

**Dentistry - Implants - Clinical performance of hand  
torque instruments**

This document is a preview generated by EVS

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11953:2010 sisaldab Euroopa standardi EN ISO 11953:2010 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.08.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.06.2010.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 11953:2010 consists of the English text of the European standard EN ISO 11953:2010.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.08.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 01.06.2010.

The standard is available from Estonian standardisation organisation.

ICS 11.060.15

### Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:  
Aru 10 Tallinn 10317 Eesti; [www.evs.ee](http://www.evs.ee); Telefon: 605 5050; E-post: [info@evs.ee](mailto:info@evs.ee)

### Right to reproduce and distribute belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without permission in writing from Estonian Centre for Standardisation.

If you have any questions about standards copyright, please contact Estonian Centre for Standardisation:  
Aru str 10 Tallinn 10317 Estonia; [www.evs.ee](http://www.evs.ee); Phone: 605 5050; E-mail: [info@evs.ee](mailto:info@evs.ee)

ICS 11.060.15

English Version

**Dentistry - Implants - Clinical performance of hand torque  
instruments (ISO 11953:2010)**

Médecine bucco-dentaire - Implants - Performances  
cliniques des instruments de serrage (ISO 11953:2010)

This European Standard was approved by CEN on 19 May 2010.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Foreword

This document (EN ISO 11953:2010) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

### Endorsement notice

The text of ISO 11953:2010 has been approved by CEN as a EN ISO 11953:2010 without any modification.

## Introduction

Screw-retained joints are used widely in dental implant systems and for their integrity depend on the creation and maintenance of an appropriate clamping force. Failure of such joints is a documented clinical problem that can have significant impact on the outcome of treatment. Manually operated, suitably calibrated torque wrenches or devices are widely employed in dental implant treatment to tighten screwed joints and should be capable of providing the desired torque in a consistent manner. There is, however, some evidence that this might not always be the case. This International Standard has, therefore, been developed to facilitate the availability of devices that meet the necessary clinical requirements and help ensure a successful clinical outcome.

# Dentistry — Implants — Clinical performance of hand torque instruments

## 1 Scope

This International Standard describes a classification system for hand-held torque wrenches intended for clinical use. It specifies their performance requirements in terms of accuracy and reproducibility and resistance to reprocessing. Test methods are described, and marking and labelling requirements are specified. This International Standard does not include electronically controlled devices.

## 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 1942, *Dentistry — Vocabulary*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

## 3 Terms and definitions

For the purposes of this document the terms and definitions given in ISO 1942 and the following apply.

### 3.1

#### **hand torque instrument**

manually operated mechanical device used for the tightening of dental implants or parts of a dental implant system by displaying or limiting the rotational force of the instrument

### 3.2

#### **usage**

sequence of tightening and retightening operations followed by reprocessing (including disassembly, cleaning, disinfection and/or sterilization) in accordance with the manufacturer's instructions

## 4 Classification

### 4.1 General

Screw-retained joints are secured by a clamping force resulting from the amount of tension generated in the screw, each screw having an optimal value. Torque control using a hand torque instrument to which a screwdriver tip is attached, is the most widely used method in implant dentistry. The mechanical devices commonly employed utilize the following methods for torque control.