SLOVENSKI STANDARD
SIST EN 13868:2002

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Katetri - Preskusne metode za določanje pregibanja katetrov in cevk z enojno svetlino

Catheters - Test methods for kinking of single lumen catheters and medical tubing

Katheter - Prüfverfahren für die Knickbildung von Kathetern mit Einzellumen und Schläuchen zur medizinischen Anwendung

Cathéters - Méthodes d'essai de résistance a la plicature pour cathéters a simple voie et tubes a usage médical

Ta slovenski standard je istoveten z: **EN 13868:2002**

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11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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English version

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Cathéters - Méthodes d'essai de résistance à la plicature pour cathéters à simple voie et tubes à usage médical

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This European Standard was approved by CEN on 10 May 2002.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.

Annexes A and B are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Tubes for catheters and for certain other medical uses have to be flexible, but simultaneously they need also to have an appropriate minimum strength. The strength and flexibility allow the tube to be handled easily, so it can be bent around obstacles, for example within the human anatomy. However, not all flexible tubes show the same behaviour during bending. Some tubes can bend considerably without kinking i.e without collapsing and thereby drastically reducing the cross sectional area, while others kink easily. In catheter applications, this reduction of the flow area can cause severe reduction in the flow of fluids.

1 Scope

This European Standard specifies test methods for kinking properties for single lumen catheters and medical tubing, as presented for clinical use, when bent in a single plane. It is recognized that other forces e.g. twisting will influence the behaviour of the product, but no standard test methods are yet available. It is also recognized that such tubing can be used to transport liquids or gases. However, water is used as a standard test medium, as the purpose of this standard is to ensure uniformity in the evaluation of tubing kink properties.

NOTE This method is designed for single-lumen tubing but can also be used for multi-lumen tubing. It should be ensured that the bending is done in the worst case direction, unless this would not present a possible real life situation.

2 Terms and definitions

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

2.1
kink distance
plate distance at kink in the short term test method

2.2
kink length *L*
length of the tubing loop at kink in the kink test tool in the long term test method

2.3
kink point
total collapse or distinct “knee” when kinking (see Figure A.4)

2.4
plate distance *D*
distance between the two plates of the tensile testing apparatus in the short term test method (see Figure A.3)

2.5
corrected kink distance *C*
plate distance at kink plus correction for grooves, result of the short term test method (see Figure A.3)

3 Test methods and results

In order to reflect that plastics materials show different visco-elastic properties and that there are great variations in exposure time for different kinds of medical tubing, it is necessary to have a test method for relatively short term use (< 1 h), the 'short term test method' and a test method for more static use (> 1 h), the 'long term test method'. The user shall choose the test method which best reflects the intended product function.

The test methods are specified in annexes A and B.

The tests shall be performed on test samples which are as similar as possible to the final product. Unless otherwise specified in a particular product standard, the tests shall be performed under the same conditions of use as the final product e.g. on sterilized samples if the end products are sterilized and at 37 °C if that is the case for the end products in use.

Annex A
(normative)

Kinking - Short term test

A.1 Principle

This is a method for determining the kink resistance of medical tubing for short term use (< 1h). The tubing is defined as being kinked when the bending causes a decrease in flow such that the initial flow through the straight tube is reduced by more than 50 %.

NOTE Force measurement. As an alternative principle, it has been verified that the kinking behaviour of tubing can be indicated by force measurement. By following the procedure in A.3, the plate distance at kink is defined as that distance where the corresponding force measurement starts decreasing (see Figure A.4).

A.2 Apparatus

A.2.1 Kink test tool, for short term test (see Figure A.1) having grooves of depth as given in Table A.1.

A.2.2 Tensile testing apparatus, or other means of applying push/pull forces.

A.2.3 Flow meter(s), with a range of at least 40 % to100 % of full flow through the straight tube and preferably with a quick response time.

A.2.4 Plotter, or other measurement recording device.

A.2.5 A system with constant pressure of (1 000 ± 50) mm hydrostatic head, constant temperature (see clause 3) within ± 2 °C and adequate water supply, (see Figure A.2) arranged so that the test tubing has the smallest diameter of the system thereby providing the largest resistance to the flow. If the flow is too low, a higher constant pressure can be used, but it shall be verified that it will not affect the results.

A.2.6 Caliper, to measure the plate distance.

A.3 Procedure

A.3.1 Before starting, ensure that the water and samples are equilibrated to the required test temperature, and record this temperature. If appropriate, both sample and environment should be of the typical use temperature of the product. It is important to avoid the presence of air bubbles in the tubing throughout the test.

A.3.2 Measure the full flow (100 %) in the straight tube.

A.3.3 Select a kink test tool (A.2.1, Figure A.1) with plates having grooves of depth appropriate to the size of tubing to be tested (see Table A.1). Insert the tube carefully in the grooves so it forms an arch between two parallel plates (see Figure A.1), so that the arch will remain within the plates during the entire test. The tube is kept in place by the grooves in the plates. Connect the tube to the water system (see Figure A.2).

The start distance shall be fixed, well defined (e. g. 50 mm, 100 mm or 200 mm) and at least twice the expected kink distance (the parallel plate distance at the kink point). Secure the tubes (with tape, rubber bands or similar) around the plates, to make sure that the tube will remain in the grooves (see Figure A.1).

A.3.4 Use a tensile testing apparatus to push the upper plate down at a fixed rate of 40 mm/min ± 20 mm/min.

A.3.5 Monitor the flow as a function of the plate distance. This can be done by, for example, use of a plotter, computer or voltage meter. The tube is defined as kinked when the flow is reduced to 50 % of the flow through the straight tube. Record the corresponding plate distance (*D*).

A.3.6 Repeat the procedure with at least four new tubes (all samples of equal dimensions), and record in each case the plate distance (i.e. at least 5 determinations).

A.3.7 Calculate the mean value of plate distance with 50 % of full flow. Correct this value according to Figure A.3. The corrected value is called "the corrected kink distance" (*C*) and is calculated from the expression:

$C = D + 2h - d(\sqrt{2} - 1)$

where *C* is the corrected kink distance in millimetres;

h is the depth of groove in millimetres;

d is the outside diameter of the tube in millimetres.

A.4 Expression of results

The corrected kink distance is the kink distance for the tubing.
Record the mean corrected kink distance together with the outside and inside diameters for the tubing.

The results shall be expressed as e.g.:

"Kinking test according to EN 13868, annex A (short term):

Corrected kink distance: ……..".

Table A.1 - Recommended depth of groove in kink test tool

Catheter size (Charrière)	Catheter size (outside diameter) mm	Recommended value of *h* (see Figure A.3) mm
6	2	1,4
12	4	2,8
18	6	4,2
24	8	5,7