

ICS 77.150.50

CCS H 64



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 13810-2017

Replacing GB/T 13810-2007

Wrought titanium and titanium alloys for surgical implants

外科植入物用钛及钛合金加工材

Issued on: October 14, 2017

Implemented on: May 1, 2018

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine;
Standardization Administration of the PRC**

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Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009. This Standard replaces GB/T 13810-2017 "Wrought titanium and titanium alloy for surgical implants". Compared with GB/T 13810-2017, the main technical deviations in this Standard are as follows: - modified TA1ELI, TA1, TA2, TA3, and TA4 to TA1GELI, TA1G, TA2G, TA3G, and TA4G, respectively; - expanded the range of product specifications; - deleted the delivery status of cold rolled (Y) and hot worked (R); - added the requirement that recycled materials are not permitted as raw materials for the production of ingots and processed materials; - deleted the recommended heat treatment system for specimens; - added the requirements for wire yield strength; - modified the requirements for microstructure of sheet; - added the requirements for TA1GELI, TA1G, TA2G, TA3G, TA4G surface contaminations; - modified the ultrasonic testing requirements; - added the requirements for TC20 sheet; - deleted Annex B. This Standard was proposed by China Nonferrous Metals Industry Association. This Standard shall be under the jurisdiction of National Technical Committee on Non-ferrous Metal of Standardization Administration of China (SAC/TC 243). The drafting organizations of this Standard. Bao Ti Group Co., Ltd., Baoji Titanium Industry Co., Ltd., Xi'an Saiteimai Titanium Industry Co., Ltd., Western Metal Materials Co., Ltd., Xi'an Thinking Metal Materials Co., Ltd., Nonferrous Metals Technology and Economic Research Institute. Main drafters of this Standard. Ma Zhongxian, Luo Shuiui, Pang Hong, Yang

Juanli, Feng Junning, Hu Zhijie, Ma Yuanjie, Li Youhua, Li Rong, He Shulin, Chen Zhanqian, Yan Xuebo, Yang Xiaokang, Hou Rui, Xue Sa, Wu Yanhua. Versions of standard substituted by this Standard are. - GB/T 13810-1992, GB/T 13810-1997, GB/T 13810-2007. Wrought titanium and titanium alloy for surgical implants

1 Scope

China's national standard for the wrought titanium and titanium alloy from which surgical implants are made - the bar, wire, plate, sheet and forgings that become hip and knee prostheses, bone plates and screws, spinal instrumentation and dental implants. It specifies the requirements, the test methods, the inspection rules, and the marking, packaging, transport, storage, quality certificate and contract content for wrought titanium and titanium alloys for surgical implants. Titanium is used for implants because of a property no other structural metal shares in the same degree: the oxide film on its surface is so stable and so inert that bone will grow directly against it, and the metal beneath releases almost nothing into the tissue. That is why the requirements here go beyond those of an industrial titanium standard in a particular direction. The chemical composition is controlled more tightly, especially the interstitial elements - oxygen, nitrogen, carbon, hydrogen - which govern the strength and, more importantly, the ductility and the notch sensitivity of the finished implant, and the residual elements that would be released into the body. The mechanical properties are specified for the delivery condition and, since an implant is a fatigue-loaded component that must last decades in a body that cannot easily be reopened, the microstructure is a requirement in its own right rather than a description. To those are added the ultrasonic examination for internal soundness, the surface condition and freedom from contamination and from the alpha case that hot working can leave, the dimensional tolerances, and the traceability - the quality certificate and the contract content clauses being unusually detailed because an implant material has to be traceable to its heat for the life of the device. Issued on 14 October 2017 and in force since 1 May 2018, it replaces GB/T 13810-2007.

This Standard specifies the requirements, test methods, inspection rules as well as marks, packaging, transport, storage, quality certificate and contract (or order) content of wrought titanium and titanium alloy for surgical implants. This Standard is applicable to sheet, bar and wire of wrought titanium and titanium alloy for surgical implants.

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.

GB/T 228.1-2010, Metallic materials - Tensile testing - Part

3.2 Chemical composition

3.2.1 The chemical composition of the product shall comply with the corresponding designations in GB/T 3620.1, of which the hydrogen content shall be no more than 0.008%.

3.3.2 Bar

3.3.2.1 Designation, state and specification The designation, state and specification of the bar shall comply with the provisions of Table 5.

3.3.2.2 Dimensions 3.3.2.2.1 The allowable deviation of the diameter of the bar shall comply with the requirements of Table 6.

3.3.2.4 Macrostructure Layering, cracking, porosity, shrinkage, metal or non-metallic inclusions and other visible metallurgical defects are not permitted on macrostructure of bars.

4 Test methods

4.1 Conduct the chemical composition analysis according to GB/T 4698.

4.2 Measure dimensions with tools of corresponding appropriate accuracy.

4.3 Tensile properties at room temperature are carried out according to GB/T 228.1-2010. The specimen shall comply with the requirements of Table 11.

4.4 Bending performance is according to GB/T 232. The specimen width is 15mm.

4.5 The macrostructure is in accordance with GB/T 5168.

4.6 The microstructure is tested according to GB/T 5168 and at 200 times.

4.11 Surface quality is checked visually.

5.1 Inspection and acceptance

5.2 Batching Products shall be submitted for acceptance in batches. Each batch of products shall consist of the products of the same designation, same smelting furnace number, same specifications, same manufacturing method, same heat treatment furnace batch.

5.3 Inspection items and sampling The inspection items and sampling of the products shall comply with the requirements of Table 12.

5.4 Determination of inspection results

5.4.1 When the chemical composition test result is unqualified, it shall allow to perform a re-inspection for the unqualified element. Should the re-inspection still fail, this batch of products shall be unqualified.

5.4.2 In the tensile properties, bending properties, microstructure, grain size and surface contamination tests, if the test results of one specimen fail, it shall take the specimens double the number from this batch of products for the re- inspection of unqualified item. Should the re-inspection still fail, this batch of products shall be unqualified.

5.4.3 The determination of macrostructure shall comply with the provisions of 5.4.3.1 and 5.4.3.2.

6 Marks, packaging, transport and quality certificate

6.1 Product marks The following marks (or labels) shall be made on the products that pass the inspection.

6.2 Packaging, marks, transport and storage The product packaging, marks, transport and storage shall comply with the provisions of GB/T 8180.

6.3 Quality certificate Each batch of products shall be attached with quality certificate, indicating.