

2 % (*m/m*) but not in excess of 20 % (*m/m*) shall be within 1 % (*m/m*) of the value stated [see clause 8 b) and 9.2 d)]. The percentage of nickel shall not be greater than the percentage indicated on the package label or insert (see clause 8).

Other compositions with cobalt as the basic metallic element may be permissible subject to approval by regulatory authorities (see the Introduction). For such alloys, all alloying elements with more than 0,1 % (*m/m*) shall be given on the package or in the accompanying literature.

#### 4.2 Biocompatibility

See the Introduction for guidance on biocompatibility.

#### 4.3 Corrosion resistance

See the Introduction for guidance on corrosion resistance.

Testing shall be in accordance with annex A. The total of the mean aggregate quantity of ions released shall be reported as specified in A.3.

#### 4.4 Mechanical properties

When tested in accordance with 7.3 and 7.4, the mechanical properties of the alloy shall comply with table 1.

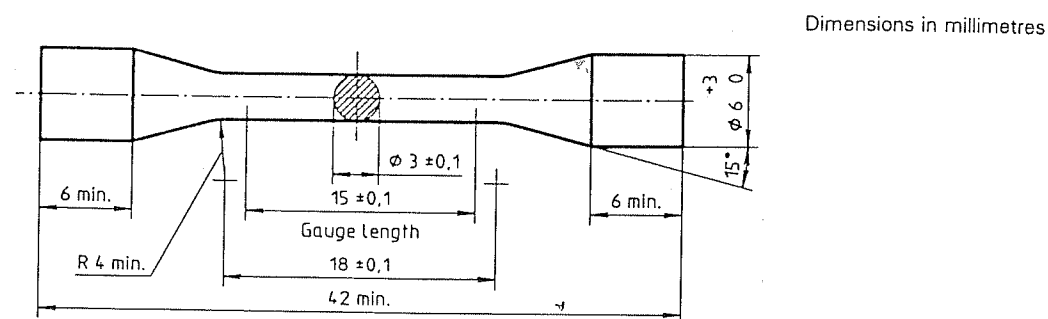


Figure 1 — Test specimen with conical shoulders

Proof stress of non-proportional elongation, $R_{p0,2}$	Percentage elongation after fracture
MPa	%
min.	min.
500	3,0

#### 5 Sampling

The sample shall be adequate to prepare the specimens required for 6.2 and A.1, and shall be from one batch.

Further sample and packaging shall be made available for visual inspection and analytical procedures in accordance with 7.1 and 7.2.

#### 6 Preparation of test specimens

##### 6.1 General

Prepare the test specimens by the lost wax process of investment casting generally used in a dental laboratory, following the manufacturer's instructions for use.

Cleanly separate the test specimens from sprues, freed of casting beads, parting lines and surface impurities and then grit blast the specimens.

Replace any test specimens with visible defects.

##### 6.2 Specimens for mechanical properties

Prepare six test specimens in accordance with figure 1 or 2.

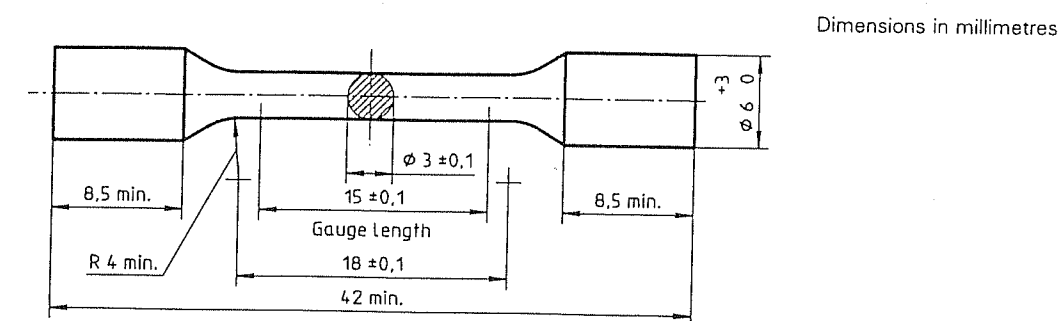


Figure 2 — Test specimen with radius shoulders

#### 7 Testing

##### 7.1 Visual inspection

Visually inspect the specimens to check that the requirements specified in clauses 8 and 9 have been met.

##### 7.2 Analytical procedures

Recognized analytical procedures shall be used in determining the composition (ISO methods where these exist).

##### 7.3 Proof stress of non-proportional elongation

Determine the 0,2 % proof stress of non-proportional elongation in accordance with ISO 6892 on test specimens (see 6.2), cast and conditioned in accordance with 6.1. Load the test specimens in a universal mechanical testing instrument at a cross-head speed of  $(1,5 \pm 0,5) \text{ mm min}^{-1}$  up to the fracture point of the specimens.

If less than four specimens comply with the requirements in table 1, take another full set of specimens and repeat the test. If less than four specimens of the new set comply, reject the alloy.

For reporting calculate the value for proof stress as the mean of the values from those four, five or six specimens of the one set which are found to comply with the requirements in table 1.

##### 7.4 Percentage elongation after fracture

Determine the percentage elongation after fracture in accordance with ISO 6892.

If less than four specimens comply with the requirements in table 1, take another full set of specimens

and repeat the test. If less than four specimens of the new set comply, reject the alloy.

For reporting calculate the value for elongation as the mean of the values from those four, five or six specimens of the one set which are found to comply with the requirements in table 1.

At least four of these specimens shall also comply with the proof stress requirement in table 1.

#### 8 Information and instructions

The following information shall be in the package or be supplied with it:

- the alloy's intended use given in unambiguous language;
- a list of all the elements present and their percentage concentration (*m/m*) if present in concentrations equal to or greater than 2 %;
- density in grams per cubic centimetre;
- 0,2 % proof stress in megapascals;
- modulus of elasticity in gigapascals;
- percentage elongation after fracture;
- Vickers hardness;
- solidus and liquidus temperatures (melting range) in degrees Celsius;
- processing instructions.

If the alloy contains more than 0,1 % (*m/m*) of nickel or other hazardous elements, this shall be clearly stated on the package, and adequately detailed instructions regarding precautions shall be given in the package or accompanying literature. Alloys with less

than 0,1 % (m/m) of nickel may be described as nickel-free.

## 9 Marking

### 9.1 Casting ingots

The casting ingots or other forms in which the alloys are supplied shall be clearly marked to identify the alloy. Dental casting alloys in accordance with this part of ISO 6871 shall be supplied in a form and size suitable for crucibles in a dental investment casting process and in a stable container.

### 9.2 Packaging

The packaging shall be clearly labelled with the following information:

a) the manufacturer's and/or distributor's name and address;

- b) trade- or brand-name of the alloy;
- c) the alloy's intended use given in unambiguous language;
- d) the three principal constituents of the alloy and their percentage by mass;
- e) batch number: each package shall be provided with a serial number or letter/number combination related to the manufacturer's records for the particular batch which shall permit positive identification;
- f) net mass in grams;
- g) a **WARNING** if the alloy contains more than 1 % (m/m) of nickel or any other hazardous elements. The warning shall also name the elements and state the percentage by mass in which they are present.