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Application Note

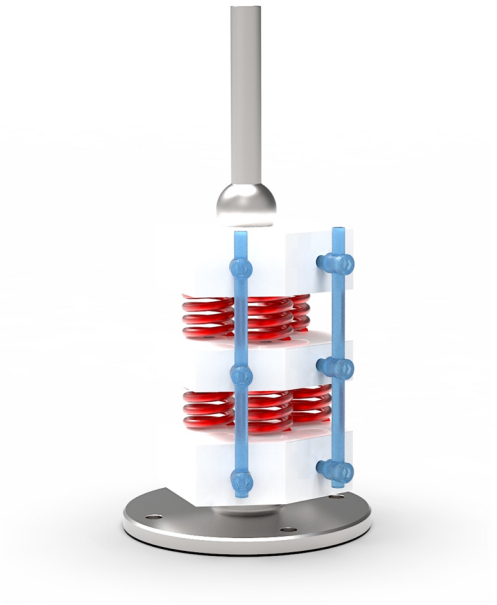
ISO 12189 – Fatigue Spinal Implant

Background

The strength of implants for the fixation of vertebral bodies must be investigated for research and development purposes as well as for market approval. This includes the examination of their fatigue properties. Test standard ISO 12189-8[1] defines the requirements for testing the fatigue strength of semi-rigid implant constructs that cannot be tested using the method described in ISO 12189-8. Methodology and applicable parameters as well as the conditions for environmental simulation are described.

Test Setup

The test fixture consists of a fixed base unit at the bottom and a punch with a ball head which can apply the axial force. The spinal implant is fixed by three plastic blocks with integrated stabilizing elements.



A cyclic, sinusoidal load is applied to the implant until the specimen breaks or until a maximum number of cycles is reached. Test frequencies of 5 Hz are common for this purpose. The test can be performed in air under laboratory conditions or in liquid test medium at 37°C body temperature.

The test result is documented as the number of cycles achieved, together with the applied force amplitude.

Equipment

The fatigue test in accordance with ISO 12189-8 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.
- **Fluid Bath EN.FB** - for physiologically relevant tests, the test can be performed in body environment. For this purpose, the sample is tested in a liquid bath which can be regulated to a temperature of 37°C.

The test system can also be equipped with an uninterruptible power supply and can therefore safely perform long-term tests.

[1]ISO 12189-8: Implants for surgery — Mechanical testing of implantable spinal devices — Fatigue test method for spinal implant assemblies using an anterior support

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