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

YY/T 0965-2025

Replacing YY/T 0965-2014

**Implants for sports medicine - Particular requirements of
artificial ligament**

运动医学植入器械 人工韧带专用要求

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Table of Contents

1.Scope	1
2 Normative References	1
3.Terms and Definitions	1
4.Expected Performance	2
5 Design Attributes	2
6.Materials	2
7 Design Evaluation	3
8.Preclinical evaluation	3
9.Test Methods	4
10 Post-IPO Follow-up	6
11 Manufacturing	6
12 Sterilization	6
13 Appendix D (Normative) Torsional Fatigue Test Method.....	16

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. This document supersedes YY/T 0965-2014 "Specific Requirements for Artificial Ligaments in Passive Surgical Implants" and is consistent with YY/T 0965-2014. Compared to previous versions, aside from structural adjustments and editorial changes, the main technical changes are as follows:

---The scope of application has been changed (see Chapter 1, Chapter 1 of the.2014 edition);

---The normative references have been changed (see Chapter 2, Chapter 2 of the.2014 edition);

---Some terms and definitions have been changed (see Chapter 3, Chapter 3 of the.2014 edition);

---The dimensional requirements and test methods have been changed (see

8.2 and Appendix A,.2014 edition of

8.2 and Appendix A);

---The requirements and test methods for tensile properties have been changed (see 8.3.1, 9.2.1 and Appendix B, 8.3,

9.2 and Appendix B in the.2014 edition);

---The requirements and test methods for fatigue testing have been revised (see 8.3.2, 9.2.2, Appendix C and Appendix D,

9.3 in the.2014 edition). Appendix C and Appendix D);

---The requirements and test methods for chemical properties have been changed (see 8.4, 9.3; 8.5,

1 Scope

YY/T 0965 is the particular requirements standard for the artificial ligament, the synthetic implant used to reconstruct a torn cruciate or other joint ligament. It specifies, for clinical use, the intended performance, the design attributes, the materials, the design evaluation, the preclinical evaluation, the post-market follow-up, the manufacture, the sterilization and the packaging, and it describes the corresponding test methods. The reach is unusual: it runs from the design inputs through to what the manufacturer has to keep watching after the device is on the market, which reflects the history of artificial ligaments as a device class where late failures matter more than early ones. For a manufacturer seeking Chinese registration of a synthetic ligament, this is the standard the whole technical file is measured against, not only the bench testing.

This document specifies the expected performance, design attributes, materials, design evaluation, and clinical application of artificial ligaments used in clinical sports medicine implants. Requirements for pre-clinical evaluation, post-marketing follow-up, manufacturing, sterilization, and packaging are described, along with corresponding test methods. This document applies to textile-type artificial ligaments; other types of artificial ligaments can refer to this document for further information.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 3923.1-2013 Textiles - Tensile properties of fabrics - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 artificial ligaments Made from artificial materials, it possesses the biomechanical strength and function of ligaments, is biocompatible, and can be used to replace human ligament tissue. A structure that facilitates surgical implantation into the human body and allows for fixation. A schematic diagram of an artificial ligament (taking the anterior cruciate ligament as an example) is shown in Figure 1. Index number explanation. 1

---Traction line; 2

---Knitting section; 4

---Free filaments. In clinical use, the traction suture is used to pull the artificial ligament into the bone tunnel; depending on the depth of the patient's bone tunnel, part of the braided portion is fixed within the bone tunnel, while the excess... The braided portion, ends, and traction threads are cut off; the free thread portion is located within the joint cavity. Figure

1. Schematic diagram of artificial ligaments (taking anterior cruciate ligament as an example).