Guidance for Industry and for FDA Reviewers/Staff

Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements

Document issued on: February 2, 2000

This document supersedes Draft Guidance release of **Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements,** dated February 22, 1999



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

Postmarket Surveillance Studies Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Postmarket Surveillance Studies Branch, HFZ-543, Office of Surveillance and Biometrics, 1350 Piccard Drive, Rockville MD 20850. 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 Daniel S. McGunagle at (301) 594-0643 or dsm@cdrh.fda.gov.

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World Wide Web/CDRH home page at http://www.fda.gov/cdrh/postsurv/plasmaspry.pdf, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 946 when prompted for the document shelf number.

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Guidance[1] for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements

This guidance document supersedes an earlier document titled "Draft Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements". The previous version was released for public comment on February 22, 1999. In preparing this document, consideration was given to comments submitted to earlier drafts of this document.

I. BACKGROUND

On February 21, 1992, the Food and Drug Administration (FDA) reclassified the metallic porous coated hip prosthesis intended for biological (i.e., cementless) fixation from class III (premarket approval required) to class II (see 21 CFR 888.3358). The reclassified porous coated hip prostheses achieved cementless fixation by using metallic porous coatings. Sintering, or diffusion bonding, processes were used to attach the metallic porous coatings to the solid metal of the prostheses. On February 15, 1994, the Center for Devices and Radiological Health's (CDRH) Orthopedic and Rehabilitation Devices Branch (ORDB) determined that hip prostheses intended for biological fixation through porous coatings applied by plasma spray production methods can be substantially equivalent to the reclassified porous coated hip prosthesis. As part of the latter decision, CDRH, using the then existing authority of section 522(a)(1)(C) of the Food, Drug and Cosmetic Act (the act), required manufacturers of plasma sprayed porous coated hip prostheses to conduct postmarket surveillance of their devices. The required postmarket surveillance consisted of prospective, long-term, follow-up of a population of patients receiving cementless implantation of the manufacturer's plasma spray coated hip prosthesis. The objective of patient follow-up was to determine the long-term revision rate for each manufacturer's plasma sprayed porous coated hip prosthesis.

When CDRH required postmarket surveillance, it believed that the term 'plasma spray' represented a single manufacturing technique that produced a single form of coating, having a single set of material properties. Since that time, CDRH has come to recognize that plasma spray

[1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

manufacturing methods are a subset of a larger group of 'thermal spray' metallic coating production methods. CDRH now recognizes that thermal spray coating methods, including plasma spray methods, can produce a wide range of metallic coatings with a wide range of material properties.

The CDRH does not believe that postmarket surveillance is necessary for thermal spray coated hip prostheses whose coatings have mechanical properties equal to, or better than, sintered or diffusion bonded porous coatings. CDRH is willing to reconsider, on a case-by-case basis, its orders requiring postmarket surveillance of a plasma spray coated hip prosthesis. Manufacturers of plasma spray coated hip prostheses who received an order to conduct postmarket surveillance, are invited to apply for reconsideration of the surveillance order. A request for reconsideration should include all of the information identified in this guidance document, should be addressed to the Required Postmarket Surveillance file number, and should be sent to:

Center for Devices and Radiological Health
Postmarket Surveillance Document Mail Center
Room 330Q (HFZ-544)
1350 Piccard Drive
Rockville, MD 20850

A request for reconsideration may be supported by data or information previously submitted to CDRH. Previously submitted data or information may be resubmitted or incorporated by reference. If data or information is incorporated by reference, applicants should state the document number, the date of submission, the section, chapter, or attachment number, and page number of the information. CDRH believes that requests for reconsideration that contain copies of all necessary data and information will be easier and faster to review.

CDRH requests that manufacturers of joint prostheses having metallic thermal spray coatings include data from the test methods described in this document in future 510(k)s for new products. CDRH intends to use the data to determine if new thermal spray coatings have material properties equal to, or better than, those described in this guidance document. The information requested can be used to determine if the new metallic thermal spray coated hip prostheses should be subject to postmarket surveillance requirements. If a new joint prosthesis requires postmarket surveillance, the requirements could be expected to be similar to those required of metallic plasma spray coated hip prostheses.

Note: This guidance document represents the agency's current thinking on the testing results that will enable FDA to reconsider the requirement for postmarket surveillance of plasma sprayed hip prostheses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. If alternative approaches satisfy the requirements of the applicable statute, regulations, or both, the alternative approaches may be used.

Suggestions and recommendations presented in this document are not mandatory requirements, but reflect data and methodologies that CDRH believes could be acceptable. In this context, please note:

This document suggests some important evaluation criteria, test procedures, and end points. There may be circumstances where alternative methods or additional information may be useful.

If the objectives of this document can be accomplished by means other than those stated herein, do not refrain from using those means.

Some of the following recommended test methods may have to be modified, and/or additional methods may be needed, to address the individual properties of a particular product.

As scientific knowledge changes and scientific techniques improve, CDRH may update this document. The basic objectives of the document, however, are likely to remain the same.

II. REQUESTED INFORMATION

Metallurgical Analysis of the Materials

The composition, trace elements analysis, and material microstructure (e.g., grain size, amounts of different phases, etc.) of the substrate and modified surfaces of the final product should be expressed quantitatively. Photomicrographs of the microstructure of the finished material should be included.

If the device assembly is made of material combinations with limited, or no, history of successful use as orthopedic implants, the corrosion over the entire surface of the final device, and interfacing components, should be equal to or less than that measured in a legally marketed device of the same function. Electrochemical methods for determining corrosion potential (E_{corr}) and rate (I_{corr}) may be used, though they may not be sensitive enough. For example, differences in particle size, sharpness and stress may cause differences in rates of corrosion for which ion release measurements may be more sensitive. Ion release measurements provide direct quantitative data on the parameter of greatest interest, viz., the amount of ions in solution. To address galvanic potential between different materials, the interfaces between coatings and substrate should be examined for signs of corrosion by optical and scanning electron microscopy.

Microstructure of the Modified Surface

The total number of different modified surface layers and the following parameters concerning each physically and/or chemically distinct layer of the modified surface should be provided:

- the surface thickness (average and range) as per American Society for Testing and Materials (ASTM) F1854;

- either drawings or photographs of the product illustrating the position of the modified surface(s) and any variation in modified surface thickness;
- the shape and size (average, standard deviation and range) of the particles or material between the pores;
- the diameter or area of the welds (average and standard deviation) between surface coating particles and between coating particles and substrate; and
- microphotographs at appropriate magnifications and locations within the modified surface so all geometrical characteristics of the microstructure listed in this document will be recognizable (either the original magnification or a magnification bar should be included with each image).

The following parameters concerning the spaces within the modified surface (i.e., voids) should be provided as per ASTM F1854:

- void size (average and standard deviation) at the surface;
- the minimum void intercept length or minimum void size of the interconnecting porosity (average, standard deviation and range) for each physically distinct layer; and
- the mean volume percent of voids.

Mechanical Properties - Modified Surface

CDRH recommends that a statistically adequate number of samples be tested at each load in each test. Generally, five plasma sprayed coating samples will be needed, unless it can be shown that a smaller number of samples can give adequate power of the test and adequate Type I and Type II errors.

Either finished devices or surface treated coupon samples processed identically to the final device should be used in the tests below.

1. The shear fatigue strength of surface coating should be tested out to at least 10^7 cycles as per ASTM F1160, or a justification for the test method used should be provided, e.g., Pilliar, 1975; or Manley, 1987.

2. The static shear strength of the surface/substrate interface should be tested by either method described in ASTM F-1044. The thermal sprayed coating should exceed 20 Mpa in shear strength. (ASTM F 1044, Levine, 1985).

3. The static tensile strength of the surface/substrate interface should be tested by either method described in ASTM F-1147. The coating should exceed 22 Mpa in tensile strength. (Levine, 1985; Ducheyne, 1986). Tension may be applied to the modified surface using a polymeric adhesive with a minimum tensile strength of 24.1 Mpa (ASTM C 633: Adhesion or Cohesive Strength of Flame-Sprayed Coatings). The properties of the adhesive should be reported.

4. The abrasion resistance of the coating should be tested as described in ASTM 1978-99. The Taber Abraser should be loaded with an H-22 wheel, use a total load of 250 g-f and each sample should be run for 100 cycles. Samples should have mass loss and cumulative mass loss determinations reported after 2, 5, 10 and 100 cycles. Mass losses should be reported as means with standard deviations. Thermal spray coatings should lose less than a total of 65 mg (by weight) when abraded for 100 cycles.

III. MANUFACTURING

The manufacturing process of the final product and the test samples should be described in enough detail to explain any significant differences in properties between the test sample and currently marketed devices.

IV. REPORTING

To help in the review, and to facilitate a reconsideration, a very brief summary (including numerical values and their units) of all information should be organized as suggested in Section VI, MODIFIED SURFACE DATA FORMS. Any additional and important information not specifically mentioned in this document should be inserted where appropriate. All the data summarized in one set of modified surface data forms should pertain to only one modified surface design. A separate set of modified surface data forms should be submitted for every modified surface having a significant difference in any property, including those listed in this document. Detailed test reports, summarizing the original data, should be included in the submission to FDA. The detailed reports should include, but not be limited to, the following information:

1. The name and address of the facility performing the test.

2. The name of the study director, investigators, and supervisors involved in the study.

3. The dates that testing was initiated and completed and date the final report was completed.

4. The objectives, methods, materials, deviations from referenced protocols and standards, results and conclusions of the test. These sections should include:

    a. a description of the test system used and a schematic or photograph of the test setup;

    b. a description of the samples tested including the differences, if any, in the composition, material structure and processing methods between the test samples and the device to be marketed;

c. the assumptions of the test, including assumed physiological loading values and environmental conditions;

d. at least 5 identical samples for each type of test specimens or statistical justification for the number of each chosen;

e. the load directions and magnitudes;

f. the full experimental data, complete to the extent that an independent conclusion can be made; and

g. a post test failure analysis of the specimens for identification of cracks, plastic deformation and any other signs of failure, including the location of the failure initiation.

5. A bibliography of all references pertinent to the report.

Note: Corrections and additions to a final report should be in the form of an amendment by the study director. The amendment should clearly identify the report that is being amended and the reasons for the correction or addition.

V. BIBLIOGRAPHY

ASTM C 501: 'Test Method for Relative Resistance to Wear of Unglazed Ceramic Tile by the Taber Abraser,' Annual book of ASTM standards, Vol. 15.02.

ASTM C 633: 'Adhesion or Cohesive Strength of Flame-Sprayed Coatings,' Annual Book of ASTM Standards

ASTM D 4060: 'Test Method for Abrasion Resistance of Organic Coatings by the Taber Abraser,' Annual book of ASTM standards

ASTM F1854: 'Test Method for Stereological Evaluation of Porous Coatings on Medical Implants'

ASTM Standard: F 1978-99: 'Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings By Using the Taber Abraser'

ASTM Draft Standard F04.03.XX: 'Porous-Surface Femoral Prosthesis for Cementless Implantation'

ASTM F 1044: 'Shear Testing of Porous Metal Coatings,' Annual Book of ASTM Standards, Vol. 13.01.

ASTM F 1147: 'Test Method for Tension Testing of Calcium Phospate and Metallic Coatings,' Annual Book of ASTM Standards, Vol. 13.01.

ASTM F 1160: 'Shear and Bending Fatigue Testing of Calcium Phosphate and Porous Metal Coated Medical Coatings,' Annual Book of ASTM Standards, Vol. 13.01.

ASTM F 748: 'Selecting Generic Biological Test Methods for Materials and Devices,' Annual Book of ASTM Standards, Vol. 13.01.

ASTM F 981: 'Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone,' Annual Book of ASTM Standards, Vol. 13.01.

Ducheyne, P. and M. Martens: 'Orderly Oriented Wire Meshes as Porous Coatings on Orthopaedic Implants II: The Pore Size, Interfacial Bonding and Microstructure After Pressure Sintering of Titanium OOWM,' Clin. Matls. 1:91-98, 1988.

Greenwald, A.S.; et al.: 'A New Method of Fatigue Testing for Proximally Supported Femoral Stems,' 16th Annual Meeting for the Society for Biomaterials, pp. 221, May 20-23, 1990.

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Manley, M., et al: 'Effects of Repetitive Loading on the Integrity of Porous Coatings,' Clin. Orthop. 217:293-302, 1987.

Messersmith, P.B.; Cooke, F.W.: 'Stress Enhancement and Fatigue Susceptibility of Porous Coated Ti-6Al-4V Implants: An Elastic Analysis,' JBMR 24:591-601, 1990.

Pilliar, R.M., H.U. Cameron, and Macnab, I: 'Porous Surface Layered Prosthetic Devices,' Biomed. Eng. 10:126-131, 1975.

Webster's II New Riverside University Dictionary, Ed. Soukhanov, A. H., The Riverside Publishing Co., 1984.

Wolfarth, D.; et al: 'Parametric Analysis of Interfacial Stress Concentrations in Porous Coated Implants,' J. Appl. Biomatl. 1:3-12, 1990.

VI. MODIFIED SURFACE DATA FORMS

The data may be presented using the following format.

_ The names of any implants using either of the modified surfaces described below.
_ The names (if any) given to the modified surfaces described below.
_ The manufacturer performing the surface treatment processes.

Metallurgical Analysis of Materials

	Test Method	Modified Surface	Unmodified Substrate
Composition			
Trace Elements			
Grain Size			
Corrosion			

Microstructure of the Modified Surface

_ Number of coating layers.
_ Coating thickness (average and range).
_ Provide either drawings or photographs showing the location of the modified surface and values of intended variations in thickness of the modified surface.
_ Description of the approximate shape of the particles or material between the pores.
_ Diameter/width (average, standard deviation and range) of the particles or material between the pores
_ Diameter or area of the welds (average, standard deviation) between coating particles and coating particles and substrate.
_ Supply photomicrographs.
_ Pore diameter (average and standard deviation) at the surface.
_ Minimum void intercept length or minimum pore diameter (average, standard deviation and range).
_ Mean volume percent of voids.

Mechanical Properties - Modified Surface

	Test Method	Mean ± Standard Deviation
Shear Fatigue Strength		
Static Shear Strength		
Static Tensile Strength		

Plastic Deformation		

Abrasion Results	**@ 2 cycles**	**@ 5 cycles**	**@10 cycles**	**@100 cycles**
Mass Loss ± Standard Deviation				
Cumulative Mass Loss ± Standard Deviation				

Manufacturing

Provide a brief description of the manufacturing process of the final product and all test specimens. List all differences in composition, material structure and processing methods between the test samples and the marketed device.

Reporting

Provide detailed test reports including methods, materials, results, raw data and conclusions.

Bibliography

The origin (e.g., published literature article or unpublished internal test report) of the data for each of the test results summarized in this form should be identified. Reference citations may be located next to their respective test results or listed with the name of the test in a separate bibliography.