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STANDARD

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9585

Implants for surgery — Determination of bending strength and stiffness of bone plates

Implants chirurgicaux — Détermination de la résistance au pliage et de la rigidité des plaques pour os



Reference number ISO 9585:1990(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

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International Organization for Standardization

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Implants for surgery — Determination of bending strength and stiffness of bone plates

1 Scope

This International Standard describes a test method for determining the bending strength and stiffness of straight bone plates. It may also be used to test plates having a small initial curvature intended to produce pre-loading of the bone when fitted and to test the straight portion of angled plates. This test method is not recommended for plates of length less than 50 mm nor for plates designed to be used with, or forming parts of, intramedullary devices.

NOTE 1 A test method for plates of length less than 50 mm is in preparation.

2 Definitions

For the purposes of this International Standard, the following definitions apply.

2.1 moment: Turning effect of a force about an axis, expressed numerically by the product of the force F and the distance h measured perpendicularly from the axis to the line of action of the force.

Unit: N·m

2.2 bending moment, $M_{\rm b}$: Moment acting about an axis perpendicular to the long axis of a body and generally producing lateral deflection.

Unit: N·m

2.3 deflection: Linear displacement due to bending measured perpendicular to the original axis of the plate.

Unit: m

2.4 bending strength: Value of the bending moment at fracture, or at a specified proof point, whichever is the lower.

Unit: N·m

2.5 equivalent bending stiffness: Stiffness of the plate calculated from the dimensions of the test configuration and the slope S of the linear part of the load/deflection diagram defined by the mechanical test.

Unit: N·m²

NOTE 2 This equivalent bending stiffness takes account of the holes or slots in the plate.

3 Apparatus

3.1 Test rig, to produce a loading system in accordance with figure 1, the four rollers (indicated by hatched circles) being so constrained that their axes remain parallel.

3.2 Rollers, of cylindrical form and of equal diameters within the range of 8 mm to 13 mm, or of profiled form corresponding to the cross-section of the plate to be tested, and having a mean diameter within the range 8 mm to 13 mm. It is desirable that one of the rollers be secured to the specimen to restrain longitudinal movement and that all rollers are secured to maintain their relative position.

3.3 Means of applying forces, e.g. a mechanical testing machine.

3.4 Device(s), for measurement of relative displacement(s).

4 Procedure

4.1 General

Conduct bending tests using the apparatus specified in clause 3. Use the cylindrical rollers to test flat plates and plates of curved cross-section, in which the deviation from flatness at the centre of the plate does not exceed b/6, where b is the width of the plate. Test other plates using rollers of suitable profile.