



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0315-2023

Wrought titanium and titanium alloy dental implant

钛及钛合金牙种植体

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1 Scope

YY 0315 is the mandatory Chinese standard for dental implants made of wrought titanium and titanium alloy, the screws placed in the jaw to carry a crown or a bridge. Being a YY standard without the /T suffix, compliance is compulsory in China. It sets the requirements such an implant has to meet and the test methods that verify them, covering the material the implant is made from, its mechanical strength, the state of its surface and the marking and information that accompany it. Dental implants are among the fastest-growing device categories in China and among the most closely reviewed, since the product is load-bearing, permanently implanted and sold in very large volumes. The 2023 edition takes effect in December 2026, which is the date a manufacturer planning to keep or obtain a Chinese registration has to work back from.

This Document specifies the performance requirements, packaging, labeling, and instructions for use of uncoated dental implants made of wrought titanium and titanium alloys; and describes the corresponding test methods. This Document applies to dental implants made of titanium and titanium alloys with chemical compositions conforming to GB/T 13810, ISO 5832-2, ISO 5832-3, ISO 5832-11, or ASTM F67, ASTM F136, ASTM F1295, and ASTM F1472 for surgical implants. This Document does not apply to dental

implant accessories and additively manufactured titanium and titanium alloy dental implants.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB/T 1804 General tolerances - Tolerances for linear and angular dimensions without individual tolerance indications

GB/T 4698 (all parts) Methods for chemical analysis of titanium sponge, titanium and titanium alloys

GB/T 9937 Dentistry - Vocabulary

GB/T 13810-2017 Wrought titanium and titanium alloy for surgical implants

YY/T 0343 Liquid penetrant inspection of metallic surgical implants

YY/T 0521 Dentistry - Implants - Dynamic fatigue test for endosseous dental implants

YY/T 1619 Dentistry - Vocabulary for dental implants systems and related procedure
Pharmacopoeia of the People's Republic of China (2020 Edition) ISO 5832-

3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in GB/T 9937 and YY/T 1619 and the following apply.

3.1 Implant neck The portion of the dental implant that crosses the gum line. NOTE.
Applicable to dental implants at the soft tissue level.

4 Materials

The technical indicators of materials used in the fabrication of titanium and titanium alloy dental implants shall comply with the relevant provisions of GB/T 13810, ISO 5832-2, ISO 5832-3, ISO 5832-11, ASTM F67, ASTM F136, ASTM F1295, and ASTM F1472 concerning titanium and titanium alloy materials for surgical implants.

5.1 Chemical properties

5.1.1 For dental implants without special surface treatment, according to the test in 6.1.1.1, the chemical composition of titanium and titanium alloy dental implants shall comply with the relevant provisions of GB/T 13810, ISO 5832-2, ISO 5832-3, ISO 5832-11, or ASTM

F67, ASTM F136, ASTM F1295, and ASTM F1472 concerning the chemical composition of titanium and titanium alloy materials for surgical implants.

5.1.2 For dental implants with special surface treatment, the surface chemical composition shall comply with the detailed information provided by the manufacturer, as tested in 6.1.2. The chemical composition of the dental implant matrix, according to test in 6.1.1, shall comply with the relevant provisions of GB/T 13810, ISO 5832-2, ISO 5832-3, ISO 5832-11, or ASTM F67, ASTM F136, ASTM F1295, and ASTM F1472 concerning the chemical composition of titanium and titanium alloy materials for surgical implants.

5.2 Microstructure According to test in 6.2, the microstructure of the dental implant shall comply with the relevant provisions of

3.3.3.5 in GB/T 13810-2017. The grain size shall comply with the relevant provisions of 3.3.3.6 in GB/T 13810-2017.

5.3 Dimensions

5.3.1 Geometric dimensions of each part According to the test in 6.3.2.1, the length and diameter tolerances of the dental implant are $\pm$

0.2 mm. Angular tolerances shall conform to the precision tolerance grades for angles specified in GB/T 1804. The cone angle shall conform to the specifications in Table 1.

5.3.2 Fit between dental implant and implant abutment

5.3.2.1 Fit at the implant connection According to the test in 6.3.2.2.1, the connection between the dental implant and the implant abutment shall fit well.

5.3.2.2 Clearance between dental implant and implant abutment According to the test in 6.3.2.2.2, the clearance between the dental implant and the implant abutment shall be $\leq$ 0.035 mm.

5.3.2.3 Thread deviation For dental implants with two- or multi-segment threaded connections, the thread designation, nominal diameter, pitch, tolerance grade, and tolerance zone position of the connection threads shall be provided. For example, M1.6x0.35-6H. For non-standard threads, the dimensions and tolerances of the threaded connection shall be provided, such as pitch, major diameter, pitch diameter, and minor diameter. According to the test in 6.3.2.2.3, the thread deviation shall conform to the provisions of the manufacturer.

5.4 Surface properties

5.4.1 Appearance According to the test in 6.4.1, the surface of the dental implant shall be free from macroscopic defects caused by processing, such as scratches, cracks, sharp

edges, burrs, and rolled edges of the threaded joint; and free from foreign matter.

5.4.2 Surface defects According to the test in 6.4.2, the smooth surface of the dental implant shall not have discontinuous defects (such as pore inclusions, looseness, etc.).

5.4.3 Roughness According to the test in 6.4.3, for soft tissue level dental implants, the implant neck shall be a smooth surface with a roughness $R_a \leq 1.6 \mu\text{m}$.

5.5 Cleanliness According to the test in 6.5, the dental implant shall be free from any visible foreign matter.

5.6 Mechanical properties

5.6.1 Torsional resistance According to the test in 6.6.1, under worst-case conditions, the maximum torque between the dental implant and the implant abutment shall meet the following requirements.

- a) External connection $\geq 50 \text{ N}\cdot\text{cm}$;
- b) Internal connection $\geq 70 \text{ N}\cdot\text{cm}$.

5.6.2 Tightening performance According to the test in 6.6.2, after applying the maximum tightening torque, the dental implant and its components shall not exhibit deformation or breakage upon visual inspection. The maximum loosening torque shall be at least 75% of the maximum tightening torque.

5.6.3 Fatigue limit According to the test in 6.6.3, the fatigue limit of the dental implant shall meet the fatigue performance provisions in the technical documents provided by the manufacturer.

5.7 Sterility According to the test in 6.7, when delivered in a sterile condition, the product shall be sterile.

5.8 Bacterial endotoxins According to the test in 6.8, the endotoxin limit for each dental implant shall not exceed

6.1 Chemical properties

6.1.1 Chemical composition of dental implants without special surface treatment Tests shall be conducted in accordance with the relevant provisions of GB/T 4698 (all parts), using atomic absorption spectrometry, and/or general rules of inductively coupled plasma atomic emission spectrometry, or other precise and sensitive analytical methods.

6.1.2 Chemical composition of dental implant surface The chemical composition of the surface of dental implants with special surface treatment can be analyzed using energy dispersive spectroscopy (EDS) or optical spectroscopy.

6.2 Microstructure Microstructure shall be tested according to