

TECHNICAL REPORT

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Implants for surgery — Partial and total hip joint prostheses — Guidance for laboratory evaluation of change of form of bearing surfaces

*Implants chirurgicaux — Prothèses partielle et totale de hanche — Recommandations
pour l'évaluation en laboratoire du changement de forme des surfaces articulaires*



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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.

The main task of ISO technical committees is to prepare International Standards. In exceptional circumstances a technical committee may propose the publication of a technical report of one of the following types:

- type 1, when the necessary support within the technical committee cannot be obtained for the publication of an International Standard, despite repeated efforts;
- type 2, when the subject is still under technical development requiring wider exposure;
- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical reports are accepted for publication directly by ISO Council. Technical reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 9326, which is a technical report of type 2, was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Annex A of this Technical Report is given for information only.

Introduction

A laboratory assessment of the “wear” of an experimental hip joint prosthesis is a critical stage in the development of a design from prototype to production. In materials science, a number of laboratory methods (such as the pin-on-disc method) are commonly used to assess the wear properties of different combinations of materials, but the geometry of the counterfaces, the loads applied, and the conditions are far removed from those that appertain to hip joint prostheses in service. In order to obtain a better representation of conditions *in vivo*, simulators have been devised (see ISO/TR 9325) in which the wear properties of prostheses can be studied.

The evaluation of the amount of wear of a prosthesis in a simulator is complicated principally by three factors:

- a) the amount of wear is usually very small and difficult to quantify with precision;
- b) the changes of form of the bearing surface that take place in the prosthesis during testing may be a combination of true wear and other factors such as creep and other forms of distortion;
- c) the act of making wear measurements during the course of the test can itself affect the surface properties and hence the wear properties of the counterfaces.

These and other factors have to be taken into account in the preparation of standard methods of assessing the wear of hip joint prostheses under test in a hip joint simulator. In addition, the choice of method can often depend on the construction materials, the design of the prosthesis and the data that are being sought from the test. All of the currently available methods of determining wear have some disadvantages, and the reason for preparing this type 2 Technical Report is to highlight the disadvantages and advantages of a number of methods. It is hoped that this will lead to greater awareness of the problems in making measurements and offer greater comparability in the measurements themselves. It is possible that, in due time, the experience gained as a result of the use of this Technical Report will facilitate the preparation of standard methods of measuring wear.