INTERNATIONAL STANDARD

ISO 18250-7

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Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 7: Connectors for intravascular infusion

Dispositifs médicaux — Connecteurs pour systèmes de livraison de réservoir pour des applications de soins de santé —

Partie 7: Connecteurs pour perfusion intravasculaire

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Foreword

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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. www.iso.org/directives

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For an explanation on the voluntary nature of standards, 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

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

A list of all the parts in the ISO 18250 series can be found on the ISO website.

In this document, 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 smaller type.

— TERMS DEFINED IN STANDARD OR AS NOTED: SMALL CAPITALS.

— *Compliance requirements: italic type.*

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document,

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document, 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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

During the development of the standard for enteral small-bore CONNECTORS (ISO 80369-3), it became clear that the risk of MISCONNECTIONS was not limited to the PATIENT access CONNECTORS and that the whole enteral system needed to be considered. The possible MISCONNECTION between enteral feed RESERVOIR access CONNECTORS and the spikes typically used on intravenous administration sets was also reviewed. However, as feed RESERVOIR CONNECTORS are not exactly within the definition of small-bore CONNECTORS, it was decided to develop a separate standard (ISO 18250-3) for these CONNECTORS, taking into account the risks of MISCONNECTIONS with other devices such as intravenous (IV) bags.

During the development of ISO 18250-3, it became apparent that the ubiquitous intravenous spike was specified in various ISO medical device standards but that the geometry and materials requirements for the female port on the intravenous RESERVOIR were not defined. However, the performance of this female port was defined in various ISO standards.

This document, therefore, specifies the design, dimensions and materials for the female port. It makes reference to existing performance standards. It also includes tests to validate that the spike and the female port do not interconnect with the other RESERVOIR CONNECTORS of the ISO 18250 series.

This document also includes analysis sufficient to include traditional LUER CONNECTORS of ISO 80369-7 as permissible RESERVOIR CONNECTORS for intravascular APPLICATIONS.

This document is not a device standard as it specifies only the requirements of the interfaces for CONNECTORS used in intravascular RESERVOIRS and INTRAVASCULAR INFUSION SETS.

Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 7: Connectors for intravascular infusion

1 *Scope

This document specifies the interface dimensions and requirements for the design and functional performance of CONNECTORS intended to be used to connect INTRAVASCULAR INFUSION SETS to INTRAVASCULAR INFUSION RESERVOIRS.

This document does not specify the dimensions and 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.

EXAMPLES Medical devices which may use intravascular RESERVOIR CONNECTORS are the following:

— Administration ports on IV fluid RESERVOIRS and the mating spikes of IV administration/INTRAVASCULAR INFUSION SETS/lines, e.g., IV bags/containers and the spike inlet ends of IV sets;

— Devices intended to be connected in series between the administration port of IV fluid RESERVOIRS and the mating spikes of IV administration/giving lines;

— Syringes and syringe IV sets utilizing LUER CONNECTORS.

The following CONNECTORS are excluded from the scope of this document:

— Stoppers for bottles as specified in ISO 8536-2;

— Compounding/admixture ports on IV RESERVOIRS and intended mating devices.

EXAMPLES Rubber stoppers used for injection into the RESERVOIR and the mating pharmacy admixture devices (syringes, needles, reconstitution devices, and other ancillary equipment used to access the compounding or admixture ports).

— The fill ports of non-powered (i.e. elastomeric) pumps.

NOTE 1 Details of alternative spikes that are in common use are located in Annex G for informational purposes.

NOTE 2 Manufacturers are encouraged to incorporate the CONNECTORS specified in this document into INTRAVASCULAR INFUSION medical devices or ACCESSORIES, even if not currently required by the particular medical device standards. It is expected that when the particular medical device standards are revised, requirements for RESERVOIR CONNECTORS, as specified in ISO 18250, will be included.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

ISO 3826 (all parts), *Plastics collapsible containers for human blood and blood components*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*[1)]

ISO 15747, *Plastic containers for intravenous injections*

ISO 15759, *Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process*

ISO 18250-1, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18250-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
INTRAVASCULAR INFUSION SET
medical device for transferring liquids from an intravascular RESERVOIR to an intravascular catheter

3.2
INTRAVASCULAR INFUSION
administration of parenteral injection product into a blood vessel, including transfusion of blood products

3.3
LUER CONNECTOR
small-bore CONNECTOR that contains a conical mating surface with a 6 % (LUER) taper intended for use in intravascular or hypodermic APPLICATIONS of medical devices and related ACCESSORIES

[SOURCE: ISO 80369-7:2016, definition 3.1]

4 General requirements

4.1 Non-interconnectability through conformance to this document

Conformance to Clause 5 (materials), Clause 6 (dimensions), and Clause 7 (physical performance) of this document is sufficient to demonstrate conformance to ISO 18250-1 (i.e. non-interconnectability with clinical APPLICATIONS other than intravascular).

NOTE 1 A summary of the evaluation and residual risks of the NON-INTERCONNECTABLE characteristics of the designs for this document is included in F.2.

4.2 * Intravascular RESERVOIR CONNECTOR types

CONNECTOR Type 1: Spikes and Administration Ports. Spikes are intended to be on the INTRAVASCULAR INFUSION SET. Administration ports are intended to be on the RESERVOIR.

CONNECTOR Type 2: LUER CONNECTORS. Male LUER CONNECTORS are intended to be on the RESERVOIR (e.g. the syringe). Female LUER CONNECTORS are intended to be on the INTRAVASCULAR INFUSION SET.

1) Under preparation. Stage at the time of publication ISO/FDIS 8536-4:2018.

5 Material requirements

5.1 CONNECTOR Type 1: spikes and administration ports

Intravascular spikes shall be fabricated from materials with a tensile or flexural modulus (E) equal to or greater than 700 MPa.

Intravascular administration ports may be made from materials having any value for tensile or flexural modulus (E); it may vary within all ranges of flexible elastomers through semi-rigid and rigid polymers.

5.2 CONNECTOR Type 2: LUERS

LUERS used as intravascular RESERVOIR CONNECTORS shall conform to the materials requirements of ISO 80369-7.

Check compliance of 5.1 and 5.2 *by inspection of the technical file.*

6 Dimensional requirements

6.1 CONNECTOR Type 1: Spikes and Administration Ports

Intravascular spikes shall conform to the geometry for spikes defined in either ISO 8536-4 or ISO 1135-4 unless the use of these dimensions creates an unacceptable risk when attempting to make a CONNECTION to a RESERVOIR.

Intravascular administration ports shall meet the dimensional requirements defined in B.1.

6.2 CONNECTOR Type 2: LUERS

LUER CONNECTORS used as intravascular RESERVOIR CONNECTORS shall conform to the design/dimensional requirements of ISO 80369-7.

Check compliance of 6.1 and 6.2 *by inspection of the technical file.*

7 Performance requirements

7.1 * CONNECTOR Type 1: Spikes and Administration Ports

Intravascular spikes shall conform to the performance requirements for spikes defined in either ISO 8536-4 or ISO 1135-4.

Intravascular administration ports shall meet the performance requirements of ISO 15747, ISO 15759, ISO 3826-1, or ISO 3826-4.

7.2 CONNECTOR Type 2: LUERS

LUER CONNECTORS used as intravascular RESERVOIR CONNECTORS shall conform to the performance requirements of ISO 80369-7.

Check compliance of 7.1 and 7.2 *by inspection of the technical file.*

Annex A
(informative)

Rationale and guidance

A.1 General

This annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document 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 document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

The scope excludes stoppers for bottles as specified in ISO 8536-2 as by their nature the risk of unintentional CONNECTION cannot be mitigated by geometrical constraints without modifying the whole design of the stopper. These stoppers are considered less safe than the RESERVOIR CONNECTORS specified in this document and are therefore not recommended.

Subclause 4.2 Intravascular RESERVOIR CONNECTOR Types

CONNECTOR Type 2: A simple yet significant limitation of the ISO 80369-7 LUER is recognized by the working group to prevent its use in all intravascular RESERVOIR CONNECTOR APPLICATIONS: this is that the LUER does not permit the venting necessary to displace removed fluid in rigid and semi-rigid RESERVOIRS. The result of this is that the container will draw a vacuum that cannot be overcome by gravity or by the vacuum generated by typical IV pumps, thus stopping flow. Spikes that conform to ISO 8536-4 and ISO 1135-4 permit multiple interior lumens so that venting is possible.

Use of the male LUER on the RESERVOIR side is intended to prevent usability errors of transposing the orientation of the administration set.

The orientation of CONNECTORS promoted in 4.2 is consistent with the MISCONNECTION analysis of F.2. If manufacturers or device standards committees choose to use alternate orientations, then MISCONNECTION analysis should be revisited by the entity implementing the change.

Subclause 7.1 Performance requirements for CONNECTOR Type 1: spikes and administration ports

The working group debated multiple times how best to specify performance for the traditional spike and port CONNECTOR type 1. Initially the working group adopted / adapted applicable CONNECTION tests from various known device standards. The results of this work compiled four CONNECTION tests (penetration force, liquid leakage, flow rate, and adhesion strength tests), with specified reference fittings to permit consistent results.

Debate within the committee centered on what was the minimum criteria necessary for a CONNECTION – this criteria of course depends on the specific APPLICATION within INTRAVASCULAR INFUSION. With so many established device standards already providing various elements of CONNECTION testing, it was decided that to centralize these tests here in this document would force duplication of work and expense for some manufacturers.

It was decided therefore not to (re)define performance characteristics for CONNECTOR type 1 in this document, but to ensure that manufacturers are at least conforming to one of the existing recognized device standards. However, it is further recognized that these standards do not fully test the CONNECTION (for instance, in some cases not all tests are conducted, or in others the tests only are conducted with one half of the CONNECTION.)

Table A.1 provides a summary of the strength/weakness of these existing device standards to fully define the performance of this CONNECTOR type 1.

Table A.1 — Limitations to CONNECTOR Type 1 performance requirements by applicable device standards

Standard	Penetrating force	Liquid leakage	Flow rate	Adhesion strength
ISO 8536-4	Not tested	♂ :6.2	6.10	♂ : 6.3
ISO 1135-4	Not tested	♂ : 5.2	5.9	♂ : 5.3
ISO 15747	4.1.8	♀ : 4.1.2, 4.1.3	Not tested	4.1.9
ISO 15759	6.4	♀ : 5.1	Not tested	6.5, 6.6
ISO 3826-1	Not tested	♀ : 6.2.7	5.3	Not tested
ISO 3826-4	6.2.8	6.2.10	Not tested	6.2.9

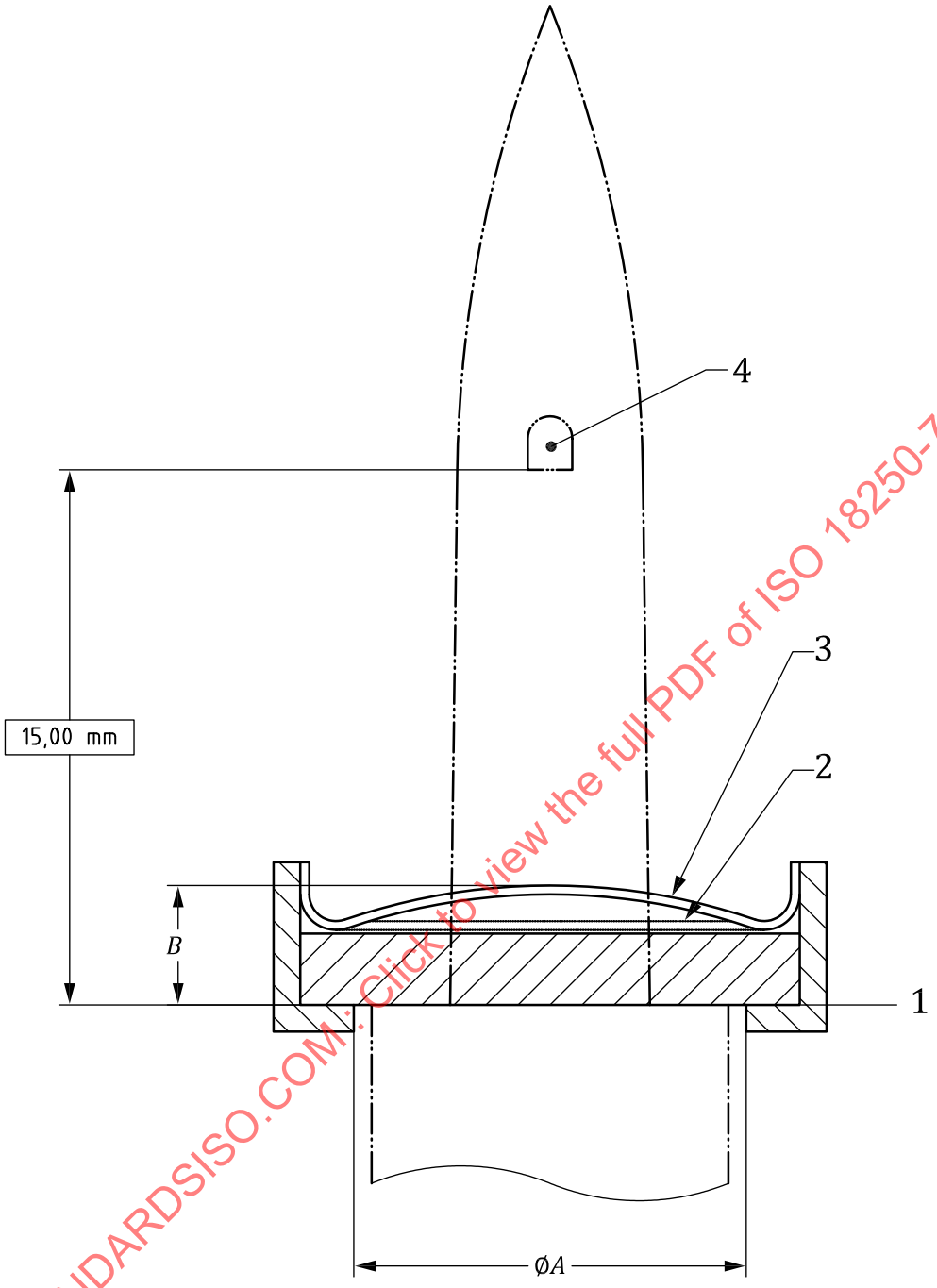
Annex B.1 Design of CONNECTOR Type 1 administration port CONNECTORS

Annex B is a compilation and generalization of known, commercialized intravascular RESERVOIR CONNECTORS available during the time of development of this document. These are intended to mate with the spikes of ISO 8536-4 and ISO 11354. Dimensional surveys were sent to manufacturers participating in the development process. B.1 design can be interpreted in many ways, but in essence it shows how manufacturers have put the legacy performance requirements into practice. As a result, the table in Annex B indicates minimum and maximum values for various features; it does not provide a nominal nor espouse a set of target dimensions. As a result, the dimensions of commercialized product would not be distributed normally between the minimum and maximum, but might exist anywhere between them. The intention is to specify limits to main functional dimensions and therefore to freeze the allowed design space. It is hoped this will limit new designs which exceed those dimensions and thereby maintain validity of the CAD analysis.

In defining distance B, manufacturers should take into account deformation of the septum during piercing, particularly if the lateral extension of the septum is large, so that the septum may be deformed on a longer distance along the penetration axis, hence prevent establishing a fluid path to the lumen of the INTRAVASCULAR INFUSION SET.

Diameter E was added to Figure B.1 to account for the exterior features of commercialized IV RESERVOIR ports. Exterior features of commercialized RESERVOIRS were surveyed, and the maximum diameter listed shows the extent of the commercialized devices. The possible external features of the CONNECTOR might exist anywhere within this theoretical cylinder, thus MISCONNECTION prevention features of other parts of the ISO 18250 series shall assure that they do not provide possible interference/mating with those exterior features. Dimension E extends to a singular CONNECTOR (i.e., administration port) only unless that administration port is somehow combined with in singular assembly that includes other features (such as a medication port).

The generic geometry of B.1 can be interpreted in a variety of ways. The following series of illustrations capture several commercial interpretations of these CONNECTORS that can be described using the geometry of B.1.



Key

1 level '0': Spike insertion stop – location where insertion travel of the spike will or could be stopped
2 free standing septum
3 in use septum
4 fluid channel opening
ØA minimum internal diameter before the spike septum
B depth from "Level 0" to last septum surface to be pierced to access solution

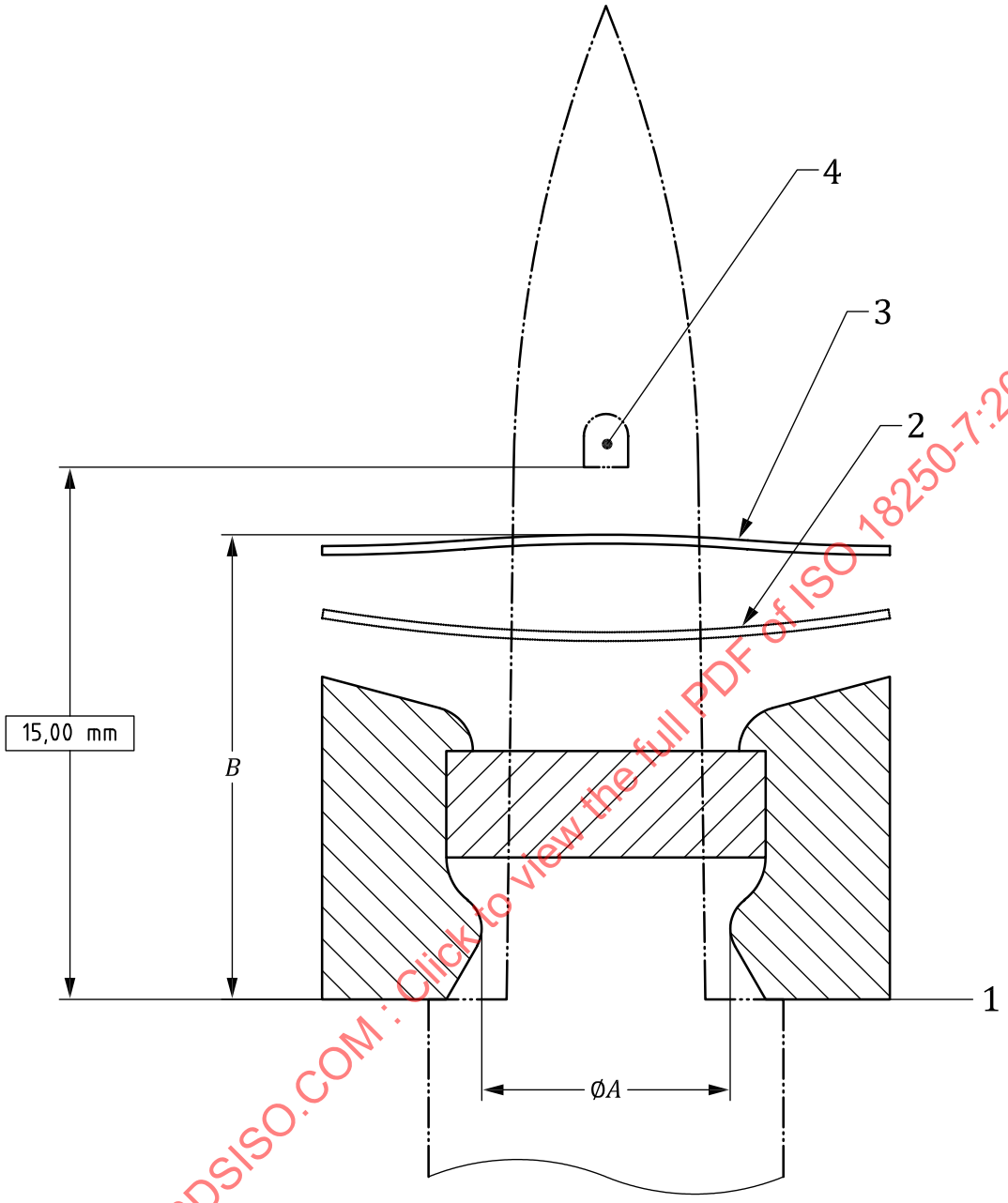
Figure A.1 — Single liner for administration port

This type of closure is typical for blow-fill-seal containers. A liner covered by a housing having a relatively large opening provides an exposed elastomeric surface with both medication and administration piercing areas. The liner is trapped between the housing and a support which may

eventually incorporate a membrane ("bottle head membrane" in case of Blow Fill Seal containers) oriented in the direction of the fluid. The membrane usually deforms by several millimetres during spike insertion.

Due to the large septum, spike movement is not stopped by contact with the housing, but when the protective cap seat makes contact with the exposed surface of the septum.

Such a closure may provide resealing properties to deter leakage if the spike is disconnected.



Key

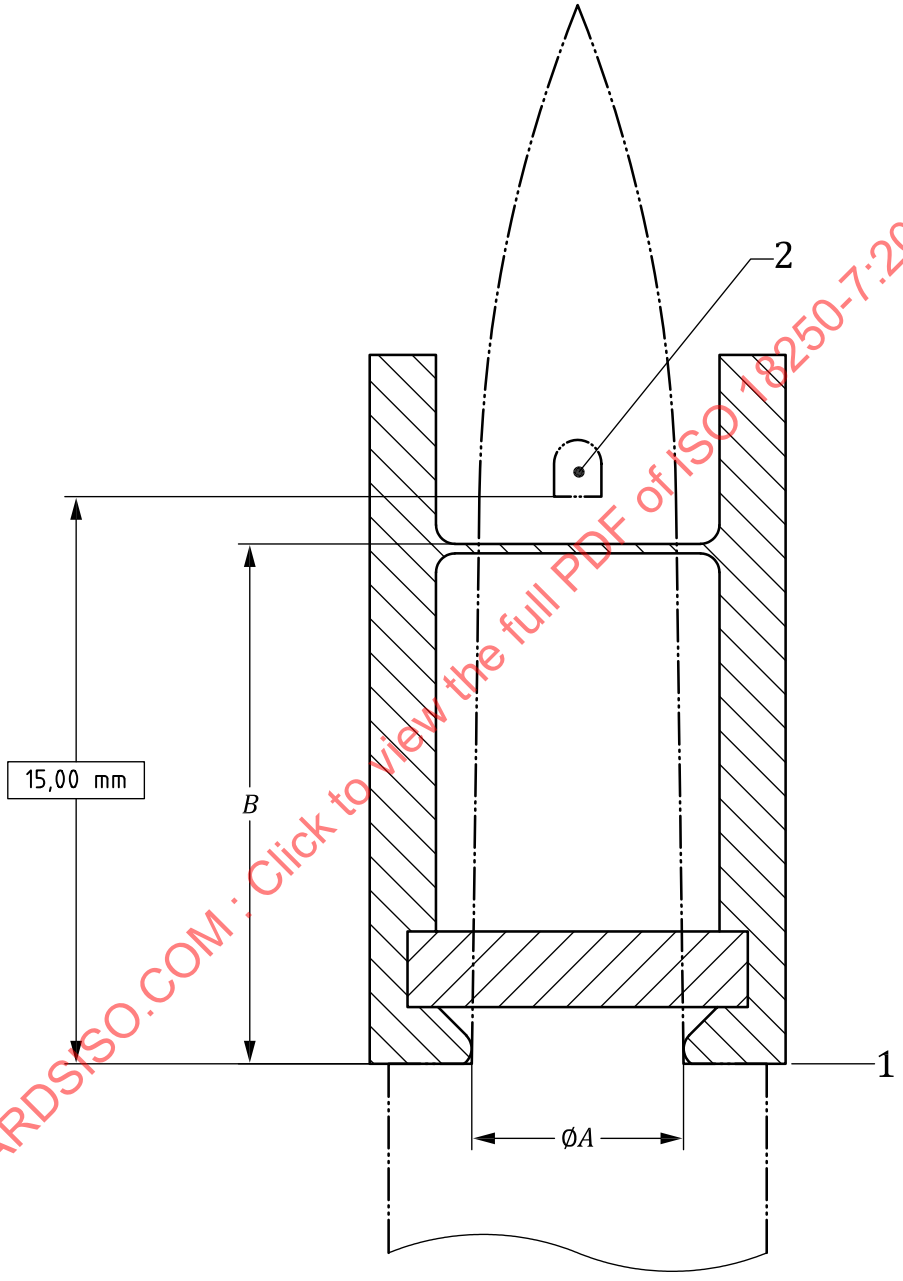
1 level '0': Spike insertion stop – location where insertion travel of the spike will or could be stopped
2 free standing bottle-head
3 in use bottle-head
4 fluid channel opening
ØA minimum internal diameter before the spike septum
B depth from "Level 0" to last septum surface to be pierced to access solution

Figure A.2 — Dedicated administration septum in a housing, without hard stop

In this example, the maximum inner diameter of the housing is larger than the diameter of the spike. As such, maximum insertion depth is defined by the contact of the spike's protective cap ring with the housing. An elastomeric sealing element provides tightness around the spike and friction with the spike.

A second membrane can be present. In that case, it shall be pierced in order to access the fluid and can provide tightness before piercing if the stopper is not welded into the housing (e.g., force- or form-fitted).

Such a closure may provide resealing properties to deter leakage if the spike is disconnected.



Key

1 level '0': Spike insertion stop – location where insertion travel of the spike will or could be stopped

2 fluid channel opening

ØA minimum internal diameter before the spike septum

B depth from "Level 0" to last septum surface to be pierced to access solution

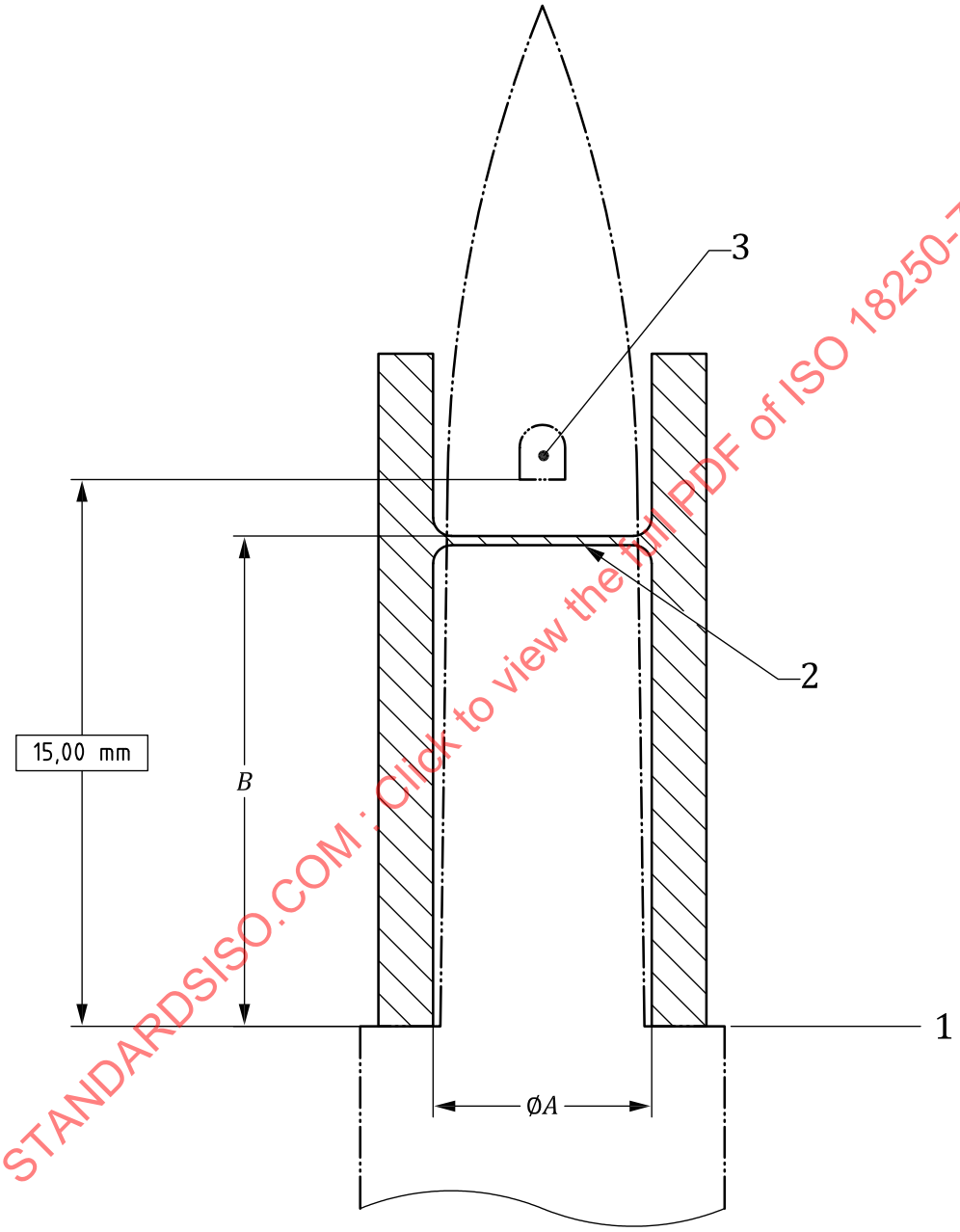
Figure A.3 — Dedicated administration septum in a housing, with hard stop

In this example, the maximum inner diameter of the housing is smaller than the diameter of the spike. As such, the housing limits the insertion. The septum and the presence of housing deformation provide

tightness around the spike and friction with the spike (given that the spike stays in constant contact with the deformed housing).

A second membrane shall be pierced in order to access the fluid and can provide tightness before piercing if the stopper is not welded into the housing (e.g., force- or form-fitted).

Such a closure may provide resealing properties to deter leakage if the spike is disconnected.



Key

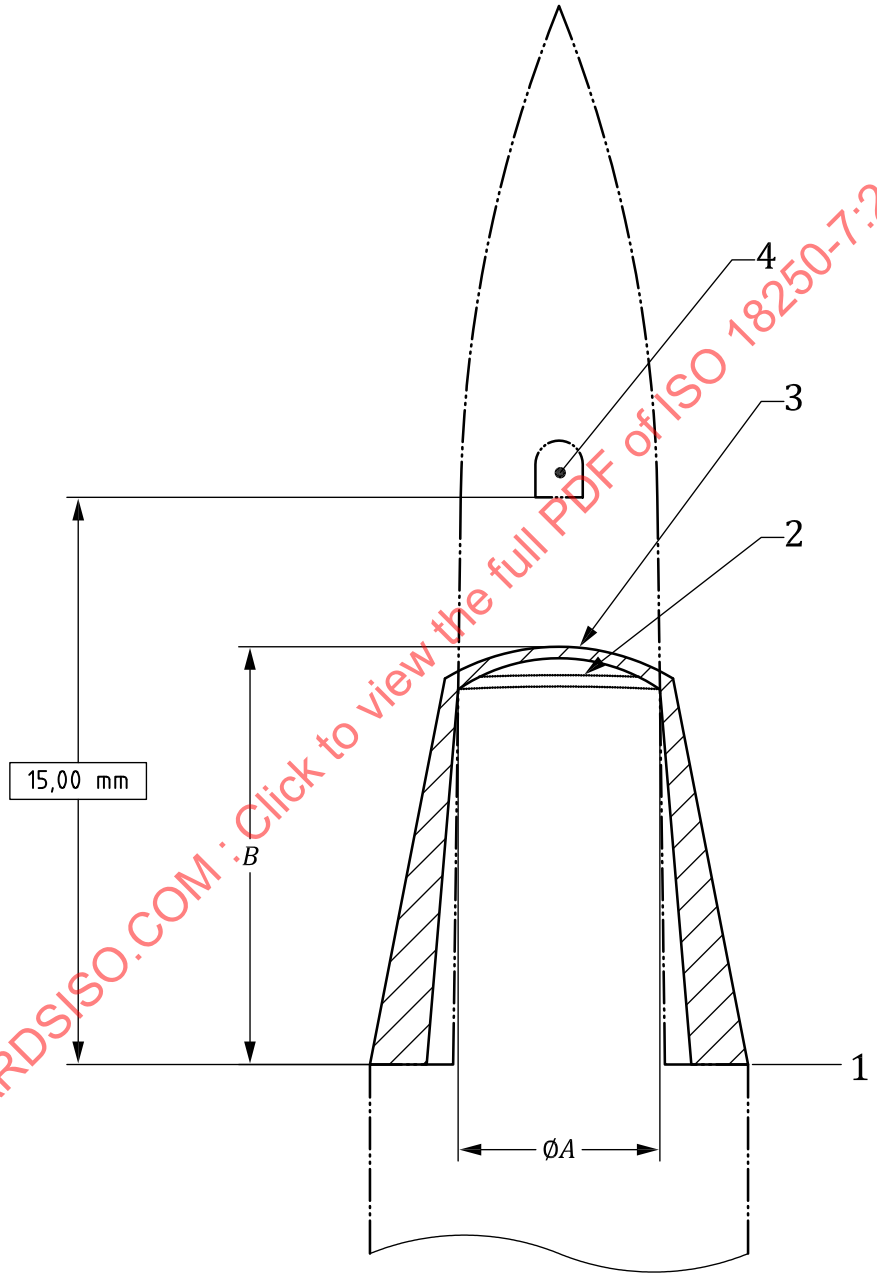
1 level '0': Spike insertion stop – location where insertion travel of the spike will or could be stopped
2 membrane too thin to be taken into account for *ØA*
3 fluid channel opening
ØA minimum internal diameter before the spike septum
B depth from "Level 0" to last septum surface to be pierced to access solution

Figure A.4 — Flexible tube-like administration port

This example shows a tube-like port for IV bags. Tightness around the spike and friction with the spike are provided by deformation of the tube itself, which is usually made of a soft material.

Maximum insertion depth is defined by the contact of the spike's protective cap ring with the outer lips of the tube.

Such a closure is not resealable, so leakage will occur if the spike is disconnected.

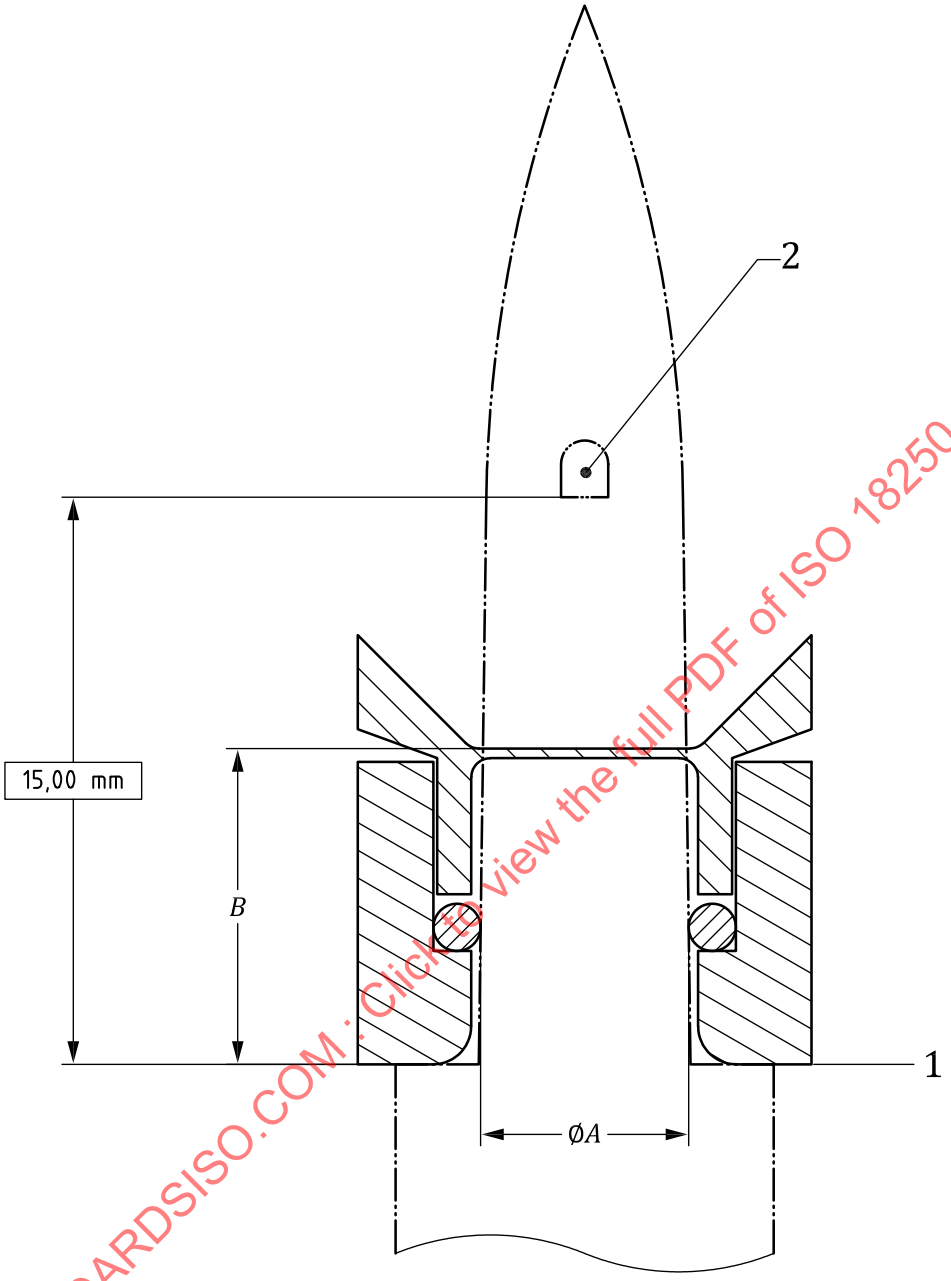


Key

1 level '0': Spike insertion stop – location where insertion travel of the spike will or could be stopped
2 free standing septum
3 in use septum
4 fluid channel opening
ØA minimum internal diameter before the spike septum
B depth from "Level 0" to last septum surface to be pierced to access solution

Figure A.5 — One-part closure with breakable insertion area made of semi-rigid material

Such a closure is not resealable, so leakage will occur if the spike is disconnected.



Key

1 level '0': Spike insertion stop – location where insertion travel of the spike will or could be stopped
2 fluid channel opening
ØA minimum internal diameter before the spike septum
B depth from "Level 0" to last septum surface to be pierced to access solution

Figure A.6 — Tube like administration port with sealing element

Such a closure is not resealable, so leakage will occur if the spike is disconnected.

Annex B
(normative)

Design of CONNECTORS*

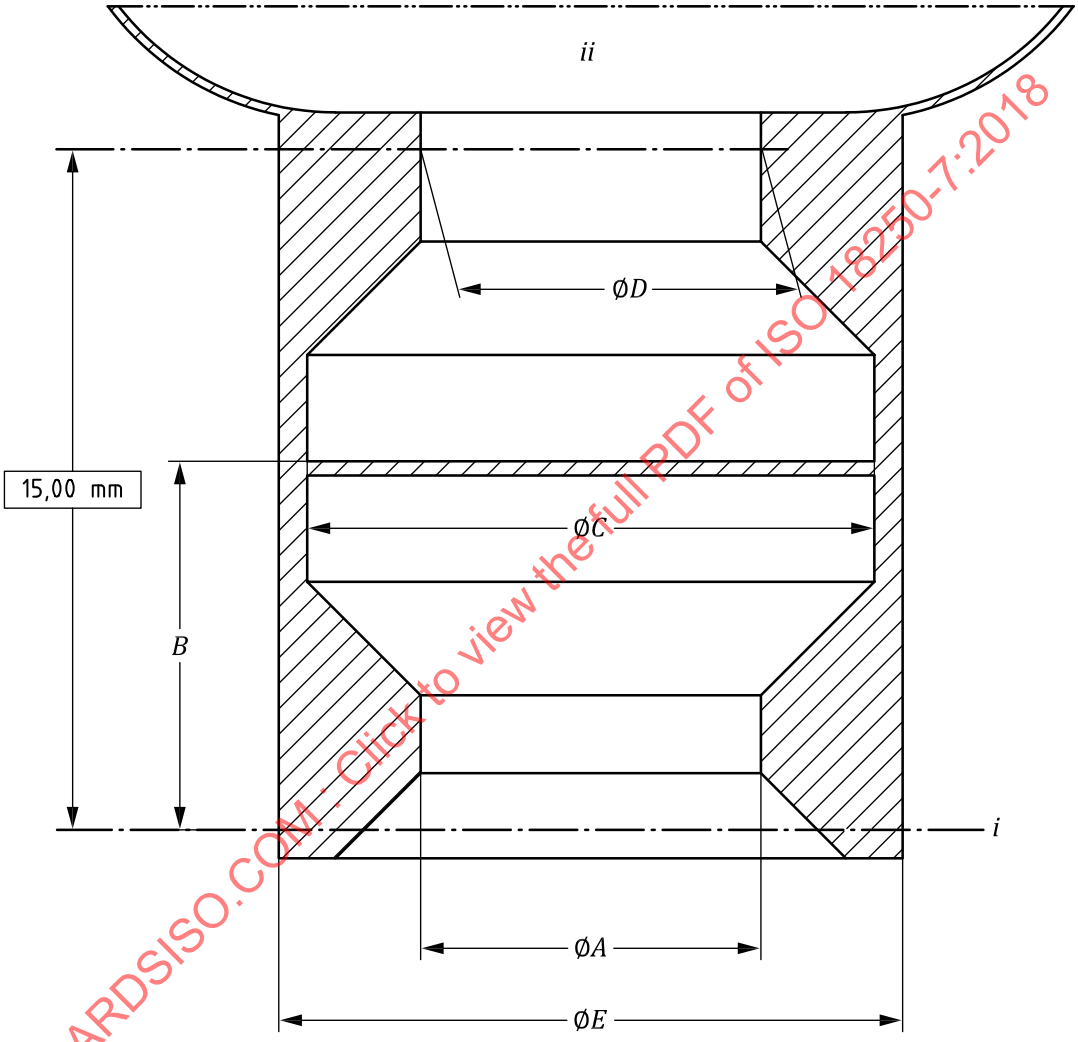


Figure B.1 — CONNECTOR Type 1: Administration port CONNECTOR

Table B.1 — CONNECTOR Type 1: Administration port CONNECTOR dimensions

Reference	Designation	Dimensions mm	
		Minimum	Maximum
i	Level '0': Spike insertion stop – location where insertion travel of the spike will be or could be stopped	N/A	N/A
ii	This location designates the RESERVOIR containing infusate	N/A	N/A
Ø*A*	Minimum internal diameter before the spike septum	4,20	21,00
B	Depth from "Level 0" to last septum surface to be pierced to access solution	>0,00	14,00

Table B.1 *(continued)*

Reference	Designation	Dimensions mm	
		Minimum	Maximum
ØC	Inside diameter of female at septum or membrane	4,20	N/A
ØD	Minimum inner diameter of closure's components (housing and/or septum/septa) at 15,00 mm from "Level 0"	4,20	N/A
ØE	Diameter of the cylinder that encompasses the outside surfaces of the external features of the port	4,60	46,00

Annex C
(informative)

Assessment of RESERVOIR CONNECTORS and their attributes with CONNECTIONS to medical devices within this intravascular APPLICATION

RESERVOIR CONNECTORS are the CONNECTORS attached to the solution RESERVOIR along with the mating CONNECTOR as attached to the INTRAVASCULAR INFUSION SET and/or devices intended to be connected in series between the administration port of IV fluid RESERVOIRS and the mating spikes of INTRAVASCULAR INFUSION SETS.

CONNECTORS that are used with solution RESERVOIRS only for the purpose of mixing, compounding, or transferring fluid (and that are not used for direct administration to the PATIENT) are not in the scope of this document.

Table C.1 contains examples of RESERVOIR CONNECTORS with intravascular APPLICATIONS. The table contains an assessment by the working group of the important attributes of RESERVOIR CONNECTORS as they relate to the intended CONNECTION as associated with a solution RESERVOIR.

Table C.1 — Examples and attributes of RESERVOIR CONNECTOR types within this ISO 18250 series APPLICATIONS

RESERVOIR CONNECTOR types:	Flowrate range	Type of CONNECTION		Risk		Functionality		
	ml/min	Connection	Dis-con-nection	Therapy disruption	Infection control	Locking needed	Slip needed	Venting
INTRAVASCULAR INFUSION SET spike and intravascular port (CONNECTOR Type 1)	0 to 1 200	yes	yes	yes	yes	no	yes	yes
INTRAVASCULAR INFUSION SET spike and intravascular port (non removable) (CONNECTOR Type 1)	0 to 1 200	yes	no	yes	yes	yes	no	yes
Devices intended to be connected in series between the administration port of intravascular fluid RESERVOIRS and the mating spikes of INTRAVASCULAR INFUSION SETS (CONNECTOR Type 1)	0 to 1 200	yes	yes	yes	yes	no	yes	yes
LUERS - CONNECTOR Type 2	0 to 1 200	yes	yes	yes	yes	yes	yes	no

Annex D
(informative)

Summary of usability and requirements for CONNECTORS for intravascular RESERVOIRS

D.1 User Profile

The user profile is a summary of the mental, physical and demographic traits of an intended user population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements.

Users are expected to perform an intended action in an intended use of RESERVOIR CONNECTORS, ACCESSORY, process or service in accordance with the directions, specifications, instructions and information provided by the manufacturer.

Users include:

a) Clinical users such as physicians, nurses at all levels, and paramedical staff;

b) Non-clinical users such as cleaners, maintainers, and installers;

c) Homecare providers, PATIENTS, and relatives;

d) Pharmacy or laboratory users responsible for mixing of drugs, filling syringes and RESERVOIRS, storage, and dispensing of drugs.

The user profile is summarized in Table D.1.

Table D.1 — User profile

	Homecare users	**Clinical users**	**Non-clinical users**	***In vitro* diagnostic laboratory and pharmacy users**
user skills:	No training	Extensive clinical training	Limited clinical training	Bioengineering, central processing
PATIENT contact:	Direct PATIENT contact	Direct PATIENT contact	Direct PATIENT contact	No PATIENT contact

D.2 Use Environments

— Facilities: Hospitals, surgery suites, PATIENT rooms, home, labor & delivery, intensive care units, doctors' offices, pain clinics, pharmacy, field hospitals, PATIENT transport systems, infusion clinics, assisted care, and emergency medical services.

— Temperature: The following temperature environments might be experienced for RESERVOIR CONNECTORS:

  — Ambient temperature, -40 °C to +60 °C (for field use in emergency medical services);

  — Fluid temperature 10 °C to 43 °C (for hypo/normo/hyperthermia treatments).

— Usability under stress: Ignoring labels, attempting force-fit, etc.

— Proximity of liquid(s).

— Use of gloves.

— Proximity of other CONNECTOR-bearing equipment (e.g., other ISO 18250 or ISO 80369 APPLICATIONS).

D.3 Use Scenarios

Use scenarios for RESERVOIR CONNECTORS for INTRAVASCULAR INFUSION APPLICATIONS can differ by user group and are comprised of the multitude of sub-APPLICATIONS of the CONNECTORS within different sub-specialties.

A summary of use scenarios by user group is included in Table D.2.

Table D.2 — Use scenarios

Sub-specialty use scenario:	Homecare users	Clinical users	Non-clinical users	*In vitro* diagnostic laboratory and pharmacy users
1. Parenteral				
— Chemotherapy		X		X
— Infusion by gravity or pressure	X	X		X
— Intravascular injections	X	X		X
— Parenteral nutrition, including TPN (Total Parenteral Nutrition)	X	X	X	X
2. Blood and blood products				
— Transfusion	X	X		
3. Medication preparation				
— Add-mixture through RESERVOIR administration port	X	X		X
— Compounding	X	X		X

D.4 Generic user needs

The following user needs attributes are expected for RESERVOIR CONNECTORS:

— Minimal user training on the use of CONNECTORS;

— Easy to manipulate without the use of tools;

— Easy to assemble/disassemble by hand, especially in wet environment or with the use of gloves;

— Security/integrity of CONNECTION -- cannot unintentionally self-disconnect;

— Does not provide a secure or leak-proof CONNECTION with other RESERVOIR CONNECTOR APPLICATIONS within the ISO 18250 series;

— Does not leak under normal use;

— Maximum flowrate:

  — Cardiovascular equipment, diluted blood: 4 l/min, at 3 bar with a dynamic viscosity of 7 mPa·s to prevent haemolysis;

  - I.V. pump, aqueous solutions: 1 200 ml/min at 300 mmHg pressure;
- Viscosity of solutions:
  - A typical viscosity for contrast media is between 2 mPa·s and 10 mPa·s and typical bolus injection rates are 5 ml/s to 10 ml/s; typical pressure limitation is 2 100 kPa;
- Compatible with disinfection, decontamination and sterilization.

D.5 Usability assessments

CONNECTOR Type 1: Spikes and Administration Ports:

Spikes and corresponding administration ports have been in use for intravascular CONNECTIONS in clinical settings for several decades with widespread use beginning in the 1950's and 1960's. Present form use of plastic spikes and port systems date into the 1970's with design formalization in the 1990's within the ISO 8536 series. Installed manufacturing capacity for both INTRAVASCULAR INFUSION SETS (spikes) and RESERVOIRS is greater than one billion units per year as of 2017. The consistency of supply indicates that market surveillance activities deem the existing designs (spikes of ISO 8536-4 and ISO 1135-4 and RESERVOIR port systems per ISO 15747, ISO 15759, ISO 3826-1, and ISO 3826-4) are usable and accepted for general INTRAVASCULAR INFUSION. Since clinical workflow is not intended to be impacted by the introduction of ISO 18250-7 CONNECTOR type 1, no additional usability or verification evaluations to ensure fitness for use were deemed necessary.

CONNECTOR Type 2: LUERS:

Reference ISO 80369-7:2016, Annex G.

Annex E
(informative)

Summary of RESERVOIR CONNECTOR design requirements for INTRAVASCULAR INFUSION

Table E.1 — RESERVOIR CONNECTORS specific design requirements for INTRAVASCULAR INFUSION

	Criteria	Requirement(s)	Remark(s)
1	Fluid type: a) Liquid b) Gas c) Both	a	Eventually (c) in case venting of the reservoir is needed to withdraw the liquid (e.g., rigid and semi-rigid containers).
2	Operating pressure range: — Maximum — Minimum — Sub atmospheric? (yes/no)	Type 1: (gravity) 20 kPa for 15 s; (pressure infusion) 50 kPa for 15 minutes Type 2: 2 100 kPa to –10 kPa	
3	Rated pressure range: — Minimum — Maximum	See Item 2	
4	Is there a need for a leak test? a) No b) Yes (Reference for TEST METHOD)	b Type 1: Per ISO 8536-4, ISO 1135-4, ISO 15747, ISO 15759, ISO 3826-1, and/or ISO 3826-4 Type 2: Per ISO 80369-7	
5	Rated flowrate range: — Minimum — Maximum	Type 1: Per ISO 8536-4, ISO 1135-4, ISO 15747, ISO 15759, ISO 3826-1, and/or ISO 3826-4 Type 2: Per ISO 80369-7	
6	Internal diameter range (through bore): — Minimum — Maximum	Type 1: Spike: <5,00 mm Port: 4,20 mm to 21,00 mm Type 2: 0 mm to 2,9 mm	
7	Rated temperature range: — Minimum — Maximum	During storage: –40 °C to +60 °C In use: 10 °C to 43 °C	

Table E.1 *(continued)*

	Criteria	Requirement(s)	Remark(s)
8	Minimum range of CONNECTOR mating diameters: — Minimum — Maximum	Type 1: Spike: Per ISO 8536-4 Port: flexible – nominal from 4,20 mm to 21,00 mm Type 2: Per ISO 80369-7.	
9	General layout a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	Type 1: a, b, c, d Type 2: c	
10	Method of keying: a) Collar b) Plug c) Other (specify)	N/A	
11	Quick release? a) No b) Yes i) Single-handed operation ii) Double-handed operation	Type 1: a Type 2: a	
12	Positive locking/locking feature? a) No b) Yes	Type 1: a Type 2: a,b	
13	Need for visual indication of locking status? a) No b) Yes	a	
14	Need for indication of evidence of tampering? a) No b) Yes	a	
15	Need for a syringe in the APPLICATION? a) No b) Yes	b - Type 2	

Table E.1 *(continued)*

	Criteria	Requirement(s)	Remark(s)
16	Need for an absence of sharp edge? a) No b) Yes	Type 1: a Type 2: b	
17	Minimum axial force in normal use, to remain attached force (Reference for TEST METHOD)	Type 1: Per ISO 8536-4, ISO 1135-4, ISO 15747, ISO 15759, ISO 3826-1, and/or ISO 3626-4 Type 2: Per ISO 80369-7	Type 2: assumes LUER lock CONNECTIONS
18	Constructional materials (excluding seals): a) Rigid material i) Metal ii) Plastic b) Semi-rigid material	Type 1: a-ii, b Type 2: a-i, a-ii	
19	Need for use of semi-rigid material? a) No b) Yes, mating part of CONNECTOR (apart from seal)	See 18	
20	MRI compatibility? a) No, with labeling b) No, without labeling c) Yes, with labeling d) Yes, without labeling	b or d	Device Requirement
21	Stress-cracking resistance? a) No b) Yes (Specify limits)	Type 1: Per ISO 8536-4, ISO 1135-4, ISO 15747, ISO 15759, ISO 3826-1, and/or ISO 3626-4 Type 2: Per ISO 80369-7	
22	Externally, how is CONNECTOR to be distinguishable from non-IV delivery CONNECTORS? (describe)	NON-INTERCONNECTABLE characteristics	
23	Proposal for color-coding? a) No b) Yes (Reference standard)	a	Device Related
24	Labeling/Symbols/Marking? (e.g. not for IV) a) No b) Yes	a	Device Related

Table E.1 *(continued)*

	Criteria	Requirement(s)	Remark(s)
25	Other method for indicating intended use? a) No b) Yes (Indicate method)	a	Device Related
26	Biocompatibility considered? a) No b) Yes	b	Device Related
27	Reuse variants: a) Multiple PATIENT use b) Single PATIENT use c) Single use d) Non-reusable (indicate method of auto-disabling)	a, b, or c	Multiple PATIENT use refers to pharmacy
28	Decontamination needed? a) No, single use only b) Yes, cleaning and disinfection (indicate method) c) Yes, cleaning and sterilization (indicate method)	a b - Isopropyl Alcohol (e.g. spray, immersion or wiping) c - Steam	
29	How is ISO 18250-2 incompatibility achieved? a) Dimensional b) Other (indicate method)	Not yet defined	
30	How is ISO 18250-3 incompatibility achieved? a) Dimensional b) Other (indicate method)	a,b – WG5 CAD Analysis	
31	How is ISO 18250-4 incompatibility achieved? a) Dimensional b) Other (indicate method)	Not yet defined	
32	How is ISO 18250-5 incompatibility achieved? a) Dimensional b) Other (indicate method)	Not yet defined	Do not anticipate 18250-5

Table E.1 *(continued)*

	Criteria	Requirement(s)	Remark(s)
33	How is ISO 18250-6 incompatibility achieved? a) Dimensional b) Other (indicate method)	a,b – WG5 CAD Analysis	
34	How is ISO 18250-8 incompatibility achieved? a) Dimensional b) Other (indicate method)	a,b – WG5 CAD Analysis	
35	How is ISO 18250-9 incompatibility achieved? a) Dimensional b) Other (indicate method)	Not yet defined	

Annex F
(informative)

Summary of engineering analysis and residual MISCONNECTIONS for CONNECTORS for intravascular RESERVOIRS

F.1 Summary of the engineering analysis of the design

CONNECTOR Type 1: Spikes and administration ports

The port design of B.1 is intended to mate with the spikes of ISO 8536-4 and ISO 1135-4.

— Retention is intended to be achieved through diametrical interference of features ØA and/or ØD to the outer diameters of the spikes and/or by the septum itself. Balance is necessary on these diameters as these features shall provide sufficient retention, but also allow manual insertion and removal of spikes.

— The septum at position B of ØC is intended to be pierced by the spike and potentially to provide fluid sealing capabilities. This septum represents the fluid barrier of the RESERVOIR (i.e., it is wet on one side and dry on the other).

— The last septum surface to be pierced is positioned at a maximum distance B from the inlet (Level zero) to ensure that the fluid lumen of the spike is always beyond the septum. Septums positioned at the maximum position shall still allow flow into the lumen of the spike.

— Diameter E represents the outer features of the port, which based on survey of existing, marketed devices, exist anywhere within the range specified. Note this outer dimension E is not intended to be a diameter or a cylindrical surface – it can be asymmetric on the axis of the CONNECTOR and can have any variety of features – so long as all those features exist within the theoretical cylinder described by E.

CONNECTOR Type 2: LUERS

Summary of the engineering analysis for type 2 CONNECTORS (LUERS) can be found in ISO 80369-7:2016, Annex G.

F.2 CAD PROCESS

A three dimensional CAD analysis was conducted for TC 210/WG 5. As defined per the ISO 18250-1:2018, 5.1, the CONNECTORS defined in ISO 18250-7 were compared to the CONNECTORS of the other APPLICATION parts of ISO 18250 series and to the defined surfaces of both ISO 17256[2)] and ISO/IEC 80601-2-74.

The process of making this comparison included modeling all of the CONNECTORS in 3-Dimensional CAD software. Each CONNECTOR had multiple configurations created including the Least Material Condition (LMC), the nominal, and the Maximum Material Condition (MMC). The models of these three configurations were superimposed on each other to create a graphical representation of the geometrical bounds of each CONNECTOR type.

Those superimposed models were then compared one CONNECTOR after the next to check for areas of unintended interconnectability (i.e., an engineering assessment of whether or not the CONNECTION, anywhere within the allowable tolerances or within certain interference conditions would fail the ISO 18250-1:2018, B.3 physical tests.)

2) Under preparation. Stage at the time of publication ISO/DIS 17256:2018.

The residual concerns (where a CONNECTION could be established and liquid flow is likely) are summarized in the tables below for each CONNECTOR Type. Suggestions to manufacturers are included there to indicate what may be done to further prevent this residual MISCONNECTIONS from occurring when the CONNECTORS are being incorporated into a medical device.

NOTE Since ISO 18250-2 (respiratory) and ISO 18250-9 (irrigation) are not yet defined, it is expected that there may be MISCONNECTION potential between the ISO 18250-7 and the CONNECTORS of these existing, commercialized device categories.

Table F.1 — CONNECTOR Type 1: Spikes and Administration Ports: Residual MISCONNECTION Risks

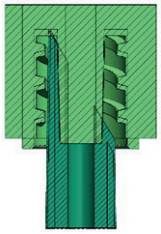
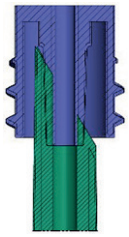
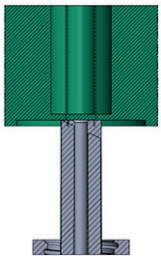
	ISO 18250-7 CONNECTOR	Misconnecting CONNECTOR	Illustration	Assessment	ISO 18250-7 Risk Statement
F.1a	IV1 Intravascular Spike, Type 1 ISO 8536-4 ISO 1135-4 Non-Vented Tip	N2 Male Neural Lock Connector (i.e. ISO 18250-6 / ISO 80369-6 N2 Male)		Possible Neural RESERVOIR to INTRAVASCULAR INFUSION SET CONNECTION. Fluid transfer possible if connection is made. The MISCONNECTION would most likely leak.	The cap/seal on both components would need to be removed in order to misconnect. The connection of a conical male (Neural) to the oval hole in the spike would be awkward and non-intuitive. MISCONNECTION between these two CONNECTORS is considered an unlikely event and therefore make the risk of this MISCONNECTION acceptable. Manufacturers of Type 1 spikes may mitigate by adjusting spike ID to be incompatible with the Neural N2 Male Cone OD.
F.1b	IV1 Intravascular Spike, Type 1 ISO 8536-4 ISO 1135-4 Non-Vented Tip	AC Male Apheresis Reservoir Connector (i.e. ISO 18250-8 Male)		CONNECTION possible. No fluid transfer due to intended orientation of CONNECTOR.	The cap/seal on both components would need to be removed in order to misconnect. CONNECTORS represent giving set to giving set. No fluid would be transferred if a CONNECTION occurred. The risk of this MISCONNECTION is acceptable.

Table F.1 *(continued)*

	ISO 18250-7 CONNECTOR	Misconnecting CONNECTOR	Illustration	Assessment	ISO 18250-7 Risk Statement
F.1c	IV1 Intravascular Administration Port, Type 1	E1R Cross Connector (i.e. ISO 18250-3 Male Cross Connector)		Probable CONNECTION, fluid transfer possible if septa in IV1 Port is broken. Leakage expected.	Physical testing of Intravascular Administration Ports, Type 1, was performed. The septum of commercially available intravascular administration ports tested were not able to be pierced by the cross connector when a force of 70N was applied. This would result in a connection, but without probable fluid transfer. Both RESERVOIR CONNECTOR systems have been in use for several years and there have been no known MISCONNECTIONS. Therefore, the risk of this MISCONNECTION is acceptable.