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AMENDMENT 1
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Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

AMENDMENT 1: Test methods

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 1: Prothèses endovasculaires

AMENDEMENT 1: Méthodes d'essai

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

Amendment 1 to International Standard ISO 25539-1:2003 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This Amendment adds Annexes D and E to the document. These annexes are for information only.

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Add the following annex before the Bibliography.

Annex D
(informative)

Test methods

D.1 General

The information included in this annex is intended to provide guidance for pre-clinical *in vitro* testing performed in order to verify the design of the endovascular system, and to provide guidance for reporting. It is recognized that testing intended to ensure that the device meets the specifications of this part of ISO 25539, during manufacture may not be conducted in accordance with the details outlined in this annex.

The intent of this annex is to identify the purpose of and important parameters for the testing described in this International Standard. To ensure consistency in the testing of devices, use of this annex is recommended in developing the methodology for the testing required by this International Standard. If the methods developed are not consistent with the guidance provided in this annex, the differences should be justified.

In some cases in this annex, one or more of the methods for the tests identified in the body of this International Standard have been combined into a single method. It was recognized during the drafting of these test methods that they should be combined to reflect the manner in which this testing is often conducted. It is also recognized that additional methods may be combined when testing is conducted for a specific device. For those tests performed simultaneously, the report should provide the individual test results for each of the tests listed in the body of this International Standard.

A test method for stent-free surface area has not been included in this annex. It was recognized during the drafting of the test methods that measurement of this parameter is generally not applicable for endovascular prostheses.

The methods included in this annex are grouped as follows:

— D.5.1 Endovascular system testing: dimensions (D.5.1.1 and D.5.1.2); simulated use (D.5.1.3 to D.5.1.5); strength (D.5.1.6);

— D.5.2 Delivery system testing: balloon inflation and deflation time; strength (D.5.2.2 to D.5.2.7);

— D.5.3 Implant (endovascular prosthesis): dimensions (D.5.3.1 to D.5.3.4); permeability (D.5.3.5 to D.5.3.7); strength (D.5.3.8 to D.5.3.17); stability (D.5.3.18 to D.5.3.20).

D.2 Sampling

A sampling plan should be utilized which will ensure that adequate representation of the data has been obtained for each parameter measured. The design characteristics of the graft material, stent/attachment system, endovascular prosthesis, delivery system and endovascular system must be verified to be representative of the devices to be released for distribution, including all sizes, configurations and components.

The sampling should fully represent the range of device sizes and may not necessarily require the testing of each size. A rationale should be provided for sample selection. It may be necessary to conduct an analysis to identify the size(s) of the device with the greatest potential for failure.

Sampling should ensure adequate representation of the expected variability in the manufacture of devices.

For those tests with specified confidence and reliability parameters, the sample size should have a statistical basis. For all tests, the number of samples should be justified.

Additional recommendations regarding sampling are included with each test method as appropriate.

D.3 Conditioning of test samples

All samples should be subjected to sterilisation, including multiple sterilizations if appropriate, unless justification is provided for use of non-sterilized products.

Samples should be subjected to conditions that are normally encountered, which may affect the test results. Conditioning may include loading the endovascular prosthesis on or inside the delivery catheter, preconditioning of the endovascular system as recommended in the instructions for use (IFU) and deployment of the prosthesis.

A simulated physiological environment (e.g. a temperature-controlled water bath) should be used when appropriate.

D.4 Reporting

For the purposes of this annex, reporting relates to requests from a national regulatory authority.

The test report for the pre-clinical *in vitro* testing should include an executive summary of all testing. This summary should include identification of tests, with the rationale for the omission of any tests identified in Annex B or the selection of alternative tests. The information provided in each test report should be based upon a prospectively defined test protocol.

A summary of results, with acceptance criteria and any potential clinical significance of the results, should be included and may be in tabular form. Consideration should be given to the anatomical, physiological, and morphological conditions of the intended use in establishing the acceptance criteria. Justification and clinical applicability of acceptance criteria for each test should be provided. A table of contents should be provided and pages should be numbered sequentially.

Individual test reports should include the following information:

a) purpose: state the purpose of the test as it corresponds to ISO 25539-1;

b) materials: list all materials (e.g. test articles, equipment) used in performing the test, using figures and diagrams as appropriate;

c) sampling: state the sampling plan, including the basis for and the number of samples tested (selection of test article should be justified, e.g. sizes, conditioning);

d) acceptance criteria: state the acceptance criteria for the test results;

e) test method: describe in detail the method used to perform the test, including any prospectively defined inspection procedures and provide a justification for critical test parameters;

f) protocol deviations: describe any deviations and their potential significance on the interpretation of the results;

g) expression of results: describe testing results expressed in units as indicated in the test method;

h) conclusion: state conclusions, based on comparing results to acceptance criteria, including any potential clinical significance of these results.

D.5 Test methods

NOTE 1 The tolerances and accuracy levels dictated throughout the following methods are stated as nominal acceptable levels. Depending upon design specification levels, equipment with tighter tolerances or higher levels of accuracy may be needed.

NOTE 2 As used within the context of this annex, “shall” indicates requirements strictly to be followed in order to conform to the recommended test method.

D.5.1 Endovascular system

D.5.1.1 Dimensional verification and component dimension compatibility

D.5.1.1.1 Purpose

The purpose of this test is to determine the endovascular system dimensions including, but not limited to, the outer diameter, guidewire lumen diameter and useable length, for verification to design specifications, and to evaluate the dimensional compatibility between the endovascular system and the recommended accessory devices listed in the product instructions for use (IFU). The relevant design evaluation sections of ISO 25539-1 include 7.2.1 Ability to access, 7.2.2 Ability to deploy and 7.2.3 Ability to withdraw.

D.5.1.1.2 Materials

D.5.1.1.2.1 Endovascular system

D.5.1.1.2.2 Accessory devices, necessary to accomplish deployment in accordance with the IFU.

D.5.1.1.2.3 Measuring equipment for diameters, (e.g. micrometer, optical profile projector, laser-micrometer) capable of measuring to an accuracy of ± 0,1 mm or appropriate profile hole gauges manufactured to a tolerance of ± 0,1 mm.

D.5.1.1.2.4 Measuring equipment for length, capable of measuring to an accuracy of ± 1 mm.

D.5.1.1.2.5 Wire mandrels/pin gauges, (for the delivery system inner lumen), manufactured to a tolerance of ± 0,03 mm.

D.5.1.1.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.1.1.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.1.1.5 Test method

Develop a test method based on the following:

a) Insert an appropriate guidewire or appropriately sized mandrel into the endovascular system lumen to verify the lumen dimension and guidewire compatibility;

b) measure the maximum outer diameter of the endovascular system using the appropriate measuring instrument or verify that the outer diameter fits through the appropriately sized profile hole gauge – it is only necessary to measure the region of the endovascular system intended to be passed through the specified introducer sheath;

c) measure the length of the endovascular system using an appropriate measuring instrument – it is only necessary to measure the region of the endovascular system intended to be passed through the introducer sheath;

d) measure all other appropriate dimensions;

e) verify compatibility with all types of recommended accessory components.

D.5.1.1.6 Expression of results

Length shall be expressed in centimetres (cm). Other dimensions shall be expressed in millimetres (mm). Results regarding the compatibility of the recommended accessory devices and the verification of the lumen and outer diameters, if applicable, shall be documented.

D.5.1.1.7 Test report

The test report shall be in accordance with Clause D.4. The test report shall include the maximum, minimum, mean and standard deviation of all measured dimensions, the results of any verified dimensions, and the results of the observations of the accessory compatibility.

NOTE Additional guidance may be found in ASTM F2081-01[28].

D.5.1.2 Profile/diameter test

D.5.1.2.1 Purpose

The purpose of this test is to determine the maximum diameter along sections of the endovascular system in order to evaluate the dimensional compatibility between the endovascular system and the vasculature, including the lesion to be treated. The relevant design evaluation section of ISO 25539-1 includes 7.2.1 Ability to access.

D.5.1.2.2 Materials

D.5.1.2.2.1 Endovascular system

D.5.1.2.2.2 Measuring equipment for diameters, (e.g. micrometer, optical profile projector, laser-micrometer), capable of measuring to an accuracy of ± 0,1 mm.

D.5.1.2.2.3 Recommended guidewire, or equivalent, as appropriate.

D.5.1.2.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.1.2.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.1.2.5 Test method

Develop a test method based on the following:

a) if applicable, insert an appropriate guidewire into the endovascular system such that it extends past the end of the endovascular system;

b) measure the maximum outer diameter of the endovascular system; consideration should be given to the potential for asymmetry, it is necessary to measure the region that is intended to pass through a vessel and/or vessel lesion, and the region that contains the implant.

D.5.1.2.6 Expression of results

Diameters measured shall be expressed in millimetres (mm).

D.5.1.2.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the measured outer diameter of the endovascular system and the diameter of the region containing the implant for each size tested.

NOTE Additional guidance may be found in ASTM F2081-01[28].

D.5.1.3 Assessment of haemostasis

D.5.1.3.1 Purpose

The purpose of this test is to evaluate the ability of any seal or valves in the system to maintain an adequate haemostatic seal. The relevant design evaluation section of ISO 25539-1 includes 7.2.5 Haemostasis.

D.5.1.3.2 Materials

D.5.1.3.2.1 Endovascular system

D.5.1.3.2.2 Accessory devices, necessary to accomplish deployment in accordance with the instructions for use (IFU).

D.5.1.3.2.3 Model (or fixture), representative of “worst-case” conditions for leakage (e.g. introduction, tortuosity, withdrawal). This may require the use of an appropriate anatomical model as described in D.5.1.4 Simulated use models.

D.5.1.3.2.4 Pressurized fluid fixture, capable of delivering water or appropriate fluid, at physiological temperature (37 ± 2) °C and appropriate pressure (e.g. 100 mm Hg).

D.5.1.3.2.5 A means for collecting and measuring the total fluid leakage from the endovascular system, to an accuracy of ± 5 % of the total leakage.

D.5.1.3.2.6 Timer, with an accuracy of ± 1 s.

D.5.1.3.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.1.3.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.1.3.5 Test method

Develop a test method based on the following:

a) connect the model to the fluid fixture;

b) place the reservoir(s) where it (they) collect(s) the fluid leakage;

c) insert the appropriate accessory devices (e.g. guidewire, introducer sheath) in the fixture and start timing;

d) using the IFU, follow the steps of deployment, including any modular components; insert, deliver and deploy the implant in the fixture or model;

e) the pressurized fluid exposure shall be representative of anticipated clinical conditions, simulating blood loss during introduction, deployment and withdrawal in the clinical setting;

f) withdraw the delivery system and stop timing;

g) measure and record the amount of fluid leakage and the elapsed time in which leakage occurred; leakage between the model and the introducer sheath need not be included.

D.5.1.3.6 Expression of results

Record all critical observations. The leakage rate shall be expressed in milliliters per minute (ml/min).

D.5.1.3.7 Test report

The test report shall be in accordance with Clause D.4 and include the maximum, minimum, mean and standard deviation of the leakage rate. The test fluid shall be identified, and should include the density and/or viscosity. Typical pressurized time in the clinical setting should be considered when interpreting results. Report any critical observations.

D.5.1.4 Simulated use models

D.5.1.4.1 Purpose

The purpose of this test is to evaluate the performance of the endovascular system using a model(s) that simulate(s) the intended use conditions. This test addresses the requirements for qualitative evaluation of simulated use, flex/kink, pushability, torquability and trackability of the endovascular system. Conformability of the deployed prosthesis to the vessel wall shall also be evaluated. The relevant design evaluation sections of ISO 25539-1 include 7.2.1 Ability to access, 7.2.2 Ability to deploy, 7.2.3 Ability to withdraw, 7.3.1 Ability to accurately deploy and 7.3.2 Fixation effectiveness.

D.5.1.4.2 Materials

D.5.1.4.2.1 Endovascular system

D.5.1.4.2.2 Accessory devices, necessary to accomplish deployment in accordance with the instructions for use (IFU).

D.5.1.4.2.3 Anatomical model, that includes a delivery pathway and a deployment location. The angulation and tortuosity of the intended implant location and delivery pathway should be considered in the design of the model.

D.5.1.4.2.4 Pressurized fluid fixture, capable of delivering water or appropriate fluid, at physiological temperature (37 ± 2) °C, pulsatile pressures, and antegrade or retrograde flow, as appropriate.

D.5.1.4.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.1.4.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.1.4.5 Test method

Develop a test method based on the following:

a) connect the anatomical model to the fluid fixture and allow the test system to stabilize at temperature and pressure;

b) insert the appropriate accessory devices (e.g. guidewire, introducer sheath) in the fixture;

c) using the IFU, follow the steps of deployment, including any modular components; insert, deliver and deploy the implant in the model and withdraw the delivery system;

d) evaluate the ease of advancing the delivery system into the model (pushability), the ability to transmit torque from the proximal end to the distal end of the catheter (torquability) and the ability of the delivery system to track over a guidewire during insertion around bends in the model (trackability);

e) note any anomalies, such as kinking or buckling of the system, the inability to fully and accurately deploy the implant, implant dislodgment while withdrawing the delivery system and any other appropriate observations;

f) visually inspect the deployed endovascular prosthesis in the anatomical model; note the conformance to the model vessel wall, the placement accuracy, kinks, bends, twisting, component separation, any damage and any other critical observations;

g) inspect the delivery system, note any damage and any other critical observations.

D.5.1.4.6 Expression of results

For each test, all critical observations and aspects of the ability to access, deploy, and withdraw the endovascular system should be documented.

D.5.1.4.7 Test report

The test report shall be in accordance with Clause D.4 and shall include all critical observations and aspects of the ability to access, deploy and withdraw the endovascular system. The test fluid shall be identified and

should include the density and/or viscosity. The results for flex/kink, pushability, torquability and trackability of the endovascular system should be individually documented as well as the conformity to the vessel wall of the implant. The report shall include a description of the anatomical model used, including the geometry and material of construction.

D.5.1.5 Visibility

D.5.1.5.1 Purpose

The purpose of this test is to evaluate the ability to visualize the endovascular system and/or endovascular prosthesis using the imaging techniques specified in the instructions for use (IFU). The relevant design evaluation sections of ISO 25539-1 include 7.2.1 Ability to access, 7.2.2 Ability to deploy, 7.2.3 Ability to withdraw and 7.3.1 Ability to accurately deploy.

D.5.1.5.2 Materials

D.5.1.5.2.1 Endovascular system

D.5.1.5.2.2 Radiological phantom tissue model, or equivalent, with appropriate accessories, such as radiopaque markers and a ruler.

D.5.1.5.2.3 X-ray/fluoroscopy machine, capable of operating at clinically relevant power levels.

NOTE Visibility is significantly affected by variations in equipment and parameter settings. When selecting the equipment used for this evaluation, consideration should be given to this variability.

D.5.1.5.2.4 Accessory devices, necessary to accomplish deployment in accordance with the IFU.

D.5.1.5.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.1.5.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.1.5.5 Test method

Develop a test method based on the following:

a) position the endovascular system and the phantom tissue model to simulate clinical conditions;

b) use the X-ray/fluoroscope to visualize the endovascular system and any radiopaque markers;

c) qualitatively examine the X-ray/fluoroscopic images for ease of visibility; e.g. the degree of visibility may be assessed by locating the exact ends, orientation of critical points and/or parts of the endovascular system, alternatively, the degree of visibility may be compared to a specified control device;

d) repeat a) to c) above for the prosthesis during deployment and after withdrawal of the delivery system.

D.5.1.5.6 Expression of results

This is a qualitative assessment. Record the degree of visibility for all applicable components at the various stages of testing and any comparison to a specified control.

D.5.1.5.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the assessment of visibility and visual results (e.g. representative fluoroscopic images). The test report shall also include a model of the imaging equipment, the parameter settings and details of the phantom tissue model.

D.5.1.6 Force to deploy

D.5.1.6.1 Purpose

The purpose of this test is to determine the force to deploy the endovascular prostheses. All applicable steps of the deployment process are evaluated. The relevant design evaluation section of ISO 25539-1 includes 7.2.2 Ability to deploy.

D.5.1.6.2 Materials

D.5.1.6.2.1 Endovascular system

D.5.1.6.2.2 Accessory devices, necessary to accomplish deployment in accordance with the instructions for use (IFU).

D.5.1.6.2.3 Anatomical model, that includes a delivery pathway and a deployment location. The angulation and tortuosity of the intended implant location and delivery pathway should be considered in the design of the model.

D.5.1.6.2.4 Force measuring mechanism, (e.g. force gauge, universal mechanical testing system), capable of measuring force to an accuracy of ± 5 % of the reported value.

D.5.1.6.2.5 Gripping fixture

D.5.1.6.2.6 Temperature controlled environment, (37 ± 2) °C.

D.5.1.6.3 Sampling

Sampling shall be in accordance with Clause D.2. Devices to be tested should represent worst-case deployment force conditions (e.g. greatest bulk within the sheath or cover, highest compression ratio). The effect of device diameter and length should be taken into consideration in the selection of devices for testing.

D.5.1.6.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.1.6.5 Test Method

Develop a test method based on the following:

a) prepare the endovascular system in accordance with the IFU;

b) insert the endovascular system into the anatomical model;

c) secure the endovascular system such that it remains stationary during testing;

d) attach the deployment mechanism to the load measuring equipment;

e) allow the device to stabilize at physiological temperatures;

f) initiate and complete the deployment in accordance with the IFU at a rate that simulates clinical use while measuring the force to deploy the implant;

g) record any anomalous observations (e.g. buckling) for each test sample.

D.5.1.6.6 Expression of results

The maximum force of each step required to deploy the implant is recorded in newtons (N). Also record any anomalous observations (e.g. buckling) for each test sample.

D.5.1.6.7 Test report

Test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the deployment forces and any anomalous observations.

D.5.2 Delivery system

D.5.2.1 Balloon inflation and deflation time (balloon expandable or balloon assisted)

D.5.2.1.1 Purpose

The purpose of this test is to determine the time required to inflate the balloon to the maximum recommended inflation pressure, volume or diameter and to measure the time required to deflate the balloon. This test provides information that may be clinically useful for treatment planning (e.g. potential occlusion time). The relevant design evaluation section of ISO 25539-1 includes 7.2.2 Ability to deploy.

NOTE This test may also be of importance in evaluating the ability to withdraw.

D.5.2.1.2 Materials

D.5.2.1.2.1 Delivery system, or appropriate balloon sub-assembly.

D.5.2.1.2.2 Recommended guidewire, or equivalent.

D.5.2.1.2.3 Temperature controlled water bath, (37 ± 2) °C.

D.5.2.1.2.4 Contrast medium, in accordance with the instructions for use (IFU).

D.5.2.1.2.5 Inflation device, syringe or equivalent, fitted with a means of measuring pressure or volume to an accuracy of ± 5 % of the reported value, and of maintaining the inflation pressure or volume.

D.5.2.1.2.6 Rigid tube, of a diameter that represents the largest recommended prosthesis or vessel diameter for the compliant balloon under test. No tube is necessary for non-compliant balloon testing.

D.5.2.1.2.7 Timer, with an accuracy of ± 0,2 s.

D.5.2.1.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.1.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.1.5 Test method

Develop a test method based on the following:

a) insert the appropriate guidewire in the device;

b) submerge the device in the water bath and insert into the rigid tube, if appropriate;

c) allow it to reach the equilibrium test temperature;

d) inflate the balloon in accordance with the IFU, simulating clinical use;

e) time the balloon inflation period to the maximum inflation pressure, volume or diameter as indicated in the IFU;

f) deflate the balloon in accordance with the IFU and time the balloon deflation period.

D.5.2.1.6 Expression of results

The inflation and deflation times should be expressed in seconds.

D.5.2.1.7 Test report

The test report shall be in accordance with Clause D.4 and include the maximum, minimum, mean and standard deviation of the balloon inflation and deflation times. The definition of the inflation and deflation endpoints shall also be reported.

D.5.2.2 Balloon rated burst pressure (RBP) for non-compliant balloons (balloon expandable or balloon assisted)

D.5.2.2.1 Purpose

The purpose of this test is to determine the rated burst pressure (RBP) of the balloon. This is accomplished using burst pressures as measured by the test method and calculating an appropriate safety margin using the mean and standard deviation. The relevant design evaluation section of ISO 25539-1 includes 7.2.2 Ability to deploy.

NOTE This test may also be of importance in evaluating the ability to withdraw.

D.5.2.2.2 Materials

D.5.2.2.2.1 Delivery system, or appropriate balloon sub-assembly.

D.5.2.2.2.2 Temperature controlled water bath, (37 ± 2) °C.

D.5.2.2.2.3 Fluid for inflation, (e.g. room temperature water).

D.5.2.2.2.4 Leak detection mechanism, (e.g. dye in the test fluid, pressure drop monitor, flow rate monitor).

D.5.2.2.2.5 Inflation device, syringe or equivalent, fitted with a means of measuring pressure to an accuracy of ± 5 % of the reported value, and capable of maintaining the inflation pressure.

D.5.2.2.2.6 Timer, with an accuracy of ± 1 s.

D.5.2.2.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.2.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.2.5 Test method

Develop a test method based on the following:

a) submerge the device in the water bath;

b) allow it to reach the equilibrium test temperature;

c) inflate the balloon to a value less than the estimated rated burst pressure; hold the inflation pressure constant for 30 s and inspect for balloon leakage or bursting;

d) if no leakage is noted, increase the pressure by an increment appropriate to the balloon being tested and hold the pressure for 30 s;

e) repeat step d) until the balloon leaks or bursts [any persistent leak or decrease in pressure, whether due to failure of the balloon, shaft or proximal or distal seals, should be considered a failure ("bursting") in this test]; record the burst pressure and describe the location and failure mode (e.g. seal leaks, balloon rupture, fragmentation).

D.5.2.2.6 Expression of results

The burst pressures should be expressed in kilopascals (kPa). Calculate the mean and standard deviation of the burst pressure. Appropriate confidence and reliability parameters should be used for determining RBP.

D.5.2.2.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the mean burst pressure (MBP), the calculated RBP, the maximum, minimum and standard deviation of the burst data and any observed failure modes.

D.5.2.3 Balloon volume to burst for compliant balloons (balloon expandable or balloon assisted)

D.5.2.3.1 Purpose

The purpose of this test is to determine the volume required to burst a compliant balloon and to calculate the safety factor of inflation volume. The relevant design evaluation section of ISO 25539-1 includes 7.2.2 Ability to deploy.

NOTE This test may also be of importance in evaluating the ability to withdraw.

D.5.2.3.2 Materials

D.5.2.3.2.1 Delivery system, or appropriate balloon sub-assembly.

D.5.2.3.2.2 Temperature controlled water bath, (37 ± 2) °C.

D.5.2.3.2.3 Fluid for inflation, (e.g. room temperature water).

D.5.2.3.2.4 Leak detection mechanism, (e.g. dye in the test fluid, pressure drop monitor, flow rate monitor).

D.5.2.3.2.5 Inflation device, syringe or equivalent, fitted with a means of measuring volume to an accuracy of ± 5 % of the reported value, and capable of maintaining the inflation volume.

D.5.2.3.2.6 Rigid tube, with a diameter that represents the recommended prosthesis or vessel diameter for the balloon under test.

D.5.2.3.2.7 Timer, with an accuracy of ± 1 s.

D.5.2.3.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.3.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.3.5 Test method

Develop a test method based on the following:

a) submerge the device in the water bath and insert into rigid tube;

b) allow it to reach the equilibrium test temperature;

c) using an inflation rate simulating clinical use, inflate the balloon to the diameter of the tube and hold the diameter for 30 s; record the volume, V_1;

d) if no leakage is noted, increase the volume by an increment appropriate to the balloon being tested and hold for 30 s;

e) repeat step d) until the balloon leaks or bursts [any persistent leak or decrease in pressure or volume, whether due to failure of the balloon, shaft, or proximal or distal seals, should be considered a failure ("bursting") in this test]; record the volume at burst, V_2, and the failure mode (e.g. seal leaks, balloon rupture, fragmentation);

f) calculate the safety factor as follows: $\frac{V_2}{V_1}$.

D.5.2.3.6 Expression of results

Volume shall be expressed in millilitres (ml). The safety factor is expressed as a dimensionless ratio.

D.5.2.3.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the volume at the desired diameter, the volume at failure, and the safety factor. The observed failure mode(s) shall also be included.

D.5.2.4 Balloon rated fatigue (balloon expandable or balloon assisted)

D.5.2.4.1 Purpose

The purpose of this test is to determine the ability of the balloon to withstand repeated inflation cycles. The relevant design evaluation section of ISO 25539-1 includes 7.2.2 Ability to deploy.

NOTE This test may also be of importance in evaluating the ability to withdraw.

D.5.2.4.2 Materials

D.5.2.4.2.1 Delivery system, or appropriate balloon sub-assembly.

D.5.2.4.2.2 Temperature controlled water bath, (37 ± 2) °C.

D.5.2.4.2.3 Fluid for inflation, (e.g. room temperature water).

D.5.2.4.2.4 Leak detection mechanism, (e.g. dye in the test fluid, pressure drop monitor, flow rate monitor).

D.5.2.4.2.5 Inflation device, syringe or equivalent, fitted with a means of measuring pressure or volume with an accuracy of ± 5 % of the reported value, and capable of maintaining the inflation pressure or volume.

D.5.2.4.2.6 Rigid tube, with a diameter which represents the largest recommended prosthesis or vessel diameter for the compliant balloon under test. No tube is necessary for non-compliant balloon testing.

D.5.2.4.2.7 Timer, with an accuracy of ± 1 s.

D.5.2.4.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.4.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.4.5 Test method

Develop a test method based on the following:

a) submerge the device in the water bath and insert into rigid tube, if appropriate;

b) allow it to reach the equilibrium test temperature;

c) inflate the balloon, using clinically relevant rates, to the maximum pressure, volume or diameter as indicated in the instructions for use (IFU), for a minimum of 30 s or for the length of time stated in the IFU;

NOTE If the length of time stated in the IFU is longer than 30 s, the specified length of time should be used for this test, unless adequate justification is provided for using the shorter duration.

d) deflate balloon using clinically relevant rates;

e) repeat steps c) and d) for the number of cycles required to establish an appropriate safety factor (e.g. at least 2 times the maximum number of cycles expected in clinical use);

f) if any persistent leak or decrease of pressure or volume occurs during testing, record the number of cycles and the mode of failure; any such leak or decrease in pressure due to failure of the balloon, shaft, or proximal or distal seals, should be considered a failure in this test.

D.5.2.4.6 Expression of results

The maximum inflation diameter, pressure, or volume used shall be expressed with diameter in millimetres (mm), pressure in kilopascals (kPa) or millimetres of mercury (mm Hg), or volume in millilitres (ml).

D.5.2.4.7 Test report

The test report shall be in accordance with Clause E.4 and shall include the number of cycles successfully completed, the maximum number of cycles expected clinically, the achieved safety factor, any observed failure modes and the maximum inflation diameter, pressure or volume.

D.5.2.5 Bond strength

D.5.2.5.1 Purpose

The purpose of this test is to determine the bond strength of the joints and/or fixed connections of the delivery system. The relevant design evaluation sections of ISO 25539-1 include 7.2.1 Ability to access, 7.2.2 Ability to deploy and 7.2.3 Ability to withdraw.

D.5.2.5.2 Materials

D.5.2.5.2.1 Delivery system, or appropriate component joints and/or fixed connections.

D.5.2.5.2.2 Universal mechanical testing system, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value, a constant rate of traverse and appropriate gripping fixtures.

D.5.2.5.2.3 Temperature controlled environment, (37 ± 2) °C, as appropriate.

D.5.2.5.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.5.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.5.5 Test method

Develop a test method based on the following:

NOTE For bonds that will be subjected to physiological temperatures, testing should be performed at 37 °C ± 2 °C.

a) using a mechanical testing system with an appropriate crosshead speed (e.g. 200 mm/min), apply tension to the bonded joint until the bond breaks or loses functional integrity;

b) record the peak force at which failure occurs and describe the type and location of the failure.

D.5.2.5.6 Expression of results

Bond strength shall be expressed in newtons (N).

D.5.2.5.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the type and location of the failure, and the maximum, minimum, mean and standard deviation of the bond strength.

NOTE Additional guidance may be found in ISO 10555-1[9].

D.5.2.6 Torsional bond strength

D.5.2.6.1 Purpose

The purpose of this test is to determine the torque required to cause failure of bonded joints of the delivery system components. The relevant design evaluation sections of ISO 25539-1 include 7.2.1 Ability to access, 7.2.2 Ability to deploy and 7.2.3 Ability to withdraw.

D.5.2.6.2 Materials

D.5.2.6.2.1 Delivery system, or appropriate component joints and/or fixed connections.

D.5.2.6.2.2 Recommended guidewire, or equivalent, if appropriate.

D.5.2.6.2.3 Torque testing system, equipped with a suitable gauge capable of measuring with an accuracy of ± 5 % of the reported value.

D.5.2.6.2.4 Temperature controlled environment, (37 ± 2) °C, as appropriate.

D.5.2.6.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.6.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.6.5 Test method

Develop a test method based on the following:

NOTE For bonds that will be subjected to physiological temperatures, testing should be performed at 37 °C ± 2 °C.

a) insert the delivery system or component over the guidewire, if appropriate;

b) affix one end of the test sample in a clamping apparatus;

c) attach the other end of the test sample to the torque gauge;

d) apply a twisting force, at a rate characteristic of that used in a typical clinical deployment, to one end of the sample until the joint and/or delivery system breaks or loses functional integrity;

e) record the torque value at which failure occurs and the failure mode and location.

D.5.2.6.6 Expression of results

Torsional bond strength shall be expressed in newton metres (Nm).

D.5.2.6.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the mode and location of the failure, and the maximum, minimum, mean and standard deviation of the torsional bond strength.

D.5.2.7 Tubing longitudinal tensile strength

D.5.2.7.1 Purpose

The purpose of this test is to determine the longitudinal strength of tubing used in the delivery system. The relevant design evaluation section of ISO 25539-1 includes 7.2.2 Ability to deploy and 7.2.3 Ability to withdraw.

D.5.2.7.2 Materials

D.5.2.7.2.1 Delivery system tensile samples

D.5.2.7.2.2 Universal mechanical testing system, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value, a constant rate of traverse, and appropriate gripping fixtures.

D.5.2.7.2.3 Temperature controlled environment, (37 ± 2) °C, as appropriate.

D.5.2.7.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.2.7.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.2.7.5 Test method

Develop a test method based on the following:

a) using the mechanical testing system with an appropriate crosshead speed and gauge length (typically a strain rate of 5 mm/min/mm to 20 mm/min/mm), apply a tensile strain until the test sample breaks, passes the yield (0,2 % offset) point, elongates excessively or reaches some other pre-determined failure condition;

b) record the value of the applied tensile force at which failure is reached.

NOTE 1 Figure 1 represents a 0,2 % strain offset on a stress/strain curve.

NOTE 2 Methods to determine the 0,2 % strain offset are described in ASTM D638-03[25].

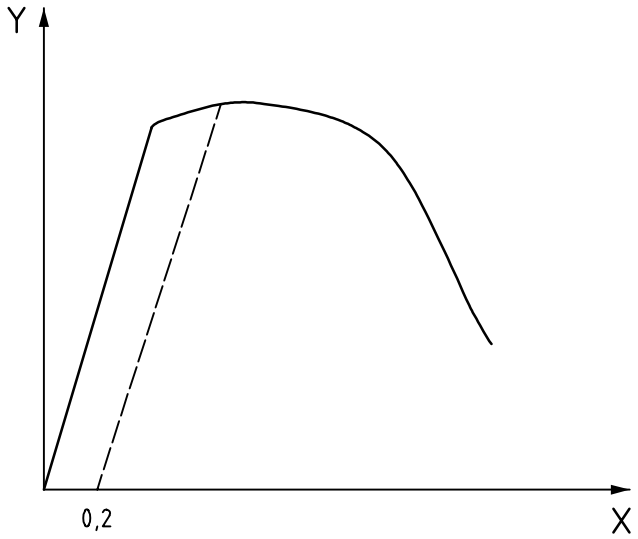
D.5.2.7.6 Expression of results

The tubing longitudinal tensile strength shall be expressed in newtons (N).

NOTE For the purposes of this test, longitudinal tensile strength is expressed in units of force rather than in units of stress.

D.5.2.7.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the definition of failure and the maximum, minimum, mean and standard deviation of tubing longitudinal tensile strengths.



Key

X stress (%)
Y strain

Figure D.1 — Representation of 0,2 % strain offset on a stress/strain curve

D.5.3 Implant (endovascular prosthesis)

D.5.3.1 Dimensional verification

D.5.3.1.1 Purpose

The purpose of this test is to determine the outer diameter(s), length(s) and, if appropriate, wall thickness(es) of the endovascular prosthesis in the deployed state for verification to design specifications. The relevant design evaluation section of ISO 25539-1 includes 7.3.6 Sizing.

NOTE 1 Other measurements may be needed to completely verify the dimensions of a particular implant.

NOTE 2 This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.1.2 Materials

D.5.3.1.2.1 Endovascular system

D.5.3.1.2.2 Measuring equipment for diameters, (e.g. micrometer, optical profile projector, laser-micrometer, calibrated calipers) capable of measuring to an accuracy of ± 0,1 mm.

D.5.3.1.2.3 Measuring equipment for wall thickness(es), (e.g. microscope with calibrated eyepiece, constant load thickness gauge, optical profile projector, laser-micrometer) capable of measuring to an accuracy of ± 5 % of the reported value.

D.5.3.1.2.4 Measuring equipment for lengths, capable of measuring to an accuracy of ± 1 mm.

D.5.3.1.2.5 Temperature controlled environment, (37 ± 2) °C for prostheses with dimensions that are sensitive to changes between ambient and physiological temperatures.

D.5.3.1.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.1.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment.

D.5.3.1.5 Test method

Develop a test method based on the following:

a) outer diameter(s) shall be measured at multiple locations after deployment in accordance with the instructions for use (IFU);

b) for length(s) and wall thickness(es), the test method shall be performed in accordance with ISO 7198:1998, sections 8.4 and 8.7, respectively.

NOTE For non-circular cross-sections, it may be appropriate to measure and report the maximum and minimum values.

D.5.3.1.6 Expression of results

Diameters and wall thickness(es) shall be expressed in millimetres (mm). Length(s) shall be expressed in millimetres (mm) or centimetres (cm).

D.5.3.1.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of all measured and calculated dimensions.

NOTE Additional guidance may be found in ASTM F2081-01[28].

D.5.3.2 Implant diameter to balloon inflation pressure (balloon-expandable devices)

D.5.3.2.1 Purpose

The purpose of this test is to determine the relationship between the prosthesis diameter and the balloon inflation pressure for balloon-expandable devices. This test provides data that may be clinically useful for device sizing and treatment planning. The relevant design evaluation section of ISO 25539-1 includes 7.3.6 Sizing.

D.5.3.2.2 Materials

D.5.3.2.2.1 Endovascular prosthesis

D.5.3.2.2.2 Balloon, for expansion of the prosthesis.

D.5.3.2.2.3 Inflation device, syringe, or equivalent, fitted with a means of measuring pressure to an accuracy of ± 5 % of the reported value, and capable of maintaining the inflation pressure.

D.5.3.2.2.4 Fluid for inflation, (e.g. room temperature water).

D.5.3.2.2.5 Measuring equipment for diameters, (e.g. micrometer, optical profile projector, laser-micrometer) capable of measuring to an accuracy of ± 0,1 mm.

D.5.3.2.2.6 Temperature controlled environment, (37 ± 2) °C, as appropriate.

D.5.3.2.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.2.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading and preconditioning.

D.5.3.2.5 Test method

Develop a test method based on the following:

a) initiate deployment of the prosthesis to enable device expansion;

b) position the balloon within the prosthesis;

c) inflate the balloon incrementally, allowing the system to stabilize between intervals; pressures should be chosen to determine the prosthesis diameter at appropriate intervals (e.g. 1 atmosphere of pressure or 1 bar) over the indicated range of diameters;

d) determine the average outer diameter of the prosthesis at each pressure interval at appropriate locations along the length of the prosthesis; these measurements should be taken immediately after stabilization (take into consideration that orthogonal projections at the same location may produce different results);

e) inflation should be terminated when the prosthesis diameter reaches the labelled maximum outer diameter.

NOTE The entire test should be completed rapidly to minimize the effects of viscoelastic behaviour and to better simulate the inflation method used clinically.

D.5.3.2.6 Expression of results

The prosthesis diameters should be expressed in units of millimetres (mm) and the associated pressures in kilopascals (kPa) and/or atmospheres of pressure (atm).

D.5.3.2.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the endovascular prosthesis diameter measurements and associated pressures. These data may be reported in tabular or graphical format.

D.5.3.3 Implant length to diameter relationship

D.5.3.3.1 Purpose

The purpose of this test is to determine the relationship between endovascular prosthesis length and endovascular prosthesis diameter following deployment in order to assess potential for foreshortening. The relevant design evaluation sections of ISO 25539-1 include 7.3.1 Ability to accurately deploy and 7.3.6 Sizing.

NOTE This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.3.2 Materials

D.5.3.3.2.1 Endovascular system

D.5.3.3.2.2 Measuring equipment, for length, capable of measuring to an accuracy of ± 1 mm.

D.5.3.3.2.3 Clear rigid tube, with inner diameters corresponding to the minimum and maximum vessel diameters indicated in the instructions for use (IFU) for each prosthesis size under test.

D.5.3.3.2.4 Accessory devices, necessary to accomplish deployment in accordance with the IFU.

D.5.3.3.2.5 Temperature controlled environment, (37 ± 2) °C for prostheses with dimensions that are sensitive to changes between ambient and physiological temperatures.

D.5.3.3.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.3.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.3.3.5 Test method

Develop a test method based on the following:

NOTE 1 For a balloon expandable stent with significant recoil, there may be difficulty in obtaining appropriate apposition of the prosthesis to the wall of the tube. Alternative methodology may need to be developed to appropriately evaluate this attribute for such devices.

a) deploy the prosthesis in accordance with the IFU into the rigid tube that represents the minimum target diameter;

b) measure the prosthesis length within the tube;

c) repeat steps a) and b) at the maximum target diameter.

NOTE 2 Devices may be re-used, if appropriate and justified.

NOTE 3 The implant-length-to-diameter relationship may be affected by angulation. Additional testing or analyses should be considered in order to evaluate the effect of angulation on this parameter, as appropriate.

D.5.3.3.6 Expression of results

Prosthesis length shall be reported in centimetres (cm) or millimetres (mm) and diameter shall be reported in millimetres (mm).

D.5.3.3.7 Test reports

The test report shall be in accordance with Clause D.4 and include the maximum, minimum, mean and the standard deviation of the device length at each corresponding diameter. These data should be reported in a tabular format.

D.5.3.4 Recoil (balloon-expandable devices)

D.5.3.4.1 Purpose

The purpose of this test is to determine the amount of elastic recoil after the deployment of a balloon-expandable prosthesis. The relevant design evaluation section of ISO 25539-1 includes 7.3.6 Sizing.

NOTE This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.4.2 Materials

D.5.3.4.2.1 Endovascular system

D.5.3.4.2.2 Accessory devices, necessary to allow for appropriate expansion of the prosthesis.

D.5.3.4.2.3 Inflation device, syringe or equivalent, fitted with a means of measuring pressure to an accuracy of ± 5 % of the reported value, and capable of maintaining the inflation pressure.

D.5.3.4.2.4 Fluid for inflation, (e.g. room temperature water).

D.5.3.4.2.5 Measuring equipment for diameters, (e.g. micrometer, optical profile projector, laser-micrometer) capable of measuring to an accuracy of ± 0,1 mm.

D.5.3.4.2.6 Temperature controlled environment, (37 ± 2) °C for prostheses with material properties that are sensitive to changes between ambient and physiological temperatures.

D.5.3.4.2.7 Timer, with an accuracy of ± 1 s.

D.5.3.4.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.4.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading and preconditioning.

D.5.3.4.5 Test method

Develop a test method based on the following:

a) initiate deployment of the prosthesis to enable device expansion;

b) inflate the balloon to expand the prosthesis using the recommended inflation pressure and hold the pressure to allow the balloon and prosthesis to stabilize (approximately 30 s);

c) determine the average outer diameter of the prosthesis at appropriate locations along the length;

NOTE Measurements at various rotational positions at the same longitudinal location may yield different results and should be considered when determining the average outer diameter.

d) deflate and remove the balloon catheter;

e) allow the prosthesis to stabilize (approximately 30 s);

f) repeat step c) at the same locations;

g) calculate the average percent recoil at each longitudinal location and/or for the entire length of the prosthesis, as appropriate; calculate the prosthesis recoil as follows:

$$\% \text{ Recoil} = \frac{(\text{diameter}_{\text{inflated}} - \text{diameter}_{\text{final}})}{\text{diameter}_{\text{inflated}}} \times 100$$

D.5.3.4.6 Expression of results

The prosthesis recoil shall be expressed in percent (%).

D.5.3.4.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the recoil measurements at each longitudinal location and/or for the entire length of the prosthesis, as appropriate.

NOTE Additional guidance may be found in ASTM F2079-02[27].

D.5.3.5 Integral water permeability/leakage

D.5.3.5.1 Purpose

The purpose of the test is to determine the rate of water leakage through the entire endovascular prosthesis, incorporating all modular components and extension devices (e.g. cuffs, iliac extenders), if applicable, and of the independent modular components. The complete prosthesis test provides information to characterize total leakage. The independent test is intended to provide leakage information exclusive of the modular junctions and may be helpful in identifying areas of greater leakage (e.g. suture holes). The relevant design evaluation section of ISO 25539-1 includes 7.3.4 Permeability.

D.5.3.5.2 Materials

D.5.3.5.2.1 Endovascular prosthesis

D.5.3.5.2.2 Materials listed in ISO 7198:1998, 8.2.3.2, as appropriate.

D.5.3.5.2.3 Means for collecting and measuring the total fluid leakage through the endovascular prosthesis.

D.5.3.5.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.5.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.3.5.5 Test method

Testing shall be performed on the prosthesis in the deployed state, incorporating all modular components, and extension devices and on each independent modular component in accordance with the method outlined in ISO 7198:1998, 8.2.3 Determination of integral water permeability/leakage.

D.5.3.5.6 Expression of results

The surface area of the prosthesis or area under test shall be calculated, and the integral water permeability shall be expressed in millilitres per centimetre squared per minute (ml/cm^2/min).

D.5.3.5.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the integral water permeability/leakage of the test samples. Areas of significant leakage shall be identified and reported.

D.5.3.6 Water entry pressure

D.5.3.6.1 Purpose

The purpose of this test is to determine the water entry pressure of the endovascular prostheses constructed of non-textile materials. The relevant design evaluation section of ISO 25539-1 includes 7.3.4 Permeability.

D.5.3.6.2 Materials

D.5.3.6.2.1 Endovascular prosthesis

D.5.3.6.2.2 Materials listed in ISO 7198:1998, 8.2.4.2, as appropriate.

D.5.3.6.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.6.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.3.6.5 Test method

Testing shall be performed in accordance with the method outlined in ISO 7198:1998, 8.2.4 Determination of water entry pressure.

D.5.3.6.6 Expression of results

The water entry pressure shall be expressed in kilopascals (kPa).

D.5.3.6.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the water entry pressures.

D.5.3.7 Water permeability

D.5.3.7.1 Purpose

The purpose of this test is to determine the rate of fluid flow through the wall of the endovascular prosthesis. The relevant design evaluation section of ISO 25539-1 includes 7.3.4 Permeability.

D.5.3.7.2 Materials

D.5.3.7.2.1 Endovascular prosthesis

D.5.3.7.2.2 Materials listed in ISO 7198:1998, 8.2.2.2, as appropriate.

D.5.3.7.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.7.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.3.7.5 Test method

Testing shall be performed in accordance with the method outlined in ISO 7198:1998, 8.2.2 Determination of water permeability.

D.5.3.7.6 Expression of results

The surface area of the prosthesis or area under test shall be calculated, and the water permeability shall be expressed in millilitres per square centimetre per minute (ml/(cm^2/min).

D.5.3.7.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the water permeability measurements for the test samples.

D.5.3.8 Burst/circumferential strength

D.5.3.8.1 Purpose

The purpose of this test is to determine the pressurized burst strength or circumferential strength of the appropriate components of the implant (e.g. graft material). It may also be appropriate to determine the burst strength of the finished product in cases where processing may reduce the strength. The relevant design evaluation section of ISO 25539-1 includes 7.3.3 Implant integrity.

D.5.3.8.2 Materials

D.5.3.8.2.1 Endovascular prosthesis

D.5.3.8.2.2 Materials listed in ISO 7198:1998, 8.3.3.3.2 or 8.3.1.2, as appropriate.

D.5.3.8.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.8.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment.

D.5.3.8.5 Test method

Testing shall be performed in accordance with the method outlined in ISO 7198:1998, 8.3.3.3 Determination of pressurized burst strength or 8.3.1 Determination of circumferential tensile strength.

D.5.3.8.6 Expression of results

The burst strength of each sample is expressed in kilopascals (kPa). The circumferential strength shall be expressed as kilonewtons per millimetre (kN/mm).

D.5.3.8.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the burst strength or circumferential strength.

D.5.3.9 Crush resistance

D.5.3.9.1 Purpose

The purpose of the test is to determine the force, as measured perpendicular to the longitudinal axis, required to permanently deform or fully collapse the endovascular prosthesis. The relevant design evaluation section of ISO 25539-1 includes 7.3.7 Patency.

NOTE Although similar, crush resistance, local compression and radial force tests measure different attributes of the endovascular prosthesis, as follows:

— the crush resistance test measures the ability of the prosthesis to resist permanent deformation along the entire length of the device;

— the local compression test measures the ability of the prosthesis to resist permanent deformation under a localized (e.g. point) load;

— the radial force test measures the force exerted by the prosthesis on the vessel in the deployed state.

D.5.3.9.2 Materials

D.5.3.9.2.1 Endovascular prosthesis

D.5.3.9.2.2 Universal mechanical testing system, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value and a constant rate of traverse;

D.5.3.9.2.3 Test fixture, capable of exerting a normal downward force (e.g. flat lower and upper plates) with appropriate length, width and separation between the fixtures to accommodate the test article;

D.5.3.9.2.4 Temperature controlled environment, (37 ± 2) °C for prostheses with material properties that are sensitive to changes between ambient and physiological temperatures.

D.5.3.9.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.9.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment.

D.5.3.9.5 Test method

Develop a test method based on the following:

a) place the endovascular prosthesis between the test fixtures;

b) measure the length of the segment to be tested;

c) compress the endovascular prosthesis continuously or incrementally using a uniform rate of compression (e.g. 200 mm/min) until plastic deformation or full collapse occurs;

d) record the force and associated deflection at which plastic (permanent) deformation or full collapse occurs.

NOTE The method for determining the force and deflection at which plastic deformation begins is not defined in this International Standard since this method will be specific to the device design under evaluation.

D.5.3.9.6 Expression of results

Report the crush resistance of the endovascular prosthesis as force per unit axial length in newtons per millimetre (N/mm) and the associated deflection at which plastic deformation or collapse occurs in millimetres (mm).

D.5.3.9.7 Test report

The test report shall be in accordance with Clause D.4 and shall include a description of the method used for determining the force and deflection at which plastic deformation begins. Report the maximum, minimum, mean and standard deviation of the crush resistance.

D.5.3.10 Flex/kink

D.5.3.10.1 Purpose

The purpose of this test is to determine the minimum radius that the endovascular prosthesis can accommodate without kinking. Both the endovascular prosthesis, incorporating all modular components and extension devices (e.g. cuffs, iliac extenders), and the independent modular components should be evaluated, as appropriate. The relevant design evaluation sections of ISO 25539-1 include 7.3.5 Modularity and 7.3.7 Patency.

D.5.3.10.2 Materials

D.5.3.10.2.1 Endovascular prosthesis

D.5.3.10.2.2 Materials listed in ISO 7198:1998, 8.9, as appropriate.

D.5.3.10.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.10.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment.

D.5.3.10.5 Test method

Testing shall be performed on the prosthesis in the deployed state, incorporating all modular components and extension devices, and on each independent modular component in accordance with the method outlined in ISO 7198:1998, 8.9 Determination of kink diameter/radius.

NOTE Device segments may exhibit different kink resistance along the length. As such, multiple measurements may be necessary to fully characterize the flex/kink properties of the device.

D.5.3.10.6 Expression of results

The kink diameter/radius shall be expressed in millimetres (mm).

D.5.3.10.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the kink diameter/radius for the test samples.

D.5.3.11 Local compression

D.5.3.11.1 Purpose

The purpose of this test is to determine the deformation of the device in response to a localized compressive force, perpendicularly applied to the longitudinal axis of the device. The relevant design evaluation sections of ISO 25539-1 include 7.3.2 Implant integrity and 7.3.7 Patency.

NOTE 1 Although similar, crush resistance, local compression and radial force tests measure different attributes of the endovascular prosthesis, as follows:

— the crush resistance test measures the ability of the prosthesis to resist permanent deformation along the entire length of the device;

— the local compression test measures the ability of the prosthesis to resist permanent deformation under a localized (e.g. point) load;

— the radial force test measures the force exerted by the prosthesis on the vessel in the deployed state.

NOTE 2 This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.11.2 Materials

D.5.3.11.2.1 Endovascular system

D.5.3.11.2.2 Universal mechanical testing system, with compressive capability, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value, a constant rate of traverse and appropriate load application fixtures.

D.5.3.11.2.3 Probe, for applying compressive force. The design of the probe (e.g. shape, cross-sectional area) shall be appropriate for the endovascular prosthesis design and potential *in vivo* local compressive forces.

D.5.3.11.2.4 A fixture that prevents full-deployment of self-expanding devices, where over-sizing is required in clinical use.

D.5.3.11.2.5 Temperature controlled environment, (37 ± 2) °C for prostheses with material properties that are sensitive to changes between ambient and physiological temperatures.

D.5.3.11.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.11.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading and preconditioning.

D.5.3.11.5 Test method

— Develop a test method based on the following:

a) deploy the endovascular prosthesis modular component such that the configuration imitates clinical use (e.g. where oversizing is required, a fixture that prevents full deployment may be necessary to adequately simulate the initial compression condition) and allows for application of a compressive force directly to the endovascular prosthesis;

b) compress the endovascular prosthesis continuously or incrementally using a uniform rate of compression (e.g. 200 mm/min) until plastic deformation or full collapse occurs; the location of the load application on the prosthesis shall be recorded;

c) record the force and associated deflection at which plastic (permanent) deformation or full collapse occurs;

d) if the structure of the endovascular prosthesis is non-symmetric, repeat the test for the appropriate regions of the device, using new devices as appropriate.

NOTE The method for determining the force and deflection at which plastic deformation begins is not defined in this International Standard since this method will be specific to the device design under evaluation.

D.5.3.11.6 Expression of results

The force shall be recorded in newtons (N), displacement shall be reported in millimetres (mm) and area of compression probe in square millimetres (mm^2).

D.5.3.11.7 Test report

The test report shall be in accordance with Clause D.4. Report the maximum, minimum, mean and standard deviation of the compressive force and displacement for each region tested, the location of the load application and the design of the probe (e.g. shape, cross-sectional area). Justify the number and location of the load application(s).

D.5.3.12 Longitudinal tensile strength

D.5.3.12.1 Purpose

The purpose of this test is to determine the longitudinal tensile strength of the individual modular components of the endovascular prosthesis. The relevant design evaluation section of ISO 25539-1 includes 7.3.3.6 Longitudinal tensile strength.

D.5.3.12.2 Materials

D.5.3.12.2.1 Endovascular prosthesis

D.5.3.12.2.2 Materials listed in ISO 7198:1998, 8.3.2.2, as appropriate.

NOTE Consideration should be given to the use of an appropriate fixture (jaws adapters) which will avoid damage to the stent/attachment system component.

D.5.3.12.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.12.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment.

D.5.3.12.5 Test method

Testing shall be performed on each individual modular component in accordance with the method outlined in ISO 7198:1998, 8.3.2 Determination of longitudinal tensile strength. For this test the minimum load to cause failure shall be determined rather than the load at yield or break.

D.5.3.12.6 Expression of results

The longitudinal tensile strength shall be expressed in newtons (N).

D.5.3.12.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the longitudinal tensile strength for each modular component tested.

D.5.3.13 Migration resistance

D.5.3.13.1 Purpose

The purpose of this test is to determine the force required to displace the prosthesis within a mock artery. This test provides an estimation of the resistance to migration provided by the fixation mechanism(s) of the prosthesis (e.g. active fixation, radial force). The relevant design evaluation section of ISO 25539-1 includes 7.3.2 Fixation effectiveness.

NOTE This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.13.2 Materials

D.5.3.13.2.1 Endovascular system

D.5.3.13.2.2 Accessory devices, necessary to accomplish deployment in accordance with the instructions for use (IFU).

D.5.3.13.2.3 Mock artery, or simulated vessel with appropriate diameter, length, and mechanical properties for the endovascular prosthesis design (e.g. to accommodate hooks/barbs).

D.5.3.13.2.4 Universal mechanical testing system, equipped with a suitable load cell, or a force gauge, capable of measuring force to an accuracy of ± 5 % of the reported value.

D.5.3.13.2.5 Test fixture, capable of securely holding the mock artery and the endovascular prosthesis.

D.5.3.13.2.6 Temperature controlled environment, (37 ± 2) °C for prostheses with material properties that are sensitive to changes between ambient and physiological temperatures.

D.5.3.13.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.13.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.3.13.5 Test method

Develop a test method based on the following:

a) deploy the endovascular prosthesis into the mock artery, in accordance with the IFU, such that the length of the prosthesis within the mock artery is approximately the minimum recommended in the IFU (e.g. anchoring zone, neck length);

b) secure the sample in the test fixture(s);

c) using a uniform rate of separation (typically 50 mm/min to 200 mm/min), pull out the endovascular prosthesis from the mock artery and record the peak force.

NOTE The migration resistance may be affected by angulation and vessel disease (e.g. calcification). Additional testing or analyses should be considered in order to evaluate the effect of angulation and vessel disease on this parameter.

D.5.3.13.6 Expression of results

The migration resistance force shall be expressed in newtons (N). The length of the prosthesis within the mock artery shall be expressed in millimetres (mm).

D.5.3.13.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the migration resistance force. The length of the prosthesis within the mock artery shall be reported.

D.5.3.14 Pull test for modular components (or overlapping endoprostheses)

D.5.3.14.1 Purpose

The purpose of this test is to determine the force required to separate the modular components of an endovascular prosthesis or to separate overlapping endoprostheses in the deployed state. The relevant design evaluation section of ISO 25539-1 includes 7.3.5 Modularity.

NOTE This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.14.2 Materials

D.5.3.14.2.1 Endovascular system

D.5.3.14.2.2 Accessory devices, necessary to accomplish deployment in accordance with the instructions for use (IFU).

D.5.3.14.2.3 Universal mechanical testing system, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value, a constant rate of traverse and suitable gripping fixtures.

D.5.3.14.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.14.4 Conditioning

Conditioning shall be in accordance with Clause D.3. For prostheses with material properties that are sensitive to changes between ambient and physiological temperatures, a temperature-controlled environment should be used. Testing should be conducted in a fluid environment if this environment may affect the force required to separate modular components.

D.5.3.14.5 Test Method

Develop a test method based on the following:

a) deploy/assemble the modular components of the prosthesis, or the overlapping prostheses, in accordance with the IFU; the length of the overlap between the modular components or prostheses should approximate the minimum recommended in the IFU.

NOTE The use of an external constraint at or near the modular junction or prostheses overlap should be considered, as appropriate (e.g. overlap region not within an aneurysm). A constraint should not be used if the junction of the modular components or the overlap of the prostheses may be located within an aneurysm;

b) secure the sample in the test fixture(s);

c) using a uniform rate of separation (typically 50 mm/min to 200 mm/min), pull apart the modular components and record the peak force;

d) repeat the test for all modular junctions, including cuffs and extenders.

NOTE The force to separate the modular components or prostheses may be affected by the angulation between the components. Additional testing or analyses should be considered to evaluate the effect of angulation on this parameter.

D.5.3.14.6 Expression of results

Force shall be expressed in newtons (N). The rate of separation shall be expressed in millimetres per minute (mm/min). The length of the junction or overlap shall be expressed in millimetres (mm).

D.5.3.14.7 Test report

The test report shall be in accordance with Clause D.4 and include the maximum, minimum, mean and standard deviation of the force to separate the modular components or prostheses. The length of the junction or overlap shall be reported.

D.5.3.15 Radial force

D.5.3.15.1 Purpose

The purpose of this test is to determine the force exerted by a self-expanding implant as a function of the implant diameter, under the conditions of expansion and compression. The relevant design evaluation sections of ISO 25539-1 include 7.3.2 Fixation effectiveness and 7.3.7 Patency.

NOTE 1 Although similar, crush resistance, local compression and radial force tests measure different attributes of the endovascular prosthesis, as follows:

— the crush resistance test measures the ability of the prosthesis to resist permanent deformation along the entire length of the device;

— the local compression test measures the ability of the prosthesis to resist permanent deformation under a localized (e.g. point) load;

— the radial force test measures the force exerted by the prosthesis on the vessel in the deployed state.

NOTE 2 This test is not designed to evaluate the entire system; however, the system is required to deploy the prosthesis that is under test.

D.5.3.15.2 Materials

D.5.3.15.2.1 Endovascular system

D.5.3.15.2.2 Universal mechanical testing system, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value, a constant rate of traverse, and appropriate gripping fixtures.

D.5.3.15.2.3 Expansion and compression clamps/fixtures, such as "Clamshell", "V" Block, or a circumferential tension device such as a loop or snare. The fixture diameter/dimensions should be appropriate for the implant being tested.

D.5.3.15.2.4 Temperature controlled environment, (37 ± 2) °C for prostheses with material properties that are sensitive to changes between ambient and physiological temperatures.

NOTE When selecting the test fixture, consideration must be given to the width or area under study, the effects of friction and the influence of the fixture geometry on the measured loads.

D.5.3.15.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.15.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading and preconditioning.

D.5.3.15.5 Test method

Develop a test method based on the following:

a) testing should be completed at the appropriate location(s) [e.g. fixation zone(s)] for each device;

b) deploy the endovascular prosthesis within the fixture such that the initial diameter is less than or equal to the minimum vessel diameter indicated in the instructions for use (IFU);

c) measure the radial force as a function of diameter as the implant is expanded to the maximum indicated vessel diameter; the speed of testing should be such that the results represent static conditions;

d) measure the radial force as a function of diameter as the implant is compressed to the minimum indicated vessel diameter; the speed of testing should be such that the results represent static conditions.

D.5.3.15.6 Expression of results

Radial force shall be expressed in newtons per unit length in millimetres (N/mm). The length shall be defined as the length of the prosthesis within the fixture.

D.5.3.15.7 Test report

The test report shall be in accordance with Clause D.4 and shall include a description of the prosthesis location(s) tested, the minimum, maximum, mean and standard deviation of the radial force at the minimum and maximum diameters for each device size tested. Results from both expansion and compression shall be reported, with the respective speeds used during testing.

D.5.3.16 Strength after repeated puncture (for A-V access)

D.5.3.16.1 Purpose

The purpose of this test is to determine the strength of the endovascular prostheses following repeated dialysis-needle punctures. The relevant design evaluation section of ISO 25539-1 includes 7.3.3 Implant integrity.

D.5.3.16.2 Materials

D.5.3.16.2.1 Endovascular prosthesis

D.5.3.16.2.2 Materials listed in ISO 7198:1998, 8.3.4.2, as appropriate.

D.5.3.16.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.16.4 Conditioning

Conditioning shall be in accordance with Clause D.3.

D.5.3.16.5 Test method

Testing shall be performed in accordance with the method outlined in ISO 7198:1998, 8.3.4 Determination of strength after repeated puncture.

D.5.3.16.6 Expression of results

The strength before and after puncturing shall be expressed in the units specified in ISO 7198:1998, 8.3.4.

D.5.3.16.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the maximum, minimum, mean and standard deviation of the strength before and after puncturing of the sample implant.

D.5.3.17 Strength of graft to stent/attachment system bond

D.5.3.17.1 Purpose

The purpose of this test is to determine the strength of the fixation or bond between the graft material and the stent or attachment system. The relevant design evaluation section of ISO 25539-1 includes 7.3.3 Implant integrity.

D.5.3.17.2 Materials

D.5.3.17.2.1 Endovascular prosthesis, or a segment of the prosthesis, which is representative of the bonding method(s) used in the finished device.

D.5.3.17.2.2 Universal mechanical testing system, equipped with a suitable load cell capable of measuring force to an accuracy of ± 5 % of the reported value, a constant rate of traverse, and appropriate gripping fixtures.

D.5.3.17.2.3 Design of the fixturing, appropriate for the bonding method(s) and potential *in vivo* forces.

D.5.3.17.2.4 Temperature controlled environment, (37 ± 2) °C for bonds that are temperature sensitive.

D.5.3.17.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.17.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment.

D.5.3.17.5 Test method

Develop a test method based on the following:

a) secure the sample in the test fixture(s);

b) apply a load to the bond using a constant crosshead speed (e.g. 200 mm/min) and record the force required to initiate separation of the components and the peak force required to completely separate the components; if more than one bonding method or technique is utilized in the design of the device, all methods shall be evaluated.

D.5.3.17.6 Expression of results

The forces shall be expressed in newtons (N). It may be appropriate to normalize the results (e.g. by area, length, number of fixation points).

Qualitatively assess and record the mode of failure (e.g. tear in covering, rupture of suture, separation of bond).

D.5.3.17.7 Test reports

The test report shall be in accordance with Clause D.4 and shall include the mode of failure and the maximum, minimum, mean and standard deviation of the force required to initiate separation of the components and the peak force required to completely separate the components. The test report shall also include an assessment of the relevance of the results to the integrity of the prosthesis.

D.5.3.18 Corrosion assessment

D.5.3.18.1 Purpose

The purpose of this assessment is to evaluate the susceptibility of the metallic components of the prosthesis, to corrosion in a simulated physiological environment for the intended implant duration. The relevant design evaluation section of ISO 25539-1 includes 7.3.3 Implant integrity.

D.5.3.18.2 Materials

D.5.3.18.2.1 Endovascular prosthesis, or appropriate test samples of the prosthesis (e.g. segments, sections, components, subassemblies).

NOTE Test samples should be appropriate to the type of corrosion under evaluation (e.g. crevice, pitting, fretting, galvanic).

D.5.3.18.2.2 Materials, apparatus and test conditions, as specified in the test methods selected for this evaluation.

D.5.3.18.2.3 Suitable standard reference samples.

D.5.3.18.3 Sampling

Sampling shall be in accordance with Clause D.2.

D.5.3.18.4 Conditioning

Conditioning shall be in accordance with Clause D.3 and shall include loading, preconditioning and deployment. For metallic test samples, the metal(s) under evaluation shall undergo all manufacturing, fabrication and finish processing, as well as all post processing steps such as cleaning.

D.5.3.18.5 Test Method

Develop a test method based on the following:

a) evaluate all metallic components of the implant using appropriate corrosion test methods and assessment; in cases where different metals may be in contact clinically, they shall be in similar contact during evaluation (e.g. when a stent may be placed within the endovascular prosthesis).

NOTE Corrosion assessment includes, but is not limited to, evaluation of test results, review of literature and consideration of the historical clinical performance of the material(s) under assessment. Guidance on corrosion assessment may be found from a variety of sources (e.g. literature, text books, standards, regulatory guidance documents). The Bibliography includes a partial list of references regarding corrosion terminology, equipment, test procedures and methods.

D.5.3.18.6 Expression of results

Test data shall be expressed in units appropriate to the methods selected.

D.5.3.18.7 Test report

The test report shall be in accordance with Clause D.4 and shall include the complete corrosion assessment, including a summary of all test data, analyses and referenced information, comparisons to applicable controls, any appropriate comparison between *in vivo* and *in vitro* performance and conclusions regarding the anticipated corrosion resistance of the endovascular prosthesis. For quantitative data, the maximum, minimum, mean and standard deviation shall be included. Applicable requirements indicated in the guidance documents used for testing should also be included.

D.5.3.19 Fatigue and durability test (pulsatile)

D.5.3.19.1 Purpose

The purpose of this test is to evaluate aspects of the long-term integrity of the endovascular prosthesis under cyclic (pulsatile) radial loading conditions. The relevant design evaluation section of ISO 25539-1 includes 7.3.3 Implant integrity.