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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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Contents

Page

Foreword ... iv

Introduction ... v

1 Scope ... 1

2 Normative references ... 1

3 Terms and definitions ... 1

4 Principle ... 2

5 Reagents and materials ... 3
5.1 Fluid test medium (optional) ... 3
5.2 Test specimen ... 4

6 Apparatus ... 8
6.1 Testing machine ... 8
6.2 Means of mounting and enclosing the test specimen ... 8
6.3 Temperature control system (optional) ... 8

7 Procedure ... 8

8 Test report ... 9

9 Accuracy and bias ... 10
9.1 Accuracy ... 10
9.2 Bias ... 10

Bibliography ... 11

Foreword

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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.