

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

YY/T 1860.1-2024

**Non-active surgical implants - Implant coating - Part 1: General
requirements
(English Translation)**

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Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 Directives

for Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This document is Part 1 of YY/T 1860 Non-active Surgical Implants - Implant Coating. YY/T

1860 has issued the following part.

---Part 1.General Requirements.

This document modifies and adopts ISO 17327-1.2018 Non-active Surgical Implants - Implant

Coating - Part 1.General Requirements.

The technical differences between this document and ISO 17327-1.2018 and the causes for the

differences are as follows.

---Use the normative reference YY/T 0640 to replace ISO 14630 (see Chapter 3), so as to adapt to the technical conditions of China and enhance the operability.

This document makes the following editorial modifications.

---The "source" in the NOTE of 3.11 is deleted (see 3.11 in ISO 17327-1:2018);

---Use national standards and industry standards to replace the corresponding international and foreign standards in Appendix C (see Appendix C; Appendix C in ISO 17327-1:2018), so as to adapt to the technical conditions of China and enhance the operability.

Please be noted that certain content of this document may involve patents. The institution issuing this document does not undertake the responsibility of identifying these patents.

This document was proposed by National Medical Products Administration.

This document shall be under the jurisdiction of National Technical Committee 110 on Surgical

Implants and Orthopedic Devices of Standardization Administration of China (SAC/TC 110).

The drafting organizations of this document. Tianjin Medical Devices Quality Supervision and

Testing Center; Center for Medical Device Evaluation. NMPA; Beijing NATON Technology Group Co., Ltd.; Suzhou MicroPort Technology Co., Ltd.; TRAUSON Medical Devices (China)

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1 Scope

This document specifies the general requirements for implant coatings, including surface coatings and surface modification, used for non-active surgical implants. This document specifies the requirements related to generic coating properties, including chemical composition

and phase composition, surface texture, coating coverage integrity, dissolvability, coating thickness, adhesion strength, abrasion resistance, porosity and pore size, and surface wettability.

This document applies to surface coatings, which are defined as layers of material intentionally

added to a substrate that have any properties different from those of the substrate's natural surface.

This document applies to surface modification, which is the intentional transformation or reconstruction of the surface of the original substrate to form a new surface material

composed

of the substrate's own material and possible foreign materials, and to form a surface layer with

different properties.

Since the correlated characteristics of the coatings and the required level of characterization

depend largely on the intended application of the implant, the generic properties of the general

requirements in this document are not intended to override or replace the provisions of specific

application property standards.

This document does not apply to structurally modified surfaces with the sole purpose of changing the surface roughness or raw material strength.

This document does not apply to naturally passivated metal surfaces. Although this document

applies to intentionally passivated metal surfaces, mature materials passivated by conventional

techniques (e.g. nitric acid impregnation) are generally non-hazardous and can be described in

a very basic mode.

This document does not apply to coatings for implants that use living tissues.

This document does not apply to laminated boards, i.e. multi-layer composites, for example, artificial blood vessels composed of different expanded polytetrafluoroethylene layers, but the

exposed surface of the laminated boards can be an implant coating (see 3.1, NOTE 2).

This document does not apply to coverings, for example, stent grafts.

NOTE 1: this document does not contain biocompatibility requirements. However, this is a key characteristic of devices and coatings and needs to be addressed during risk assessment.

NOTE 2: this document is complementary to the applicable standards on non-active surgical implants and YY/T 0640.

NOTE 3: this document does not require the manufacturer to establish a quality management

system. However, the application of a quality management system, for example, the one described in ISO 13485, can help ensure that the implants perform as expected.

NOTE 4: although fully porous implants are not coatings, some of the considerations in this document can also be applied to them.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only

versions with a specified date are applicable to this document. In terms of references without a

specified date, the latest version (including all the modifications) is applicable to this document.

YY/T 0640 Non-active Surgical Implants - General Requirements (YY/T 0640-2016, ISO 14630.2012, IDT)

3 Terms and Definitions

The terms and definitions defined in YY/T 0640 and the following are applicable to this document.

ISO and IEC provide databases of terms used in standards at the following websites.

3.1 implant coating

Surface coating (3.2) or surface modification (3.3).

NOTE 1: implant coatings are considered as a constituent part of the implant.

NOTE 2: laminated boards, i.e. composite materials made of multiple layers of the same or different materials with the same or different internal structures, assembled in a sandwich and bonded by heat, pressure, forging, welding or adhesives, are not considered as implant coatings. However, the exposed surfaces of the laminated boards can be implant coatings.

NOTE 3: coverings of other materials (e.g. grafts) added to structures (e.g. stents) solely to reduce the permeability of the structure and specifically used to bridge various elements in the structure are not considered as implant coatings.