

ICS 11.040.30
CCS C31

YY

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

YY 1116-2020

Absorbable surgical sutures

可吸收性外科缝线

Issued on: July 1, 2025

Implemented on: March 1, 2021

Issued by: National Medical Products Administration

Table of Contents

- 1 Scope
- 2 Normative references
- 3 Classification of sutures
- 4 Requirements
 - 4.1 Appearance
 - 4.2 Wire diameter
- 5.2 Appendix A,.2010 Edition
- 5.3 And 5.4, and

Foreword

4.6.3 water content of this standard is a recommended clause, and other technical content is a mandatory clause. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY 1116-2010 "Absorbable Surgical Sutures". Except for editorial changes, the main technical changes are as follows:

- The non-applicable scope of the standard has been increased (see Chapter 1);
- Modified the suture classification (see Chapter 3, Chapter 3 of the.2010 edition);
- Modified the requirements of appearance (see 4.1.1, 4.1.1 of.2010 edition);
- Added the expression of the single value of the converted wire diameter (see Table 2,.2010 version 5.2.3);
- Modified the names of breaking strength and connection strength (see 4.3 and 4.4, the.2010 edition of
- Deleted the needle requirement (see 4.4.2 of the.2010 edition);
- Modified the requirement of suture length (see 4.5, 4.5 in.2010 edition);
- The water content requirements have been revised (see 4.6.3, 4.6.3 of the.2010 edition);

1 Scope

YY 1116 is the mandatory Chinese standard for absorbable surgical sutures, the synthetic and natural sutures that hold a wound while it heals and are then broken down by the body. It sets the requirements such sutures have to meet and the test methods that verify them, covering the diameter and its consistency, the straight-pull and knot-pull tensile strength, the strength retention profile over time in vivo, the absorption behaviour, the needle attachment where supplied armed, and the sterility and packaging. The strength retention curve is the whole design problem: the suture has to hold longer than the tissue takes to heal and disappear soon after. Sutures are manufactured in China in very large volume for export. Being a YY standard without the /T suffix, compliance is compulsory.

YY/T 04666.1 Medical devices used for medical device labeling, marking and information symbols. Part

1.General requirements Pharmacopoeia of the People's Republic of China (2015 Edition-Fourth Edition)

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article. For undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 191 Graphical signs for packaging, storage and transportation

GB/T 6682-2008 Analytical laboratory water specifications and test methods

GB/T 9737-2008 General Rules for the Determination of Easily Carbonized Substances in Chemical Reagents

GB/T 9969 General Rules for Use of Industrial Products

GB/T 14233.1-2008 Medical transfusion, blood transfusion, injection equipment inspection methods Part

GB/T 16886 (all parts) Biological evaluation of medical devices

3 Classification of sutures

3.1 There are two forms of sutures with and without suture needles, both of which are provided in a sterile form.

3.2 Sutures are divided into two categories. Class A and Class B according to manufacturing material, standard, dyeing, structure and coating treatment (see Table 1).

---Class A sutures are made of healthy mammalian collagen. They are available in flat (untreated with chromium salt) and chrome (treated with chromium salt).

---B type suture, made of synthetic polymer material, single strand without or with coating, multiple strands with coating.

4.1 Appearance

4.1.1 The surface of the suture should be smooth, uniform in color, evenly even, no stains, no knots. The surface of multi-strand sutures should be coated.

4.1.2 If the suture has needles, the needle and thread connection should be smooth and free of burrs.

4.2 Wire diameter

4.2.1 The single value of all sutures should be within the range of the single value of the wire diameter of the corresponding specifications specified in Table 2.

4.2.2 The average value of each suture should be within the range of the average value of the wire diameter of the corresponding specifications specified in Table 2.

4.3 Breaking strength The average and single value of the suture breaking strength should...

5.2 Appendix A,.2010 Edition

5.2 and Appendix B);

---Modified the test methods of breaking strength and stitching strength (see Appendix B of

5.3 And 5.4, and

5.4.1 of.2010 edition);

---Modified the soluble compound test method (see 5.6.1.1,.2010 edition of 5.6.1.1);

---Revised the heavy metal test method (see 5.6.2.1,

5.6.2.1 of the.2010 edition);

---Modified the water content test method (see appendix C of 5.6.3,

5.6.3 and appendix C of.2010 edition);

---Modified the fading test method (see Appendix D of 5.6.4,

5.6.4 of.2010 edition);

---Modified the type inspection (see Chapter 6, Chapter 6 of the.2010 edition);

---Revised the label and instructions (see Chapter 7, Chapter 7 of the.2010 edition);

---Modified the suture storage and transportation conditions and validity period (see 8.5,.2010 version of

8.2 and 8.3). Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This standard was proposed by the State Drug Administration. This standard is under the jurisdiction of the National Technical Committee for Standardization of Surgical Instruments (SAC/TC94). Drafting organizations of this standard. Shanghai Pudong Jinhuan Medical Products Co., Ltd., Shanghai Medical Device Testing Institute, Huaiyin Medical Devices Co., Ltd. Co., Ltd., Jiangsu Medical Device Inspection Institute. The main drafters of this standard. Zhang Yanqing, Huang Shuze, Lu Guangheng, Shi Zhigang, Wang Fengcai, Yao Yao, Gao Bai, Shi Yang, Zhang Naiming, Hu Yuwen. The previous editions of the standard replaced by this standard are as follows: