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

*Médecine bucco-dentaire — Implants — Performances cliniques des
instruments de serrage*

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Foreword

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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.

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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.

4.2 Type 1

These devices have a preset “break” mechanism. The break mechanism design incorporates either a hinge, located close to the central long-axis of the screwdriver tip, or a clutch located around the long-axis of the screwdriver tip. The locking mechanism is held rigidly by a compression spring acting on a cam or a clutch, so designed that at the desired torque it is unlocked, permitting a) flexure or b) slip of the handle (“break point”), and thus indicating to the operator that the desired torque has been achieved. Therefore, the instrument provides both tactile and auditory feedback to the operator.

4.3 Type 2

These devices operate as Type 1 but have an adjustable compression spring which allows the value of the “break” torque to be selected.

4.4 Type 3

These devices have a similar configuration to Type 1, but incorporate a torque beam rather than a “break” mechanism. This beam is deformed linearly in relation to the applied torque, which can be measured by the operator using a scale built into the instrument.

4.5 Type 4

These devices place the torque-limiting mechanism in a casing with an output shaft designed to couple with a customized contra-angle dental handpiece. A suitable screwdriver tip is placed in the handpiece and torque applied by rotating the casing of the torque applicator until the drive is decoupled by the torque-limiting mechanism. Both tactile and auditory feedback is provided.

5 Requirements — Accuracy and reproducibility

The accuracy and reproducibility of the torque at “break” or the indicated torque, when tested in accordance with 6.2, shall lie within the manufacturer's stated specification. For compliance, all values, both initial and after reprocessing, shall lie in that stated range. The number of usages before the device needs recalibrating or discarding shall be stated by the manufacturer. See 7 d).

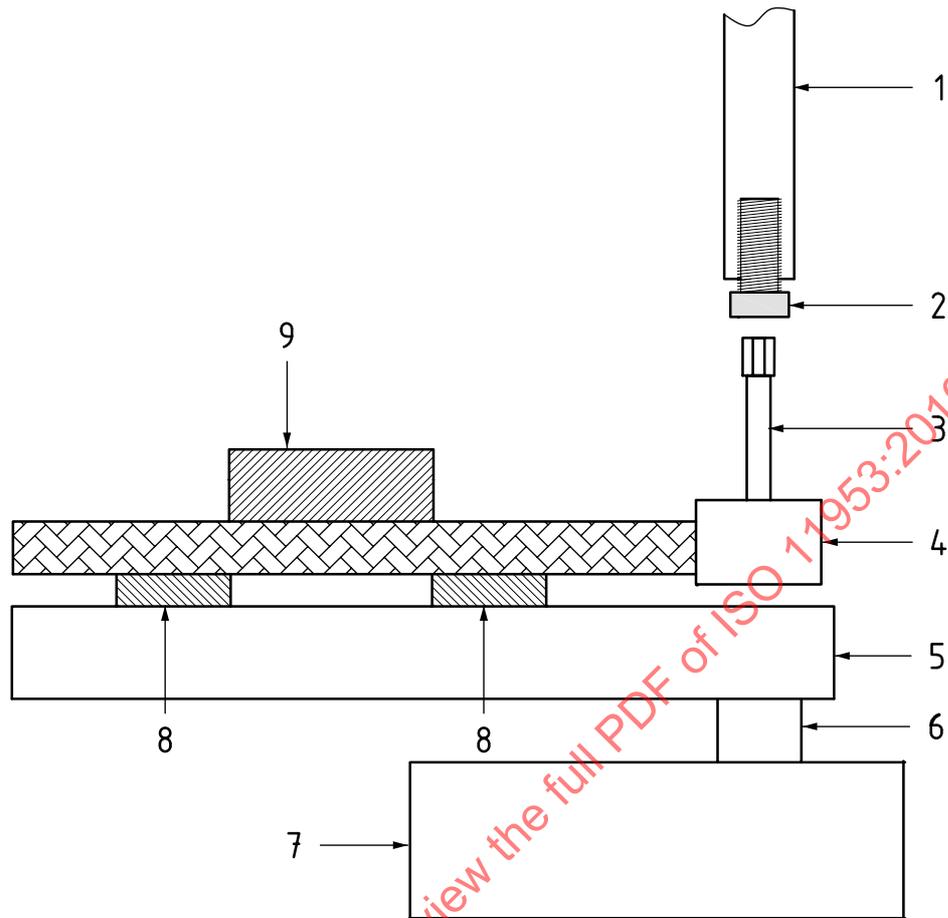
6 Test methods

6.1 Apparatus

6.1.1 Test rig

Examples of test rigs suitable for this purpose are shown in Figures 1 and 2.

For devices incorporating a hinge break mechanism, it is necessary to impart freedom so that a break may occur.

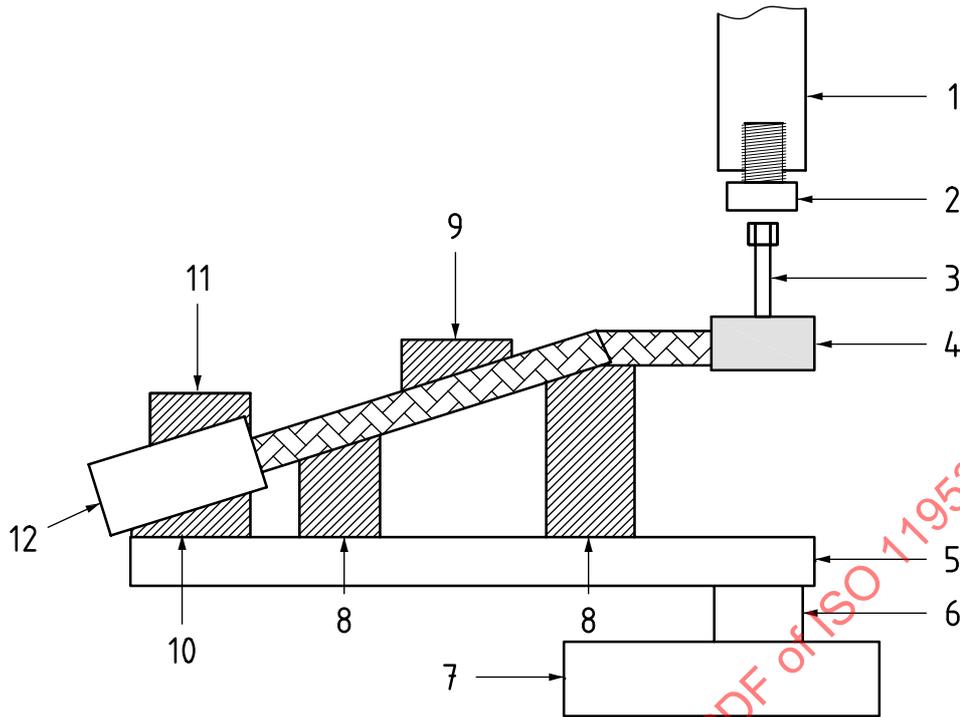


Key

- 1 drive shaft
- 2 prosthetic screw
- 3 screwdriver tip
- 4 tightening device
- 5 support beam
- 6 support shaft
- 7 torque measuring device
- 8 supports
- 9 clamp

NOTE 1 and 2 can be a single unit if desired.

Figure 1 — Test rig: Type 1, 2 and 3 devices



Key

- 1 drive shaft
- 2 prosthetic screw
- 3 screwdriver tip
- 4 contra-angle handpiece
- 5 support beam
- 6 support shaft
- 7 torque measuring device
- 8 handpiece supports
- 9 handpiece clamp
- 10 torque applicator support
- 11 torque applicator clamp
- 12 torque applicator

Figure 2 — Test rig: Type 4 devices

The two principal components are:

- a) a horizontal support beam (5) secured on a vertical support shaft (6) which is free to rotate around its central vertical axis. The bearings in which the shaft rotates shall be capable of withstanding vertical loads of 20 N;
- b) a torque measuring device (7) mounted on the support shaft, which imparts a rotational stiffness to the assembly similar to that of an integrated dental implant. This device shall be capable of measuring the torque with an accuracy of $0,1 \text{ N}\cdot\text{cm} \pm 5 \%$.

The test rig shall be calibrated and the accuracy of the assembly validated both before and after each test series.

The tightening device (4) is secured horizontally to the support beam by means of supports (8) and a clamp (9) so that with a screwdriver tip (3) in place it shall be aligned vertically upwards and concentric with the central long axis of the support shaft (6). For Type 4 devices the drive sleeve of the torque limiting mechanism shall be secured so as to prevent its rotation relative to the handpiece.

A vertical (drive) shaft (1) is arranged so that its central long axis is concentric with that of the support shaft and is capable of rotation up to $0,25 \text{ s}^{-1}$ (15 r/min) to simulate clinical use. This shaft has a mechanism for holding a prosthetic screw (2) concentric with its long axis. The mounting for the vertical shaft may be moved vertically so that its central long axis remains concentric with that of the support shaft. The screwdriver tip shall be subjected in function to a downward force of $10 \pm 1 \text{ N}$.

The test rig shall be equipped with a mechanism to stop the rotation of the drive shaft at a torque in excess of the target torque level. This torque is dependent on the design of the tightening device and shall be set as follows:

- **Type 1:** at a minimum level so as to consistently cease rotation of the drive shaft immediately after the break action;
- **Type 2:** at a level in accordance with the manufacturer's instructions, using hand-held magnification (2×) to read the scale;
- **Type 3:** at a level in accordance with the manufacturer's instructions, using an electrical contact to provide control of the tightening system by detection of the indicated torque;
- **Type 4:** at a minimum level so as to consistently cease rotation of the drive shaft immediately after the break action.

6.1.2 Prosthetic screw

The prosthetic screw shall be as supplied by the manufacturer for use with the screwdriver tip employed in the test rig. Where the screw and drive shaft are a single unit, the features that are designed to engage with the screwdriver tip shall be of the same dimensions as those of the prosthetic screw as supplied by the manufacturer.

6.1.3 Screwdriver tip

The screwdriver tip shall be as supplied by the manufacturer for use with the hand torque instrument being tested.

6.2 Test procedure

6.2.1 Mechanical test

6.2.1.1 Type 1 and Type 4 devices

Fit the tightening device and apply it to the prosthetic screw. Rotate it until the desired torque has been reached. Counter-rotate the drive shaft until the instrument is unloaded and then re-tighten. Repeat the tightening/torque-releasing sequence twenty times (or as deemed appropriate) and record the torque achieved at the break point at the end of each sequence. Repeat in accordance with 6.2.2.

6.2.1.2 Type 2 and Type 3 devices

Carry out the procedure as for Type 1 devices at the minimum and the maximum torque settings as stated by the manufacturer. In the case of Type 3 (torque beam) devices this is the point at which the scale indicates the desired torque, as derived from the closing of the electrical contact.