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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.40

C 35

YY/T 1141-2017

Replacing YY/T 91141-1999, YY 91071~91073-1999

General technique requirements for osteotome

骨凿通用技术条件

Issued on: September 25, 2017

Implemented on: October 1, 2018

Issued by: China Food and Drug Administration

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Foreword

This Standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces YY/T 91141-1999 “General technical conditions for osteotomes”, YY 91071-1999 “Osteotomes”, YY 91072-1999 “Gouges”, and YY 91073-1999 “Methods of test for cutting performance of chisels - Osteotomes Gouges”. As compared with YY/T 91141-1999, YY 91071-1999, YY 91072-1999, and YY 91073-1999, the main technical changes are as follows:

- MODIFY the requirements for material of osteotome;
- MODIFY hardness requirements;
- DELETE the surface finish requirement of osteotome, and CHANGE to the surface roughness requirement;
- MODIFY the use performance method of osteotome;
- DELETE the requirements for inspection rules, packaging, transport, and storage.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority of this document shall not be held responsible for identifying any or all such patent rights.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of National Technical Committee 110 on Implants for Surgery and Orthopedic Devices of Standardization Administration of China (SAC/TC 110).

Drafting organizations of this Standard: Tianjin Medical Device Quality Supervision and Inspection Center, Beijing Fule Science & Technology Development Co., Ltd., Naton Intl. Orthopaedic Research Center.

Main drafters of this Standard: Zhang Zhenghui, Zhang Wenhui, Qiu Wanyu, Guo Zixue, Jiang Yao, Li Renyao.

This Standard replaces YY/T 91141-1999, YY 91071~91073-1999.

The previous versions of YY/T 91141-1999 were released as follows:

- WS 2-302-1983, YY/T 91141-1999.

General technique requirements for osteotome

1 Scope

This Standard specifies the type and basic dimensions, material, requirements, test methods, and marking of osteotome.

This Standard applies to surgical instruments used in orthopedic chisel.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the versions with the dates indicated are applicable to this document. For the undated references, the latest version (including all the amendments) are applicable to this document.

GB/T 230.1-2004 Metallic Rockwell hardness test - Part 1: Test method (scales A, B, C, D, E, F, G, H, K, N, T)

GB/T 1220 Stainless steel bars

GB/T 4340.1 Metallic materials - Vickers hardness test - Part 1: Test method

GB/T 10610 Geometrical product specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture

YY/T 0149-2006 Medical instruments of stainless steel - Test methods of corrosion resistance

YY/T 0294.1 Surgical instruments - Metallic materials - Part 1: Stainless steel

YY/T 1052 Marking requirements for surgical instruments

3 Terms and definitions

The following terms and definitions are applicable to this document.

3.1 Osteotome

A chisel tool used to cut bones in orthopedic surgery.

4 Requirements

4.3.1.2.2 Gouge with bent head

When the head diameter is 6 mm or 8 mm, APPLY to the test piece with an acting force of 14000 N (test material with a hardness of not less than 28 HV1 or higher hardness, such as a flat fuse of 40 mm×15 mm×3.2 mm); the cutting depth shall be ≥1.9 mm.

When the head diameter is 10 mm or 12 mm, APPLY to the test piece with an acting force of 14000 N (test material with a hardness of not less than 28 HV1 or higher hardness, such as a flat fuse of 40 mm×15 mm×3.2 mm); the cutting depth shall be ≥1.7 mm.

4.3.2 Osteotome strength

The cutting edge of osteotome shall have good chiseling performance. The osteotome is hammered 10 times with a 1180 g drop hammer falling from a height of 260 mm. After chiseling, there shall be no curved blade or broken blade.

4.4 Hardness

The hardness of the head of osteotome shall not be less than 35 HRC or 350 HV10. The enterprise shall also specify the maximum hardness.

4.5 Dimensions

It shall comply with the technique requirements of the product.

4.6 Corrosion resistance

It shall not be lower than the requirements of Grade b of boiling water test method for corrosion resistance of medical instruments of stainless steel in YY/T 0149-2006.

5 Test methods

5.1 Material

The chemical composition shall be sampled on the final product. The test shall be carried out in accordance with the method specified in the standard of the selected material. It shall comply with the provisions of 4.1.

5.2 Surface quality

5.2.1 It shall be observed by eyesight or touched by hand. It shall meet the requirements of 4.4.1.

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Accountable person and shareholder: Wayne Zheng

About Us (Goodwill, Policies, Fair Trading...): <https://www.chinesestandard.net/AboutUs.aspx>

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: <https://www.linkedin.com/in/waynezhengwenrui/>

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