SLOVENSKI STANDARD
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Sterilni uretralni katetri za enkratno uporabo

Sterile urethral catheters for single use

Sterile Harnblasenkatheter zur einmaligen Verwendung

Sondes urinaires stériles non réutilisables

Ta slovenski standard je istoveten z: **EN 1616:1997**

ICS:

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

SIST EN 1616:2000 **en**

EUROPEAN STANDARD **EN 1616**

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Descriptors: medical equipment, disposable equipment, urinary tract catheters, specifications, dimensions, flow rates, tensile strength, junctions, safety, labelling

English version

Sterile urethral catheters for single use

Sondes urinaires stériles non réutilisables Sterile Harnblasenkatheter zur einmaligen Verwendung

This European Standard was approved by CEN on 1997-01-10. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

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

Annexes A, B, C and D form normative parts of this European Standard. Annex E is for information.

1 Scope

This European Standard specifies requirements for sterile, single-use urethral catheters, with and without balloons.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publications referred to applies.

EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled 'Sterile'.
EN 980	Information supplied by the manufacturer for medical devices - Graphical symbols for medical devices
prEN 1041	Terminology, Symbols and Information provided with Medical Devices - Information provided with medical devices supplied by the manufacturer
EN 1618 : 1997	Catheters other than intravascular catheters - Test methods for common properties
EN 20594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1 : 1986).

3 Definitions

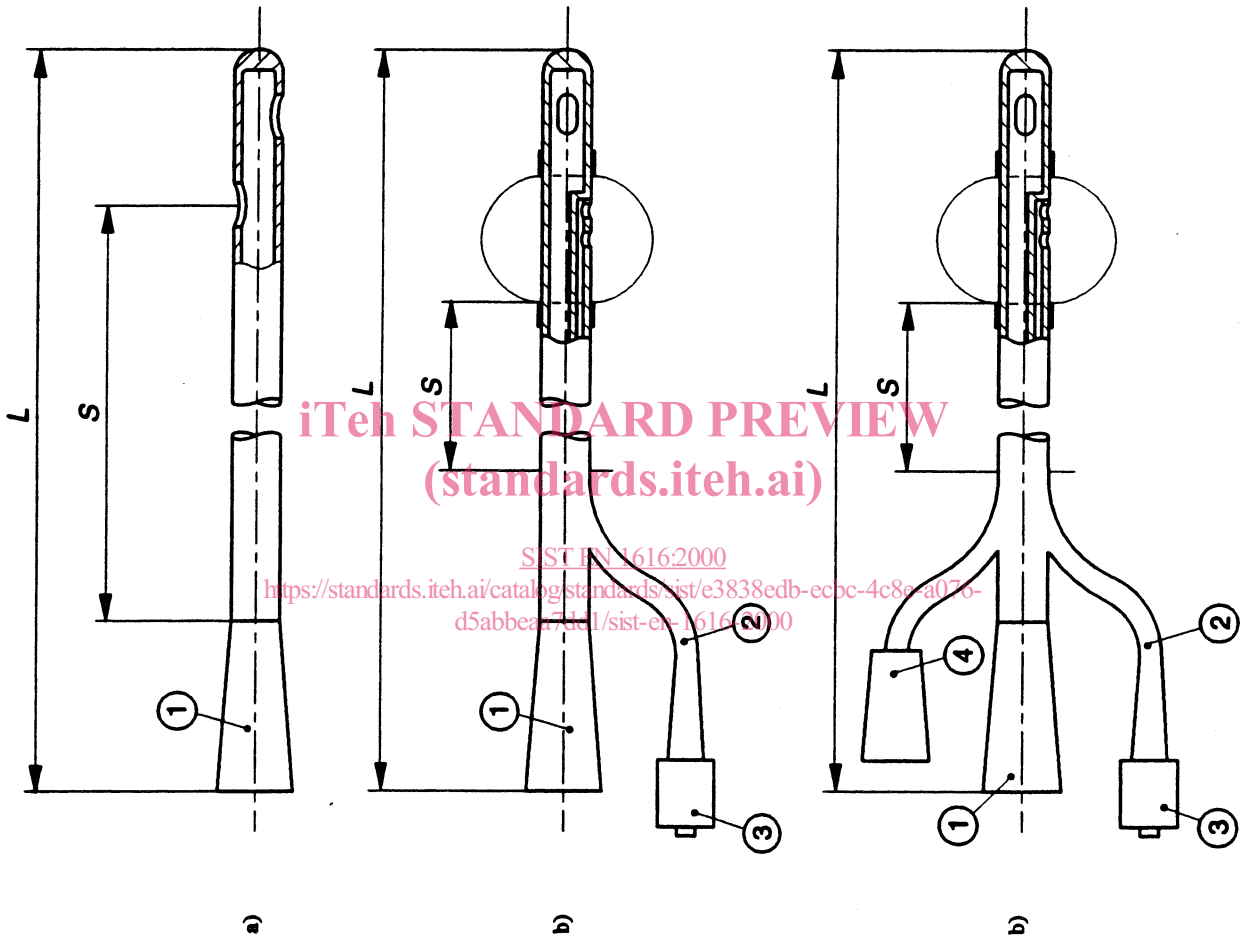
For the purposes of this European standard, the following definitions apply.

3.1 urethral catheter: Tubular device intended for being introduced into the vesical cavity through the urethra in order to provide drainage and/or flushing of the bladder.

3.2 balloon capacity: Volume of liquid to be introduced into the catheter in order to fill the inflation channel and inflate the balloon.

3.3 shaft: Portion of the catheter excluding the tip, balloon(s), funnel(s) and/or sideport.

3.4 outside diameter: Maximum dimension measured across the cylindrical portion of the shaft.



1. Drainage funnel
2. Inflation funnel
3. Valve
4. Irrigation funnel

L is the overall length
S is the effective length

Figure 1: Typical urethral catheters a) without and b) with balloon

4 Requirements

4.1 General

All tests shall be carried out on the product in the ready-for-use state.

4.2 Surface finish

When the catheter is ready for use (e.g. treated according to the manufacturer's instructions) and is examined by normal or corrected-to-normal vision at 2,5 times magnification, the surface of the shaft, tip, balloon and eyes shall appear free from extraneous matter.

4.3 Dimensions

4.3.1 *Size designation*

The size of the catheter shall be designated by its nominal outside diameter expressed in mm to the nearest 0,1 mm. Tolerances on this stated size shall be ± 0,33 mm. The balloon capacity shall be expressed in ml.

NOTE: Additional units can also be given.

4.3.2 *Lengths*

The minimum overall length (L) and shaft lengths (S) shall be as given in table 1 (see also figure 1).

4.4 Strength

When tested in accordance with the method given in annex A, neither the tip nor the funnel shall become detached from the shaft, and the shaft shall not show any sign of breaking.

4.5 Connector security

When tested in accordance with the method given in annex B, the drainage funnel shall not part from the test connector.

4.6 Balloon security

4.6.1 When tested in accordance with the method given in annex C, the balloon shall not leak and shall not occlude the drainage eyes.

NOTE: The change in profile at each end of the uninflated balloon should be smoothly blended with the shaft. The balloon should be capable of approximately symmetrical expansion when filled with water at ambient temperature to its specified balloon capacity.

4.6.2 When tested by the method given in annex D the percentage of water recovered shall be not lower than the value given in table D.2.

4.7 Kinkability

NOTE: This sub-clause will be prepared when a test method has been developed.

4.8 Flow rates

When tested in accordance with the method given in annex E of EN 1618 : 1997, the minimum flow rates shall be as given in table 2.

4.9 Biocompatibility

The device shall be evaluated for biocompatibility and shall be free from biological hazard.

NOTE: Methods for evaluation for biocompatibility are given in EN 30993.

4.10 Sterility

The device shall comply with EN 556.

4.11 Corrosion test

When tested in accordance with the method given in annex A of EN 1618 : 1997, the test specimen shall not show any evidence of corrosion.

5 Symbols and labelling

The symbols and information provided with catheters shall be as specified in EN 980 and prEN 1041, and in addition the following information shall be given:

a) the manufacturer's stated minimum and maximum balloon inflation volumes;
b) the designated size as given in 4.3.1.

Table 1 : Shaft dimensions

Catheter type	*L* (minimum) mm	*S* (minimum) mm
Paediatric without balloon	150	n.a[1)]
Paediatric with balloon	220	150
Female without balloon	150	n.a.
Female with balloon	220	130
Male without balloon	360	n.a.
Male with balloon	360	275
n.a. = not applicable		

Table 2 : Average flow rates

Designated size		Average flow rate (minimum)	
Outside diameter mm	Charrière equivalent[1] FG/Ch/Fr	Drainage lumen ml/min	Irrigation lumen ml/min
2,0	6	10	n.a[2]
2,7	8	15	n.a
3,3	10	30	n.a
4,0	12	50	n.a
4,7	14	70	25
5,3	16	100	25
6,0	18	100	25
6,7	20	100	25
7,3	22	100	30
8,0	24	100	30
8,7	26	100	30
9,3	28	100	n.a
10,0	30	100	n.a

[1] The Charrière equivalent is given for information.

[2] n.a = not applicable.

Annex A (normative)

Test method for determining the strength of the catheter

A.1 Principle

Catheters fitted with balloons may be in-situ for prolonged periods. Such catheters are therefore immersed for 14 days in simulated urine prior to testing. This step is omitted for catheters without balloons. A tensile force is applied to the union of the tip and shaft of the catheter. For catheters with lateral eyes, the tensile force is to be applied to the eyes. For catheters with no lateral eyes, the tensile force is applied between the shaft of the catheter and the drainage funnel. On removal of this force, the catheter is examined for signs of failure.

A.2 Reagents

A.2.1 Simulated urine, pH approximately 6,6, of the following composition, the reagents being of recognized analytical grade:

Urea		25,0 g
Sodium chloride		9,0 g
Disodium hydrogen orthophosphate, anhydrous		2,5 g
Ammonium chloride		3,0 g
Creatinine		2,0 g
Sodium sulfite, hydrated		3,0 g
Distilled water	to	1,0 l

WARNING: This solution can support microbial growth. There is a strong possibility that large numbers of micro-organisms will be present in the solution at the end of the tests described in A.3 and C.3. These procedures should be carried out by trained personnel taking appropriate precautions in the handling of the immersed catheter and the disposal of the contaminated solution.

A.3 Apparatus

A.3.1 Device for suspending catheter with lateral eyes, comprising a pin which passes through a drainage eye of the catheter, the pin having a diameter of between 50 % and 75 % of that of the drainage lumen of the catheter to be tested. An example of a suitable device is shown in figure A.1 a).