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Implants for surgery — Mechanical testing of implantable spinal devices — Fatigue test method for spinal implant assemblies using an anterior support

Implants chirurgicaux — Essais mécaniques des dispositifs spinaux implantables — Méthode d'essai de fatigue des ensembles d'implants spinaux utilisant un support antérieur

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 12189 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

Introduction

Different concepts of posterior spinal fusion devices such as “rigid” and “semi-rigid” or “dynamic” systems are available on the market. Some of these existing spinal implants are not indicated in major instability cases (“semi-rigid” or “dynamic” implants, hook- and wire-based fixation implants, artificial ligaments, etc.), because they have been designed to allow load-sharing with the anterior column. This document strongly emphasises the effects of the load-sharing phenomenon, largely described in the literature, as a very important feature regarding the load patterns to which the spinal implants are submitted.

As these different concepts result in different implant behaviour, a corpectomy configuration construct might not always be appropriate for testing, since total corpectomy without subsequent provision for anterior support occurs very seldom in clinical practice, and also because this kind of construct neglects the influence of anterior column support on implant loading. Moreover, some kinds of implant are often too flexible to be tested on their own or in a corpectomy configuration. This International Standard is intended to allow fatigue testing of flexible spinal implants and allow biomechanical fatigue testing of any kind of spinal implants, particularly semi-rigid and dynamic implants, regardless of their intrinsic rigidity. This document describes compression/flexion fatigue testing; additional mechanical tests, such as multi-directional testing (shear, torsion, lateral bending), might be required to assess clinical device safety.

For devices which are able to withstand loading in a corpectomy configuration, the test should be performed without anterior support in accordance with ASTM F1717 to demonstrate that, in a worst-case scenario, the device can support full load.

This International Standard is related to the methods for fatigue test of spinal implant assemblies (for fusion or motion preservation) with an anterior support.

Implants for surgery — Mechanical testing of implantable spinal devices — Fatigue test method for spinal implant assemblies using an anterior support

1 Scope

This International Standard specifies methods for fatigue testing of spinal implant assemblies (for fusion or motion preservation) using an anterior support. It is intended to provide a basis for the assessment of intrinsic static and dynamic strength of spinal implants.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10243, *Tools for pressing — Compression springs with rectangular section — Housing dimensions and colour coding*

ASTM F1717, *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
active length of the longitudinal element
straight line distance between the centre of attachment of the superior anchor and the centre of attachment of the inferior anchor

3.2
model moment arm
perpendicular distance to the applied load between the insertion point of an anchor and the load application centre

3.3
failure
permanent deformation resulting from fracture; plastic deformation or loosening beyond the ultimate displacement that would render the spinal implant assembly ineffective or unable to adequately resist load

3.4
insertion point of an anchor
location where the anchor is attached to the segment model

3.5
intended spinal location
anatomic region of the spine intended for the application of the spinal implant assembly

NOTE Spinal implant assemblies are developed for specific spinal locations such as the anterior cervical spine or the posterior cervical, thoraculumbar, lumbar and lumbosacral spine.

3.6
maximum run-out load
maximum load that can be applied to a spinal implant assembly where all of the tested constructs have withstood 5 000 000 cycles without a failure

3.7
spinal implant assembly
complete spinal implant configuration as intended for surgical use

NOTE A spinal implant assembly will contain anchors, interconnections and longitudinal elements and can contain transverse elements.

3.8
spinal implant construct
complete spinal implant assembly attached to the appropriate test support

3.9
UHMWPE test block
component of the test apparatus for mounting the spinal implant assembly

NOTE 1 A specific design of UHMWPE test blocks is required for each intended spinal location and intended method of application. Figures 1, 2 and 3 describe the recommended designs for the test blocks (lumbar samples) and Figure 4 describes the recommended design for cervical samples; however, alternate designs can be used as long as equivalent performance is demonstrated.

NOTE 2 Spinal implant assemblies contain different types of anchors. Each type of anchor has an intended method of application to the spine.

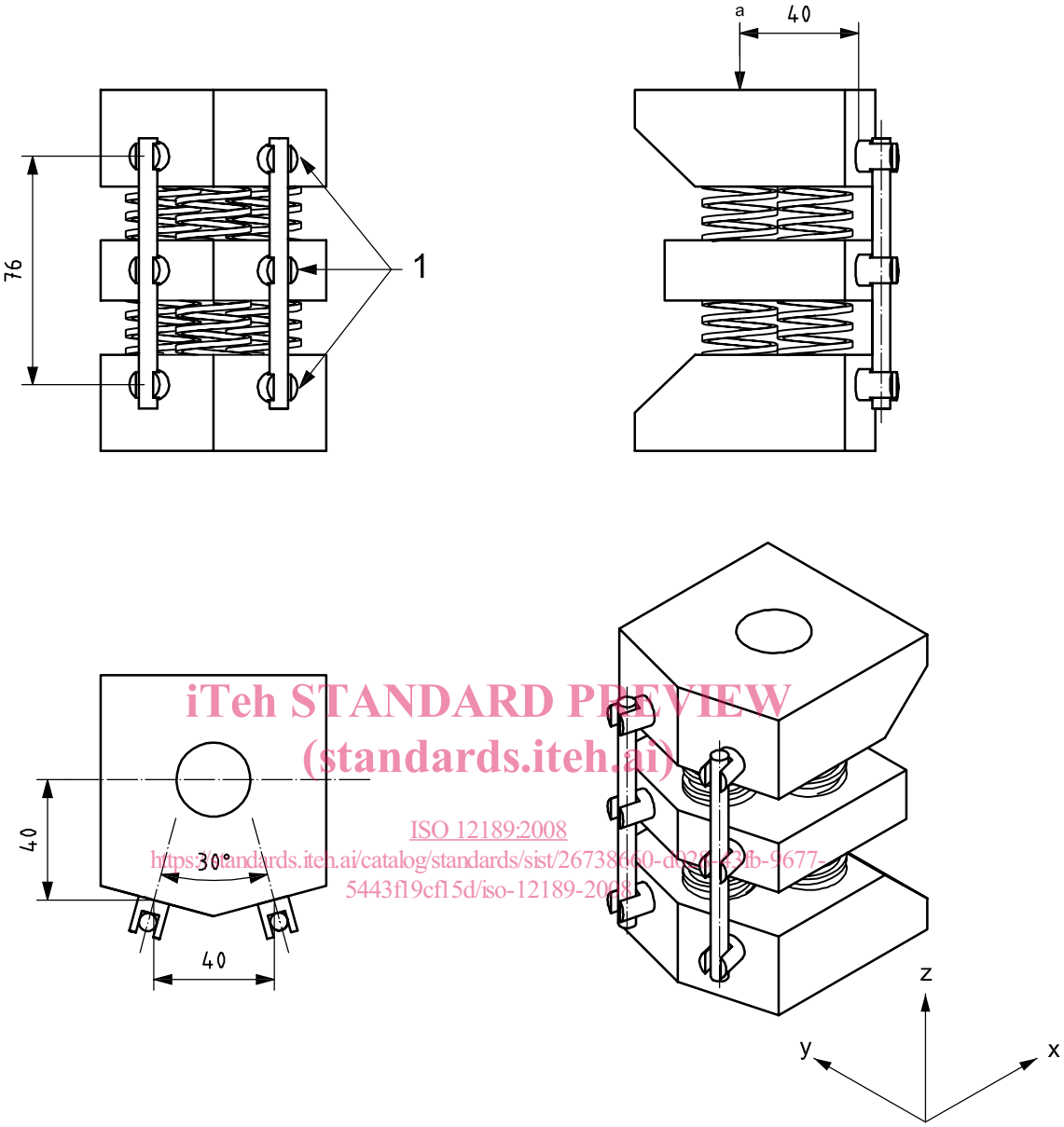
4 Principle

The aim of this International Standard is to provide a fatigue test method that allows for testing of spinal devices that are not suited to corpectomy testing.

This protocol is based on the use of modified Ultra-High Molecular Weight Polyethylene (UHMWPE) test blocks (derived from those used in corpectomy or corporectomy testing) and springs (see Figure 1). This test support is composed of test blocks, made of UHMWPE representing vertebrae, and standardized springs representing the intervertebral disc stiffness. The springs are chosen from the “standardized” panel offered by ISO 10243. Then, fatigue tests in flexion compression are performed on the spinal implant construct (see Figure 1) in order to evaluate the spinal implant assembly (fatigue testing).

The insertion points shown in Figure 1 should be adhered to if possible. In situations where the design of the spinal implant assembly or the manufacturer's surgical instructions for installation dictate otherwise, the attachment points may deviate from these dimensions.

Dimensions in millimetres



Key

1 insertion points

a Load.

Figure 1 — A standard lumbar bilateral construct containing rods and screws

5 Reagents and materials

5.1 Fluid test medium (optional)

The use of a simulated body fluid, saline (9 g NaCl per 1 000 ml water), may be considered. In this case, it is necessary (before the fatigue test) to introduce the fluid test medium to completely immerse the contact surfaces of the test spinal implant construct. The temperature of the fluid test medium should be maintained at 37 °C ± 2 °C, and measurements during the tests should be taken at a location representative of the bulk temperature of the fluid.