

# ISO 20697:2018 (E)

## Sterile drainage catheters and accessory devices for single use

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Intended performance
5	General requirements
5.1	Risk management
5.2	Biocompatibility
5.3	Detectability
5.4	Surface finish
5.5	Size designation
5.5.1	General
5.5.2	Outer diameter
5.5.3	Effective length
5.5.4	Nominal balloon inflation volume
5.6	Connector
5.7	MRI compatibility
5.8	Sterilization
6	Specific requirements
6.1	Kink stability
6.2	Corrosion resistance
6.3	Resistance to deformation
6.4	Peak tensile force
6.4.1	Connections
6.4.2	Drainage catheters and other accessory devices
6.5	Impact resistance
6.6	Flow rate
6.7	Retention strength
6.8	Balloon safety
6.9	Catheter inflation lumen integrity and volume maintenance
6.9.1	General
6.9.2	Compliant balloon
6.9.3	Non-compliant balloon
6.10	Inflated balloon resistance to traction
6.11	Freedom from leakage during aspiration or vacuum
7	Information supplied by the manufacturer
7.1	General
7.2	Marking on the device and/or packaging
7.3	Instructions for use
Annex A	(informative) Test method for determining kink stability
A.1	Principle
A.2	Apparatus
A.3	Procedure
A.4	Test report

**Annex B (normative) Test method for corrosion resistance**

- B.1 Principle**
- B.2 Reagents**
- B.3 Apparatus**
- B.4 Procedure**
- B.5 Test report**

**Annex C (normative) Test method for resistance to deformation by suction**

- C.1 Principle**
- C.2 Apparatus**
- C.3 Procedure**
- C.4 Test report**

**Annex D (normative) Test method for determining peak tensile force of connections**

- D.1 Principle**
- D.2 Apparatus**
- D.3 Procedure**
- D.4 Test report**

**Annex E (normative) Test method for determining peak tensile force of drainage catheter**

- E.1 Principle**
- E.2 Apparatus**
- E.3 Procedure**
- E.4 Test report**

**Annex F (normative) Test method for impact resistance of collection device**

- F.1 Principle**
- F.2 Apparatus**
- F.3 Procedure**
- F.3.1 Collection device**
- F.3.2 Suction source**
- F.4 Test report**

**Annex G (normative) Test method for determination of flow rate through catheter**

- G.1 Principle**
- G.2 Reagent**
- G.3 Apparatus**
- G.4 Procedure**
- G.5 Expression of results**
- G.6 Test report**

**Annex H (informative) Test method for retention strength**

- H.1 Principle**
- H.2 Apparatus**
- H.3 Procedure**
- H.4 Test report**

**Annex I (normative) Test method for determining balloon safety**

- I.1 Principle**
- I.2 Reagents**
- I.3 Apparatus**
- I.4 Procedure**
- I.5 Test report**

**Annex J (normative) Test method for determining inflation lumen leakage and/or function and/or balloon deflation (catheter with compliant balloon)**

- J.1 Principle**
- J.2 Apparatus and reagents**
- J.3 Procedure**
- J.4 Test report**

**Annex K (normative) Test method for determining balloon size and deflation reliability (catheter with non-compliant balloon)**

- K.1 Principle**
- K.2 Apparatus and reagents**
- K.3 Procedure**
- K.4 Test report**

**Annex L (normative) Test method for determining inflated balloon resistance to traction**

- L.1 Principle**
- L.2 Apparatus**
- L.3 Procedure**
- L.4 Test report**

**Annex M (normative) Test method for resistance to leakage during aspiration or vacuum**

- M.1 Principle**
- M.2 Reagent**
- M.3 Apparatus**
- M.4 Procedure**
- M.5 Test report**

**Page count: 37**