GUIDANCE DOCUMENT FOR TESTING BONE ANCHOR DEVICES

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Please Forward Your Comments To:

Division of General and Restorative Devices

Center for Devices and Radiological Health
U.S. Food and Drug Administration

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I. CONTENTS

II. PREFACE

The purpose of this document is to recommend to the device manufacturer or sponsor of a future premarket notification (510k), Investigational Device Exemption (IDE), Premarket Approval (PMA) application, reclassification petition, or master file important information that should be provided to the FDA so that the substantial equivalence and/or safety and effectiveness of bone anchor or suture anchor devices can be determined.

Bone anchors or suture anchors are devices which attach soft tissue to bone. This may be achieved by tieing one end of a suture to soft tissue and the other end to a device which "anchors" the suture to the bone. In this document, "anchor" refers to the device the suture is attached to and "bone anchor" refers to the anchor plus attached suture (if there is a suture).

Suggestions and recommendations presented in this document are not mandatory requirements, but reflect data and methodologies which the Office of Device Evaluation (ODE), Division of General and Restorative Devices (DGRD) has determined to be acceptable. In this context, several points should be remembered:

1. The guidance document is primarily intended to include scientific recommendations. Therefore, it suggests some important evaluation criteria, test procedures and end points. There may be circumstances where an alternative method or additional information may be useful and this document has included some examples. If the manufacturer or sponsor can answer the same scientific issues by means other than those included in this guidance document, they should not refrain from doing so. Because the scope of this document does not specify any particular type of bone/suture anchor device, some of the recommended test methods may need modification to address the properties of a particular product.

2. The guidance document should be viewed as a living document. As scientific knowledge changes and scientific techniques are improved, FDA will periodically revise the document.

III. ESTIMATION OF CLINICAL LOADS APPLIED TO THE DEVICE FOR COMPARISONS TO BENCH TEST RESULTS

The maximum expected clinical loads applied to the device and tissues should be measured, calculated, or obtained from other scientific sources and compared to the results of the fixation strength tests described below. If this data is impossible to obtain, the strength of each healthy tissue indicated for repair by the bone anchor should be determined or calculated. This provides an upper limit for the maximum expected loads on the device. For example, if the fixation strength of the bone anchor approaches this upper load limit, clinical data may not be required.

IV. PRECLINICAL TEST DATA

The fixation strength of the bone anchor device should be evaluated in a bone model which simulates the density and bone structure of the bony site for which it is indicated. The results should be compared to a legally marketed predicate device or an established and validated surgical procedure using a suture (control) for the same intended use as the test device.

The loads to displace the test and control bone anchor devices from the bone model (e.g., cadaver bone) should provide precise data on failure loads and mechanisms that clinical data are unable to provide. However, these in vitro test methods may not adequately simulate actual in vivo conditions because of tissue strength variability between different joints and bony sites and the variability resulting from different surgical techniques. The number of anchors, orientation of the device and suture, patient parameters (e.g., applied loads) and other unknown variables complicate the usefulness of the results. Therefore, the worst case situation should be tested (e.g., the suture loaded perpendicular to the surface of the bone test sample).

If a previously cleared suture is packaged and sterilized with a bone anchor, the following should be provided:

suture diameter, needle attachment strength and knotted tensile strength if the suture was not sterilized prior to packaging with the anchor;

if already sterilized before packaging, the method of initial sterilization and a statement from the suture company that the second sterilization method is acceptable.

Documentation should be maintained regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the suture. Any deviation of the source material or processing requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

Clinical data may be required if the intended use, materials, design or some combination of these differ substantially from a legally marketed predicate device and increase risks to health (e.g., see Appendix 1). Examples might include new absorbable materials not previously cleared for implant use or a new design with a pull-out strength that is less than the predicate device.

To help FDA in its review and to facilitate a determination of substantial equivalence, a very brief summary of all mechanical test data should be organized into a table as suggested in Appendix 2. Any additional and important information not specifically mentioned should be inserted into this organization where appropriate. Detailed test reports from which the summarized data originated should be organized in a similar manner and included in the submission to FDA. The detailed reports should include, but are not limited to, the information contained in Appendix 3.

APPENDIX 1 POSSIBLE FAILURE MECHANISMS OF BONE ANCHORS

Loss of fixation is the primary cause of bone anchor failure. Loss of fixation may occur due to inadequate:

SOFT TISSUE STRENGTH

One possible failure mechanism is suture cutting through the soft tissue to which it is tied. This is something all suture retaining devices have in common. This failure mechanism is dependent only on the suture, soft tissue and surgical technique so the failure mechanisms involving the bone anchor may be evaluated independently of the soft tissue strength.

SUTURE STRENGTH

The suture is a probable point of failure, partly because the suture is usually weaker than the anchor. The suture may fail at the anchor, knot or some unexpected flaw mechanically isolated from the anchor.

BONE OR ANCHOR STRENGTH

The anchor may fracture and loosen from the bone or the bone may fracture, resulting in anchor displacement from the bone due to inadequate fixation. Bone fractures are more likely to occur at bony sites which contain greater amounts of cancellous or more porous bone.

SUTURE FATIGUE RESISTANCE

Notching of the suture as the suture rubs against bone or the anchor during cyclic motion may result in suture breakage. This may not be an important issue except in special applications where healing would not be sufficient to bear expected loads by six weeks.

ANCHOR FATIGUE RESISTANCE

Cyclic stresses in the device may exceed the endurance limit of the anchor design, resulting in device fracture, loosening and loss of fixation. This may not be an important issue if the tissue heals soon (less than six weeks).

APPENDIX 2 The materials, methods and results of fixation strength testing should be organized as follows:

fixation strength test:

- anchor type;
- suture:
  - name,
  - material,
  - size,
  - number,
  - knot type,
  - sterility
- test subject or substrate:
  - type (e.g., human cadaver tibia),
  - cortical bone thickness and depth of bone at anchor implant site
  - quantitative description of microstructure, porosity and defects;
- distance between drill holes;
- presoaking time and medium;
- angle of applied loads;
- displacement rate;
- other methods;
- fixation strength;
- failure mode (e.g., see appendix 1);

summary:

- statistical evaluation of the differences between the results for the test and control specimens;
- the maximum possible loads that the suture and anchor could experience under clinical conditions;
- the strength of the healthy tissues indicated for repair;

all references (authors, title, etc.).

APPENDIX 3

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
    - List of dependent, independent and uncontrolled variables, e.g.:
        - Test and control sample parameters
        - Environment composition, pH, volume, flow, temperature, replacement
        - Electromagnetic fields, applied charges, 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 made and clinical implications of results
9. Appendices
    - Experimental data
    - Calculations
    - Bibliography of all references pertinent to the report