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Application Note

ISO 9585 – Osteosynthesis Implants

Background

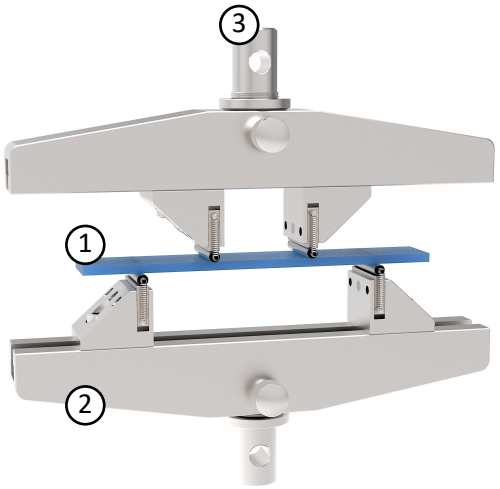
The static and dynamic strength of bone plates or so-called osteosynthesis plates must be tested for research and development as well as for product approval. This test can be carried out in accordance with the ISO 9585[1] standard, which defines the methodology and parameters for the mechanical testing of the static and dynamic strength of osteosynthesis plates. The test is carried out according to standards in a three- or four-point bending test.

Test Setup

The static and dynamic strength of the bone plates are determined in 3-point or 4-point bending tests, whereby the bending device consists of two fixed and parallel supports.

The bone plate (1) is fixed or clamped on the specimen holder (2). A cyclic, sinusoidal load is applied to the implant via a punch (3) until the specimen breaks or until the maximum number of cycles is reached.

Testing in a liquid bath (heated to body temperature) with Ringer's solution increases the physiological relevance of the test. Force and displacement signals - i.e. the deflection of the sample - must be recorded during the test.



Equipment

The fatigue test according to ISO 9585 can be performed easily, reliably and reproducibly with servo-dynamic testing systems from **THELKIN** and the corresponding specimen holder:

- **THELKIN Servo-Dynamic Load Frame SDL-M-010** - complies with the specifications of the standard and enables simple and safe specimen mounting, programming of the test as well as data acquisition and test execution.
- **4-Point-Bending Fixture FI.BE.4P** - enables fast and precise positioning of the specimen.

The test system can also be equipped with an uninterruptible power supply, thus enabling long-term tests to be performed safely.

[1]ISO 9585: Implants for surgery — Determination of bending strength and stiffness of bone plates.

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