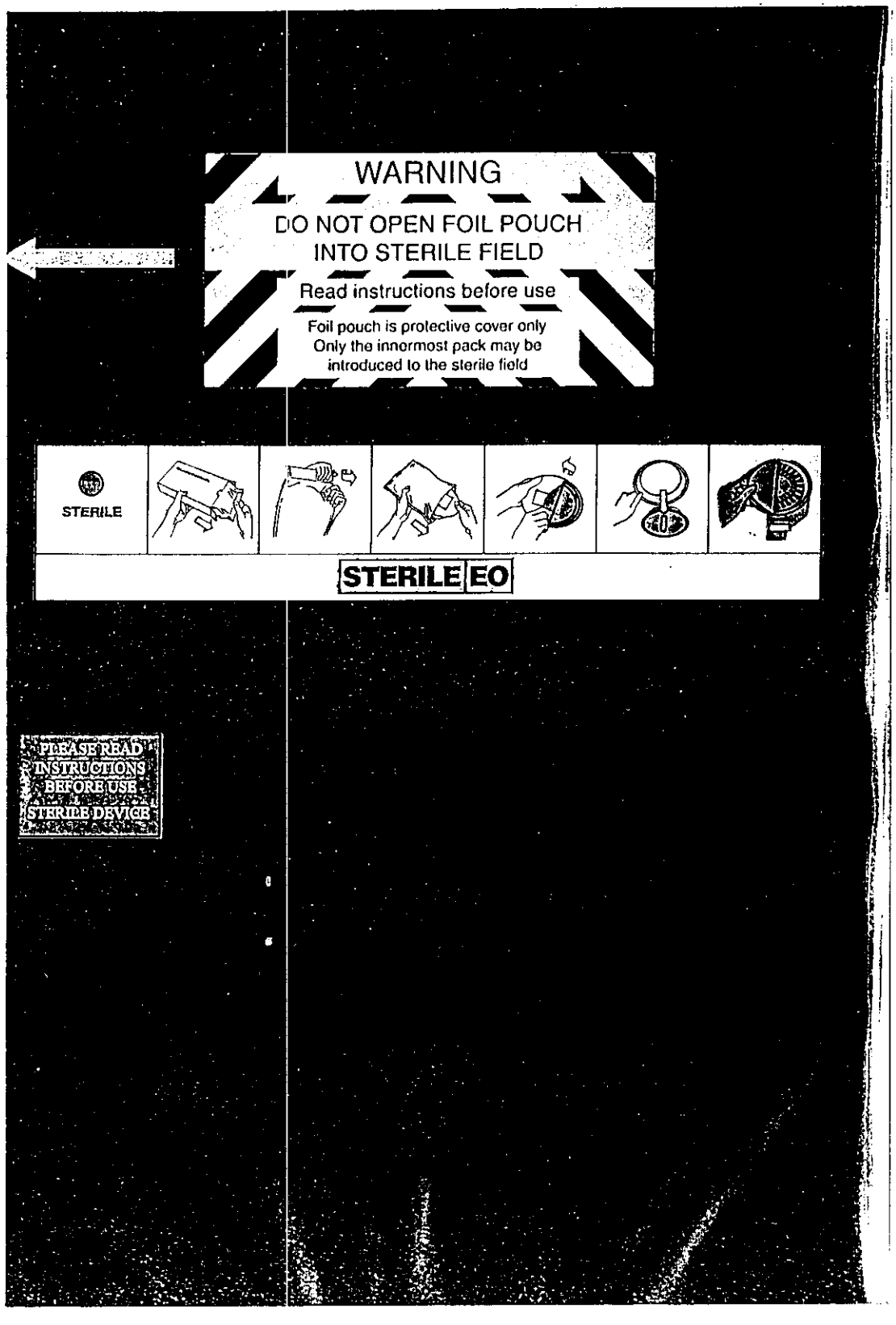
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

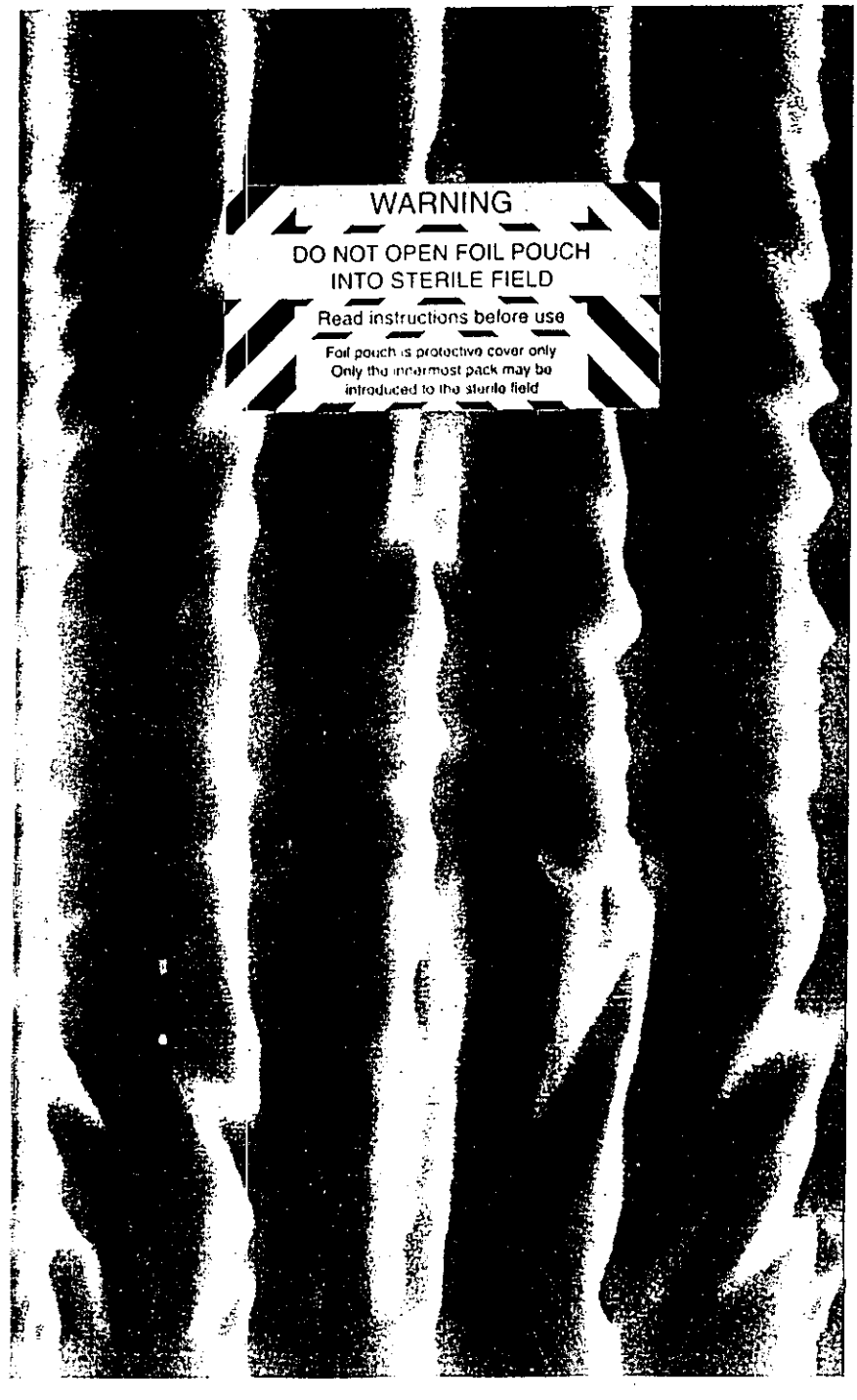
FOIL BAG – FRONT



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

FOIL BAG – BACK



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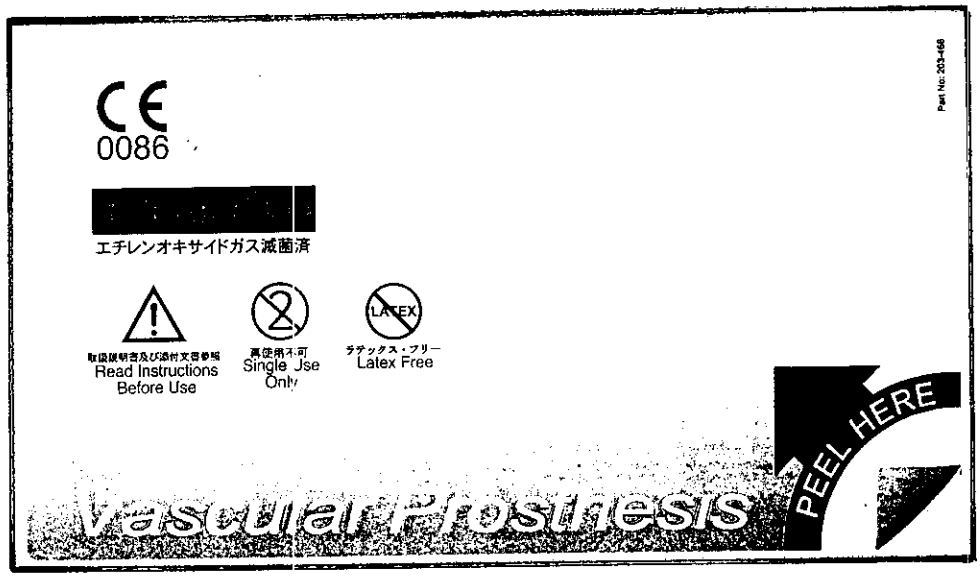
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – SEALED PRODUCT



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

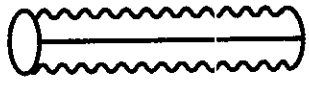
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSOFT PLUS - BOX LABEL

Gelsoft™ Plus
Gelatin Impregnated
Knitted Vascular Prosthesis

Gelsoft™ Plus
Gelatin Impregnated
Knitted Vascular Prosthesis

8mm



STRAIGHT
15cm

VASCUTEK
TERUMO

Catalogue No. カタログ番号 REF 631508P

Lot No. ロット番号 LOT 11111 4896

Serial No. シリアル番号 SN 0000000004

製造年月日 Man. Date 2004/01

使用期限 Use By. 2009/01

+H9606315 08P1-

+SS09010000000004-8

Material of Manufacture: POLYESTER GELATIN

(01) 05037881115337(240)631508P

(17)090131(21) 0000000004

8 mm

Diameter 直径 8mm
Usable Length 使用可能長 15cm
REF Catalogue No. カタログ番号 631508P
LOT Lot No. ロット番号 11111 4896
SN Serial No. シリアル番号 0000000004
Gelsoft™ Plus Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 8mm
Usable Length 使用可能長 15cm
REF Catalogue No. カタログ番号 631508P
LOT Lot No. ロット番号 11111 4896
SN Serial No. シリアル番号 0000000004
Gelsoft™ Plus Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 8mm
Usable Length 使用可能長 15cm
REF Catalogue No. カタログ番号 631508P
LOT Lot No. ロット番号 11111 4896
SN Serial No. シリアル番号 0000000004
Gelsoft™ Plus Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 8mm
Usable Length 使用可能長 15cm
REF Catalogue No. カタログ番号 631508P
LOT Lot No. ロット番号 11111 4896
SN Serial No. シリアル番号 0000000004
Gelsoft™ Plus Gelatin Impregnated Knitted Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Part No. 203-442 -C

36
44

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSOFT PLUS – OUTER TYVEK

Gelsoft™ Plus
Gelatin Impregnated
Knitted Vascular Prosthesis

STRAIGHT

REF **Catalogue No.** カタログ番号
631508P

Diameter 直径
8mm

Usable Length 使用可能長
15cm

LOT Lot No. ロット番号
11111 4896

Man. Date 製造年月日
2004/01

Use By 使用期限
2009/01

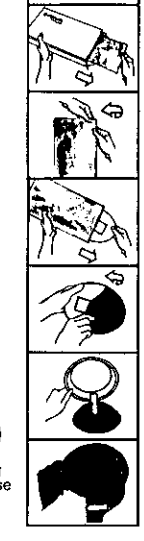
Do Not Preclot
プレクロッティング禁止

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

STERILE



Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-442 -A

37
45

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

GELSOFT PLUS – FOIL BAG LABEL

Gelsoft™ Plus
Gelatin Impregnated
Knitted Vascular Prosthesis

STRAIGHT

REF **Catalogue No.** カタログ番号
631508P

D ameter 直径
8mm

Usable Length 使用可能長
15cm

LOT Lot No. ロット番号
11111 4896

Man. Date 製造年月日
2004/01

Use By 使用期限
2009/01

Do Not Preclot
プレクロッティング禁止

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

STERILE

8 mm

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-442 -B

38
46

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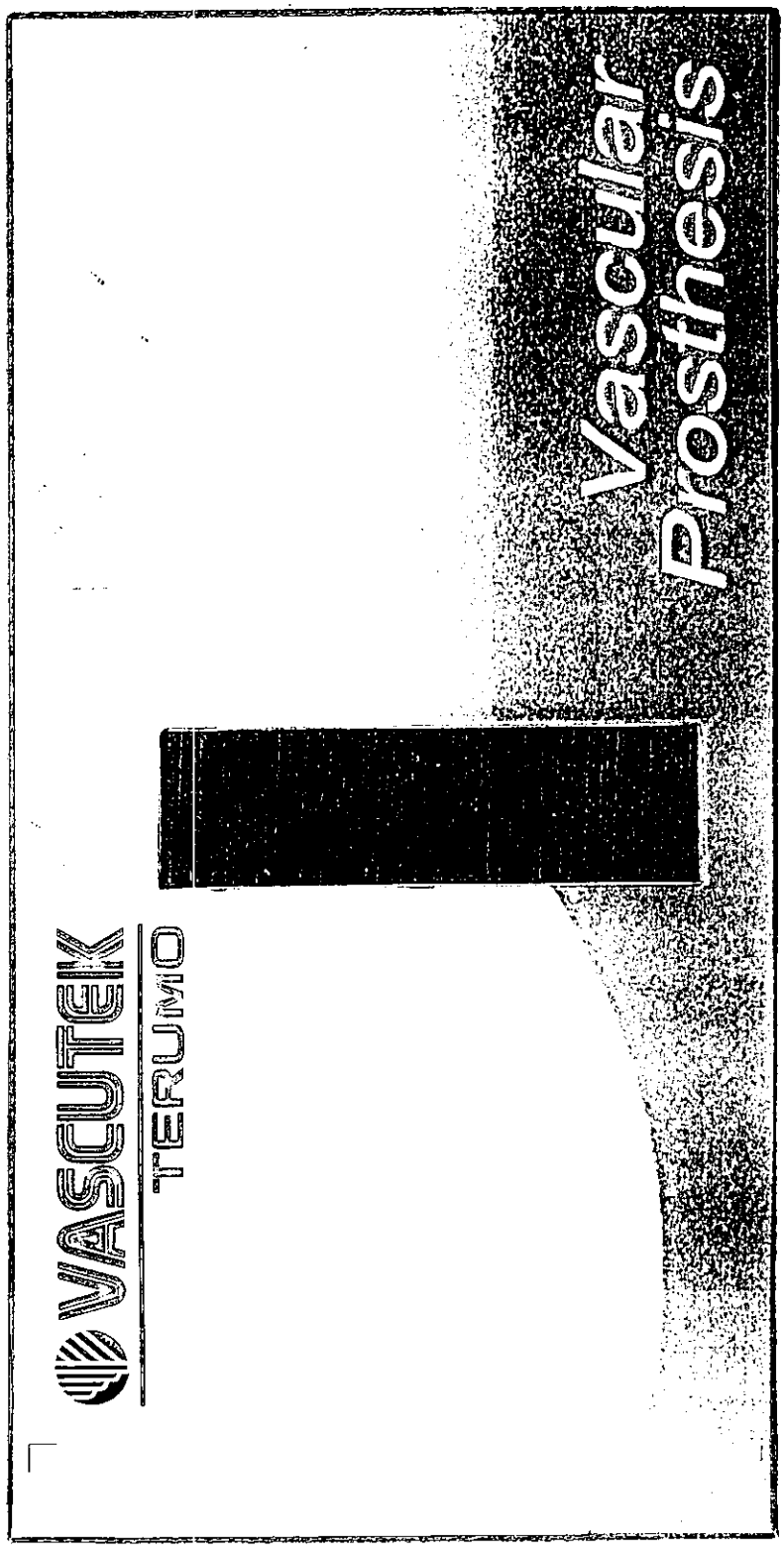
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – TOP PANEL



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Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – BOTTOM PANEL

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – SIDE PANELS

Manufactured by -
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue, Inchinnan
Renfrewshire, PA4 9RR Scotland

Patent Nos: US5732572, US4747848, US6352554, US6368347, EP0691829, EP0183365

Gelsoft™, Gelseal™, Gelweave™, Gelweave Valsalva™, SEALPTFE™, Taperflo™, Unity™, Equi-Flo™ & Fluoropassiv™ are Trademarks of Vascutek Ltd

200-155

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Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

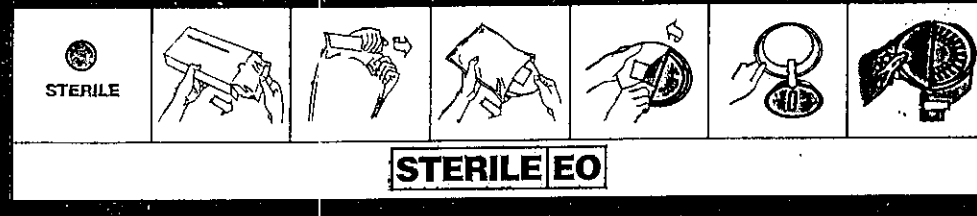
FOIL BAG – FRONT

WARNING

DO NOT OPEN FOIL POUCH
INTO STERILE FIELD

Read instructions before use

Foil pouch is protective cover only
Only the innermost pack may be
introduced to the sterile field

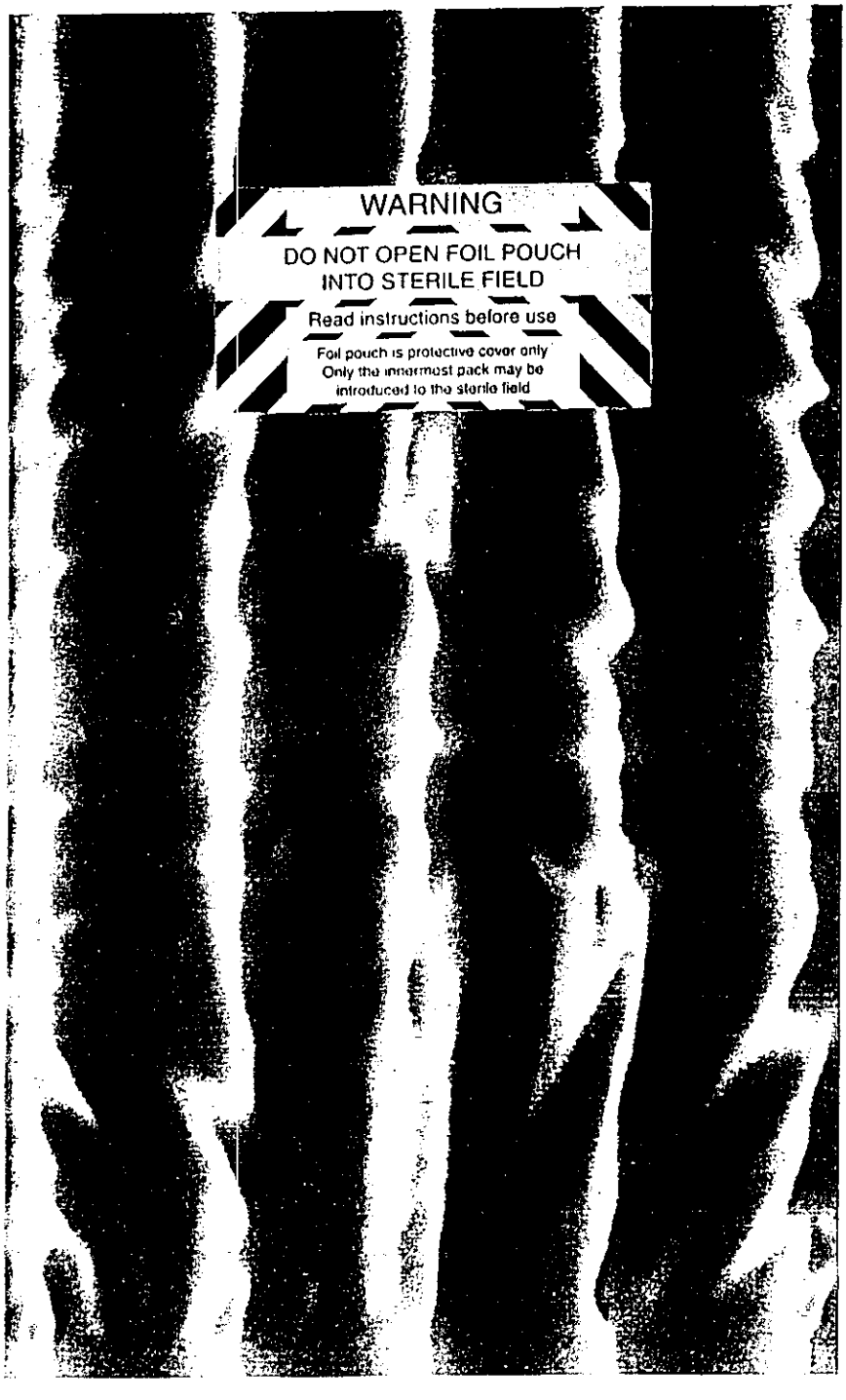


PLEASE READ
INSTRUCTIONS
BEFORE USE
STERILE DEVICE

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

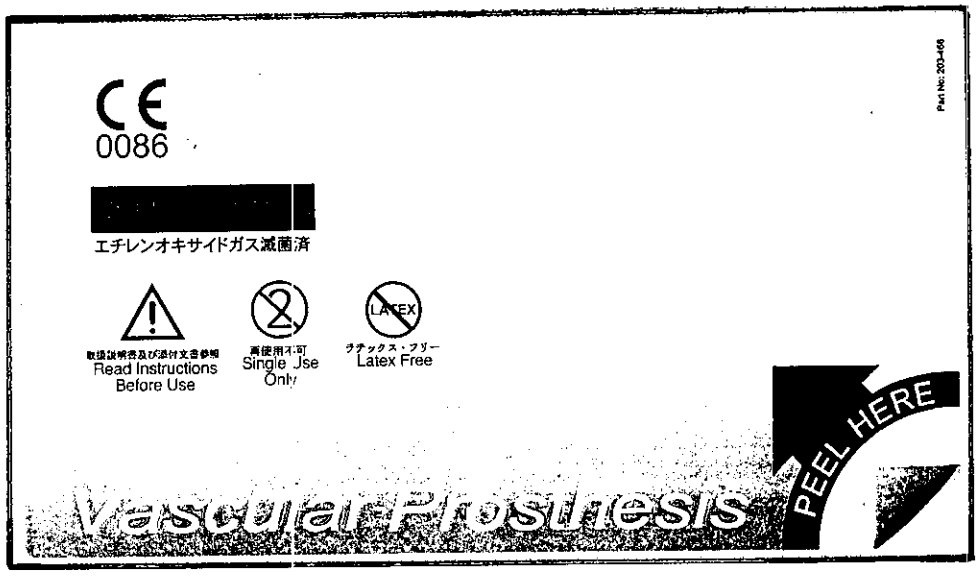
FOIL BAG – BACK



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – SEALED PRODUCT



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR FABRIC - BOX LABEL

Fluoropassiv™
Gelatin Impregnated
Thin Wall Knitted Carotid Patch

10mm x 100mm

VASCUTEK
TERUMO

Material of Manufacture:
POLYESTER GELATIN
FLUOROPOLYMER

Fluoropassiv™
Gelatin Impregnated
Thin Wall Knitted Carotid Patch

REF Catalogue No. **921010F**

Man. Date 2005/07 | Use By. 2010/07

LOT Lot No. 11111/1 9000

Size 10mm x 100mm

SN Serial No. 0000000036

* + H960921010F1G *

* + SS10070000000036G7 *

(01) 05037881010250(240)921010F

(17) 100731(21)0000000036

Size 10mm x 100mm
REF Catalogue No. 921010F
LOT Lot No. 11111/1 9000
SN Serial No. 0000000036
Fluoropassiv™ Gelatin Impregnated Thin Wall Knitted Carotid Patch
Manufactured by:VASCUTEK Ltd a TERUMO Company
Newmains Avenue, Inchinnan, Renfrewshire
PA4 9RR Scotland

Size 10mm x 100mm
REF Catalogue No. 921010F
LOT Lot No. 11111/1 9000
SN Serial No. 0000000036
Fluoropassiv™ Gelatin Impregnated Thin Wall Knitted Carotid Patch
Manufactured by:VASCUTEK Ltd a TERUMO Company
Newmains Avenue, Inchinnan, Renfrewshire
PA4 9RR Scotland

Size 10mm x 100mm
REF Catalogue No. 921010F
LOT Lot No. 11111/1 9000
SN Serial No. 0000000036
Fluoropassiv™ Gelatin Impregnated Thin Wall Knitted Carotid Patch
Manufactured by:VASCUTEK Ltd a TERUMO Company
Newmains Avenue, Inchinnan, Renfrewshire
PA4 9RR Scotland

Size 10mm x 100mm
REF Catalogue No. 921010F
LOT Lot No. 11111/1 9000
SN Serial No. 0000000036
Fluoropassiv™ Gelatin Impregnated Thin Wall Knitted Carotid Patch
Manufactured by:VASCUTEK Ltd a TERUMO Company
Newmains Avenue, Inchinnan, Renfrewshire
PA4 9RR Scotland

Part No. 203-450 -C

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR FABRIC – OUTER TYVEK

Fluoropassiv™
Gelatin Impregnated
Thin Wall Knitted Carotid Patch

REF **Catalogue No.** 921010F

SIZE 10mm x 100mm

LOT Lot No. 11111/1 9000

Man. Date 2005/07

Use By. 2010/07

Do Not Preclot

Read Instructions Before Use

Single Use Only

STERILE

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-450 -A

47

55

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR FABRIC – FOIL BAG LABEL

Fluoropassiv™
Gelatin Impregnated
Thin Wall Knitted Carotid Patch

REF **Catalogue No.**
921010F

SIZE
10mm x 100mm

LOT Lot No.
11111/1 9000

Man. Date
2005/07

Use By.
2010/07

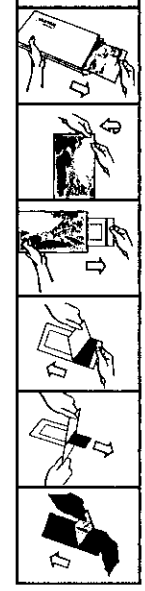
Do Not Preclot

[redacted]

Read Instructions Before Use

Single Use Only

STERILE



Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

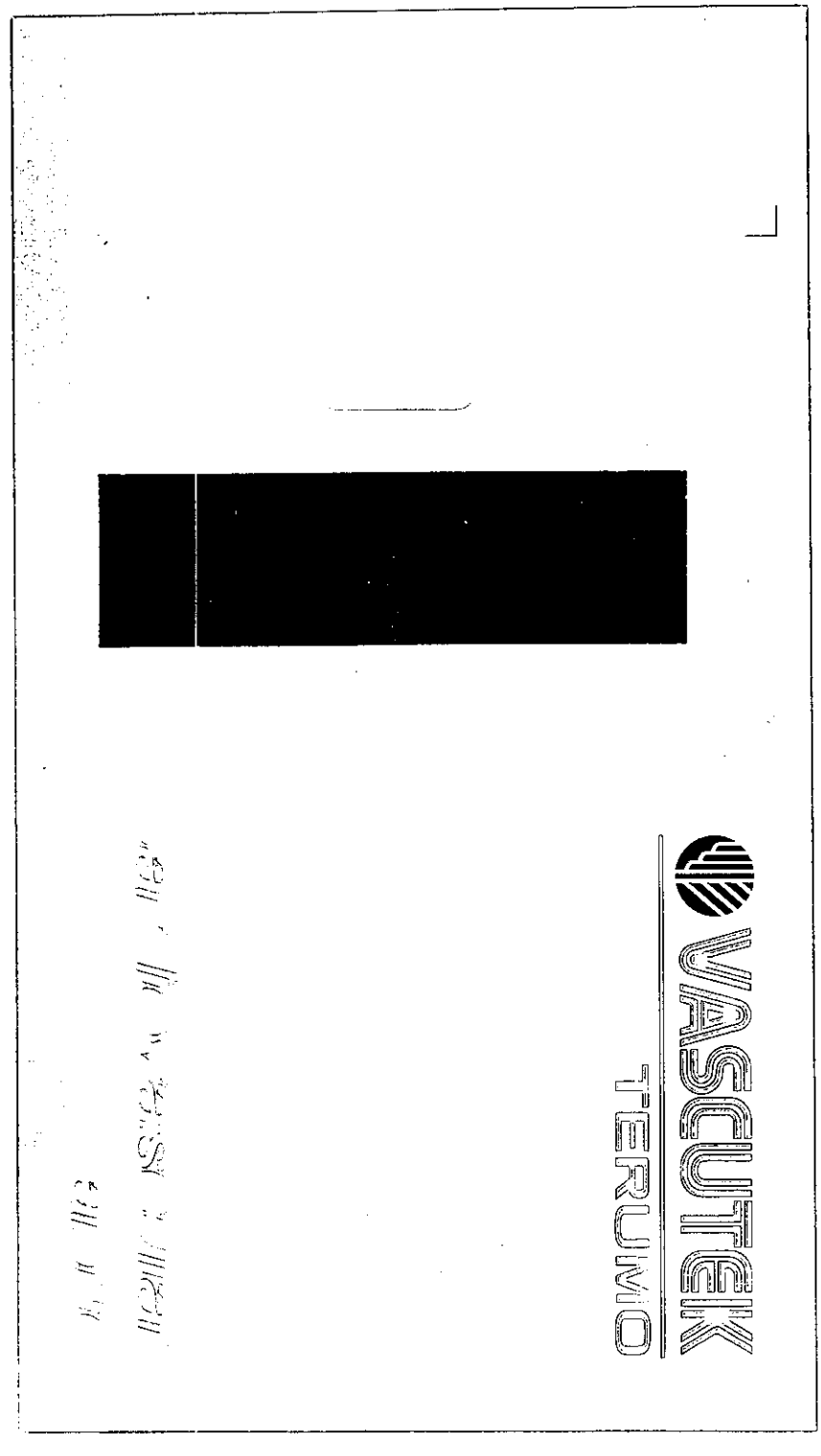
Part No. 203-450 -B

48
56

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR PATCH BOX – TOP PANEL



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR PATCH BOX – BOTTOM PANEL

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR PATCH BOX – SIDE PANELS

Manufactured by -
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue Inchinnan
Renfrewshire, PA4 9RR Scotland

Patent Nos. US5732572, US4778849, EP0691829, EP0183365

Gelsoft™, Gelseal™ & Fluoropassiv™ are Trademarks of Vascutek Ltd.

200-152

CAUTION:
Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR PATCH BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

CARDIOVASCULAR PATCH - FOIL BAG – FRONT

WARNING

DO NOT OPEN FOIL POUCH INTO STERILE FIELD

Read instructions before use

Foil pouch is protective cover only
Only the innermost pack may be introduced to the sterile field

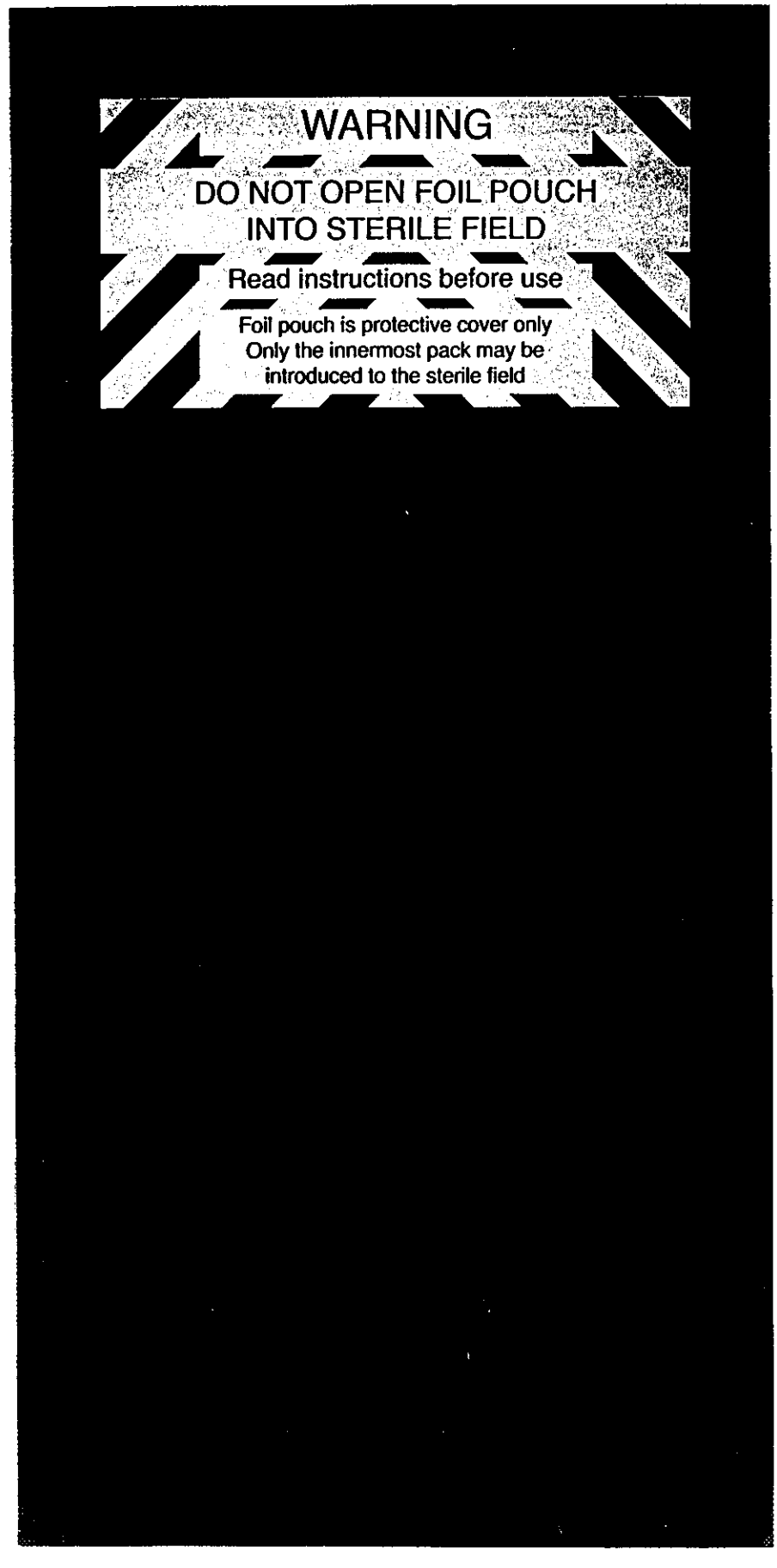
PLEASE READ
INSTRUCTIONS
BEFORE USE

STERILE DEVICE

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

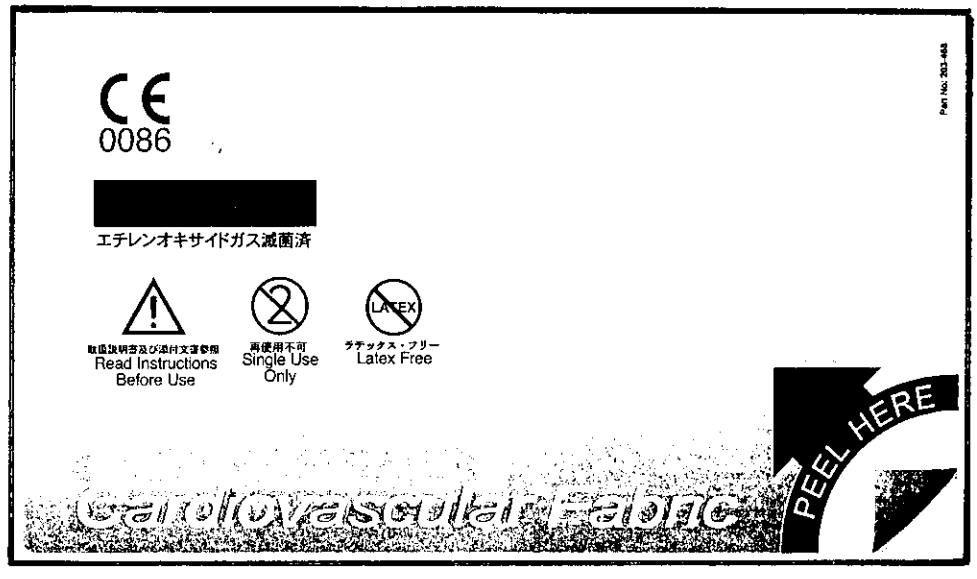
CARDIOVASCULAR PATCH - FOIL BAG – BACK



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – CARDIOVASCULAR PATCHES



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

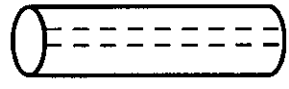
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALPTFE - BOX LABEL

SEALPTFE™
Gelatin Sealed
ePTFE Vascular Prosthesis

SEALPTFE™
Gelatin Sealed
ePTFE Vascular Prosthesis

6mm



Thin Wall
50cm

VASCUTEK
TERUMO

Catalogue No. カタログ番号 REF **T50S06S**

Lot No. ロット番号 LOT 11111 4785

Serial No. シリアル番号 SN 0000000003

製造年月日
Man. Date
2004/01

* + H960T50S06S1 + *

使用期限
Use By.
2009/01

* + SS09010000000003 + 1 *

Material of Manufacture: ePTFE GELATIN

(01) 05037881005379(240)T50S06S

(17)090131(21) 0000000003

6 mm

Diameter 直径 6mm
Usable Length 使用可能長 50cm
REF Catalogue No. カタログ番号 T50S06S
LOT Lot No. ロット番号 11111 4785
SN Serial No. シリアル番号 0000000003

SEALPTFE™ Gelatin Sealed ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 6mm
Usable Length 使用可能長 50cm
REF Catalogue No. カタログ番号 T50S06S
LOT Lot No. ロット番号 11111 4785
SN Serial No. シリアル番号 0000000003

SEALPTFE™ Gelatin Sealed ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 6mm
Usable Length 使用可能長 50cm
REF Catalogue No. カタログ番号 T50S06S
LOT Lot No. ロット番号 11111 4785
SN Serial No. シリアル番号 0000000003

SEALPTFE™ Gelatin Sealed ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 6mm
Usable Length 使用可能長 50cm
REF Catalogue No. カタログ番号 T50S06S
LOT Lot No. ロット番号 11111 4785
SN Serial No. シリアル番号 0000000003

SEALPTFE™ Gelatin Sealed ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Part No. 203-446 -C

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALPTFE – OUTER TYVEK

SEALPTFE™

Gelatin Sealed
ePTFE Vascular Prosthesis

Thin Wall

STERILE

REF **Catalogue No.** カタログ番号
T50S06S

Diameter 直径
6mm

Usable Length 使用可能長
50cm

LOT Lot No. ロット番号
11111 4785

Man. Date 製造年月日
2004/01

Use By 使用期限
2009/01

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions Before use

再使用不可
Single Use only

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-446 -A

57
65

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALPTFE – FOIL BAG LABEL

SEALPTFE™

Gelatin Sealed
ePTFE Vascular Prosthesis

Thin Wall

REF **Catalogue No.** カタログ番号
150S06S

Diameter 直径
6mm

Usable Length 使用可能長
50cm

LOT Lot No. ロット番号
11111 4785

Man. Date 製造年月日
2004/01

Use By 使用期限
2009/01

[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read Instructions
Before use

再使用不可
Single Use
only

STERILE

6 mm

Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

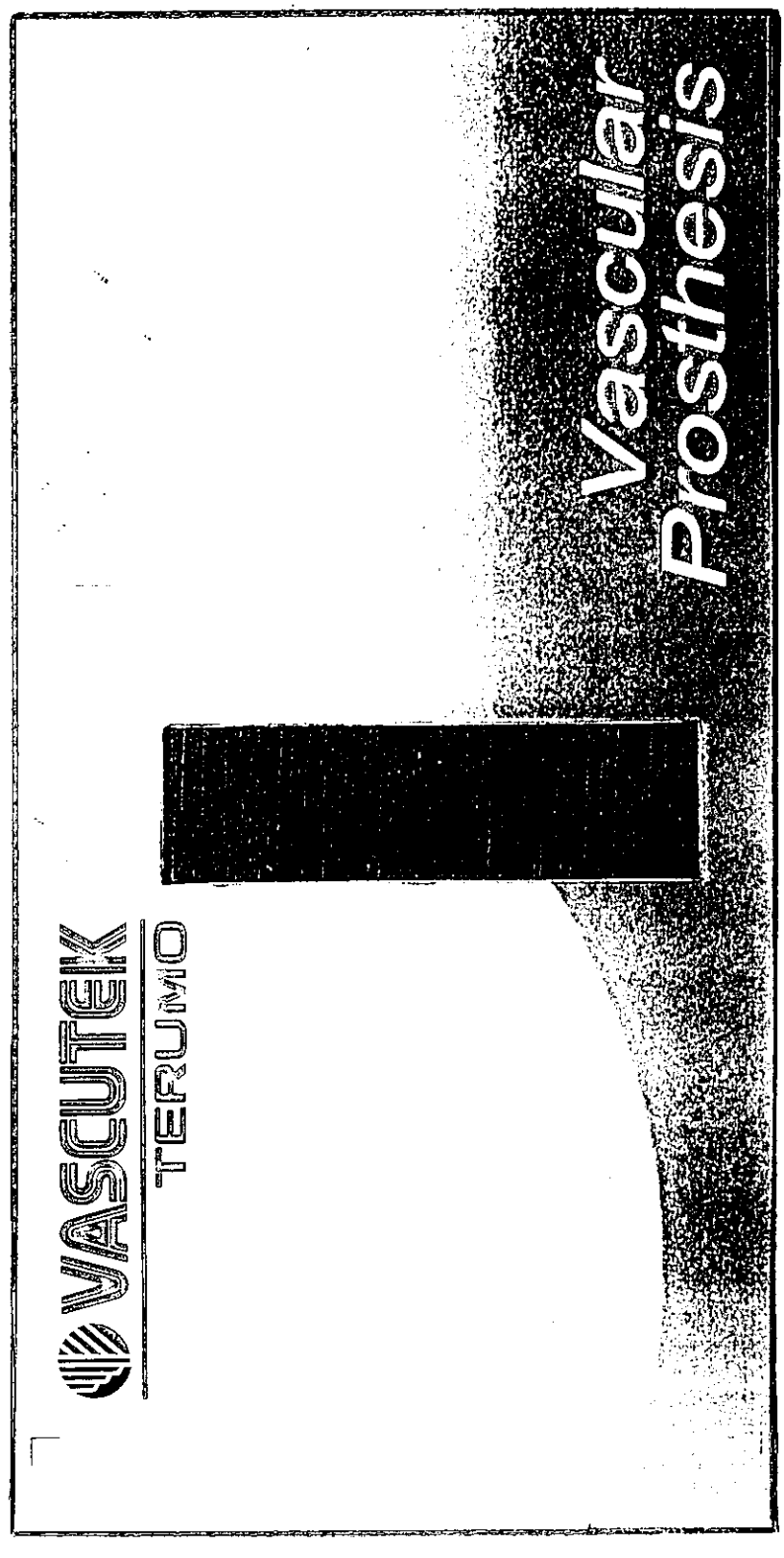
Part No. 203-446 -B

58
66

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – TOP PANEL



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – BOTTOM PANEL

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SEALED PRODUCT BOX – SIDE PANELS

Manufactured by ~
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue, Inchinnan
Renfrewshire, PA4 9RR Scotland

Patent Nos: US5732572, US4747848, US6352554, US6368347, EP0691829, EP0183365

Gelsoft™, Gelseal™, Gelweave™, Gelweave Valsalva™, SEALPTFE™, Taperflo™, Unity™, Equi-Flo™ & Fluoropassiv™ are Trademarks of Vascutek Ltd.

CAUTION:
Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

200-155

62

70

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

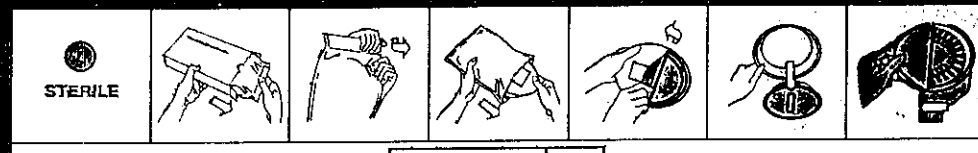
FOIL BAG – FRONT

WARNING

DO NOT OPEN FOIL POUCH
INTO STERILE FIELD

Read instructions before use

Foil pouch is protective cover only
Only the innermost pack may be
introduced to the sterile field



STERILE EO

PLEASE READ
INSTRUCTIONS
BEFORE USE
STERILE DEVICE

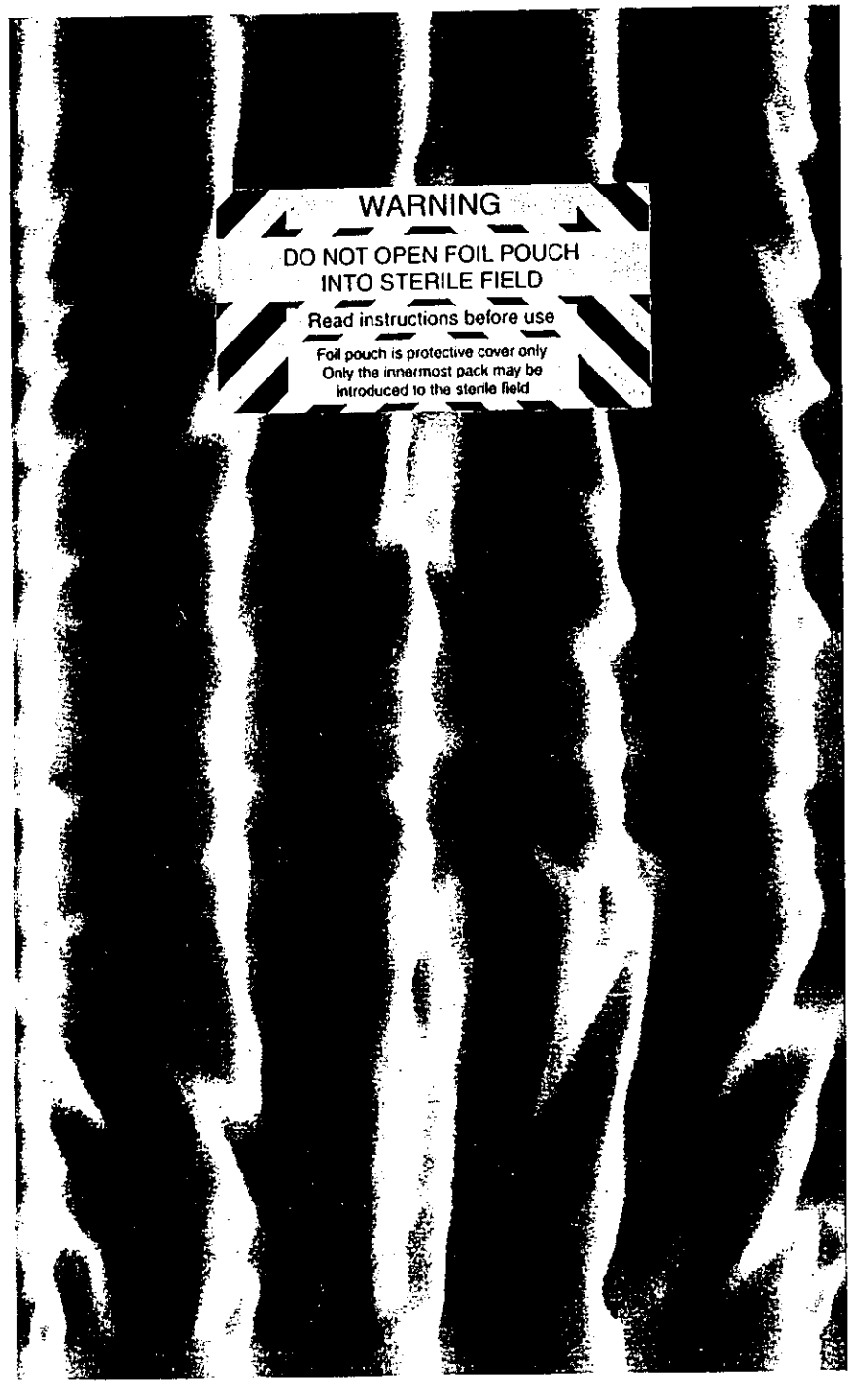
63

71

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

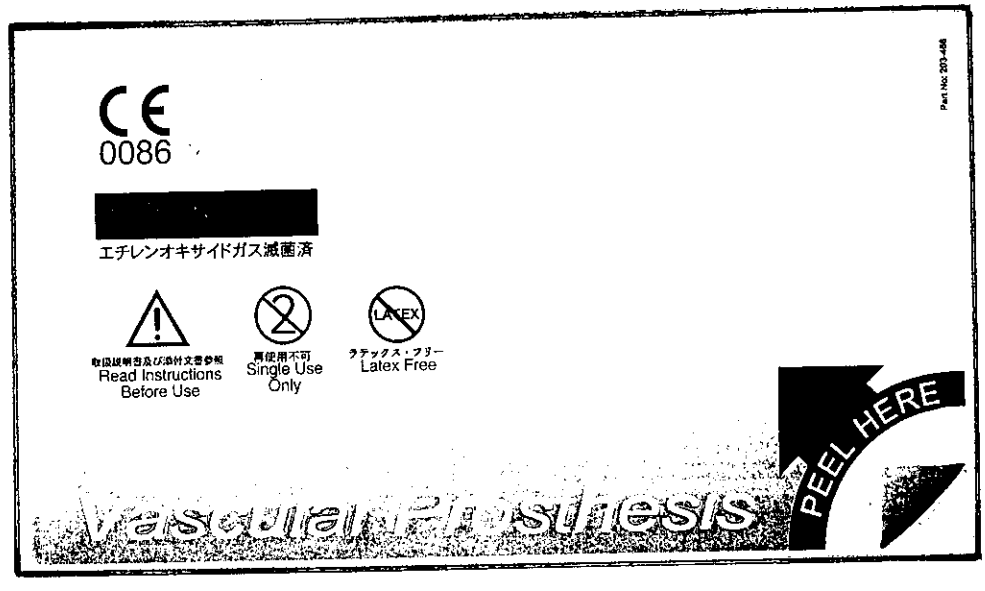
FOIL BAG – BACK



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – SEALED PRODUCT



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MAXIFLO - BOX LABEL

MAXIFLO™
ePTFE Vascular Prosthesis

MAXIFLO™
ePTFE Vascular Prosthesis

8mm

Standard Wall Full Support

70cm

VASCUTEK
TERUMO

Catalogue No. カタログ番号 REF **S70S08R**

Lot No. ロット番号 LOT 11111 7485

Serial No. シリアル番号 SN 0000000002

製造年月日 Man. Date 2004/01

+H960S70S08R10

使用期限 Use By. 2009/01

+S0090100000000204

Material of Manufacture: ePTFE
POLYPROPYLENE

(01) 05037881000701(240)S70S08R

(17)090131(21) 0000000002

8 mm

Diameter 直径 8mm
Usable Length 使用可能長 70cm
REF Catalogue No. カタログ番号 S70S08R
LOT Lot No. ロット番号 11111 7485
SN Serial No. シリアル番号 0000000002
MAXIFLO™ ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 8mm
Usable Length 使用可能長 70cm
REF Catalogue No. カタログ番号 S70S08R
LOT Lot No. ロット番号 11111 7485
SN Serial No. シリアル番号 0000000002
MAXIFLO™ ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 8mm
Usable Length 使用可能長 70cm
REF Catalogue No. カタログ番号 S70S08R
LOT Lot No. ロット番号 11111 7485
SN Serial No. シリアル番号 0000000002
MAXIFLO™ ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Diameter 直径 8mm
Usable Length 使用可能長 70cm
REF Catalogue No. カタログ番号 S70S08R
LOT Lot No. ロット番号 11111 7485
SN Serial No. シリアル番号 0000000002
MAXIFLO™ ePTFE Vascular Prosthesis
Manufactured by VASCUTEK Ltd a TERUMO Company Newmains Avenue Inchinnan, Renfrewshire PA4 9RR Scotland

Part No. 203-445 -B

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MAXIFLO – OUTER TYVEK

MAXIFLO™

ePTFE Vascular Prosthesis

Standard Wall Full Support

REF **Catalogue No.** カタログ番号
S70S08R

Diameter 直径
8mm

Usable Length 使用可能長
70cm

LOT Lot No. ロット番号
11111 7485

Man. Date 製造年月日
2004/01

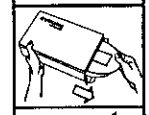
Use By 使用期限
2009/01

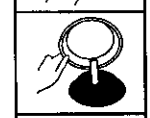
[redacted]
エチレンオキサイドガス滅菌済

取扱説明書及び添付文書参照
Read instructions Before use

再使用不可
Single Use only

STERILE





Manufactured by ~
VASCUTEK Ltd
a **TERUMO** Company
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

VASCUTEK
TERUMO

Part No. 203-445 -A

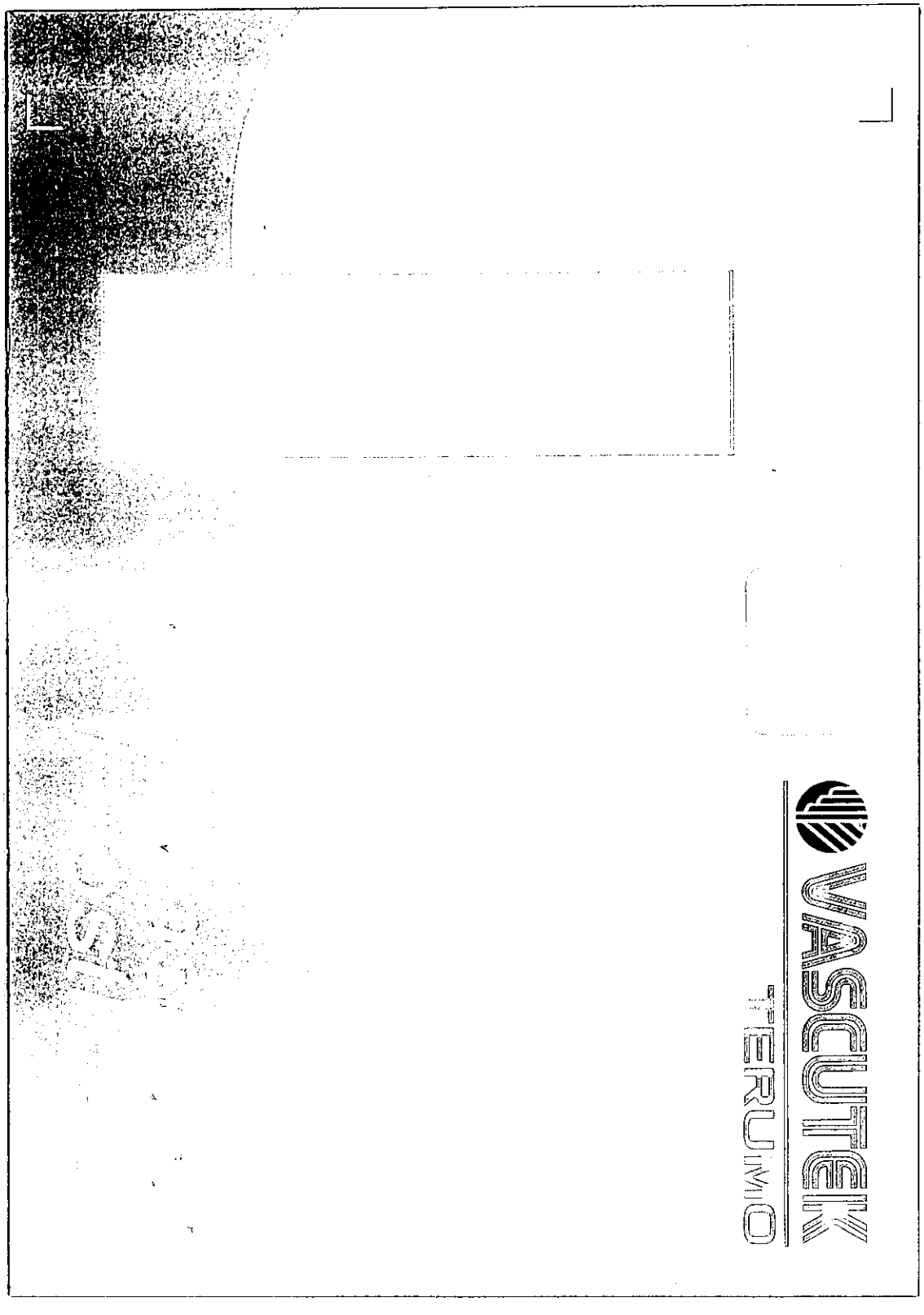
67

75

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

UNSEALED PRODUCT BOX – TOP PANEL



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

UNSEALED PRODUCT BOX – BOTTOM PANEL

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

UNSEALED PRODUCT BOX – SIDE PANELS

Manufactured by ~
VASCUTEK Ltd
a TERUMO Company
Newmains Avenue, Inchinnan
Renfrewshire, PA4 9RR Scotland

Twilltweave™, VP1200K™, MAXIFLO™ & Unity™ are Trademarks of Vascutek Ltd.

200-154

CAUTION:
Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

70 78

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

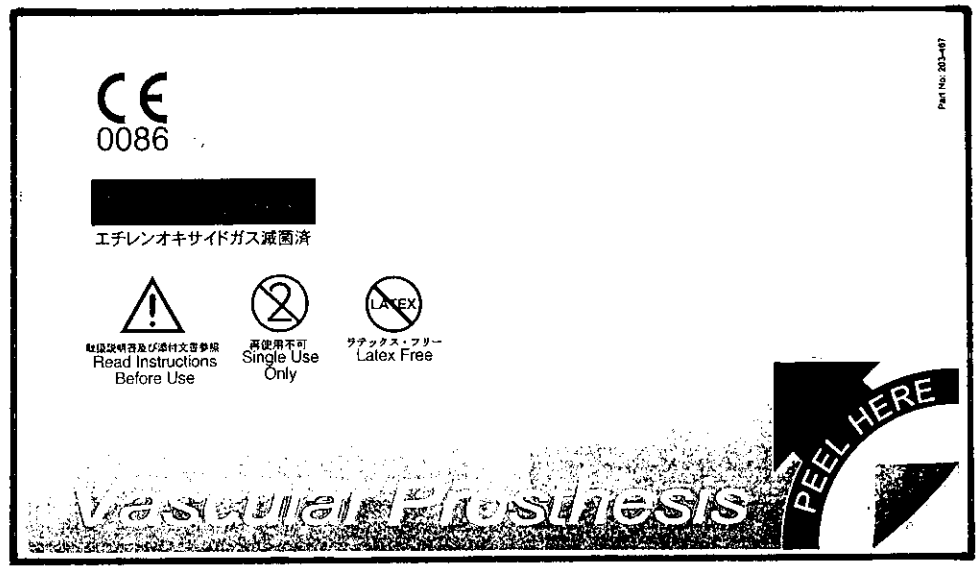
Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

UNSEALED PRODUCT BOX – END PANELS

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

MULTILINGUAL CAUTIONS BOOKLET – UNSEALED PRODUCT



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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Mr. Edward E. Newton
Regulatory Affairs Manager
Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K992832
Sulzer Vascutek ePTFE Vascular Prosthesis
Regulatory Class: II (Two)
Product Code: 74 DSY
Dated: August 20, 1999
Received: August 23, 1999

Dear Mr. Newton:

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 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). 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 call 301-796-8118.

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

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) 594-4648. 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" (21CFR 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/dsma/dsmamain.html."

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological 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 call 301-796-8118.

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

510(k) Number (if known): K992832

Device Name: Sulzer Vascutek ePTFE Vascular Prosthesis

Indications For Use: Sulzer Vascutek ePTFE grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992832

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Lisa Kennell

Subject: 510(k) Number 992832

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.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to 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

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

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

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

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 days

Predicate Product Code with class: 74 II DSY

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

Review: [signature] (Branch Chief) CSPB Chief (Branch Code) 18 Nov '99 (Date)

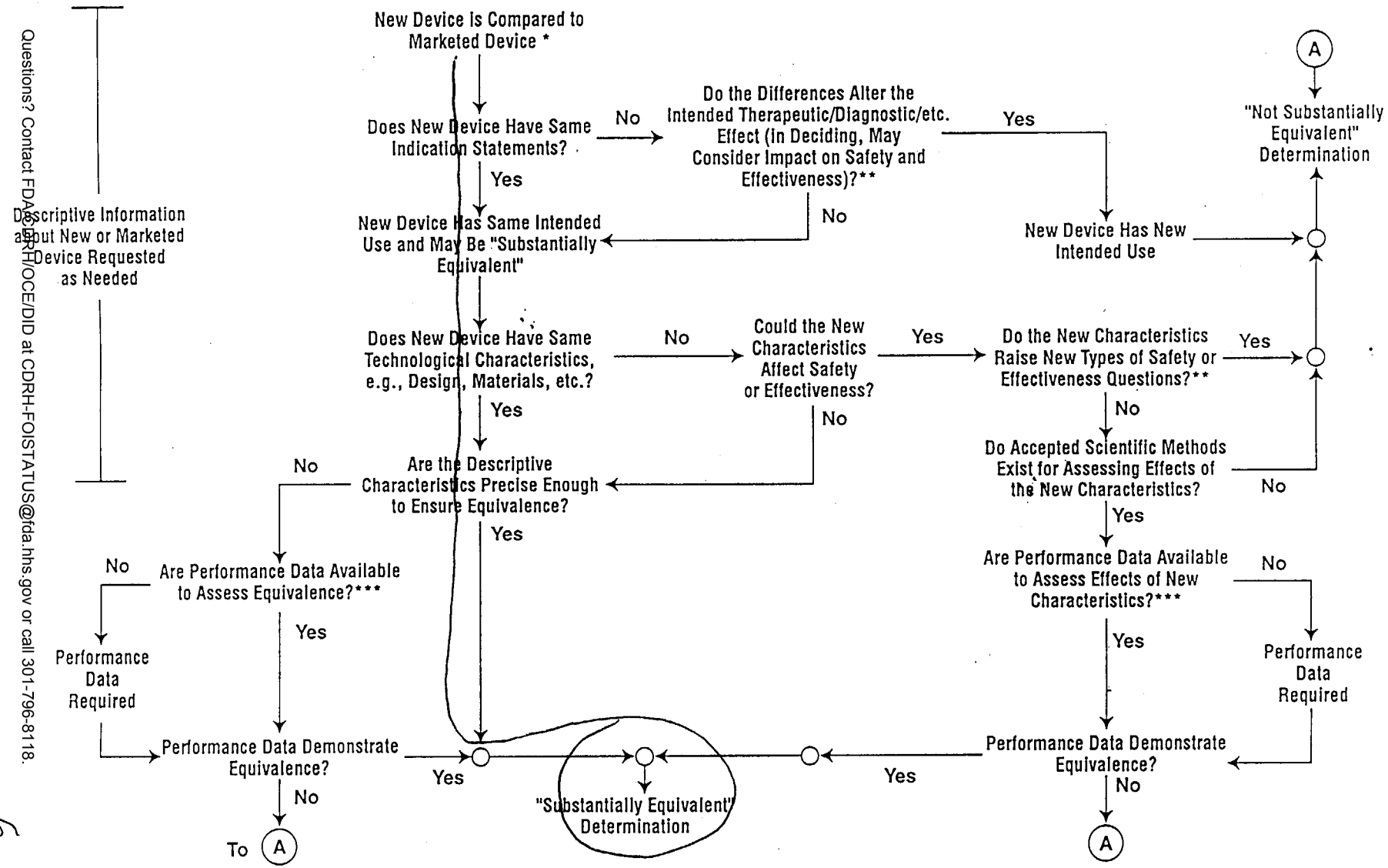
Final Review: [signature] for CMW (Division Director) 18 Nov '99 (Date)

Revised:8/17//99

4

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

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (·endments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** ·ay Be 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 call 301-796-8118.

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

5

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

To: K992832 for the Sulzer Vascutek ePTFE Vascular Prosthesis
From: Lisa Kennell, microbiologist, DCRND LK 11/18/99
Subject: Summary of review and recommendation
Date: November 18, 1999

BL 18 NOV '99

An expedited review of the information in the summary section of this 510(k) revealed the following:

- The device is an ePTFE vascular graft in sizes >6 mm (Class II), that are for bypass or A-V fistula placement. A full range of options will be available, i.e., they will be offered in both normal and thin-walled, with and without external helical support, and will have an ink marker on the external surface for orientation purposes. The ePTFE is stated to be of virgin base resin, to which no additives or extrusion aids have been added. The ink is the same ink as is on the Possis Perma-Pass™ graft, and the polypropylene helical support material is identical to that used in another graft by this firm. The indications for use are the same as those of the predicate graft.

- Sterilization is by 100% ETO to an SAL level of 10^{-6}, and residue limits meet those of the 1978 Federal Register. Resterilization is not permitted.

- The packaging and shelf life are identical to other grafts made by this firm.

- *In Vitro* testing consisted of water entry pressure, suture retention (straight and oblique), kink radius, intra-nodal distance, crush resistance (supported grafts), peel strength (supported grafts), balloon burst, burst after 18 months of simulated needle penetration, inside diameter, wall thickness, and longitudinal tensile strength for the standard wall and thin wall versions of this graft compared to those of an Impra competitor marketed graft. All parameters were comparable.

- Biocompatibility testing or a rationale for omission of some tests. Tests performed on the device (with ink applied) included: cytotoxicity, irritation, pyrogenicity, implantation hemolysis, and acute systemic toxicity (i.e., only the acute tests were run). The firm rationalized that no additional testing is needed because of a long history of use, and the fact that no additives are put into the resin. I agree with this approach.

- Other tests conducted included SEM [showing similar ultrastructure of the Sulzer grafts (normal and thin walled) compared to the competitor], and

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Digital Scanning Calorimetry (DSC) to assess the percentage of sintering compared to a competitor graft.

- An animal study is under Attachment 6. The firm states in the cover letter that the results indicate that the test device performed similarly as the Impra control graft. A very cursory review of the results under Attachment 6 describes a canine study (n = 18 animals) involving infrarenal aortic placement of thin-walled grafts to assess blood loss and oozing at anastomoses, thrombogenic potential via β-thromboglobulin generation and healing out to 6 months (histologically and SEM). The Sulzer graft performed more favorably with respect to leakage at implant and patency, and similarly with respect to healing. Assessments were made at 1 week, 1 and 6 months. The author hypothesized that the significantly better blood leakage in the Sulzer graft is probably due to a slightly more compact fibrillar and nodular internal structure, narrower interfibrillar space, or better wall flexibility.

- Attachment 8 contained literature, but none of the articles related to this graft specifically.

The file contains the perfunctory Truthful and Accurate statement, Indications for Use statement, and 510(k) summary.

RECOMMENDATION

The information in the summary section of the file suggests that the physical, mechanical, biological, and animal performance of the subject graft is similar to those of the predicate graft. I recommend a substantial equivalence letter be issued

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K992832

Reviewer: Lisa Kennell

Division/Branch: DCRND/CSPG

Device Name: Sulzer Vascutek ePTFE Vascular Prosthesis

Product To Which Compared (510(K) Number If Known): K853101, K984182, K791810

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is Device Subject To 510(k)?	✓		If **NO** = Stop
3. Same Indication Statement?	✓		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	✓		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If **NO** = Go To 10 If **YES** = Stop **SE**
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?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

1. Intended Use: For creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial bleed vessles.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

   See memo attached.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: N/A

2. Explain why not subject to 510(k): N/A

3. How does the new indication differ from the predicate device's indication: N/A

4. Explain why there is or is not a new effect or safety or effectiveness issue: The materials, construction, mechanical, biological, and physical properties are similar to the predicate, and healing in the animal model was similar, so there are no new effects.

5. Describe the new technological characteristics: N/A

6. Explain how new characteristics could or could not affect safety or effectiveness: see 4 above.

7. Explain how descriptive characteristics are not precise enough: N/A

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: See 4 above.

9. Explain why existing scientific methods can not be used: N/A

10. Explain what performance data is needed: N/A

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: See 4 above.

ATTACH ADDITIONAL SUPPORTING INFORMATION

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Vascutek EPTFE Vascular Prosthesis | K992832

Submitter (Company): Sulzer Medica

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS YES	SPECIALS NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				N/A		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					N/A		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					assumed		
v) performance (bench, animal, clinical) testing	NA				✓		
vi) safety characteristics	NA				✓		
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special				

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) 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				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) 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							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

inapplicable requirements or deviations noted below					
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:					✓		
i) component & material					✓		
ii) identify patient-contacting materials					✓		
iii) biocompatibility of final sterilized product					✓		
b) Sterilization and expiration dating information:					✓		
i) sterilization method					✓		
ii) SAL					✓		
iii) packaging					✓		
iv) specify pyrogen free					✓		✓
v) ETO residues					✓		
vi) radiation dose							
c) Software validation & verification:					N/A		
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**
Date: 8/25/99

Reviewer: Jerome H. Smallwood
Concurrence by Review Branch: ____

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

REVISED:3/14/95

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
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?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

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.		

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

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 23, 1999

SULZER MEDICA
1300 EAST ANDERSON LANE
AUSTIN, TX 78752
ATTN: EDWARD E. NEWTON

510(k) Number: K992832
Received: 23-AUG-1999
Product: SULZER VASCUTEK EPTFE VASCULAR PROSTHESIS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

992832

SULZER *MEDICA*

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

Phone (512) 435-3200
FAX (512) 435-3350
WATS (800) 648-1579 (US and Canada)

FDA/CDRH/ODE/DMC
2 Aug 99 09 50

August 20, 1999

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Subject: 510(k) Notification

Dear Sir/Madam:

In compliance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR §807 Subpart E, this pre-market notification is being submitted by Sulzer Carbomedics Inc. on behalf of Sulzer Vascutek Ltd. regarding the intent to manufacture, distribute, and market the following medical devices:

Classification Name: Vascular graft prosthesis of 6 mm and greater diameter.

Common/Usual Name: Vascular graft

Proprietary Name(s): Sulzer Vascutek ePTFE Vascular Prosthesis

Establishment Registration: 9612515 (Sulzer Vascutek Ltd.)

Classification: The Food and Drug Administration has classified vascular grafts as Class II devices under classification 21 CFR §870.3460 and this device would be reviewed by the DCRND Cardiovascular. Classification number 74DSY.

Performance Standards:

Performance standards do not exist for this product classification. Until a performance standard is established, Sulzer Vascutek will manufacture the product under the general control previsions of the 1990 device regulations. Even though preference standards do not exist, testing has been done in accordance with the FDA Draft Guidance Document entitled, *Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses* (December 1993), FDA blue book memorandum #G95-1 regarding the biological evaluation of medical devices, and the AAMI Vascular Prosthesis Standard (VP20, June 1994).

CV II

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

SKS

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Labeling/Promotional Material:

Draft copies of the labeling are enclosed as Attachment 1. Promotional materials have not been prepared for this device.

Substantial Equivalence Summary:

The Sulzer Vascutek line of expanded polytetrafluoroethylene (ePTFE) vascular prostheses consist of grafts available in diameters of 6 mm and larger .

The Sulzer Vascutek ePTFE graft line will include straight standard wall and thin wall grafts with and without externally reinforced configurations. Details regarding the sizes and configurations of Sulzer Vascutek ePTFE grafts are provided in Attachment 2.

The grafts are designed for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

The mechanical properties and ultra structure of the Sulzer Vascutek ePTFE grafts are similar to ePTFE grafts currently in commercial distribution. Comparative mechanical and chemical data is attached. Biocompatibility and animal study results are also included along with draft labeling and Instructions for Use.

The ePTFE grafts are manufactured at the Sulzer Vascutek plant in Scotland and meet the QSR regulations regarding the manufacture of medical devices. Sterilization is performed at Sulzer Vascutek using an appropriate validated Ethylene Oxide cycle. The details of the sterilization process are presented in Section 5. The grafts have been tested using the ISO 10993-biocompatibility standard and meet all requirements for a long-term implantable device. The units are packaged in PET blister trays with Tyvek® lids. Shelf life on this package has shown the package to be stable for at least five years.

Sulzer Carbomedics believes that the information provided in this premarket notification is adequate to support the substantial equivalence of the Sulzer Vascutek ePTFE graft line to the Impra Vascular Grafts as defined in 510(k) K791810 that was cleared on October 9, 1979.

The following information is submitted in conformance to 21 CFR §807.87. An original and two copies are included per the regulations. A 510(k) Substantial Equivalence Decision-Making Process outline is provided which includes applicable references to the notification.

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

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Sulzer Carbomedics and Sulzer Vascutek regard the enclosed information to be confidential and request that FDA not disclose the existence of this application under the provisions of 21 CFR §814.9(b) or its contents under 21 CFR §814.9(c). Sulzer Carbomedics Inc. and Sulzer Vascutek have taken all reasonable and prudent precautions to protect the confidentiality of the existence of this application for the Sulzer Vascutek ePTFE line of Vascular Prostheses.

Do not hesitate to contact me at (512) 435-3407 if you have any questions or require further information.

Sincerely,

Edward E. Newton

Edward E. Newton
Regulatory Affairs Manager

Attachment

cc: Paul Burns - Sulzer Vascutek Ltd.

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

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  - B. DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist 4
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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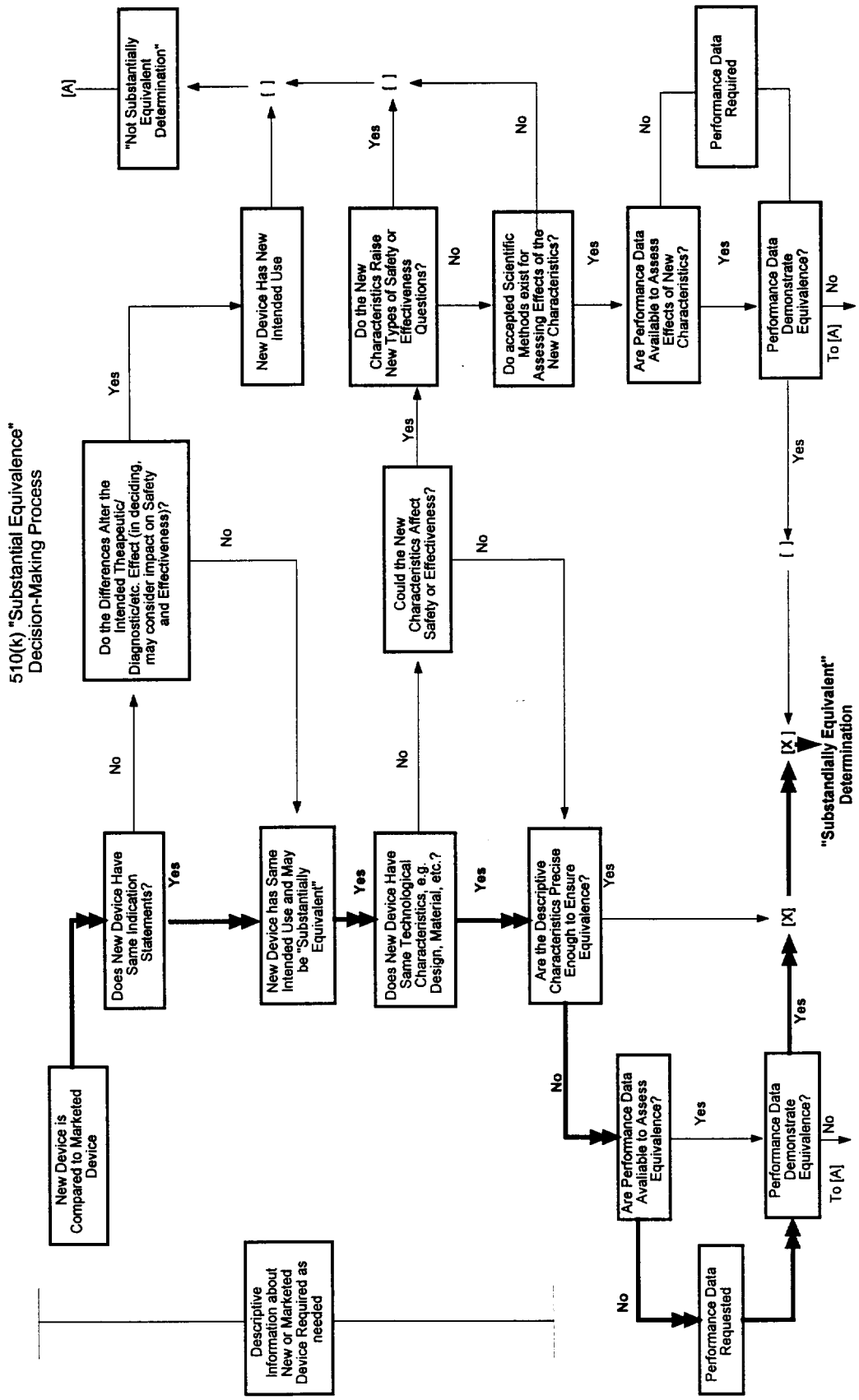

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DCRND Screening Checklist for Premarket Notification 510(k)

Device: Sulzer Vascutek ePTFE Vascular Prosthesis K99_____

Submitter: Sulzer Carbomedics Inc., sponsor for Sulzer Vascutek Ltd.

Items which should be included (circle missing & needed information)	X		X if item Needed & MISSING	Submission Reference	
	Yes	No		Section #	Page #
1. General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new or modification, g) predicate device identified, h) 513/514 compliance (none yet available)	X			a) Sec. 1 b) Sec 1 and Cover Ltr. c) Cover Ltr. and Sec 2 d) Sec. 2 e) Cover Ltr. and Sec. 3 f) Cover Ltr. g) Cover Ltr. and Sec. 6	8 8 8 8 8 - 14-15
2. SMDA requirements: 510(k) summary or statement (any Class device)	X			None	7
Class III Certification & Summary (if Class III)	N/A			N/A	N/A
3. Proposed Labeling: a) package labels, b) statement of intended use, c) advertisements or promotional materials.	X			a) Attachment 1 b) Sec. 5.A. c) Sec. 5.C.2.	16-25 9 11
4. Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals.	X			Sec. 5 Attachment 1 Attachment 2	9-14 16-25 26-29
5. Comparison information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: a) labeling, b) intended use, c) physical characteristics, d) anatomical sites, e) performance (bench, animal, clinical) testing, f) safety characteristics.	X			a) Attachment 1 b) Sec. 6 and Table 3 c) Sec. 6 and Table 3 d) Sec. 6 and Table 3 e) Sec. 5.D , 5.E, 5.F. f) Sec. 5..D, 5..E, 5.F.	16-25 14-15 14-15 14-15 11-14 11-14
6. Certification of identical material/formulation OR, provide the following: a) specify material for each component, b) identify patient-contacting materials, c) biocompatibility data of final sterilized product.	X			Sec. 5	9-14
7. Sterilization and expiration dating information: a) sterilization method: If ETO, ETO residues OR, if radiation, radiation dose, b) validation method, c) SAL, d) expiration date, e) packaging description, f) if labeled "pyrogen-free", specify pyrogen test method.	X			a) Sec. 5.B.3. b) Sec. 5.B.3 c) Sec. 5.B.3 d) Sec. 5 e) Sec. 5.C.1 f) N/A	10 10 10 9-14 11 N/A
8. Software validation & verification: a) level of concern, b) development documentation, c) hazard analysis, d) certification.	N/A	N/A	N/A	N/A	N/A
9. Meets current DCRND guidelines and applicable standards for this device: a) specify guidance, b) comply with content.	X			a) Sec. 4, and 5.D. b) Sec. 4, and 5.D.	8,11-12 8,11-12

Items shaded under "No" are necessary for all submissions.
Any checks in the last (Needed & MISSING) column requires resubmission.

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

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REVIEWER:	DIVISION/BRANCH: DCRND Cardiovascular
TRADE NAME: Sulzer Vascutek ePTFE Vascular Prosthesis	COMMON NAME: Vascular Graft
PRODUCT TO WHICH COMPARED: 510(k) NUMBER IF KNOWN	Impra ePTFE Vascular Grafts (K791810, cleared October 9, 1979)

	YES	NO	Section #	Page #
1. IS PRODUCT A DEVICE?	X			
2. DEVICE SUBJECT TO 510(k)?	X			
3. SAME INDICATION STATEMENT?	X		None Section 6 Table 3	6 14-15 15
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?		X	Section 5 Section 6	9-14 14-15
5. SAME TECHNOLOGICAL CHARACTERISTICS?	X		Section 6 Tables 1 and 3	14-15 12 and 15
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?		X	Section 5 Section 6	9-14 14-15
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X		Section 6 Table 1	14-15 12
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		X	Section 5 Section 6	9-14 14-15
9. ACCEPTED SCIENTIFIC METHODS EXIST?	X		Tables 1 and 3	12 and 15
10. PERFORMANCE DATA AVAILABLE?	X		Section 5	9-14
11. DATA DEMONSTRATE EQUIVALENCE?	X		Section 5 Section 6	9-14 14-15

Note: In addition to completing page two, "YES " responses to Questions 4, 6, 8, and 11 and every "NO" response requires an explanation on page three and/or page four.

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

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DRAERD Premarket Notification 510(k)
Reviewer's Screening Checklist

510(k) Number and Device Name: K99_____ Sulzer Vascutek ePTFE Vascular Prosthesis

Submitter: Sulzer Carbomedics Inc., sponsor for Sulzer Vascutek Ltd.

ITEM	PRESENT		NEEDED	Submission Reference	
	Yes	No	(Y/N/?)	Section #	Page#
1. General information (i.e., trade and classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	X			Cover Ltr. Section 1 Section 4	---- 8 8
- Reason for 510(k) - new device or modification	X			Cover Letter	----
- Identification of legally marketed equivalent device	X			Cover Letter Section 6	---- 14-15
2. Proposed Labeling, Labels, Advertisements	X			Attachment 1	16-25
- Description of new device/notification	X			Section 5	9-14
- Intended use statement	X			Section 5.A.	9
- Diagrams, Engineering Drawings, Photographs		X	N/A	N/A	N/A
3. Comparison of similarities/differences to name legally marketed equivalent device	X			Section 6	14-15
- Equivalent Device Labeling. Labels, Advertising	X			Attachment 7	231-244
- Intended use of equivalent device	X			Table 3 Section 5.A.	15 9
4. List of all patient contacting materials in new device	X			Table 3	15
- Comparison of materials in new device	X			Table 3	15
5. Biocompatibility information/data for patient contacting materials	X			Section 5.E. Table 2	12-13 13
- Certification – identical material/formulation	X			Section 5.B.1	10
6. Performance data: Bench data	X			Section 5.D.	11-12
Animal data	X			Section 5.F.	14
Clinical data		X	N	N/A	N/A
7. Sterilization information	X			Section 5.B.3.	10
8. Software validation & verification		X	N	N/A	N/A
9. 510(k) summary or statement	X			None	7
10. If Class III, Class III Certification and Summary		X	N	N/A	N/A
11. If kit, kit certification		X	N	N/A	N/A

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

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NARRATIVE DEVICE DESCRIPTION

1. **INTENDED USE**: The grafts are designed for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

2. **DEVICE DESCRIPTION**

   SUMMARY: See Cover Letter, Section 5 on pages 9 through 14 and Section 6 on pages 14 and 15.

1. **EXPLAIN WHY NOT A DEVICE:** Not applicable

2. **EXPLAIN WHY NOT SUBJECT TO 510(k):** Not applicable

3. **HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:** There is no difference in device indications.

4. **EXPLAIN WHY THERE IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENSS ISSUE:** The Sulzer Vascutek ePTFE Vascular Prosthesis is equivalent in intended use, base material, and function to the Impra ePTFE graft (K791810, cleared October 9, 1979).

5. **DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:** There are no new technological characteristics for the Sulzer Vascutek ePTFE grafts as compared to the predicate device.

6. **EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:** See Section 5 on pages 9 through 14, and Section 6 on pages 14 and 15.

7. **EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:** In vitro and animal testing conducted. See Section 5 on pages 9 through 14, and Section 6 on pages 14 and 15.

8. **EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:** Not applicable

9. **EXPLAIN WHY EXISTING SCIENTIFIC METHODS CANNOT BE USED:** Not applicable

10. **EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:** See Section 5 on pages 9 through 14, and Section 6 on pages 14 and 15.

11. **EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS SUBSTANTIALLY EQUIVALENT:** Side-by-side *in vitro* testing was performed for the Sulzer Vascutek ePTFE graft and Impra ePTFE predicate device. Biocompatibility testing of Sulzer Vascutek ePTFE grafts demonstrated the devices are non-toxic. Animal studies were conducted that demonstrated that the Sulzer Vascutek ePTFE grafts have the same healing characteristics as the predicate Impra ePTFE grafts. The results of the *in vitro* testing and animal testing demonstrated that the Sulzer Vascutek ePTFE graft is substantially equivalent to the predicate devices for systemic vascular repair and AV access.

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

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INDICATIONS FOR USE STATEMENT

510(K) Number (if known): Unknown

Device Name: Sulzer Vascutek ePTFE Vascular Prosthesis

Indications for Use: Sulzer Vascutek ePTFE grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____

Prescription Use _____ OR Over-the-Counter Use _____

(Optional Format 1-2-96)

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

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K992832

SULZER MEDICA

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

Phone (512) 435-3200
FAX (512) 435-3350
WATS (800) 648-1579 (US and Canada)

510(k) SUMMARY
SULZER VASCUTEK ePTFE VASCULAR PROSTHESIS

The Sulzer Vascutek expanded polytetrafluoroethylene (ePTFE) graft line is substantially equivalent to devices in commercial distribution by Impra, a division of C. R. Bard. All devices referenced under this application are 6mm in diameter or greater and are used to treat diseased or occluded systemic arteries and for A/V access. In addition, the application covers externally supported graft designs.

The device is composed of polytetrafluoroethylene, which has been fabricated in tubular form and expanded to impart porosity to the structure. Similar devices have been used clinically since the 1970's with few reported complications or material failures. ePTFE typically is used as a synthetic conduit to replace natural vessels or as a shunt for AV/dialysis access. The mechanical properties of Sulzer Vascutek ePTFE such as strength, suture retention, and handling are substantially equivalent to products currently in commercial distribution.

Sulzer Vascutek ePTFE grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

In vitro testing conducted on the Sulzer Vascutek ePTFE graft line shows it to be substantially equivalent to Impra commercial grafts. Results from animal studies demonstrate that the Sulzer Vascutek standard wall grafts to be equivalent to Impra standard wall grafts. Results from biomaterial testing demonstrate that the Sulzer Vascutek ePTFE grafts are biocompatible and non-toxic.

In summary, all testing demonstrates that the Sulzer Vascutek ePTFE graft line to be substantially equivalent to the grafts in commercial distribution by Impra, Division of C.R. Bard for the reconstruction and bypass of diseased or occluded systemic blood vessels and construction of subcutaneous a-v conduits for blood access.

Common name of the Device:	Vascular Graft
Trade name of Proprietary Name:	Sulzer Vascutek ePTFE Vascular Prosthesis
Submitter and Contact Person:	Edward E. Newton Regulatory Affairs Manager 1300 E. Anderson Lane, Austin, TX 78752 Phone: (512) 435-3407 Fax: (512) 435-3350
Submission Submitted on:	August 20, 1999

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

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PREMARKET 510(k) NOTIFICATION
SULZER VASCUTEK ePTFE VASCULAR PROSTHESIS

1. **Common/Generic Name:** Vascular Graft

   Trade Name: Sulzer Vascutek ePTFE Vascular Prosthesis

   Classification Name: Prosthesis, Vascular Graft, of 6mm and greater diameter

2. **Establishment Registration Number:** 9612515 (Sulzer Vascutek Ltd.)

   Establishment Address:

   Manufacturer:

   Sulzer Vascutek Limited
   Newmains Avenue
   Inchinnan, Renfrewshire
   PA4 9RR Scotland, U.K.

   Sponsor:

   Sulzer Carbomedics Inc.
   1300 East Anderson Lane
   Austin, Texas 78752
   U.S.A.

   Official Contact:

   Edward E. Newton
   Regulatory Affairs Manager
   1300 East Anderson Lane
   Austin, Texas 78752
   Phone (512) 435-3407
   Fax (512) 435-3350

3. **Classification:**

   The Food and Drug Administration has classified cardiovascular vascular grafts as Class II devices under classification 21 CFR §870.3460 and these devices would be reviewed by the DCRND Cardiovascular, classification number 74DSY.

4. **Performance Standard:**

   Performance standards do not exist for this product classification. Until a performance standard is established, Sulzer Vascutek will manufacture the product under the general control previsions of the 1990 device regulations. Even though preference standards do not exist, testing has been done in accordance with the FDA Draft Guidance Document entitled, *Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses* (December 1993), FDA blue book memorandum #G95-1 regarding the biological evaluation of medical devices, and the AAMI Vascular Prosthesis Standard (VP20, June 1994).

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

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5. Device Description

Sulzer Vascutek ePTFE grafts are manufactured from virgin expanded polytetrafluoroethylene resin. The Sulzer Vascutek graft line will include regular (0.70mm thickness) and thin wall (0.48mm thickness) grafts, and externally reinforced configurations. A description of the two types are provided below:

Graft Type	Description
Straight	The internal diameter is constant the length of the graft. No external support present
Reinforced	The reinforced or supported graft has an external polypropylene support, which provided increased kink and compression resistance for implantation in areas such as axillo-femoral.

Sulzer Vascutek ePTFE grafts are supplied sterile. The method of sterilization used is ethylene oxide. A shelf-life of five years has been established for the device.

A listing of the sizes and configurations of the Sulzer Vascutek ePTFE grafts is provided in Attachment 2.

A. Intended Use

Sulzer Vascutek ePTFE grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

Copies of draft labeling for the Sulzer Vascutek ePTFE grafts are enclosed in Attachment 1.

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

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B. Materials and Manufacturing Process

1. Materials

The Sulzer Vascutek line of ePTFE grafts is constructed of virgin expanded polytetrafluoroethylene resin. No additives or extrusion aids are present in the final product. The standard wall, thin wall, and helical supported grafts are all constructed of the same base resin. A printed line is placed on the outside of the graft material using a non-contact ink jet printer using Video Jet #16-5600 Ink. This ink is being used with the Possis "Perma-Pass™" PTFE graft material (K984182, cleared February 1, 1999).

Biomaterial testing has shown the graft including the ink to be non-toxic. The biocompatibility test results are provided in Section 5.E. and the *in-vivo* animal study results are provided in Section 5.F. The external support used on the reinforced grafts is composed of polypropylene and is heat bonded to the outside surface of the graft. The polypropylene material used in the construction is the same material used in the Sulzer Vascutek externally supported textile graft line (K853101/A, cleared February 24, 1986).

2. Manufacturing

(b)(4) Confidential and Proprietary Information

[redacted]

3. Sterilization

(b)(4) Confidential and Proprietary Information

[redacted]

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

C. Packaging, Labeling, and Advertising

1. Packaging and Shelf-Life

The Sulzer Vascutek ePTFE vascular graft packaging is identical to the packaging used with other of Sulzer Vascutek vascular grafts. The device is packaged in a Tyvek® lidded, double PETG polymer blister package. The materials used for the ePTFE grafts is identical to the materials used for the Sulzer Carbomedics Carbo-Seal® Ascending Aortic Prosthesis that was approved on March 17, 1997 (PMA/S P900060/S12).

Comprehensive testing has been conducted on the ePTFE packaging including testing for package deformation, peel strength, microbiological challenge, and shelf life. The results of this testing have been previously submitted to the FDA in support of Sulzer Carbomedics Carbo-Seal® Device.

2. Labeling and Advertising

Examples of draft labeling for Sulzer Vascutek ePTFE grafts is presented in Attachment 1. Promotional material has not been prepared at this time.

D. *In Vitro* Testing

In vitro testing was conducted in accordance with the FDA Draft Guidance Document entitled, *Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses* (December 1993), FDA blue book memorandum #G95-1 regarding the biological evaluation of medical devices, AAMI Vascular Prosthesis Standard (VP20, June 1994), and ISO 7198.

All detailed reports are presented in Attachment 3. Impra ePTFE grafts were used as the predicate device. Attachment 4 includes SEM photos of the Sulzer Vascutek standard and thin wall grafts. Inner and outer surfaces are shown at a magnification of 500x. Also included are similar SEM photographs for the Impra predicate ePTFE graft. The results show that the graft materials are virtually identical in ultrastructure.

Differential Scanning Calorimetry (DSC) is the method of choice for showing the percent sintering of an ePTFE graft material. The results are shown in Figures 1 to 4 and are included in Attachment 3 and demonstrates that the ePTFE graft material produced by Sulzer Vascutek is 100% sintered and is virtually identical to the DSC curves obtained for Impra graft material.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

A summary of the mechanical test results are provided in Table 1 for Sulzer Vascutek and Impra 6 mm standard wall and thin wall ePTFE grafts.

Table 1. Summary of Mechanical Test Results.
(Mean Data Only – See Attachment 3 for Complete Reports)

Test Description	Test Method	Units	Standard Wall 6 mm Diameter		Thin Wall 6 mm Diameter	
	AAMI VP-20		Sulzer Vascutek	Impra	Sulzer Vascutek	Impra

(b)(4) Confidential and Proprietary Information

[redacted]

* **Test results reported in 510(k) K984182 for the Possis Medical Perma-Pass Vascular Graft (cleared February 1, 1999) that used the Impra ePTFE graft as the predicate device.**

** **Sulzer Vascutek Test Method (see Attachment 3).**

The test values obtained exceed the physiological requirements for the intended clinical use of the device. The results demonstrate that the Sulzer Vascutek ePTFE Vascular Prostheses has a level of safety and effectiveness comparable to currently marketed Impra ePTFE vascular grafts.

E. Biocompatibility Testing

Biocompatibility studies were conducted in accordance with FDA blue book memorandum #G95-1 regarding the biological evaluation of medical devices. Detailed results are presented in Attachment 5 and show the grafts materials to be non-toxic. Results of the biocompatibility test results are summarized in Table 2 on the following page.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

(b)(4) Confidential and Proprietary Information

[redacted]

Table 2. Biocompatibility Test Results for Sulzer Vascutek ePTFE Grafts.

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

F. Animal Study

Results of the dog study which was conducted at Laval University by Dr. Guidoin is given in Attachment 6. Results indicate that the Sulzer Vascutek ePTFE grafts have the same healing characteristics as seen with the Impra predicate ePTFE grafts. In addition, the Sulzer Vascutek ePTFE grafts were shown to be similar to the predicate Impra ePTFE grafts in terms of safety and did not illicit any adverse biological reactions

G. Summary of Testing

The cumulative *in vitro* and animal experience with the Sulzer Vascutek ePTFE graft indicate acceptable performance characteristics in terms of the function of the graft material and biocompatibility.

Based upon the information contained in this premarket notification, we propose that the *in vitro*, biocompatibility, and animal testing demonstrate the substantial equivalence of the Sulzer Vascutek ePTFE grafts as compared to currently marketed predicate devices.

6. Substantial Equivalence Summary

Sulzer Carbomedics considers the Sulzer Vascutek ePTFE graft to be substantially equivalent in base material (ePTFE), intended use, and function as the Impra ePTFE graft that received marketing clearance on October 9, 1979 (K791810).

A comparison of the characteristics of the Sulzer Vascutek ePTFE and predicate device is provided below in Table 3.

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

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Table 3. Comparison of Sulzer Vascutek ePTFE Graft with Predicate Device.

Characteristic	Sulzer Vascutek ePTFE Grafts	Impra ePTFE Grafts
Indications For Use	The creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.	The creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.
Material	ePTFE	ePTFE
Configuration	Straight Externally Reinforced	Straight Externally Reinforced
Packaging	Tyvek® lidded, double PETG polymer blister package	Tyvek® lidded, double vacuum filled polymer blister package
Wall Thickness	Standard = 0.70mm Thin Wall = 0.48mm	Standard = 0.65mm Thin Wall = 0.43mm
Printed Reference Line	Present	Present
Sterilization Method	Ethylene Oxide	Ethylene Oxide

In summary, the Sulzer Vascutek ePTFE graft is substantially equivalent in intended use, graft material, function, and mechanical properties to the Impra ePTFE graft as defined in 510(k) K791810 (cleared October 9, 1979).

Copies of the labeling for the predicate device is provided in Attachment 7.

The Clinical Papers reference information is contained within Attachment 8.

A Truthful and Accurate Statement for the Sulzer Vascutek ePTFE graft is provided in Attachment 9.

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

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ATTACHMENT 1

Draft Labeling for Sulzer Vascutek ePTFE Grafts

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

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INSTRUCTIONS FOR USE
ePTFE GRAFTS

DRAFT

USA

DESCRIPTION

This range of Sulzer Vascutek grafts is manufactured from both supported and unsupported ePTFE (expanded polytetrafluoroethylene). The external polypropylene support, where applicable, provides a kink resistance and a smooth flow surface. This support is designed to be peeled off at the ends of the prosthesis to facilitate the fashioning of the anastomoses. It is supplied sterile and will remain so for the stated shelf life or unless the packaging is opened or damaged.

Warning: - Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

Peelable Support

INDICATIONS

The creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

Treatment	Configuration	Graft Characteristic		Typical Applications
Base Material		Supported	Unsupported	
Standard Wall	Straight	High Strength & Compression Resistant	High Strength	Systemic vascular repair, primarily for axillo – femoral/bi-femoral bypass and femoral popliteal reconstruction.
Thin Wall	Straight	Thin, Soft Handle & Compression Resistant	Thin with Soft Handle	Systemic vascular repair, but NOT for axillo – femoral/bi-femoral bypass reconstruction.

CONTRAINDICATIONS

1. Thin wall grafts are not recommended for axillofemoral or axillobifemoral bypass reconstruction because of the potential for anastomotic disruption during extreme body movement.
2. Grafts with an external support over the entire length are NOT recommended for blood access purposes.
3. Grafts only to be implanted by Vascular Prosthesis Consultant Surgeons who are experienced with the specific techniques required by these medical devices.
4. Unsupported grafts must not be implanted in such areas where total or partial occlusion can occur as a result of the movement of a patient's body.

CAUTIONS

1. **DO NOT PRECLOT.** No preclotting required.
2. **DO NOT USE BEYOND THE INDICATED EXPIRY DATE.**
3. **For single use only.**
4. **DO NOT RESTERILIZE.** This product must not be resterilized.
5. Clamping may damage any vascular prosthesis. Atraumatic clamps, ideally with soft shod jaws, should be used with a minimum application of force on the unsupported section of graft only. Excessive force must be avoided, as it will damage the polypropylene support.
6. **DO NOT PUNCTURE GRAFTS IN THE SUPPORTED AREA.** Care must be taken not to puncture the opposite side of the graft when suturing.
7. Use a non-cutting tapered needle with non-absorbable monofilament polypropylene or PTFE suture stitched a suitable distance from the graft edge. To minimize suture line bleeding pull the suture at an angle of 90^0.
8. Store in a clean, dry area not less than 0^{0}C (32 ^{0}F) and not more than 50^0 C (122^{0}F).
9. Avoid wetting graft. Exposure to oil, alcohol, aqueous solutions or any of these fluids when pressurized may result in wetting, which will affect the hydrophobic property of the material and may result in increased seroma formation.
10. **Never cut or open a graft to form a surgical patch.**
11. ePTFE grafts are neither elastic in a radial or longitudinal direction, therefore care must be taken as follows :-

(i) *When using embolectomy or balloon angioplasty catheters within the lumen of a graft, the inflated balloon size must be carefully matched to the inside diameter of the graft. Failure to size the catheter correctly or the over-inflation of the balloon may result in rupture of either the graft or the balloon.*

(ii) *Excessive tension on the prosthesis must be avoided.*

(iii) *Cut the graft long enough to cater for a full stretch of the body in the relevant area and to ensure that no stress exists on the anastomoses in the axillofemoral/bi-femoral bypass and femoral popliteal reconstruction. The patients body mass and the likely extremes of their posture must be considered when determining the length of graft to be implanted, otherwise stress may be placed on the axillary anastomosis during full body or limb extension. Failure to consider these aspects may cause anastomic disruption, resulting in excessive bleeding, loss of function or possible amputation of limb and in the worst case, death.*

(iv) *The graft must not be filled with blood before it has been passed through the tunnel. Exerting pressure may cause blood components to be passed through the graft wall leading to the possible formation of seroma.*

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INSTRUCTIONS FOR USE
ePTFE GRAFTS

DRAFT

USA

THROMBECTOMY
Should a postoperative occlusion occur, declotting can be performed by carrying out a longitudinal incision with stay sutures for thrombectomy procedures. When a transverse incision is used, a horizontal mattress suture technique may be required to aid closure.

OPERATIVE TECHNIQUE
When implanting a Sulzer Vascutek prosthesis, select a bullet tipped tunneller suitably sized to ensure that the graft will have a snug fit.

STERILIZATION
Sulzer Vascutek ePTFE grafts are sterilized in ethylene oxide, supplied sterile and may be re-sterilized provided that the graft has not been contaminated or exposed to any radiation equipment The Tyvek® seal on both intermediate and inner trays must be intact. Any damage to the trays renders the prosthesis non-sterile. In the event of damage to the primary packaging, the product must not be used and should be returned immediately to the supplier.

Sulzer Vascutek does not recommend the resterilization of these prostheses.
DO NOT STERILIZE WITH ANY TYPE OF RADIATION STERILIZATION EQUIPMENT.

ADDITIONAL LABELS
Additional labels are attached to this leaflet for inclusion in patient records to enable the tracking of this device.

ANGIOACCESS

- When implanting an unsupported prosthesis care must be taken to ensure that a subcutaneous tunnel is created of similar size to the graft, such that a snug fit is achieved.
- To reduce the risk of hematoma formation it is suggested that the graft not be used for AV Access during the two weeks following implant.
- The blood access needle should be inserted at an angle of 45° (bevel upward) until the graft has been penetrated. Care must be taken not to puncture the opposite side of the graft.
- Do not cannulate at the same site. Rotate areas to reduce chance of graft damage and the possibility of perigraft hematoma or pseudoaneurysm formation. If using a supported graft do not cannulate near or within the supported portion.

Disclaimer of Warranties
Many factors are outside Sulzer Vascutek's supervision and control after sale of this device.
Sulzer Vascutek has no control over the conditions under which the device is used, the diagnosis of the patient or the methods or procedures used for implantation. Therefore, Sulzer Vascutek makes no warranty or guarantee of this device, expressed or implied.

SULZER VASCUTEK MAKES NO WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ANY WARRANTY OR REPRESENTATION BY ANY OTHER PERSON OR FIRM IS VOID. SULZER VASCUTEK NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH SALE OF THIS DEVICE. SULZER VASCUTEK WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THIS DEVICE.

Some jurisdictions do not allow the exclusion of or limitations on an implied warranty. Similarly, some jurisdictions do not allow the exclusion or limitations of incidental or consequential damages. Therefore, some of the above exclusions may not apply. This warranty gives specific legal rights. The patient may also have other rights which vary from jurisdiction to jurisdiction.

Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
SCOTLAND PA4 9RR

Tyvek® Du Pont Registered Trade Mark

39 18

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

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CARTON LABEL

Sulzer Vascutek
expanded PTFE
Vascular Prosthesis

CE
0086

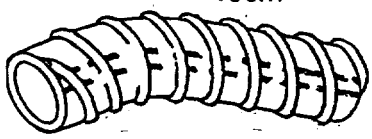
Sulzer Vascutek
expanded PTFE
Vascular Prosthesis

Cat No: **S40S10R**
Batch No: **1111/1**
Use by: **2004/7** 40cm

Serial No: **x x x x x x x x**

BAR CODE NUMBER PLACED HERE

10mm



Standard Wall, Straight Supported

Sterile Lot No.: 1111

Date of Manufacture: 1999/7

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

Records processed under FOIA Request #2016-0876; Released by CDRH on 08-16-2016

DRAFT

PEEL HERE

INNER TYVEK® BLISTER LID

Sulzer Vascutek

STERILE

TRACKING LABEL
PLACED HERE

SULZER*MEDICA*

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

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OUTER TYVEK® BLISTER LID

Sulzer Vascutek
expanded PTFE
Vascular Prosthesis

CE 0086

Standard Wall, Straight Supported

- **Please Read Instructions Before Use**
- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
- **Single Use Only**
- Do Not Preclot
- Sterilized in Ethylene Oxide
- Must Not be Used After Expiration Date
- Store in a Clean Dry Area at Between 0-50°C (32-122°F)

Diameter:	**10mm**
Usable Length:	**40 cm**
Cat No:	**S40S10R**
Batch No:	**11111/1**
Sterile Lot No:	**1111**
Use by:	**2004/7**
Man. Date:	**1999/7**
Materials of Manufacture:	**PTFE and POLYPROPYLENE SUPPORT**

SULZER*MEDICA*

For ordering, please contact: -
Sulzer Vascutek USA, Inc.
1300-C East Anderson Lane
Austin, Texas 78752

Toll Free: 1 (888) 758 8000

Manufactured by ~
Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

203-337

TRACKING LABEL
PLACED HERE

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

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DRAFT

OUTER TYVEK® LABEL

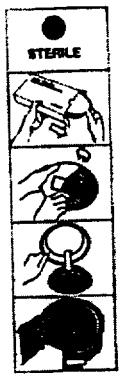
Sulzer Vascutek

expanded PTFE

CE 0086

Vascular Prosthesis

Standard Wall, Straight Supported



- **Please Read Instructions Before Use**
- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
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Diameter:	**10mm**
Usable Length:	**40 cm**
Cat No:	**S40S10R**
Batch No:	**11111/1**
Sterile Lot No:	**1111**
Use by:	**2004/7**
Man. Date:	**1999/7**
Materials of Manufacture:	**PTFE and POLYPROPYLENE SUPPORT**

SULZER*MEDICA*

For ordering, please contact: -
Sulzer Vascutek USA, Inc.
1300-C East Anderson Lane
Austin, Texas 78752

Toll Free: 1 (888) 758 8000

Manufactured by ~
Sulzer Vascutek Ltd.
Newmains Avenue
Inchinnan, Renfrewshire
PA4 9RR Scotland

203-337

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

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PATIENT LABEL

Sulzer Vascutek Ltd.

Newmains Avenue Inchinnan
Renfrewshire PA4 9RR Scotland

TYPE: **PTFE**

CONSTRUCTION:

Standard Wall, Straight Supported

MATERIAL OF MANUFACTURE:

PTFE

POLYPROPYLENE SUPPORT

Part No. 203-026/1

DIAMETER	10mm
USABLE LENGTH	40cm
CAT No.	S40S10R
BATCH No.	
STERILE LOT No.	
DATE:	

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

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DRAFT

Sulzer Vascutek
Vascular Prosthesis

VASCULAR GRAFTS ARE SUBJECT TO DEVICE TRACKING

SULZER *MEDICA*

CAUTION:
Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

PRODUCT CARTON

Sulzer Vascutek
Vascular Prosthesis

SULZER *MEDICA*

For ordering please contact~
Sulzer Vascutek USA Inc.
1300-C East Anderson Lane
Austin, Texas 78752
Toll Free 1(888) 758-8000

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

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OPEN HERE

SULZER*MEDICA*

Sulzer Vascutek

Sulzer Vascutek
Vascular Prosthesis

- **Please Read Instructions Before Use**
- **Only the Innermost Pack Containing the Sterile Device May be Introduced to the Sterile Field**
- **Sterile Unless Opened or Damaged**
- **Single Use Only**
- **Do not Preclot**
- Sterilized in Ethylene Oxide
- Must Not be Used After Expiration Date
- Store in a Clean Dry Area at Between 0-50°C (32-122°F)

Classification:

Unsealed Grafts are Synthetic Vascular Prostheses ie. ePTFE. Those featuring an External Support are Compound Vascular Prosthesis and also contain Polypropylene

PRODUCT CARTON

For ordering please contact–
Sulzer Vascutek USA Inc.
1300-C East Anderson Lane
Austin, Texas 78752

200-063/4

SULZER*MEDICA*

Sulzer Vascutek
Vascular Prosthesis

Vascusoft™, Triaxial™ and Twillweave™ are products of Sulzer Vascutek Ltd.

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ATTACHMENT 2

Sizes and Configurations of Sulzer Vascutek ePTFE Grafts

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

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SULZER VASCUTEK ePTFE VASCULAR PROSTHESIS

Catalog Number	Description	Length (cm)	Diameter (mm)
S10S06	Standard Wall, Straight	10	6
S10S07	Standard Wall, Straight	10	7
S10S08	Standard Wall, Straight	10	8
S10S10	Standard Wall, Straight	10	10
S20S06	Standard Wall, Straight	20	6
S20S08	Standard Wall, Straight	20	8
S30S06	Standard Wall, Straight	30	6
S40S06	Standard Wall, Straight	40	6
S40S07	Standard Wall, Straight	40	7
S40S08	Standard Wall, Straight	40	8
S40S10	Standard Wall, Straight	40	10
S50S06	Standard Wall, Straight	50	6
S50S07	Standard Wall, Straight	50	7
S50S08	Standard Wall, Straight	50	8
S50S10	Standard Wall, Straight	50	10
S60S06	Standard Wall, Straight	60	6
S70S06	Standard Wall, Straight	70	6
S70S07	Standard Wall, Straight	70	7
S70S08	Standard Wall, Straight	70	8
S70S10	Standard Wall, Straight	70	10
S80S06	Standard Wall, Straight	80	6
S80S07	Standard Wall, Straight	80	7
S80S08	Standard Wall, Straight	80	8
S80S10	Standard Wall, Straight	80	10
S90S06	Standard Wall, Straight	90	6
S90S08	Standard Wall, Straight	90	8
S40S06CR	Standard Wall, Straight Central Supported	40	6
S40S07CR	Standard Wall, Straight Central Supported	40	7
S40S08CR	Standard Wall, Straight Central Supported	40	8
S50S06CR	Standard Wall, Straight Central Supported	50	6
S50S07CR	Standard Wall, Straight Central Supported	50	7
S50S08CR	Standard Wall, Straight Central Supported	50	8
S50S06ER	Standard Wall, Straight End Supported	50	6
S10S06R	Standard Wall, Straight Supported	10	6
S20S06R	Standard Wall, Straight Supported	20	6
S20S07R	Standard Wall, Straight Supported	20	7
S20S08R	Standard Wall, Straight Supported	20	8
S30S06R	Standard Wall, Straight Supported	30	6
S30S08R	Standard Wall, Straight Supported	30	8
S40S06R	Standard Wall, Straight Supported	40	6
S40S07R	Standard Wall, Straight Supported	40	7
S40S08R	Standard Wall, Straight Supported	40	8
S40S10R	Standard Wall, Straight Supported	40	10
S50S06R	Standard Wall, Straight Supported	50	6
S50S07R	Standard Wall, Straight Supported	50	7
S50S08R	Standard Wall, Straight Supported	50	8
S50S10R	Standard Wall, Straight Supported	50	10
S60S06R	Standard Wall, Straight Supported	60	6

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

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SULZER VASCUTEK ePTFE VASCULAR PROSTHESIS

Catalog Number	Description	Length (cm)	Diameter (mm)
S60S07R	Standard Wall, Straight Supported	60	7
S60S08R	Standard Wall, Straight Supported	60	8
S60S10R	Standard Wall, Straight Supported	60	10
S70S06R	Standard Wall, Straight Supported	70	6
S70S07R	Standard Wall, Straight Supported	70	7
S70S08R	Standard Wall, Straight Supported	70	8
S70S10R	Standard Wall, Straight Supported	70	10
S80S06R	Standard Wall, Straight Supported	80	6
S80S07R	Standard Wall, Straight Supported	80	7
S80S08R	Standard Wall, Straight Supported	80	8
S80S10R	Standard Wall, Straight Supported	80	10
S90S06R	Standard Wall, Straight Supported	90	6
S90S08R	Standard Wall, Straight Supported	90	8
T10S06	Thin Wall, Straight	10	6
T10S07	Thin Wall, Straight	10	7
T10S08	Thin Wall, Straight	10	8
T10S10	Thin Wall, Straight	10	10
T20S06	Thin Wall, Straight	20	6
T20S08	Thin Wall, Straight	20	8
T30S06	Thin Wall, Straight	30	6
T40S06	Thin Wall, Straight	40	6
T40S07	Thin Wall, Straight	40	7
T40S08	Thin Wall, Straight	40	8
T50S06	Thin Wall, Straight	50	6
T50S07	Thin Wall, Straight	50	7
T50S08	Thin Wall, Straight	50	8
T60S06	Thin Wall, Straight	60	6
T60S07	Thin Wall, Straight	60	7
T70S06	Thin Wall, Straight	70	6
T70S07	Thin Wall, Straight	70	7
T70S08	Thin Wall, Straight	70	8
T80S06	Thin Wall, Straight	80	6
T80S07	Thin Wall, Straight	80	7
T80S08	Thin Wall, Straight	80	8
T90S06	Thin Wall, Straight	90	6
T90S08	Thin Wall, Straight	90	8
T10S06R	Thin Wall, Straight Supported	10	6
T10S08R	Thin Wall, Straight Supported	10	8
T30S06R	Thin Wall, Straight Supported	30	6
T30S08R	Thin Wall, Straight Supported	30	8
T50S06R	Thin Wall, Straight Supported	50	6
T50S07R	Thin Wall, Straight Supported	50	7
T50S08R	Thin Wall, Straight Supported	50	8
T60S06R	Thin Wall, Straight Supported	60	6
T60S07R	Thin Wall, Straight Supported	60	7
T60S08R	Thin Wall, Straight Supported	60	8
T70S06R	Thin Wall, Straight Supported	70	6
T70S07R	Thin Wall, Straight Supported	70	7

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

SULZER VASCUTEK ePTFE VASCULAR PROSTHESIS

Catalog Number	Description	Length (cm)	Diameter (mm)
T70S08R	Thin Wall, Straight Supported	70	8
T80S06R	Thin Wall, Straight Supported	80	6
T80S07R	Thin Wall, Straight Supported	80	7
T80S08R	Thin Wall, Straight Supported	80	8

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

ATTACHMENT 3

In Vitro Test Reports

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

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

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Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

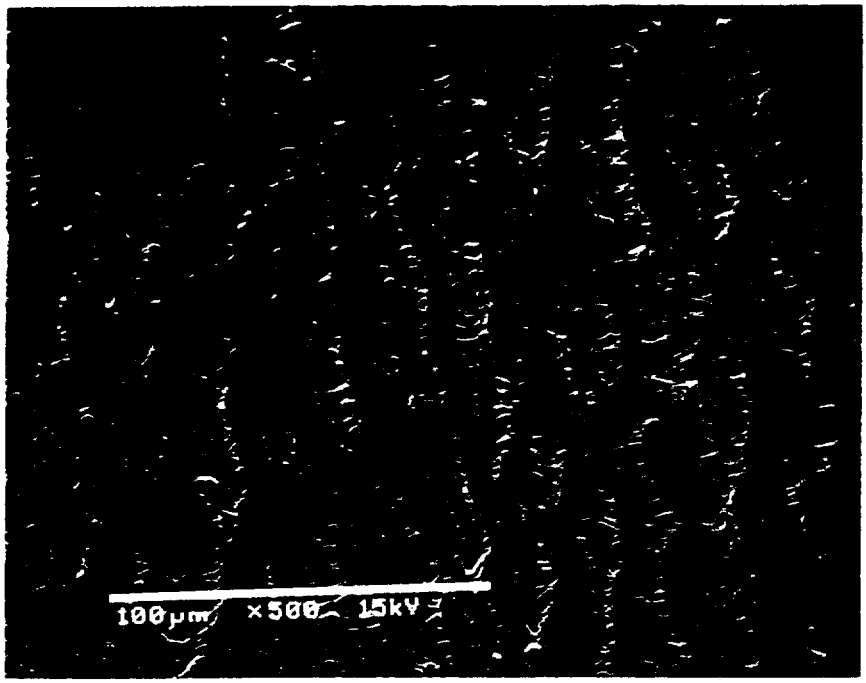
ATTACHMENT 4

SEM Photographs of Sulzer Vascutek and Impra ePTFE Graft Materials

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Vascutek ePTFE Graft
6 mm Standard Wall



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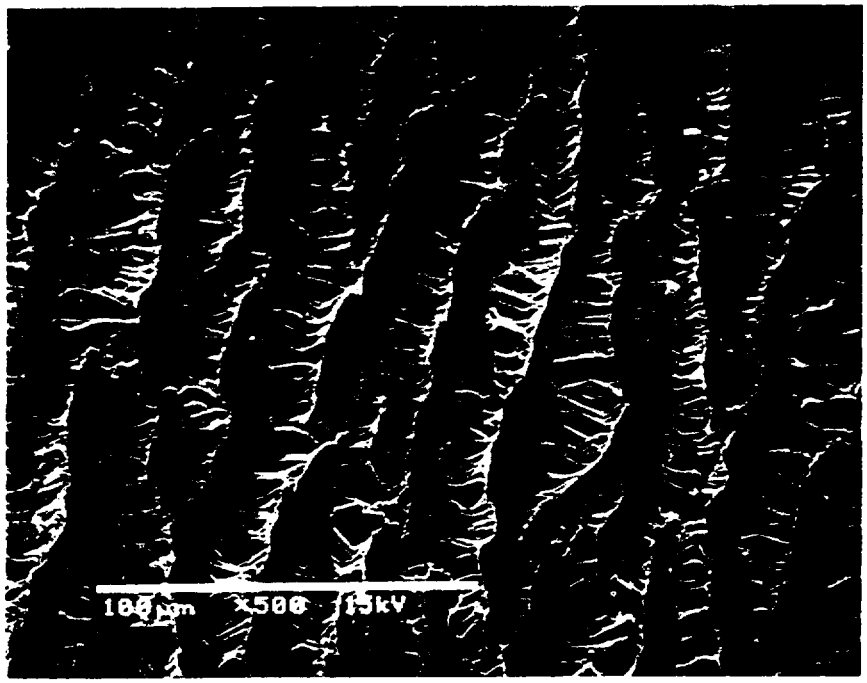
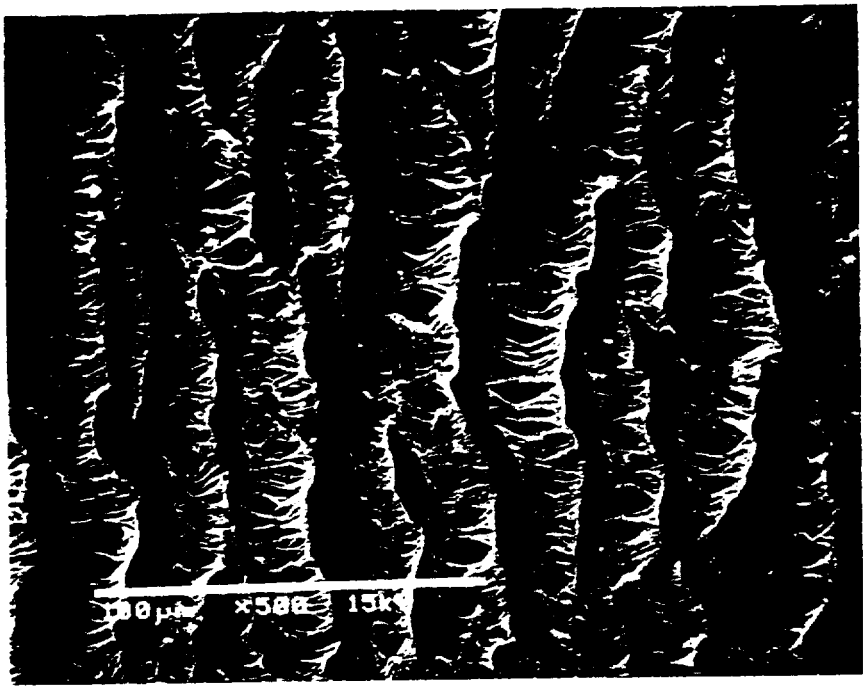


Outer Surface (500x)

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

Vascutek ePTFE Graft
6 mm Thin Wall
L990608-05



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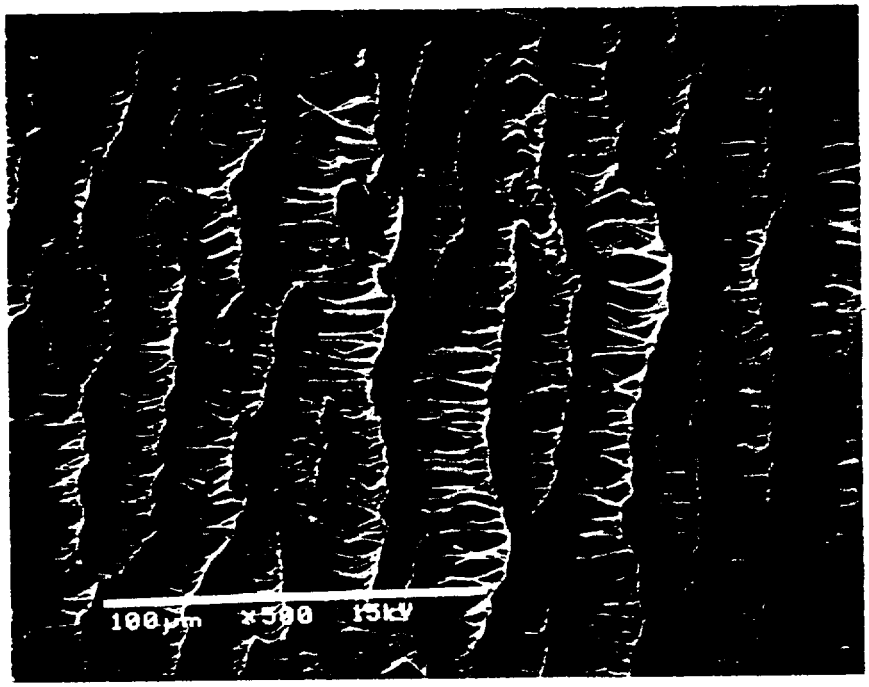
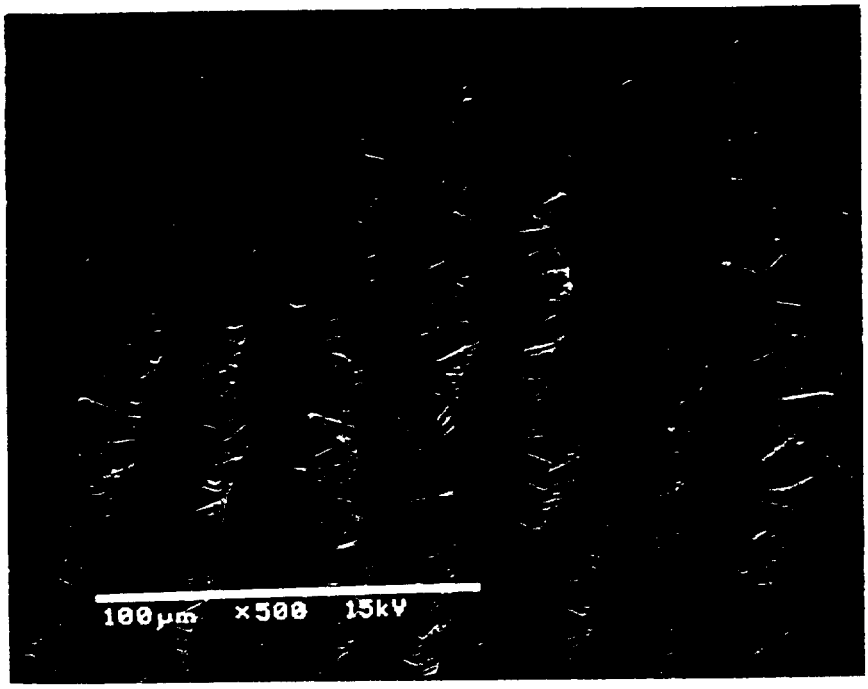


Outer Surface (500x)

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

IMPRA Graft
6 mm Thin Wall



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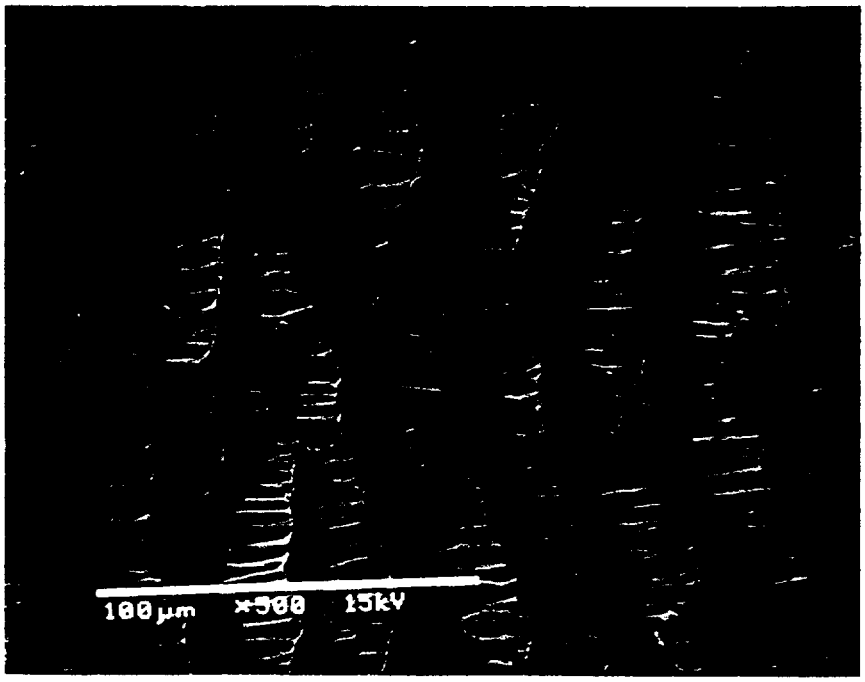
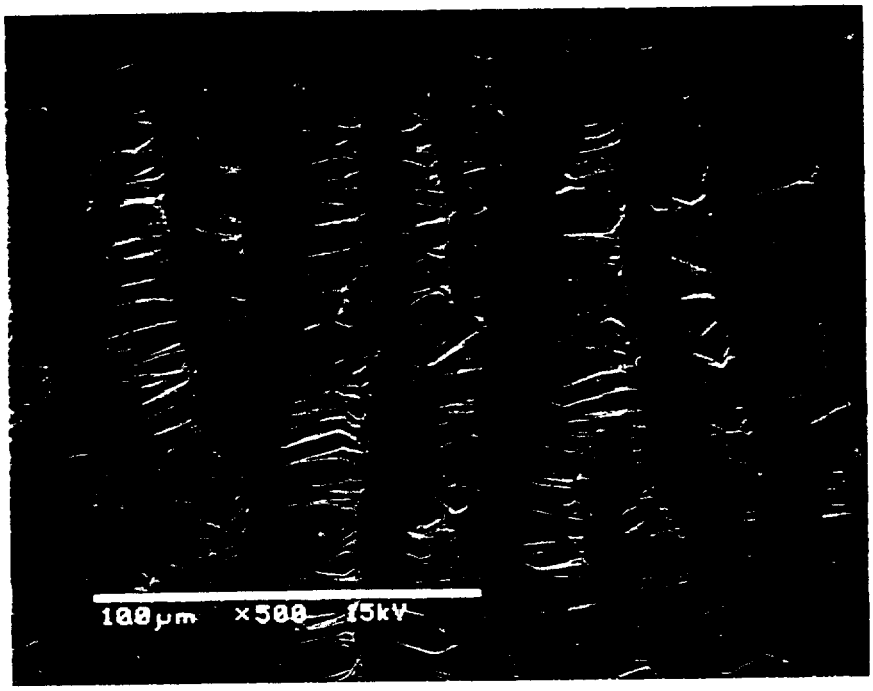


Outer Surface (500x)

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

IMPRA Graft
6 mm Standard Wall
Lot 3379 VM



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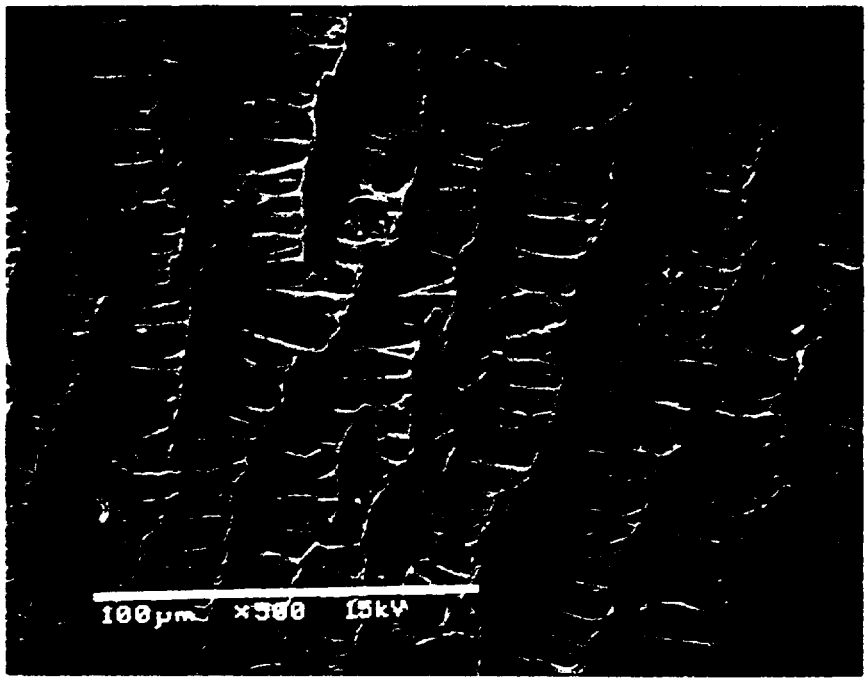

Outer Surface (500x)

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

ATTACHMENT 5

Biocompatibility Test Reports for Sulzer Vascutek ePTFE Grafts

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

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Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

ATTACHMENT 6

Animal Study Report for Sulzer Vascutek ePTFE Grafts

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

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Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

ATTACHMENT 7

Labeling for Predicate Device

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

IMPRA®
The Fine Line of Excellence

IMPRA, Inc.
P.O. Box 1740
Tempe, AZ 85280-1740
(602) 894-9515

FAX (602) 966-7062
1-800-321-4254
USA & Canada

IMPRA is a registered trademark of IMPRA, Inc.

PTFE VASCULAR GRAFT

IMPRA®
The Fine Line of Excellence

IMPRA®.M.R.
The Fine Line of Excellence

Expanded PTFE Vascular Graft

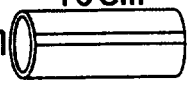
Product Code: 40S06

Exp. Date: Mar 2000

STERILE

40cm

6mm



Lot No: 33797 VM

+H03840S061U

+133797VMUK

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

253 232

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

2

24256

S019050

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

Printed in U.S.A.

Contents sterile unless inner package opened or damaged
Stérile. Vérifier l'intégrité du protecteur individuel de stérilité avant usage
Inhalt steril, sofern die innere Packung ungeöffnet und nicht beschädigt ist
Contenuto sterile. Non utilizzare se la confezione è stata aperta o danneggiata
No utilizar si el envase interior ha sido abierto o dañado
内袋パッケージが破損または開封されていない場合に限り、当製品は無菌です

PTFE Vascular Graft–STERILE
Prothèses vasculaire en PTFE–STERILE
Gefäßprothese aus PTFE–STERIL
Protesi vascolare in PTFE–STERILE
Injerto Vascular de PTFE–ESTERILE
移植用ポリテトラフルオル
エチレン人工血管—滅菌済

REF **Product Code** 40S06 STRAIGHT
Référence
Artikelnummer
Codice prodotto
Código del producto
製品コード

Quantity 1
Quantité
Stück
Quantità
Cantidad
数量

Sterile EIO **Sterilized with ETO**
Stérilisation: oxyde d'éthylène
Sterilisiert mit Ethylenoxid
Sterilizzato con ossido di etilene.
Esterilizado con óxido de etileno
エチレンオキシドによる滅菌

LOT **Lot No.** 33797 VM
Nº de lot
Chargen–Nr./Ch.-B.
Lotto N.
Número de lote
ロット番号

Single Use
Usage unique
Für den Einmalgebrauch
Monouso
Un sólo uso
再使用不可

Mfg. Date Mar 1995
Date de fabrication
Herstellungsdatum
Data Fabbricazione
Fecha de fabricación
製造年月日

Exp. Date Mar 2000
A utiliser avant
Verwendbar bis
Data di scadenza
Fecha de caducidad
有効期限

IMPRA® The Fine Line of Excellence

CE 0344

IMPRA, Inc.
P.O. Box 1740
Tempe, Arizona 85280-1740
FAX: (602) 966-7062
(602) 894-9515
(800) 321-4254 in USA and Canada

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S04356A

IMPRA CANADA, Inc.
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Ste 200
Longueuil, Quebec
CANADA J4K 3S7
Tel: (514) 442-2011
Fax: (514) 442-2012

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P.O. Box 226
1257 Croix de-Rozon
Geneva, SWITZERLAND
Tel: 41 (22) 771 35 80
Fax: 41 (22) 771 31 24
Tlx. 421348

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IMPRA (UK) Ltd
4 De Salis Court
Hampton Lovett
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UNITED KINGDOM
Tel: 44 (905) 79 63 03
Fax: 44 (905) 79 63 13

IMPRA MEDICA S.A.R.L.
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94472 Boissy St Leger Cedex
FRANCE
Tel: 33 (1) 45 69 02 02
Fax: 33 (1) 45 95 17 44
Tlx. 263377

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

254 233

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

PTFE
Vascular Graft

STERILE
Contents sterile unless inner package opened or damaged

STERILE
Contenu stérile tant que l'emballage intérieure n'ait été ouvert ou endommagé

STERIL
Inhalt steril sofern die innere Packung ungeöffnet und nicht beschädigt ist

STERILE
Sterilita garantita solo con confezione interiore

ESTERIL
Contenido estéril a menos que el embalaje interno haya sido abierto o dañado

滅菌済
プラスチックケースが損傷していたり、
開封されていた場合は、
滅菌は無効になります。

WARNING:
To resterilize with either gas or steam, remove the product from the PVC tray with clean instruments or gloved hands and place in a hospital sterilization pouch. Do not resterilize in the original container.

IMPRA
The Fine Line of Excellence

IMPRA, INC.
2445 W. 10th Place
Tempe, Arizona 85281 USA

TWX 910-950-0122
(602) 894-9415
Toll Free (800) 321-4254

Caution: Federal law (USA) restricts this device to sale by or on order of a physician.

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

25-231

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

PTFE
Vascular Graft

STERILE
Contents sterile unless inner package opened or damaged

STERIL
Inhalt steril sofern die innere Packung ungeöffnet und nicht beschädigt ist

ESTERIL
Contenido estéril a menos que el embalaje interno haya sido abierto o dañado

STERILE
Contenu stérile tant que l'emballage intérieure n'ait été ouvert ou endommagé

STERILE
Sterilita garantita solo con confezione interna integra

滅菌済
プラスチックケースが損傷していたり、開封されていた場合は、滅菌は無効になります。

SEE ENCLOSED DIRECTIONS FOR USE FOR INDICATIONS AND CONTRAINDICATIONS

Voir le Mode d'Emploi ci-joint pour les Indications et Contre-indications

Bitte beachten Sie die beiliegende Gebrauchsinformation

Consultare le instruzioni per l'uso allegate, per le Indicazioni e le controindicazioni

Ver incluídas las instrucciones de uso para Indicaciones y contraindicaciones

適応、禁忌症については、同封の取扱説明書をご覧下さい。

WARNING:
To resterilize with either gas or steam, remove the product from the tray with clean instuments or gloved hands and place in a hospital sterilization pouch. Do not resterilize in the original container.

Expanded PTFE Vascular Graft
SINGLE USE

Type: STRAIGHT
Prod. Code: 40S06
Mfg. Date: Mar 1995 Lot No: 33797 VN
Lgth: 40cm I.D.: 6mm
Exp. Date: Mar 2000

CE 0344 S043356A

IMPRA®, M.R.
The Fine Line of Excellence

IMPRA, Inc.
P.O. Box 1740
Tempe, AZ 85280-1740
(602) 894 9515
FAX: (602) 966-7062

1-800-321-4254
USA & Canada

® IMPRA is a registered trademark of IMPRA, Inc.
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Printed in USA

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

S015548

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

256 235

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

This device complies with the requirements of Directive 93/42/EEC concerning medical devices.
Ce produit est conforme aux exigences essentielles de la Directive 93/42/CEE relative aux dispositifs médicaux.
Dieses Produkt entspricht der Richtlinie 93/42/EWG über Medizinprodukte.
Questo dispositivo è conforme ai requisiti della Direttiva 93/42/EEC concernente i dispositivi medici.
Este dispositivo cumple con los requisitos de la Directiva 93/42/EEC respecto a los dispositivos médicos.

CE
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IMPRA, Inc.
P.O. Box 1740
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1-800-321-4254
USA & Canada

Official European Representative Office
IMPRA MEDICA GmbH
Hofer Strasse 1
81737 München
GERMANY
Tel: 49 (89) 67.20.51
Fax: 49 (89) 67.92.242

S04778-

PTFE VASCULAR GRAFT

Directions for Use

Mode d'emploi
Gebrauchsinformation
Istruzioni per l'uso
Manual de uso
取扱説明書

IMPRA®
The Fine Line of Excellence

S01154F

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

Records processed under FOIA Request #2016-6076; Released by CDRH on 08-16-2016.

ENGLISH

DIRECTIONS FOR USE

Description:

IMPRA® grafts are constructed of expanded polytetrafluoroethylene (ePTFE). All IMPRA ePTFE vascular grafts are supplied sterile unless the package is opened or damaged. The graft is intended for single patient use only.

Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

Indications for Use:

IMPRA ePTFE grafts are indicated for use as a vascular prosthesis only. Insufficient clinical data is available on which to base any conclusions regarding the use of IMPRA grafts in aortocoronary bypass procedures or Thinwall grafts in blood access.

Straight and Tapered Configurations: The creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels.

IMPRA CenterFlex™, Stepped, and Short Tapered Configurations: The creation of subcutaneous arteriovenous conduits for blood access. Stepped and tapered configurations minimize the risk of steal syndrome and high cardiac output.

IMPRA CenterFlex, Stepped CenterFlex, and Short Tapered CenterFlex grafts have approximately 5.5 centimeters of an external spiral bead support in the center of the graft. This spiral support is NOT designed to be removed.

IMPRA Flex™ Configurations: With a removable external spiral bead support over the full length of the graft, are used in bypass or reconstruction of occluded or diseased vessels, where compression or kinking could jeopardize patency.

Vascular Patches and Short Segments: Repair and closure of peripheral veins and arteries; revision and patching of IMPRA grafts; and patching of the arteriotomy after endarterectomy.

Femoral Artery Access Cuff Configurations: Provides access to the femoral artery for the insertion of intra-aortic balloon pump catheters.

Contraindications:

1. Thinwall and Thinwall Flex grafts are NOT recommended for axillofemoral or axillobifemoral bypass procedures because of the danger of anastomotic disruption during extreme body movement.
2. IMPRA Flex grafts with external support over the full length of the graft are NOT recommended for blood access procedures.
3. IMPRA Vascular Patch grafts are NOT indicated for aortic or myocardial repair, pericardial membrane closure, or soft tissue repair.

Warnings:

1. In blood access applications, do NOT cannulate that portion of the CenterFlex graft with the external spiral support.
2. DO NOT REMOVE THE EXTERNAL SPIRAL BEAD SUPPORT FROM ANY CENTERFLEX CONFIGURED GRAFT. Attempts to remove the CenterFlex bead may damage the graft. If damage occurs, discard the graft.
3. IMPRA grafts and IMPRA Flex grafts are not elastic in the longitudinal direction. Therefore, care must be taken to cut the graft long enough to allow for a full range of body movements and to eliminate stress on the anastomoses in axillofemoral, axillobifemoral, or femorofemoral bypass procedures. Consider the patient's body weight and posture in determining the correct length to be implanted. This is especially true where stress may be placed on the axillary anastomosis during extreme body movement. Failure to cut the graft to an appropriate length may result in anastomotic disruption, leading to excessive bleeding, loss of limb or limb function, or death. Refer to page 3, "Axillofemoral Bypass Procedures," for further instructions.
4. Do not sterilize with any type of radiation sterilization equipment.

Precautions:

1. When using a Flex graft, slowly unwind the beading by peeling at a right angle to the graft. Rapid unwinding and/or removal of the beading parallel to the axis of the graft may damage the product. See page 2, "IMPRA Flex to Natural Vessel (End-to-Side)," for detailed instructions.
2. IMPRA and IMPRA Flex grafts are not radially elastic. Therefore, when embolectomy or balloon angioplasty catheters are used within the lumen of an IMPRA graft, care must be taken to match the inflated balloon size to the inner diameter of the graft. Over-inflation of the balloon or use of an inappropriate sized catheter may cause damage to the graft or to the balloon.
3. If clamping is necessary, use only atraumatic or appropriate vascular smooth jawed or shod clamps to avoid damage to the graft wall during implantation. Avoid repeated or excessive clamping at the same location on the graft.
4. Preclotting of this graft is unnecessary (see Reference #2). Attempts to preclot this graft or to immerse it in any solution prior to implantation may affect the hydrophobic properties of the graft, resulting in possible seroma formation when the graft is implanted.
5. Exposure to oil, alcohol, aqueous solutions, or these fluids under pressure can cause wetting. Wetting alters the hydrophobic properties of ePTFE which can result in excessive seroma formation.
6. When examining the anastomosis intraoperatively, do not forcibly inject any solution through the lumen of the graft as this may affect its hydrophobic properties, resulting in possible seroma formation. For more information, ask for Technical Report TR-100.

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7. Avoid filling the graft with blood or fluid prior to passing it through the tunnel. Pressure exerted on the graft may cause blood components to pass through the wall of the graft leading to possible seroma formation.

8. Utilization of a small diameter tapered, noncutting needle will minimize bleeding from suture holes. Topical thrombin and other hemostatic agents may be applied to the suture line to minimize bleeding.

9. During the early postoperative period, the natural progression of wound healing renders the graft translucent in appearance. When the material is in this state, it is recommended that a longitudinal incision with stay sutures be used for thrombectomy procedures. If a transverse incision is used, the use of a horizontal mattress suture technique and/or Teflon pledgets may be required to aid in closure.

10. Do not expose ePTFE to either an open flame or to a laser without first providing adequate ventilation since highly toxic decomposition products will be produced at temperatures above 400°C (752°F) (see Reference #1).

Adverse Reactions:

Potential complications which may occur with any vascular prosthesis include, but are not limited to: disruption or tearing of the suture line, graft, and/or host vessel; suture hole bleeding; thrombosis; seroma formation; swelling of the implanted limb; formation of hematomas or pseudoaneurysms; infection; steal syndrome; skin erosion.

Opening the Package:

Holding the outer tray in one hand, peel back the lid so the inner tray can be removed. Peel back the inner tray lid slowly and carefully remove the graft using sterile atraumatic instruments or gloves. Protect the graft against damage from sharp or heavy instruments.

Operative Techniques:

USE OF KELLY-WICK TUNNELER WITH IMPRA FLEX AND CENTERFLEX GRAFTS:

For IMPRA Flex, CenterFlex, and similar products, select a bullet tip one or two millimeters larger than the internal diameter (ID) of the graft being implanted to allow free passage of the Flex beading. For example, when implanting a 6 mm ID graft, use the 7 mm or 8 mm bullet tip to create the tunnel. If resistance occurs when pulling the graft through the tunnel, select the next larger sized bullet tip and resize the tunnel. Switch to a tip of the same size as the ID of the graft prior to pulling the graft through the tunnel.

Anastomotic Preparation:

For an end-to-side connection, fashion an "S" cut at the end of the graft (Figure 1).

Fig. 1

IMPRA Flex to Natural Vessel (End-to-Side):

To remove the Flex beading (see Precaution #1), hold the graft firmly with one gloved hand. With the other gloved hand, gently grasp and lift the end of the beading with gloved fingers or atraumatic instruments. Slowly unwind the beading by peeling at a right angle to the graft (Figure 2). Rapid unwinding and/or removal of the beading parallel to the axis of the graft may damage the product. In addition, the use of surgical blades or sharp instruments to remove the beading may damage the graft. If damage occurs, that segment of the graft should not be used. Remove and trim off only enough beading to fashion an "S" cut in the graft as illustrated in Figure 3.

Fig. 2 Fig. 3

IMPRA Flex to IMPRA Flex (End-to-Side):

Remove two or three short segments of beading with blunt-nosed scissors and cut a hole in the base tube as illustrated in Figure 4.

Fig. 4

Prepare second IMPRA Flex graft as illustrated in Figures 2 and 3 and suture together as shown in Figure 5.

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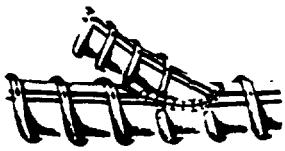

Fig. 5

IMPRA Flex to Natural Vessel or to IMPRA Flex (90° End-to-Side):

Trim the graft as close to the end of the beading as possible and suture as illustrated in Figure 6.

Fig. 6

IMPRA Flex to IMPRA Flex (End-to-End):

Align grafts such that the beading will form a continuous spiral and suture as illustrated in Figure 7.

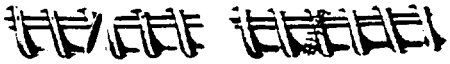

Fig. 7

Suturing:

Best results are achieved using a noncutting tapered needle with a nonabsorbable 5.0 or 6.0 monofilament polypropylene suture approximately the same size as the needle. An expanded PTFE suture may also be used with IMPRA grafts. Take 2 mm suture bites into the graft. Care must be taken to follow the curve of the needle (Figure 8) and pull the suture at a 90° angle to minimize suture hole elongation and bleeding (see Precaution #8 and #9).

Avoid the following: excessive tension which may cause suture holes to elongate or tear; undue tension on the suture line; gaps between the graft and host vessel; and inappropriate suture placement and bites. Failure to follow these suturing procedures may lead to anastomotic bleeding.

Application of a topical hemostatic agent will aid in controlling any bleeding that may occur (see Precaution #8). Always follow the manufacturer's instructions for these agents.

Fig. 8

Axillofemoral Bypass Procedures:

IMPRA Flex regular wall grafts are recommended for extra-anatomic procedures because of their resistance to compression and kinking (see Contraindications #1).

The recommended position for the axillary anastomosis is as medial as possible in the first third of the axillary artery (see Reference 3). Anchoring the anastomosis to the least mobile part of the artery will help prevent anastomotic disruption during sudden or full range of motion. Because IMPRA ePTFE grafts are not elastic in the longitudinal direction, it is imperative that the graft is cut long enough to allow full range of motion of the shoulder and arm. Full extension of the patient's arm (Figure 9) prior to cutting the graft for the axillary anastomosis will assure adequate graft length to minimize tension on the anastomosis.

By placing an IMPRA Flex graft under the major pectoral and minor pectoral muscles as well as tunneling close to the mid-axillary line, stress on the graft anastomosis is minimized. The patient should be made aware of the fact that sudden or extreme movements of the arm or shoulder should be totally avoided for a period of 6 to 8 weeks to allow for proper stabilization of the graft (see Warning #3).

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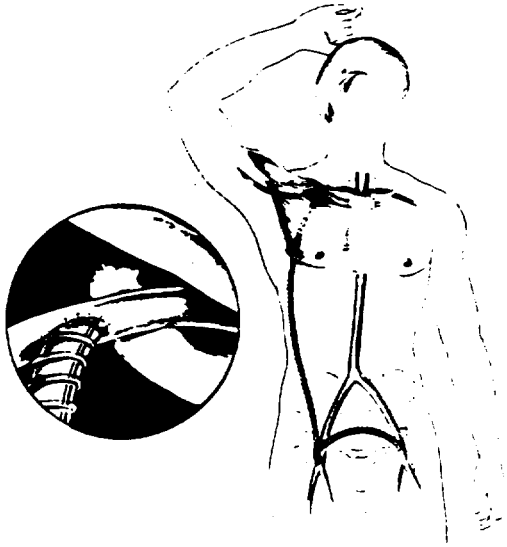

Fig. 9

Thrombectomy:

In the event of a postoperative occlusion, IMPRA grafts can be declotted as follows (see Precautions #2 and #9):

If a longitudinal incision is used, place stay stitches as illustrated in Figure 10 before introducing the embolectomy catheter.

Fig. 10

If a transverse incision is used, no stay stitch is necessary and a horizontal mattress suture technique will aid in closure (see Figure 11).

Fig. 11

Follow catheter manufacturer's instructions regarding size, selections, and balloon inflation, matching the balloon size to the inner diameter of the graft.

Do not place undue stress on the anastomosis or incision when placing or removing the catheter.

In the event of postoperative occlusion, IMPRA Flex grafts can be declotted as follows (see Precautions #2 and #9):

If a longitudinal incision is used, cut through the spiral beading and base tube as illustrated in Figure 12. After closure, the spiral beading will realign itself.

Fig. 12

If a transverse incision is used, a horizontal mattress suture (Fig. 11) technique will aid in closure.

Angiography:

Should angiography be performed at the time of the procedure, the artery proximal to the graft should be used for injection if possible.

Angioaccess:

1. When implanting a non-externally supported graft, care should be taken to create a subcutaneous tunnel that approaches in size the diameter of the graft. This can be accomplished with dilation using a Kelly-Wick tunneler, thus allowing a snug fit in order to minimize the chance of subcutaneous bleeding. See instructions for "Use of IMPRA KELLY-WICK TUNNELER WITH IMPRA FLEX AND CENTERFLEX GRAFT." Ask for Technical Report TR-101 for additional information.
2. It is recommended that the graft be left in place for approximately two weeks prior to use. Immediate use will significantly increase the risk of hematoma formation within the tunnel.
3. For proper cannulation, insert the blood access needle at a 45° angle with the bevel up until the graft is penetrated (see Figure 13). The needle is then advanced parallel to the graft. If the blood access needle is inserted such that the angle between the needle axis and the graft is too small, tears in the superficial wall of the graft can occur. If the needle is inserted at a 90° angle, puncturing the far wall of the graft is possible, leading to hematoma formation.

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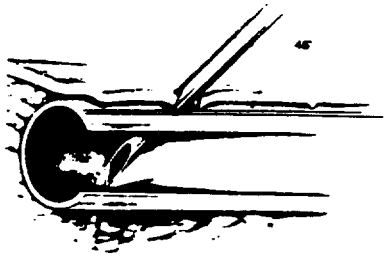

Fig. 13

4. ROTATE CANNULATION SITES. Repeated cannulation in the same area may lead to damage of the graft wall or formation of a perigraft hematoma or pseudoaneurysm.
5. When the CenterFlex graft is used for blood access, do NOT cannulate at or near that portion of the graft with the external support as illustrated in Figure 14.

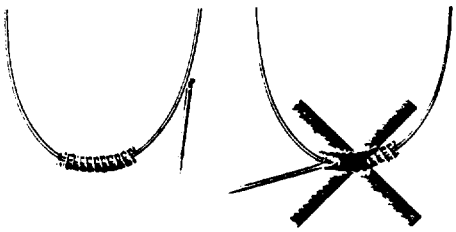

Fig. 14

6. Do not cannulate within 1" of proximal and distal anastomosis (see Figure 15).

Fig. 15

7. Strict adherence to aseptic technique is recommended to minimize infection.
8. After needle withdrawal, use moderate digital pressure to compress the cannulation site to assist in hemostasis. Use of commercially available stasis clamps may lead to clot formation, restricting flow through the graft.

Femoral Artery Access Cuff (Flanged) Graft Insertion:

Place the flanged graft over the shaft of the IABP (intra-aortic balloon pump) catheter with the flanged end toward the artery. Suture the flanged end to the arteriotomy as shown in Figure 16.

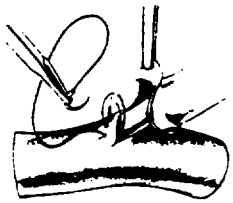

Fig. 16

After the balloon has been positioned, tie a suture around the graft as close as possible to the flanged end to effect a proper seal around the balloon catheter. Upon termination of the IABP procedure, the graft may be used as a patch for the arteriotomy.

Resterilization Instructions:

IMPRA ePTFE grafts and vascular patches can be resterilized ten times by either gas or steam as long as they have not been contaminated with blood or any foreign material. To resterilize, gently remove the graft or vascular patch from the plastic tray with clean atraumatic instruments or gloved hands and place in a hospital sterilization pouch. Sterility of resterilized IMPRA grafts is the responsibility of the hospital facility. DO NOT STERILIZE WITH ANY TYPE OF RADIATION STERILIZATION EQUIPMENT.

Steam:

1. Gravity Displacement Minimum Requirements:
   250°F (121°C) for 30 minutes at 15 psi (1.034 BAR)
   270°F (132°C) for 15 minutes at 30 psi (2.07 BAR)
2. Prevacuum (flash) Minimum Requirements:
   270°F (132°C) for 4 minutes at 30 psi (2.07 BAR)

Expanded PTFE should NEVER be exposed to temperatures in excess of 482°F (250°C).

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Ethylene Oxide (ETO) Gas:

Follow your specific sterilizer equipment manufacturer's recommendations, or utilize cycles which have been previously established and validated for your facility.

Vascular Education Services:

Various educational materials, in-services, and workshops are available. For further information, call 1-800-321-4254 in the U.S.A. and Canada or the company listed below.

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ATTACHMENT 8

Clinical Papers Reference Information

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ePTFE arteri

Expanded polytetrafluoroethylene arterial prostheses in humans: chemical analysis of 79 explanted specimens

Robert Guidoin, Sophie Maurel, Nabil Chakfé, Thien How*, Ze Zhang, Marie Therrien, Maxime Formichi and Camille Gosselin
Department of Surgery, Laval University, and Biomaterials Institute, St-François d'Assise Hospital, Québec, QC, Canada

The expanded polytetrafluoroethylene (ePTFE) vascular prostheses are widely used as small and medium diameter blood conduits when an autologous venous material is not available or is not suitable. The long-term performance of a prosthesis is dependent on several factors, including its healing characteristics and its stability *in vivo*. This study was undertaken to assess whether chemical degradation of ePTFE occurs when such arterial substitutes are implanted in humans. Seventy-nine ePTFE grafts excised for complications were analysed using the following techniques: measurement of the contact angle (θ), electron spectroscopy for chemical analysis (ESCA or XPS), Fourier transform infra-red spectroscopy (FTIR) and differential scanning calorimetry (DSC). The results were compared with those obtained from virgin ePTFE and virgin ePTFE washed prostheses. The measurement of the contact angle (θ) permits the comparison of the level of hydrophobicity of material after *in vivo* residency. The contact angles of explanted ePTFE grafts are greater than those of virgin ones but remain close to those of washed virgin prostheses. The ESCA method allowed investigation of the chemical changes which occur on the surface of ePTFE prostheses after implantation because of the low penetration of the X-ray (about 50 Å). This study did not reveal any chemical degradation of the ePTFE with time of implantation for periods up to 6.5 yr. Changes in the surface composition were probably related to lipid and/or protein uptake. The FTIR spectroscopy provides information about the chemical composition of material. Compared with the virgin ePTFE prostheses, the FTIR spectra of explanted prostheses showed specific bands which are characteristic of lipid and/or protein absorptions. The bulk properties of ePTFE studied by DSC did not show any significant changes with time of implantation. It is concluded that ePTFE grafts remain stable *in vivo* for periods up to 6.5 yr.

Keywords: Vascular prostheses, polytetrafluoroethylene, grafting, blood conduit

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The expanded PTFE vascular graft, first introduced clinically in the mid-1970s, is now widely used in biomedical applications. Its major field of application is in vascular surgery, where it is used as a blood conduit for arterial[1,2] and venous[3] reconstruction or as an arterio-venous shunt for haemodialysis blood access[4,5]. It is also used as a patch for arterial angioplasty[6], for the repair of congenital heart defects[7,8] and, more recently, as a suture[9] material. Expanded PTFE (ePTFE) patches have also been used for hernia repair[10] and, more recently, as a substitute for the anterior cruciate ligament[11,12].

Expanded PTFE vascular prostheses are widely recognized as good alternatives for the bypass of peripheral arteries when the autologous saphenous vein is not available or is not suitable[2,13-15]. While their clinical performance has been studied and reported extensively, little work has been undertaken to investigate their physico-chemical characteristics. There remains a lack of understanding of the *in vivo* behaviour of ePTFE in reference to its stability in biological systems.

One of the first reported causes of failure of ePTFE vascular prostheses was related to a wall weakness which resulted in aneurysm formation. These early cases of dilatation were addressed by the two major manufacturers in different ways. One solution was to provide an external reinforcement wrap of microfibrillar PTFE to provide increased circumferential strength (Gore-Tex® Vascular Grafts, W.L. Gore & Associates Inc., Flagstaff, AZ, USA) (*Figure 1*). The other approach was merely to increase the wall thickness of the grafts (Impra® grafts,

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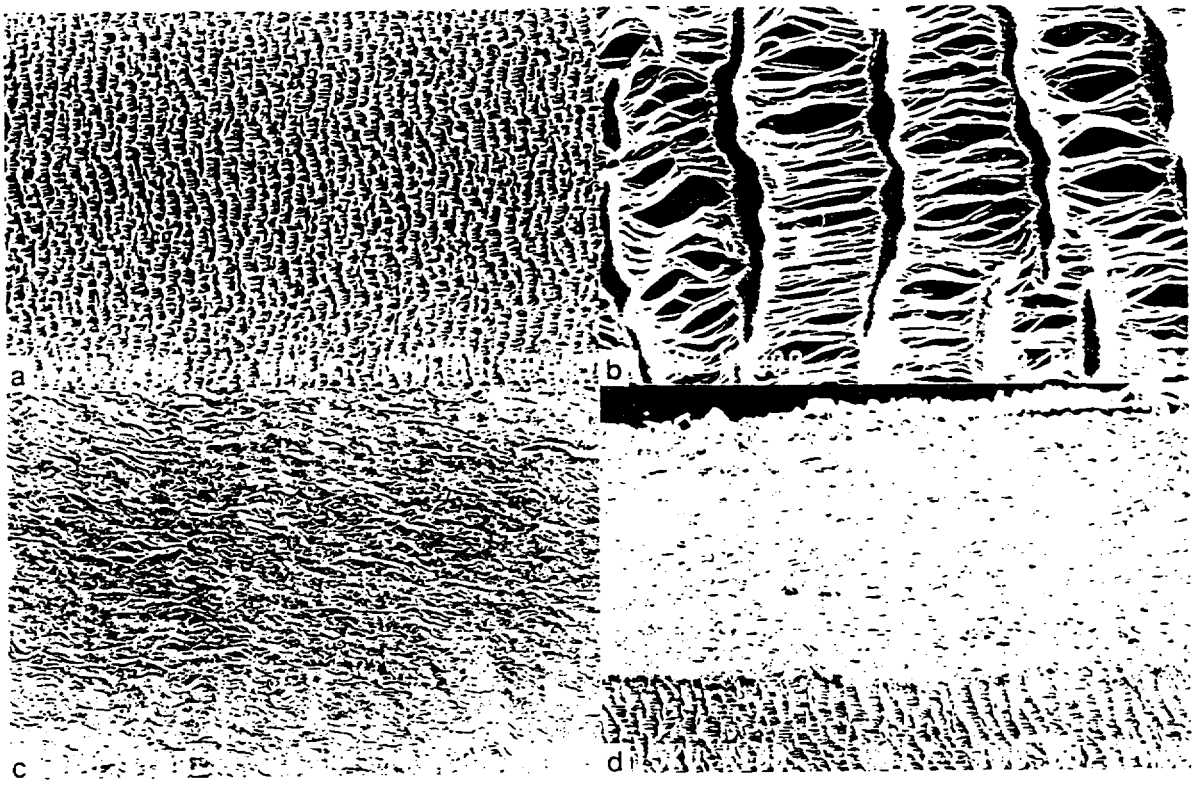

Figure 1 Scanning electron photomicrographs of the virgin reinforced Gore-Tex prosthesis: **a, b,** luminal surface; **c,** external surface; **d,** cross-section.

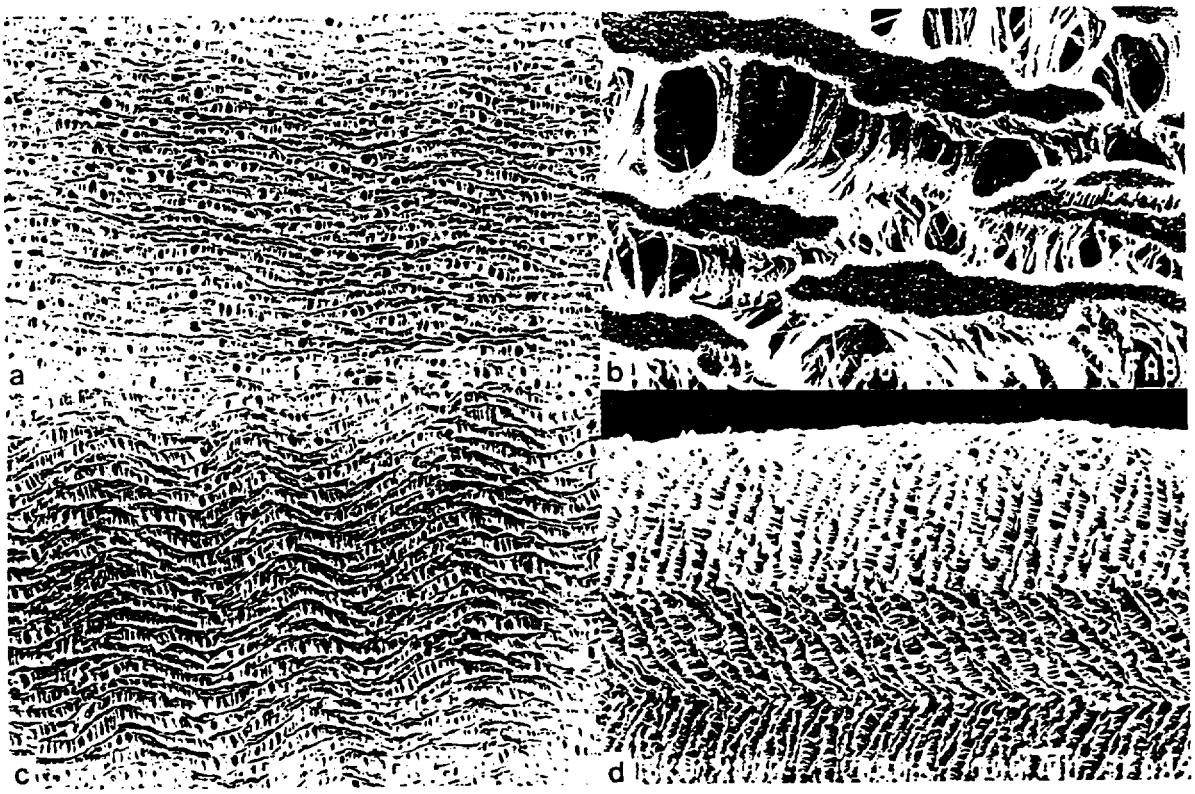

Figure 2 Scanning electron photomicrographs of the virgin Impra prosthesis: **a, b,** luminal surface; **c,** external surface; **d,** cross-section.

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Table 1 Comparison of the four techniques used in this study

	Surface required (cm^2)	Depth of analysis	Number of grafts on which analysis was carried out	Types of information	Types of data
Contact angle	3	Two or three outer atomic layers	53	Surface wettability	Water/PTFE angle (°)
ESCA	2	50 Å	79	Surface elemental composition	% F:C % O
FTIR	4	0.4–2.3 m	25	Molecular bondings	Absorbance position (cm^{-1}) and intensity
DSC (°C)	1	Bulk material	79	Thermal behaviour	Melting point Heat of fusion (J/g)

Impra Inc., Tempe, AZ, USA) (*Figure 2*). We previously investigated explanted ePTFE grafts and we observed some alterations[16]. Therefore, we questioned the chemical stability of the ePTFE by analysing 79 explanted specimens. The specimens were analysed by means of four physico-chemical techniques; namely, measurement of the contact angle (θ), electron spectroscopy for chemical analysis (ESCA or XPS), Fourier transform infra-red spectroscopy (FTIR) and differential scanning calorimetry (DSC) in order to determine any chemical change in the explanted grafts compared with the virgin ePTFE (*Table 1*).

MATERIALS AND METHODS

Material

Prostheses

Between 1979 and 1988, 370 microporous ePTFE vascular grafts were collected from more than 20 hospitals across Canada, France and Italy. Forty-six of these had been implanted as arterio-venous shunts. Of the 324 remaining specimens used for arterial reconstruction, 26 were excluded because of lack of clinical information. Minimum information for the inclusion of a specimen in this study was implant site and date of implantation. The 298 remaining specimens have been described extensively in the parallel study of the healing characteristic of these grafts[17].

For this study, we selected from the pool of 298 specimens a sub-group of 79 which had an adequately large surface area for the chemical tests, and where the clinical history of the patients was sufficient. Not all of these specimens had the minimum surface area requirement of 10 cm^2 (*Figures 3* and *4*). Consequently, only 20 underwent all the tests while all of the remaining 59 specimens were analysed by ESCA and DSC. Contact angle and FTIR were performed on some samples (*Table 2*).

These 79 ePTFE grafts were retrieved from autopsies and reoperations after periods of implantation ranging from 1 to 2451 d (6.5 yr) (*Figure 5*), with an average duration of 522 d. They were retrieved in 15 surgical centres in Canada, France and Italy from 79 patients (67 men, 11 women and one non-documented case) whose mean age at implantation was 62 yr (range: 33–88 yr) (*Table 3*).

The indications for operation were mainly rest pain and gangrene (*Table 4*), and the majority of the grafts were implanted as femoropopliteal and axillofemoral bypass (*Table 5*). The two principal causes of explantation of the prostheses were thrombosis and infection (*Table 6*). The numbers of grafts examined by each analytical technique as a function of the sites of implantation are

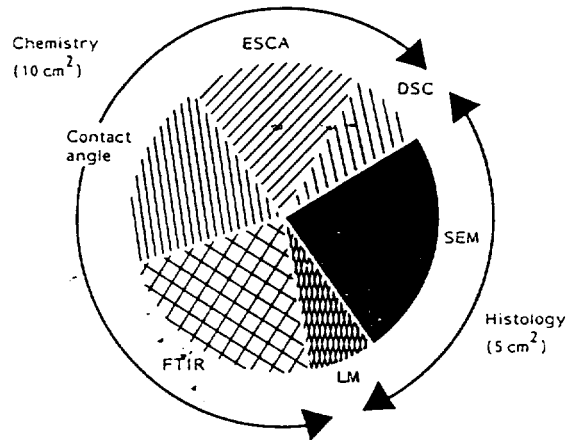

Figure 3 Surface of graft necessary for the chemical analysis after pathological study.

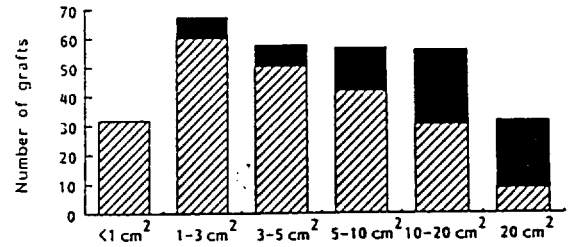

Figure 4 Selection of the 79 explanted grafts among the 298 specimens investigated extensively for the healing characteristics. ■, Grafts used for chemical analysis; ▨, remaining grafts of the retrieval programme.

Table 2 Number of prostheses in which each chemical analysis technique was performed

Contact angle	ESCA	FTIR	DSC	
×	×	×	×	20
	×	×	×	5
×	×		×	33
	×		×	21
53	79	25	79	

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Table 3 Number of prostheses on which chemical analysis was performed, the origin of the prostheses and sites of implantation

Origin	Site			Total chemical analysis
	Femoropopliteal	Femorodistal	Extra-anatomic	
Canada excluding PQ	4	0	2	6
PQ excluding QC	1	0	1	2
QC	30	2	9	41
Total Canada:	35	2	12	49
France excluding Nice	8	0	5	13
Nice	2	1	11	14
Total France:	10	1	16	27
Italy	3	0	0	3
Total:	48	3	28	79

PQ, Province of Québec; QC, Québec City.

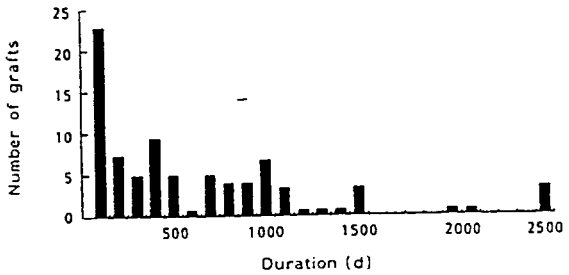

Figure 5 Duration of implantation of the 79 explanted prostheses investigated for chemical characteristics.

Table 4 Indication for operation; the second column gives the number of prostheses for each indication for the sub-group of prostheses on which chemical analyses were carried out

Indication for operation	Number of prostheses (chemical analysis)
Claudication	15
Rest pain	30
Gangrene	17
Aneurysm	3
Acute ischemia	5
Subacute ischemia	5
Other	3
Unknown	1
Total:	79

reported on *Table 7*. The sites of implantation were divided into extra-anatomical (axillofemoral, femorofemoral and axillopopliteal) and anatomical sites (femoropopliteal and femorodistal) in order to evaluate whether the fatty subcutaneous environment in which the extra-anatomical grafts are placed could affect the stability *in vivo*.

Of the 79 grafts, 72 were reinforced Gore-Tex vascular grafts, three Impra grafts and four thin-walled reinforced Gore-Tex vascular grafts (*Figure 6*). The internal diameter was 8 mm for 38 grafts, 6 mm for 34, and for the remaining seven grafts it was not indicated and could not be determined. The year of implantation of the grafts was noted, as it provides a rough indication of the year of its manufacture. This is relevant, since modifications to the grafts were made by the manufacturers at various times.

Retrieval programme

This work is part of an ongoing co-operative retrieval programme for collecting and evaluating arterial prostheses implanted in humans. A standard procedure was developed for the preparation of all the graft specimens.

After excision, the prostheses were opened longitudinally and rinsed carefully with heparinized saline. They were fixed and stored in a buffered solution of 1.5% glutaraldehyde and then sent to the Institut des Biomatériaux, Hôpital St-François d'Assise (Québec, Canada) for analysis. These prostheses were first examined macroscopically and photographed. Representative areas of the internal and external capsules were selected for pathologic studies and scanning electron microscopy (SEM).

Table 5 The mean duration and the sites of implantation of the prostheses on which chemical analyses were performed

Site	Number of specimens	Duration of implantation (d)
Femoropopliteal	48	586
Femorodistal	3	927
Extra-anatomic	28	371

Table 6 The main causes for explanation of the prostheses

Reasons for explanation	Chemical analysis sub-group number of prostheses
Thrombosis	42
Infection	23
Autopsy	7
False aneurysm	3
Anastomotic stenosis	2
Unknown	2
Total:	79

The specimens were then subjected to a standard washing process to remove all adherent tissues. This was accomplished by boiling the specimens for 5 min in a 5% sodium bicarbonate solution followed by immersion in a commercial bleach solution, twice for 2 h each, at room temperature. Finally, the specimens were rinsed in

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Table 7 Number of prostheses retrieved from the three main sites examined by each of the four chemical analysis techniques

Sites available	Number of prostheses	Contact angle	ESCA	FTIR	DSC
Femoropopliteal	48	30	48	13	48
Femorodistal	3	3	3	2	3
Extra-anatomic	28	20	28	8	28
Total:	79	53	79	23	79

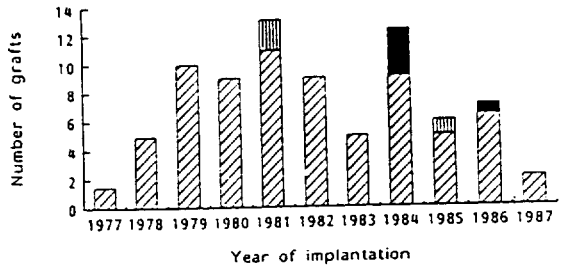

Figure 6 Types and number of prostheses per year of implantation. ▥, Impra; ■, Gore-Tex thin wall; ▨, Gore-Tex.

distilled water for at least 1 h. After drying at room temperature for 24 h, the specimens were stored in capped Petri dishes.

The cleaned specimens were examined macroscopically and photographed. Some were prepared for SEM examination and those to be used for chemical analyses were dried in a vacuum oven at 40 ± 2°C for 48 h and stored in tightly capped bottles.

The minimum quantity of the samples required for the four chemical analyses were: one sample of 2 cm^2 for FTIR spectroscopy and, finally, a piece of prosthesis weighing between 5 and 10 mg for DSC.

Methods

Contact angle (θ)

The sessile drop method using a standard Ramehart contact angle goniometer, at constant temperature, pressure and humidity, was employed for this study. A drop of distilled and filtered water was placed on the surface of the flattened sample by means of a micrometer syringe and the angle formed between the tangential line of the drop and the sample surface (the contact angle) was measured. For each surface of explanted prosthesis, at least five drops were placed, the contact angles measured at two diametrically opposite sides of the drops, and the average angle was determined. It was assumed that an equilibrium contact angle was reached when the angle no longer changed with time[18].

Contact angle measurements were also performed on virgin washed prostheses, in order to evaluate surface modifications which may have been induced by the standard washing procedure.

The results were analysed in terms of several clinical parameters such as duration, year and site of implantation, and diagnosed infection, in order to determine whether there is any correlation between contact angle and these parameters. The depth of analysis is about two or three outer atomic layers (*Table 1*).

Electron spectroscopy for chemical analysis (ESCA or XPS)

Both internal and external surfaces of the virgin and explanted prostheses were investigated with a VG Scientific Escalab MK II which uses a Mg Kα soft X-ray beam of 1253.6 eV energy, operated at 12 kV and 20 mA. The pressures in the preparation and analytical chambers ranged from 10^{-7} to 10^{-9} torr and 8×10^{-5} to 10^{-10} torr, respectively. A pass energy of 200 eV was used to collect the widescan spectra. This was reduced to 20 eV for the high resolution spectra of the C1s.

Surface elemental compositions relative to fluorine were calculated from peak intensities on the survey scans with correction for atomic sensitivity[19]. The penetration of X-ray in the surface of material is about 50 Å (*Table 1*).

Fourier transform infra-red spectroscopy

The washed specimens were flattened and pressed against a ZnSe crystal on which the incident beam angle was 45° (index of refraction 2.4). The crystal was then mounted in a reflectance attachment (Harrick Company, NY, USA). The spectra were acquired using a Bomem DA3-0.02 FTIR spectroscope.

The sampling depth investigated was from 0.4 to 2.3 m (*Table 1*) for the scanning range 4000–700 cm^{-1}, according to the equation proposed by Harrick[20]. Typically, 500 scans were averaged for each spectrum, with 2 cm^{-1} resolution.

Differential scanning calorimetry

A computer controlled differential scanning calorimeter (DSC 7, Perkin-Elmer, Analytical Instruments Division, Montréal, Canada) was used to characterize the thermal properties of the ePTFE specimens. The measurements were made from 280 to 400°C at a scanning rate of 10°C/min. The samples, weighing from 5 to 10 mg, were placed in solid standard aluminium pans after being dried in a temperature controlled vacuum oven for at least 48 h at 40 ± 2°C. After the first scan, each specimen was quenched *in situ* to 280°C and a second scan was performed under the same conditions. All measurements were made using an indium reference.

RESULTS

Contact angle

The contact angle measurements were performed on 53 explanted ePTFE vascular grafts, 51 of which were reinforced Gore-Tex vascular grafts, one thin-walled Gore-Tex vascular graft and one Impra. Thirty prostheses have been retrieved from the femoropopliteal site, three from the femorodistal site and 20 from the extra-anatomic site (*Table 7*). The mean values of contact angle

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Table 8 Means and standard deviation of contact angle measurements on virgin, virgin washed and explanted grafts

Grafts	Contact angle (θ)	
	Internal side	External side
Virgin Impra	108.6 ± 4.1° (N = 1)	104.7 ± 6.1° (N = 1)
Virgin Gore-Tex	110.3 ± 3.9° (N = 1)	94.6 ± 5.8° (N = 1)
Washed virgin Impra	145.3 ± 3.7° (N = 1)	136.6 ± 5.6° (N = 1)
Washed virgin Gore-Tex	147.1 ± 3.8° (N = 1)	139.2 ± 5.4° (N = 1)
Washed explanted PTFE	144.7 ± 4.6° (N = 46)	136.3 ± 7.1° (N = 48)

Means were calculated from 10 measurements performed on five different locations of each of the N samples examined.

in these grafts were 136.3 ± 7.1° for the external surface (n = 48) and 144.7 ± 4.6° for the internal surface (n = 46) (*Table 8*). In seven samples, the results were not meaningful since the water droplet was gradually absorbed into the material leaving only a thin film on the surface. The contact angle was essentially 0° in these cases and was excluded in the calculation of the mean values.

As shown in *Table 8*, the mean values of contact angle were similar for Gore-Tex vascular grafts and Impra grafts. As in the case of explanted grafts, the contact angles were always greater on the internal than on the external surfaces. The contact angles were greater in the washed virgin grafts, on both surfaces, than in the untreated virgin grafts, but were very similar to those of the explanted grafts.

No significant trend was observed in contact angle with the duration, year and site of implantation, or with diagnosed graft infection.

Electron spectroscopy for chemical analysis (ESCA or XPS)

For the ESCA analysis, 79 explanted specimens have been studied (*Table 7*). These prostheses have been retrieved from the three main sites (48 from the femoropopliteal site, three from the femorodistal site and 28 from the extra-anatomic site). The survey scans for the virgin prostheses indicated the presence of mainly fluorine and carbon. Virtually no oxygen was detected (*Table 9*). Polytetrafluoroethylene, a fully fluorinated polymer $(-CF_2-CF_2)_n$, is made up of two times more fluorine than carbon atoms, implying that the ratio F:C should be two; but in practice the ratio deviates from this value because of the influence of impurities, end groups and laboratory contamination. In the case of the virgin ePTFE grafts, the F:C ratio averaged 1.6 (*Table 9*).

The C1s spectra of virgin prostheses on both the internal and external surfaces generally have one major peak corresponding to the CF_2 bondings at about 292.3 eV binding energy and a smaller peak from C–C bondings at 285.0 eV overlapped with a broad satellite shoulder.

The main difference between virgin washed prostheses was the presence on the latter of a small amount of oxygen (<13%), originating from the detergent used in the standard washing procedure (*Table 9*). The F:C ratio of these washed prostheses was very similar to that of the virgin grafts. We also observed minor contaminations, such as sodium and chlorine, which may be attributed to the washing process in which sodium bicarbonate and bleach were used. The detection of silicon was not surprising, since it is a common contaminant in the laboratory atmosphere.

High resolution scans of washed, virgin grafts showed a more complex C1s spectrum, since they exhibited an additional C–O bonding peak at 286.0 ± 0.1 eV in between the CF_2 and CC peaks.

The high resolution C1s spectra, determined in 59 explanted specimens, also showed, in general, these two well-separated strong peaks, but with an increased intensity of the C–C bondings. In some specimens, another small peak overlapping the C–C bonding peak was observed and was attributed to the presence of C–O groups. *Table 10* gives the peak assignment for the C1s spectra.

The survey scans in all explanted specimens were recorded and the levels of various contaminants determined. In addition to minor contaminations on all the explanted samples, larger amounts of oxygen and carbon were detected in some of the samples (*Figure 7*). This was accompanied by decreased F:C ratios ranging from 1.2 to 1.8 in slightly contaminated samples for the 79 specimens studied. The F:C ratios in the explanted specimens were assessed in terms of four parameters, namely the duration, year, site of implantation and the presence of clinical infection. There was no observable trend between the four clinical parameters and the oxygen content and F:C ratio.

The low F:C ratios were often related to a high oxygen content (see explant no. 1 in *Table 9*). We postulated that a high level of oxygen could be related to a lipid uptake, rather than a protein uptake, because of the absence of nitrogen in most of the cases. The F:C ratio is modified, not only by degradation of the material, but also by this lipid uptake. In order to assess the usefulness of the F:C ratio as an alteration index, we retained only the prostheses with an oxygen content lower than 3%, as this excludes all specimens without proteins or lipids. This threshold of 3% was chosen because it corresponded to the maximum content of oxygen detected in the washed virgin prostheses (*Table 9*). In these specimens, the mean F:C ratio was found to be 1.66 ± 0.07 and remained relatively constant with the time of implantation (*Figure 8*). In contrast, when the oxygen level was higher than 3%, the F:C ratio varied erratically. Low F:C ratios always occurred in samples with high oxygen content.

Fourier transform infra-red spectroscopy

Only 23 specimens have been studied using FTIR (*Table 7*) (13 from femoropopliteal sites, two from femorodistal

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Table 9 Elemental composition from ESCA survey scan results for internal and external surfaces of virgin, virgin washed and some of the explanted ePTFE prostheses

Prosthesis	Year of implantation	Duration of implantation (d)	Surface	%C	%F	%O	%F:%C
Virgin Gore-Tex			Internal	39	61	0	1.6
			External	38	62	0	1.6
Virgin Impra			Internal	39	61	0	1.6
			External	39	61	0	1.6
Virgin Gore-Tex Washed			Internal	37	60	3	1.6
			External	38	59	3	1.6
Virgin Impra washed			Internal	36	60	4	1.7
			External	37	61	2	1.6
Explant no. 1	1979	2	Internal	42	49	9	1.2
			External	37	61	2	1.6
Explant no. 2	1981	21	Internal	36	61	3	1.7
			External	37	61	2	1.6
Explant no. 3	1981	31	Internal	37	61	2	1.6
			External	37	61	2	1.6
Explant no. 4	1981	92	Internal	37	61	2	1.6
			External	35	62	3	1.8
Explant no. 5	1984	137	Internal	38	59	3	1.6
			External	39	58	3	1.5
Explant no. 6	1983	279	Internal	36	62	2	1.7
			External	36	61	3	1.7
Explant no. 7	1982	301	Internal	35	62	3	1.8
			External	36	61	3	1.7
Explant no. 8	1980	306	Internal	37	61	2	1.6
			External	36	61	3	1.7
Explant no. 9	1986	335	Internal	38	59	3	1.6
			External	39	59	2	1.5
Explant no. 10	1980	353	Internal	36	61	3	1.7
			External	36	62	3	1.8
Explant no. 11	1979	379	Internal	37	60	3	1.6
			External	37	60	3	1.6
Explant no. 12	1979	486	Internal	37	61	2	1.6
			External	38	61	1	1.6
Explant no. 13	1978	648	Internal	37	62	1	1.7
			External	37	62	1	1.7
Explant no. 14	1978	784	Internal	37	61	2	1.6
			External	37	61	2	1.6
Explant no. 15	1985	848	Internal	36	60	4	1.7
			External	36	61	3	1.7
Explant no. 16	1979	943	Internal	37	61	2	1.6
			External	37	61	2	1.6
Explant no. 17	1978	1463	Internal	36	62	2	1.7
			External	36	61	3	1.7
Explant no. 18	1977	2451	Internal	35	62	3	1.8
			External	35	62	3	1.8

Trace elements of silicon, sodium and chlorine were also detected in the virgin explanted prostheses.

Table 10 Peak assignment of C1s ESCA high resolution spectra

Groups	Bonding energy (eV)
C–C	285.0
C–O	286.5
F–C–F	292.3

and eight from extra-anatomic sites). The typical spectrum for virgin PTFE prostheses covering the range 700–4000 cm^{-1} consisted of two major peaks at 1209 and 1146 cm^{-1} which were assigned to symmetric and asymmetric CF_2 stretch and CC stretch, and minor peaks near 2851 and 2931 cm^{-1} related to CH stretching modes.

Differential scanning calorimetry

For the DSC analysis, 79 explanted specimens have been studied (*Table 7*). These prostheses have been retrieved from the three main sites (48 from the femoropopliteal site, three from the femorodistal and 28 from the extra-anatomic site). The first and second fusion curves for the 79 explanted grafts and the virgin prostheses did not reveal obvious differences among them. A typical virgin spectrum exhibited a major fusion peak centred at 330°C and a small endothermal peak at 380°C. During the second fusion experiment, the smaller peak was found to be significantly decreased in height (*Figure 10*). The first fusion spectrum in most specimens included a flat portion or shoulder at the upper temperature side of the major peak which disappeared on the second fusion spectra. This flat portion is probably caused by a small peak and represents the unsintered component in the material.

The first mean melting temperature, measured at the end of the peak, was 330 ± 1°C, the same as the second melting temperature (see *Figure 10*). In the explanted specimens, these values were not found to be affected by

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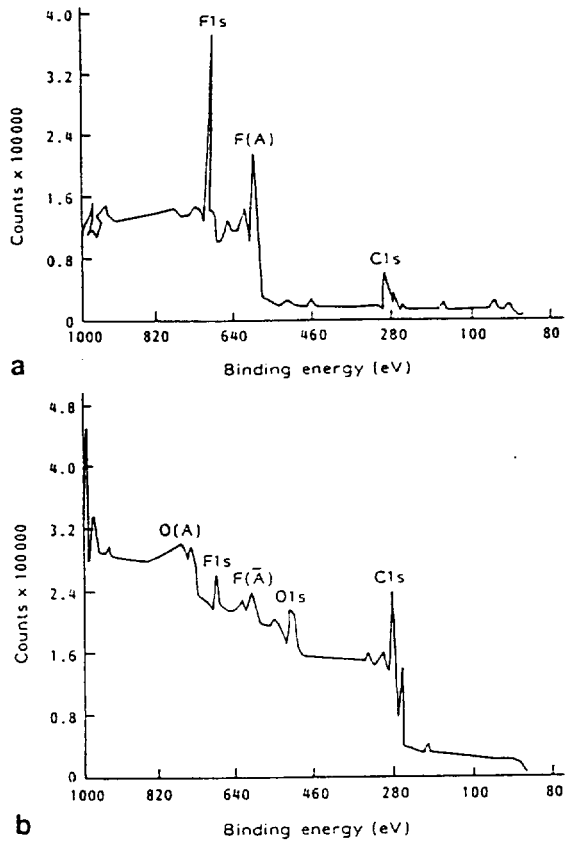

Figure 7 **a**, Typical ESCA survey scan spectra; **b**, heavily contaminated grafts

either duration, year and site of implantation, or the presence of clinical infection (*Table 12*).

Of the 79 prostheses studied, only three were Impra grafts. Their fusion curves were less symmetric than those of Gore-Tex vascular grafts, suggesting that the Impra grafts have a slightly greater unsintered component than Gore-Tex vascular grafts.

DISCUSSION

The methodology

With a study based on a prostheses retrieval programme there are inherent limitations which must be borne in mind. All the retrieved specimens were surgically excised for complications such as thrombosis, infection or false aneurysm formation[17]. The alteration in chemical properties undergone by these grafts may not necessarily be the same as those of patent and uncomplicated grafts. Biopsy of patent grafts, which has been carried out in humans[21], is not a practical proposition for obvious reasons.

Despite these limitations, a retrieval programme does have certain advantages when compared with experimental studies. Although *in vitro* tests can provide information on the mechanical or chemical stability of a biomaterial, the *in vivo* conditions in humans cannot be duplicated accurately. Animal experiments can provide

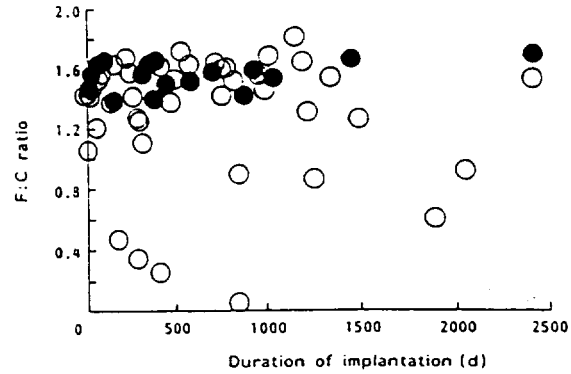

Figure 8 F:C ratio on external sides of explanted grafts *versus* duration of implantation and oxygen level. ○, % F:C external (% O > 3); ●, % F:C external (% O < 3).

Table 11 Peak assignment FR spectra obtained from the explanted grafts

Frequency (cm^{-1})	Relative intensity*	Main assignments†
2922	w	$\nu_a(-CH_2-)$
2851	w	$\nu_s(-CH_2-)$
1740	w	$\delta(-C=O)$
1466	vw	$\delta(-CH_2-)$
1382	vw	$\delta(-CH_3)$
1204	vs	$\nu_s(C-F)$
1149	vs	$\nu_a(C-F)$; $\delta(C-C)$

*Relative intensity based on sample at room temperature. vw, very weak; w, weak; vs, very strong.
†ν_a, asymmetric stretching; ν_s, symmetric stretching; δ, bending.

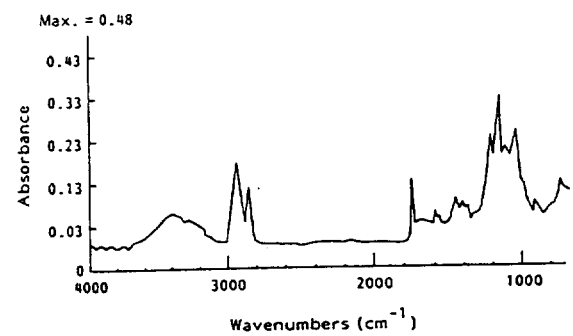

Figure 9 Typical FTIR spectrum of explanted PTFE graft.

useful data on the performance of vascular grafts but there are interspecies differences in healing[22] and, moreover, these experiments are rarely conducted for periods exceeding 6 months.

The four chemical analysis techniques were chosen because they are well established in biomaterials investigations and also because the results are complementary. As shown in *Table 1*, different depths of the biomaterials are analysed and each technique yields data on a different aspect of the chemical behaviour of ePTFE.

The purpose of the contact angle study was to determine the surface wettability of explanted PTFE vascular grafts by liquid–solid angle measurement. This method has been reported to give useful information with

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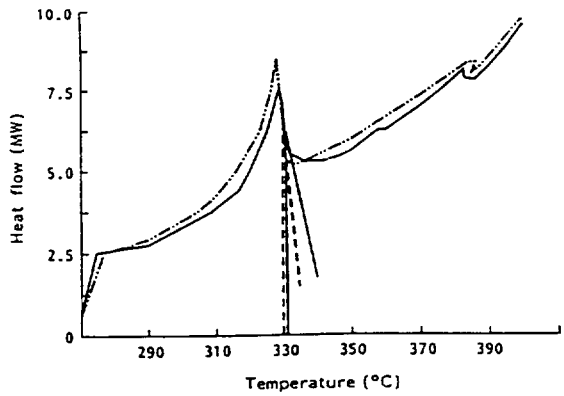

Figure 10 Representative DSC curves of explanted PTFE graft. ——, First melting; —· ·—, second melting.

regard to the modification of the surface chemical properties induced by contact with blood[23]. Indeed, it is known to be a valuable tool in comparing the relative hydrophobicity of fluorinated polymers[24] and other polymers used for biomedical applications[25].

X-ray photoelectron spectroscopy (XPS), also named electron spectroscopy for chemical analysis (ESCA), is based upon the kinetic energy analysis of photoelectrons ejected from the sample surface by a beam of soft X-rays. Only the electrons emitted from the surface region (10–200 Å), which is not involved in collisions, will contribute to the photoemission signal. ESCA was used here as it can provide either elemental composition or detailed structural information of the uppermost layer of the graft samples[26, 27].

FTIR is a widely used method to determine the chemical composition of polymers. It is useful for the comparison of the internal and external surfaces of prostheses. It was employed here to compare the structure of virgin and explanted grafts in order to identify the presence of contamination at a depth of 2.3 m.

DSC measures the amount of energy absorbed or released by a sample as it is heated, cooled or held at a constant temperature, thus allowing accurate measurements of either its endothermic or exothermic behaviour such as the melting temperature. This technique allows the calculation of the degree of sintering of ePTFE which is known to influence its mechanical properties[28, 29].

The implications of the results

Contact angle

Contact angle measurements on polymer surfaces are usually made with samples obtained from commercial sources, and they often contain additives which have hydrophilic properties and tend to concentrate at the surface[30]. This may result in lower contact angles with liquids such as water. The contact angle for water on virgin PTFE is known to be high for such a hydrophobic polymer. Fowkes *et al.*[31] reported a value of 107.9°, Collins *et al.*[32] found 109°, whereas Hu and Adamson[33] mentioned angles of 98°. In addition, Good and Koo[34] indicated that contact angle increased with the size of the drop and their values ranged from 109 to 117.3° for PTFE. The effect of drop size has also been reported by Ponter and Yekta-Fard[35].

The present values of contact angle for virgin ePTFE grafts agree well with values reported previously. However, the washed virgin grafts and the retrieved grafts were found to have contact angles greater than those of the virgin grafts. This was possibly due to the standard washing process which may have removed the hydrophilic impurities from the surfaces of the grafts. If this were true, it may result in enhanced hydrophobicity. Although the washing procedure did not remove all lipids and/or proteins in the explanted grafts, these were not found to affect greatly the surface wettability. In a few isolated cases, however, where the contact angle was zero, significantly high lipid and protein uptake were noted.

ESCA

A low F:C ratio was often related to a high oxygen content. The observation may be related to a lipid and/or protein deposition on the surface of the grafts, which was corroborated by a lipid uptake observed on SEM. Moreover, the absence or very low content of nitrogen atoms in most of the cases suggests the lipids were

Table 12 DSC results for explanted ePTFE prostheses

Prosthesis	Year of implantation	Duration of implantation (d)	First melting temperature (°C)	Second melting temperature (°C)
Explant no. 1	1979	2	330	330
Explant no. 2	1981	21	330	330
Explant no. 3	1981	31	330	330
Explant no. 4	1981	92	330	330
Explant no. 5	1984	92	330	329
Explant no. 6	1983	279	330	329
Explant no. 7	1982	301	330	330
Explant no. 8	1980	306	329	329
Explant no. 9	1986	335	329	329
Explant no. 10	1980	353	329	330
Explant no. 11	1979	379	329	330
Explant no. 12	1979	486	329	329
Explant no. 13	1978	648	332	330
Explant no. 14	1978	784	329	329
Explant no. 15	1985	848	329	330
Explant no. 16	1979	943	329	331
Explant no. 17	1978	1463	329	329
Explant no. 18	1977	2451	329	329

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responsible for the low F:C ratio. This may occur in two ways. The increased number of carbon and oxygen atoms may lead to a decreased percentage of fluorine. The lipids may also mask the ePTFE surface and therefore reduce the number of photoelectrons emitted from the material surface.

In order to avoid the erroneous results which may be obtained in explanted grafts which are highly contaminated with lipids, a threshold of 3% oxygen content was chosen, below which the specimens were considered to be free of lipid and/or protein contamination. This threshold corresponds to the level of oxygen observed in the virgin prostheses after the cleaning procedure. When the F:C ratio was assessed as a function of time of implantation in prostheses with an oxygen level lower than 3%, it was found to be relatively constant up to the maximum period of implantation. This indicates that ePTFE grafts remain stable, even after 6.5 yr of implantation in man.

If one assumes that degradation of the main chain of PTFE macromolecules is accompanied by a loss of fluorine atoms, this was not observed in the present study, even for the prostheses implanted for 6.5 yr. This type of degradation would probably not ever be detectable in clinical specimens. Although chemical degradation did not occur, the high level of lipid deposit on the ePTFE prostheses may affect their mechanical behaviour. The measurement of the mechanical properties is beyond the scope of this study.

FTIR

Fourier transform infra-red spectroscopy generally confirmed the results of ESCA analysis. Almost all the explanted samples gave an absorption near 1740 cm^{-1} originating from carboxylic acids in lipids, and this peak was always accompanied by the absorptions at 1466 and 1382 cm^{-1} which were assigned to ethyl and methyl groups (*Table 11*)[36]. The intensities of these three peaks, and the two peaks at 2922 and 2851 cm^{-1} due to C-H stretching in ethyl groups, increased simultaneously when a higher oxygen level was detected. In the cases of heavily contaminated samples, absorptions were also observed in the region between 3000 and 3500 cm^{-1} indicating that hydroxy or amine groups may have been present[37].

Since most of the new absorptions in the IR spectra can be assigned to lipid or protein uptake, and since it is difficult to identify the origin of the overlapped peaks in the high frequency region, no evidence of chemical degradation has been derived.

DSC

The differential scanning calorimeter is a useful tool for determining the percentage of sintering[28,29], a parameter related to the bulk physical properties of the ePTFE. The measurement involves melting point determinations during two successive fusions of an ePTFE sample. After a first fusion, the PTFE material recrystallizes in a less ordered state whose melting point is lower than that of the first fusion[28]. If the shape of the second fusion peak corresponds to 100% sintering, the flat portion of the first fusion curve, on the right-hand side of the peak, indicates the presence of unsintered PTFE resin. The flat portion was observed in most of the samples and its presence was not related to the period of implantation of the ePTFE specimens. Therefore, implantation of the ePTFE grafts did not result in significant changes in thermal properties.

CONCLUSIONS

This chemical study of 79 ePTFE surgically excised vascular grafts has not demonstrated any degradation of the ePTFE related to the time of implantation. The only modifications which were observed by means of surface analysis techniques were related to lipid uptake. This lipid uptake can artificially modify the atom proportions or mask the ePTFE when surface-sensitive tools such as ESCA are used. Lipid uptake is known to damage polydimethylsiloxane[38] and it acts as a plasticizer on polyester[39]. The consequences of lipid uptake on ePTFE prostheses are not known and need further investigation. We conclude that ePTFE is chemically stable after implantation in man for periods of up to 6.5 yr.

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Long-term results with the above-knee popliteal expanded polytetrafluoroethylene graft

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Since approximately 30% to 40% of autogenous vein bypass grafts to the femoropopliteal level may occlude within 5 years of implantation, additional vein will be required for subsequent revisions. We undertook a study to determine whether the preferential use of an above-knee expanded polytetrafluoroethylene bypass graft to save vein is an appropriate option. We reviewed our experience with 114 above-knee expanded polytetrafluoroethylene bypass reconstructions. Life-table analysis of primary and secondary graft patency was carried out by the method of Peto and statistically analyzed for the influence of clinical indication, runoff as determined by both preoperative and intraoperative completion arteriography, smoking, and diabetes. The 5-year primary patency rate of 57% for patients with claudication was comparable to contemporary randomized or retrospective series with below-knee autogenous vein for that indication, and it was superior to the patency rate for limb salvage. The status of the runoff vessels was an important determinant of outcome. The 59 limbs with good arteriographic runoff (2 to 3 vessels) had a markedly higher 5-year patency rate (70%) than the poor arteriographic runoff (0 to 1 vessels) group (30%). Continued cigarette smoking and diabetes mellitus also appeared to affect adversely primary graft patency in our hands. Our data support the use of preferential above-knee expanded polytetrafluoroethylene grafts in patients with good angiographic runoff. This approach does not appear to prejudice the limb against secondary revisionary procedures or the use of a new autogenous graft, if required. (J VASC SURG 1990;11:517-24.)

Atherosclerosis can affect adversely the long-term results of infrainguinal reconstruction in the following two ways: (1) Cardiac and cerebrovascular involvement lower than 5-year cumulative survival to approximately 50% to 60%; and (2) progression of distal atherosclerotic occlusive disease becomes the most common cause of graft failure 1½ years after surgery. Dos Santos[1] has stated that "reconstructive vascular surgery is the surgery of ruins." This statement emphasizes not only the progressive nature of atherosclerosis, but also the requirement for repeat infrainguinal procedures after graft failure. In our experience approximately 30% to 40% of femoral popliteal vein bypass procedures will fail by 5 years and require another bypass. Although most vascular surgeons use noninvasive hemodynamic postoperative surveillance of infrainguinal bypass grafts to detect the failing graft before frank occlusion, this approach is not always successful.[2]

Once a vein graft has occluded, the results with revision are quite disappointing. Whittemore et al.[3] demonstrated a 38% cumulative patency rate at 5 years when failed reversed vein grafts were treated by an interposition arm vein, saphenous vein jump graft, or an entirely new graft; whereas Cohen et al.[4] from the same institution showed a comparable 31% cumulative patency rate at 5 years for failed vein grafts with localized vein graft stenosis treated by thrombectomy and patch angioplasty. These data suggest that once a vein graft has thrombosed, the results of surgical revision are disappointing. In 1983 we advocated "sparing the saphenous vein" when an above-knee segment of popliteal artery was available for bypass placement with an expanded polytetra-

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fluoroethylene (ePTFE) graft.[5] We theorized that the vein could then be used if atherosclerosis progressed to cause failure. The early primary patency rate in our series of 51 above-knee ePTFE grafts was 63% at 2 years, which was comparable to that of a below-knee reversed autogenous saphenous vein group (72%) contemporaneously treated at our institution. These data suggested that the synthetic graft might be an acceptable alternative to a vein graft when placed in the above-knee position. Subsequent articles by Rosen et al.,[6] Sterpetti et al.,[7] and recently by Quiñones-Baldrich et al.[8] have also advocated the "vein sparing approach," although the latter two series included ePTFE to the below-knee position.

Implicit in this approach is the assumption that the placement of an ePTFE graft to the above-knee position will not preclude placement of a subsequent vein bypass graft if the ePTFE graft occludes. The causes of graft failure and the condition of the distal vascular bed after ePTFE graft occlusion must be known before this approach is universally accepted. It is the purpose of this report to (1) review our experience with above-knee ePTFE grafts followed over a 10-year period to determine the cumulative primary and secondary patency rates; (2) to assess the influence of the preoperative degree of ischemia, angiographic runoff, and atherosclerotic risk factors on long-term patency of above-knee ePTFE grafts; and (3) to determine the causes of above-knee ePTFE graft failure and their impact on secondary graft patency.

MATERIAL AND METHODS

A review of all infrainguinal arterial bypass procedures performed at the New England Medical Center and entered into the vascular registry during the 11-year period between 1976 and 1987 identified 114 procedures where ePTFE grafts were placed to the above-knee popliteal artery.

All records were reviewed by one of the authors (E.J.P.), and data were compiled according to the standards suggested by the Ad Hoc Committee on Reporting Standards for reports dealing with lower extremity ischemia.[9] The patient's age and sex as well as a history of cigarette smoking, diabetes, hypertension, coronary artery disease, hyperlipidemia, and renal or pulmonary disease or both were noted.

All patients underwent preoperative noninvasive laboratory investigations to determine segmental lower extremity pressures, ankle/brachial index (ABI), and pulse volume amplitude.[10] Preoperative arteriography was also performed in all patients to define the anatomy of the arterial tree and to assess runoff status. Postcompletion intraoperative arteriography was also used to determine runoff status. Angiographic runoff was defined as *good* if two or three tibial vessels were in continuity with the popliteal artery and were patent to the ankle and *poor* if only one or no tibial vessels were patent to the ankle.

The indications for surgery were disabling claudication (grade I, chronic limb ischemia) and critical ischemia. Critical ischemia was further defined as ischemic rest pain (grade II, chronic limb ischemia) or acute tissue loss as a result of ischemia (grade III, chronic limb ischemia).

All procedures were performed with 5 or 6 mm internal diameter ePTFE grafts (W.L. Gore & Associates, Inc., Elkton, Md.). The anastomoses were carried out with continuous 5.0 or 6.0 polypropylene (monofilament) sutures. Systemic intravenous heparin was administered and not reversed. Low molecular weight dextran 40 was infused during surgery and converted to aspirin therapy on the second or third postoperative day. Prophylactic antibiotics were used routinely. As mentioned previously, after completion of the anastomoses intraoperative angiography was performed to confirm graft patency and runoff status as well as rule out any correctable technical errors.

Patient follow-up

Noninvasive studies were performed after operation to obtain objective evidence of improved limb perfusion. Patients were seen in follow-up by one of the three staff surgeons (T.F.O'D., W.C.M., A.D.C.). Postoperative complications, wound hematomas or infections, cardiac morbidity, early graft thrombosis, and operative mortality (within 30 days of surgery) were compiled.

Patients were seen initially after operation at 2- to 3-month intervals by the attending surgeons, and noninvasive studies were performed at each visit. Graft thrombosis was suspected if there was a deterioration in the clinical status of the limb (i.e., a return or worsening of claudication or critical ischemia) and was confirmed by clinical examination and noninvasive studies or arteriography or both. A failure of limb salvage, amputation of a limb in the presence of a patent graft, was not considered a failure of the graft. However, removal of a graft because of infection was considered a graft failure. Patients with acute deterioration in limb status had emergency arteriogrpahy and intervention where indicated.

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Graft patency

Primary graft patency was defined as uninterrupted patency of the graft from the time of operation. Patients requiring extension of a graft because of subsequent development of distal atherosclerosis were not considered as primary graft failure if the graft was patent at the time of the second operation. By contrast, if thrombectomy or lytic therapy alone or combined with surgical revision was required for an occluded graft, it was considered a failure of primary patency. Secondary patency was defined as restoration of flow in an occluded graft by thrombectomy, thrombolysis or patch angioplasty or both, and/or minor extension of the graft to a site distal to the cause of the occlusion. The cumulative patency of the secondary procedure was determined for those limbs that had intervention to correct primary graft failure.

Statistics

All results were analyzed by actuarial methods and presented in the form of life tables, according to procedures established by the Society for Vascular Surgery/International Society for Cardiovascular Surgery committee on guidelines for reporting lower extremity ischemia.[9] Comparisons of life-table estimates were done with the log rank test for significance; standard errors were computed according to the method of Peto et al.[11] Comparisons were made of ABI values between the different groups by use of the Student unpaired t test on samples of equal variance. Differences were considered to have reached statistical significance at the 95% level ($p = 0.05$).

Between January 1976 and September 1987, 114 patients had above-knee femoropopliteal reconstructions with ePTFE vascular grafts. In 98 (86%) patients the decision to use ePTFE was made before surgery, and no attempt made to explore the greater saphenous vein. In eight (7%) the saphenous vein had been removed for use in coronary artery bypass reconstruction,[4] peripheral arterial reconstruction,[2] or because of varicosities.[2] The greater saphenous vein was explored in an additional eight (7%) patients and found to be of insufficient caliber (less than 3 mm internal diameter). As an indication of the extent of peripheral arterial disease, nearly 40% of the patients had inflow procedures either previously, 32 patients (28 aortobifemoral and four axillofemorofemoral bypass grafts) or concomitantly, 11 patients (four axillofemorofemoral, five femorofemoral, one aortobifemoral bypass grafts and one percutaneous angioplasty of an iliac stenosis). Five patients had previous femoropopliteal bypass procedures on the ipsilateral limb and 15 on the contralateral limb.

Patient characteristics

Seventy-six (67%) patients were men, and 38 (33%) were women. The mean age was 65 years (range 42 to 86 yers), and one half of the patients were between 60 and 69 years old. Indications for surgery were disabling claudication in 44 (39%) cases and critical ischemia in 70 (61%) cases. Eighty-one (71%) patients were habitual cigarette smokers at the time of surgery, and despite repeated advice to the contrary they continued smoking after surgery. Thirty-one (27%) patients suffered from diabetes mellitus, and 71 (62%) had medically controlled hypertension. Overt coronary artery disease (symptomatic angina or a history of a previous myocardial infarction or both) was present in 65 (57%) of patients of whom nine (8%) had prior coronary bypass surgery.

RESULTS

Perioperative morbidity and mortality

The most frequent source of morbidity was wound complications (nine patients, 8%). Five patients had minor wound morbidity, which did not prolong their hospital stay. Two were superficial wound infections, two were small hematomas not requiring drainage, and one was a seroma. Three patients developed purulent inguinal wound infections that required drainage, whereas one patient had necrosis of the groin wound, which necessitated operative debridement and subsequent skin garfting. Five patients (4%) had postoperative urinary tract infections. Despite the high prevalence (57%) of known underlying coronary artery disease, only three patients (2.6%) suffered myocardial infarctions on postoperative days 1, 3, and 5. All three patients had urgent reconstructions for critical ischemia and tissue loss. Two of the three myocardial infarctions were fatal, and the patients died on postoperative days 1 and 3. One respiratory arrest occurred from which the patient was successfully resuscitated. The operative mortality was 1.4% (2/114 patients).

Early graft occlusion

Two grafts thrombosed in the postoperative period (1.4% acute graft occlusion rate), both in patients with ischemic tissue loss. One occurred at the time of resuscitation in the patient who had a respi-

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Table I. Above-knee femoropopliteal reconstruction without graft intervention

			Withdrawn patent				
Mo experience	*At risk*	*Failed*	*Lost*	*Duration*	*Died*	*Patency (%)*	*Standard error (%)*
0-1	114	3	3	2	2	100.00	0.00
1-6	104	10	3	4	3	97.29	1.57
6-12	8	9	1	1	1	87.46	3.38
12-18	72	8	2	3	3	77.92	4.32
18-24	56	10	0	4	0	68.75	5.14
24-30	42	3	1	1	0	56.02	5.73
30-36	37	3	0	3	0	51.92	5.92
36-42	31	1	0	3	0	47.53	6.18
42-48	27	1	0	4	0	45.92	6.50
48-54	22	1	0	1	0	44.08	7.03
54-60	20	0	0	1	0	42.03	7.16
60-66	19	0	0	3	0	42.03	7.34
66-72	16	2	0	1	1	42.03	8.00
72-78	12	2	0	1	0	36.43	8.38
78-84	9	0	0	3	0	30.09	8.39
84-90	6	0	0	2	0	30.09	10.27
90-96	4	0	0	0	0	30.09	12.58
96-102	4	0	0	0	1	30.09	12.58
102-108	3	0	0	1	0	30.09	14.53
108-114	2	0	0	1	0	30.09	17.79
114-120	1	0	0	0	0	30.09	25.16
120-126	1	0	0	0	0	30.09	25.16
126-132	1	1	0	0	0	30.09	25.16

ratory arrest. No further attempts at reconstruction were made so that she had an above-knee amputation at 14 days after operation. The second patient had no additional surgery.

Noninvasive hemodynamics

The mean preoperative ABI for the entire series, 0.42 ± 0.02, increased twofold to 0.89 ± 0.02 after bypass surgery ($p = 0.0001$). Differences in ABI between the disabling claudication (0.53 ± 0.03) and critical ischemia (0.34 ± 0.03) groups were statistically different before operation ($p = 0.001$) but not after operation—disabling claudication group (0.87 ± 0.04) and critical ischemia group (0.91 ± 0.03).

Graft patency

The mean patient follow-up was approximately 3 years (mean 34 months) and ranged from 1 to 137 months. The life-table anaylsis for cumulative patency is summarized in Table I, and life tables for primary and secondary graft patency are displayed in Fig. 1. Primary patency was 47% at 3 years for the entire series and decreased to 42% at 5 years, whereas the secondary patency rate was 57% and 45%, respectively, at the same time intervals. Fig. 2 compares cumulative life tables by indication for surgery. The patency rate for the disabling claudication group was 71% and 57% at 3 and 5 years, respectively, whereas the patency dropped significantly lower to 45% and 37% for the critical ischemia group at 3 and 5 years ($p < 0.01$). Fig. 3 shows that cumulative patency was higher in those limbs with good angiographic runoff (80% at 30 months) than in the poor runoff group (52% at 30 months $p < 0.005$). Noninvasive hemodynamics provided further functional evidence of the differences observed with runoff. Before operation the ABI in the good angiographic runoff group (0.49 ± 0.03) was higher than that in the poor runoff group (0.37 ± 0.04 $p < 0.05$). The difference between the two runoff groups persisted after surgery (0.91 ± 0.03 good runoff group and 0.81 ± 0.03 poor runoff group $p < 0.05$).

Continued cigarette smoking in 71% of patients in our series had a significant effect on patency rates. Five-year patency rate for smokers was 40% compared to 66% for nonsmokers ($p < 0.05$). Diabetes also adversely affected the 5-year cumulative patency rate ($p < 0.05$).

Graft failure

Table I shows that 39 grafts failed in the first 5 years after implantation. Most occluded within the intermediate period of graft failure (6 to 18 months). Eleven (9%) major amputations were performed, seven above the knee and four below the knee; 10

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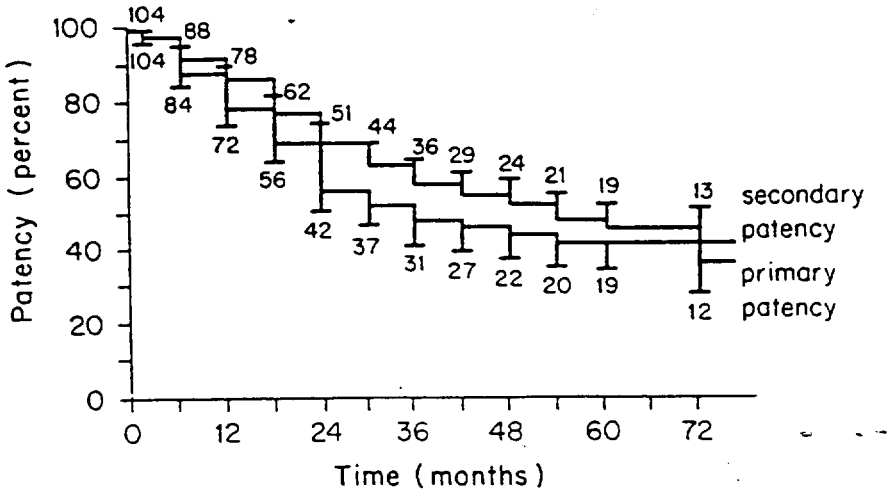

Fig. 1. Life-table curves of the primary and secondary patency of 114 above-knee ePTFE femoropopliteal bypass grafts. The 2-year primary patency rate of 69% had decreased to 42% by 5 years. The benefits of simple revisionary procedures in the first 2 to 3 years after graft implantation was observed in improved secondary patency, but this advantage appeared to disappear by 5 years after implantation.

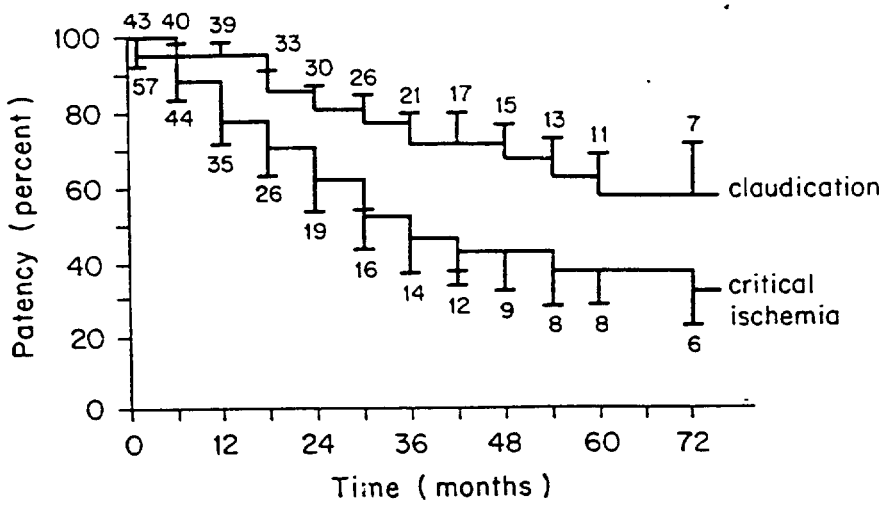

Fig. 2. Life-table curves of primary patency for femoropopliteal above-knee ePTFE grafts in patients with claudication (n = 44) and critical ischemia (n = 57). The claudication group had a superior 5-year primary patency of 62% in contrast to the lower primary patency of the limb salvage group (37%) ($p < 0.01$).

in patients with critical ischemia and one where disabling claudication was the indication. One patient had a below-knee amputation for a nonhealing ulcer in the presence of a patent graft. Our approach to a failed above-knee ePTFE graft has been to perform either a surgical thrombectomy or direct intraarterial lytic therapy to determine the cause of graft failure.[12] Either a local procedure for intimal hyperplasia of the distal anastomosis or graft extension for distal atherosclerotic disease is carried out based on the cause. Fig. 4 compares the cumulative patency rate for 31 patients treated by a secondary procedure and

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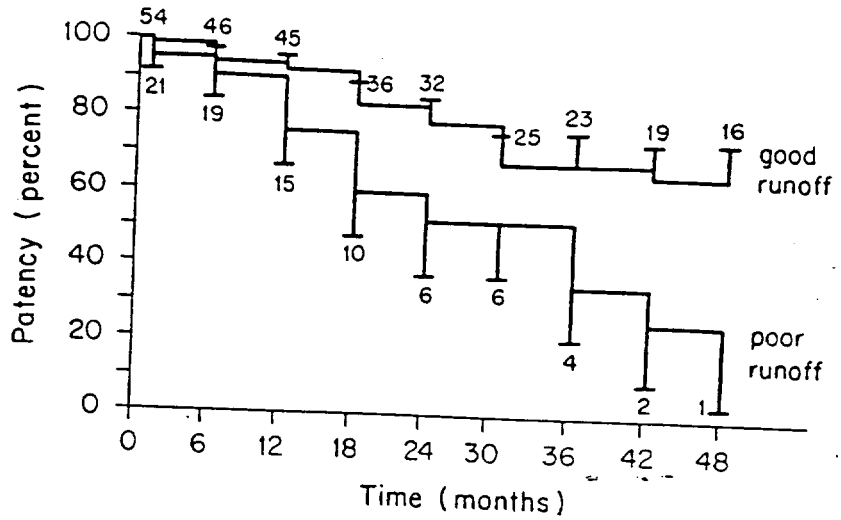

Fig. 3. Life-table curves of primary patency for above-knee ePTFE grafts with good angiographic runoff (2 to 3 vessels, $n = 59$) and poor angiographic runoff (0 to 1 vessels, $n = 23$). The limbs with good runoff show a superior primary patency rate above that of the poor runoff group ($p < 0.005$).

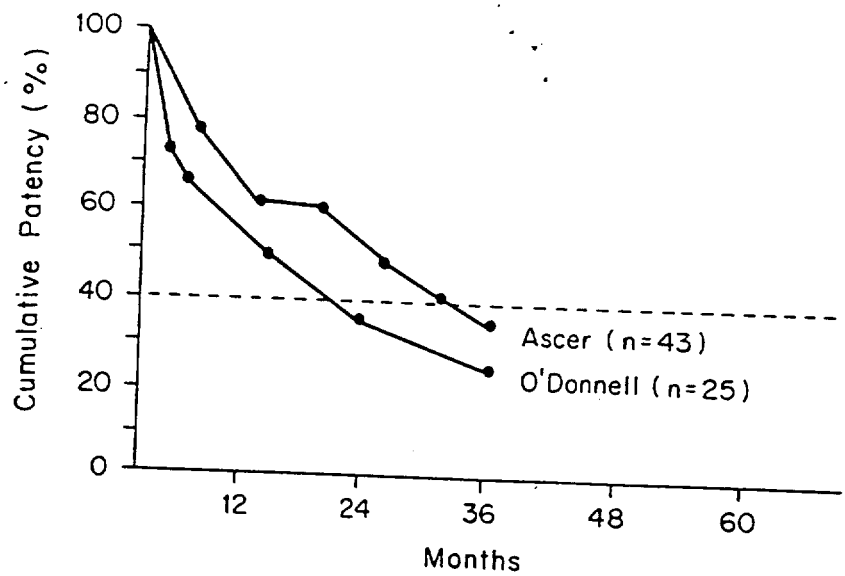

Fig. 4. Comparison of patency rates for secondary surgical procedures for above-knee ePTFE grafts. These curves represent the cumulative patency for those grafts which occluded and underwent secondary procedures. Both our series and that of Montefiore group had patency rates of less than 40% by 36 months.

is compared to a similar group reported by Ascer et al.[13] Although the early 12-month results are encouraging in both groups, by 30 months both have decreased to a level comparable to that found in secondary procedures for failed vein grafts.[3]

DISCUSSION

A review of our series in which ePTFE graft material to the above-knee popliteal artery was used preferentially as the initial revascularization procedure reveals that (1) the overall 5-year cumulative

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Table II. Comparison of infrainguinal e-PTFE bypass grafts to below-knee vein grafts

Author	*No. of limbs*	*Primary patency (%)*	
		3 yr	*5 yr*
Veith[10]	91	59	38
Kempczinski[13]	138	62	55
Sterpetti[7]	90	62	58
Quinones-Baldrich[8]	101	64	57
Present series	114	47	42
Present series (good runoff)	59	73	70
Vein			
Leather[14]	304	86	79
Porter[15]	272	85	82
Veith[10]	147	80	68
Kent[18]	396	Reversed	78
		In situ	75

patency rate of our series is lower than that generally encountered with vein grafts to the below-knee popliteal artery; (2) the degree of angiographic runoff markedly affected our long-term patency results; (3) revision of the above-knee bypass graft with either patch angioplasty or vein graft extension yielded results that are inferior to those reported for an in situ or reversed vein bypass grafts to the below-knee popliteal artery, and finally, (4) failure of an above-knee ePTFE graft did not prevent a revisionary procedure or result in a significant bias toward amputation, which is an important factor when considering the sequencing of these bypass grafts. Table II compares the available series on above-knee ePTFE bypass grafts to recently published series that used autogenous vein. Although only one series used a randomized comparison, it is apparent that the 5-year cumulative patency rate in the ePTFE series is inferior to that of autogenous vein. No series with ePTFE reports a 5-year cumulative patency rate in excess of 60%, whereas the in situ series of Leather et al.[14] and the reversed vein series of Taylor et al.[15] average 80%. One recognizes the weaknesses of this comparison. However, in the absence of other randomized trials and the 20% difference in patency rates between the two approaches makes vein appear superior to synthetic graft for the general population. The results of the reversed autogenous vein group from the randomized trial are superior to those of ePTFE.[10] Our 5-year primary patency with ePTFE was similar to that of the above-knee ePTFE grafts in the randomized trial. Three series, those of Sterpetti et al.,[7] Quiñones-Baldrich et al.,[8] and Kempczinski[17] report comparable 5-year patency rates and appear superior to ours, but they are inferior to those of the vein graft series (Table II).

The chief purpose of this review was to identify those factors that might influence the long-term cumulative patency of above-knee ePTFE grafts. Angiographic runoff was a critical factor in determining cumulative primary patency. The 59 grafts with good arteriographic runoff (2 to 3 vessels) had a markedly higher 4-year patency rate (70%) than the poor arteriographic runoff group (28%). Continued cigarette smoking and diabetes mellitus adversely affected primary graft patency in our hands. This information should be helpful in tailoring the preferential use of an above-knee ePTFE popliteal bypass graft to the appropriate candidate. If the preoperative arteriogram demonstrates poor angiographic runoff then our data would suggest that an above-knee ePTFE bypass would not be the best initial procedure, especially if the patient had diabetes. The use of autogenous vein in the diabetic patient would seem logical given both our poorer results with above-knee ePTFE grafts in diabetic patients and the diminished 5-year survival of diabetic patients after femoropopliteal bypass surgery.

The sequencing of a prosthetic graft first followed by an autogenous vein graft if failure of the prosthetic graft occurs was addressed in a small series by Rosen et al.[6] He reported eight patients from a series of 59 who initially had undergone above-knee ePTFE graft placement but required subsequent below-knee in situ bypass graft placement for graft failure—the sequenced group. This compilation group was compared to a contemporaneous series of their patients who underwent an initial in situ below-knee vein graft reconstruction. The cumulative limb salvage rate at 3 years for the sequenced group (87%) was higher than that of both the prosthetic alone or in situ alone groups. Eleven of the 16 in situ alone patients with failed grafts required an amputation.

With failure of an above-knee ePTFE graft in

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addition to leaving a vein available for subsequent bypass surgery the residual arterial bed should be amenable to bypass placement. Distal atherosclerotic disease was the predominant cause of failure in our above-knee ePTFE group as reported previously by us.[12] The popliteal artery was the predominant site of atherosclerotic disease progression. Whether this process is a variant of intimal hyperplasia or not is debatable. This process did not prevent subsequent surgery for revision.

Our approach of using the original above-knee ePTFE graft as a base for either a distal extension with autogenous vein or a patch of the distal anastomosis yielded results comparable to those described by Ascer et al.[13] (Fig. 4). Indeed these results are similar to those observed with secondary procedures for vein graft failure.[3,4] Therefore universal use of the primary above-knee ePTFE graft as a base for graft extension after surgical thrombectomy or lytic therapy does not appear appropriate. Certainly for patients with inflow disease or recurrence of atherosclerosis at the distal anastomosis this would seem reasonable. If distal atherosclerotic disease involves the popliteal artery, but not in continuity with the anastomosis, then a new autogenous graft, preferably an in situ vein bypass graft, would appear to be a better option.

Why not use a vein graft as the initial procedure? Most series average a 20% to 30% incidence of graft failure that require revision. Whittemore et al.[3] reviewed their experience with revision of failed vein bypass grafts and observed an unacceptable 3-year patency rate. Apparently the best results with graft failure can be achieved by use of a new vein graft as reported recently by Edwards et al.[16] Given the systemic nature of atherosclerosis and its propensity for involvement of the contralateral limb it would appear reasonable to delay the use of autogenous vein until it is required. If the above-knee popliteal artery is of good quality we currently advocate limiting the use of vein graft as the initial procedure, except in patients with poor runoff or in patients with diabetes.

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Six-year prospective multicenter randomized comparison of autologous saphenous vein and expanded polytetrafluoroethylene grafts in infrainguinal arterial reconstructions

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Autologous saphenous vein (ASV) and polytetrafluoroethylene (PTFE) grafts were compared in 845 infrainguinal bypass operations, 485 to the popliteal artery and 360 to infrapopliteal arteries. Life-table primary patency rates for randomized PTFE grafts to the popliteal artery paralleled those for randomized ASV grafts to the same level for 2 years and then became significantly different (4-year patency rate of 68% ± 8% [SE] for ASV vs. 47% ± 9% for PTFE, $p < 0.025$). Four-year patency differences for randomized above-knee grafts were not statistically significant (61% ± 12% for ASV vs. 38% ± 13% for PTFE, $p > 0.25$) but were for randomized below-knee grafts (76% ± 9% for ASV vs. 54% ± 11% for PTFE, $p < 0.05$). Four-year limb salvage rates after bypasses to the popliteal artery to control critical ischemia did not differ for the two types of randomized grafts (75% ± 10% for ASV vs. 70% ± 10% for PTFE, $p > 0.25$). Although primary patency rates for randomized and obligatory PTFE grafts to the popliteal artery were significantly different ($p < 0.025$), 4-year limb salvage rates were not (70% ± 10% vs. 68% ± 20%, $p > 0.25$). Primary patency rates at 4 years for infrapopliteal bypasses with randomized ASV were significantly better than those with randomized PTFE (49% ± 10% vs. 12% ± 7%, $p < 0.001$). Limb salvage rates at 3½ years for infrapopliteal bypasses with both randomized grafts (57% ± 10% for ASV and 61% ± 10% for PTFE) were better than those for obligatory infrapopliteal PTFE grafts (38% ± 11%, $p < 0.01$). These results fail to support the routine preferential use of PTFE grafts for either femoropopliteal or more distal bypasses. However, this graft may be used preferentially in selected poor-risk patients for femoropopliteal bypasses, particularly those that do not cross the knee. Although every effort should be made to use ASV for infrapopliteal bypasses, a PTFE distal bypass is a better option than a primary major amputation. (J VASC SURG 1986; 3:104-14.)

It is generally believed that autologous saphenous veins (ASVs) provide the best possible conduit for all arterial reconstructions below the inguinal ligament. However, these veins may be unavailable or inadequate to use as an arterial graft in many patients. This fact plus the disadvantages of the harvest of autologous vein have prompted surgeons to seek an alternative arterial prosthesis for bypasses to the popliteal and infrapopliteal arteries. Numerous graft materials have been used with early encouraging results only to later fall into disfavor because of poor mid- and long-term patency rates or late complications such as aneurysmal dilatation.

Polytetrafluoroethylene (PTFE) grafts were first used as arterial conduits in patients in 1976.[1] As femoropopliteal bypasses in patients with infrain-

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Table I. Patients, operations, and risk factors in the three centers

	Centers			Total	
	I	*II*	*III*	*No.*	*%*
No. of patients in study	520	175	64	759	—
No. of operations in study	622	206	64	892*	—
Exclusions after entrance into study†	36	1	10	47	—
Popliteal operations in study	375	82	28	485	—
Operative indications					
Gangrene (%)	42	6	18	—	35
Ulcer (%)	29	16	18	—	26
Rest pain (%)	25	20	56	—	26
Claudication (%)	3	51	4	—	11
Unknown (%)	1	7	4	—	2
Diabetes (%)	71	26	54	—	62
Age (yr)					
Mean ± SD	71 ± 11	61 ± 1	65 ± 8	69 ± 11	—
70-80 (%)	38	18	21	—	33
>80 (%)	18	6	4	—	15
Previous infrainguinal operation (%)	17	5	18	—	15
Infrapopliteal operations in study	211	123	26	360	—
Operative indications					
Gangrene (%)	61	12	31	—	42
Ulcer (%)	22	16	19	—	20
Rest pain (%)	16	47	50	—	29
Claudication (%)	0	24	0	—	8
Unknown (%)	1	1	0	—	1
Diabetes (%)	78	37	50	—	62
Age (yr)					
Mean ± SD	72 ± 10	65 ± 11	68 ± 11	70 ± 11	—
70-80 (%)	48	35	27	—	42
>80 (%)	23	7	15	—	17
Previous infrainguinal operation (%)	14	26	27	—	19

*During the study period, 29 other bypasses were performed to the popliteal or an infrapopliteal artery for causes other than arteriosclerosis.
†For reasons see text.

guinal arteriosclerosis, these grafts were reported to have early and mid-term patency results comparable to ASV grafts, although the PTFE grafts were generally employed in patients who were judged not to have a usable ASV.[2,3] More recently, late patency results extending over 5 years have been documented.[4,5] On the basis of these reports, PTFE grafts have become the most commonly used synthetic conduit for arterial reconstructions below the inguinal ligament. Moreover, several surgeons, citing the advantages of decreased duration and complexity of operation and the ability to spare a healthy saphenous vein for future use as a limb salvage or coronary bypass, have advocated the preferential use of PTFE grafts for femoropopliteal bypass even in patients who had an adequate greater saphenous vein in the involved extremity.[6,7] Nevertheless, the exact indications for use of PTFE grafts in infrainguinal arterial reconstructions have remained unclear and controversial. This confusion and controversy were fueled by a number of reports showing that PTFE grafts to arteries at and below the knee performed poorly.[8-10]

In the final analysis the indications for the use of any bypass graft depend on the results that can be achieved with it compared with other available alternatives in a variety of situations. The problem with the evaluation of the relative effectiveness of PTFE compared with other grafts in infrainguinal bypass operations is that *many variables other than graft material* can influence patency results. Without rigorous standardization of these other patient-related and surgeon-related variables, comparative evaluations of various graft materials by the same surgeons are meaningless, and similar comparisons of data obtained from different surgeons are of even less value.

Because of these considerations and the resulting uncertainty about the indications for use of PTFE grafts below the inguinal ligament, in November 1978, we began a randomized prospective multicenter comparison between PTFE and ASV grafts as infrainguinal arterial bypass conduits. Our primary purpose was to compare the relative efficacy of PTFE and ASV grafts in bypasses to the popliteal and infrapopliteal arteries in patients who could have either

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Table II. Details and numbers of operations

	Centers			
	I	*II*	*III*	*Total*
Common femoral to popliteal artery				360
Above-knee	152	21	7	180
Below-knee	108	61	11	180
Superficial femoral or popliteal to popliteal artery				125
Above-knee	64	0	4	68
Below-knee	51	0	6	57
Common femoral to distal artery				225
Anterior tibial	45	48	3	96
Posterior tibial	18	34	6	58
Peroneal	27	39	5	71
Superficial femoral or popliteal to distal artery				135
Anterior tibial	70	1	5	76
Posterior tibial	18	0	5	23
Peroneal	33	1	2	36

graft. This study also provided answers to a number of secondary questions. (1) Were there, within the overall patient groups having bypasses to the popliteal and infrapopliteal arteries, subsets of patients with differing results? For example, were results different for above-knee and below-knee femoropopliteal bypasses, or for those with good and poor outflow from the popliteal artery as measured angiographically? (2) Were results in patients who had to have an *obligatory PTFE* graft because of inadequate or unavailable ASV or poor general condition different from results in patients who could have had an ASV graft but who actually received a *randomized PTFE* graft? (3) What was the relationship between graft patency and limb salvage in patients undergoing bypass operations for limb salvage?

This article reports data that fulfill the primary purpose and answer some of the secondary questions addressed by our study. It thereby clarifies the indications for the use of PTFE grafts below the inguinal ligament and highlights some of the advantages and disadvantages of this use.

METHODS

Our methods were detailed in a previous preliminary report[11] and will only be summarized briefly here. From November 1978 onward, the three cooperating centers in New York (center I), Chicago (center II), and Milwaukee (center III) with nine participating surgeons attempted to enter into the study all patients who required a bypass to the popliteal or an infrapopliteal artery to control ischemia caused by arteriosclerosis. In general the three surgical groups had a conservative attitude toward performing these operations in the treatment of intermittent claudication and an aggressive attitude toward performing them to control limb-threatening or critical ischemia.[12] Although there were some differences in surgical techniques and philosophies between the three groups, there were many similarities. All nine surgeons had a demonstrated interest in and considerable experience with the operations being studied. All operations were performed in the most meticulous fashion possible, often with optical magnification and intraoperative angiographic control. Some details relating to risk factors, operative indications, and the number and kinds of operations entered into the study by the three centers are presented in Tables I and II.

Exclusions and numbers of patients and operations. Patients with infrainguinal arteriosclerosis who could be treated solely by a deep femoral artery reconstruction or solely by percutaneous transluminal angioplasty of the superficial femoral, popliteal, or an infrapopliteal artery were not included in the study. Overall, these were patients with less severe, stenotic disease. Patients who required an infrainguinal bypass for reasons other than arteriosclerosis were excluded from the study. Such exclusions, which numbered 29 during the period of the study, included bypasses for trauma, embolic disease *without* arteriosclerosis, adventitial cysts, entrapment syndromes, and tumor surgery. After these exclusions, 892 operations in 759 patients were entered into the study data base and subjected to the randomization procedure described later. Those operations considered to be *sequential bypasses* (two or more distal sites of insertion) or requiring *composite grafts* (with ASV

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Table III. Operative indications, risk factors, and mortality in patients receiving the three types of grafts

	Bypasses to popliteal artery			*Bypasses to tibial or peroneal artery*		
	Randomized ASV	*Randomized PTFE*	*Obligatory PTFE*	*Randomized ASV*	*Randomized PTFE*	*Obligatory PTFE*
No. of operations	147	171	167	106	98	156
Indications						
Gangrene (%)	29	33	25	41	43	41
Ulcer (%)	27	29	25	23	21	17
Rest pain (%)	22	26	28	21	24	37
Claudication (%)	18	11	4	11	11	4
Unknown (%)	4	1	18	4	1	1
Bypass insertion						
Below-knee (%)	33	31	36	—	—	—
Into isolated segment (%)	19	19	20	—	—	—
Previous infrainguinal operation (%)	12	12	34	12	27	56
Diabetes (%)	58	68	61	73	60	87
Age (yr)						
Mean ± SD	68 ± 10	69 ± 11	70 ± 12	70 ± 12	69 ± 11	70 ± 11
70-80 (%)	37	33	29	35	39	41
>80 (%)	9	16	20	17	12	15
Operative mortality (%) (within 30 days)	3	5	8	6	4	6

ASV = autologous saphenous vein; PTFE = polytetrafluoroethylene.

and PTFE segments) were excluded from the present analysis. During the study period, approximately 25 patients received vein grafts without randomization *(obligatory vein grafts)*. These were performed in patients who (1) refused randomization, (2) had a bypass with overt infection in or immediately adjacent to an anastomotic site, or (3) had a tibiotibial bypass. Some bypass operations to an isolated tibial artery segment also fell into this category as did some operations conducted after failure of a study bypass performed with a PTFE graft.

Randomization. All patients in the study who were believed to have a usable ipsilateral ASV were randomly selected to have as their bypass conduit either a ***randomized ASV*** or a ***randomized PTFE*** graft. Randomization techniques were as previously reported.[11] All patients believed, on the basis of history of prior removal or saphenous venography, not to have an ipsilateral ASV segment long enough to serve as the required bypass received an ***obligatory PTFE*** graft. This group was augmented by patients originally randomized to receive an ASV graft but who at operation were found to have a diseased, absent, or small ASV. Size criteria for vein unacceptability were a minimum distended diameter of <4.0 mm for grafts to the popliteal artery and <3.0 mm for grafts to infrapopliteal arteries. Occasional critically ill patients were placed in the obligatory PTFE group to shorten the duration of the operative procedure. All PTFE grafts to the popliteal artery were 6 mm in diameter; all those to infrapopliteal arteries were tapered from 6.5 mm proximally to 4.5 mm distally. The distribution of operative indications, risk factors, and mortality data in the operations with the three types of grafts is shown in Table III.

Before randomization all patients were told about the nature of the study and informed consent was obtained in accord with each center's institutional review board policy. Results in the randomized groups of patients were continually monitored in each center so that randomization of bypasses to the infrapopliteal or popliteal level could be discontinued if and when statistically significant differences became apparent. The last patient was entered into the infrapopliteal portion of the study in April 1983, whereas randomization of bypasses to the popliteal artery was continued until March 1985.

Pharmacologic management. Systemically administered heparin was given during periods of arterial occlusion and was neutralized thereafter with protamine. Antiplatelet agents (aspirin, 0.3 gm and dipyridamole, 125 mg) were administered postoperatively three times daily to all patients in all three centers. Compliance with the reduced dosage of these drugs that the patients were asked to take after hospital discharge (0.3 gm and 100 mg each day, respectively) was difficult to determine and certainly not uniform. One center (I) attempted to begin these agents 48 hours before operation. However, spot checks revealed that this preoperative drug admin-

istration was not uniform, and some patients received no preoperative antiplatelet medication.

Follow-up information and definitions. All study patients were seen after operation on a regular basis by one of the nine operating surgeons. The frequency of these visits was, if possible, every 2 months for the first postoperative year, every 3 to 4 months for the second postoperative year and every 4 to 6 months thereafter.

Graft patency intervals were established on the basis of unequivocal pulse examination evidence of patency as determined by one of the participating surgeons and, if there was any doubt, confirmation by segmental limb pressure measurements, pulse volume recordings, or angiography.[11] Any change in pulse examination or noninvasive parameters was an indication for angiography, which was used liberally in these study patients.[13,14] No patency interval was included unless the patient was examined by one of the authors or had objective evidence of graft patency by angiography or noninvasive laboratory criteria. No presumption of patency was made on the basis of mail or telephone contact.

One definition of graft failure was the first graft occlusion with thrombosis at any time after operation. If graft patency could be restored by some form of reintervention such as thrombectomy, this secondary patency interval was recorded but not considered further for purposes of the present analysis. Grafts that developed anatomic, functionally important defects in their lumen or at, proximal to, or distal to one of their anastomoses were also considered to have failed if some form of reintervention (angioplasty or operation) was required to correct the defect. Detection of these failing grafts[14] or hemodynamic failures[13] was one of the benefits of the frequent follow-up required by the present study; relatively simple reinterventions were made possible; and graft thrombosis was prevented with considerable benefit to the patients.

Limb salvage intervals were also determined at the time of all follow-up visits. In every instance in which a limb was saved, it proved to be of functional value either in enabling bipedal gait in patients whose other lower extremity was intact or had a functional prosthesis, or in permitting transfer if the patient had a contralateral major amputation.

Data management and reduction. All raw data relating to the patients, their operative details, and their follow-up examinations were collected and submitted to one center. These raw data were entered into an IBM AT computer with a data base management program (Dataease, Software Solutions Inc.). Patency and limb salvage intervals were ended, and the graft and limb withdrawn from the study, when patients died or were irretrievably lost to follow-up. Patency intervals were also ended and the graft and limb withdrawn from the study at the time of a major amputation of a limb with a patent graft. Primary patency intervals were ended and the graft considered failed at the time of first graft thrombosis or reintervention for a failing graft. From this data base and the associated graft patency intervals and limb salvage intervals cumulative graft patency and limb salvage rates were calculated by the life-table method for different groups and subgroups of operations according to standard methods.[15-17] When two or more life-table rates were compared, the statistical significance of observed differences was evaluated by the log rank test.[16,17]

Although the primary focus of our study was the influence of the graft employed, the size and depth of the collaborative data base that was collected also permitted analysis of the effect of a large number of other variables. Only a few of these can possibly be included in the present report. Others will be the subject of subsequent communications. In addition each of the three centers was free to collect additional data on other variables as part of the cooperative study. These data may also be suitable for separate analysis and reporting.

RESULTS

Randomized ASV and PTFE grafts to the popliteal artery

Graft patency. Fig. 1 shows the cumulative life-table primary patency rates for all these grafts, most of which were used as a femoropopliteal bypass.* Important differences in patency only became apparent after 2½ years. After 4 years of observation in meaningful numbers of patients, these differences were statistically significant ($p < 0.025$).

Fig. 2 shows the patency rates of the two types of grafts inserted into the above-knee popliteal artery (Fig. 2, *A*) and the below-knee popliteal artery (Fig. 2, *B*). There is a trend toward superior patency for ASV grafts in the above-knee position ($p > 0.25$), but only in the below-knee position is there a statistically significant difference between ASV and PTFE grafts ($p < 0.05$). The patency rates for randomized

*Three popliteal-to-popliteal bypasses were also included in this group.

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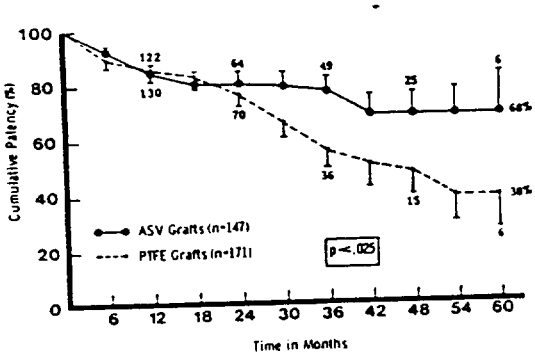

Fig. 1. Cumulative life-table primary patency rates for all randomized bypasses performed to popliteal artery with autologous saphenous vein *(ASV)* and polytetrafluoroethylene *(PTFE)* grafts. Number with each point indicates number of patent grafts observed for that length of time. Standard error of each point is shown.

below-knee grafts of both types appear to be superior to those for above-knee grafts, although the reasons for this remain unclear. Differences in uncontrolled patient-related factors other than those prompting the selection of the above-knee or below-knee popliteal artery for graft insertion may contribute to these patency differences. Thus, this study should not be considered to provide firm evidence that preferential use of the below-knee popliteal artery would improve femoropopliteal graft patency.

When randomized bypasses to isolated popliteal artery segments were considered separately, no significant difference in patency rates between the ASV and PTFE grafts could be observed up to 2 years after operation (70% ± 18% [SE] vs. 75% ± 11% 2-year patency, respectively, $p > 0.75$). Insufficient numbers of these grafts were observed beyond 2 years to permit meaningful comparison for longer periods. The larger number of randomized operations performed to popliteal arteries with angiographically better runoff had significantly better patency rates with ASV grafts than with PTFE grafts (81% ± 5% vs. 77% ± 5% 2-year patency and 73% ± 7% vs. 54% ± 9% 4-year patency, respectively, $p < 0.025$). This better runoff subgroup of operations had uninterrupted flow from the popliteal artery down to at least one infrapopliteal artery for a distance of 5 cm or more.

Limb salvage. When all patients who had randomized bypasses to the popliteal artery to treat critical ischemia were considered together, there were no statistically significant differences in limb salvage rates between those whose operations were performed with an ASV graft and those with a PTFE graft (Fig. 3).

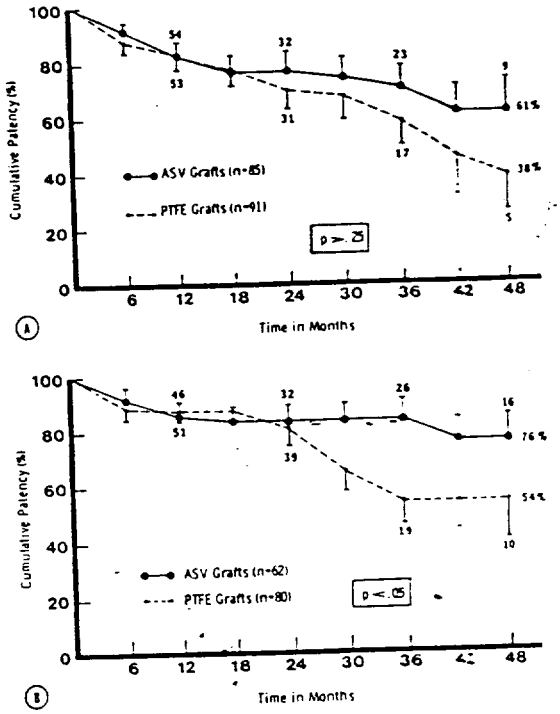

Fig. 2. Cumulative life-table primary patency rates for all randomized autologous saphenous vein *(ASV)* and polytetrafluoroethylene *(PTFE)* bypasses performed to popliteal artery (A), above-knee; (B), below-knee. Number with each point indicates number of patent grafts observed for that length of time. Standard error of each point is shown.

In no randomized popliteal bypass subgroup, on the basis of location of the distal anastomosis or angiographic runoff, was there a statistically significant difference in limb salvage rates in patients with ASV and those with PTFE grafts. In contrast to patency rates (Fig. 2), limb salvage rates for randomized above-knee popliteal bypasses with both ASV and PTFE tended to be slightly better (78% ± 13% and 77% ± 13% 4-year limb salvage, respectively) than those for below-knee popliteal bypasses with ASV and PTFE (75% ± 14% and 62% ± 14% 4-year limb salvage, respectively). Limb salvage rates for ASV and PTFE limb salvage bypasses to isolated popliteal artery segments (83% ± 15% and 77% ± 11% at 2 years, respectively) were somewhat worse than comparable rates for ASV and PTFE limb salvage bypasses to popliteal arteries with angiographically better runoff (91% ± 4% and 83% ± 5% at

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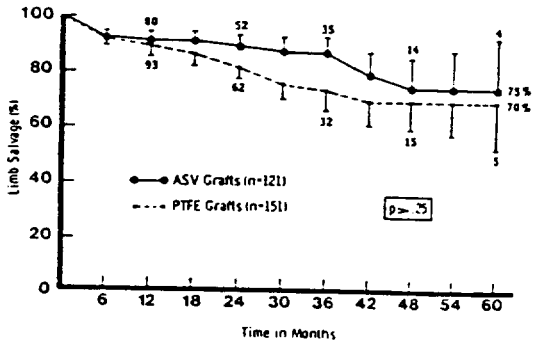

Fig. 3. Cumulative life-table limb salvage rates for all patients with randomized autologous saphenous vein *(ASV)* and polytetrafluoroethylene *(PTFE)* grafts to popliteal artery. All operations represented here were performed to control critical ischemia. Number with each point indicates number of operated limbs observed to be intact for that length of time. Standard error of each point is shown.

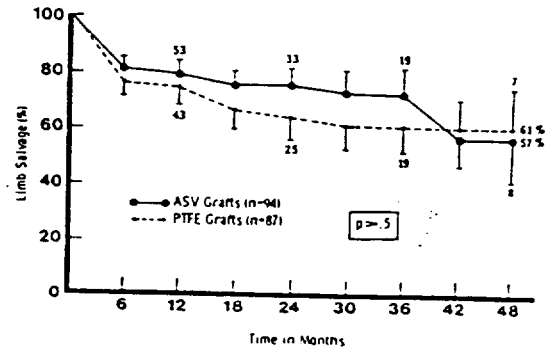

Fig. 5. Cumulative life-table limb salvage rates for patients with randomized autologous saphenous vein *(ASV)* and polytetrafluoroethylene *(PTFE)* grafts to infrapopliteal arteries. All operations represented here were performed to control critical ischemia. Number with each point indicates number of operated limbs observed to be intact for that length of time. Standard error of each point is shown.

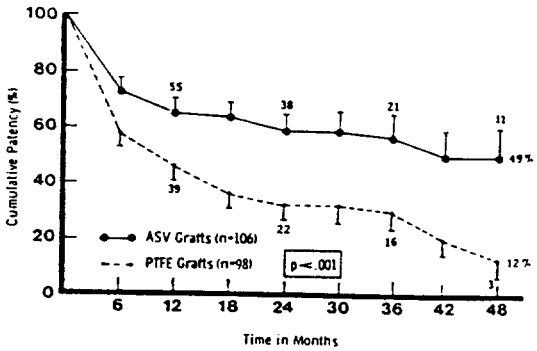

Fig. 4. Cumulative life-table primary patency rates for all randomized bypasses to infrapopliteal arteries with autologous saphenous vein *(ASV)* and polytetrafluoroethylene *(PTFE)* grafts. Number with each point indicates number of grafts observed to be patent for that length of time. Standard error of each point is shown.

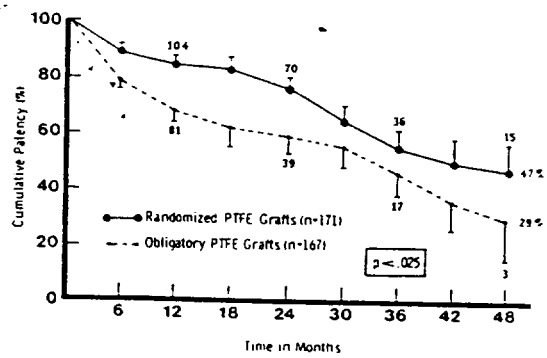

Fig. 6. Cumulative life-table primary patency rates for all randomized and obligatory polytetrafluoroethylene *(PTFE)* bypasses to popliteal artery. Number with each point represents number of patent grafts observed for that length of time. Standard error of each point is shown.

2 years, respectively, and 77% ± 10% and 73% ± 10% at 4 years, respectively).

Randomized ASV and PTFE grafts to infrapopliteal arteries

Graft patency. Cumulative patency rates for bypasses with these two types of grafts are shown in Fig. 4. Patency differences became apparent within 1 month of operation and increased progressively thereafter. At 4 years these differences were highly statistically significant ($p < 0.001$).

Limb salvage. There was no significant difference in limb salvage rates between patients with randomized ASV distal grafts and those with randomized PTFE distal bypasses (Fig. 5).

Obligatory vs. randomized PTFE grafts

Graft patency. Patency rates for randomized PTFE grafts to the popliteal artery were significantly better ($p < 0.025$) than those for obligatory PTFE grafts to the same artery (Fig. 6). However, there was no significant difference between patency rates of randomized and obligatory PTFE grafts to infrapopliteal arteries (29% ± 6% and 18% ± 5% 3-year patency and 12% ± 7% and 7% ± 7% 4-year patency, respectively, $p > 0.5$).

Limb salvage. No significant differences in limb salvage rates were present in patients with randomized and obligatory PTFE limb salvage bypasses to the popliteal artery (69% ± 10% and 68% ± 19% 4-year limb salvage, respectively, $p > 0.25$). How-

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ever, patients with obligatory PTFE bypasses to infrapopliteal arteries had significantly worse limb salvage rates than did patients with randomized PTFE grafts to the same arteries (61% ± 9% vs. 38% ± 9% 3-year limb salvage and 61% ± 14% vs. 19% ± 12% 4-year limb salvage, respectively, $p < 0.01$).

DISCUSSION

These results show clearly that femoropopliteal bypasses performed with randomized PTFE grafts have patency rates inferior to those performed with randomized ASV grafts (Fig. 1). This fact does not support the routine preferential use of PTFE grafts for femoropopliteal arterial reconstructions. However, because patency rates with the two grafts in the femoropopliteal position remain similar for 2 years after operation and only diverge thereafter, a case can be made for the preferential use of PTFE grafts as femoropopliteal bypasses in poor-risk patients with a life expectancy of 2 to 3 years or less. This case is strengthened by the similar limb salvage rates in patients with femoropopliteal bypasses performed to control critical ischemia with both types of grafts (Fig. 3) and by the previously stated advantages of simplifying the operation, eliminating complications of vein harvest, and preserving the ipsilateral ASV for future use.[6,7] On the other hand, life expectancy is difficult to predict accurately, and the limb salvage rates after our PTFE bypasses were only achieved at a cost of more frequent reoperation for graft failure. This plus the significantly superior primary patency of ASV grafts below the knee and the trend toward lower limb salvage rates after a below-knee PTFE femoropopliteal bypass mandate that this graft not be used in this position in preference to a good ipsilateral ASV except in the worst-risk patients.

Equivalent patency and limb salvage rates were observed for ASV and PTFE bypasses to *isolated popliteal artery segments* with angiographically poor outflow or runoff. These data support the impression that such bypasses are worthwhile for limb salvage and cast doubt on the use of angiographic evaluation of runoff from the popliteal artery to exclude patients from limb salvage attempts. However, the number of cases and the period of observation in our study were insufficient to provide reliable information beyond the second postoperative year. Therefore, preferential use of PTFE grafts in this circumstance should be restricted only to patients with poor expectations of surviving beyond 2 years.

The patency and limb salvage results from this study also support the continued use of PTFE grafts for femoropopliteal bypass when a patient's ipsilateral ASV is absent, diseased, or inadequate. Since such obligatory PTFE femoropopliteal grafts were performed in higher risk circumstances than comparable randomized PTFE grafts (Table III), it is not surprising that the latter had significantly better patency rates (Fig. 6). However, there is no good explanation for the observation that limb salvage rates after these obligatory PTFE popliteal bypasses were no worse than those after randomized PTFE popliteal bypasses.

The present study confirms the clear superiority of randomized ASV grafts over randomized PTFE grafts for arterial reconstructions to infrapopliteal arteries.[11] This superiority was obvious from the first postoperative month and increased progressively thereafter (Fig. 4). However, this patency difference was not reflected in differing limb salvage rates because failure of a randomized PTFE distal bypass was not always associated with a renewed threat to the limb; and, when it was, a secondary vein bypass often resulted in continuing limb salvage. Obligatory PTFE distal bypasses had slightly lower patency rates but significantly lower limb salvage rates than randomized PTFE distal bypasses. These data mandate that every effort be made to perform all infrapopliteal bypasses with autologous vein. Techniques that facilitate vein availability, such as use of the superficial femoral or popliteal arteries for bypass origins[18] and utilization of arm veins,[19] certainly are appropriate in this regard. The poor patency and limb salvage results that were observed in the group of patients that had to have an obligatory PTFE distal bypass raise the question of whether a primary amputation should be performed in preference to a PTFE distal bypass if autologous vein is truly not available, and some have suggested this approach.[20] The 3-year limb salvage rate of 38% ± 9% obtained in such cases in the present study would argue against such a conclusion, particularly since the life expectancy of patients who require this kind of operation is so limited.[21] Obviously, however, there is a need for better small artery prostheses for use when autologous vein is not available.

Questions can also be raised concerning the relative merits of (1) PTFE grafts compared with other nonvein grafts and (2) reversed ASV grafts as used in this study compared with other kinds of autologous vein grafts, such as those fashioned from upper extremity veins or by the in situ technique. Unfortunately no valid statements can be made about these relative values on the basis of the present study. An abundance of patient-related and surgeon-related variables preclude valid comparisons between the present data and those from other published reports.

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This underscores the importance of the present study, for only when these other variables are controlled can the true merits of proposed "improved techniques" or "better grafts" be adequately evaluated.

Even in our study, in which an effort was made to eliminate the influence on results of patient-related factors by randomization, it is still possible that a chance maldistribution of such risk factors could lessen the validity of some of our findings. The distribution and impact of these patient-related risk factors will be examined further in subsequent reports.

The present study, in addition to providing a valid comparison of two grafts and answering some secondary questions, raises other issues. One of these is the reason why limb salvage rates in patients whose operation was performed to control critical ischemia were so much higher than graft primary patency rates. One reason is that during the period of graft function, gangrenous and infectious foot lesions had been permanently healed so that critical ischemia did not recur when the graft failed. A second reason was the effectiveness of reoperation, which was employed regularly by all nine surgeons when primary arterial reconstructions failed and the involved limb was again threatened.

The present results may also contribute to an improved understanding of similarities and differences between ASV and PTFE grafts in regard to the mechanisms whereby femoropopliteal reconstructions with them fail. Such failures in the first 2 postoperative months are thought to be caused by technical factors or an improper choice of operation; those that occur from 2 to 18 months after operation are mostly a result of neointimal hyperplasia; and failures that occur more than 18 months after operation are largely due to progression of atherosclerosis.[22-25] ASV and PTFE grafts to the popliteal artery failed with roughly equal frequency up to 18 months; thereafter the PTFE grafts failed more frequently. This suggests that PTFE grafts, at least in the femoropopliteal position, may be disadvantaged because they promote progression of distal atherosclerosis in some as yet unclarified way.

In the last 15 years numerous claims have been made regarding the superiority of various grafts and technical modifications as means for improving the results of infrainguinal arterial reconstructive surgery. Usually these claims are made on the basis of a relatively short-term follow-up of a limited number of cases. Historical controls, frequently those from other centers, are offered to sustain the claim of superiority, and the new graft or technical modification becomes widely adopted. Although the present study required a large number of patients and many years to complete, the effort seems to have been justified by the value of the information gained. A large data base relating to infrainguinal bypass operations has been generated, which will permit a number of secondary questions not addressed in the present report to be answered in future communications. Most important, however, a valid comparison of the efficacy of ASV and PTFE grafts employed to treat infrainguinal arteriosclerosis now exists, and usage of PTFE grafts need no longer be based on whim, hope, or unjustified claims. It would seem appropriate to subject many other aspects of infrainguinal arterial surgery to the same kind of scrutiny by other similar studies.

We thank Dr. D. Emerick Szilagyi for his advisory participation in some aspects of this study.

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DISCUSSION

Dr. Robert W. Hobson (Newark, N.J.). This multi-institutional data collection serves as the model for cooperative study efforts confirming the excellence of autogenous saphenous vein as well as the increasingly convincing evidence on the limitations of polytetrafluoroethylene (PTFE) for bypass procedures in limb salvage cases. These data offer advantages in larger sample sizes over individual institutional reports such as our 5-year clinical follow-up of 246 femoropopliteal and tibial bypasses with autogenous saphenous vein used preferentially and obligatory PTFE in the absence of a vein, which we were privileged to present before this society last year (1984) in Atlanta. However, the close correlation between these data presented today and our past series stimulated my discussion. In our series, below-knee femoropopliteal bypass with autogenous saphenous vein at 5 years resulted in limb salvage and patency rates of 83% and 74%, respectively, whereas comparable data for PTFE were 35% and 22% respectively. For tibial bypasses at 5 years after operation, limb salvage and patency rates were 53% and 47% for saphenous vein, respectively, and 20% and 15% for PTFE, respectively (J Vasc Surg 1985; 2:174-85).

On the basis of our series and its comparability to your multi-institutional assessment, I would like to present several questions.

You have reported on the status of above-knee and below-knee popliteal bypass with PTFE. I would appreciate your comments on the number of patients in whom such a bypass has been accompanied by a sequential or jump graft, cephalic or saphenous vein to the tibial level, discarding use of PTFE to a tibial artery entirely as we recommended.

Can you outline for us the management of the occluded PTFE vascular prosthesis? As we reported in 1984, our data did not support thrombectomy and distal revision of the tibial bypass, as we were unable to achieve any increase in either limb salvage or patency. Occlusion of our PTFE bypasses also resulted in substantial distal ischemia; however, your data demonstrate limb salvage in excess of patency, suggesting that prosthetic occlusion is well tolerated in a large number of patients. Could you please explain this apparent difference in our series?

Finally, can you give us any insight into institutional differences within the overall data that might account for this close correlation between our individual series and this cooperative effort?

We regard this as the definitive work on the role of PTFE in peripheral vascular occlusive disease.

Dr. Roger C. Rosen (Boston, Mass.). This study has demonstrated that a polytetrafluoroethylene (PTFE) graft to the popliteal artery can achieve primary patency rates similar to autologous saphenous vein for up to 2 ½ years. Since the goal of infrainguinal revascularization is to maintain a viable extremity for the longest period of time, then perhaps the subsequent period of limb salvage can be max-

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imized by an initial prosthetic bypass to the popliteal artery, when feasible, followed by a more distal vein bypass when the prosthetic graft fails.

At the Boston Veterans Administration Medical Center we have examined this concept of *staged reconstructions*. The limb salvage rates following infrainguinal arterial reconstruction of 134 patients who were at risk for limb loss were examined. There were 59 above-knee popliteal prosthetic grafts (PTFE or umbilical vein), 75 below-knee popliteal or tibial in situ saphenous vein grafts; eight patients had a staged reconstruction, that is, a prosthetic graft followed by an in situ saphenous vein (ISV) reconstruction.

An above-knee prosthetic and a below-knee popliteal or tibial ISV graft achieve similar 3-year limb salvage rates of 75% and 71%, respectively. The staged group, albeit small, achieved 87% limb salvage at 3 years. Therefore, we believe that, if feasible, an initial prosthetic above-knee popliteal bypass should be considered. If failure occurs because of distal disease, a distal vein bypass can be performed. This staged reconstruction may prolong limb salvage for a greater length of time than an initial ISV graft alone.

I would like to ask the authors to give their thoughts with regard to this concept of staged reconstruction.

Dr. Martin L. Schulman (Great Neck, N.Y.). Let me congratulate the authors on presenting a classic study that will stand as a model of integrity and application of the scientific method.

My remarks concern the preliminary results of a randomized comparative study, started 4 years ago, of superficial femoral and popliteal veins vs. reversed saphenous veins as primary femoropopliteal bypass grafts. Results at 2 years, showing 87% patency of deep leg veins and 67% patency of the saphenous veins are statistically significant. More importantly, they are clinically significant, because we know the causes of failure of deep leg vein grafts, as a result of an intensive angiographic follow-up, with 214 postoperative arteriograms performed in the 62 deep leg vein cases.

Our results with a third autogenous graft source, arm veins, as reported at this society's meeting in 1982, were disappointing.

Three of the four occlusions occurring in deep leg veins between 1 month and 2 years were associated with advanced distal disease and were not graft-related. The hyperplastic changes frequently seen in the body of saphenous vein grafts were only seen once.

Deep leg vein occlusions in the third year were all intrinsic, because of recurrent distal anastomotic hyperplasia, usually treated by percutaneous angioplasty, and the embolization of graft mural thrombi in patients in whom, by present criteria, unacceptably large grafts were used.

Lessons learned during the course of this study, leading to modifications in technique, strategy, and graft selection, support a realistic expectation of significantly improved late results in the future.

At present, after an 11-year experience with these grafts, we use superficial femoral and popliteal veins preferentially as femoropopliteal bypass grafts.

Dr. Veith (closing). We had hoped that this study would settle things once and for all. Obviously, it has not. The reason is that there are two aspects to our study. One is the data or the facts, and the other is the interpretation of these facts. We are still in the process of interpretation as we sift through some of the details, but I think the facts are there for everybody to interpret once they have read the article. Clearly, some physicians are going to come up with different opinions on the basis of these facts, and I think these differences of opinion are responsible for some of the points raised in the discussion.

Dr. Hobson, I think that may account for some of our disagreement. One of the many variables that we have not yet analyzed, but will, is the interinstitutional variation. I do not think it will make much difference, but we are going to look at it all the same.

When do we use sequential grafts? In general, we favor the simplest procedure possible. In patients with a patent popliteal segment, the simplest operation is usually an above-knee femoropopliteal bypass. We generally restrict the use of sequential bypasses to patients who have extensive gangrene or infection in the foot and who need more blood supply to heal the foot. We believe our patency data justify this approach.

We have recently changed some of our thinking concerning reoperations for failed grafts. For failed above-knee PTFE femoropopliteal grafts, the follow-up patency rates for reoperations that include a thrombectomy are excellent. It is not as good with PTFE bypasses below the knee and certainly not good with tibial bypasses. Thus in both those circumstances we have changed our recommendation and prefer to do a totally new bypass, preferably with vein, when a PTFE graft fails.

Dr. Rosen, your approach is reasonable. However, we presently oppose the use of prosthetic grafts preferentially above the knee and certainly below the knee in a young patient who has a life expectancy of maybe 10 or 15 years. Of course it is difficult to judge life expectancy accurately. Moreover, there is as yet no conclusive proof that in situ vein grafts are superior to reversed vein grafts when both operations are performed with equal care and commitment.

Dr. Schulman, we agree that the saphenous vein is not always perfect. The arterial systems into which we put these grafts are not perfect either, and most of the failures resulted from deterioration in the patient's arteries, not from a problem in the graft. It is of interest, of course, that as surgeons become involved in this field, their results get better in general and in the specific procedure in which they have a particular interest.

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Number 1

Expanded polytetrafluoroethylene femoropopliteal grafts: Forty-eight-month follow-up

L. E. Evans, M.D., M. W. Webster, M.D., D. H. Brooks, M.D., *and* H. T. Bahnson, M.D., *Pittsburgh, Pa.*

Ninety-eight expanded polytetrafluoroethylene (PTFE) grafts were used for femoropopliteal reconstruction in 81 patients. Forty-eight-month follow-up is now available for 20 grafts and 36-month follow-up is available for 51 grafts. Seventy-four percent of the patients were men. Thirty-one percent had diabetes mellitus. 38% had hypertension. 36% had atherosclerotic heart disease, 18% had prior myocardial infarction, 17% had a previous operation for aortoiliac disease, and 14% had a previous ipsilateral femoropopliteal bypass procedure. The indication for operation was claudication in 47%, rest pain in 20%, and ischemic pregangrene or gangrene in 32% of patients. Distal runoff was angiographically graded as good (76%) or poor (24%). Seventy-three grafts were anastomosed to the proximal or midpopliteal artery (above the knee); 25 grafts were anastomosed to the distal popliteal artery (below the knee). Graft occlusion was determined by the return of ischemic symptoms, disappearance of previously palpable pulses, or by angiographic or Doppler assessment. There were no operative deaths. Nonocclusive causes of graft loss were death (7), amputation (2), infection (2), and aneurysm (5). The overall cumulative patency rate calculated by the life-table method, according to the criterion of occlusion alone, was 75% at 6 months, 68% at 1 year, 63% at 2 years, 58% at 3 years, and 48% at 4 years. Preoperative symptoms, the number of patent outflow vessels, popliteal anastomosis placed above or below the knee, or hypertension did not adversely affect graft patency. Diabetes mellitus was associated with significantly increased graft failure. The PTFE graft is an acceptable alternative for femoropopliteal reconstruction for the patient without a suitable autologous saphenous vein.

From the Department of Surgery, University of Pittsburgh School of Medicine, Pittsburgh, Pa.

CLINICAL EXPERIENCE with expanded polytetrafluoroethylene (PTFE) grafts for arterial reconstruction in the femoropopliteal position began at the Health Center of the University of Pittsburgh in October, 1974. The initial clinical evaluation reported by Campbell, Brooks, and Bahnson[1] demonstrated acceptable short-term patency and limb salvage rates. Since October, 1974, PTFE has been used for femoropopliteal bypass in the majority of patients who lacked a suitable autologous saphenous vein. In 1979 Campbell et al.[2] reported a composite summary of the initial 2-year experience with 131 lower extremity bypass grafts implanted both in the femoropopliteal and femorotibial position in the three hospitals of the health center. The cumulative patency rate at 2 years was 75.7%. Since that time Haimov, Ciron, and Jacobson[10] have reported a patency rate of 74% at 1 year and 58% at 2 years. Veith, Gupta, and Daly[11] have reported a patency rate of 77% at 3 years.

This report is an analysis of the 98 consecutive femoropopliteal and femoral distal popliteal PTFE grafts implanted at Presbyterian-University Hospital from October, 1974, through September, 1979.

Cumulative patency rates are compared with respect to symptoms at the time of operation, quality of distal runoff, graft diameter, and anastomotic site as well as the presence or absence of diabetes mellitus or hypertension.

MATERIAL AND METHODS

The physical characteristics and tissue response to expanded PTFE grafts (Gore-Tex)* have been

*W.L. Gore and Associates, Elkton, Md.

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described previously.[2, 3, 6] Early failures caused by aneurysmal dilatation of the original PTFE graft[4] prompted the clinical introduction of a reinforced two-layer PTFE graft in 1975. The grafts implanted prior to November, 1975, were the original unreinforced Gore-Tex product. Grafts subsequently implanted were of the modified reinforced material. No graft aneurysms have developed in the reinforced grafts. Between October, 1974, and November, 1979, seventy-three femoropopliteal (above the knee) and 25 femoral distal popliteal (below the knee) PTFE grafts were implanted in 98 limbs of 81 patients. For the purpose of analysis, patients receiving more than one graft have been considered as a separate patient for each graft. The patient population (Table I) consisted of 73 men, ranging in age from 44 to 88 years (median, 62 years) and 25 women, ranging in age from 48 to 87 years (median, 69 years). Thirty (31%) of the patients had adult-onset diabetes mellitus, 37 (38%) were hypertensive, and 35 (36%) had documented atherosclerotic heart disease based upon abnormal electrocardiogram tracings, anginal symptoms, past myocardial infarction, or congestive heart failure. Eighteen patients had a history of a previous myocardial infarction. One patient had required coronary artery bypass. Three patients had undergone carotid endarterectomy and two others had had cerebral vascular accidents with subsequent resolution of symptoms. Severe aortoiliac disease had necessitated previous aorto bi-iliac bypass in one patient, aortobifemoral bypass in 14 patients, and axillofemoral bypass in two patients. One aortobifemoral graft had been subsequently revised to a femorofemoral bypass. Ten patients had undergone one previous ipsilateral femoropopliteal bypass using either autologous vein, Dacron, or Gore-Tex. Three patients had undergone two previous procedures.

The indication for operation was severe and disabling claudication in 46 patients (47%), rest pain in 20 patients (20%), ischemic pregangrene or gangrene in 31 patients (32%), and replacement of a patent aneurysmal graft with no recurrent symptoms in one patient (1%). Distal runoff was assessed angiographically in 91 cases preoperatively and in two cases intraoperatively after insertion of the graft. The quality of distal runoff was graded good in 71 cases (76%), if two or three trifurcation vessels were patent; or poor in 21 cases (24%), if there was one patent distal vessel or an isolated popliteal segment.

An antibiotic, usually a cephalosporin, was administered 6 to 12 hours preoperatively and continued for 2 to 5 days postoperatively. The patients routinely received heparin intraoperatively but only rarely were dextran or anticoagulants administered postoperatively.

Table I. Characteristics of the patient population

Diabetes mellitus	31%
Hypertension	38%
Coronary artery disease	36%
Previous myocardial infarction	18%
Cerebrovascular disease	6%
Previous inflow grafts	17%
Failed ipsilateral femoropopliteal grafts	14%

Of the 73 grafts (74%) anastomosed at the proximal or midpopliteal artery (above the knee), 37 were 8 mm in diameter, 29 were 6 mm in diameter, and five were tapered. The diameter of two grafts was unrecorded. Of the 25 grafts (26%) anastomosed to the distal popliteal segment (below the knee), there were six 8 mm grafts, eleven 6 mm grafts, two 4 mm grafts, and four tapered grafts. The diameter of two grafts was unrecorded. Grafts were sutured routinely to the popliteal artery in end-to-side fashion using continuous synthetic suture. Proximal anastomoses to the common femoral artery or to the prosthetic material of previously placed inflow grafts were also end-to-side.

Patient follow-up consisted of chart review, telephone interviews with patients and their referring physicians, evaluation by Doppler measurement of segmental arterial pressures, and direct Doppler auscultation of graft flow when distal pulses were not palpable. The date of graft occlusion was determined by the first noted return of acute ischemic symptoms, the disappearance of previously palpable pulses, the angiographic demonstration of graft occlusion, or the absence of graft flow by Doppler auscultation. Cumulative patency rates were calculated using the Life-Table and Survival Program of the Health Center Computing Facility, University of California, Los Angeles, California, revised December 27, 1977.[1] Statistical comparison of graft patency rates was performed according to this program using the Breslow modification of the generalized Wilcoxon statistic. An interval width of 1 month was used in the calculation of patency rates. Utilizing the life-table method, graft failure caused by occlusion was assessed independently as well as in conjunction with nonocclusive causes of graft attrition.

The nonocclusive causes of graft loss were infection (two) or graft aneurysm (five) which necessitated the removal of a patent graft, major amputation (two) caused by progressive necrosis or pain despite a patent graft, and death caused by unre-

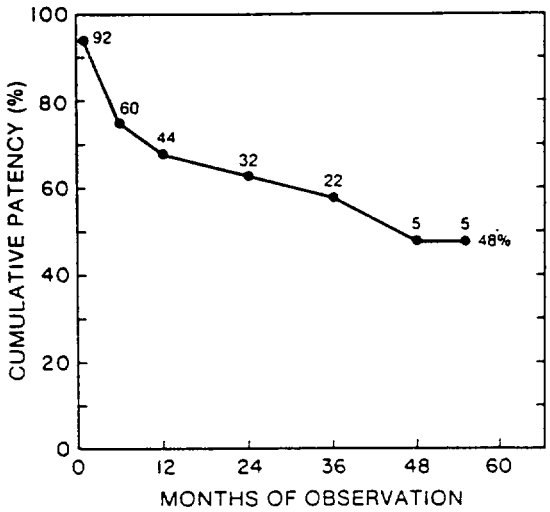

Fig. 1. Cumulative patency rate by the life-table method for 98 PTFE femoropopliteal bypass grafts. The number above each time point indicates the number of patent grafts observed for that period of time after operation.

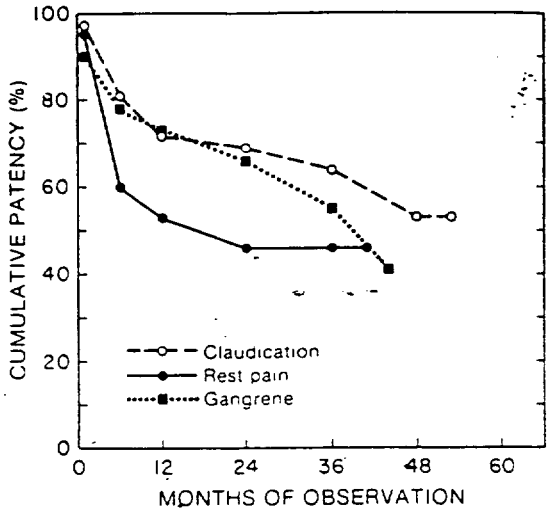

Fig. 2. Cumulative patency rate by the life-table method for PTFE femoropopliteal grafts done for claudication (N = 46), rest pain (N = 20), or gangrene or ischemic ulceration (N = 31).

Table II. Life-table analysis of graft patency (calculation based on an interval width of 1 month)

Interval (mo)	*Patent grafts (beginning of interval)*	*Occluded*	*Withdrawn patent**	*Patent graft lost during interval*	*Cumulative graft patency (%)*
0-1	98	5	0	1 (infection)	94
1-6	92	17	5	1 (amputation)	75
				1 (infection)	
				3 (aneurysms)	
				5 (deaths)	
6-12	60	5	7	2 (lost to follow-up)	68
				1 (aneurysm)	
				1 (death)	
12-24	44	3	7	2 (lost to follow-up)	63
24-36	32	2	6	1 (amputation)	58
				1 (aneurysm)	
36-48	22	3	13	1 (death)	48
48-55	5	0	5		48

*Grafts patent at the termination of the study but the length of follow-up lies within the given interval.

lated illness (seven) with a patent graft at the time of death.

RESULTS

Ninety-eight PTFE grafts were implanted from October, 1974, through November, 1979. Fifty-one grafts had been implanted more than 36 months and 20 of these had been implanted more than 48 months. There was no operative death. Postoperative complications included pulmonary embolus (one), urinary tract infection (one), hematoma (two), and infected inguinal seroma (two). Both inguinal infections resulted in infection of the graft, requiring its subsequent removal. Four patients have required thrombectomy of the graft. One patient who underwent successful thrombectomy at 4 days underwent an amputation 1 month later for persistent pain despite a patent graft. Another patient who under-

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went thrombectomy at 11 days died with a patent graft 6 months later from an unrelated cause. A third successful thrombectomy was performed 22 months postoperatively. This patient required amputation with a patent graft 5 months later because of progressive necrosis. A fourth patient required thrombectomy on three occasions. His graft remains patent at 40 months.

Infection in two grafts required removal at 28 and 60 days. Aneurysmal dilatation occurred in eight of the original 20 unwrapped grafts. One of these grafts had occluded prior to revision. Five patent aneurysmal grafts, one of which had ruptured, were replaced at 1,2,4,10, and 30 months. One patient who underwent below-knee amputation following distal graft occlusion had aneurysmal dilatation of the proximal portion of the graft at the time of this study. One aneurysmal graft remains functional at 54 months. Seven patients died with patent grafts. These deaths occurred at 2,3,4,5,5.9, and 45 months postoperatively. Causes of death were myocardial infarction (one), ovarian carcinoma (one), colonic carcinoma (one), renal failure secondary to polycystic kidneys (one), complications of aortic aneurysmectomy (one), and unknown causes (two). Persistent pain or progressive necrosis lead to major amputation despite a patent graft in two patients at 1 and 27 months. Four patent grafts were lost to follow-up at 7,10,14, and 18 months. Forty-three grafts remain patent. The occlusion of 35 grafts and failure of seven grafts caused by infection (two) and aneurysm (five) resulted in 12 below-knee amputations and seven above-knee amputations. One patient died of sepsis, one of myocardial infarction, and one of cerebral vascular accident following amputation.

The cumulative patency rate, calculated by the life-table method, is presented in Table II and Fig. 1. The cumulative patency rate for all grafts according to the criterion of occlusion alone was 75% at 6 months, 68% at 1 year, 63% at 2 years, 58% at 3 years, and 48% at 4 years. When the additional nonocclusive causes for graft loss were considered, cumulative graft function decreased to 65% at 6 months, 57% at 1 year, 52% at 2 years, 45% at 3 years, and 33% at 4 years. Deletion of those grafts removed because of aneurysm (a problem no longer encountered with reinforced graft material) does not significantly affect the cumulative patency rate. The highest rate of occlusion, 22 grafts, and loss due to other causes, 11 grafts, occurred during the first 6 months following implantation. The greatest interval occlusion rate (5%) was noted in the first month and remained

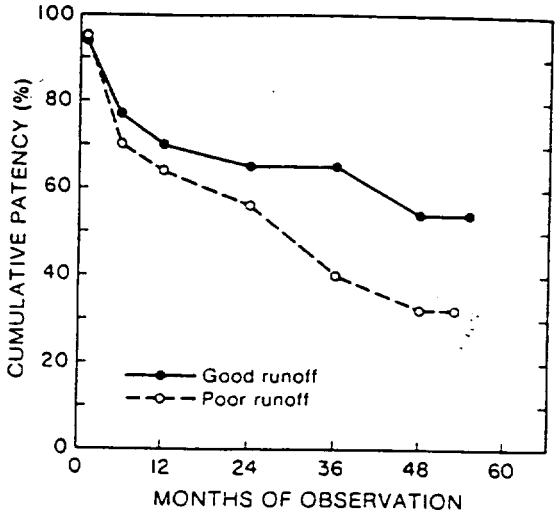

Fig. 3. Cumulative patency rate by the life-table method for PTFE femoropopliteal grafts in patients with good ($N = 71$) or poor ($N = 22$) distal runoff according to angiographic assessment ($P = 0.4$).

approximately 4% per month during the ensuing 5 months. Thereafter the interval occlusion rate decreased to less than 1% per month.

IMPACT OF RISK FACTORS

Indication for operation (Fig. 2). Forty-six grafts were implanted for disabling claudication. The cumulative patency rate for this group was 81% at 6 months, 75% at 12 months, 69% at 24 months, 64% at 36 months, and 53% at 48 months. Aneurysms (three), infection (one), amputation with patent graft (one), and deaths (five) contributed to additional graft loss from this group. Nineteen graft failures in this group resulted in five below-knee amputations and one above-knee amputation.

Twenty grafts were implanted for rest pain. The initial failure rate was highest in this group, with only 60% graft patency at 6 months. The long-term patency rate, however, was not significantly different from that of the other groups. The cumulative patency rate was 53% at 1 year, 46% at 2 years, and 46% at 3 years. Failure of 10 of the grafts implanted for rest pain resulted in three above-knee amputations and two below-knee amputations.

Thirty-one patients underwent revascularization for gangrene or ischemic ulceration. The cumulative patency rate for this group was 78% at 6 months, 73% at 12 months, 66% at 24 months, 55% at 36 months, and 41% at 44 months. Aneurysms (two),

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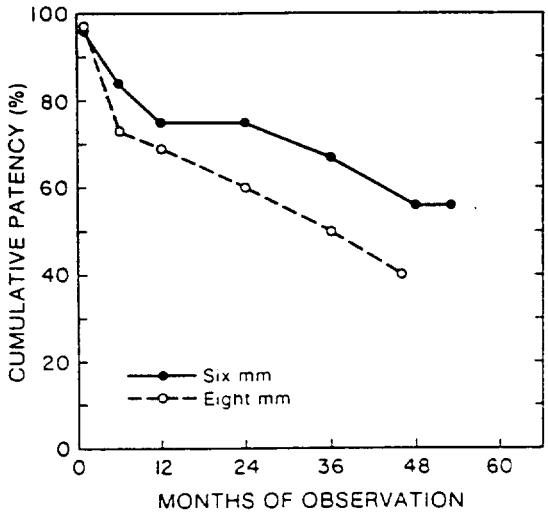

Fig. 4. Cumulative patency rate by the life-table method for PTFE femoropopliteal grafts 6 mm (N = 29) or 8 mm (N = 37) in diameter ($P = 0.7$).

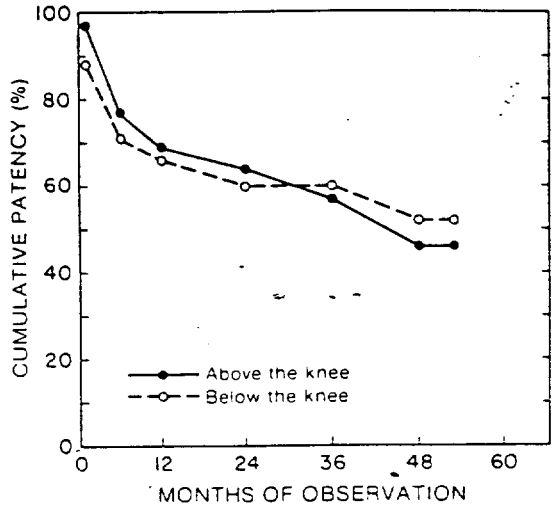

Fig. 5. Cumulative patency rates by the life-table method for PTFE femoropopliteal grafts anastomosed to the popliteal artery above the knee (N = 73) or below the knee (N = 25). ($P = 0.4$).

infection (one), amputation (one), and deaths (two) accounted for additional graft loss. Thirteen graft failures resulted in three above-knee amputations and five below-knee amputations. Although a trend toward increased patency for grafts inserted for relief of claudication was noted, no statistically significant difference between the patency rates of these three groups was demonstrated ($P = 0.3$). The proportion of graft failures resulting in amputation was higher in those patients operated upon for rest pain or gangrene than for those patients presenting with claudication.

Angiographic classification (Fig. 3). The distal runoff was considered to be good in 71 patients. In this group, the cumulative patency rate was 77% at 6 months, 70% at 12 months, 65% at 24 months, 65% at 36 months, and 54% at 48 months. For the 22 patients with poor distal runoff, the cumulative patency rate was 70% at 6 months, 64% at 12 months, 56% at 24 months, 40% at 36 months, and 32% at 48 months. The runoff was undetermined for five grafts. A trend toward improved patency in those grafts with good distal runoff was noted; however, a statistically significant difference was not demonstrated ($P = 0.4$).

Diameter of graft (Fig. 4.). Of the 73 grafts implanted above the knee, 37 were 8 mm in diameter. The cumulative patency rate for this group was 73% at 6 months, 69% at 12 months, 60% at 24 months, 50% at 36 months, and 40% at 45 months. There were no patent grafts observed longer than 45 months of this group. Twenty-nine grafts implanted above the knee were 6 mm in diameter. The cumulative patency rate for this group was 84% at 6 months, 75% at 12 months, 75% at 24 months, 67% at 36 months, and 56% at 48 months. Although not significantly different, a trend toward improved patency was noted when 6 mm grafts were used ($P = 0.2$).

Position of distal anastomosis (Fig. 5). Seventy-three grafts were anastomosed to the proximal or midpopliteal artery. The cumulative patency rate of this group was 77% at 6 months, 69% at 12 months, 64% at 24 months, 57% at 36 months, and 46% at 48 months. Twenty-five grafts were anastomosed to the distal popliteal segment below the knee. The cumulative patency rate for this group was 71% at 6 months, 66% at 12 months, 60% at 24 months, 60% at 36 months, and 52% at 48 months. There was no statistically significant difference between the patency rates of femoropopliteal grafts placed above or below the knee ($P = 0.4$).

Hypertension. Sixty-one patients were normotensive and 37 patients had medically controlled hypertension. No statistically significant difference was noted between the cumulative patency rates for these two groups.

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Diabetes mellitus (Fig. 6). Thirty-one grafts were implanted in patients with adult-onset diabetes mellitus. Twelve of those grafts became occluded within the first 6 months. The cumulative patency rate was 59% at 6 months, 55% at 12 months, 43% at 24 months, 43% at 36 months, and 24% at 48 months. One graft was lost in this group because the patient died. No losses were caused by aneurysm, infection, or amputation. Sixty-seven grafts were implanted in patients without diabetes. The patency rate in this group was 85% at 6 months, 75% at 12 months, 73% at 24 months, and 65% at 36 months. Additional losses because of aneurysms (five), infections (two), amputations (two), and deaths (six) occurred in this group. The cumulative patency rates of these groups, based upon the criterion of occlusion alone, was significantly different ($P = 0.03$).

Prior aortoiliac operations. Seventeen patients had undergone previous operation for aortoiliac occlusive disease. There was no significant difference between the patency rates of that group and those patients who had not had previous aortoiliac revascularization.

Secondary femoropopliteal bypass. Thirteen grafts were implanted in patients who had had one or two previous unsuccessful ipsilateral femoropopliteal bypass procedures. The occlusion rate for these grafts was not significantly different from that of patients undergoing primary procedures. Graft loss, however, caused by infection (one), amputation (one), and deaths (two) was proportionally higher.

DISCUSSION

Recent reports by DeWeese and Rob,[7] Codd et al.[8] and Szilagyi et al.[10] have demonstrated the effective use of reversed autologous saphenous vein for femoropopliteal reconstruction. These authors, utilizing the life-table method, have reported cumulative patency rates ranging from 59%[7, 10] to 65%[8] at 48 months. Factors such as the severity of presenting symptoms, angiographic assessment of the quality of distal runoff, and the site of the popliteal anastomosis have relatively minor value in predicting the long-term patency for saphenous vein femoropopliteal bypass grafts. Szilagyi et al.[10] have demonstrated, however, that the quality of the vein, determined by its diameter, presence of varices, fibrotic values, and diffuse sclerosis has correlated well with long-term patency. Veins judged to be of good quality had a cumulative patency rate of 62.3% at 48 months compared to a patency rate of 28.7% for veins of poor quality.

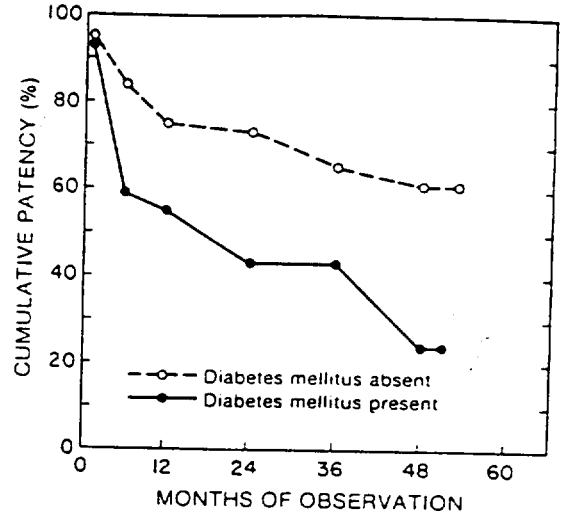

Fig. 6. Cumulative patency rates by the life-table method for PTFE femoropopliteal grafts in patients with diabetes mellitus ($N = 31$) or without diabetes mellitus ($N = 67$). ($P = 0.03$).

Our overall patency rate was 48% at 48 months utilizing PTFE vascular prostheses for femoropopliteal reconstruction. The relatively high interval failure occurring during the initial months is comparable to that seen with saphenous vein femoropopliteal bypass in other series. This early failure rate has been attributed to advanced atherosclerotic disease, technical errors in anastomoses, and the presence of a fresh thrombogenic surface. The use of intraoperative angiographic assessment of the distal anastomosis to detect technical imperfections and the postoperative use of antiplatelet agents may contribute to an improved early patency rate in the future.

Neither the severity of presenting symptoms nor angiographic assessment of outflow based on the number of patent vessels was helpful in predicting the success or failure of the bypass procedure. Grafts traversing the knee joint anastomosed to the distal popliteal artery performed as well as those anastomosed to the proximal or midpopliteal segment above the knee. Thus the construction of compound PTFE vein grafts in those situations in which the graft must be carried to the distal popliteal segment does not seem to be warranted. Although not significant, there is a trend toward improved patency if 6 mm rather than 8 mm grafts are employed. Whether this trend will prove significant with the accumulation of additional data remains to be determined. The presence of hypertension did not adversely

affect graft patency; however, the presence of diabetes was associated with a significantly greater failure rate, especially during the initial 6-month period.

Our 48-month follow-up is based on follow-up of the initial unwrapped grafts. Long-term follow-up is just becoming available on wrapped PTFE. Experimental evidence[12] suggests that wrapping has substantially diminished tissue ingrowth and effectively reduced pore size, but whether this will have an effect on patency has yet to be determined.

There has been no late aneurysm formation in the remaining original unwrapped grafts. It appears that if aneurysmal dilatation occurred in the early unwrapped grafts it was within the first several months and that subsequent tissue ingrowth has fixed the size of the graft retarding further aneurysm development.

Haimov, Giron, and Jacobson[9] in a summary of 3 years' experience with 184 PTFE femoropopliteal grafts have reported a cumulative patency rate of 58% at 2 and 3 years. Veith, Gupta, and Daly[11] have reported a cumulative patency rate of 77% at 3 years for a series of 175 PTFE femoropopliteal grafts. At present, we feel that a good autologous saphenous vein remains the most desirable material for femoropopliteal reconstruction. The results of this study, as well as those of Haimov and Veith indicate, however, that the use of a PTFE graft provides an acceptable alternative in those instances in which a high-quality saphenous vein is unavailable.

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Ten-year Follow-up of Femoropopliteal Bypass Grafts: Comparative Review of Late Patency Rates of PTFE and Saphenous Vein Grafts for Lower Extremity Ischemia

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Abstract

Between January, 1987 and June 1988, 335 femoropopliteal bypass (FPBP) operations were performed on 308 patients who had limb ischemia caused by femoropopliteal occlusion. The greater saphenous vein graft (SVG) was used whenever possible (165) and polytetrafluoroethylene (PTFE) prosthesis was used in 165. In addition, 4 Dacron grafts and 1 umbilical vein graft were used in 5 operations but were excluded from comparison in this study. The two groups did not differ significantly regarding stage of peripheral ischemia, preoperative indication, distal popliteal anastomotic site, and number of patent runoff vessels. Overall cumulative patency rates according to occlusive criteria alone were calculated by the life table method. Graft occlusion was determined by angiography, Doppler assessment, loss of previously palpable pulses, or return of symptoms. Diabetes mellitus was associated with a significantly lower patency rate.

It is concluded from this study that the saphenous vein is superior to PTFE as femoropopliteal bypass.

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Introduction

Since 1949, when Kunlin[1] performed the first femoropopliteal bypass (FPBP) utilizing the saphenous vein, this substitute has been widely used and has proved to the best choice. Following the results of early experimental[2,3] and more recent clinical reports.[4-7] polytetrafluoroethylene (PTFE) has been recommended as a satisfactory alternative. Despite extensive experience with FPBP grafts over three decades, controversy continues regarding the clinical indications for such grafts and the importance of various factors influencing long-term graft patency.[4,5,8,9] Whereas some researchers cite highly satisfactory function of such grafts in patients with limb-threatening ischemia, other reports in the literature document a much more discouraging experience in patients with advanced ischemic indications. Similarly, disagreement persists regarding the relationship of distal runoff and patency, as well as the influence of the location of the distal anastomosis above or below the knee.

More recent development of alternative prosthetic conduits, claimed by some researchers to equal or surpass the performance of autogenous vein grafts has generated still more debate. Some authors have reported patency for PTFE that is comparable to that for saphenous vein,[5-7,9] whereas others have suggested that the synthetic graft is less than satisfactory,[8,10-14]

However, a comparison of particular series is often difficult owing to wide differences in patient population, indication for operation, anatomic disease patterns, duration of follow-up study, and other variables. In seeking to define factors affecting long-term patency of FPBP grafts we reviewed our experience with a variety of grafts over an extended follow-up period of ten years.

Materials and Methods

From January, 1978, through June, 1988, a total of 308 patients underwent 335 femoropopliteal arterial reconstructions. The greater saphenous vein graft (SVG) was used whenever possible (165) and PTFE prosthesis was used in 165 operations. In addition 4 Dacron grafts and 1 umbilical vein graft were used in 5 operations but were excluded from comparison in this study. The patient population predominantly consisted of elderly men with numerous associated risk factors (Table I).

The patients ranged in age from thirty-two to eighty-five years with a mean age of fifty-three years. There were 296 men (96.1%) and 12 women (3.9%). Before surgery all patients had angiography; the quality of the outflow tract was qualified as good, fair, or poor in progressive obstruction; and the number of patent branches of the popliteal artery was noted for each patient. In addition to arteriograms, Doppler ultrasound was also used to assess the hemodynamic status of the iliac and tibial arteries.

Other methods of reconstruction of the femoral artery, such as open or closed endarterectomy, were not included unless combined with bypass grafting. Femoropopliteal grafts done for aneurysmal disease or traumatic injuries were not included in the study group.

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The bypass grafts were classified according to the possible factors affecting long-term graft patency. Five factors examined were: nature of the graft material, indication for operation, arteriographic runoff, location of the distal anastomosis, and diabetes mellitus. The cumulative graft patency rate for each group of patients was calculated according to the life table method. The shortest observation time was one year. Complications and graft patencies were recorded retrospectively. All patients were seen at regular intervals of three or four months, and the patency of the bypasses was checked both clinically and ultrasonographically. Bypasses were classified as patent if the patient had palpable pulses distal to the bypass and a triphasic wave form of the ultrasound demonstrating forward flow and had no symptoms.

Postoperatively all patients were advised to take 80 mg of acetylsalicylic acid on alternate days and 75 mg dipyridamole three times daily.

TABLE I
Risk Factors of Our Patients

Risk Factor	No. of Patients	%
Diabetes mellitus	49	15.9
Ischemic heart disease	57	18.5
Hypertension	83	26.9
Renovascular disease	3	1.0
Behet's disease	3	1.0
Cerebrovascular disease	18	5.8
Tuberculosis	15	4.9
History of smoking	312	93.1
Alcohol addiction	34	11.0

TABLE II
Nonocclusive Causes of Graft Loss

Cause of Patent Graft Loss	No. of Patients	%
Death	5	1.6
Graft infection	1	0.3
Graft aneurysm	2	0.6
Total	8	2.5

Results

The cumulative patency curve (Figure 1) for the whole group was calculated by an actual procedure. The cumulative patency rate for all grafts according to the criterion of occlusion alone was 81% at six months, and 30% in five years.

When the SVG group was compared with the PTFE group, the cumulative patency rates (Figure 2) showed that reversed SVG was superior to PTFE at the femoropopliteal position ($p < 0.05$).

The grafts were divided into two groups according to indication for operation; 226 femoropopliteal bypasses were performed because of incapacitating claudication, and their patency was significantly higher than that of the others, which were performed because of rest pain (Figure 3).

Judged by the preoperative angiograms, 102 grafts had good, 112 had fair, and 121 had poor runoff. (Figure 4). We found that good and poor runoff groups correlated significantly.

On the angiograms, 108 grafts had three calf arteries visible, 145 had two vessels visible and 77 had one vessel open. (Figure 5).

There were 149 procedures in which the distal anastomosis was placed above the knee

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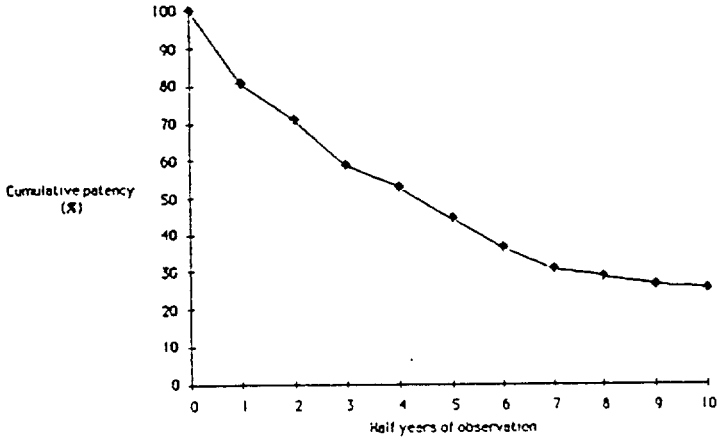

FIG. 1. Cumulative patency rate by life table method for 335 femoropopliteal bypass grafts.

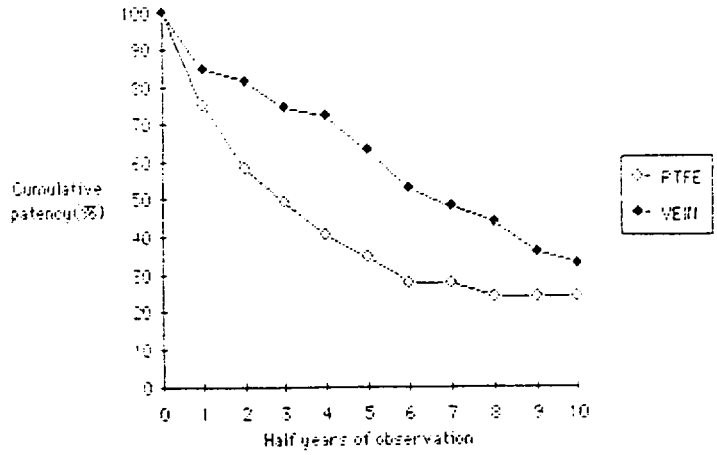

FIG. 2. Cumulative patency rate by life table method for 165 PTFE and 165 vein femoropopliteal bypass grafts.

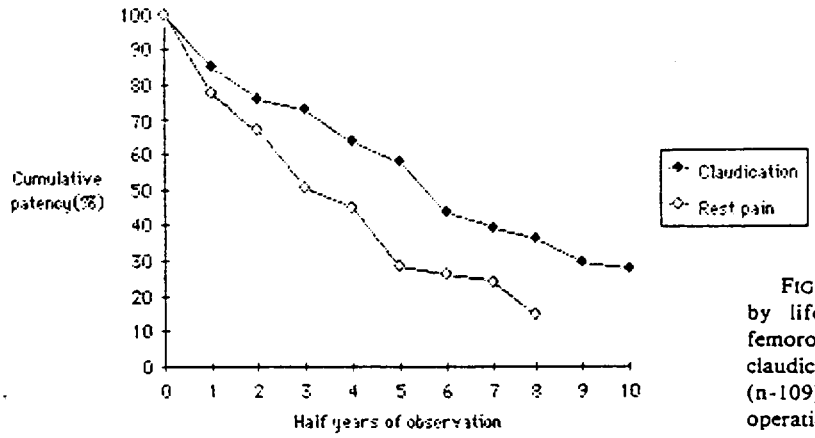

FIG. 3. Cumulative patency rate by life table method for 335 femoropopliteal bypass grafts with claudication (n = 226) or rest pain (n-109) as the indication for operation.

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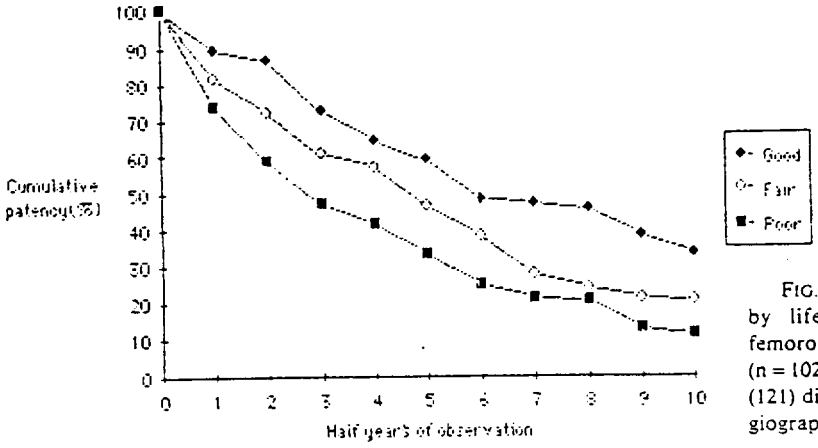

FIG. 4. Cumulative patency rate by life table method for 335 femoropopliteal grafts with good (n = 102), fair (n = 112), or poor (121) distal runoff according to angiographic assessment.

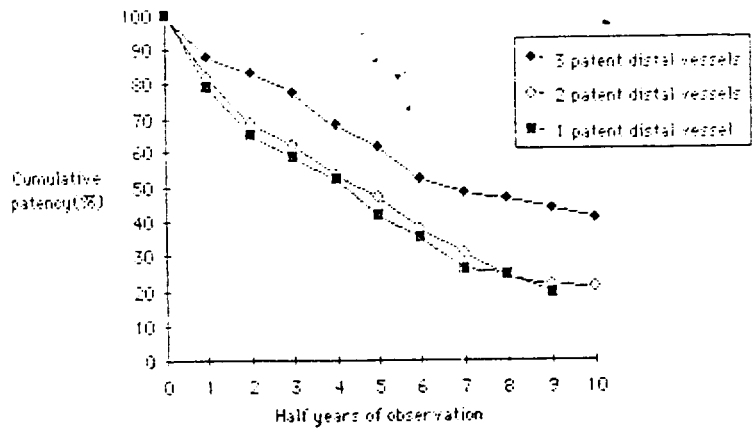

FIG. 5. Cumulative patency rate by life table method for 330 femoropop-liteal bypass grafts with three (n = 108) or two (n = 145) patent one distal vessels or one (n = 77) patent distal vessel according to angiographic assessment.

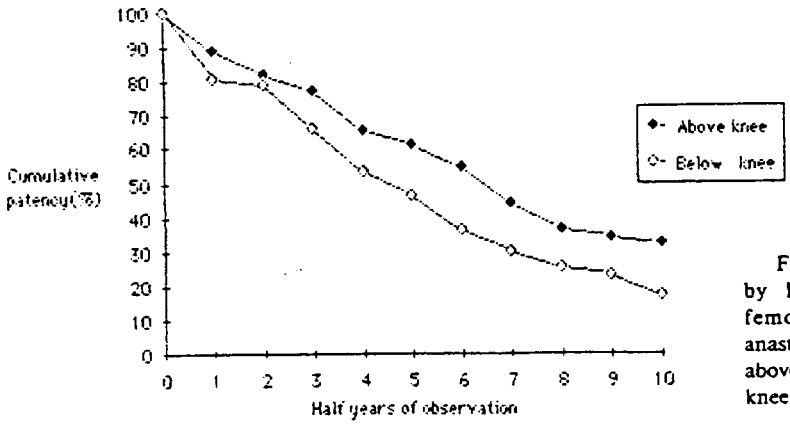

FIG. 6. Cumulative patency rates by life table method for 335 femoropopliteal bypass grafts anastomosed to the popliteal artery above the knee (n = 149) or below the knee (n = 186).

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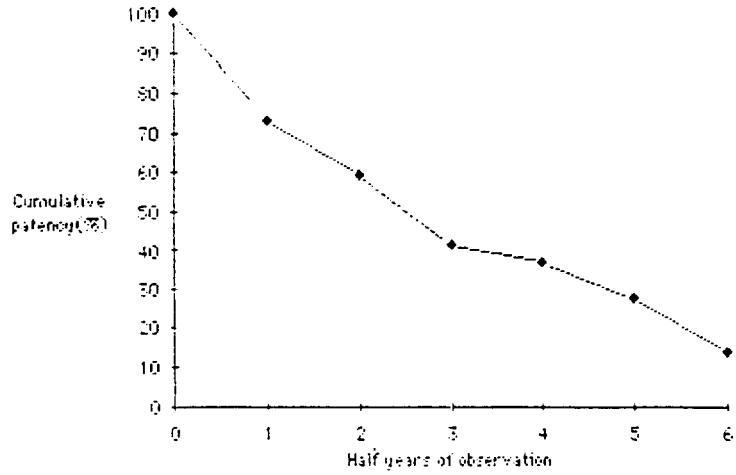

FIG. 7. Cumulative patency rate by life table method for 22 femorodistal bypass grafts anastomosed to the tibial or peroneal artery.

joint. There were 186 procedures with popliteal anastomosis placed below the knee joint. There was significantly higher cumulative patency rate in above-knee FPBP grafts than in below-knee grafts (Fig. 6). The cumulative patency curve for 22 femorodistal bypass grafts is shown in Figure 7. A significant difference was also seen when below-knee FPBP grafts and femorotibial/peroneal bypass grafts were compared.

When 49 grafts in diabetic patients were compared with 286 grafts in nondiabetics, the presence of diabetes mellitus resulted in a significantly reduced patency rate (Fig. 8).

By the life table method occlusive graft failure was assessed independently, as well as in conjunction with nonocclusive causes of graft attrition, which are displayed in Table II.

Of the 335 procedures, 68 cases had thrombosis; 43 of them had successful thrombectomies and 7 had amputations. The other 18 cases remained symptomatic after throm-

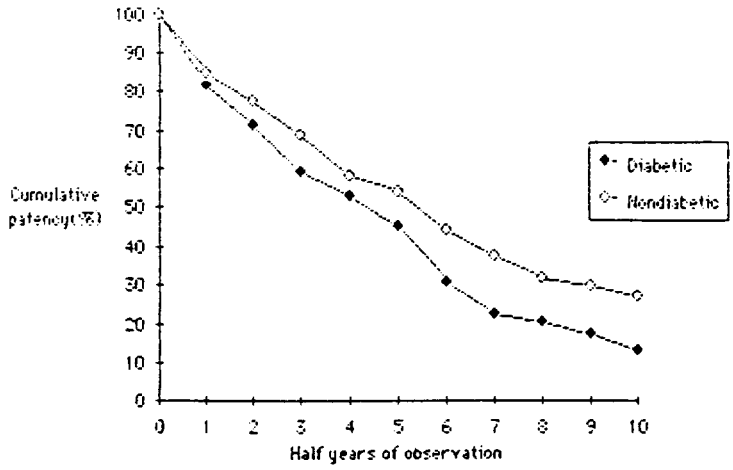

FIG. 8. Cumulative patency rate by life table method for 335 femoropopliteal grafts in patients with diabetes mellitus (n = 49) or without diabetes mellitus (n = 286).

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bectomies. Early graft thrombosis occurred in 42 grafts within thirty days after operation and late thrombosis occurred in 26; 37% of the 68 thromboses were in the SVG group and 63% were in the PTFE group.

There were 13 amputations in the SVG group (7.9%) and 12 amputations in the PTFE group (7.3%) during follow-up extending to ten years. There was no significant difference between the SVG and PTFE graft groups.

Discussion

The clinical success of femoropopliteal bypass is largely dependent upon sustained graft patency. Vascular reconstruction is hazardous in a low-flow, high-resistance area as in bypass procedures of the lower limb. Reconstruction of the occluded superficial artery has been shown to be effective when autogenous saphenous vein is used as the FPBP graft.[5,10-14] Our findings suggest that the first important factor in long-term patency is the nature of the graft itself.

The question "which prosthesis gives the best result when the saphenous vein is unavailable?" remains to be answered. PTFE graft may be a reasonable alternative to saphenous vein graft for several reasons. Atherosclerosis is a systemic disease, it may frequently involve the coronary vessels, and saphenous vein may be needed for coronary artery bypass. Femoropopliteal atherosclerotic occlusive disease is progressive and saphenous vein may be required to bypass for tibial or peroneal arteries. It would appear, however, that PTFE does not compete well with saphenous vein once the knee joint is crossed. Kinking of the prosthetic graft across the knee joint, less tolerance to flow states, and neointimal fibrous hyperplasia have been indicated as reasons for failure. Neointimal fibrous hyperplasia has been documented to occur in the lumen of this prosthesis at the suture line and also in the host artery proximal and distal to the anastomosis.[9,15,16]

Another factor implicated in late graft failure is progressive systemic atherosclerosis resulting in proximal (ie, aortoiliac) arterial obstruction and secondary graft thrombosis. This finding stresses the importance of adequate antecedent or simultaneous vascular inflow procedures and continued vigilance during postoperative evaluations.

The indication for operation and quality of runoff and popliteal anastomotic site above or below the knee were found to affect patency rates.[4,5,8] The presence of diabetes mellitus resulted in a significantly reduced patency rate, most likely because of poor runoff.[5]

Conclusions

Our experiences suggest that poor runoff influences both the short- and long-term results, but the most noticeable effects are on early patency. This correlates well with the findings of others.[17-26] It is also interesting to notice higher graft patency in patients with poor runoff and with an above-knee femoropopliteal bypass than in patients with good runoff and below-knee femoropopliteal bypass.[11]

It is clear that several factors affect the results. The results indicate the importance of the outflow tract for the outcome of revascularization, and it must be kept in mind

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that the outflow tract disease progresses and is probably the most crucial factor for limiting the function of a vascular graft.

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Seven-year Follow-up of Expanded Polytetrafluoroethylene (PTFE) Femoropopliteal Bypass Grafts

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Expanded polytetrafluoroethylene (PTFE) grafts have proven to be an acceptable short-term alternative for femoropopliteal reconstruction in those patients without suitable autologous saphenous vein. One hundred and twenty-seven femoropopliteal arterial bypass operations utilizing PTFE grafts were performed in 105 patients. Seven-year follow-up is now available for 20 grafts, 6-year follow-up for 47 grafts, and 5-year follow-up for 6[illegible] grafts. Graft occlusion was determined by angiography, L[illegible]ler assessment, loss of previously palpable pulses, or return of symptoms. Thirty nonocclusive graft losses were due to death, infection, aneurysm, amputation, or proximal occlusive disease. Overall cumulative patency rate, according to occlusive criteria alone and calculated by the life-table method, was 74% at 6 months, 63% at 1 year, 48% at 3 years, 40% at 5 years, and 35% at 7 years. Excluding early bypass failures (less than 1 year patency), 75% of grafts were patent at 3 years, 63% at 5 years, and 55% patent 7 years following operation. Diabetes mellitus was associated with a significantly lower patency rate. Patency rates were not adversely affected by graft diameter, distal popliteal anastomotic site, number of patent runoff vessels, preoperative symptoms, or prior arterial reconstruction. In patients without suitable autologus saphenous vein, the PTFE graft has proven to be a durable and dependable long-term alternative for femoropopliteal reconstruction.

POLYTETRAFLUOROETHYLENE (PTFE) vascular bypass grafts have demonstrated acceptable early patency rates when employed for femoropopliteal reconstruction in those patients lacking suitable autologous saphenous v[illegible][1-3] Enthusiasm for this conduit material has been tempered by the realization that other graft materials (*e.g.*, bovine heterograft) have shown promising early patency rates, only to later demonstrate precipitous drops in intermediate and long-term patency rates. Seven-year follow-up is now available for patients having undergone PTFE femoropopliteal reconstruction at the Presbyterian-University Hospital in Pittsburgh.

PTFE was first employed for femoropopliteal bypass at the University of Pittsburgh in 1974, and previous reports have detailed early and intermediate patency rates.[4,5] Aneurysmal dilatation of the original graft material was recognized early in the initial series,[6] and was corrected by an additional "wrap" of PTFE around the graft. PTFE was employed in those patients without suitable autologous saphenous vein, and graft patency determined by physical examination, angiography, Doppler arterial pressure measurement, or resolution of ischemic signs and symptoms.

This report analyzes the patency rates for 127 consecutive PTFE (Gore-Tex)* femoropopliteal bypass grafts performed on 105 patients. For purposes of analysis in patients receiving more than one graft, each graft has been considered separately.

Materials and Methods

The patient population consisted predominantly of elderly men with numerous associated risk factors, a situation in common with other published clinical series (Table 1). Ninety-two men, ages 44–88 (median, 63 years) and 35 women, ages 45–87 (median, 67 years) were operated upon. Operative indications included the following: limb salvage (50%), disabling claudication (30%), rest pain (18%), and previous graft aneurysmal degeneration (2%). Twenty-four patients (19%) had undergone previous proximal arterial inflow bypass procedures (aortofemoral bypass, etc.), while 22 patients (17%) had undergone previous ipsilateral femoropopliteal reconstruction. Distal arterial runoff was good (two or three vessels) in 92 patients (74%) and poor (one or no vessel) in 32 patients (26%).

Ninety popliteal anastomoses (71%) were above the knee, while 32 anastomoses (29%) were below the knee. Cumulative graft patency rates were calculated using the life-table method.[1] Graft occlusion dates were determined by the acute recurrence of ischemic symptoms, disappearance of previously palpable pulses, angiographic demonstration of flow interruption, or deterioration of Doppler pressure or wave forms.

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Submitted for publication: May 9, 1983.

* WL Gore and Associates, Flagstaff, AR.

TABLE 1. *Patient Characteristics*

Smoking history	70%
Coronary artery disease	43%
Diabetes mellitus	43%
Hypertension	40%
Previous inflow graft	19%
Failed ipsilateral femoropopliteal graft	17%

Results

Using the life-table method, occlusive graft failure was assessed independently as well as in conjunction with nonocclusive causes of graft attrition. Seven-year follow-up data were available for 20 grafts, 6-year follow-up for 47 grafts, and 5-year follow-up for 62 grafts. No patients were lost to follow-up.

Nonocclusive causes of graft loss included the following (Table 2): patient death with a patent graft (14 patients), graft aneurysmal degeneration (five), acute proximal extrafemoral arterial occlusion (five), graft infection (four), limb amputation despite a patent graft (three), and therapeutic misadventure (one) (percutaneous transluminal angioplasty of a stenotic distal anastomosis resulting in immediate graft occlusion).

The cumulative patency rate for all grafts according to the criterion of occlusion alone was 74% at 6 months, 63% at 1 year, 48% at 3 years, 40% at 5 years, and 35% at 7 years (Fig. 1). As uniformly noted in previous arterial bypass reviews, the graft attrition rate was greatest during the initial postoperative period (Fig. 2). This reflects graft occlusion or loss due to poor runoff, distal small vessel disease, technical error, or uncontrolled infection.

Exclusion of early graft failures (within the first postoperative year) allows a focused appraisal of long-term graft stability. With this proviso, life-table patency rates of the grafts patent at 1 year are as follows: 75% at 3 years, 63% at 5 years, and 55% at 7 years (Fig. 3).

A variety of patient risk factors were evaluated with respect to impact on cumulative patency rates. Patient risk factors evaluated included presence or absence of diabetes mellitus, hypertension, atherosclerotic heart disease, smoking history, previous proximal inflow operation, or ipsilateral femoropopliteal bypass. Only the presence of diabetes mellitus was shown to have a statistically significant effect on ultimate graft patency (Fig. 4), with a 44% 6-year patency rate in nondiabetics as opposed to an 18% 6-year patency rate in diabetics ($p < 0.01$).

TABLE 2. *Causes of Patent Graft Loss*

Death	14
Graft aneurysm	5
Acute extrafemoral arterial occlusion	5
Graft infection	4
Limb amputation	3
Therapeutic misadventure	1

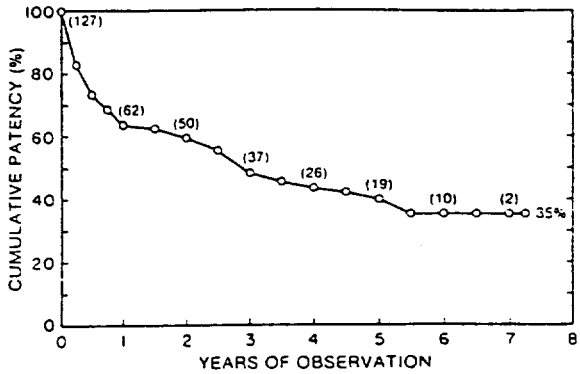

FIG. 1. Cumulative patency rate by life-table method for 127 PTFE femoropopliteal bypass grafts.

Technical aspects evaluated for predictive effect on patency rates included popliteal anastomotic site (above *vs* below the knee), graft diameter, and distal runoff (Figs 5 and 6). None were found to represent a statistically significant determinant of graft patency.

Discussion

Previous evaluations of early and intermediate patency rates for PTFE femoropopliteal bypass grafts have been hindered by differences in patient selection, diversity of reporting methodology, and data evaluation.[7,8] Nonetheless, the majority of investigators have found that PTFE provides acceptable patency rates in follow-up of up to 4 years, and a recent randomized study reported no difference in 2-year patency rates between autologous saphenous vein and PTFE.[9] The early and intermediate patency rates of the series reported in this study are comparable to that generally found in the vascular literature.[8,10]

As noted by others, there has been a relative increase in the rate of early graft failures as greater experience

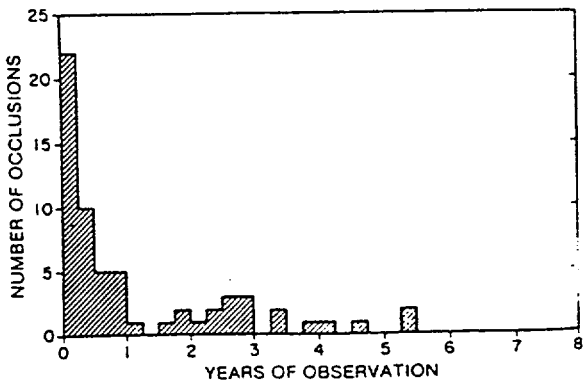

FIG. 2. Time of graft occlusion (N = 62) in 127 PTFE femoropopliteal bypass grafts.

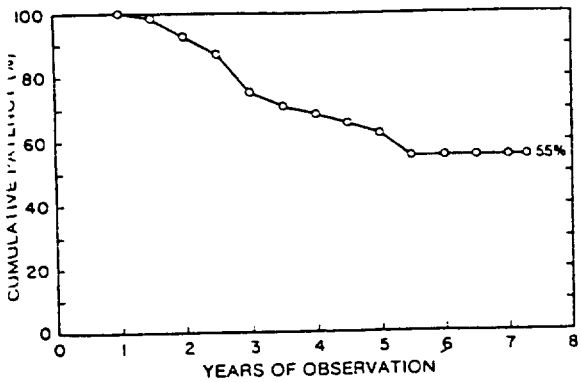

FIG. 3. Cumulative long-term (patency > 1 year) patency rate by life-table method for 62 PTFE femoropopliteal bypass grafts.

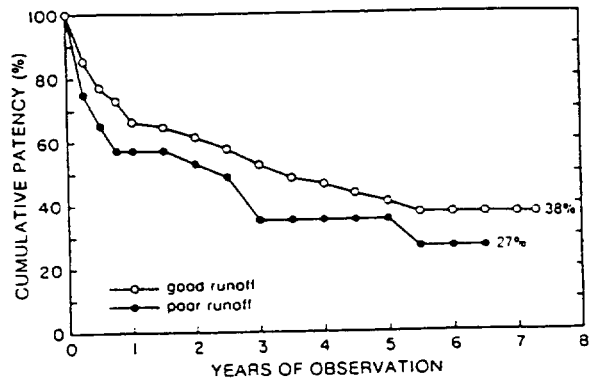

FIG. 5. Cumulative patency rate by the life-table method for PTFE femoropopliteal grafts in patients with good (N = 91) or poor (N = 33) distal runoff according to angiographic assessment.

wit' 'TFE has led to heroic attempts at limb salvage in the severely diseased limb.[1,11] In the present study, pregangrenous or gangrenous changes were evident in approximately half the patients before surgery. Hence, elimination of early failures (less than 1 year graft patency) provides a more reasoned evaluation of the long-term patency characteristics of PTFE.

Examination of the cumulative graft survival curve (Fig. 1) shows a stabilization of patency rates after 2 to 3 years. The graft occlusion rate (Fig. 2) demonstrates that occlusion ceases to be a major determinant of graft loss after 1 year—rather, nonocclusive causes (principally patient death) become operant during the long-term follow-up period. This reflects the long-recognized high death rate in this elderly population with associated systemic atherosclerosis.[7,12]

Another factor implicated in late graft failure is progressive systemic atherosclerosis resulting in acute proximal (*i.e.*, aortoiliac) arterial obstruction and secondary graft thrombosis (five patients). This finding reiterates the importance of adequate antecedent or simultaneous vascular inflow procedures and continued vigilance during postoperative evaluations.

Given the experience of other centers,[11,13,14] it is of note that neither the status of distal arterial runoff nor the location of the distal anastomosis resulted in significant differences in graft patency. The similarity in patency rates for popliteal anastomoses above or below the knee would argue against the necessity for composite grafts when crossing the knee joint in femoropopliteal bypasses.

Although the necessity to perform graft thrombectomy or revision may often be regarded as a harbinger of ultimate graft loss, reoperation is warranted. Thrombectomy was performed on eight grafts (multiple thrombectomies on two of these grafts), resulting in an average 8.4 months (range 1–27 months) of additional graft patency. Since thrombectomy extended the period of patency more than 3 months in only three of the eight involved grafts, patency

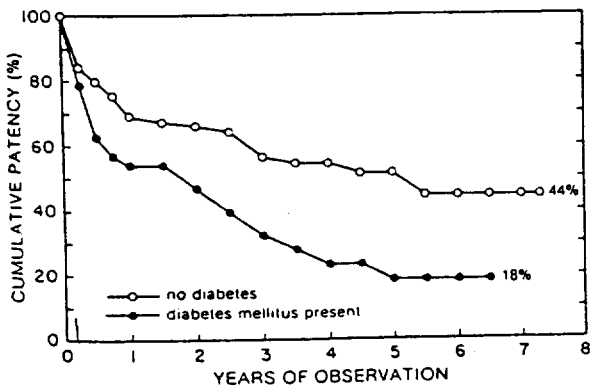

FIG. 4. Cumulative patency rate by life-table method for PTFE femoropopliteal grafts in patients with diabetes mellitus (N = 43) or without diabetes mellitus (N = 84).

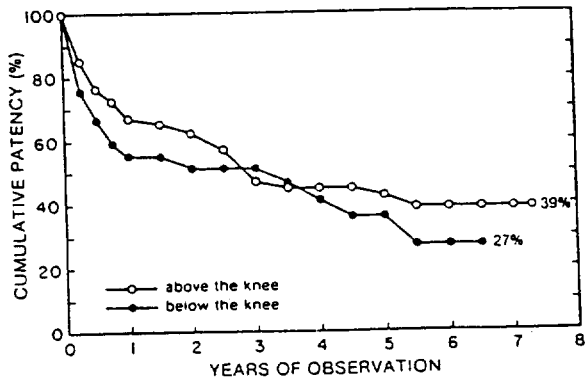

FIG. 6. Cumulative patency rates by the life-table method for PTFE femoropopliteal grafts anastomosed to the popliteal artery above the knee (N = 90) or below the knee (N = 37).

rates by the life-table method were only slightly affected by the performance of graft thrombectomy. When recalculated to consider thrombosis (despite subsequent successful thrombectomy) as the terminal event, only the 4-year (42% *vs.* 44%) and 5-year (39% *vs.* 40%) patency rates were diminished.

The revision of a proximal anastomotic false aneurysm and the bypassing of an acute proximal extrafemoral arterial occlusion have resulted in patent grafts 88 and 30 months, respectively, following revision. Hence, our experience would support the aggressive approach to acute graft occlusion advocated by Veith.[15]

The presence of diabetes mellitus resulted in a significantly reduced patency rate (Fig. 4), most likely the result of poor small vessel runoff at the time of operation as well as subsequent atherosclerotic obstruction. Early graft loss was particularly pronounced in this group of patients. Previously published studies evaluating the effect of diabetes mellitus on the patency rate in autologous saphenous vein grafts have reported conflicting results.[2,16,17] The impact of diabetes mellitus on PTFE graft patency remains as yet unclear.

PTFE aneurysmal degeneration has not occurred with reinforced protheses, and conduits that have remained *in situ* for extended periods of time have maintained structural integrity. PTFE has been shown to be a durable and dependable long-term alternative for femoropopliteal reconstruction in those patients without suitable autologous saphenous vein.

Acknowledgment

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COMPARISON BETWEEN BOVINE HETEROGRAFT AND EXPANDED PTFE GRAFTS FOR DIALYSIS ACCESS

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From 1974 to 1979, the authors performed 644 arteriovenous fistulas for hemodialysis access, of which 113 were done using bovine heterografts and 83 with expanded polytetrafluoroethylene (PTFE, Gore-Tex) grafts. Vascular access sites for hemodialysis are subject to puncture thrice weekly, which places the graft in a high risk category for infection. Outflow stenosis is also a common but unexplained complication in these grafts requiring reoperation. The purpose of this article is to compare complication and patency rates for the bovine and PTFE grafts. Retrospective analysis of the course of these patients shows a one-year graft survival of 73 per cent for bovine heterografts and 84 per cent for PTFE grafts. The rate of thrombosis of the graft due to any cause was 13 per cent. (15/113) in the bovine group and 7 per cent (6/83) in the PTFE group. There were three patients with bovine heterografts who developed pseudoaneurysms of the graft and two with PTFE grafts. Outflow stenosis either in the graft or at the anastomosis was present in 23 per cent (26/113) of the bovine heterografts and 10 per cent (8/83) of the PTFE grafts. Infection secondary to dialysis puncture or operation, which necessitated removal of the graft, was present in 16 per cent (18/113) of the bovine heterografts and 6 per cent (5/83) of the PTFE grafts.

WITH the introduction of practical hemodialysis in the 1960s, the means to markedly extend the life of the patient with failing renal function became available. Since that time much effort has been set forth to provide a convenient and reliable access to the patient's vascular system. This was satisfied early by the external arteriovenous shunt as described by Quinton and Scribner.[3] Although the external shunt provided a ready access, it was found to be less than desirable for long-term use. It has been associated with thrombosis, disruption, and infection and is inconvenient for the patient in the daily tasks of work and hygiene. The internal arteriovenous fistula was introduced by Cimino and Brescia in 1966.[1] This remains the vascular access of choice for chronic use. This usually consists of anastamosing the cephalic vein end-to-side to the radial artery at the wrist in the nondominant hand. This procedure is done with the patient as an outpatient under local anesthesia. For some individuals, the lack of a suitable artery or vein precludes construction of an arteriovenous fistula, whereas in others thrombosis occurs or the vein fails to mature adequately. In these patients an alternative is necessary. The principle has been to create an arteriovenous connection using a vascular substitute as a conduit. Various materials have been used, including saphenous vein, Sparks mandril, Dacron velour, bovine heterograft, and polytetrafluoroethylene (PTFE). Our experience with the latter two graft materials is the subject of this report.

Materials and Methods

From May 1974 to November 1979, 644 vascular procedures were performed. Of this number, 404 primary arteriovenous fistulas were created, with the remaining

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being arteriovenous grafts. The majority were bovine heterografts and PTFE grafts (Gore-Tex®, W. L. Gore) with the others being saphenous vein (26) and Dacron velour (18). Of the 113 bovine heterografts, three were lower-extremity grafts with the remainder being upper-extremity grafts. Of these 31, (28%) were straight grafts (usually radiocephalic) and 79 (72%) were of a loop configuration. Of the 83 PTFE grafts, all were upper extremity, with 10 (12%) straight grafts and 73 (88%) loop grafts. The grafts were placed in the nondominant arm whenever possible. The grafts were placed with the patients as inpatients with general anesthesia or axillary block, often with local supplementation. The grafts in the majority of cases were 8 mm in diameter. Whenever the arterial anastomosis was to be done in the antecubital fossa, the brachial artery was isolated with the radial and ulnar branches. The radial branch was used as the site of the anastomosis whenever it was of adequate size and quality. The goal of arteriovenous grafting is to provide ample length of relatively straight sections of graft to allow for rotation of puncture sites. For this reason, whenever a loop configuration was used the loop was tunneled well down the forearm, making a smooth curve, and brought back to the cephalic vein at the antecubital fossa or tunneled laterally just superior to the medial epicondyle to the brachial vein in the midupper arm. The patients received prophylactic antibiotics, usually a cephalosporin.

Results

In the 113 bovine heterografts followed for up to 66 months, there were 73 complications for a complication rate of 65 per cent. The most frequently encountered complication was outflow stenosis in 26 grafts (23%), which was repaired by patch angioplasty or bypass graft. Ten grafts (8.8%) thrombosed without outflow stenosis and required only thrombectomy for salvage. There were 15 graft failures (13.3%) secondary to thrombosis from any cause, in which revision was not attempted or was unsuccessful. Infections occurred in 18 grafts (16%) with all resulting in loss of the graft and requiring removal of the graft. Other complications seen were pseudoaneurysm (3) and "steal" syndrome (1). The one-year patency for the bovine heterografts was 73 per cent.

There were 33 complications seen in the 83 PTFE grafts followed for up to 46 months, for a complication rate of 40 per cent. Outflow stenosis was seen in 8 patients (10%) and was successfully treated with patch angioplasty or bypass. Graft failure occurred in 6 cases (7.2%), in which revision was not done or unsuccessful. There were 10 cases (12%) in which the graft required thrombectomy without revision, with 8 of these occurring within the first two months after implantation. Only five infections were encountered in which the graft was lost, for an infection rate of 6 percent. There were two pseudoaneurysms and two cases in which "steal" phenomenon necessitated early removal of the graft. One-year graft patency was 84 per cent.

Whenever the follow-up period for the bovine heterograft was adjusted to correspond the that for the PTFE grafts, there were a total of 58 complications for a complication rate of 51 per cent. These complications are compared in Table 1.

In these comparable groups, there is no statistical difference when each category is examined, but in those categories in which the graft failed or required revision there is a statistical difference ($P < 0.05$).

TABLE 1. *Complications*

	BH* (%)	PTFE (%)
Thrombosis (thrombectomy)	10 (8.8)	10 (12)
Thrombosis (failed)	18 (15.9)	6 (7.2)
Outflow stenosis (revised)	16 (14.2)	8 (9.6)
Infection	12 (10.6)	5 (6)
Pseudoaneurysm	1 (0.9)	2 (2.4)
Steal phenomenon	1 (0.9)	2 (2.4)
Totals	58 (51)	33 (40)

BH = bovine heterograft, PTFE = polytetrafluoroethylene graft.
* Adjusted after follow-up.

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Discussion

The complications occurring in both groups of patients were similar and most often related to outflow stenosis or problems at the dialysis puncture sites. Although the complications were similar, the ease with which they could be handled varied. Outflow stenosis could usually be corrected in both groups either by patching with vein or PTFE or by bypassing to a higher arm vein, but the bovine heterografts and a higher incidence of infection following reoperation. Infection of a bovine heterograft required prompt removal of the graft. The PTFE graft appeared more resistant to the infection, and the spread to anastomotic sites, when it occurred, came from dissection of the purulent process along the graft rather than suppuration of the graft itself. Butler[2] described controlled tissue ingrowth with the development of a neointima on the PTFE graft, which was postulated to increase resistance to infection by mobilizing host defenses to the wall of the graft. Several of the PTFE graft infections were controlled by limited resection of the infected portion of graft with ligation proximal and distal. We have not attempted rerouting a new graft around the site of infection at the same time as anastomosis to the transected ends of the original graft, as described by Butler.[2]

Of the infections encountered in the bovine heterografts, the majority occurred early after implantation or revision. Only one of the five PTFE graft infections appeared attributable to operation, with the others occurring at dialysis puncture sites.

The bovine heterograft appears to undergo degenerative changes with time, which can result in aneurysmal dilatation or even loss of integrity of the graft wall, an observation earlier reported by Tellis.[4] The PTFE graft does not appear to degenerate.

Early thrombosis of the bovine heterograft or the PTFE graft could often be corrected by thrombectomy alone and may be related to volume changes and hypotension or technical problems of inadequate flushing or hematoma formation resulting in compression of the graft or venous outflow.

Summary

The PTFE graft for vascular access has a decreased complication rate as compared to the bovine heterograft. Patency appears to be improved, although the difference is not statistically significant. PTFE grafts have additional advantages of economy, a variety of sizes, and availability. When complications do occur, they are usually more easily taken care of with PTFE grafts and are less likely to become secondarily infected. At the present time, the PTFE graft appears to be the graft of choice for vascular access.

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A three-year follow-up on standard versus thin wall ePTFE grafts for hemodialysis

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Purpose: Expanded polytetraflouroethylene (ePTFE) grafts are the most popular prosthetic grafts for hemodialysis patients in whom autogenous fistulas cannot be constructed. Long-term studies to study the durability and complication rate of the different wall configurations of ePTFE grafts have not been carried out. The primary, secondary, and cumulative patency and other complications between standard thickness (STD) and thin wall (THN) 6 mm stretch ePTFE grafts (WL Gore & Assoc, Flagstaff, AZ) was prospectively evaluated.

Methods: From September 1993 to August 1995, 108 patients receiving new grafts were randomized into 2 groups: those receiving STD grafts (n = 56) or those receiving THN (n = 52) grafts. Data prospectively collected included day of first access, primary patency, interventions required, and long-term results. Infections, pseudoaneurysms, and mortality were also documented. Student's unpaired *t*-test was used to compare the 2 groups, and log-rank life tables were constructed and compared.

Results: Mean follow-up examination time was 38.1 ± 0.8 months for STD grafts and 35.1 ± 1.0 months for THN grafts ($P<.03$). Longer patency was noted in the STD group of grafts (18.2 months for STD vs. 12.1 months for THN).

Biographical data and complications, including pseudoaneurysm (6% vs. 5%), infection (2% vs. 3%), and mortality (22% vs. 19%), between STD and THN groups were not different statistically. Mean primary (18.2 months vs. 12.1 months), secondary (20.9 months vs. 13.7 months), and cumulative patency times (22.2 months vs. 15.2 months) for the STD group were significantly more than those for the THN group ($P<.000$ by log rank of life tables). Other complications were not different between groups.

Conclusion: Standard thickness ePTFE is the graft of choice when placing ePTFE arteriovenous grafts for hemodialysis. (J Vasc Surg 1998;28:464-70.)

INTRODUCTION

Since its introduction, the expanded polytetraflouroethylene grafts (ePTFE) has become the prosthetic graft of choice when placing artificial arteriovenous access for hemodialysis.[1-3] Standard thickness ePTFE grafts were used initially; however, when thin wall ePTFE grafts became available, many centers began using this new wall configuration because of its increased flexibility and ease of handling. Thin wall grafts were used in preference to standard thickness ePTFE grafts, despite a lack of scientific data showing that the 2 wall configurations are comparable in durability and patency rates. There is subjective opinion that the thin wall structure might predispose patients to pseudoaneurysms or other complications related to repeated needle punctures of the conduit. The patency and complication rates of standard thickness stretch 6 mm ePTFE grafts were compared with those of thin wall stretch 6 mm ePTFE grafts (WL Gore & Associates, Flagstaff, AZ).

MATERIALS AND METHODS

One hundred eight patients sequentially receiving new grafts were prospectively randomized into 2 groups: those receiving standard thickness stretch 6 mm ePTFE grafts (STD) and those receiving thin wall stretch 6 mm ePTFE grafts (THN). From September 1993 to August 1996, 56 patients received STD grafts, and 52 patients received THN grafts.

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Patients were then studied in the hemodialysis center, where day of first access, the length of primary patency, the interventions (type and number) required to maintain patency of the graft, and long-term results were documented. Patients were also studied for infections, occurrence of pseudoaneurysms, and mortality.

All grafts were standardized to a loop forearm placement[4] between 30 and 35 cm long, except for 2 unusual cases (1 upper arm in the STD group and 1 thigh placement in the THN group). Thus these 2 patients were excluded from analysis. If the patient had prior failed grafts or proximal arm fistulas, the contralateral forearm was used. Except for a distal failed radiocephalic fistula, the loop graft was the first access in the used forearm. All patients had temporary dual lumen hemodialysis catheters placed in either the contralateral internal jugular or, rarely, in the subclavian vein by Seldinger technique in a attempt to allow maturation of the graft for at least 14 days. All patients received 1 g of Vancomycin as a preoperative antibiotic, and all grafts were placed under the sterile conditions of an operating suite. Skin was closed by subcuticular running suture in all patients. Anesthesia choice was made by the patient and anesthesiologist; most often local anesthesia with intravenous sedation was given. Randomization of the graft type to be placed was determined in the operating suite by having the operating room nurse flip a coin out of the presence of the surgeons. The selected graft was then given to the surgical team for implantation.

The type and number of interventions for continued patency of the arteriovenous grafts were documented throughout the study. The grafts were revised by either thrombectomy or thrombectomy and revision. Revision was used when venous outlet obstruction or severe stenosis was documented by means of intraoperative arteriography. The operative approach for revision was to expose the distal mid-loop graft, open the graft, and perform a thrombectomy with an appropriately sized Fogerty catheter. Next, an intraoperative arteriogram was taken to see whether there was venous outlet obstruction, and, if present, a revision was done from the graft to vein proximal to the anastomosis. If there was no outlet obstruction and no other technical problem was present causing failure, graft and skin were closed. Interventional radiology was not used for maintenance of graft patency during this study period because most interventions now used were not available at that time.

Results were analyzed by the Student's unpaired *t*-test, life table analysis by log-rank patency curve comparisons, Fisher's exact test, and χ^2 analysis. Other than the 2 patients dropped from analysis because of nonstandard graft locations, no patients were excluded from the study follow-up, and all cases were studied to the best of the ability of researchers and hemodialysis center staff.

Table I. Patient historical data

	STD	*THN*
Average age (years)	54	55
Hypertension	77% (43/56)	73% (38/52)
Diabetes Mellitus	48% (27/56)	50% (26/52)
Tobacco use	11% (5/56)	19% (10/52)

STD, Standard graft; *THN*, thin wall graft.

RESULTS

Patient historical data is summarized in Table I. The average age for study patients was 55 years (range, 13–92 years). There were 40 men and 68 women. African Americans made up 93% of the patient population. Nonpatency adverse outcome data, including rates of infection (2% of the STD group vs. 3% of the THN group), pseudoaneurysm (6% of the STD group vs. 5% of the THN group), and mortality (22% of the STD group vs. 19% of the THN group), was not statistically different between groups. Day 11 was the average day of first access of each graft for each group. During the study, no patient died of complications from the arteriovenous grafts.

During the study period, 66% of the STD group and 73% of the THN group experienced primary failure. Average length of primary patency ± SE of the mean was 18.2 ± 2.1 months for the STD grafts, compared with 12.1 ± 1.9 months for the THN grafts ($P = .03$). Not all grafts could be revised; those that couldn't be revised had to be excluded from continued use because of infection or pseudoaneurysm. Secondary patency was similarly longer for STD grafts (22.2 ± 1.4 months) than for THN grafts (15.2 ± 1.0 months), with $P = .04$. These results are summarized in Table II.

Life table comparisons of primary (Fig. 1) and secondary (Fig. 2) patency with log-rank testing showed differences in the patency curves of the 2 groups. Of the grafts placed, the percentage of STD grafts primarily patent at 6, 12, 18 and 30 months were 62%, 49%, 40%, and 27%, respectively (Table IIIb). The percentage of THN grafts primarily patent was 39% at 6 months, 35% at 12 months, 31%

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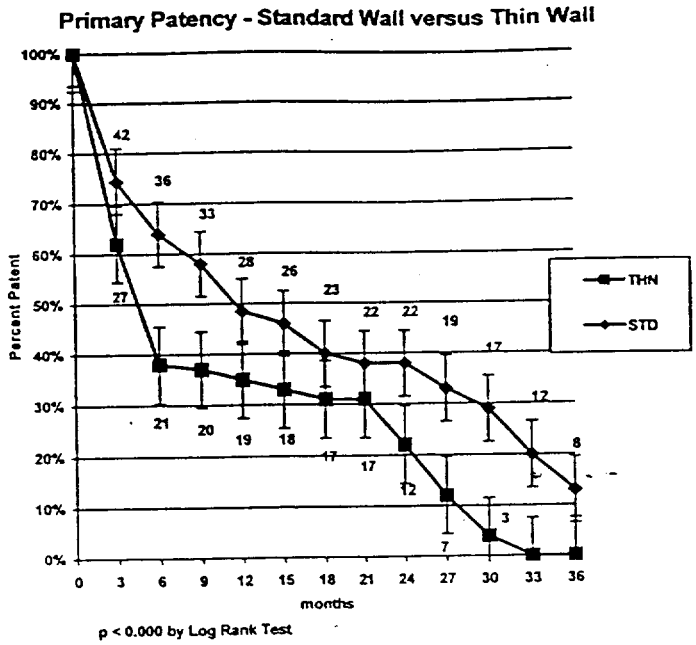

Fig. 1. Primary patency curves for patients with standard and thin wall arteriovenous grafts.

Table II. Patency times

	N	*1⁰ patency (months)*	*N revised*	*Initial 2⁰ patency (months)*	*N revised*	*Final 2⁰ patency (months)*
STD	56	18.2 ± 2.1	37	20.9 ± 1.9	9	22.2 ± 1.4
THN	52	12.1 ± 1.9	31	13.7 ± 1.8	7	15.2 ± 1.0
P		.03		.007		.04

N, Number; *1⁰*, primary; *2⁰*, secondary.

at 18 months, and 4% at 30 months (Table IIIa). The life table analysis is shown on Fig. 1. From 6 to 15 months, the STD grafts exhibited a 20% greater patency rate than the THN grafts. From 27 months on, more STD grafts were primarily patent. Few patients had grafts that were functional at more than 30 months in our study period. However, as shown in Fig. 2, secondary patency was better maintained in both groups for 2 years, with only patients with STD grafts having patencies that lasted to 36 months (Tables IVa, IVb).

As noted in Table II, many grafts were salvaged with interventions. Of the 37 STD revisions, 14 consisted of simple thrombectomy with no identifiable cause, whereas 23 required venous limb bypass. Of the 31 THN revisions, 15 were simple thrombectomies, and 16 required venous limb bypass. These rates of thrombectomies performed were not significantly different between the groups. Additional interventions were performed for cumulative patency: 1 additional simple thrombectomy was done in a STD graft (after prior revision), and 2 simple thrombectomies were done in THN grafts (again, after prior revisions.)

Many of the study patients had previous arteriovenous grafts (35% of the STD group and 52% of the THN group). χ^2 analysis showed no difference between the STD group and the THN group with respect to the number of patients without previous grafts. Of those patients with previous grafts, most had 2 or more previous arteriovenous grafts (58% of the STD group and 64% of the THN group).

The STD grafts had a mean follow-up examination time of 38.1 ± 0.8 months, as compared with a mean follow-up examination time of 35.1 ± 1.0 months for the THN grafts. This difference has a

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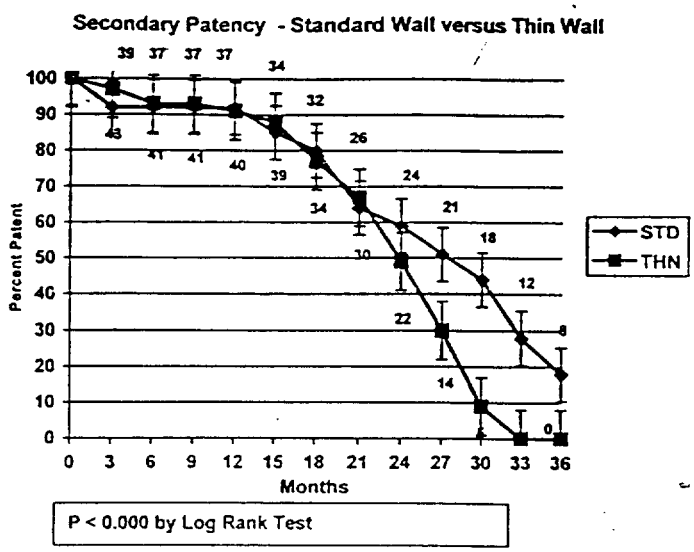

Fig. 2. Secondary patency curves for patients with standard and thin wall arteriovenous grafts.

Table IIIa. Primary patency life table data—thin wall grafts

Time (mo)	Grafts at risk	Failure	Withdrawn	Cumulative patency rate (percent)	SE (percent)
0	51	21	3	100	0.0
3	27	5	1	49.0	7.0
6	21	1	1	39.2	6.8
9	20	1	1	37.3	6.8
12	19	1	1	35.3	6.7
15	18	1	1	33.3	6.6
18	17	0	0	31.4	6.5
21	17	3	2	31.4	6.5
24	12	3	2	21.6	5.8
27	7	3	1	11.8	4.5
30	3	2	1	3.9	2.7
33	0	0	0	0	
36	0	0	0	0	

Table IIIb. Primary patency life table data—standard wall grafts

Time (mo)	Grafts at risk	Failure	Withdrawn	Cumulative patency rate (percent)	SE (percent)
0	55	9	4	100	0.0
3	42	4	2	74.5	5.9
6	36	2	1	63.6	6.4
9	33	2	3	58.2	6.7
12	28	1	1	49.1	6.7
15	26	2	1	45.5	6.7
18	23	1	1	40.0	6.6
21	22	0	0	38.2	6.5
24	22	3	3	38.2	6.5
27	19	2	2	32.7	6.3
30	17	1	4	29.1	6.0
33	12	4	4	20.0	5.4
36	8	0	0	12.7	4.5

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Table IVa. Secondary patency life table data—thin wall grafts

Time (mo)	Grafts at risk	Failure	Withdrawn	Cumulative patency rate (percent)	SE (percent)
0	44	0	1	100	0.0
3	43	1	1	97.7	3.2
6	41	0	0	93.0	3.9
9	41	0	1	93.0	3.9
12	40	1	0	90.7	4.4
15	39	5	5	88.4	4.9
18	34	2	2	79.1	6.4
21	30	8	8	67.4	7.1
24	22	8	8	48.8	7.6
27	14	9	9	30.2	7.1
30	5	5	5	9.3	6.8
33	0	0	0	0	0.44
36	0	0	0	0	

Table IVb. Secondary patency life table data—standard wall grafts

Time (mo)	Grafts at risk	Failure	Withdrawn	Cumulative patency rate (percent)	SE (percent)
0	40	1	[illegible]	100	0.0
3	39	1	[illegible]	97.4	2.5
6	37	0	[illegible]	92.3	4.3
9	37	0	[illegible]	92.3	4.3
12	37	2	[illegible]	92.3	4.3
15	34	2	[illegible]	84.6	5.8
18	32	1	[illegible]	79.5	6.5
21	26	1	[illegible]	64.1	7.7
24	24	3	[illegible]	59.0	7.9
27	21	4	[illegible]	51.3	8.0
30	18	6	[illegible]	43.6	8.0
33	12	4	[illegible]	28.2	7.2
36	8	0	[illegible]	15.4	6.1

significant P value of .03 by Student's unpaired t-test. More standard grafts were initially enrolled at the beginning of the study because of the nature of the randomization process, but the final distribution occurred during graft placement.

DISCUSSION

Patency rates and complications of the wall modifications to artificial grafts for hemodialysis access have been studied for many years in an attempt to ameliorate the disadvantages of prosthetics in hemodialysis. The modifications to prosthetic material itself in grafts have included changing the wall structure, adding luminal or extramural coatings, and incorporating layers. Dacron as a graft material had patency, bleeding, and wall integrity difficulties. Adding a coating of intraluminal Teflon did not sufficiently improve the results of a graft based on Dacron, leading most surgeons to abandon it.[5,6] The use of a silicone coating to decrease bleeding did not contribute to durable access when applied to ePTFE.[7] One attempt to reduce the effects of needle punctures on graft function was the hemocyte prosthesis. This PTFE graft incorporated a cannulation area that protected the rest of the conduit from punctures. However, this device was plagued with rates of thrombosis and infection that precluded its acceptance as a dialysis alternative.[8] One graft used a corethane/polyester composite construction, with the corethane fibers in a spun 30 to 60 μm pore layer in the lumen and the polyester reinforcing the outer layer. Although this graft has had less bleeding and equal patency in animal models, it has not yet been applied to humans.[9]

When just ePTFE material itself is studied as a variable in access graft outcomes, there is less in the literature comparing differences in ePTFE configurations. Tordior et al showed that the evolution of ePTFE to a "stretch" configuration is superior to the older, nonstretch configurations. They hypothesized

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that this advantage was caused by less intimal hyperplasia from poor compliance match problems.[10] Our group's prior study demonstrated superior short-term durability of standard thickness (0.64 mm) ePTFE grafts in comparison with thin wall (0.37 mm) ePTFE grafts,[11] but longer follow-up study of the grafts was needed. No other published study has compared the performance of differing wall thicknesses on arteriovenous graft outcomes. One study looked at similar thickness ePTFE grafts from different manufacturers,[12] but the material variable in that study was the presence or absence of an outer wrap layer of PTFE on the conduit.

Most arteriovenous graft failure ultimately results from venous outflow tract stenosis,[12] but other causes of failure include pseudoaneurysms, patient hypotension, hypercoagulable states, disadvantaged inflow and outflow vessels, and graft infection. This study attempted to control as many variables as possible in angioaccess surgery and prospectively randomize patients so that differences in graft failure could be attributed to the material wall thickness itself. The forearm loop configuration was adhered to as much as possible to avoid the influence of configuration effects on graft outcome that other studies have noted.[13] At an average follow-up examination time of 36.7 months overall for the grafts, mean primary duration of patency (as well as duration of secondary patency) was greater in the patients with the STD ePTFE grafts. The difference in follow-up examination time averages between the 2 groups probably does not have clinical significance, because most patency failures occurred before 30 months in our patients, less than either group's mean follow-up examination time. Additionally, the difference is only 3 months, a clinically small difference given the 36 months average time in a hemodialysis population.

Our data does not explain the differences in the grafts. The initial concern of propensity of the THN graft to pseudoaneurysm formation was not seen in our patients. One explanation for this is that the thick wall configuration may have greater resistance to kinking and compression from tunnel tract hematomas and thrombus. The thicker wall may also provide a more stable platform for needle hole thrombus plugging. Patient differences may also account for the outcomes; however, the current study minimized as many variables as possible. This study's patency rates are less than those described by most groups, with previously published secondary patency rates of stretch ePTFE grafts ranging from 87% to 96% at 6 months and from 86% to 93% at 12 months.[1,4,12,14,15] Our patency rates were, at best, 70% to 80% at 6 months and 55% to 75% at 12 months. In a newly published study from New Hampshire comparing all types of dialysis access, secondary patency at 1 year for 215 ePTFE grafts was 59%,[10] not significantly different from the 64% 1-year secondary patency rate at our institution.

We found a significant difference between the 2 graft configurations. The differences were present in both the intermediate period (6–12 months) of graft use, and toward the end of the life of the access (>27 months.) Because accesses were continually salvaged by revision as needed for the more difficult patients, secondary patencies converged in early follow-up between the 2 groups. The numbers of patients with grafts after 30 months declines in our series; however, when the literature on graft results in hemodialysis access is considered in overview, most patients experience failure before 30 months. More patients with STD wall grafts had functioning accesses for more months with less interventions. We conclude that, overall, standard thickness ePTFE grafts, as opposed to thin wall configurations, should be used when constructing new ePTFE hemodialysis prosthetics access.

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DISCUSSION

Dr Mitchell H. Goldman. Dr Valentine, Dr Seeger, President Clagett, members, and guests. I'd like to thank the society for the opportunity to comment on this interesting paper. Part of the reason I'm happy to do this is because it correlates with a prejudice of mine. We had some really bad experience with thin wall PTFE grafts and reverted to the standard traditional graft. However, most of our bad experiences were related to pseudoaneurysm formation and bleeding, and I was surprised to see that they did not have the same experience in Florida. Perhaps it's our East Tennessee dialysis units. But as I mentioned, we did revert to standard grafts.

Dr Lenz and her colleagues showed decreased primary and secondary patency of their thin-wall PTFE when compared with standard wall grafts. The study is a randomized prospective study, and therefore, in the tradition that Dr Clagett is about to begin, should be paid attention to. Although there may be some inherent flaws, there are too few to really comment on. And I just have 1 question for the authors. Of the primary failures reported in each group, how many were revised and how many underwent thrombectomy alone? Did that make a difference? One of my prejudices is that the venous outflow tract is associated with increased internal hyperplasia. Is there a difference in the internal hyperplasia in the outflow tract of the thin wall vs. the standard wall grafts? And did you look at that?

The other area where internal hyperplasia might play a role is in the needle puncture sights. Was there any way that you could document, either through angiographic means or direct visualization, that the puncture sights were more stenotic or more sclerosed?

I'd like to thank the authors for providing me, in advance and in a timely way, a copy of their manuscript. I commend it to your reading. Again many thanks to the Society for giving me the opportunity to make this commentary.

Dr Barbra J. Lenz. I wish to thank Dr Goldman for his kind insights. We also were surprised by the low rate of pseudoaneurysms in the thin wall group. We were expecting a much higher rate. We're not sure why that didn't turn out to be so, except that our hemanalysis nurses have a wonderful time putting on clamps, rather than just holding pressure, to provide postdialysis bleeding stoppage. As far as revising primary failure, most of our grafts were revised, rather than only thrombectomized; approximately 90% were revised. This was done primarily because of outflow tract stenosis at the venous anastomoses. This was documented by means of intraoperative arteriogram. As far as the puncture sights, the intraoperative arteriograms did not reveal any stenosis at the puncture sights. It was just all outflow stenosis, the standard internal hyperplasia that causes most of the graft failures.

I'd like to ask whether Dr Goldman's patients were all receiving dialysis at the same center? We have a number of different centers in Texas, some of which use clamps and some of which use direct digital pressure.

These cases were all at our dialysis center at the university medical center in Jacksonville, and we did have a high rate of turnover of hemodialysis nurses during this time; clamps and digital pressure were both used, but primarily clamps were used.

Thank you.

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Reinforced versus Nonreinforced Polytetrafluoroethylene Grafts for Hemodialysis Access

Earl S. Schuman, MD, Blayne A. Standage, MD, John W. Ragsdale, MD, George F. Gross, MD, *Portland, Oregon*

BACKGROUND: Two major types of polytetrafluoroethylene (PTFE) graft material have been available for the past 20 years. Previous studies have suggested that nonreinforced PTFE performs better as a hemodialysis conduit than reinforced PTFE. We have had experience with both materials for the past 20 years.

METHODS: This is an outcome study that is based on concurrent and retrospective data. Patients were accrued into the study from 1987 to 1995. There were 632 grafts that were entered onto a data base and analyzed by a biostatistician.

RESULTS: Nonreinforced PTFE performed better than reinforced PTFE in every category and subgroup. Both mean duration and life-table analysis of the primary patency were statistically significant ($P < 0.05$). The secondary patencies were similar, with 80% of the nonreinforced and 77% of the reinforced functioning at 1 year. The median duration for secondary patency of all grafts was 1,554 days. Diabetic patients comprised 50% of the patient population.

CONCLUSION: Nonreinforced PTFE performs better than reinforced PTFE as a hemodialysis conduit. Until a multicentered prospective randomized study can be achieved, a preponderance of data suggests that nonreinforced PTFE should be the material of choice for hemodialysis access. *Am J Surg.* 1997;173:407–410. © 1997 by Excerpta Medica, Inc.

Hemodialysis patients rely on their vascular access to function reliably for long durations. Polytetrafluoroethylene (PTFE) is the most commonly used synthetic material for dialysis access. These grafts are asked to withstand two punctures with 15-gauge needles an average of three times per week. The dialysis machine pumps the blood at 400 cc an hour for 3 to 3½ hours. Needle puncture sites seal with thrombus, neocapillary formation, and fibrosis. These demands lead to pseudointimal hyperplasia, an uneven, thrombogenic surface, and eventually, stenosis and thrombosis. Correction of this process can require graft thrombectomy, revision, angiography, and balloon angioplasty. A graft material that can perform under these parameters in trouble-free fashion has not yet been found.

Expanded PTFE was developed in 1969 and introduced as a hemodialysis conduit in 1976. Early versions of the graft were subject to aneurysmal dilatation. This was corrected by adding a reinforcing wrap of porous PTFE to the Gore-Tex product. Another approach involved increasing the wall thickness to achieve adequate circumferential strength. These two graft materials, Gore-Tex (reinforced) and Impra (nonreinforced), have been the mainstays for hemodialysis access. Few studies are available to compare the efficacy of these materials. Previous reviews were either retrospective or contained few patients.[1,2] Based on our previous findings, we decided to review our experience, as we have used both materials since 1976.

METHODS

This is an outcome study that is based on concurrent and retrospective data. Patients were accrued into the study from 1987 to 1995. All patients who received a new Gore-Tex or Impra graft were included. End points for the study were death of the patient, successful renal transplant, transfer to another mode of dialysis, return of renal function, transfer to another dialysis unit, or graft failure. The dates of graft implantation and all complications were entered concurrently throughout the years of this study. All other data were obtained retrospectively through review of hospital records, dialysis unit records, and charts from the nephrologists' offices. These data were entered on a data base program and transferred to the Statistical Program for Social Sciences (SPSS) for statistical analysis by a biostatistician. Multivariate analysis was done by Cox regression. Group comparison for means testing was by analysis of variance, *t* test, and cross tabulation with chi-square analysis. Life tables were generated using the Kaplan-Meier method and assessed with log rank and Breslow statistics. In some instances multiple testing was done to confirm the validity of differences that were found significant.

RESULTS

Mean patient age, duration, and complications per graft are given in Table I. All patients and their renal failure diagnosis appear in the upper portion of the Table. They are delineated by graft type in the lower portion. The overall primary and secondary patency rate for Impra were of greater duration than for the Gore-Tex material. The difference in the mean primary patency was statistically significant ($P = 0.032$). Life-table analysis confirmed the su-

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Demographic and Comparative Data

	Number	Age	Patency	Secondary Patency	Thrombosis	Rev
Total patients	632	61.5	219	520	2.20	1.
Diabetes	326	64.4	231	533	2.56	1.
Hypertension	148	63.3	212	433	1.90	1.
Glomerulosclerosis	23	43.8	243	730	2.45	1.
Analgesic nephropathy	20	53.0	129	272	2.10	0.
Nephrosclerosis	18	54.2	86	194	1.29	0.
Other	97	57.5	324	606	2.30	1.
Gore-Tex	438		224	490	2.75	1.
Diabetes	226	53.0	200	462	2.67	1.
Hypertension	84	64.0	173	354	2.57	1.
Other	128	55.0	209	441	2.05	0.9
Impra	194		350	625	2.45	1.0
Diabetes	89	58.0	307	618	2.81	1.0
Hypertension	50	62.0	277	535	2.06	0.9
Other	55	55.0	385	566	1.70	1.0

perior graft duration of Impra. This was statistically significant ($P = 0.02$) for primary patency (**Figure 1**). At 1 year, 44% of Impra grafts had not thrombosed versus 28% for Gore-Tex. Secondary patency at 1 year showed 80% of the Impra grafts still functioning versus 77% for Gore-Tex (see Figure 3).

The median duration for secondary patency of all grafts was 1,554 days. Since diabetic and hypertensive patients comprise 75% of the total population, all others were grouped for further testing to get adequate numbers for analysis. Impra was better than Gore-Tex among all subgroups of renal failure diagnosis. None of these differences was statistically significant.

Males represented 47% of the study population and were equally represented in both graft types. There was no significant difference in primary patency between males and females. The Impra material performed for a longer duration than the Gore-Tex in both males and females and was statistically significant in the female group ($P = 0.028$).

tients were assessed by age group and were divided i those under 40 (n = 102), age 40 to 65 (n = 255), a those over age 65 (n = 274). Impra performed better th Gore-Tex in each subgroup and was statistically significa in the age 40 to 65 group ($P = 0.003$). One hundred a forty-five grafts failed and 393 remained patent until a stu end point. One hundred and sixty-four patients died, 1 transferred, and 20 patients were transplanted during t course of the study. One hundred and sixty-one grafts we abandoned because of recurring proximal stenosis (loss venous real estate), infection, or poor cardiac function u able to sustain a graft fistula. There was no statistically si nificant difference between the 108 Gore-Tex grafts aba doned (25%) and the 53 Impra grafts abandoned (27%).

Forearm grafts were predominantly utilized and represent 519 grafts (82%). There were 66 upper arm grafts (10%), 3 (6%) placed in the thigh, and 8 on the chest wall (2%). The

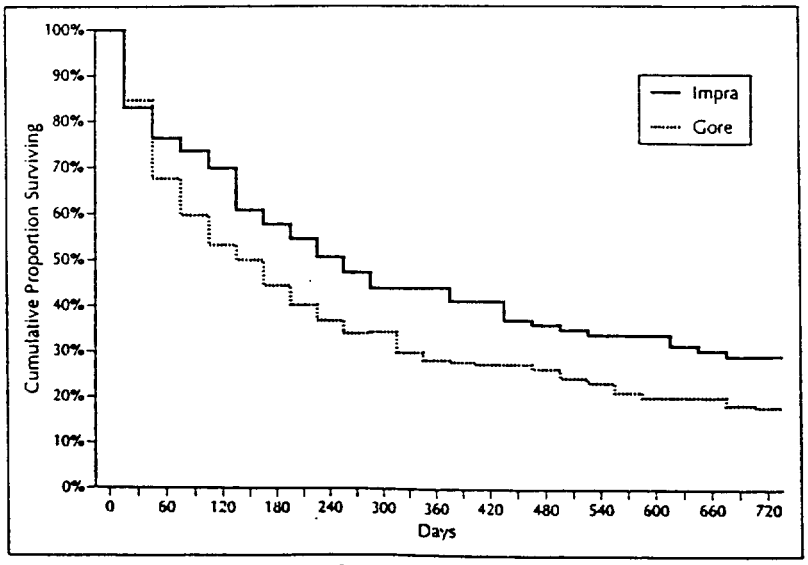

Figure 1. Primary patency life table.

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TABLE II

Comparison of Surgeons

Surgeons	% Gore-Tex	% Diabetic Patients	Primary Patency	Secondary Patency
Surgeon 1	68	55	190	534
Surgeon 2	55	52	248	495
Surgeon 3	77	47	211	421
Surgeon 4	88	55	141	270

was an equitable distribution of Impra and Gore-Tex grafts in all of these locations. There was a moderate difference in usage of the different materials by the different surgeons. This ranged from 55% to 88% use of Gore-Tex. An analysis of each surgeon's outcomes with each graft material was assessed (Table II). There was equal distribution of renal failure diagnoses. The difference between surgeon 2 and 4 approached significance ($P = 0.06$) but surgeon 4 had the highest percentage of Gore-Tex. Survival analysis of primary patency for each surgeon with both graft materials showed surgeon 4 compared with surgeon 2 was not significant ($P = 0.076$ for Gore-Tex and $P = 0.086$ for Impra). To assess the possible influence of a learning curve, each surgeon's experience was evaluated in 2-year increments. There was a slight trend toward decreasing patency rates in all subgroups but none were statistically significant.

There were some disparate data regarding thrombectomies and revisions. As shown in Table I, Impra performed better than Gore-Tex on mean number of thrombectomies and revisions per graft. However, when we assessed the number of thrombectomies and revisions per year, Gore-Tex performed better. Neither of these differences was statistically significant.

The longevity of grafts in this population is highly variable, as shown in Figure 2. Although almost 50% of the grafts were no longer functioning at the end of 1 year, some continued to function for up to 9 years. This graph shows the secondary patency of all patients and is not censored as is found in life-table analysis. Of the grafts no longer functioning at the end of 1 year, 44% were due to graft failure and 29% were due to patient death.

COMMENTS

Although PTFE has become the mainstay for hemodialysis access, there are few data in the literature to help determine if nonreinforced has any difference in outcome than reinforced PTFE. Any aspect that improves access function is significant for this large and increasing population. Approximately 120,000 patients per year are on hemodialysis. Dialysis access is one of the most common vascular procedures in America. It is estimated that 20% of all admissions of end stage renal disease (ESRD) patients are related to their vascular access.[3]

In 1985 Palder et al[1] reviewed their experience with PTFE in a small randomized trial and noticed that patients who received Impra grafts had better outcomes than those who received Gore-Tex. We noticed similar results in 1987, with Impra grafts having better patency rates in a small cohort of study patients.[2] Other studies evaluating characteristics of each graft type have found no differences in compliance, tissue ingrowth, and histologic incorporation.[4,5] One study did suggest a significant disruption of the outer wrap of the reinforced PTFE after numerous needle punctures.[5] Most of these studies involved small numbers, making it difficult to draw firm conclusions. We had hoped to have similar numbers of each graft type in our current study. It was assumed that having nurses "randomly" pick a graft would lead to equality. However, nursing staff and young surgeon familiarity with Gore-Tex led to its use in higher numbers. We still amassed sufficient numbers in each group to produce significant data.

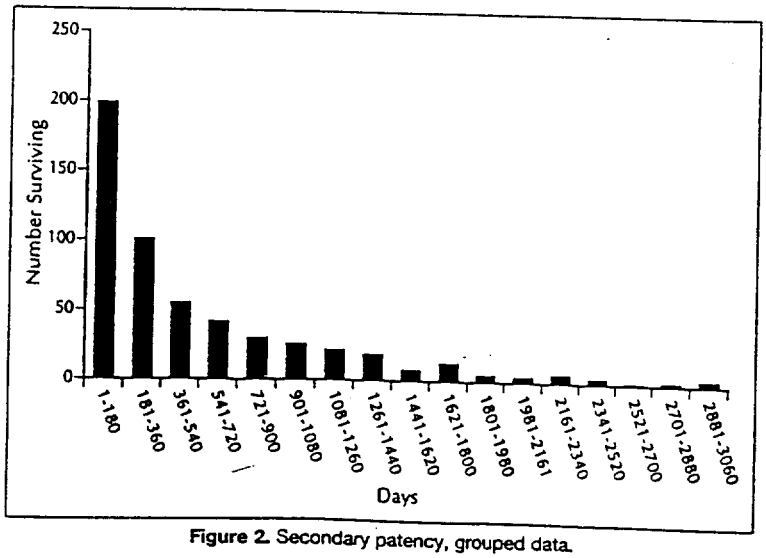

Figure 2. Secondary patency, grouped data.

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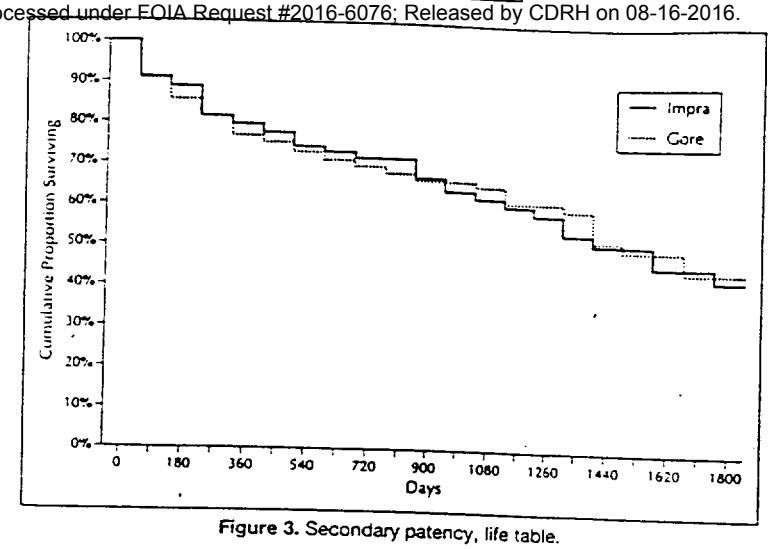

Figure 3. Secondary patency, life table.

The large number of diabetic patients shows the increasing trend seen nationwide. Owing to a busy endocrine unit, we have an even larger number of diabetic patients than the national average. For the period 1987 to 1990, the United States Renal Data Systems reports 34% of all patients with ESRD had diabetes mellitus.[6] There were similar numbers of diabetic patients in each graft type of our study. Impra had better primary and secondary durations but primary patency is more significant for this evaluation. Secondary patency can reflect the surgeon's tenacity at ensuring graft function with multiple procedures. Primary patency is a product of technical factors at the time of graft placement, proper use of the graft by dialysis personnel, and characteristics of the graft material. The latter is a significant factor since technical problems and dialysis personnel errors occur equally in both graft types.

Many patients came from other dialysis units to have us place their access. They were a moderate part of the early decline in secondary patency as shown in Figures 2 and 3. Most of these patients were lost to follow-up. Almost 50% of the grafts had reached a study end point within 1 year of access placement, mostly because of graft abandonment or patient death. This demonstrates the challenge that these severely ill patients present.

Although PTFE is durable and reliable for dialysis access, there is a preponderance of data that suggest nonreinforced PTFE functions better than reinforced PTFE. The next study to evaluate this should be a multi-institutional randomized trial. Until then, nonreinforced PTFE should be considered the graft of choice for hemodialysis access.

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Expanded polytetrafluoroethylene arterial prostheses in humans: histopathological study of 298 surgically excised grafts

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The expanded polytetrafluoroethylene vascular prosthesis is considered to be the best synthetic alternative for peripheral arterial reconstruction. Most studies on the healing characteristics of expanded polytetrafluoroethylene prostheses have been carried out on animals, and very few data are available on prostheses implanted in humans long term. We implanted 298 expanded polytetrafluoroethylene grafts as arterial substitutes in humans. The mean duration of implantation was 523 d and the grafts were implanted mainly for infrainguinal or axillofemoral bypass. The cellular and collagen infiltration of the microporous expanded polytetrafluoroethylene structure was generally poor. Infiltration occurred mainly in the external region of the prosthetic wall and increased with the duration of implantation. The external reinforcement was not a major factor in limiting tissue infiltration. The luminal surfaces were covered with a thin, irregular layer of organized fibrin, interspersed with exposed expanded polytetrafluoroethylene areas. Mineral deposits were observed in five cases. Despite poor healing, the clinical performance of expanded polytetrafluoroethylene vascular prostheses is relatively good. Since the chief advantage of this material is good mechanical stability *in vivo*, any modifications of the graft to improve healing characteristics or thrombogenic properties should not be made at the expense of stability *in vivo*.

Keywords: Vascular prostheses, PTFE graft, healing characteristic, explant

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Since it was first introduced as an experimental[1-3] and as a clinical[4-6] vascular implant material, the expanded polytetrafluoroethylene (ePTFE) graft is widely acknowledged as the most reliable synthetic arterial substitute for peripheral arterial bypass when the autologous vein is not available.

The healing characteristics of this vascular prosthesis when implanted for a long period are very important, since they provide information which may be useful when considering improvements to the prosthesis, or when planning new developments. The *in vivo* stability of the prosthesis is also of paramount importance and has been investigated[7].

Although the healing characteristics of ePTFE vascular prostheses have been studied extensively in animal models, particularly to determine the optimal internodal distance[8-13], little work has been done on human explanted grafts[14-16]. Analysis of biopsies of patent and uncomplicated prostheses have been carried out[14], but are rarely performed because of ethical considerations. Since uncomplicated prostheses retrieved at autopsies are rare, surgical excision following a complication, mainly thrombosis, is the principal source of material for this type of study.

In this paper, we report on our analysis of the healing characteristics of the ePTFE prostheses implanted as arterial substitutes in humans, carried out on 298 grafts collected over 10 yr in our cooperative graft-retrieval programme, involving centres in Canada, France and Italy. Our specific aims were to investigate the luminal surface, collagen infiltration and the external encapsulation in ePTFE grafts using the naked eye, light microscopy and scanning electron microscopy (SEM). The effects of the external reinforcement in Gore-Tex® (W. L. Gore & Associates Inc., Flagstaff, AZ, USA) vascular grafts on the healing process were also assessed by these techniques.

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MATERIALS AND METHODS

Prostheses

From 1979 to 1988, 370 ePTFE vascular prostheses were collected from the participating institutions. Forty-six were implanted as vascular access for haemodialysis and were not considered in this study. A total of 324 prostheses originated from various vascular reconstructive procedures. Twenty-six of these 324 prostheses were excluded from the study because of insufficient clinical information. The minimum criteria for inclusion of any particular graft in the study were that the site and duration of implantation were known.

The remaining 298 prostheses retained for this study were harvested in 26 different centres in Canada, France and Italy. Nine of these centres provided more than 10 specimens (*Table 1*). Of the prostheses, 281 were reinforced Gore-Tex vascular grafts (*Figure 1*), 15 were Impra®, either regular (*Figure 2*) or externally supported (*Figure 3*), one was a Vitagraft® (*Figure 4*) and one was a Bard® PTFE (*Figure 5*). They were mainly standard wall, rarely thin wall, tapered or externally supported. Only one bifurcated Gore-Tex vascular graft was available for study (*Table 2*).

The patients

Of our patients, 234 were men, 57 women and 7 unknown. The mean age of the patients at the time of the implantation was 63 ± 10.0 yr (range 23–88 yr) and the women were generally older than the men (67.4 ± 11.6 *versus* 61.9 ± 9.5 yr) (*Table 3*).

Those patients had been previously operated on for different purposes: claudication, 53; rest pain, 106; gangrene, 65; and ischaemia, 27 (*Table 4*). The most common operation was femoropopliteal bypass, followed by axillofemoral bypass and femorodistal bypass, with 146, 59 and 44 cases, respectively (*Table 5*). The number of patent distal arteries in patients undergoing infra-inguinal bypass is given in *Table 6* and indicates that most of the patients were high-risk. Cardiovascular risk factors of the patients before surgery are summarized in *Table 7*. They include: diabetes 52, hypertension 121, dyslipidemia 54 and smoking 197. All these factors are likely to impair the chances of success of the procedure.

Details of previous vascular operations and thrombectomies of the graft before explantation are given in *Table 8*. Most procedures were secondary, indicating that the implantation of the ePTFE was associated with previous reconstruction failures or progression of the patient's atherosclerosis. In 106 cases (35.6%), the ePTFE graft was anastomosed to another arterial substitute, more frequently an aortobifemoral polyester prosthesis (*Table 9*).

Table 1 Source of the explanted prostheses

Origin	Number	Percentage
Québec City	136	45.6
St-François d'Assise (J.F. Girard, C. Rouleau, C. Gosselin)	67	22.5
Hôtel-Dieu (G. Laroche, P. Roy)	21	7.0
Enfant-Jésus (P. Roy, D. Marois)	19	6.4
CH Laval University (J. Awad)	18	6.0
St-Sacrement (Y. Douvilie, H.P. Nöel, R. Labbé)	11	3.7
Province of Québec (outside Québec City)	28	9.4
Jewish Hospital Montreal (N. Sheiner, J. Zeltzer, N. Miller)	25	8.4
Other hospitals	3	1.0
Canada (outside the Province of Québec)	16	5.4
France	113	37.9
Nice (M. Batt, G. Avril, N. Boas, R. Hassen-Khodja)	57	19.1
Marseille (R. Courbier, J.M. Jausseran, M. Formichi)	24	8.1
Strasbourg (J.G. Kretz, N. Chakfé)	11	3.7
Other hospitals	21	7.0
Italy		
Trento (C. Picetti)	5	1.7
Total	298	100.0

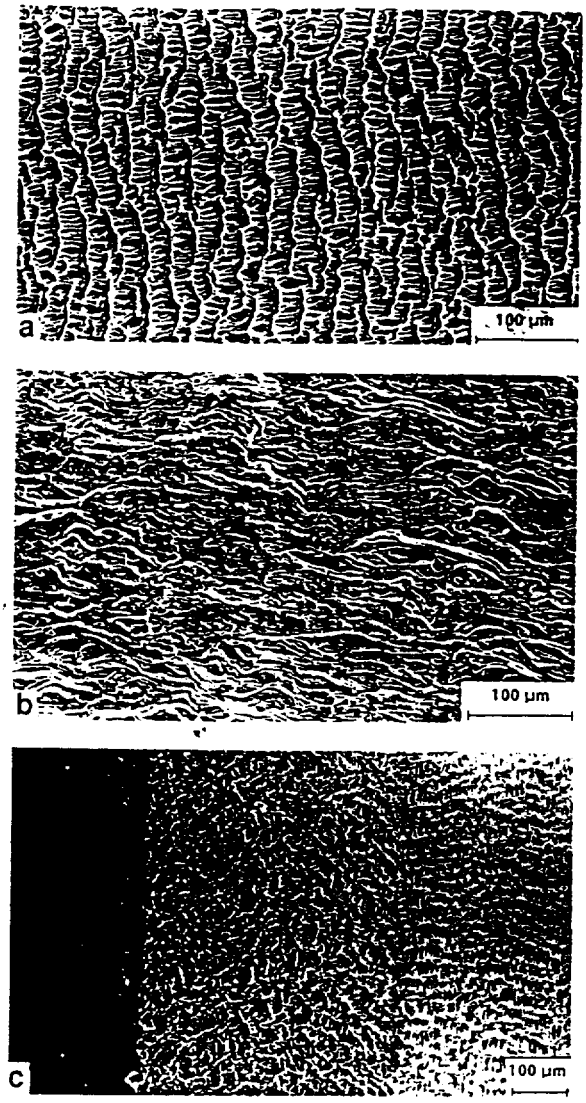

Figure 1 Scanning electron photomicrograph of the virgin Gore-Tex prosthesis. **a**, Flow surface; **b**, outer surface, showing the external reinforcement; **c**, cross-sectional view (outer surface on the left).

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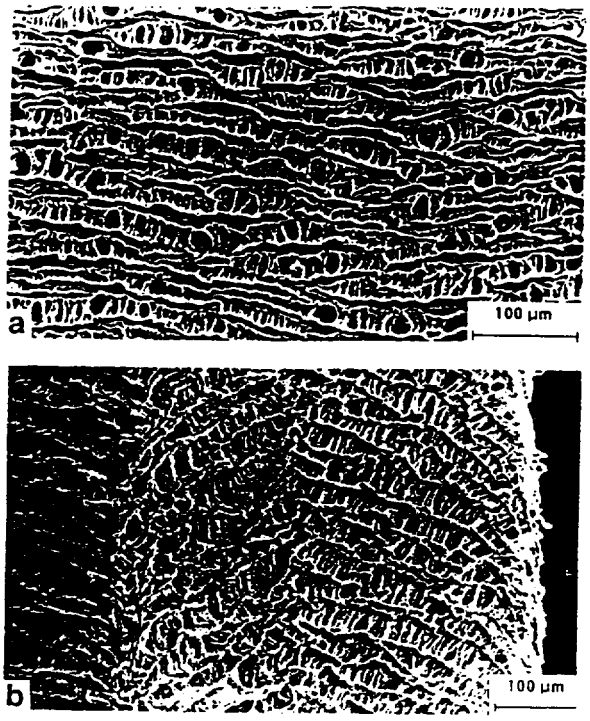

Figure 2 Scanning electron photomicrograph of virgin Impra ePTFE prosthesis. **a**, Flow surface; **b**, cross-sectional view.

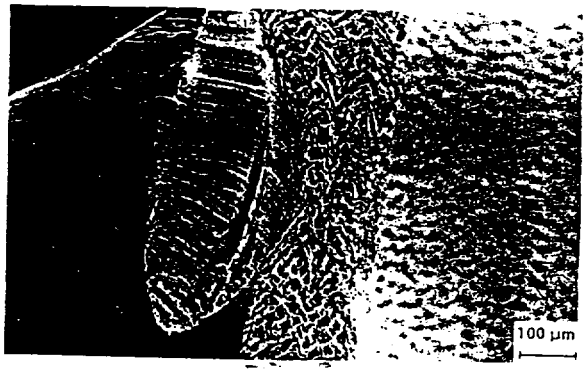

Figure 3 Scanning electron photomicrograph of virgin Impraflex, cross-sectional view with the external support.

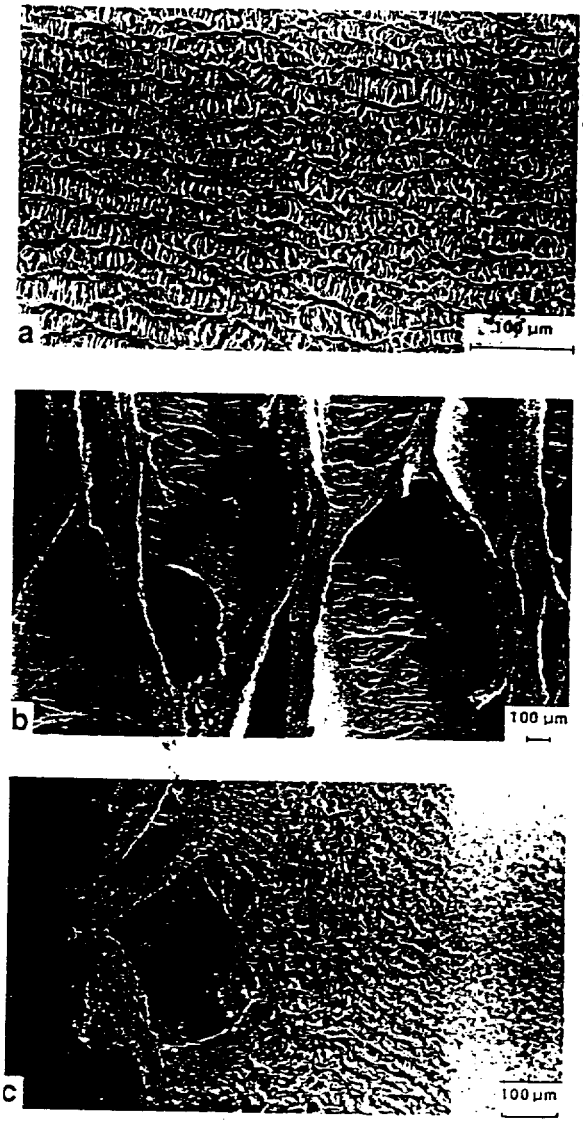

Figure 4 Scanning electron photomicrograph of virgin Vitagraft ePTFE prosthesis. **a**, Flow surface with a structure equivalent to the Impra grafts with nodes perpendicular to the blood flow and interrelated by fibrils; **b**, externally, however, the nodes are larger (500 µm) with prominent grooves and fibrils of up to 1 mm in size; **c**, cross-sectional view.

The reasons for explantation of the prostheses were mainly surgical removal for complications (96.6%) and the rest at autopsy (3.4%). The mean duration of implantation of the prostheses was 523.3 d (range 1–3442 d) and the median 300.5 d. The most frequent complications requiring removal of the grafts were thrombosis and infection, followed by false aneurysm (*Table 10*). The relationship is given between the two main causes of explantation, thrombosis and infection, and the number of previous vascular operations (*Table 11*) and thrombectomies (*Table 12*).

Graft harvesting and processing

After excision in the operating theatre (or in the autopsy room), each graft was opened longitudinally and carefully rinsed with heparinized saline. It was then fixed and stored in a buffered solution of 1.5% glutaraldehyde and shipped, with a form containing the relevant clinical data, to the Institut des Biomatériaux, Hôpital St-François d'Assise, Québec City, Québec, Canada, for investigation.

As part of our ongoing graft-retrieval programme, a standard procedure was developed for the preparation of the specimens before they underwent a series of pathologic investigations. Each graft was first examined and photographed with a Tessovar macrophotography optical *system* (Carl Zeiss, Oberkökchen, Germany). Special attention was paid to the grafts described by the surgeon as aneurysmal, dilated or removed because of false

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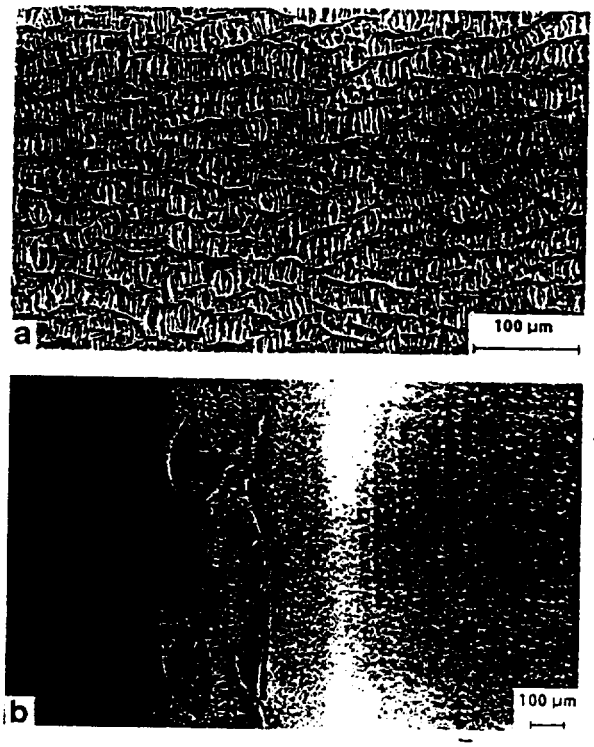

Figure 5 Scanning electron photomicrograph of virgin Bard ePTFE prosthesis. **a**, Flow surface; **b**, cross-sectional view.

aneurysm. The internal capsule was observed by the naked eye to assess the patency, presence of overt infection, cleanliness of the flow surface and the presence of any occlusive thrombi. The external capsule was observed by the naked eye and with the Tessovar optical system and was classified into four broad categories according to its thickness: (0): absent, (1): thin, (2): moderately thick and collagenous, and (3): very thick, involving fatty tissues.

Histology

Appropriate representative segments were then selected for pathological studies. Each segment was divided into two subspecimens. The first piece was post-fixed in Perfix solution and dehydrated with ethanol for light microscopy. It was then clarified with toluene, then embedded in paraffin. Sections 4 µm thick were then stained for light microscopy using Weigert, Masson Trichrome, Dahl and Gram stains. In histological examination by light microscopy, three main areas of the prosthesis, namely the external capsule, the microporous wall and the luminal surface, were selected for detailed study. In addition, in reinforced Gore-Tex vascular grafts, the integrity of the reinforcing film was assessed.

1. The external capsule: The thickness of the collagenous capsule was classified according to the following categories: absent (0), thin (1), intermediate (2) and thick (3). The presence of non-specific chronic inflammatory reaction was observed. When present, the intensity was broadly classified as: low (1), moderate (2) with many mononuclear cells present and high (3) with many giant cells. When no inflammatory reaction was observed a score of 0 was recorded.
2. Microporous structure infiltration: The infiltration of collagen, fibrin, erythrocytes and chronic inflammatory cells within the wall structure of the prosthesis was assessed. The presence and intensity of infiltration was classified into the following four categories:

Table 2 Types and sizes of the prostheses

Prostheses	Number	Diameter (mm)							
		5	6	7	8	6–4	8–6	14/7	Unknown
Gore-Tex	281								
Standard wall	240	1	87	1	89	–	–	–	62
Thin walled	15	1	7	–	4	–	–	–	3
Ringed	14	–	12	–	2	–	–	–	–
Ringed thin walled	1	–	1	–	–	–	–	–	–
Tapered	9	–	–	–	–	6	3	–	–
Bifurcated	1	–	–	–	–	–	–	1	–
Patch	1	–	–	–	–	–	–	–	–
Impra	15								
Standard wall	13	1	4	–	2	–	–	–	6
Impraflex	2	–	–	–	–	–	–	–	2
Bard									
Double helix	1	–	–	–	–	–	–	–	1
Vitagraft	1	–	–	–	–	–	–	–	1

Table 3 Age (years) of the patients at the time of the implantation

	Number of patients	Number of patients of known age	Mean	Standard deviation (s.d.)	Median	Range
Total	298	290	63.0	10.03	63.0	23–88
Men	235	228	61.9	9.5	62.0	24–88
Women	56	56	67.4	11.6	70.0	23–86
Unknown	7	6	63.2	2.6	63.5	59–66

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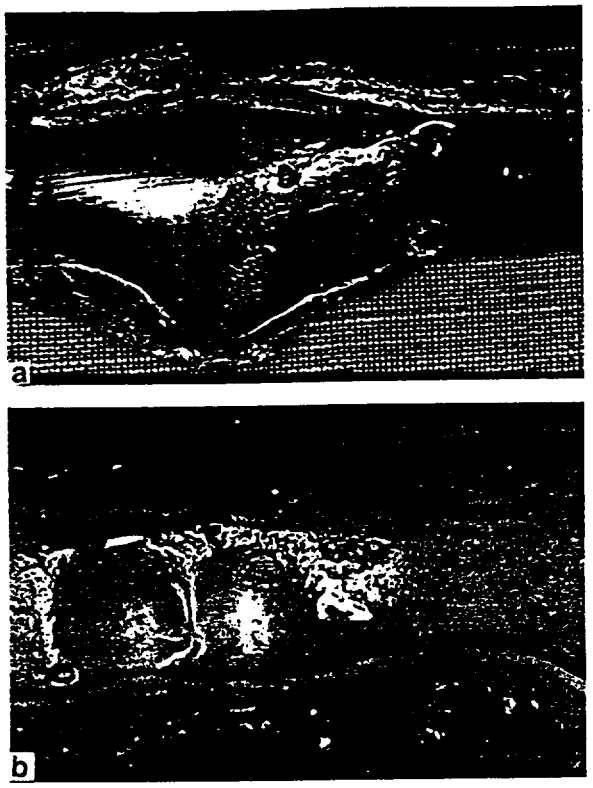

Figure 6 Photomacrographs of explanted Gore-Tex vascular grafts. **a,** Graft implanted as femoropopliteal bypass for 1.8 yr and excised for thrombosis. Note the thick external capsule and the lack of internal encapsulation; **b,** below-knee femoropopliteal bypass graft implanted for 1.9 yr and excised for thrombosis. The external capsule is thick and fatty. An internal capsule has also formed on the luminal surface.

absent (0), light (1), intermediate (2) and high (3). This infiltration was quantified in three areas of the thickness of the prosthesis: external, medial and internal.

3. The luminal surface: On the luminal surface, the presence and the distribution of fibrin coating on the prosthesis lumen, thrombus with blood cells, collagen or intimal hyperplasia were determined. The Gram stain was used to detect the presence of Gram$^+$ and Gram$^-$ bacteria, and the Dahl stain to detect mineralization.

Table 4 Indications for surgery

Indication	Patients	Percentage
Claudication	53	17.8
Rest pain	106	35.6
Gangrene	65	21.8
Acute ischemia	13	4.4
Subacute ischemia	14	4.7
Aneurysm or false aneurysm	9	3.0
Removal of an infected graft	8	2.7
Arterial trauma	2	0.7
Supra-aortic vessels revascularization	2	0.7
Unknown	26	8.7
Total	298	100.0

Table 5 Sites of implantation

	Patients	Percentage
Femoropopliteal	146	49.0
Above knee (54, 18.1%)		
Below knee (66, 22.2%)		
Unknown (26, 8.7%)		
Femorodistal	44	14.8
Axillofemoral	59	19.8
Femorofemoral	22	7.4
Ilio or aortofemoral	10	3.4
Femoral bifurcation	6	2.0
Supra-aortic arteries	5	1.7
Axillopopliteal	4	1.3
Aortobifemoral	1	0.3
Aortomesenteric	1	0.3
Total	298	100.0

4. The reinforcing film: The integrity of the external reinforcing film in Gore-Tex vascular grafts was examined and classified as intact and well preserved (0), infiltrated with collagenous tissue, causing the

Figure 11 Light microscopy photomicrographs showing collagen infiltration in an Impra graft implanted for 2.9 yr as femorodistal bypass and excised for thrombosis. Note that the microporous structure has been reorganized in the region of high collagenous infiltration near the external surface of the prosthesis (Masson trichrome, original magnification, ×100).

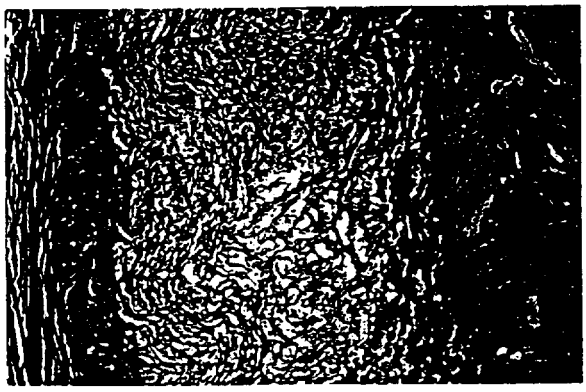

Figure 12 Light microscopy photomicrographs illustrating the infiltration of the ePTFE microstructure by collagen and cellular components in a Gore-Tex vascular graft implanted for 1 yr and 2 months as above-knee femoropopliteal bypass and excised for thrombosis. Note the presence of collagen on both the inner and outer surfaces but there is no infiltration through the graft microstructure (original magnification ×100).

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Figure 13 Light microscopy illustrating the infiltration of the ePTFE microstructure in a thin walled Gore-Tex vascular graft implanted for 275 d as below-knee femoropopliteal bypass and excised for thrombosis. The collagen is present mostly in the external capsule with some infiltration into the wall, but this is confined to the external region. The inner region of the graft is filled with fibrin and some erythrocytes. There is no internal capsule (Masson trichrome, original magnification ×100).

Figure 14 Light microscopy photomicrographs showing a well-preserved external reinforcing film in Gore-Tex vascular grafts. **a**, Intact reinforcement in a graft implanted for 1.9 yr as a below-knee femoropopliteal bypass and excised for thrombosis (haematoxylin–eosin, original magnification ×250); **b**, infiltrated and slightly lifted external reinforcement in a graft implanted for 233 d for above-knee femoropopliteal bypass and excised for thrombosis (haematoxylin–eosin, original magnification ×400).

external wrap to be partly lifted from the ePTFE structure (1) or completely separated from the prostheses by tissue infiltration (2).

Scanning electron microscopy and microanalysis

The second subspecimen, whose counterpart was investigated in histology, was post-fixed in thiocarbohydrazide and osmium tetroxide for examination by SEM. Dehydration was achieved by immersion in a series of ethanol solutions of increasing concentrations, culminating in pure ethanol, followed by critical-point drying using liquid CO_2 as the transfer medium. The specimen was then coated with gold–palladium and examined in a Jeol 35CF scanning electron microscope at 15 kV accelerating voltage.

The remaining graft specimens were cleaned using a series of 5% $NaHCO_3$ baths, followed by rinsing with distilled water for morphological evaluation by SEM and chemical investigations developed in a forthcoming study[7].

Morphological examination of the specimens by SEM was conducted, with particular attention paid to the following: organized or unorganized fibrin, uncovered areas of prosthesis, the presence of lipids, cholesterol, bacteria, leucocytes and endothelial-like cells on the luminal surfaces.

If mineral grains were observed after the cleaning process, they were coated with carbon, and microanalysis was performed using a multichannel energy dispersive spectrometer (PGT System 4, Princeton Gamma Tech). Finally, a specimen was investigated by X-ray diffractometry (XRD). A Gandolfi camera 114.6 mm in diameter recorded X-ray diffraction lines. A copper target (Cu: 1 Ka = 0.1542 nm) and a nickel filter were used with a Philips PW1010 generator (40 kV, 20 mÅ).

Table 6 Number of patent distal arteries in patients with infrainguinal bypass grafts

Number of distal run-off vessels	FPAK (n = 54)	FPBK (n = 66)	FP unknown (n = 26)	FD (n = 44)
0	3	12	2	7
1	14	25	4	21
2	11	13	2	2
3	14	8	5	2
Unknown	12	8	13	5

Femoropopliteal bypass: above knee (FPAK), below knee (FPBK) or not known (FP unknown), femorodistal bypass (FD).

Table 7 Cardiovascular risk factors of the patients before the operation (n = 298)

Cardiovascular risk factor	Present	Absent	Unknown
Diabetes	52	197	49
Hypertension	121	128	49
Dyslipidemia	54	188	56
Obesity	19	203	76
Smokers	197	49	52
Other localizations of atheroma	84	153	61

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Table 8 Number of previous vascular operations and thrombectomies of the grafts before implantation (n = 298)

Number of procedures	0	1	2	3	4	5	6	7	8	Unknown
Previous vascular operations: number of grafts	68	73	45	27	21	6	4	5	3	46
Thrombectomies: number of grafts	158	54	23	8	2	0	1	0	0	52

RESULTS

Macroscopic observations

The thickness of the external capsule (*Table 13*) tended to increase with the duration of implantation (*Figure 6*).

Table 9 Anastomoses with another arterial substitute

Arterial substitute to which ePTFE prosthesis is anastomosed		Number (n = 106)
Dacron®	Proximal	76
	Distal	1
	Both	2
PTFE	Proximal	7
	Distal	3
Dacron® proximal and PTFE distal		1
Autologous vein	Proximal	1
	Distal	9
Human umbilical vein	Proximal	1
	Distal	5

The other factor found to influence the macroscopic encapsulation was the presence of clinically overt infection. External encapsulation was found to be poorest in the infected grafts. However, the presence of infection was not found to influence the internal encapsulation significantly.

Light microscopy

1. The external capsule: The collagenous external capsule was present within the first month of implantation in ca. 39% of the cases. The thickness of this capsule generally increased with time of implantation and it was classified as intermediate (2) and thick (3) in 67.6%, 72.5% and 85% of the cases at 1–6, 6–24 and more than 24 months, respectively (*Figure 7*). After 1 month, prostheses which did not have an external capsule were mainly the infected ones. A non-specific chronic inflammatory reaction was observed in this external capsule. It was located against the outer surface of the ePTFE structure and consisted of mononucleate and some giant cells. The

Table 10 Cause of graft explantation and duration of implantation (in days)

	Number	Percentage	Mean duration	Median
Surgical removal	288	96.6	-	-
Thrombosis	194	65.1	513.8	300.5
Infection	56	18.8	422.3	282.5
False aneurysm	17	5.7	791.5	684.0
Anastomotic stenosis	4	1.3	405.5	347.0
Patent graft with associated surgery	4	1.3	617.5	17.5
Dilatation	2	0.7	1808.0	1808.0
Prosthetic degradation	2	0.7	743.5	743.5
Perigraft seroma	2	0.7	606.0	606.0
Unknown	7	2.4	943.4	733.0
Autopsies	10	3.4	-	-
Post-operative myocardial deficiency	3	1.0	5.3	-
Septicemia	1	0.3	1.0	-
Haemorrhage	1	0.3	1.0	-
Syndrome of revascularization	1	0.3	1.0	-
Cancer	1	0.3	141.0	-
Late myocardial infarct	1	0.3	114.0	-
Unknown	2	0.7	405.5	-

Table 11 Number of previous vascular operations and cause of explantation of the grafts

	0	1	2	3	4	5	6	7	8	Unknown
Thrombosis (n = 195)	48	44	23	16	14	5	4	3	2	36
Infection (n = 56)	8	16	16	6	5	1	0	1	0	3

Table 12 Number of thrombectomies of the grafts and cause of explantation

	0	1	2	3	4	5	6	Unknown
Thrombosis (n = 195)	103	41	12	0	1	0	0	38
Infection (n = 56)	25	9	8	7	1	0	1	5

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Table 13 Macroscopic examination of the external capsule (mean duration of implantation in days)

$n = 298$	Absent (0)	Thin (1)	Intermediate (2)	Thick (3)	Not examined
External capsule	74.0	80.0	91.0	47	6
Mean duration of implantation (days)	271.5	449.2	668.1	764	-

intensity of the chronic inflammatory reaction generally increased with the duration of implantation (*Figure 8*). Of the grafts retrieved within 1 month of implantation, 29% had an inflammatory reaction score of 2 or 3, compared with 53%, 65.2% and 66% for those retrieved at 1–6, 6–24 and more than 24 months, respectively. The intensity of chronic inflammatory reaction was also examined in terms of the thickness of the external capsule (*Figure 9*). It was found that the percentage of grafts with inflammatory-reaction scores of 2 and 3 increased as the external capsule became thicker.

2. Infiltration of the microporous structure: In prostheses retrieved within the first few days of implantation, the microporous structure was infiltrated by erythrocytes and fibrin. After longer periods of implantation, the internodal space was filled mainly by proteinaceous materials, particularly in the region close to the luminal surface. The collagen infiltration into the internodal space was generally minimal. In the external region of the graft wall, the score of collagen infiltration was 1 and 2 in 12.9% of the grafts within 1 month of implantation (*Figure 10*). The score was 2 and 3 in 20.6% of the cases at 1–6 months, 41.2% at 6–24 months and 43.2% at more than 24 months. *Figures 10a–c* show the collagen infiltration in the external medial and internal regions as a function of time of implantation. The score of collagen infiltration increased with the duration of implantation and was generally highest in the external, and lowest in the internal region of the prosthesis (*Figure 11*). It was also much higher in non-infected grafts than in infected ones.

Cellular infiltration of the microporous structure was minimal. It consisted principally of inflammatory cells and was observed in greater numbers in the external region of the graft (*Figures 12* and *13*). However, several points were noted:

- We observed large differences in the healing of identical prostheses retrieved after the same period of implantation.
- Infiltration by collagen and proteinaceous materials was extremely irregular in different specimens obtained from the same prosthesis and, sometimes, even on the same histological site. The factors responsible for the differences in infiltration at adjacent areas of the graft are unknown.
- The external reinforcement of the Gore-Tex vascular grafts was one, but not the only, factor limiting collagen infiltration. A thick collagenous

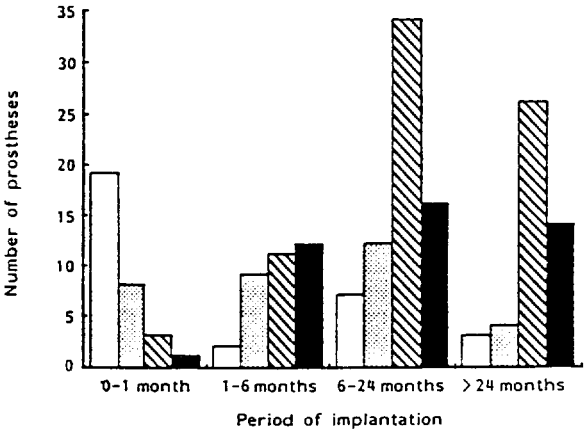

Figure 7 Number of prostheses (non-infected) of various external capsule thicknesses as a function of time of implantation. □, Absent (0); ▨, thin (1); ▧, intermediate (2); ■, thick (3).

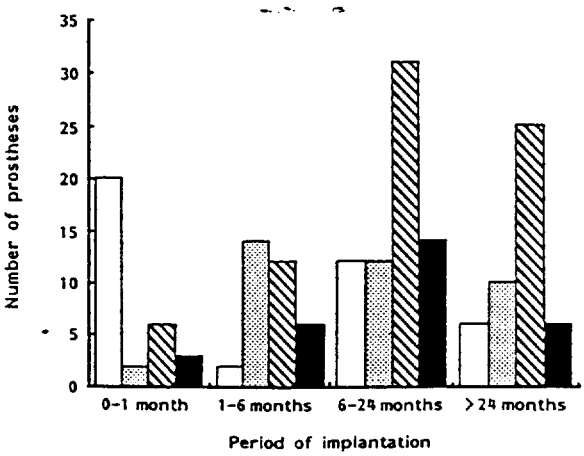

Figure 8 Intensity of chronic inflammatory reaction as a function of time in non-infected prostheses. □, Absent (0); ▨, low (1); ▧, moderate (2); ■, high (3).

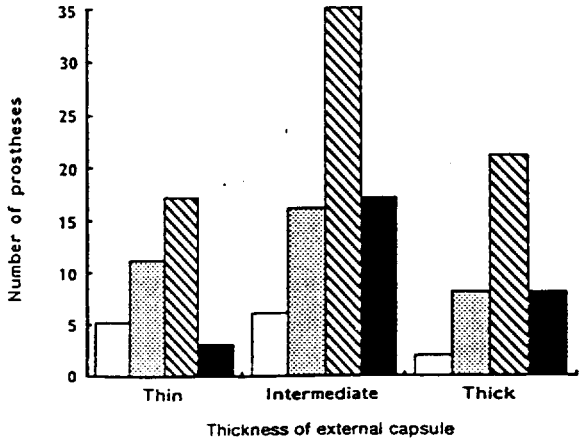

Figure 9 Intensity of chronic inflammatory reaction in the external capsule as a function of its thickness in non-infected prostheses. □, Absent (0); ▨, low (1); ▧, moderate (2); ■, high (3).

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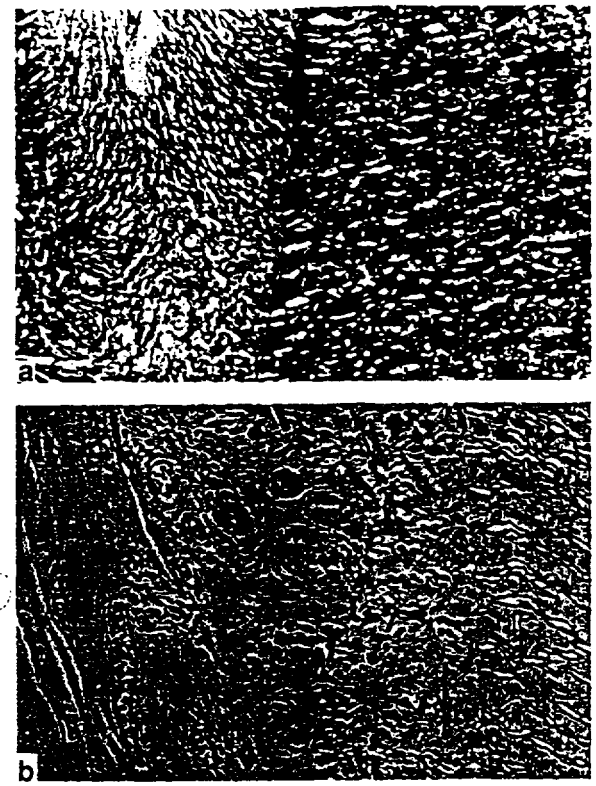

Figure 17 Light microscopy photomicrographs showing a lifted and/or dissociated external reinforcing film in Gore-Tex vascular grafts. **a,** External reinforcement completely lifted from the wall of a graft implanted for nearly 2 yr as an axillofemoral bypass (Masson trichrome, original magnification ×250); **b,** external reinforcement dissociated from the wall of a graft implanted for 2.6 yr as a femoropopliteal bypass and excised for thrombosis (haematoxylin–eosin, original magnification ×400).

Figure 18 Light microscopy photomicrograph of an externally supported Impraflex graft implanted for 2 yr as femorofemoral bypass and explanted for thrombosis. Note that there is a lack of collagen infiltration underneath the external support where the microstructure has been compressed (Weigert, original magnification ×100).

external capsule was frequently observed in these grafts (*Figure 14*), whereas in some Impra grafts without the external reinforcement, little collagen infiltration was noted.

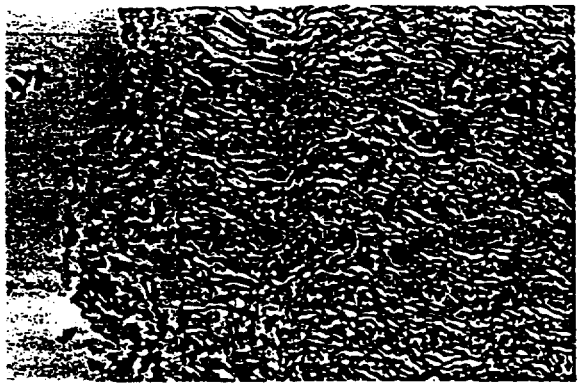

Figure 19 Light microscopy photomicrograph showing the presence of Gram$^+$ bacteria within the microstructure of a Gore-Tex vascular graft implanted for 3 yr as a below-knee femoropopliteal bypass and explanted because of infection (original magnification ×250).

- The collagen infiltration was found to propagate through the wall of the graft, from the outer to the inner surface. This was confirmed by the observation that the covered areas of externally supported grafts were not infiltrated by collagen, whilst the adjacent areas, not covered by the external support, were.
- Cellular infiltration into the microporous structure was minimal, even in the presence of an intense chronic inflammatory reaction with giant cells on the outer surface of the graft. This was the case with grafts with and without external reinforcement.

3. The luminal surface: The luminal surface of the prostheses was poorly healed. It was covered by a thin fibrin film. The coverage was incomplete and bare patches and thrombus deposits were frequently seen. Collagen was found on the luminal surfaces of only 24 grafts and was confined mostly to the vicinity of the anastomoses. It was also seen in thrombosed grafts, and in grafts where the structure was distorted by the suture line, resulting in an increased infiltration from the surrounding tissue. This occurred mainly in the anastomotic regions where the ePTFE graft was joined to another prosthesis. Anastomotic intimal hyperplasia was observed in four cases.
4. The external reinforcement: Various degrees of lifting of the external reinforcement in Gore-Tex vascular grafts were seen. The lifting can occur within the first month of implantation and the percentage of affected grafts and the degree of the lifting of the external reinforcement were found to increase with the time of implantation (*Figure 15*). Of the prostheses retrieved within 1 month of implantation, 25% had a lifted external reinforcement (score 1 and 2) but this increased to 58.1% at 1–6 months, 72.9% at 6–24 months and 79.2% at >24 months (*Figure 16*). Collagen infiltration into the external region of the prosthesis was found to be greater in grafts where the external reinforcement was lifted (*Figure 17*). It may be deduced, therefore, that collagen infiltration occurs in the space created by the lifting of the thin reinforcement film.
5. External support: The presence of an external support resulted in various degrees of compression of the

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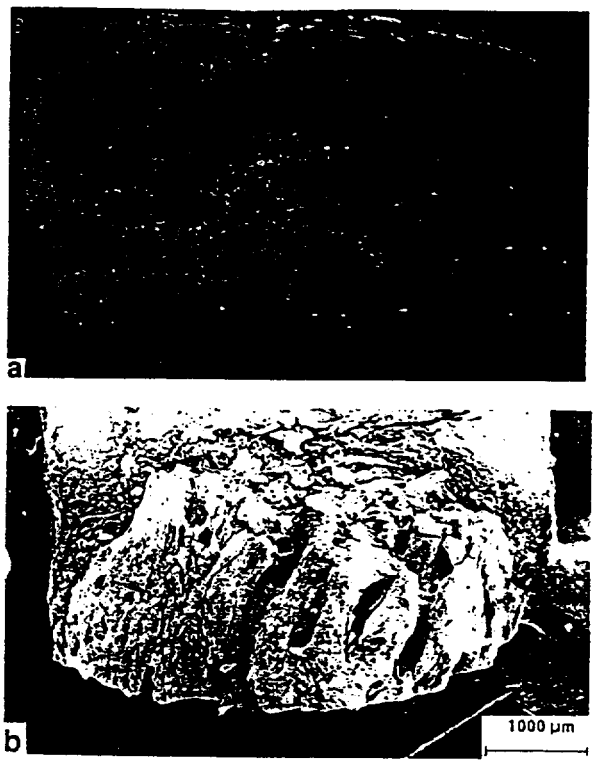

Figure 23 Mineralization on the outer surface of a Gore-Tex vascular graft implanted as above-knee femoropopliteal bypass for 2.3 yr and excised for thrombosis. **a,** Photomacrograph of the cleaned prosthesis showing partial encrustation by the mineral (original magnification ×3.2); **b,** scanning electron photomicrograph of a small portion of the specimen (original magnification ×20).

ePTFE structure. The addition of external support prevented penetration of cellular elements into the portion of the vascular graft wall underlying the external support (*Figure 18*).

Infection

Infection was the cause of explantation of the prosthesis in 56 cases. The mean duration of implantation of these prostheses was 422.3 d. Of these prostheses, 41 were analysed with light microscopy. The Gram stain demonstrated bacteria in only 8 (24.2%) of the 33 cases where this was carried out. Acute inflammatory reaction into the prosthetic structure was observed in 10 of the 41 cases (24.4%) and was located mainly in the outer region of the wall (*Figure 19*). Bacteria were observed on the luminal surface in 31 (55.4%) of the 56 infected grafts studied by SEM.

Scanning electron microscopy

Two hundred and eighty-four grafts were examined by SEM. The luminal surface was in most cases partially covered by organized fibrin, and unorganized fibrin strands were rarely seen (*Table 14*) (*Figure 20*). In 69.7% of the grafts, bare patches devoid of fibrin deposits were observed. Lipid deposition was found to be present in 81.4% of the grafts, but cholesterol was less abundant,

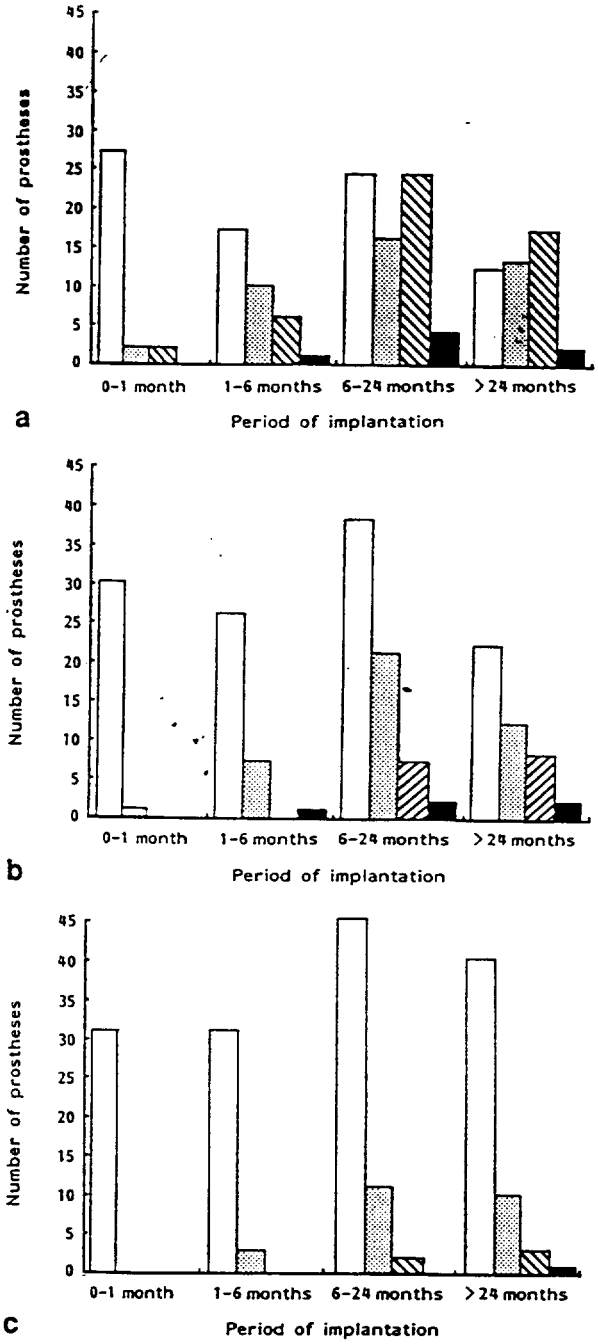

Figure 10 The degree of collagen infiltration into the expanded PTFE microstructure as a function of time in prostheses. **a,** External; **b,** medial; **c,** luminal portions of the wall. □, Absent (0); ▨, low (1); ▧, moderate (2); ■, important (3).

being present in only 34.5% (*Table 15*) (*Figure 21*). Leucocytes were rarely observed (12.7%). In only four grafts were endothelial-like cells observed within a few millimetres of the anastomoses. Bacteria were present on the luminal surfaces in 56.3% of all the grafts examined (*Figure 22*). Considering only the grafts removed because of clinical infection, bacteria were seen in 55.4% of the cases. There did not appear to be a correlation between

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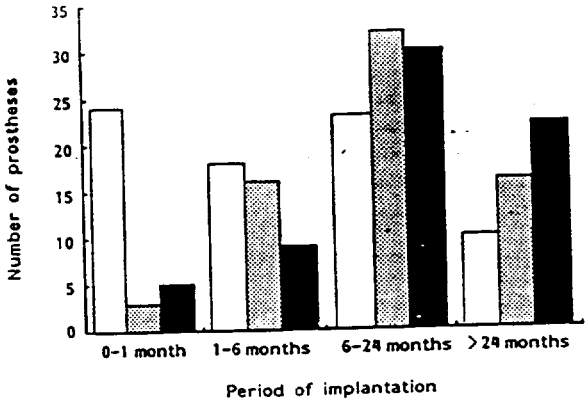

Figure 15 The condition of the external reinforcement in Gore-Tex vascular grafts as a function of the time of implantation. □, Intact (0); ▨, partly lifted (1); ■, completely separated (2).

the presence of bacteria and the duration of implantation of the prosthesis.

Mineral deposits

Mineral deposits remaining on the prosthesis after cleaning were seen in five cases. In four, they appeared as small loose stones. In the remaining case, the mineral deposits were firmly anchored to the outer surface of the graft (*Figure 23*). These occurred in Gore-Tex vascular grafts with a mean duration of implantation of 929.8 d (range: 115–2261, median: 810). No predisposing factors were noted. There were four men and one woman with a mean age at implantation of 62.2 yr (range: 44–77 yr). Four grafts were implanted as a femoropopliteal bypass below the knee, and one as an iliofemoral bypass. The cause of explantation was thrombosis in four cases and autopsy in one.

The microanalysis associated with SEM showed characteristic X-ray peaks corresponding to phosphorus and calcium in the five cases. XRD by means of a Gandolfi camera confirmed the identification of hydroxyapatite $Ca_5(PO_4)_3(OH)$ (JCPDS-record card 9-432) in one specimen.

DISCUSSION

The objective of this study was to investigate the healing characteristics of the ePTFE prostheses implanted as arterial substitutes to assess their function in humans. To determine whether this objective has been achieved, various issues relating to the methodology of the study and the interpretation of the results must be addressed.

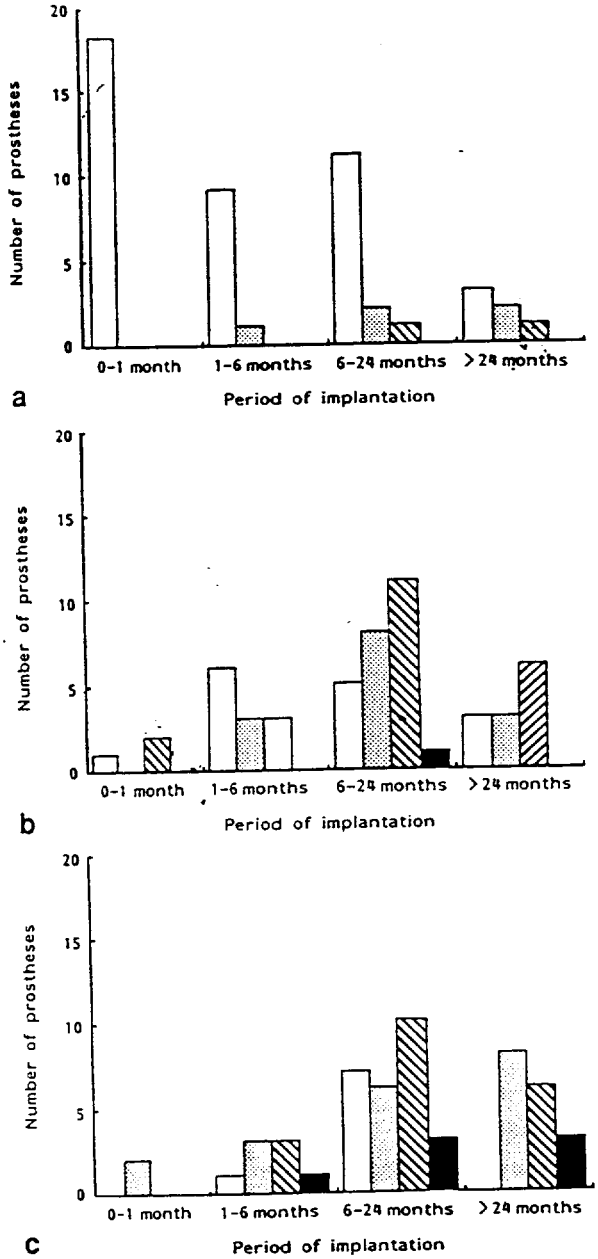

Figure 16 The degree of collagen infiltration into the external portion of the prosthesis wall as a function of time of implantation when the external reinforcement is **a**, intact; **b**, partly lifted; **c**, completely separated. □, Absent (0); ▨, low (1); ▧, moderate (2); ■, important (3).

The methodology

A study based on a graft-retrieval programme has unavoidable limitations for the bias in the collection of

Table 14 Fibrin on the luminal surface observed by SEM

n = 284	Absent	Rare	Abundant	Very abundant
Unorganized fibrin	124	129	27	4
Organized fibrin	34	98	111	41

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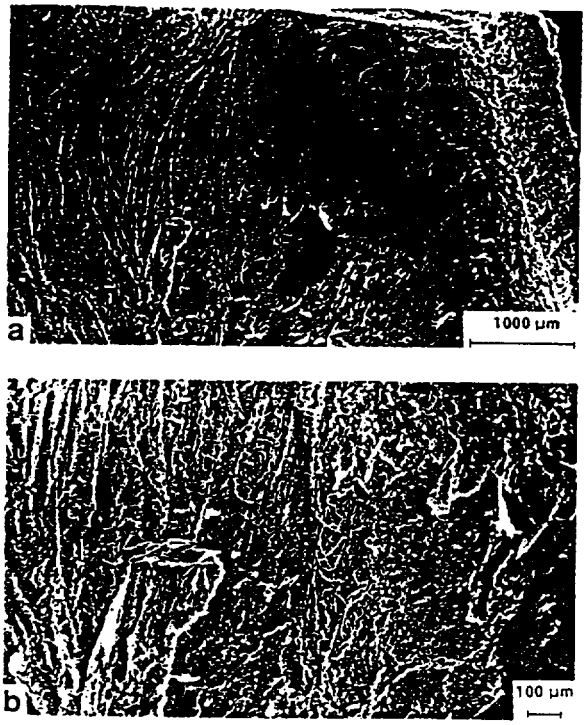

Figure 20 SEM photomicrographs of the luminal surface of a Gore-Tex vascular graft (8 mm diameter) implanted in an hypertensive 64 yr old male for 1464 d as an axillofemoral graft. The graft was explanted because of thrombosis. The luminal surface of the non-thrombosed segment is smooth and glistening and completely coats the **a**, ePTFE skeleton but is devoid of any **b**, endothelial cells.

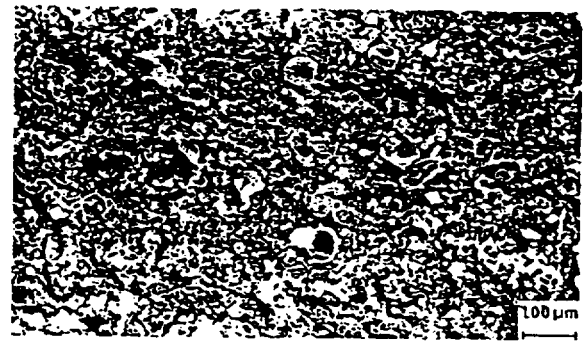

Figure 21 SEM photomicrograph of the luminal surface of a Gore-Tex vascular graft implanted as a femorofemoral graft for 6 yr in a 45 yr old male. The graft was explanted because of thrombosis. The luminal surface of the non-thrombosed segment is coated with blood cells, fibrin, cholesterol and lipids. Such a surface is highly thrombogenic.

Figure 22 SEM photomicrographs of the luminal surface of a 6 mm diameter Gore-Tex vascular graft implanted in 71 yr old female for 5 months as a left femoropopliteal above-knee bypass. The graft was explanted because of thrombosis. The luminal surface is altered by the presence of a mild bacteremic colonization, resulting in fibrinolysis of the fibrin with blood cells entrapping. The resulting tissue is made of bundles of collagen.

the specimens. Not all the surgeons supplied all their excised grafts for investigation. Those who participate actively in our programme did, whilst a few may only have provided their more unusual cases to obtain indications of the cause of prosthetic complication and/or failure. The specimens collected may not exactly reflect the complications encountered with this type of prosthesis. The second limitation of the retrieval programme is that the main source of material is specimens surgically excised for complications, i.e. thrombosis, infection or pseudoaneurysm. The healing characteristics of these grafts may be different from those of patent grafts. Autopsies are missing from patients who died of causes unrelated to a vascular prosthesis. Any of those would be of the highest interest, since the alternative blood conduit fulfilled its purpose.

A retrieval programme, however, has advantages compared with experimental studies. It can reveal long-term effects and complications unforeseen by experimental evaluations, since the latter are rarely conducted for more than 6 months. It provides a study of the healing characteristics of these prostheses in humans, which are known to be different from those observed in experimental animals[17]. Healing characteristics in dogs at 1 month are thought to correlate with healing in man at 3–8 months[18, 19]. But patients frequently suffer from hypertension, diabetes or hypercholesterolemia, conditions that are difficult to reproduce in animal models[20, 21] whose blood properties are different[22]. Also, many of the patients who develop atherosclerosis are smokers[23].

Table 15 SEM findings on the luminal surface of the grafts

n = 284	Present	Absent
Non-covered areas	196	88
Bacteria	160	124
Leucocytes	36	248
Endothelial-like cells	4	280
Lipids	231	53
Cholesterol	98	186

The healing characteristics

The following discussion refers only to non-infected grafts, since it has been shown that the healing characteristics are influenced by the presence of infection. The histological results indicate that the collagenous external encapsulation may begin within 1 month of implantation and by month 6, most grafts have developed an external capsule. The proportion of grafts with a moderately thick to thick capsule (score 2 and 3) increased with the time of

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implantation. The accompanying non-specific inflammatory reaction, consisting of mononucleate cells and giant cells, was found to be a function of the time of implantation and the thickness of the external capsule. Infiltration of the microporous structure of the prosthesis was minimal, and occurred non-uniformly along the graft. The internodal spaces of the graft were filled mainly with proteinaceous material, but rarely with collagen. Collagen infiltration was found to originate mainly from the external capsule and then to progress slowly with time of implantation toward the internal surface of the prosthesis. The factors controlling this infiltration are difficult to determine. It has been suggested that the external reinforcement of the Gore-Tex prosthesis may interfere with host connective tissue ingrowth, although this has not been confirmed experimentally[10]. Due to the limited number of explanted Impra grafts in our series and the variability between patients, it was not possible to determine whether there were any differences in infiltration between prostheses with or without external reinforcement. Lifting was found to be rare within 1 month and increased in frequency with the time of implantation. The collagen infiltration into the external region of the prostheses increased with the lifting of the external reinforcement. However, since many grafts, in which the external reinforcement was not present, demonstrated no increased infiltration, we may conclude that the external reinforcement was not the only factor influencing connective tissue infiltration. It was also frequently noted that an intense chronic inflammatory reaction in contact with the outer surface of the prosthesis occurred without any cellular infiltration into the prosthesis. This indicated that the ePTFE microporous structure of the base tube could inhibit this infiltration.

Two other factors may be involved in tissue infiltration in ePTFE grafts. The first relates to the modifications of the hydrophobicity of the prostheses at the time of the implantation. The hydrophobic properties of these prostheses may be altered by contamination with alcohol or oils[24, 25] or by introduction of fluids such as heparin or antibiotic solutions, under pressure, before the implantation[25, 26]. The second factor is the mean internodal distance of the prostheses. The early experimental studies of ePTFE prostheses reported on the effect of internodal distance on the healing characteristics[2, 6–9]. Internodal distances from 0.5 to 100 μm were proposed, but a value of 30 μm was adopted by the manufacturers. During the past few years, the influence of the internodal distance on the healing characteristics of ePTFE grafts in experimental models has again been the subject of several reports[11–13, 27]. The tissue ingrowth and endothelialization of the luminal surface was found to be enhanced when the internodal distance was >30 μm, and an optimum value of 60 μm was proposed[13]. Larger internodal distances may lead to neointimal hyperplasia[8, 13]. However, since these studies were carried out in experimental models, usual caution must be exercised when applying the results clinically. Other parameters affected by internodal distance are the mechanical properties and the mechanical stability *in vivo* of the prostheses. These should also be considered before the internodal distance is changed. Our observations of virgin and cleaned, explanted prostheses indicate that the internodal distance is not constant. Indeed, there was a large variation in both the internodal distance and in the number of fibrils joining two adjacent nodes. These may account for the variability in the collagen infiltration within the same prosthesis. The uniformity of the internodal distance and the number of fibrils in ePTFE prostheses must be controlled before attempts are made to modify these parameters.

The luminal surface covering consisted mainly of irregularly organized fibrin interspersed with bare patches. Collagen infiltration, as described previously[28, 29], was observed in the vicinity of the anastomoses and at locations where the structure had been damaged by needle-holders, vascular clamps and/or tweezers. Endothelial-like cells were not present on the luminal surface except in four cases where they were limited to within a few millimetres of the anastomoses. As in previous pathological[16] and microbiological[30] studies, bacteria were observed on the luminal surfaces of non-infected prostheses in a similar proportion of the cases.

Mineral deposits have been observed rarely. However, one case of ossification of a Gore-Tex vascular graft implanted for 3 yr[31] and several occurrences of atheromatous changes in ePTFE prostheses with mineral deposits[29, 32] have been described. Mineral deposits in the pseudointima of ePTFE prostheses implanted in piglets were described in the first experimental study of Soyer *et al.*[1]. The mineral deposits seen in this study consisted of hydroxyapatite and were located in the surrounding tissues, except for one case where they were fixed on to the outer surface of the prosthesis.

The low rate of acute inflammatory reaction in the presence of bacteria on the luminal surface observed by SEM, and within the wall structure using the Gram stain, is in agreement with a previous study[33]. Moreover, greater destruction of the external capsule than the internal one in the case of infected grafts indicates an external localization and propagation of the infectious process. The infectability of these prostheses is of particular interest because they are implanted mainly in ischemic and potentially infected tissues. The infectability of ePTFE grafts has been experimentally studied in bacteremia models and was found to be lower than in Dacron® or human umbilical vein grafts[34–36]. The infectability was shown to decrease after 7 d of implantation when the microporous structure was filled[37]. Moreover, the ePTFE grafts were shown to be more mechanically stable than bioprostheses when they were infected[38–40]. Attempts have been made to immobilize antibiotics on benzalkonium-treated ePTFE prostheses with encouraging experimental results[41, 42], but it does not appear that clinical trials have been conducted.

Implications of the study

Despite their low compliance[43, 44] and minimal healing characteristics, the ePTFE prostheses are at present the best synthetic grafts for small diameter arterial bypass. They have provided acceptable results in clinical practice[45, 46], particularly in infrainguinal bypasses[47–49]. A randomized study comparing ePTFE prostheses with saphenous vein in above-knee femoropopliteal bypass[50] yielded similar patency rates. Consequently, the use of

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the ePTFE as the graft of choice for this type of bypass has been advocated[51-53] to preserve the saphenous vein for a later below-knee femoropopliteal or aorto-coronary bypass. However, there has recently been an increase in the use of all available veins for infrainguinal bypasses[54] and consequently, in some surgeons' practices, a fall in the number of implanted synthetic grafts.

This graft-retrieval study shows that ePTFE heals poorly in humans. Although some evidence suggests that the healing characteristics may be improved by alcohol pretreatment of the prosthesis, leading to increased tissue ingrowth[24], these alterations in the hydrophobic properties may also induce graft ultrafiltration and perigraft seroma formation.

Increased internodal distance has also resulted in improved healing in experimental models[13, 27]. However, before this is implemented in devices to be used in humans, it has to be ascertained that this parameter can be properly controlled during manufacture. Moreover, increased fibrous infiltration into the graft may lead to a thick neointima.

Improvement in the blood compatibility of ePTFE grafts has been attempted in several ways. Anticoagulant fixation[55, 56] to the material has been studied but not applied clinically. Denucleation to remove trapped air within the graft microstructure, thus avoiding gas-blood interactions[57, 58], may lead to ultrafiltration and seroma formation. Chitosan-impregnated and mechanically roughened ePTFE prostheses have also been investigated experimentally[59]. The injection, under pressure, of proteins within the microporous structure to improve endothelial cell seeding may also lead to ultrafiltration[60, 61].

Attempts to increase the infection-resistance of ePTFE by antibiotic fixation have been made using a cationic surfactant, benzalkonium[62, 63] or by cyanoacrylate tissue adhesives[64]. The former technique may be responsible for delayed mineral deposit formation because of a crystalline nidus present on the surface of the biomaterial.

CONCLUSION

Expanded PTFE prostheses retrieved surgically for complications and at autopsies have been shown to be minimally healed. Nonetheless, they have provided acceptable results in clinical practice for use in medium diameter vessel replacement. Their principal advantage over other prosthetic materials is excellent *in vivo* mechanical stability. Modifications of the expanded PTFE microstructure and surface treatments have been advanced by various authors to improve the patency rates and healing characteristics. We suggest that these changes should only be considered if the mechanical stability is in no way affected.

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ATTACHMENT 9

Truthful and Accurate Statement

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510(k) Notification

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Manager of Quality Assurance and Regulatory Affairs of Sulzer Vascutek, I believe to the best of my knowledge, that all the information submitted in the premarket notification for the Sulzer Vascutek ePTFE Vascular Prosthesis is truthful and accurate and that no material fact has been omitted.

Paul Burns

Paul Burns
Manager of Quality Assurance and Regulatory Affairs
Sulzer Vascutek Ltd.

13/8/99

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