

Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters

DRAFT GUIDANCE

**This guidance document is being distributed for comment purposes only.
Document issued on: May 30, 2008**

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance document, contact either Suzanne Kaiser at 240-276-4222 or by email: suzanne.kaiser@fda.hhs.gov; or Kathryn O'Callaghan at 240-276-4222 or by email: kathryn.ocallaghan@fda.hhs.gov.



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

**Interventional Cardiology Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation**

Contains Nonbinding Recommendations

Draft - Not for Implementation

Preface

Additional Copies

Additional copies are available from the Internet at:

<http://www.fda.gov/cdrh/ode/guidance/1608.pdf>. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (**1608**) to identify the guidance you are requesting.

Table of Contents

I.	INTRODUCTION.....	1
II.	BACKGROUND	2
III.	THE CONTENT AND FORMAT OF AN ABBREVIATED 510(K) SUBMISSION	3
IV.	SCOPE	5
V.	DEVICE DESCRIPTION	6
VI.	RISKS TO HEALTH.....	6
	Table 1: Risk / Mitigation Recommendations for PTCA Devices	7
VII.	BIOCOMPATIBILITY TESTING	7
VIII.	PERFORMANCE TESTING	9
A.	Content and Format of Test Data	9
	Table 2: Four Corners Test Paradigm Example.....	13
B.	Bench Testing	13
	Dimensional and Functional Attributes.....	13
1.	Catheter Diameter and Balloon Profile	13
2.	Minimum Balloon Burst Strength.....	14
	Table 3: PTCA Catheter Balloon Sizes recommended for RBP Testing.....	14
3.	Balloon Compliance (Diameter vs. Pressure).....	15
	Table 4: Balloon Compliance Example.....	16
4.	Balloon Inflation and Deflation Time	16
5.	Balloon Fatigue (Repeat Balloon Inflations)	16
6.	Tensile Strength	17

Contains Nonbinding Recommendations

Draft - Not for Implementation

7. Tip Pull Test	17
8. Flexibility and Kink Test.....	17
9. Torque Strength	18
10. Balloon Preparation.....	18
11. Radiopacity	18
12. Coating Durability and Particulate Generation	18
Additional Tests for Catheters Intended for Infusion of Contrast Media or Other Fluids	19
1. Catheter Body Burst Pressure	19
2. Contrast Media Flow Rate	20
Additional Tests for Catheters Intended for In-Stent Restenosis or for Stent Expansion following Stent Deployment	20
1. Minimum Balloon Burst Strength (in Stent).....	20
2. Balloon Fatigue (Repeat Balloon Inflations; in Stent).....	21
IX. ANIMAL TESTING	22
X. CLINICAL INFORMATION.....	22
XI. STERILIZATION AND SHELF LIFE.....	24
A. Sterilization.....	24
B. Shelf Life	24
XII. LABELING	25
APPENDIX A: TEST SUMMARY	29
APPENDIX B: APPLICABLE STANDARDS.....	30

Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters; Draft Guidance for Industry and FDA

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance document.

I. Introduction

This draft guidance document was developed as a special control guidance to support the reclassification of certain Percutaneous Transluminal Coronary Angioplasty (PTCA) catheters into class II (special controls). The device is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion; treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion. This draft guidance will be issued in conjunction with a Federal Register notice announcing the notice of panel recommendation which recommends reclassifying certain PTCA catheters and designating this document as the special control for this device type. This guidance is issued for comment purposes only. If an order reclassifying this device type is not issued, this guidance document will not be issued as a special control.

Following the effective date of an order reclassifying the device, any firm submitting a 510(k) for a PTCA catheter will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.¹

¹ We recommend that manufacturers document how they address the recommendations of this guidance in their design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

Contains Nonbinding Recommendations

Draft - Not for Implementation

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of PTCA catheters, other than cutting/scoring PTCA catheter devices. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in 21 CFR 807, Subpart E, (2) address the specific risks to health associated with PTCA devices identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

This draft guidance document reflects our careful review of what we believe are the relevant issues related to PTCA catheters and what we believe would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

II. Background

This special controls guidance document lists the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these PTCA devices and lead to a timely review of premarket notification submissions. This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, **Format for Traditional and Abbreviated 510(k)s** at <http://www.fda.gov/cdrh/ode/guidance/1567.html>, and “**How to Prepare a 510(k) Submission**” on FDA Device Advice at <http://www.fda.gov/cdrh/devadvice/314.html>.²

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial

² We recommend that you include a table of contents at the front of your submission. Each line listing in the table of contents should refer to major section titles and the page numbers where each section can be found.

Contains Nonbinding Recommendations

Draft - Not for Implementation

equivalence for a new device, particularly once a special controls guidance document has been issued. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

III. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling must be sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). (Please refer to **Section XII. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain:

Description of the device and its intended use

We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to **Section V. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an “indications for use” enclosure.³

³ Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Description of device design requirements

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the Risk Analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design, and the results of this analysis. (Please refer to **Section VI. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections VII - X** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply or have applied to your test results.⁴ (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.⁵

⁴ If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

⁵ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for a PTCA catheter.

IV. Scope

The scope of this document is limited to the device described below.

Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (product code LOX).

A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

Contains Nonbinding Recommendations

Draft - Not for Implementation

This document does not apply to cutting/scoring PTCA catheters (product code NWX). A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

V. Device Description

We recommend that you identify your device by regulation and product code described in **Section IV. Scope**, and include the following information:

Device components and theory of operation

We recommend that you identify all components and accessories included in the submission.

Photograph or drawing of the device

We recommend that you provide a photograph or drawing of the device, as well as a functional block diagram (including all accessories). If additional diagrams, dimensions, tolerances, and/or schematics are useful to fully describe and characterize the device, we recommend that you include them for each device, accessory or component included in the 510(k) submission.

Technological characteristics

We recommend that you describe the technical and performance specifications and include a brief description of the device design requirements in this section. The specifications may include performance-related product measurement tolerances, operating limitations, and any other functional, physical, and environmental specifications of the device. We also recommend that you describe ranges and/or accuracy of the specifications.

Patient-contacting materials

We also recommend that you provide a list of all patient contacting components and their respective materials. For each component, you should identify the generic material of construction and the unique material identifier.

VI. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the PTCA devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. We recommend that you conduct a risk analysis to identify any other risks specific to your device

Contains Nonbinding Recommendations

Draft - Not for Implementation

and include the results of this analysis. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Table 1: Risk / Mitigation Recommendations for PTCA Devices

Identified Risk	Recommended Mitigation Measures
Adverse Tissue Reaction	Section VII. Biocompatibility Testing
Device Failure	Section VIII. Performance Testing Section XI. Sterilization and Shelf Life
Adverse Interaction with Other Devices	Section VIII. Performance Testing Section IX. Animal Testing
User Error	Section IX. Animal Testing Section X. Clinical Information Section XII. Labeling
Vessel Damage	Section IX. Animal Testing Section X. Clinical Information
Infection	Section XI. Sterilization and Shelf Life

VII. Biocompatibility Testing

FDA recommends that you conduct biocompatibility testing as described in the FDA-modified **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, <http://www.fda.gov/cdrh/g951.html> for external devices in contact with the circulating blood for a limited duration (i.e., less than 24 hours).⁶ We recommend that you select biocompatibility tests appropriate for the duration and level of contact with your device. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing.

Sample Preparation

⁶ You may access a list of the FDA-recognized sections of ISO 10993 from the FDA website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

Contains Nonbinding Recommendations

Draft - Not for Implementation

It is important to understand how the test samples compare to the final sterilized product. For biocompatibility testing conducted using extraction samples, we recommend that you:

- determine the appropriate amount of test material as outlined in **ISO 10993-12** or an equivalent method, using surface area to extractant volume ratios (mass to extractant volume ratios should only be used if surface area cannot be calculated)
- use both polar and nonpolar extractants.
- describe the condition of the extraction vehicle (e.g., color, presence of any particles)
- explain any changes in the post-extraction vehicle (compared to pre-extraction)
- describe the details of storage conditions, if applicable.

If extraction samples are not used immediately, we recommend that you follow the storage conditions described in **ISO 10993-12** or an equivalent method. We also recommend that you explain how storage does not affect your test results.

Cytotoxicity

We recommend that vehicles include both mammalian cell culture media (MEM) and 5% serum, as these materials will allow for extraction of both polar and nonpolar constituents from the test sample.

Sensitization (Guinea Pig Maximization Method)

We recommend that test reports confirm that all female animals used in the testing are not pregnant, as pregnancy can reduce the ability of a female animal to detect a sensitization response.

We recommend either that you run concurrent controls, or that the test laboratory run controls within 3 months of the test samples. We also recommend you provide protocols and results from positive control testing to confirm that you used the same methods for both the positive control testing and the test samples.

Hemocompatibility

For blood-contacting devices (regardless of contact duration), we recommend that you consider hemolysis, immunology (complement activation), and *in vivo* thromboresistance.

Immunology testing should appropriately address the various complement activation pathways. We recommend that you assess *in vitro* C3a and SC5b-9 fragment activation using standard testing methods, such as those outlined in **ASTM F2065-00e1** and **ASTM F1984-99 (2003)**, or an equivalent method. Alternatively, you may provide a rationale for

Contains Nonbinding Recommendations

Draft - Not for Implementation

omitting this testing, if all the materials used in the formulation and processing of the device have a history of previous use in blood-contacting devices with similar contact duration.

In addition, you may assess *in vivo* thrombogenicity during preclinical animal testing in lieu of a separate canine *in vivo* thrombogenicity test.

Material-mediated Pyrogenicity

We recommend that you assess pyrogenic responses to chemical leachants over the duration of device contact with the patient. We recommend that you assess material-mediated pyrogenicity using traditional biocompatibility extraction methods, such as those outlined in the **USP 28 <151> Rabbit Pyrogen Test** (e.g., 50°C for 72 hours; 70°C for 24 hours; or 120°C for 2 hours) or an equivalent method.

Endotoxin-mediated Pyrogenicity

We recommend that you consider pyrogenic responses to gram-negative bacterial endotoxin using a standard method, such as those outlined in the **USP 28 <85> Bacterial Endotoxin Limulus Amoebocyte Lysate (LAL) Test**, or an equivalent method. We recommend that your specifications include the test procedure and acceptance criteria for endotoxins. All blood-contacting cardiovascular devices and combination products should be pyrogen-free. Pyrogenicity testing is used to help define limits to protect patients from the risk of febrile reaction.

VIII. Performance Testing

A. Content and Format of Test Data

For traditional 510(k) submissions, we recommend that you present test data in a summary that includes the elements described below.

Test Summaries

We recommend that you briefly describe all tests performed. If you follow an FDA-recognized standard without deviation, you may choose to reference that standard instead of describing the test methods.

Test Data Summaries

You should include test data summaries for all tests. The summaries should contain:

- minimum measured value (min)
- maximum measured value (max)
- mean
- standard deviation of the test data (std. dev.).

Contains Nonbinding Recommendations

Draft - Not for Implementation

Summary of Conclusions

You should summarize your conclusions regarding whether the results support the safety and effectiveness of your device for each test.

You should include full test reports for all tests performed, as described below.

What information should you include in test reports?

Your test reports should include the sections described below.

Test Specimen Information

Your test specimen description should include:

- number of test specimens
- size (diameter, length, or other relevant dimensions) of all test specimens
- rationale for the number of test specimens and sizes tested
- whether the specimens are representative of the finished product
- sterilization parameters and number of sterilization cycles applied to the test specimens.

Test Protocol

You should submit your test method or protocol. It should contain enough detail that an individual familiar with intravascular catheter testing will be able to interpret the test results.

Protocol Deviations

You should describe any protocol deviations and their impact on the conclusions you draw from the test.

Test Parameters and Acceptance Criteria

You should report the test parameters and acceptance criteria that you use, including:

- an explanation of and rationale for critical test parameters
- specifications or acceptance and rejection criteria
- a rationale for the specification or acceptance and rejection criteria based on the clinical requirements of the device.

Raw Data

We recommend that you include all raw data in appendices, or make the raw data available for our review upon request.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Test Results

You should summarize your test results and include statistical analysis when it is appropriate.

Data Analysis

You should analyze the data, including any outlying points and anomalous results, and explain whether the data meet the given acceptance criteria.

Conclusions

We recommend that you describe the conclusions drawn from the test results, and the clinical significance of the conclusions.

Should your tests have a test protocol?

Yes, you should establish protocols for all experiments or computational analyses, including acceptance criteria when applicable, before you perform the tests. Established test protocols help to ensure consistent repetition of tests and allow comparison of data between test runs.

We recommend that you present test protocols to us before conducting tests. We will review your protocol and provide comments. Our input before testing may improve your ability to demonstrate the performance characteristics of your device.⁷

What information should test protocols contain?

Your test protocols should assess the worst-case conditions that your device is likely to experience. Both device configuration and physiologic conditions affect the performance of devices in the human body. We recommend that you evaluate extreme device dimensions, tolerances, sizes, and any other important device parameters in your testing program. We also recommend that you examine the outer limits of physiologic variables such as blood pressure, vascular compliance, and anatomic types. You should clearly state all test conditions in the test protocol and support them with references to applicable literature, standards, or both.

Occasionally, the worst performing combination of device configuration and physiologic conditions occurs in the mid-range of the relevant variables. You should check for this situation when developing your protocols to ensure that you test the worst performing combination.

⁷ FDA input before testing may improve your ability to demonstrate the performance characteristics of your device. The branch is available to discuss your protocol with you. See also the section entitled **Pre-IDE Process in CDRH Device Advice** at <http://www.fda.gov/cdrh/devadvice/ide/approval.shtml>.

Contains Nonbinding Recommendations

Draft - Not for Implementation

What if you believe a test is not applicable to your device?

The tests we describe in this guidance are those we generally have reviewed in PTCA catheter submissions and that we have considered necessary in the past to support the safety and effectiveness of these devices. Certain tests, however, may apply only to specific designs or clinical indications. These tests are identified under separate headings. We believe that each test helps to support the safety and effectiveness of PTCA catheters. Each test's clinical or engineering significance is described.

For PTCA catheters with certain indications, some of the tests in this guidance may not apply. If you believe a test recommended in this guidance does not apply to your device, you should include a heading for the test in your test summary, followed by an explanation of why the test is not applicable. We will then be aware that you did not inadvertently omit it from your application.

Your explanation should include a rationale for why you think the test is not applicable to your device. Your rationale should clearly demonstrate, by reference to a Failure Modes and Effects Analysis (FMEA) or other risk analysis method, that the particular test or data set is not applicable. Alternatively, you may identify measures you have taken to mitigate the risks associated with the device in the failure mode that would usually be tested using the test that you have not performed.

What sample size should you use for tests?

You should use a statistically significant sample size whenever possible. When using a statistically significant number of samples is not possible, you should provide a scientific rationale to support the number of samples tested in your test summary and test protocols, and provide reasonable assurance that the test results support the safety and effectiveness of the device.

Should you test finished product?

We recommend you conduct testing on the finished product. The devices you test should be sterilized by the final production process, including repeat sterilization cycles. If you conduct testing on any samples that are not finished, sterilized product, we recommend you indicate this in the test protocols and test summary. We also recommend that you explain why the samples you use adequately represent the finished product.

Which device sizes should you test?

You should test the full range of sizes that you intend to market. The recommended default paradigm is a 2 x 2 factorial of the largest and smallest diameters and lengths, also known as the "four corners" paradigm for each different device design. We recommend a different set of sizes for some of the tests in this section.

Table 2 illustrates the four corners concept for a typical PTCA catheter. If you do not test a device using the four corners paradigm or the recommended sizes for a particular

Contains Nonbinding Recommendations

Draft - Not for Implementation

test, you should provide a scientific rationale to support the sizes that you do test in the test summary and test protocols. For some tests, we may recommend that you perform an analysis to identify the size or sizes that represent the worst case.

Table 2: Four Corners Test Paradigm Example

Balloon Diameter (mm)	Balloon Length (mm)			
	10	20	30	40
2.0	X			X
2.25				
2.5				
2.75				
3.0				
3.25				X
3.50				
3.75				
4.0	X		X	

X = Recommended sizes for testing

B. Bench Testing

The specific design characteristics of a device will determine the non-clinical testing that should be performed. Testing should ensure that the device design and construction are suitable for the intended use. We recommend you conduct the testing described below on completed catheters or suitable subassemblies. We recommend that you use product which has been exposed to a validated sterilization cycle or to a cycle validated to be equivalent if using smaller lots produced for clinical studies or during device development. Where appropriate, testing involving the balloon catheter should be done in an environment which simulates *in vivo* conditions (e.g., 37°C water or saline bath).

You should provide a complete report for each test conducted for our review. Each test report should include the information outlined in **Section VIII. A. Content and Format of Test Data** above. You should explain any omission, substitution, or combination of the tests outlined below. A tabular format is desirable, please see the example provided in **Appendix A**. We may also recommend additional testing to evaluate new designs or features of a device. Additionally, we recommend that you provide testing that compares your device to a currently legally marketed device.

Dimensional and Functional Attributes

1. Catheter Diameter and Balloon Profile

Significance

Contains Nonbinding Recommendations

Draft - Not for Implementation

The outside diameter of the catheter shaft and the profile of the deflated balloon determine whether the device is compatible with accessory devices such as introducers or guiding catheters.

Recommendation

FDA recommends you report the outer diameter of the catheter shaft as well as the largest deflated balloon profile. We recommend that you also identify the axial location of the largest deflated balloon profile (including the inner member or wire). We recommend that you inflate the balloon to nominal pressure according to your instruction manual, then deflate the balloon and re-measure the profile. We recommend you use the results to identify the minimum size (French or diameter) of accessory devices intended for use with the balloon catheter (e.g., introducer or guiding catheter). We recommend the methods described in ASTM F2081 or equivalent methods.

2. Minimum Balloon Burst Strength

Significance

The rated burst pressure (RBP) is the pressure at which 99.9% of balloons can survive with 95% confidence. Failure of a balloon to survive at the RBP could result in device failure or vessel damage.

Recommendation

FDA recommends that you conduct this testing on complete catheters or subassemblies in which the balloon is mounted on the catheter shaft. If the entire range of device sizes will have a single labeled RBP, we recommend that you conduct testing on the longest length of every balloon diameter and the shortest length of both the smallest diameter and largest diameter. Half and quarter sizes should also be tested. **Table 3** illustrates the recommended test matrix.

Table 3: PTCA Catheter Balloon Sizes recommended for RBP Testing

Balloon Diameter (mm)	Balloon Length (mm)			
	10	20	30	40
2.0	X			X
2.25				X
2.5				X
2.75				X
3.0				X
3.25				X
3.50			X	
3.75			X	
4.0	X		X	

Contains Nonbinding Recommendations

Draft - Not for Implementation

*Table assumes a single labeled RBP

Additionally, we recommend that you test the balloon sizes as shown in **Table 3** for each different labeled RBP. We recommend that you test balloons that are not constrained by any test fixture such as tubing, and that you inflate the balloons incrementally until failure.

We recommend that you record as test failures any loss of:

- integrity of the balloon, such as a rupture or leak
- pressure due to failure of the balloon, shaft, or seals.

We recommend that you record the pressure at which the device failed and the failure mode. We also recommend that you calculate RBP as the pressure at which 99.9% of the balloons will survive with 95% confidence based on statistical analysis of the test data.

3. Balloon Compliance (Diameter vs. Pressure)

Significance

The diameter of a deployed PTCA balloon varies with inflation pressure. A compliance chart in the labeling that relates balloon diameter to balloon pressure guides selection of catheter size to fit the target vasculature site. Incorrect selection of catheter size may lead to device failure or vessel damage.

Recommendation

FDA recommends that you test balloon sizes as illustrated in **Table 3**, and that you test multiple product lots. We recommend that you explain why you chose the test sample size. We recommend that you include data showing inflation pressure versus balloon diameter over the full range of recommended inflation diameters, and report the final results in the instructions for use, the outside package labeling, or both. A graphical or tabular presentation (i.e., a compliance chart) is desirable. We recommend that you identify the nominal inflation pressure and RBP, as shown in the example below. The compliance chart may include pressures up to (but not exceeding) 25% above the RBP, if you provide data and statistics demonstrating that 99% of the balloons will not fail at the listed pressure with 95% confidence. We also recommend that you describe how you performed any data rounding and show all instances. **Table 4** below shows an example of compliance chart for a balloon with 3.0 mm, 3.5 mm, and 4.0 mm diameters, with a RBP of 16 atmospheres (atm). (The nominal diameter occurs at 9.0 atm.)

Contains Nonbinding Recommendations

Draft - Not for Implementation

Table 4: Balloon Compliance Example

Pressure (atm)	Balloon Nominal Diameter where x = balloon diameter at the given pressure		
	3.0 mm Balloon Diameter (mm)	3.5 mm Balloon Diameter (mm)	4.00 mm Balloon Diameter (mm)
9.0	X	X	X
10.0	X	X	X
11.0	X	X	X
12.0	X	X	X
13.0	X	X	X
14.0	X	X	X
15.0	X	X	X
16.0*	X	X	X

*RBP

4. Balloon Inflation and Deflation Time

Significance

Balloons occlude the target vessel and obstruct blood flow while inflated. Inflation and deflation times affect occlusion time. Excessively slow deflation of a balloon could lead to prolonged ischemia and damage to the myocardium.

Recommendation

FDA recommends that you specify the balloon inflation and deflation times and demonstrate, using techniques recommended in your instruction manual (e.g., predilation), that the balloon inflates and deflates within those times. We recommend that you test the largest diameter at the longest balloon length, and evaluate which other sizes to test. We also recommend you provide the clinical basis for your acceptance criteria.

5. Balloon Fatigue (Repeat Balloon Inflations)

Significance

Balloons on PTCA catheters are often inflated multiple times during clinical use. Failure of the balloon to withstand multiple inflations could lead to device failure or vessel damage.

Recommendation

FDA recommends that you determine the repeatability, to 20 inflations, of successful balloon inflation to the RBP. We recommend that you test device sizes according to the “four corners” paradigm:

- largest diameter/longest length

Contains Nonbinding Recommendations

Draft - Not for Implementation

- largest diameter/shortest length
- shortest diameter/longest length
- shortest diameter/shortest length.

We recommend that you test balloons that are not constrained by any test fixture such as tubing, and that you inflate the balloons incrementally until they reach the RBP. For each sample, we recommend that you hold the RBP for 30 seconds (or the time specified in the instructions for use), deflate the balloon, and inflate it again to the RBP, for a total of 20 cycles. We recommend that you report any loss of pressure, whether due to failure of the balloon, shaft, or proximal or distal seals, as a test failure. We recommend that you record all failure modes, and that your results demonstrate that 90% of the balloons will survive the test with at least 95% confidence.

6. Tensile Strength

Significance

Failure of bonds in the catheter could lead to device failure or vessel damage.

Recommendation

FDA recommends that you test the bond strength at locations where adhesives, thermal fusion, or other joining methods are used for bonding components of the catheter. We recommend that testing demonstrate that all bonds can withstand tensile forces greater than those that may be experienced during clinical use. We also recommend you provide the clinical basis for your acceptance criteria.

7. Tip Pull Test

Significance

Failure of bonds in the distal tip could lead to device failure or vessel damage.

Recommendation

For devices with one or more joints in the distal tip (e.g., spring or nose-cone tips), FDA recommends that you determine the tensile force that will separate the distal tip from the catheter.

8. Flexibility and Kink Test

Significance

Catheters may be subjected to flexural forces during use. Inability to withstand flexural forces that are typical of clinical use could lead to device failure or vessel damage.

Recommendation

Contains Nonbinding Recommendations

Draft - Not for Implementation

FDA recommends that you conduct testing at a bend radius that is appropriate for the intended anatomy to demonstrate that the catheter will not kink.

9. Torque Strength

Significance

Catheters may be subjected to torsional forces during use. Inability to withstand torsional forces that are typical of clinical use could lead to device failure or vessel damage.

Recommendation

FDA recommends that you measure the torque strength of the catheter when the distal tip is not free to rotate, by rotating the proximal end of the catheter until failure. We recommend that you report the number of rotations to failure and the failure mode for each sample tested. Additionally, we recommend that you test the catheter in a fixture that simulates the anatomy of the aortic arch and coronary arteries. We recommend that you report the number of turns to failure in the device labeling. We also recommend you provide the clinical basis for your acceptance criteria.

10. Balloon Preparation

Significance

The recommended instructions for use and techniques for preparation, delivery, and retraction, if properly followed, should safely and reliably deliver the balloon to the intended location without adversely affecting the device.

Recommendation

FDA recommends that you conduct testing to demonstrate that the balloon catheter can be safely and reliably prepared, delivered, and retracted using the recommended techniques and instructions for use, without damage to the device.

11. Radiopacity

Significance

Insufficient radiopacity may hamper safe and reliable delivery of the balloon to the intended location.

Recommendation

FDA recommends that you demonstrate that the radiopaque markers on the balloon catheter can be seen under typical fluoroscopic methods.

12. Coating Durability and Particulate Generation

Significance

Contains Nonbinding Recommendations

Draft - Not for Implementation

Premature delamination or degradation of a coating may lessen its benefit. Delaminated coating may form embolized particulate that may cause clinical complications.

Recommendation

FDA recommends that you address the aspects described below for any coatings applied to the surfaces of your device.

Physical Structure and Chemical Properties

We recommend that you describe the coating's physical structure, such as coating thickness, and indicate its chemical characterization.

Intended Function

We recommend that you describe the clinical purpose and intended function of the coating, such as enhanced radiopacity, thromboresistance, or lubricity.

Loading History

We recommend that you evaluate the PTCA catheter for coating durability at the following time points for each coating durability test:

- before expansion and/or deployment
- after inflation to the largest labeled diameter.

We recommend you test coating durability under the worst-case conditions of use. For example, for balloons intended for ISR or post-deployment stent expansion, we recommend that you evaluate the coating durability and particulate generation after tracking the device through simulated anatomy and inflating to the largest labeled diameter within a stent.

Particle Count or Analysis Methods

If you evaluate coating durability using particle count or analysis methods, or both, we recommend that you address the clinical significance of the number and size of observed particles.

Additional Tests for Catheters Intended for Infusion of Contrast Media or Other Fluids

1. Catheter Body Burst Pressure

Significance

Contains Nonbinding Recommendations

Draft - Not for Implementation

The catheter body should be designed to withstand pressures typically needed to achieve contrast media flow rates used in clinical practice. Inability to withstand pressures that are typical of clinical use could lead to device failure or vessel damage.

Recommendation

FDA recommends that you determine the maximum pressure that the catheter body can withstand during injection. We recommend you conduct the testing under clinical use conditions, i.e., including use of a syringe, automatic injector, etc. The contrast medium or fluid should be representative of worst case clinical conditions. We also recommend you provide the clinical basis for your acceptance criteria.

2. Contrast Media Flow Rate

Significance

The catheter should be designed to achieve clinically acceptable contrast media flow rates. Inability to achieve acceptable flow rates could lead to user error and adverse clinical consequences.

Recommendation

FDA recommends that you conduct testing that demonstrates that the catheter is capable of achieving clinically acceptable contrast media flow rates. We recommend that testing be done at maximum catheter burst pressures (as identified in the test described above), as well as pressures typical of clinical use. We recommend that you report the maximum flow rate in the device labeling. We also recommend you provide the clinical basis for your acceptance criteria.

Additional Tests for Catheters Intended for In-Stent Restenosis or for Stent Expansion following Stent Deployment

If you label a PTCA catheter for in-stent restenosis, or for stent expansion immediately following stent deployment (for purposes of securing the stent to the vessel wall and ensuring that the stent is completely deployed), we recommend you conduct the following tests within an expanded stent.

1. Minimum Balloon Burst Strength (in Stent)

Significance

The rated burst pressure (RBP) is the pressure at which 99.9% of balloons can survive with 95% confidence. Use of a PTCA catheter inside a stent may have an effect on the RBP. Failure of a balloon to maintain integrity at the RBP could result in device failure or vessel damage.

Recommendation

FDA recommends that you conduct this testing on complete catheters or subassemblies in which the balloon is mounted on the catheter shaft. We

Contains Nonbinding Recommendations

Draft - Not for Implementation

recommend that you conduct testing on representative sizes as shown in the example in **Table 3**, for each labeled RBP. We recommend that you inflate the balloons incrementally until failure.

We recommend that you record as test failures any loss of:

- integrity of the balloon, such as a rupture or leak
- pressure due to failure of the balloon, shaft, or seals.

We recommend that you record the pressure at which the device failed and the failure mode. We also recommend that you calculate RBP as the pressure at which 99.9% of the balloons will survive with 95% confidence based on statistical analysis of the test data. We recommend that you specify RBP in the device labeling.

2. Balloon Fatigue (Repeat Balloon Inflations; in Stent)

Significance

Balloons on PTCA catheters are often inflated multiple times during clinical use. Use of a PTCA catheter inside a stent may affect balloon fatigue strength. Failure of the balloon to withstand multiple inflations could lead to device failure or vessel damage.

Recommendation

FDA recommends that you determine the repeatability, to 10 inflations, of successful balloon inflation to the RBP. We recommend that you test device sizes according to the “four corners” paradigm:

- largest diameter/longest length
- largest diameter/shortest length
- shortest diameter/longest length
- shortest diameter/shortest length.

We recommend that you inflate the balloons incrementally until they reach the RBP. For each sample we recommend that you hold the RBP for 30 seconds (or the time specified in the instructions for use), deflate the balloon, and inflate it again to the RBP, for a total of 10 cycles. We recommend that you report any loss of pressure, whether due to failure of the balloon, shaft, or proximal or distal seals, as a test failure. We recommend that you record all failure modes, and that your results demonstrate that 90% of the balloons will survive the test with at least 95% confidence.

IX. Animal Testing

For devices with notable dissimilarity from legally marketed PTCA devices (e.g., new indications, designs, or technology), we recommend that you conduct preclinical testing in animals to confirm safety of the procedure, to evaluate the functional characteristics of the device design and to validate the performance of other interventional cardiovascular devices used in conjunction with the PTCA catheter. We recommend that you evaluate PTCA devices in an appropriate animal model that closely approximates the intended use of the device in humans, and that you provide this information in your submission. We encourage you to contact the review branch early in the product development process to discuss your study design. General recommendations for animal testing of PTCA devices are discussed below.

Device

We recommend that you use the finished, sterilized devices including the delivery catheters in your studies. Studies should include a reasonable representation of all device sizes.

Control

We recommend that you consider the inclusion of a control device to facilitate evaluation of the histopathology results. A PTCA catheter currently marketed in the U.S. is one example of an appropriate control device.

Acute Observations

We recommend that preclinical animal testing address:

- damage to vessel wall
- potential to cause thrombosis or hemolysis over the course of the procedure
- angiographic assessment during procedures, including evaluation of flow rate, thrombus formation and vessel injury.

Follow-Up Observations

We recommend the animal studies include 4-6 follow up observations with detailed pathology at 24 to 48 hours post-treatment as described below.

Pathology

We recommend that the evaluations performed on necropsied animals include gross assessment of the device as well as careful histological examination of the vessel segment where the device was deployed. The vessel segment should be examined for vessel injury and inflammation. The animal study report should include the full pathology report, providing line listings and clear copies of photographs and photomicrographs.

X. Clinical Information

Well-designed bench and/or animal testing may be sufficient to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most PTCA

Contains Nonbinding Recommendations

Draft - Not for Implementation

devices, FDA may recommend that you collect clinical data for a PTCA device with any one of the following:

- indications for use dissimilar from legally marketed PTCA device of the same type
- designs dissimilar from designs previously cleared under a premarket notification
- new technology; i.e., technology different from that used in legally marketed PTCA devices.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

If you conduct a clinical study, your study design should address the concerns described below. We recommend you contact the review branch early in your device development process to discuss the study design appropriate to your device.

Study Design

We recommend that you conduct a multi-center, prospective registry study designed to collect data to support the safety and effectiveness of your device. For devices that will be indicated for use for in-stent restenosis, your study should include a sufficient number of in-stent restenosis patients.

Primary Safety Endpoint(s)

We recommend that your study include a primary safety endpoint such as acceptable rates for in-hospital and out-of-hospital complications. Complications are typically defined as clinically significant major adverse cardiac events (MACE) including death, myocardial infarction (MI, Q-wave and non-Q-wave), coronary artery bypass graft (CABG) surgery, and repeat target vessel revascularization.

Primary Efficacy Endpoint(s)

We recommend that your study include a primary efficacy endpoint such as a clinically meaningful decrease in post-procedure percent diameter stenosis. This endpoint is typically assessed by collecting and analyzing qualitative and quantitative angiographic data recorded both by the physician during the procedure and by post-procedure independent core lab analysis.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, and will be conducted in the United States, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. We believe that the PTCA device addressed by this guidance document is a significant risk device as defined in 21 CFR 812.3(m)(4).⁸ In addition to the requirement of having an FDA-

⁸ See Significant Risk and Nonsignificant Risk Medical Device Studies, <http://www.fda.gov/oc/ohrt/irbs/devices.html#risk>.

Contains Nonbinding Recommendations

Draft - Not for Implementation

approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

XI. Sterilization and Shelf Life

A. Sterilization

FDA recommends that you provide sterilization information in accordance with the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>. You should sterilize the device to a sterility assurance level (SAL) of 1×10^{-6} using a sterilization cycle that has been validated in accordance with the QSR.

PCTA catheters are devices in contact with circulating blood; therefore we recommend you test the devices for pyrogenicity. We also recommend you provide a:

- description of the method used to make the determination, e.g., limulus amoebocyte lysate (LAL);
- identification of the testing endpoint reached and rationale for selecting that endpoint;
- description of the extraction technique used to obtain the test fluid from the test device, showing that all clinically relevant contact surface of the test device were assessed and;
- identification of the reference method used, e.g., USP, ANSI/AAMI ST 72, or FDA guidance.

B. Shelf Life

FDA recommends that shelf life testing address package integrity to ensure sterility, as well as stable device functionality over the expected life cycle. To evaluate device functionality, we recommend that you assess each of the bench tests described in Section VIII B. and repeat all tests that evaluate design characteristics affected by aging. For example, aging can affect the performance of most polymer materials used for PTCA balloons; therefore, tests that evaluate the performance of the balloon should be repeated after aging. We also recommend that you provide the protocol used for your shelf life testing, the results of the testing, and the conclusions drawn from your results.

XII. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.⁹

We recommend that you include the following items in the labeling for all PTCA devices, modifying as appropriate for specific catheter designs. If you do not include any of these items, we recommend you explain your rationale in your submission.

Device name

We recommend that you include both brand name and generic device name.

Description

We recommend that you include a description of the catheter identifying the important components and the functions of each.

Indications for Use

The indications for use described in the labeling should be supported by appropriate information in the 510(k) submission. An example of an indications for use statement is as follows:

The device is indicated for:

- balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
- treatment of acute myocardial infarction
- in-stent restenosis, and/or
- post-deployment stent expansion.

Contraindications

Labeling should indicate this device is contraindicated for treatment of the unprotected left main coronary artery and for coronary artery spasm in the absence of a significant stenosis.

⁹ Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of the FDCA and 21 CFR 801 before a medical device is introduced into interstate commerce. Final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Warnings

In addition to any warnings specific your type of PTCA device, the labeling should address sterilization, selection of appropriate balloon diameter, treatment of special populations, procedures for manipulating the balloon, RBP, and the inflation medium, for example:

This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery warrants careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the: "Use Before" date specified on the package.

For balloons that have not been cleared for stent expansion, the labeling should address the exclusion of that indication from the intended use, for example: This balloon is not intended for the expansion or delivery of a stent.

Precautions

In addition to any precautions specific to your type of PTCA device, the labeling should advise users to verify functionality before use, and that the device should only be used by physicians trained in PTCA, for example:

Before angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

The catheter system should be used only by physicians trained in percutaneous transluminal coronary angioplasty.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Labeling should also include a precaution about the administration of recommended anticoagulant and vasodilator therapy, if not included in the Directions for Use section.

For balloons that have not been cleared for the treatment of ISR, labeling should advise the safety and effectiveness of this use have not been established, for example:

The safety and effectiveness of this PTCA balloon catheter for the treatment of ISR has not been established.

Adverse Effects

If a clinical study was performed to support the submission, labeling should list the adverse events observed, along with a brief narrative statement about the source of each.

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- acute vessel closure
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypotension
- hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- stroke, air embolism and embolization or fragmentation of thrombotic or atherosclerotic material.

Clinical Studies (if performed)

If a clinical study was performed to support the submission, we recommend that you include a summary of the experience, including:

- purpose
- conclusions
- study design
- results.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Directions for Use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we recommend submitting clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

We recommend that you provide specific instructions for use of the PTCA device. We recommend that you state the rated burst pressure (RBP) of the balloon. For PTCA devices intended for infusion of contrast media or other fluids, we also recommend that you state the catheter body burst pressure. We recommend that you indicate the deflated balloon profile in the instructions for use, the outside package labeling, or both. We recommend that you include balloon compliance data which shows how balloon diameter varies as a function of inflation pressure. A tabular or graphical representation is desirable.

For post-deployment stent expansion:

In addition to the above labeling recommendations, we recommend that the device labeling also include the following statements:

The subject device was tested on the bench with the [brand name] stent.

All stents should be deployed in accordance with the manufacturer's indications and instructions for use.

Revision Date

We recommend that you include the date of modified labeling.

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Appendix A: Test Summary

Test	Sizes Tested and Sample Sizes	Test Method or Standard Reference	Accept/Reject Criteria	Results
Dimensional and Functional Attributes	Catheter Diameter & Balloon Profile			
	Minimum Balloon Burst Strength (RBP)			
	Balloon Compliance (Diameter vs. Pressure)			
	Balloon Inflation and Deflation Time			
	Balloon Fatigue (Repeat Balloon Inflations)			
	Tensile Strength			
	Tip Pull Test			
	Flexibility and Kink Test			
	Torque Strength Test			
	Balloon Preparation			
	Radiopacity			
Coating Durability and Particulate Generation				
Additional Tests for Catheters Intended for Infusion of Contrast Media or Other Fluids	Catheter Body Burst Pressure			
	Contrast Media Flow Rate			
Additional Tests for Catheters Intended for In-Stent Restenosis or for Stent Expansion following Stent Deployment	Minimum Balloon Burst Strength (RBP; in Stent)			
	Balloon Fatigue(Repeat Balloon Inflations; in Stent)			

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Appendix B: Applicable Standards

A list of FDA-recognized standards is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<u>ISO Standards</u>
10993 Biological Evaluation of Medical Devices
11134 Sterilization of health care products – Requirements for validation and routine control – industrial moist heat sterilization
11135 Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
11137 Sterilization of health care products – Requirements for validation and routine control – radiation sterilization and ANSI/AAMI/ISO 11137:1994 (Amendment 1:2002)
11607 Packaging for terminally sterilized medical devices
11737 Sterilization of medical devices – microbiological methods <ul style="list-style-type: none">• Part 1 – Estimation of the population of microorganisms on product• Part 2 – Tests of sterility performed in the validation of a sterilization process• Part 3 – Guidance on evaluation and interpretation of bioburden data
14161 Sterilization of health care products – Biological indicators – Guidance for the selection, use and interpretation of results, 2ed.
14937 Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices

<u>ASTM Standards</u>
F748 Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices
F1984-99 (2003) Whole Complement Activation in Serum by Solid Materials
F2081-01 Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
F2065-00e1 Alternative Pathway Complement Activation in Serum by Solid Materials