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GUIDANCE DOCUMENT FOR TESTING ACETABULAR CUP PROSTHESES

DRAFT

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PLEASE FORWARD YOUR COMMENTS TO:

Orthopedic Devices Branch

Division of General and Restorative Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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list each part of each component of the total hip system including:

1. the name of the component and each its parts
2. a description of the function of each major design feature
3. other components and tissues contacting the component
4. the material composition of each component to include:
   - a. previous submission to FDA or other references
   - b. voluntary standards and any deviations
   - c. any trade names for the materials
   - d. establishments which process the material
5. major processing methods
6. details about the design
   - a. diameters and head-cup clearance
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composition and microstructure
- number of physically and/or chemically distinct layers
- thickness of each layer
- the locations of the modified surfaces on the implant
- variation in the modified surface thickness
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MEASUREMENTS FOR ALL INTERFACES

wear particles, wear markings, material transfer and corrosion
roughness and appropriate dimensions
weight measurement
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- volume of mass loss

in vivo vs in vitro wear rates, wear particles and surfaces

PREFACE

The purpose of this document is to recommend to the device manufacturer or sponsor of premarket notifications (510(k)), Investigational Device Exemption (IDE), Premarket Approval (PMA), reclassification petition, or master file important information that should be submitted to FDA in order for FDA to determine the substantial equivalence and/or safety and effectiveness of acetabular cup protheses. This information includes important issues and concerns, properties that should be evaluated, summaries of possible test methods, rationale/purpose of each test, pass/fail criteria or typical results for each test, literature citations, and a format for organizing data for submission to FDA.

The development of this guidance document is based on an evaluation of the literature and on the experience of the Orthopedic and Rehabilitation Devices Branch (ORDB) and is primarily intended to be a scientific position paper. Therefore, it suggests some important evaluation criteria, test procedures, and end points that FDA feels are necessary to provide reasonable assurance of substantial equivalence and/or safety and effectiveness of acetabular cup prostheses. Although this guidance document contains certain administrative requirements, it does not replace the requirements of the 21 CFR 801 or 807 or the statue.

FDA may require information in addition to what is contained in this document if circumstances require it. In other instances, the sponsor may be able to sufficiently justify the omission of some tests. Suggestions and recommendations presented in this document are not mandatory requirements, but reflect data and methodologies which ORDB has determined to be acceptable. Therefore, the words "should", "must" and "shall" are not used in a regulatory sense and should not be construed as such. They express FDA's current feeling as to what constitutes good scientific decision making.

The guidance document should be viewed as a living document. As scientific knowledge changes and scientific techniques are improved, FDA will revise the document. Nonetheless, the basic objectives will remain the same.

MATERIALS AND DESIGN DESCRIPTION

Each part of each component of the total hip system should be listed along with the following information:

1 the name of the component and each its parts;

2 a description of the function of each major design feature (examples are given in APPENDIX 1: PARTS/COMPONENTS AND THEIR MAJOR DESIGN FEATURES);

3 the names of all other components and tissues that are expected to contact the component and the type of interface (i.e., articulating, fixed mating part, coating, tissue fixation);

4 the material composition of each component to include:

- a the document number of any previous submission to FDA or other reference which fully characterized the material (e.g., a master file, 510k, literature article);
- b a brief description of the material or the name and number of the voluntary standards that applies to the material (any difference in the final product and the requirements in the referenced standard must be itemized and justified);
- c any trade names for the materials; and
- d the names of establishments which process the material.

5 the major processing methods which determine the material microstructure and hence, its properties; and

6 details about the design (e.g., engineering drawings, model numbers, sizes, photographs) which should include the ball and liner design tolerances and manufacturing variability for interfaces. For example, this might include the following for the articulating interface:

- a diameters and head-cup clearance;
- b sphericity;
- c roughness; and
- d waviness.

The thinnest part of any UHMWPE articulating insert must be greater than 4 mm if attached to a metal or ceramic backing (conforming insert) and greater than 6 mm if there is no backing (nonconforming

insert) (Bartel, D.L.; Burstein, A.H.; Toda, M.D.; Edwards, D.L.: 'The Effect of Conformity and Plastic Thickness on Contact Stresses in Metal-Backed Plastic Implants'. J. Biomech. Engr., 107, pp. 193-9, Aug., 1985).

EVALUATION OF SURFACE TREATMENTS/COATINGS

See the "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement".

EVALUATION OF CALCIUM PHOSPHATE (Ca-P) COATINGS

See the "Calcium Phosphate (Ca-P) Coatings Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants".

KINEMATICS

The range of motion of the ball-acetabular cup combination and of the metal shell and polymer insert (bipolar device) should be reported.

STRESS ANALYSIS

High stresses leading to deformation, fracture or increased wear of the components may be due to:

1. poor tolerances (e.g., too large or too small a ball-cup clearance or a too tight press fit connection);

2. inadequate instructions for attachment (e.g., excessive use of force);

3. local stress risers (e.g., corners);

4. thermal expansion of parts during sterilization; and

5. thin cross-sections.

These parameters may be evaluated in a stress analysis with mechanical testing to justify assumptions made in the analysis.

ATTACHMENT LOADS

The following loads should be determined:

1 assembly by the surgeon (minimum and maximum recommended loads),

2 disassembly by the surgeon,

3 inadvertent disassembly in the patient,

4 any possible relationship between loosening and assembly loads.

Inadvertent disassembly may be evaluated by tensile, torsional or cantilever loading before and after cyclic testing (see below). Tensile loading is simple and the results easy to interpret. For example, an insert is either pulled or pushed along the axis of the cup till failure of the locking mechanism, a load exceeding a safety factor is reached, the disengagement force becomes negligible or assembly becomes difficult (see ASTM draft Standard Test Method for Static Evaluation of Liner Locking Mechanism - Push Out Test).

Torsional loading is the most clinically relevant loading configuration at cup interfaces. The torque due to friction at the ball-liner interface is about 2.4 N-meters. The locking mechanism should exceed this by some safety factor (e.g., 12 N-meter (105 in-lb) for a safety factor of five (Semlitsch, M.; et al. 1977)).

Loosening may also be determined by measuring relative displacement between parts every 10,000 cycles of cyclic loading. An LVDT can measure the displacement while an axial compression load of 50 lbf and a torsional fatigue of +- 22 in-lbf are applied.

FATIGUE PROPERTIES

Cyclic fatigue testing should be considered for an acetabular cup which has the same design as a predicate cup except for differences in features which may affect the fatigue life. Whether evaluated separately or in a single test, the corrosion and fatigue properties of the device assembly and wear properties of both the articulating and non-articulating (mechanically locked) interfaces should be examined in any test performed, where possible.

CYCLIC WEAR, DEGRADATION AND CORROSION

Cyclic testing should be considered for an acetabular cup which has the same design as a predicate cup except for differences in features which may affect loosening, cracking, deformation, corrosion, degradation and wear at interfaces. To simulate actual clinical wear mechanisms for both articulating and non-articulating (mechanically locked) interfaces as much as possible, the following test method and measurement parameters should be considered:

DEVICE CHARACTERIZATION

The cup dimensions and tolerances that would be expected to result in the highest stresses (i.e., worst case) must be tested.

Test samples must be the final product to be shipped for clinical use.

In addition to the information listed in the MATERIALS AND DESIGN DESCRIPTION section of this documents, the exact composition and microstructure of the substrate and any modified surface present must be fully characterized quantitatively from a representative sample of the test specimens. The tolerances for the analyses must be reported. Surfaces exposed to wear must also include the following:

total number of physically and/or chemically distinct surface layers;

thickness of each layer;

drawing or photographs showing the locations of the modified surfaces on the implant and any variation in the modified surface thickness; roughness.

TEST METHODS FOR ALL INTERFACES

At least three identical test specimens and three identical controls must be tested. The number of samples depends on the standard deviation and the desired levels of statistical significance and difference in results between test and control specimens.

Polymer samples should be presoaked until a steady state fluid absorption (determined by weighing) is approached (about 30 days for UHMWPE). Samples must be stored and tested in isolation within a noncorrosive chamber.

Three polymer controls which are soaked as are the wear specimens but not wear tested, should be weighed to correct for ongoing fluid sorption by the wear tested components during the wear test. The soak controls should be agitated and cyclically loaded (except for tangential wear motions) as are the wear test specimens.

The volume and concentration of surrounding fluids shall be maintained during testing by avoiding evaporation or by replacing water loss.

Other test parameters should also be included in the methods if the in vitro results will more closely duplicate the in vivo results.

METHODS FOR TESTING FRETTING AND/OR CORROSION/DEGRADATION BETWEEN NON-ARTICULATING, "MECHANICALLY LOCKED," MODULAR IMPLANT COMPONENTS"

Specimens must be cyclically loaded in a joint simulator or other appropriate instrumentation. The device orientation and loading profile must simulate worst case fretting motions, cyclic stresses, three body wear and corrosion/degradation environment which could occur during clinical use.

Interpretation of the results may be simpler using a 37 +- 1 C, aerated saline test solution having a pH of 7.3 +- 0.5 (carbonate buffered). This is because saline leaves no deposits and the solution composition does not change with time. Ringer's or Hanks solutions may better simulate physiologic conditions and may be appropriate if corrosion is not an issue, but control of the composition, measurements of surface deposits and interpretation of the results must be more stringent than if saline is used. A 0.2% sodium azide or other suitable antibiotic may also be used. A 37 C temperature is preferred, though room temperature may be used if this has no effect on mechanisms (e.g., polymer deformation or creep). Solution temperature and pH must be monitored throughout the test. Accelerated testing (e.g., change in temperature, pH, P_{O^2}, electric potential) must be validated with a real time control.

The surfaces exposed to solution should be the same for all specimens and simulate corrosion as it might occur clinically. Corrosion testing of modular devices requires that corrosion is induced at appropriate interfaces and not at the outer surface. It is not

enough to merely pit the outer surface of the material because this does not represent the corrosion that occurs as a result of the geometry and wear occurring at the crevice (Buckley, C.A.; et al. 1992).

Corrosion test specimens should be electrically insulated from the test apparatus to avoid galvanic corrosion effects (Higo, Y.; Tomita, Y. 1994, page 152).

METHODS FOR TESTING ARTICULATING SURFACES

Specimens must be cyclically fatigue loaded in a joint simulator.

The lubricant shall consist of the following (or an equivalent pseudosynovial fluid used):

filter-sterilized blood serum,

0.2% sodium azide (or other suitable antibiotic),

20 mM EDTA (ethylene-diaminetetraacetic acid) to bind calcium and minimize its precipitation, and

37 $\pm$ 1 C temperature.

Specimens shall be clamped for testing as outlined in McKellop, H.A.; Clarke, I.C.: 'Degradation and Wear of Ultra-High-Molecular-Weight Polyethylene'. ASTM (editor): Special Technical Publication 859, 1985. Any potting medium composition and processing methods used to fix test samples must be reported.

The dynamic load profile should be representative of the human hip joint forces during walking with peak loads of 2 kN (see Davy, D.T.; Kotzar, G.M.; Brown, R.H.; Heiple, K.G.; et al.: 'Telemetric Force Measurements Across the Hip After Total Arthroplasty'; and Paul, J.P.: 'Forces Transmitted by Joints in the Human Body'. Proc. Instn. Mech. Engrs., 181, pp. 8, 1966. JBJS, 70A, pp. 45, 1988).

The average rate of loading during the entire test must be 1 Hz.

Testing which includes three body wear may be necessary to adequately test the wear resistance of surfaces to obtain a clinically meaningful result. At a minimum, the presence of three body wear should be controlled and characterized as much as possible. For example:

contamination control and measurement

characteristic wear markings

location of particles lying on or embedded in surfaces

the cup articulating surface should face up

lubricant replacement

non-filtering of the lubricant during the testing

MEASUREMENTS FOR ALL INTERFACES

Wear particles, wear markings, material transfer and corrosion (e.g., pitting, etched dendritic surface structure, discoloration) should be quantified after components are disassembled, and before and after cleaning if necessary. Material transfer that may occur while assembling or disassembling parts, prior to fretting, should be taken into account (Bhambri, S.K.; Gilbertson, L.N. , page 123).

Roughness and appropriate dimensions of each test specimen must be measured before and after testing to assess the effects of wear and deformation. For the ball-cup interface this might include: diameters; head-cup clearance; sphericity; roughness; and waviness.

Weight changes of device components should be made if the test samples are small enough compared to the losses due to wear and corrosion. Samples shall be cleaned prior to weighing as outlined in McKellop, H.A.; Lu, B.; Benya, P.: 'Friction, Lubrication and Wear of Cobalt-Chromium, Alumina and Zirconia Hip Prostheses Compared on a Joint Simulator'. Trans. Orthop. Res. Soc., pp. 401, 1992. The weight loss of each wear component shall be adjusted for the change in weight of the soak controls. The room temperature and humidity during weight measurement shall be reported. The volume of wear debris shall be calculated by dividing by the density of the material.

Test methods should be validated by comparing in vitro results to in vivo results to determine if in vitro test methods are realistically simulating what occurs in patients (e.g., three body wear). This may be determined by comparing wear particles of in vitro test samples to those of explanted devices of similar design as well as in vivo and in vitro wear and corrosion rates.

MEASUREMENTS AT NON-ARTICULATING, "MECHANICALLY LOCKED," MODULAR IMPLANT COMPONENTS".

After noting their location on all surfaces, wear particles should be washed off implant surfaces into the test solution. A sample of the wear particles should be characterized, then all metal particles in solution dissolved with an acid (e.g., HCl), and the total metal content in the solution, including particles, measured by AAS (atomic absorption spectroscopy) (Kovacs, P.; et al. 1992). Care should be taken to remove all particles from the test specimen surface and to completely dissolve particulate or oxidized metal (Margevicius, R.W.; et al. 1989).

Complimentary methods of monitoring fretting corrosion may be used in addition to those listed above. For example: fretting corrosion currents measured during cyclic loading or crack formation and fatigue strength before and after fretting.

MEASUREMENTS AT ARTICULATING SURFACES

Wear per million cycles based on the change in component mass and frictional torque must be evaluated before testing and at intervals of no greater than a third of the total number of cycles. The same countersurfaces must be assembled after each wear measurement prior to continuing the test.

REPORTING

Test reports which omit information, or are not organized the same way by each investigator, makes FDA's review more difficult and delays determinations of substantial equivalence and/or safety and effectiveness. To facilitate FDA's review, detailed reports should include the information which is organized and subdivided into separate sections (some sections may be combined to enhance clarification) as outlined in Appendix 2.

APPENDIX 1: PARTS/COMPONENTS AND THEIR MAJOR DESIGN FEATURES

MODULAR PARTS/COMPONENTS	MAJOR DESIGN FEATURES
	ACETABULAR CUP
BACKING	
ARTICULATING INSERT	SCREW HOLE DOME HOLE
LINER	SUBLUXATION LIP (DEGREES) BC FLANGE ECCENTRICITY (OFFSET) CONSTRAINT CAPTURED BALL FULLY-CONSTRAINED NONCONSTRAINED SEMI-CONSTRAINED
LOCKING RING	
RADIOPAQUE MARKER	
CEMENT SPACER	
BORE INSERT	BALL BALL (HEAD) PARTS
BIPOLAR INSERT	
STEM CENTRALIZER BONE CEMENT PLUG EXTENDER SHAFT	FEMORAL COMPONENT
COLLAR	GENERAL: CROSS-SECTION: ROUND/OVAL HANDEDNESS: LEFT/RIGHT STRAIGHT OR CURVED TAPERED DISTAL: COLLAR FLUTED SLOT (CLOTHS PIN) PROXIMAL: EXTRACTION HOLE FENESTRATION
SLEEVE CEMENT SPACER OTHER	
	SPECIFIC STYLE (SEE ASTM F 370)

MODULAR PARTS/COMPONENTS

MAJOR DESIGN FEATURES

TION MECHANISMS:
PONENT-TO-TISSUE &
PONENT-TO-COMPONENT

ADHESIVE
BOLT OR SET SCREW
BONE SCREW
- CORTICAL
- CANCELLOUS

COATING
- CALCIUM PHOSPHATE CERAMIC
- METAL
  - PLASMA SPRAYED
  - POROUS SINTERED
- NORMALIZED

SURFACE
- ROUGHENED
- SMOOTH
- TEXTURED

MORSE TAPER

OTHER
- WELDED
- BONE CEMENT
- PEG OR PIN

APPENDIX 2: TEST REPORT CONTENT

Detailed reports should be organized and subdivided into separate sections (some sections may be combined to enhance clarification) having the following headings (if applicable):

1. Report title
2. Investigators' names
3. Facility Performing the test
    - Name
    - Address
    - Phone Number
4. Dates
    - Test initiation
    - Test completion
    - Final report completion
5. Objectives/Hypothesis
6. Test and control samples
    - Sample selection criterion
    - Design
    - Materials
    - Processing methods
    - Differences between test samples, control samples and marketed device
7. Methods and Materials
    - Test setup schematic or photograph
    - Description of grips or potting medium interfacing with samples
    - Test equipment callibration schedule, methods and data
    - Discussion of dependent, independent and uncontrolled variables, e.g.:
        - Test and control sample parameters
        - Environment composition, pH, volume, flow, temperature, replacement
        - Electromagnetic fields, applied charge, irradiation
        - Load directions, points of application and magnitudes
        - Times (e.g. rates, frequencies, number of cycles)
        - Other
        - Rationale for choices of parameters, values, etc.
    - Methods of specimen examination (e.g., failure analysis)
    - Statistical justification for the number of samples
    - Chronological description of the test procedures
    - Deviations from referenced protocols and standards
8. Results
    - Time from manufacturing till testing commences
    - Discussion of the data and possible mechanisms
    - List of conclusions
    - Discussion of the objective/hypothesis
    - Simplifications and assumptions and their clinical implications
10. Appendices
    - Experimental data
    - Calculations
    - Bibliography of all references pertinent to the report

ION MEASUREMENTS

AAS (atomic absorption spectroscopy) is a method used to record the total metal content in a solution containing particles obtained from wear testing. However Margevicius, R.W.; et al. 1989 reported that in vitro corrosion is better measured by weight loss with a microbalance rather than by AAS. Weight loss records 1.5 to 3 times more than by AAS because:

1. particles remaining attached to the test specimen surface when removed from the solution, and

2. AAS is unable to detect particulate or oxidized metal which are not dissolved by acid.

On the other hand, Kovacs, P.; et al. 1992 found a correlation between solution metal ion concentration and weight loss due to controlled fretting of various metals against themselves. The metals included Ti-6Al-4V, CoCrMo and SS. Despite various parameters which affect fretting volume, simply monitoring ion concentration was a better way of measuring fretting volume than weight loss Weight loss underestimated fretting, it was not sensitive enough for assessing implant fretting and the test must be interrupted to make measurements.

FRETTING

Crevice corrosion requires diffusion so motion of the environment due to shaking or stirring may delay crevice corrosion (Kruger, J. 1979).

Attia, M.H. 1989 reviewed fretting fatigue test methods.

Fretting results in greater wear because wear debris are retained within the contact zone (Merklenberg, K.R.; Benzing, R.J. 1976).

Merritt, M.; Brown, S.A. 1988 Fretting corrosion of SS is lowered by the addition of protein to the solution due to its lubricating effect. Under static conditions, protein has been reported to cause both an increase. R.L.; Brown, et al. and a decrease in corrosion. Williams, R.L.; Brown, S.A.; Merritt, M. Protein had no effect on Ti-6Al-4V corrosion under static or fretting conditions.

Bundy, K.; et al. 1993 Disinfectants are more corrosive than Ringers solution, though not enough to cause artifacts in the assessment of corrosion attack.

Montague, A.C.; Merritt, K.; Brown, S.A.; Payer, J.H. Because Ca increases fretting corrosion of Ti-6Al-4V, the test solution Ca concentration should be specified. This effect varies with solution composition due to its effects on solubility and dissociation of Ca compounds. The fretting corrosion of Ti-6Al-4V near a site of inflammation may be significantly increased due to the presence of H2O2 there.

Buckley, C.A.; Gilbert, J.L. 1994 cyclically loaded CoCrMo (F75) balls on trunions made of either the same material or Ti-6Al-4V. The open circuit potential (OCP), fretting currents and pH of the saline solution within the crevice were measured. The fretting current decreased with the number of cycles until leveling out at around 300,000 cycles. The OCP recovered toward its resting potential even during loading. The pH at the interface was inconsistent.

Gilbert, J.L. reported that fretting currents began at load levels of about 200-300 N. This current could affect the oxide coating by affecting the potential. Clorine increased 200% which caused a decrease in pH in the head-neck region,. Scratching the surface caused a huge increase in current density. The fretting current decreased with time, possibly due to seating of the head on the neck.

Flemming, C.A.C.; et al. 1993 evaluated the effect of bore-neck angle mismatches of 6'25'' and 3'8'' on corrosion current during cyclic loading in 0.9% saline. A Ti-6Al-4V stem and F 799 CoCr head were used. The rest current for both samples was 20 nA. The minimum or critical load necessary to begin fretting for large and small mismatches was 100 and 250 N respectively. The current caused by the stick-slip fretting action depended on the load (in the 25-125 range) applied to the bore-cone with a large mismatch. (e.g., 31 nA at 25 N and 142 nA at 125 N). The current was a constant 50 nA for all loads

between 25 and 125 N for the small mismatched bore-cone. During high cycle loading, the current for both types of mismatched specimens was about the same (13-14 uA).

Smith, B.J.; Ducheyne, P. 1994 after an initial anodic drop due to fretting-induced damage, the potential remains steady reflecting continuing damage to the surface. After about 10,000 cycles, a transition in the potential versus cycles plot occurs in which the potential decreases to smaller values, reflected a much lower rate of surface damage. The less severe wear, which prevailed for the rest of the experiment, may be caused by the accumulation of wear debris between the oposing surfaces. The flow properties of the fluid and particles protect the surfaces by thick film lubrication. The particles accumulate into a film because the:

.fretting motion resulted in little exposure to the rest of the solution.
.specimen geometry prevented particles from escaping. Smith, B.J.; Ducheyne, P. 1994
.fretting motion was slow and so imparted little momentum to wear debris.

Crevice corrosion requires diffusion so motion of the environment due to shaking or stirring may delay crevice corrosion (Kruger, J. 1979).