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Small bore connectors for liquids and gases in healthcare applications —

Part 6: Connectors for neuraxial applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 6: Raccords destinés à des applications en contact avec le système nerveux (neuraxiales)

Reference number
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 3: Connectors for enteral applications*

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

An additional part on connectors for urethral and urinary applications is planned.

This corrected version of ISO 80369-6:2016 incorporates the following correction:

— in 6.3, the cross-reference to 6.1.2 has been changed to 6.1.1.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from inappropriate medication, liquid nutritional formula, or air being administered neuraxially. Many incidents have been reported leading to international recognition of the importance of these issues and a need has been identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver fluids in other APPLICATIONS.

The ISO 80369 series was developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs and dimensions of SMALL-BORE CONNECTORS to ensure that

a) they do not misconnect with other small-bore connectors, and

b) they safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design and the dimensions and drawings of SMALL-BORE CONNECTORS intended to be used in neuraxial APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

There is international evidence that 'wrong-route' medication errors with neuraxial MEDICAL DEVICES have caused deaths and severe HARM. There are reports of non-epidural medications being administered into the epidural space and local anaesthetic solutions intended for epidural administration being administered by the intravenous route.[1] [9] [14] [15] [19] There is also a report where an anaesthetic agent for intravenous use was administered into the cerebrospinal fluid via an external ventricular drain[11] and earlier reports of antibiotics being inappropriately administered by this route.

In July 2007, the World Health Organization's World Alliance for Patient Safety issued Alert 115 describing four incidents in different countries in which vincristine had been accidentally administered by the intrathecal route instead of intravenous route, as intended.[1] The Alert indicated that, since 1968, this same error had been reported 55 times from a variety of institutional settings.

These incidents occurred despite repeated warnings of the RISK and the introduction of extensive labelling requirements and recommendations, intended to standardize practice and reduce RISKS.

Other health organizations around the world have also issued detailed guidance to minimize the RISK of these 'wrong-route' errors.[9] [15] [20] [21]

Nevertheless, reports of fatal incidents following the administration of vinca alkaloids continue to be reported internationally.[22] In 2009, the Food and Drug Administration in the USA issued a Medical Devices Calendar, which included an example of a case study of a neuraxial misconnection.[12]

CONNECTORS manufactured to the dimensions set out within this International Standard are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series of standards for SMALL-BORE CONNECTORS, except as indicated in G.2. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should reduce the RISK of air, non-vascular medication and liquid nutritional formula being delivered via an alternative route, such as neuraxially, intravenously, or via an airway device.

In this International Standard, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— terms defined in ISO 80369-1 and Clause 3: small capitals.

In this part of ISO 80369, the conjunctive “or” is used as an “inclusive or” so a statement is true, if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369, and

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Small bore connectors for liquids and gases in healthcare applications —

Part 6: Connectors for neuraxial applications

1 * Scope

This part of ISO 80369 specifies requirements for SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in neuraxial APPLICATIONS. Neuraxial APPLICATIONS involve the use of MEDICAL DEVICES intended to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neuraxial APPLICATION include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epi-, extra-, or peri-dural space. Neuraxial APPLICATION anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the branchial plexus blocks or single nerve blocks. Neuraxial APPLICATION procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 For the purposes of this part of ISO 80369, local anaesthesia injected hypodermically is not considered a neuraxial APPLICATION.

EXAMPLES Intended administration includes intrathecal chemotherapy, local anaesthetics, radiological contrast agents, antibiotics, analgesics.

This part of ISO 80369 specifies dimensions and requirements for the design and functional performance of these SMALL-BORE CONNECTORS intended to be used with MEDICAL DEVICES.

This part of ISO 80369 does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 3 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into MEDICAL DEVICES, medical systems, or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in this part of ISO 80369, will be included. Furthermore, it is recognized that standards need to be developed for many MEDICAL DEVICES used for neuraxial APPLICATIONS.

NOTE 4 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for SMALL-BORE CONNECTORS intended for use with NEURAXIAL APPLICATION MEDICAL DEVICES or ACCESSORIES, which do not comply with this part of ISO 80369.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-10, *Standard test method for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2007, ISO 80369-1:2010, and ISO 80369-20:2015 and the following apply.

NOTE For convenience, the sources of all defined terms used in this document are given in Annex J.

3.1
LOCK CONNECTOR
CONNECTOR with a locking mechanism

3.2
NORMAL USE
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005/Amd1:2012, 3.97, modified replaced 'OPERATOR' with 'USER']

3.3
RATED
<value> term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005, 3.97]

3.4
SLIP CONNECTOR
CONNECTOR without a locking mechanism

3.5
USER
person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: There can be more than one USER of a MEDICAL DEVICE.

Note 2 to entry: Common USERS include clinicians, PATIENTS, cleaners, maintenance and service personnel.

[SOURCE: IEC 62366-1:2015, 3.24]

3.6
USER PROFILE
summary of the mental, physical and demographic traits of an intended USER GROUP, as well as any special characteristics, such as occupational skills, job requirements and working conditions, which can have a bearing on design decisions

[SOURCE: IEC 62366-1:2015, 3.29]

4 General requirements

4.1 General requirements for the neuraxial APPLICATION

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in neuraxial APPLICATIONS made in compliance with this part of ISO 80369 comply with ISO 80369-1:2010, unless otherwise indicated in this part of ISO 80369.

The inside diameter of the fluid lumen of male LUER CONNECTOR, as specified in ISO 80369-7:—, may contact the sealing surfaces of the N1 male CONNECTOR in LMC conditions when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in G.2.

The sealing surface of female E1 CONNECTOR, as specified in ISO 80369-3:—, may contact the thread surfaces of the N2 female CONNECTOR in LMC conditions when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in G.2.

Because the following CONNECTORS are inadequately specified, SMALL-BORE CONNECTORS for use in neuraxial APPLICATIONS should not, but may connect with:

— the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;

— the temperature sensor CONNECTOR and mating ports made in compliance with ISO 8185:2007, Annex DD;

— the nipples of EN 13544-2:2002 and EN 13544-2:2002+Amd1:2009.

The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in Annex C.

The test of Annex H shall replace ISO 80369-1:2010, Annex B.

NOTE 1 Annex H describes a deviation to the physical test NON-INTERCONNECTABLE characteristics of ISO 80369-1:2010, Annex B. A rationale for the deviation is provided in Annex A. For neuraxial SMALL-BORE CONNECTORS, Annex H, supersedes ISO 80369-1:2010, Annex B.

Where the design of the SMALL-BORE CONNECTORS of this part of ISO 80369 relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the NON-INTERCONNECTABLE characteristics shall be VERIFIED.

Check compliance by applying the tests of Annex H. Compliance also may be shown by applying a computer aided design (CAD) analysis of the dimensions of all of the ISO 80369 series SMALL BORE CONNECTORS and the SMALL BORE CONNECTOR under test, in conjunction with physical testing of the SMALL BORE CONNECTOR per Annex B where the CAD analysis does not demonstrate the NON-INTERCONNECTABLE characteristics. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE requirements of Annex H.

NOTE 2 MEDICAL DEVICES using the SMALL-BORE CONNECTORS of this part of ISO 80369 that do not rely on the dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics are presumed to comply with the NON-INTERCONNECTABLE characteristics of this part of ISO 80369.

NOTE 3 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in Annex D.

NOTE 4 The summary of the usability requirements for CONNECTORS for this APPLICATION is provided in Annex E.

NOTE 5 The summary of criteria and requirements for CONNECTORS for this APPLICATION is provided in Annex F.

NOTE 6 The summary of assessment of the design of CONNECTORS for this APPLICATION according to ISO 80369-1:2010, Clause 7, is contained in Annex G.

4.2 * Material used for SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, neuraxial SMALL-BORE CONNECTORS shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 950 MPa.

Check compliance by application of the tests of ASTM D638-10 or ASTM D790-10.

4.3 TYPE TESTS

Compliance with the requirements of this part of ISO 80369 shall be determined by TYPE TESTS.

5 Dimensional requirements for neuraxial SMALL-BORE CONNECTORS

Neuraxial SMALL-BORE CONNECTORS shall comply with the dimensions and tolerances as given in

— Figure B.1 and Table B.1 for an N1 male SLIP CONNECTOR.

— Figure B.2 and Table B.2 for an N2 male LOCK CONNECTOR.

— Figure B.3 and Table B.3 for an N2 male LOCK CONNECTOR with rotatable collar.

— Figure B.4 and Table B.4 for an N2 female CONNECTOR with swept threads.

— Figure B.5 and Table B.5 for an N2 female CONNECTOR with lugs.

Check compliance by verifying the relevant dimensions and tolerances specified in Annex B.

6 Performance requirements

6.1 Fluid leakage

6.1.1 Fluid leakage requirement

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for leakage using either the leakage by pressure decay TEST METHOD or the positive pressure liquid leakage TEST METHOD.

6.1.2 Leakage by pressure decay

Neuraxial SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the leakage by pressure decay TEST METHOD shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium. MANUFACTURERS may use a greater applied pressure or longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference CONNECTOR specified in Annex C.

6.1.3 Positive pressure liquid leakage

Neuraxial SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the positive pressure liquid leakage TEST METHOD shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa. MANUFACTURERS may use a greater applied pressure or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex C, while using the leakage reference CONNECTOR specified in Annex C.

6.2 Subatmospheric pressure air leakage

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for subatmospheric pressure air leakage. Neuraxial SMALL-BORE CONNECTORS shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied subatmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15 s and 20 s. MANUFACTURERS may use a greater applied subatmospheric pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex D, while using the stress cracking reference CONNECTOR specified in Annex C.

6.3 Stress cracking

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for stress cracking. Neuraxial SMALL-BORE CONNECTORS shall meet the requirements of 6.1.1 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check compliance by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference CONNECTOR specified in Annex C.

6.4 Resistance to separation from axial load

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. Neuraxial SMALL-BORE CONNECTORS shall not separate from the reference CONNECTOR over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between,

a) 23 N and 25 N for a SLIP CONNECTOR, and

b) 32 N and 35 N for a LOCK CONNECTOR.

MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.5 Resistance to separation from unscrewing

LOCK CONNECTORS shall be evaluated for separation from unscrewing. A LOCK CONNECTOR shall not separate from the reference CONNECTOR for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,0198 N·m to 0,0200 N·m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.6 Resistance to overriding

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for resistance to overriding. Neuraxial SMALL-BORE CONNECTORS shall not override the threads or lugs of the reference CONNECTOR while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s. MANUFACTURERS may use a greater applied torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex H, while using the separation from axial load reference CONNECTOR specified in Annex C.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of this part of ISO 80369, and is intended for those who are familiar with the subject of this part of ISO 80369 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 80369 necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the clauses and subclauses of this part of ISO 80369 to which they refer. The numbering is, therefore, not consecutive.

Clause 1 **Scope**

In 2000, a Task Group of the European standards organization CEN proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy lines by the use of a series of NON-INTERCONNECTABLE CONNECTORS, differentiated by design for use in different medical APPLICATIONS. [8] The strategy reserves the use of LUER CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function.[7] The CONNECTORS of this part of ISO 80369 are reserved for neuraxial APPLICATIONS.

MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this part of ISO 80369 to the Secretariat of ISO/TC 210, so that it can consider this feedback during the revision of the relevant part of this series of International Standards.

4.2 **Material used for SMALL-BORE CONNECTORS**

The minimum value of the nominal flexural or tensile modulus of 950 MPa was chosen for neuraxial APPLICATIONS predominantly due to current use of polypropylenes for syringe manufacturing. Usability testing, in several cases, demonstrated misconnections with other SMALL-BORE CONNECTORS of the ISO 80369 series when using low modulus materials. It is highly recommended that MANUFACTURERS choose the highest modulus material possible for their MEDICAL DEVICE with preference to be 1 500 MPa or higher wherever possible.

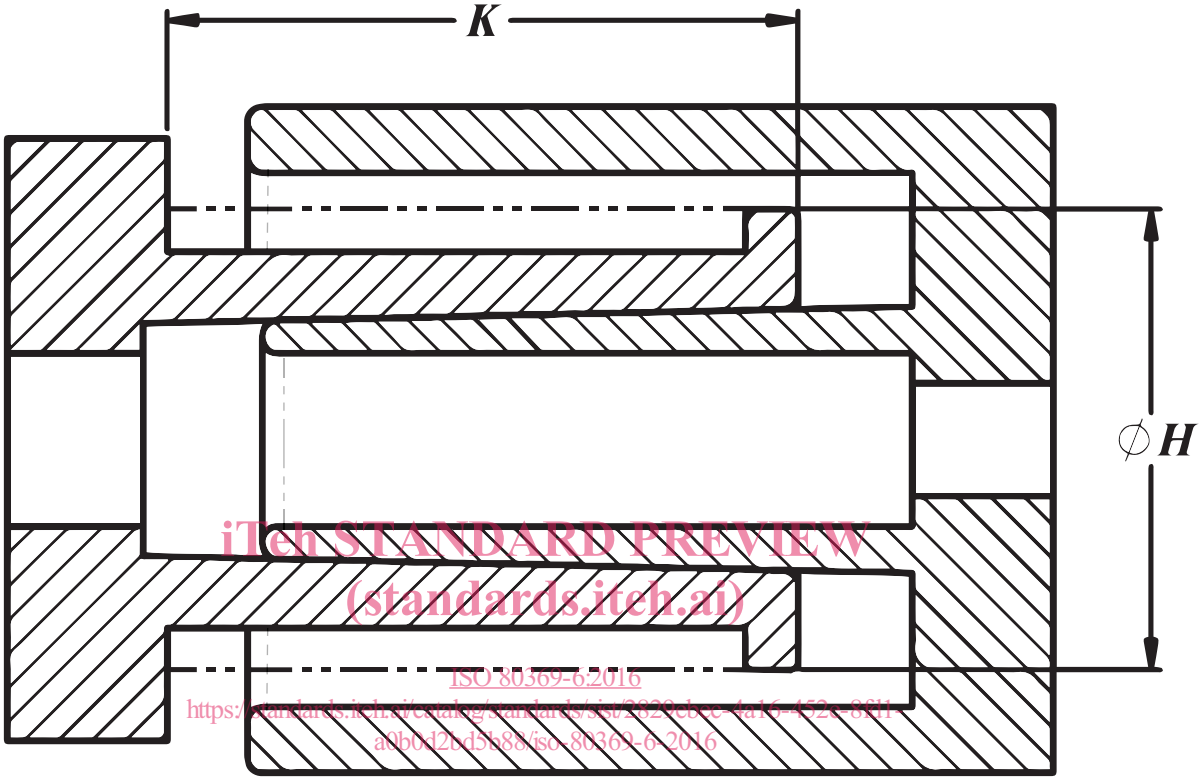
Annex B

Dimension '*K*' and '*k*' are defined to ensure an understanding by MANUFACTURERS of the extent of the CONNECTOR. Failure to comply with these minimum dimensions could result in the inability to properly connect to neuraxial CONNECTORS produced by other MANUFACTURERS. Figure A.1 and Figure A.2 illustrate this concern.

All surface finishes of parts of these CONNECTORS which do not form part of the mating surfaces should be constructed so as to avoid the possibility of any another CONNECTOR, which could be present in the clinical environment, from being able to form a fluid-tight CONNECTION to the CONNECTORS specified within this part of ISO 80369. This ensures that attempts made to connect any other CONNECTOR (not complying with this part of ISO 80369) to one specified within this part of ISO 80369 results in fluid

leakage and the failure to establish a fluid-tight path into the CONNECTORS specified within this part of ISO 80369.

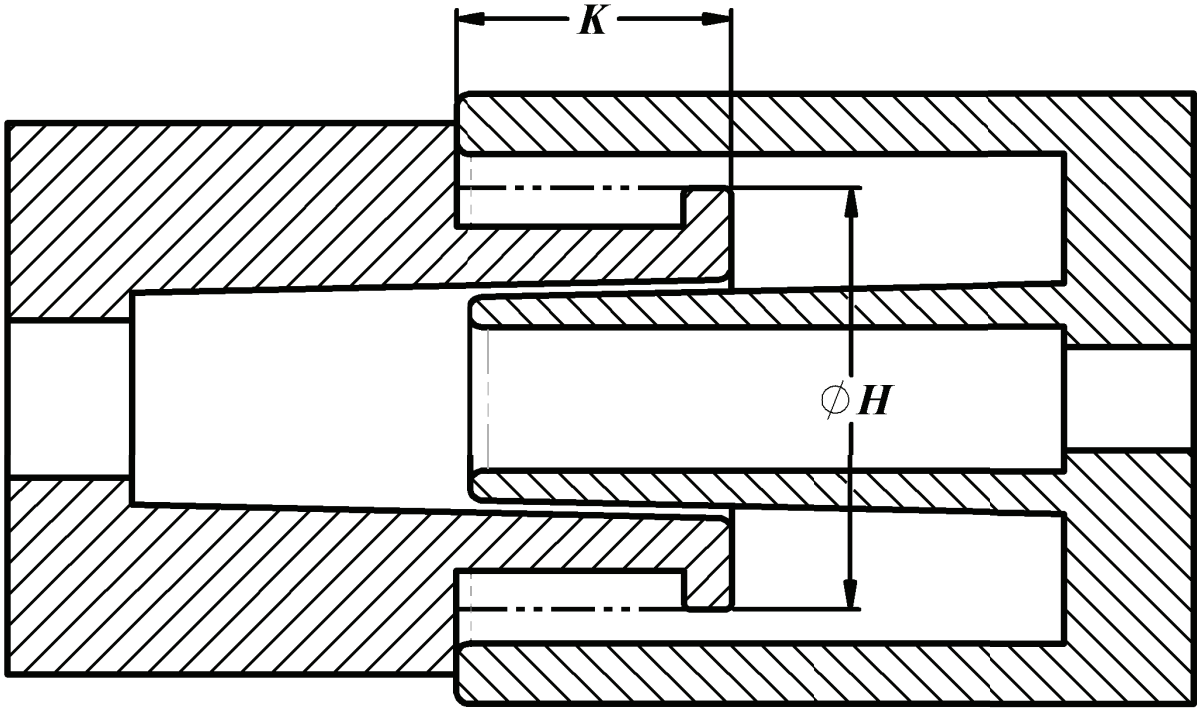
Annex B defines a maximum internal diameter of the male CONNECTOR, to prevent inadvertent male-to-male connectivity between the CONNECTORS defined within this part of ISO 80369 and any other SMALL-BORE CONNECTORS from the ISO 80369 series.



NOTE 1 Table B.4 contains the dimensions for this figure.

NOTE 2 The cones form a seal properly.

Figure A.1 — Extent of the CONNECTOR, compliant with this part of ISO 80369 (K > 8,6 mm)



NOTE 1 Table B.4 contains the dimensions for this figure.

NOTE 2 The cones do not form a seal properly.

Figure A.2 — Extent of the CONNECTOR, not compliant with this part of ISO 80369 (K < 8,6 mm)

H.1 Purpose

Several deviations from the physical testing for NON-INTERCONNECTABLE characteristics TEST METHOD of ISO 80369-1:2010, Annex B were developed. These include the following:

a) axial force up to 70 N is changed to 70 N ± 1 N to clarify the requirement;

NOTE If no axial load were applied, this would be less than 70 N and would meet the technical requirements but not the intent of this part of ISO 80369.

b) rotate up to 270° rather than 90°. CONNECTORS employ dual start threads spaced 180° apart. Rotating only 90° allows a false negative since this is less than 180°;

c) the axial separation force is changed to either 0,02 N or the weight of the CONNECTOR to allow for gravity testing if desired;

d) physical NON-INTERCONNECTABLE characteristics are defined as a combination of parts mechanically mating but also leaking at a low-flow rate that a USER might not notice;

Change to disconnection at 2 g or the weight of the CONNECTOR.

The NON-INTERCONNECTABLE characteristics TEST METHOD described in ISO 80369-1:2010, Annex B, poses technical challenges for MANUFACTURERS to perform accurately. According to the original Annex B TEST METHOD, the CONNECTORS are compressed with an axial load of 70 N and a torque of 0,12 N·m for 10 s and then are required disconnection with a force no greater than 0,02 N (2 g). Many MANUFACTURERS and test houses want to use a tensile tester to apply the axial load and the disconnection force with the same instrument. To apply the 70 N axial load, a 100 N load cell is required to handle the 70 N applied load. A typical 100 N load cell has an accuracy of 0,1 %, which means that a 100 N load

cell is only accurate to ±0,1 N. This is not sufficiently accurate to measure a 0,02 N disconnection force. Thus, the same instrument cannot measure both the applied axial load and the disconnection force with the accuracy required to perform the TEST METHOD.

Since using one instrument to apply a 70 N load and detect a 0,02 N separation force is not practical, a gravity detection method is permitted after applying the load and torque. The TEST METHOD was modified such that the CONNECTORS are required to disengage with either 0,02 N or the weight of the CONNECTOR. Most neuraxial components weigh more than 2 g so the acceptance criteria were modified to accommodate the weight of the part. Table A.1 shows representative part weights of common neuraxial components.

Table A.1 — Mass of common neuraxial components

Neuraxial component	Mass g	Equivalent force *N*
Loss of resistance (LOR) device (10 cm^3 barrel only)	4,40	0,044
Spinal needle (25 gauge) and protective sheath but no stylet	1,99	0,02
Epidural Tuohy needle (16 gauge) and protective sheath but no stylet	3,99	0,04
Syringe (20 ml barrel only)	6,70	0,067
Filter 0,2 micron flat in line	5,14	0,051
Catheter CONNECTOR	3,40	0,034

H.5 Test procedure, leakage

The NON-INTERCONNECTABLE characteristics physical TEST METHOD defined in ISO 80369-1:2010, Annex B, sets optimal and desirable goals, which are practically difficult to implement with all SMALL-BORE CONNECTORS. This TEST METHOD utilizes a very high axial load (70 N). Clinicians are highly unlikely to apply such a large force to connect two CONNECTORS when undertaking an injection of a neuraxial nature into a patient, due to the RISK of moving the needle and dislodging the tip from the target space. However, higher forces are possible when connecting MEDICAL DEVICES distant from the PATIENT, such as an administration set to an epidural filter. The 70 N axial load was established based on what a USER could physically apply, not necessarily what a neuraxial USER would likely apply in a clinical setting.

The usability study reported in G.4 demonstrated that a 70 N axial load is excessive for this APPLICATION. The average force at which USERS recognized a misconnection and stopped trying to connect was 26 N. One user did exceed 70 N (86 N). These data indicate that most clinicians would recognize a misconnection well below the axial load levels set by the original TEST METHOD.

During the same usability study, the leak rate of a misconnection was evaluated as to what leak rate the clinicians would recognize that the non-mating parts were leaking. The clinicians all stated that this misconnection would not cause a significant clinical RISK because the high force needed to make the CONNECTION combined with profuse leaking, would provide sufficient clues of a misconnection and they would stop the procedure.

USERS were asked at what leakage rate they would expect to identify a leak and stop delivering medication. The average leakage rate at which clinicians would notice a leak was 6 % and the maximum leakage rate was 25 %. By setting the minimum leak requirement at 75 %, more than 99,9 % of clinicians would recognize a misconnection and stop administering medication. To clarify, clinicians are stating that they would recognize a leak if the leak was 1 % up to 25 % of the total infusate. This is not an indication that fluid passage through the device is acceptable. This study was modelled after misconnection testing conducted by Cook.[11] This study analysed anaesthesiologists' reactions to new non-LUER CONNECTOR neuraxial MEDICAL DEVICES. Of the various misconnections noted in the report, the clinicians discounted the misconnections that leaked significantly. The clinicians stated that between the high force to connect and profuse leaking, the CONNECTION was not a clinical RISK.

A second experiment was conducted to evaluate if a low flow infusion pump with a flow rate of 4 ml/h could pump fluid through a misconnection and not be noticed by a clinician. Eight 20 gauge epidural