Guidance for Industry and FDA Staff: Guidance Document for Vascular Prostheses 510(k) Submissions

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Circulatory Support and Prosthetic Devices Branch
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Dorothy B. Abel at 301-796-6366 or by electronic mail at **dorothy.abel@fda.hhs.gov (mailto:dorothy.abel@fda.hhs.gov)**.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to **CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov)** to receive a copy of the guidance. Please use the document number 1357 to identify the guidance you are requesting.

Guidance Document for Vascular Prostheses 510(k) Submissions

Introduction

This guidance document describes a means by which vascular graft prostheses devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate vascular graft prostheses device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

This guidance was developed as a special control to support the reclassification from class III to class II for vascular graft prostheses of less than 6 millimeters in diameter. (21 C.F.R. § 870.3450). It also applies to vascular graft prostheses of 6 millimeter and greater diameter. (21 C.F.R. § 870.3460.). Vascular grafts subject to this guidance are commonly constructed of materials such as polyethylene teraphthalate and polyterafluoroethylene, and may be coated with a biological coating such as albumin or collagen, or a synthetic coating such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords. It includes vascular grafts that are intended for vascular access. It excludes vascular grafts intended for coronary and neurovasculature. It includes a tabular summary of the risks associated with the use of the device and the corresponding special controls to address these risks.

The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in

the "**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

All manufacturers must comply with the Quality Systems Regulations; (QSR) set forth in the Code of Federal Regulations at 21 C.F.R. Part 820. QSR issues of particular significance to manufacturers of permanently implantable medical devices, such as vascular grafts, include but are not limited to the following:

Overall Controls

- Management responsibility
- Design controls
- Document controls
- Purchasing controls
- Identification
- Traceability of finished and in-process devices
- Production and process controls
- Inspection, measuring and test equipment

Process Validation

- Acceptance activities
- Raw materials
- In-process and finished device acceptance
- Non-conforming product
- Corrective and preventative action
- Labeling and packaging control
- Handling and storage
- Distribution and records

It is further recommended that vascular graft manufacturers utilize relevant provisions of ANSI/AAMI VP20-1994, Cardiovascular Implants-Vascular Prostheses, where appropriate.

TABLE OF RISKS AND CORRESPONDING CONTROLS[1]

[1] Because the risks associated with large and small diameter vascular grafts and vascular access grafts are generally the same, most of these special and general controls apply equally to all vascular grafts. Some special controls, such as strength testing after repeated puncture, apply solely to grafts intended for vascular access.

RISK	CONTROLS
1. **Thrombosis Embolic Events Occlusion Stenosis**	**510(k)** Characterize the graft material in accordance with ANSI/AAMI VP20-1994, *Cardiovascular implants - Vascular prostheses* (ANSI/AAMI VP20-1994), Section 4.3 (Materials and Construction).
	Address the issue of biological safety in accordance with FDA guidance document Use of International Standard ISO 10993, "**Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (ssLINK/ucm080735.htm)**" (FDA biocompatibility guidance) and ANSI/AAMI VP20-1994, Section 4.4 (Biocompatibility and Biostability).
	Conduct (in vivo) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through in vitro testing.
	Provide a characterization of kink radius in accordance with ANSI/AAMI VP20-1994, Section 5.9 (Kink Diameter/Radius).
	Address the adequacy of attachment of the external support such that normal handling and implantation forces should not disrupt the external support, for those devices that incorporate permanent or removable external support.
	Address removal of the external support such that removal should not impair device integrity, for those devices that incorporate removable external support.
	Labeling - Instructions for Use Provide labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	Indicate that thrombosis, embolic events, occlusion, and stenosis are potential complications associated with the use of vascular grafts.
	Recommend techniques for implanting the vascular graft, e.g., tunneling (with consideration for external support, if appropriate), and methods to avoid kinking, where appropriate.
	Provide instructions, where appropriate, on how to safely perform a revision procedure in the case of occlusion.
	State that the physician should consider the need for intraoperative and postoperative patient anticoagulation therapy.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
2. **Leakage**	**510(k)**

2. **Leakage** a. **Hematoma** b. **Hemorrhage** c. **Blood Leakage (from failure to clot)**	**510(k)** Conduct all appropriate tests specified in ANSI/AAMI VP20-1994, Section 5.2 (Porosity, Water Permeability, Integral Water Permeability/Leakage, and/or Water Entry Pressure).
	Conduct (**in vivo**) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through **in vitro** testing.
	Labeling - Instructions for Use Provide labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	Provide instructions for proper pre-clotting of the graft (if applicable) and use of hemostatic agents (if applicable).
	State that potential complications associated with vascular grafts include leakage (which may occur in conjunction with hematoma, hemorrhage, and blood leakage from failure to clot).
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
3. **Biocompatibility Allergic Reaction**	**510(k)** Address the issue of biological safety in accordance with FDA biocompatibility guidance and ANSI/AAMI VP20-1994, Section 4.4 (Biocompatibility and Biostability).
	Conduct (**in vivo**) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through **in vitro** testing.
	Labeling - Instructions for Use Contraindicate device use for patients with known sensitivity to device material.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
4. **Graft Disruption:** **Axillary Anastomotic Suture Line dehiscence**	**510(k)** Conduct testing in accordance with ANSI/AAMI VP20-1994, Sections 5.3 (Strength) and 5.8 (Suture Retention Strength).
	Conduct (**in vivo**) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through **in vitro** testing.

	Labeling - Instructions for Use Provide labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	Discuss implantation techniques relating to product sizing; product placement; tunneling (with consideration for external support, if appropriate); and methods to avoid unduly stressing the axillary or femoral anastomoses.
	Indicate that the health care provider is responsible for instructing the patient as to proper postoperative care, including limiting movement of the affected area during the convalescent period.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
5. **Seroma**	**510(k)** Conduct all appropriate tests specified in ANSI/AAMI VP20-1994, *Cardiovascular implants - Vascular prostheses*, Section 5.2 (Porosity, Water Permeability, Integral Water Permeability/Leakage, and/or Water Entry Pressure).
	Labeling - Instructions for Use Provide adequate labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	State that seroma is a potential risk associated with the use of vascular grafts.
	Address techniques for graft handling and instrument manipulation (e.g., clamping).
	Provide instructions for proper implant techniques, such as tunneling (with consideration for external support, if appropriate).

RISK	CONTROLS
6. **False Aneurysm/ Pseudoaneurysm**	**510(k)** Conduct testing in accordance with ANSI/AAMI VP20-1994, Section 5.8 (Suture Retention Strength).
	Conduct testing in accordance with ANSI/AAMI VP20-1994, Section 8.3.4 (Method for Determination of Strength After Repeated Puncture), if the indications for use include vascular access.
	Conduct (i**n vivo**) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through **in vitro** testing.
	Labeling - Instructions for Use

	Provide labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	Recommend product-specific techniques for implanting and revising the vascular graft, if appropriate, and should indicate that care should be taken when cannulating the graft for dialysis access (e.g., avoidance of external support during cannulation, proper rotation of cannulation sites, post cannulation care such as proper compression to achieve hemostasis, etc).
	Provide appropriate instructions for graft handling and sizing (with consideration for external support, if appropriate, and potential arterial steal syndrome, if appropriate).
	Indicate that the health care provider is responsible for instructing the patient as to proper postoperative care.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
7. **True Aneurysm/ Dilatation**	**510(k)** Conduct testing in accordance with ANSI/AAMI VP20-1994, Section 4.4.2 (Biostability), 5.8 (Suture Retention Strength), Section 5.6 (Pressurized internal diameter), and Section 5.3 (Strength).
	Conduct (**in vivo**) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through **in vitro** testing.
	Labeling - Instructions for Use Provide adequate labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	Recommend product-specific techniques for implanting and revising the vascular graft, if appropriate, and should indicate that care should be taken when cannulating the graft for dialysis access (e.g., avoidance of external support during cannulation, proper rotation of cannulation sites, post cannulation care such as proper compression to achieve hemostasis, etc.).
	Provide instructions for graft handling and sizing.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
8. **Infection/Sterility**	**510(k)**

	Perform a sterilization validation to ensure that the sterilization process is capable of providing the Sterility Assurance Limit (SAL) of 10^{-6}, in accordance with suitable guidance (e.g., ANSI/AAMI VP20-1994, Section 4.5 (Sterility), ANSI/AAMI/ISO 11134-1993, ANSI, AAMI/ISO 11135-1994, and ANSI/AAMI/ISO 11137-1994). Alternate sterilization methods should be validated to an appropriate SAL. If resterilization is indicated, manufacturers should also perform a validation of the resterilization method in accordance with suitable guidance.
	Describe the sterilization method that will be used; the method that will be used to validate the sterilization cycle, and the SAL. Describe how the packaging serves to maintain the device sterility. For ETO sterilization, state the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol. State whether the product is non-pyrogenic, and describe the method used to make that determination. For radiation sterilization; state the radiation dose used. See also, **Sterility Review Guidance, #K90-1 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm)**.
	Conduct (**in vivo**) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through **in vitro** testing.
	Provide a statement that biological testing (including pyrogen and bioburden testing) will be or has been performed to assess acceptable limits of biological contaminants.
	Provide a statement that package shelf life validation (including package integrity/distribution testing, accelerated aging, microbial challenge testing, and real time follow-up) will be or has been performed, in accordance with ANSI/AAMI VP20-1994, Section 4.5.1 (Shelf life), to determine that the device and package will maintain their integrity for the period of time specified on the device label, or should provide a justification as to why such validation is not necessary.
	Labeling - Instructions for Use Provide labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	State that the product is supplied sterile on the product package label **and** in the Instructions for Use, if applicable.
	Provide instructions for opening the vascular grafts package.
	Instruct the user that sterility cannot be assured if the graft packaging has been opened or damaged.
	State that the health care provider is responsible for instructing the patient as to proper postoperative care.
	State that the health care provider must observe aseptic technique during implantation and postoperatively.
	Address resterilization, where resterilization is indicated.
	State that infection is a potential complication associated with the use of vascular grafts.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

RISK	CONTROLS
9. **Performance**	**510(k)** Conduct testing on finished devices in accordance with ANSI/AAMI VP20-1994, Sections 4.4.2 (Biostability), 5.2 (Porosity, Water Permeability, Integral Water Permeability/Leakage, and Water Entry Pressure), 5.3 (Strength), 5.4 (Length), 5.5 (Relaxed Internal Diameter), 5.6 (Pressurized Internal Diameter), 5.7 (Wall Thickness), 5.8 (Suture Retention Strength), and 5.9 (Kink Diameter/Radius). Manufacturers should also address applicable requirements specified in ANSI/AAMI VP20-1994, Section 5 (Introduction).
	Assure that subjecting prostheses to the maximum number of sterilization cycles recommended, (where resterilization is indicated) does not adversely affect the properties of the device, in accordance with ANSI/AAMI VP20-1994, Section 4.5 (Sterility).
	Address the adequacy of attachment of the support such that normal handling and implantation forces should not disrupt the external support, for those devices that incorporate permanent or removable external support.
	Address removal of the external support such that removal should not impair device integrity, for those devices that incorporate removable external support.
	Address shelf life testing, for new or substantially modified materials, in accordance with ANSI/AAMI VP20-1994, Section 4.5.1 (Shelf Life).
	Conduct (in vivo) preclinical and/or clinical evaluations of devices incorporating new or substantially modified materials or design, in accordance with ANSI/AAMI VP20-1994, Section 6 (Requirements for In Vivo Preclinical and Clinical Evaluation); when the risk cannot be assessed solely through in vitro testing.
	Labeling - Instructions for Use Provide labeling in accordance with ANSI/AAMI VP20-1994, Section 4.6 (General Information and Instructions for Use), Section 4.1 (Configuration and Size Designation), Section 4.2 (Intended Clinical Use Designation), and information, as appropriate, in accordance with Section 4.8 (Marking).
	Recommend product-specific techniques for implanting the vascular graft, (e.g., tunneling with consideration for external support, where appropriate, and methods to avoid kinking, where appropriate); and revising the vascular graft, if appropriate; and should indicate that care should be taken when cannulating the graft for dialysis access (e.g., avoidance of external support during cannulation, proper rotation of cannulation sites, post cannulation care such as proper compression to achieve hemostasis, etc).
	Provide appropriate instructions for graft handling and sizing (with consideration for external support, if appropriate, and potential arterial steal syndrome, if appropriate).
	State that the health care provider is responsible for instructing the patient as to proper postoperative care.
	Include a summary of the clinical studies, if clinical studies were submitted in the 510(k).

More in Guidance Documents (Medical Devices and Radiation-Emitting Products)

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)