YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1898-2024

Intravascular catheters and guidewires - Testing method for coating adhesion

血管内导管导丝 涂层牢固度试验方法

Issued on: February 7, 2024 **Implemented on: March 1, 2025**

Issued by: National Medical Products Administration

Table of Contents

1 Scope

YY/T 1898 is the test method for the adhesion of coatings on intravascular catheters and guidewires. Hydrophilic coatings are what let a guidewire cross a tortuous lesion and a catheter track over it, and they have a known failure mode: the coating delaminates and travels downstream as particulate, a phenomenon that has driven regulatory attention and recalls internationally. The method defines how a coating's integrity under simulated use is challenged and how the released particulate is assessed, which turns a qualitative concern into a measurable one. The 2024 edition takes effect on 20 July 2025. For a manufacturer of coated guidewires, catheters or delivery systems seeking Chinese registration, this is the method behind the coating integrity data.

This document describes test methods for assessing the coating fastness of medical catheters and guidewires featuring hydrophilic lubricant coatings intended for intravascular use, comprising four methods. visual inspection method, friction testing method, particulate testing method, and chemical property testing method. The hydrophilic lubricant coatings addressed in this document refer exclusively to coatings prepared using polymers that are chemically bonded to the substrate surface. They do not encompass other types of coatings, such as drug-eluting coatings or biodegradable coatings. This document applies to intravascular catheters and guidewires with hydrophilic lubricant coatings.

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.

YY/T 1556, Test methods for particle contamination of infusion, transfusion and injection equipment for medical use Pharmacopoeia of the People's Republic of China (Edition 2020, Volume IV)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 hydrophilic lubricant coating A hydrophilic substance possessing lubricating properties, immobilized on the surface of a catheter guidewire through specific strong binding forces.

3.2 coating lubricity The ease of sliding during the process of contact between the coating and human tissues, organs, or instruments used in conjunction or combination.

3.3 coating fastness The degree of adhesion between the coating and the medical device substrate. This is manifested in the integrity and durability of the coating.

4 Test methods for coating fastness

4.1 General This document specifies four test methods for characterizing coating fastness, including visual inspection, friction testing, particulate testing, and chemical property testing. An appropriate method may be selected based on the clinical intended use of the product and the objective of the test. NOTE. Other validated methods may also be employed.

4.2 Visual inspection method

4.2.1 Overview In the case of hydrophilic lubricant coating samples, when wetted, the coating absorbs water and swells into a gel-like state. During use, coatings that are poorly bonded to the catheter or guidewire substrate - or those containing defects in their dry state - may undergo peeling or localized detachment. Consequently, a visual inspection allows for the acquisition of information regarding the coating's morphology and defects, thereby enabling a preliminary assessment of its adhesion strength.

4.2.2 Test method After pretreatment, the sample shall be inspected for defects such as damage or detachment of the coating. This inspection may be performed directly or, by reference to Annex A, after staining. Pre-treatment methods include soaking, friction testing, and the selection of appropriate vascular models to simulate clinical use. One or more of these sample treatment methods may be selected based on clinical application and experimental objectives.

4.3 Friction testing method

4.3.1 Overview If the friction force or friction coefficient increases significantly as the

number of friction cycles rises, it suggests that the coating may be undergoing detachment. To a certain extent, this reflects the adhesion strength of the coating.

4.3.2 Test model Annex B presents the test model. A constant normal clamping force is applied, and under specified test conditions, a silicone sheet is rubbed repeatedly against the surface of the test specimen. The number of repetitions shall be determined with statistical significance in mind; a minimum of 10 repetitions is recommended. This parameter may also be adjusted as appropriate based on the intended clinical use of the product. The number of repeated friction cycles is recorded. A curve plotting friction force versus friction coefficient is generated, and changes in friction force and friction coefficient are monitored in real time. NOTE

1.For the purposes of this document, normal clamping force refers to the force exerted by the silicone sheet perpendicular to the contact surface between the catheter and the guidewire. NOTE 2.A single friction cycle refers to the process in which a silicone sheet applies a constant normal force to clamp the sample at a starting position, slides a specified distance, and then releases the sample to return to the starting position.

4.4 Particulate testing method

4.4.1 Overview During use, intravascular catheters and guidewires frequently encounter friction against blood vessels or associated devices. This process may result in the shedding of the device's coating. This shedding manifests as the presence of particulates - or even finer residues - within the test solution. The greater the adhesion strength of the coating, the fewer particulates or residues shall be generated. Therefore, by subjecting the device to an immersion treatment - tailored to its specific clinical application and the objectives of the test - or by simulating clinical usage within an appropriate vascular model (see Annex C), a test solution containing the shed particulates can be obtained. By employing particulate counting methods to quantify the size and number of particulates within this test solution, the adhesion strength of the coating can be assessed to a significant degree.

4.4.2 Selection of vascular models and samples An appropriate vascular model from Annex C shall be selected based on the intended clinical use of the device.

4.4.3 Preparation of test solution Depending on the site of vascular access and the complexity involved during the clinical use of the product, select either the immersion method or the vascular model friction method. Prepare the test solution in accordance with Annex D and Annex E.

4.4.4 Particle counting Count the test solution in accordance with the method specified in General Chapter 0903, "Particulate matter in injections" of the "Pharmacopoeia of the People's Republic of China (Edition 2020, Vol. IV)", or the method specified in YY/T 1556. NOTE. Alternatively, use other validated methods to perform particulate counting on the test

solution.

4.5 Chemical property testing method If detached components dissolve or form sub-micron or nano-scale particles that cannot be detected via particulate counting, the test solution may be prepared in accordance with Annex F, based on the product's clinical application and the objectives of the study. Appropriate chemical characterization methods (such as tests for reducing substances, evaporation residue, UV absorbance, or other specific analytical techniques) may be selected, so as to assess the detachment of the coating.

5 Test report

The test report shall include, but not be limited to, the following information.

a) Sample identification;

b) Sample quantity;

d) Test conditions;

e) Equipment information;

f) Test results.