

International Standard



8319/2

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Orthopaedic instruments — Drive connections — Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws

Instruments orthopédiques — Raccords d'entraînement — Partie 2: Tournevis pour vis à tête fendue, à empreinte en croix et à empreinte cruciforme

First edition — 1986-10-15

STANDARDSISO.COM : Click to view the full PDF of ISO 8319-2:1986

UDC 621.883.7 : 615.465

Ref. No. ISO 8319/2-1986 (E)

Descriptors : medical equipment, surgical implants, screwed connections, slotted head screws, cross recessed screws, surgical equipment, screwdrivers, specifications, dimensions, dimensional tolerances, tests, torsion tests, test equipment, marking.

Price based on 8 pages

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8319/2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Orthopaedic instruments — Drive connections — Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws

0 Introduction

Essential requirements for all varieties of screwdrivers are the following:

- the point should accurately engage the head of the screw;
- the materials used for the manufacture of the blade should be satisfactory from all clinical aspects;
- the screwdriver should have adequate strength.

The purpose of this part of ISO 8319 is to ensure that this is achieved without imposing undue restriction on design features.

1 Scope and field of application

This part of ISO 8319 specifies requirements for screwdrivers used in orthopaedic surgery for inserting and removing bone

screws with single slot heads, with cruciate slot or cross-recessed heads.

Screwdrivers specified in this part of ISO 8319 are suitable for use with screws which conform to ISO 9268.

2 References

ISO 683/13, *Heat-treated steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

ISO 2380, *Screwdriver blades for slotted head screws.*¹⁾

ISO 5832/5, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

ISO 6508, *Metallic materials — Hardness test — Rockwell test (scales A — B — C — D — E — F — G — H — K).*²⁾

ISO 9268, *Implants for surgery — Metal bone screws — Dimensions — Screws with conical under-surfaces.*³⁾

1) At present at the stage of draft. (Revision of ISO 2380-1979.)

2) At present at the stage of draft. (Revision of ISO/R 80-1968 and ISO 2713-1973.)

3) At present at the stage of draft. (Revision of ISO/DIS 5835/3 and ISO 5835/4-1983.) See the annex for information on the interrelationship between International Standards dealing with bone screws, bone plates and relevant tools.

3 Designs and dimensions

3.1 Screwdrivers for single slot head screws

3.1.1 Hand screwdrivers

Hand screwdrivers for single slot head screws shall either have a bit as shown in figure 1 and dimensions in accordance with table 1 or have a bit in accordance with 3.1.2.

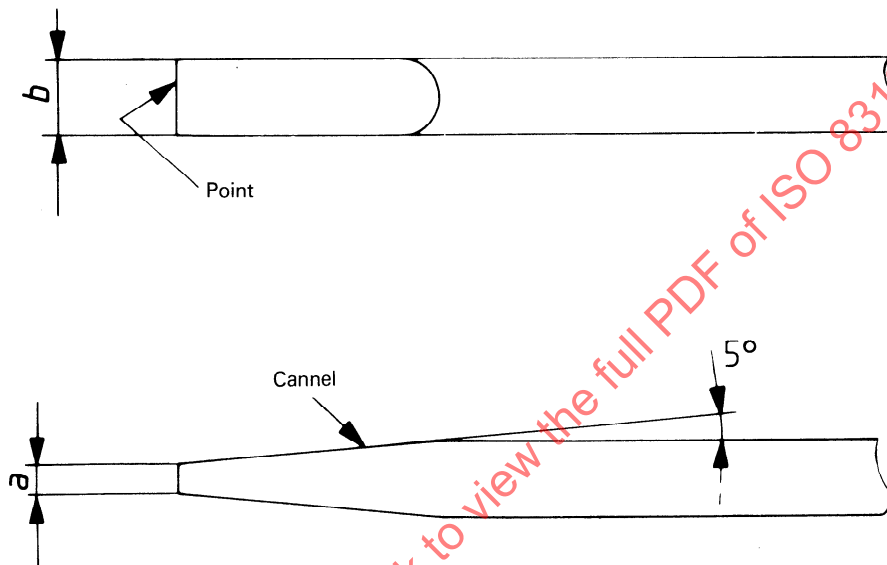


Figure 1 — Hand screwdriver bit for single slot head screws

3.1.2 Power-driven screwdrivers

Power-driven screwdrivers for single slot head screws shall have a bit as shown in figure 2 and dimensions in accordance with table 1.

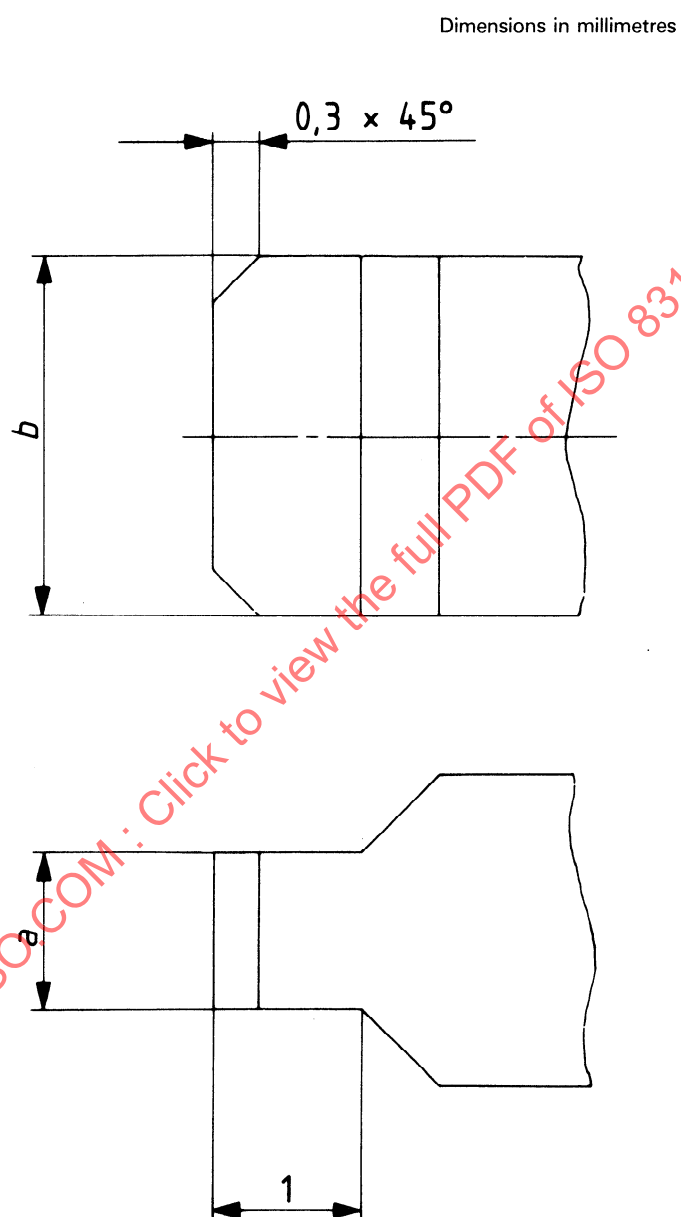


Figure 2 — Power-driven screwdriver bit for single slot head screws

3.2 Screwdrivers for screws with cruciate slot

Screwdrivers for screws with cruciate slot shall have a bit as shown in figure 3 and dimensions in accordance with table 1.

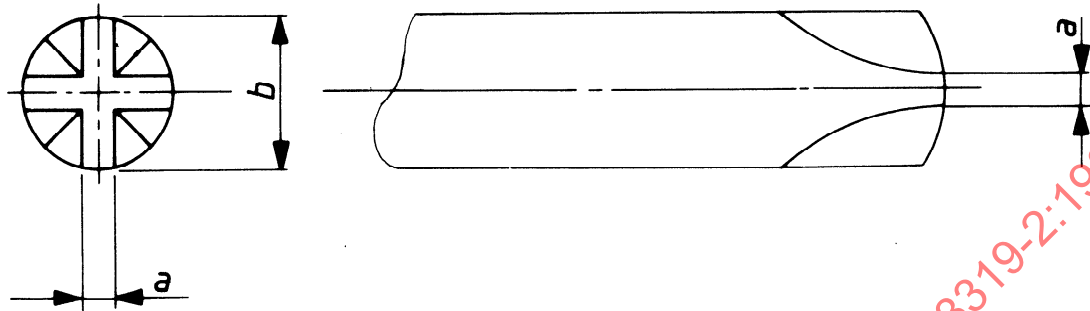


Figure 3 — Screwdriver for screws with cruciate slot

Table 1 — Dimensions of screwdriver bit

Dimensions in millimetres

Screwdriver bits		
Thickness a +0,03 -0,07	Width b max.	Screws in accordance with ISO 9268
1,1	4,8	
1,1	5,6	

3.3 Screwdrivers for cross-recessed head screws¹⁾

Screwdrivers for cross-recessed head screws shall have a bit as shown in figure 4 and dimensions in accordance with figure 4.

Dimensions in millimetres

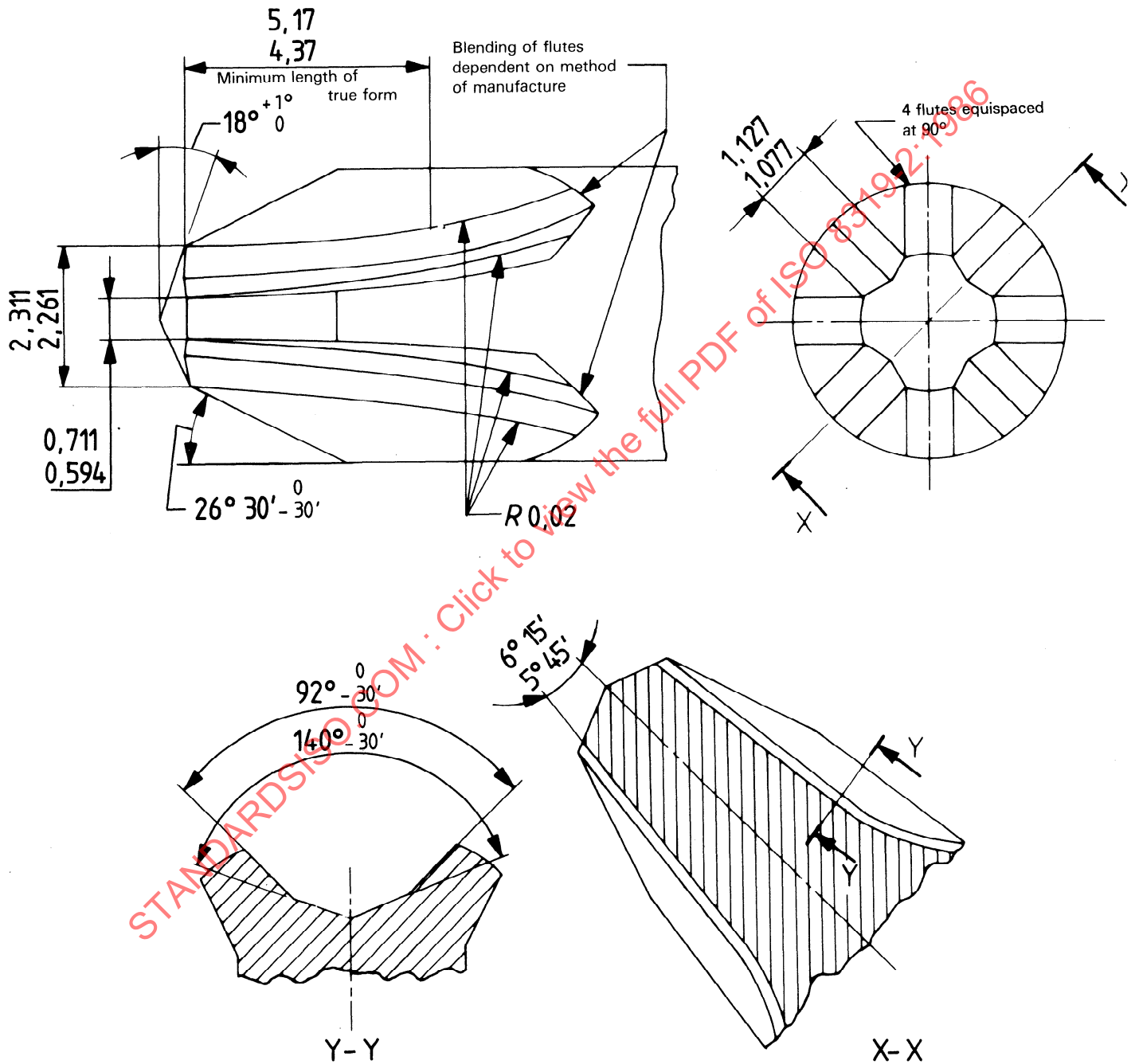


Figure 4 — Screwdriver bit for cross-recessed head screw

1) These screws are also widely known as "modified Phillips screws".

4 Materials and grades

Screwdriver blades shall be made of one of the following metals:

- a) martensitic stainless steel (for example, in accordance with grade 5, 6 or 6a of ISO 683/13);
- b) cold-worked wrought cobalt-chromium-tungsten-nickel alloy in accordance with ISO 5832/5.

5 Performance requirements

5.1 Hardness

The Rockwell hardness shall be within the range given in table 2 when tested in accordance with ISO 6508.

Table 2 — Hardness of screwdriver blades

Material	Rockwell hardness HRC
Stainless steel	48 to 54
Wrought cobalt-chromium-tungsten-nickel alloy	48 to 50

5.2 Torque test

5.2.1 Screwdrivers for single slot head screws

The screwdriver blade shall meet the test conditions laid down in ISO 2380 and the blade-to-handle connection shall withstand the appropriate test torque specified in ISO 2380.

5.2.2 Screwdrivers for screws with cruciate slot

The screwdriver blade shall meet the test conditions as laid down in 5.2.1; however, the test disc used shall comprise two slots that bisect each other at right angles.

The dimensions and tolerances of the slots and the characteristics of the test disc shall be in accordance with ISO 2380.

5.2.3 Screwdrivers for cross-recessed head screws

The screwdriver shall be capable of satisfying the requirements of the test given in 5.2.3.1 and 5.2.3.2.

NOTE — The test is to be carried out in two stages, the first (see 5.2.3.1) being on the screwdriver blade or screwdriver bit with the handle not fitted for the test. The second stage (see 5.2.3.2) includes the handle, which in this case, is used for the application of torque, thus checking the soundness of the grip of the handle on the blade.

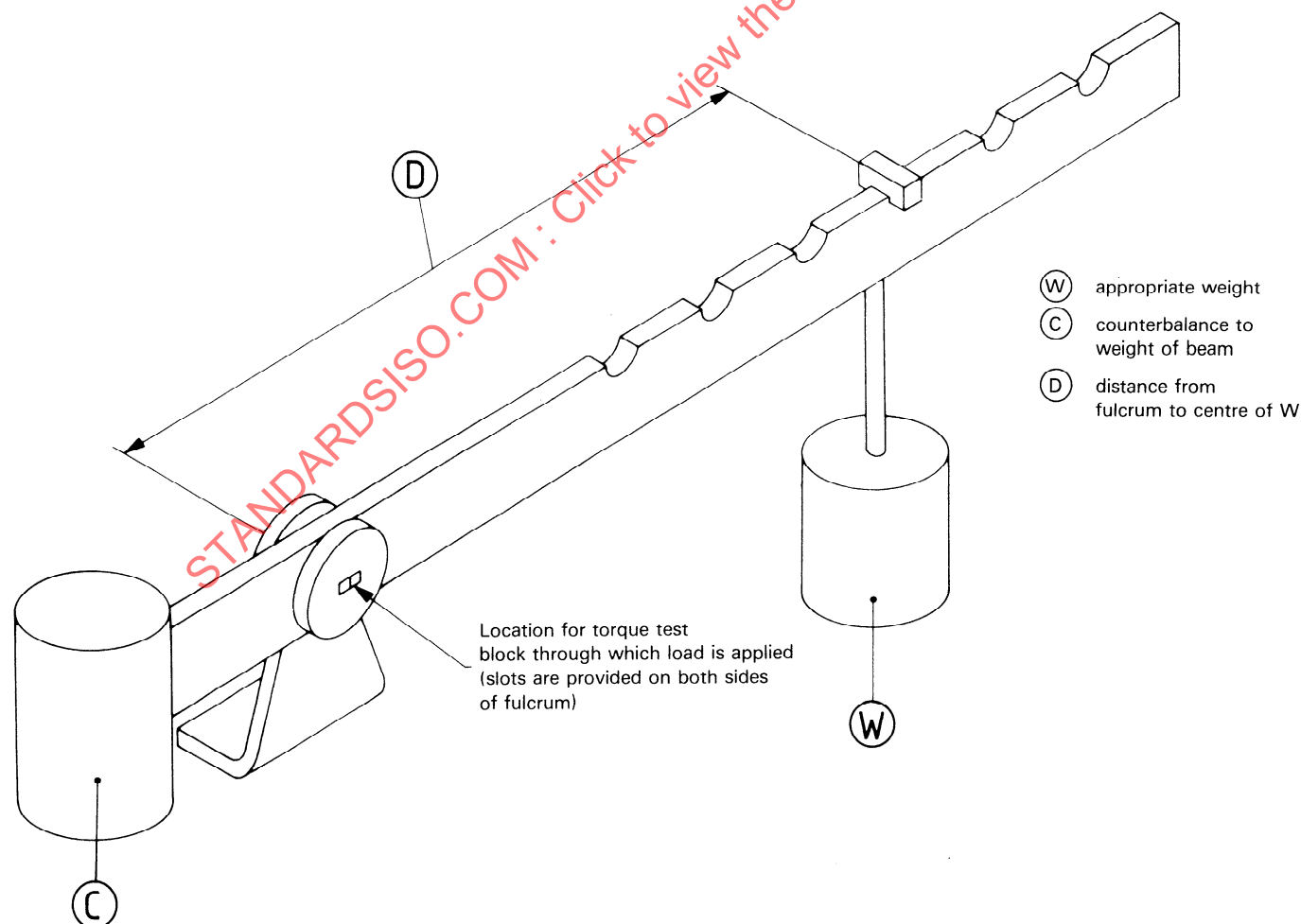


Figure 5 — Diagrammatic representation of the principle of a torque-testing device

5.2.3.1 Blades and bits

Grip the screwdriver blade or bit in a pair of jaws in the tailstock of a torque-testing device (see figure 5).

Fit the headstock of the machine with a die which complies with the requirements of figure 6.

Apply a torque of 9,7 N·m.

Following the application of the minimum test torque, the screwdriver shall not fracture or show permanent deformation.

5.2.3.2 Screwdrivers complete with handles

After the test specified in 5.2.3.1 has been completed on the screwdriver blade, fit the handle and carry out the following test.

Apply a torque of at least 9,7 N·m through the handle.

Following the application of the minimum test torque, no sign either of any loosening of the grip of the handle on the blade or of other damage shall become apparent.

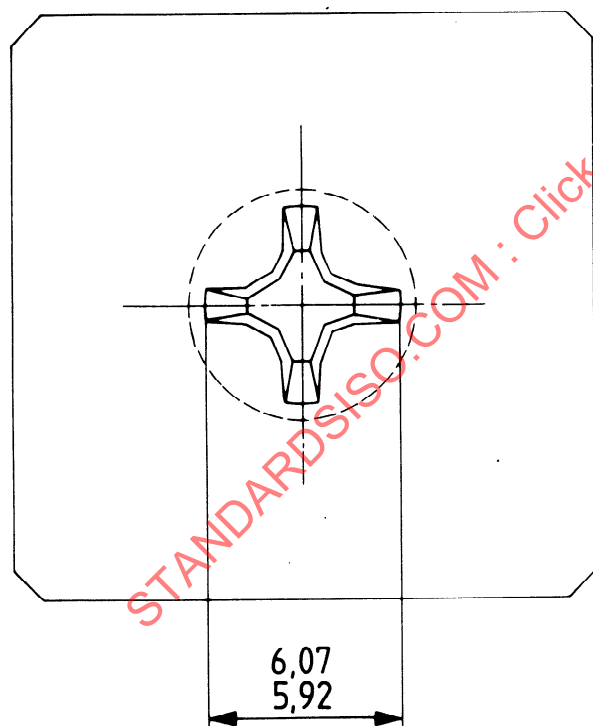
NOTE — Shape and outside dimensions of the testing die should be suitable for the torque-testing device being used.

6 Marking

The screwdriver shall be permanently and legibly marked with the following information:

- the size of the screw (code and thread diameter), in accordance with ISO 9268, with which it is intended to be used;
- the manufacturer's name or trademark;
- the number of this part of ISO 8319, if there is space available;
- the material of which it is made, if there is space available.

Dimensions in millimetres



Screwdriver point number and type number to be stamped on die

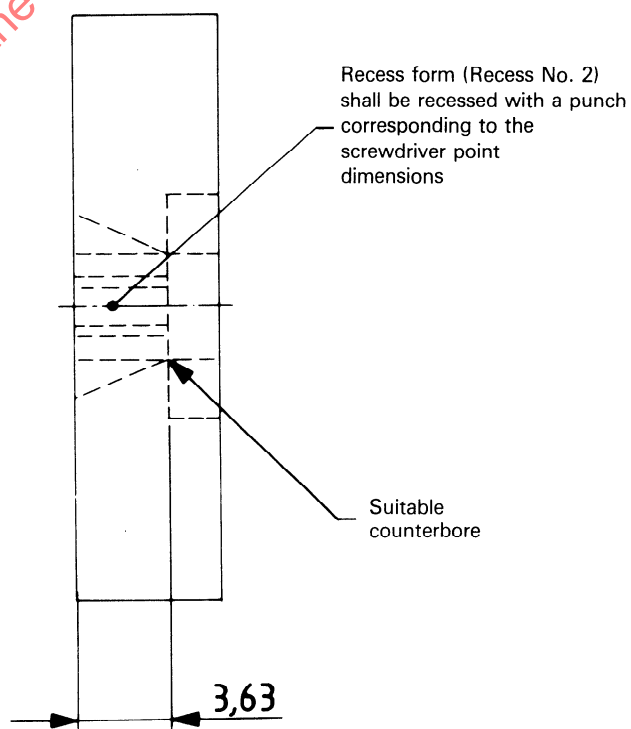


Figure 6 — Torque-testing die for bits for cross-recessed head screws