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BSI Standards Publication

Endoscopes — Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves

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TECHNICAL SPECIFICATION

ISO/TS 18340

First edition
2015-10-15

Endoscopes — Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves

Endoscopes — Mandrins de trocart, fourreaux de trocart et dispositifs d'endothérapie à utiliser avec des fourreaux de trocart

Reference number
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Foreword

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The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

Introduction

This Technical Specification is intended to help manufacturers to produce universal interchangeable reusable trocar sleeves and trocar pins and endotherapy devices which are inserted through these trocar sleeves.

TECHNICAL SPECIFICATION **ISO/TS 18340:2015(E)**

Endoscopes — Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves

1 Scope

This Technical Specification specifies the design, testing and labelling of universal interchangeable and reusable trocar sleeves and trocar pins and of endotherapy devices which are inserted through these trocar sleeves.

This Technical Specification represents the minimum requirements for the production of the products mentioned.

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 8600-1:2013, *Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*

ISO 8600-6, *Optics and photonics — Medical endoscopes and endotherapy devices — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8600-6 and the following apply.

3.1
trocar
endotherapy device consisting of two elements: trocar pin and trocar sleeve to gain internal access and perform endoscopy

3.2
trocar pin
endoscopic element with a sharp pyramidal or conical point used to puncture body cavities

Note 1 to entry: It is typically assembled and used together with a compatible trocar sleeve filling its lumen, allowing the introduction of this assembly. Following puncture the trocar pin is withdrawn providing a working channel into the cavity.

3.3
trocar sleeve
endoscopic element used together with trocar pin to create an artificial orifice for puncturing body cavities

Note 1 to entry: The trocar sleeve can be made with or without screw thread.

3.4
puncture point
tip of a trocar pin

Note 1 to entry: Puncture points can occur in varying designs: conical or pyramidal, sharp or blunt or spiral shape driven.

3.5
distal part
different kind of movable jaw parts at the end of an endoscope or an endotherapy device

3.6
nominal diameter
ND
diameter mentioned on the label

3.7
minimum inner diameter
ID_{ts}
inner dimension of a trocar sleeve

Note 1 to entry: This minimum inner diameter is comparable to the definition for instrument channel width of an endoscope.

3.8
maximum insertion portion width
OD
maximum external width of an endoscope or endotherapy device throughout the length of the insertion portion to be inserted

Note 1 to entry: The maximum width of any expandable or transformable portion of the insertion portion is not considered as a maximum insertion portion width, such as balloons, controllable parts, jaws and the like having variable insertion portion widths.

Note 2 to entry: See also ISO 8600-6:2005.

[SOURCE: ISO 8600-1:2013, definition 3.10]

4 Dimensions

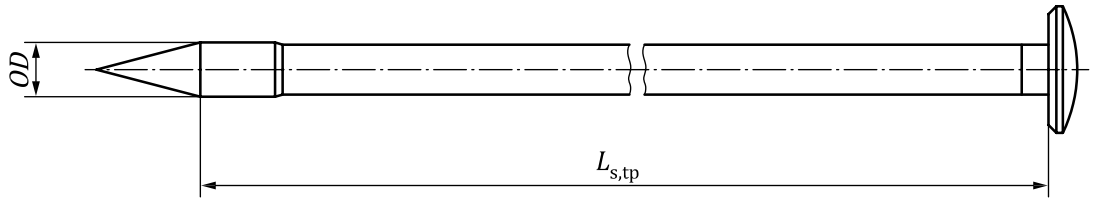
4.1 General

There is a wide range of trocar sleeves as well as endotherapy devices used with trocar sleeves with different dimensions available. If the nominal diameter of an endotherapy device is smaller than the nominal diameter of the sleeve, the usage of both together is obviously possible without problems.

In order to keep the incision small, trocar sleeves and endotherapy devices may have the same nominal diameter. In this case it is very important to ensure that the endotherapy device can be introduced through the sleeve. Thus, the maximum insertion portion width (*OD*) of the endotherapy device shall be smaller than the minimum inner diameter ($ID_{ts,min}$) of the trocar sleeve.

4.2 Trocar pin and trocar sleeve

There is no relation between working length and total length. See Figure 1 and Figure 2.



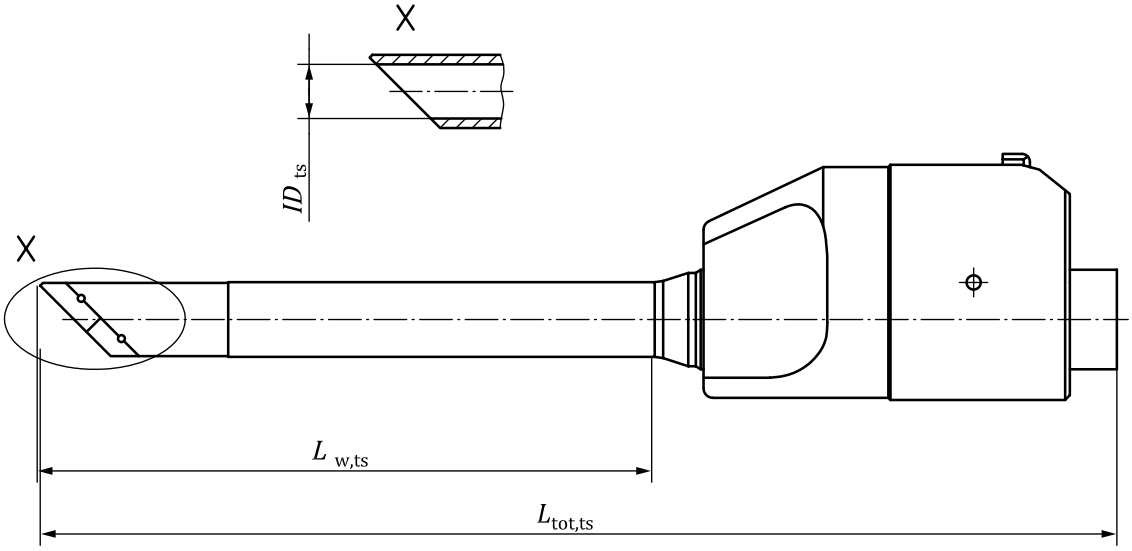
Key

$L_{s,tp}$ shaft length of the trocar pin

OD maximum insertion portion width (outer diameter) of trocar pin

NOTE Free choice of length.

Figure 1 — Trocar pin



Key

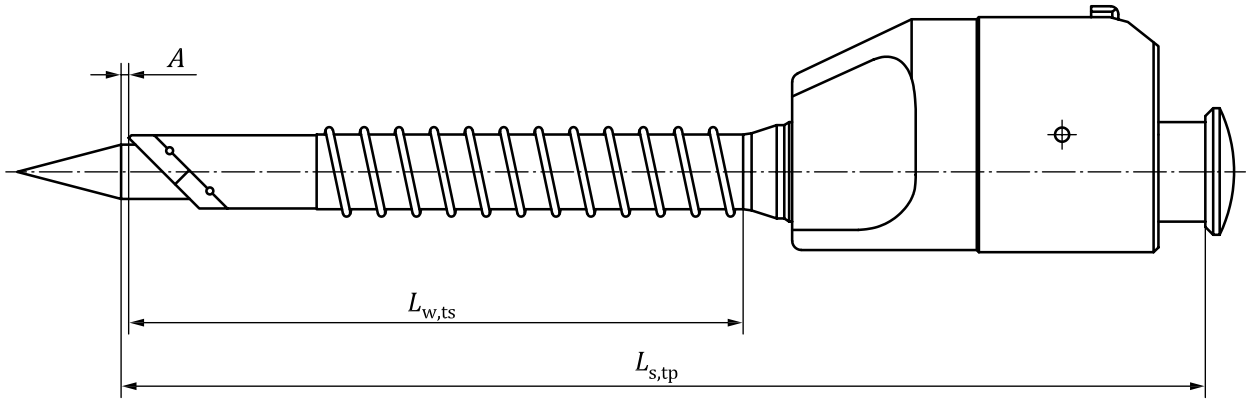
$L_{tot,ts}$ total length of the trocar sleeve

$L_{w,ts}$ working length of the trocar sleeve

ID_{ts} inner diameter of the trocar sleeve

NOTE Free choice of intermediate sizes.

Figure 2 — Trocar sleeve without trocar pin (schematic)



Key

A visible area of the cylindrical part of trocar pin ≥ 0

$L_{w,ts}$ working length of the trocar sleeve

$L_{s,tp}$ shaft length of the trocar pin

NOTE Free choice of intermediate sizes.

Figure 3 — Trocar sleeve with trocar pin (schematic)

If the nominal diameter is < 5 mm, the inner diameter shall be 0,05 mm larger. If the nominal diameter is ≥ 5 mm the inner diameter shall be 0,1 mm larger. See Table 1 for details.

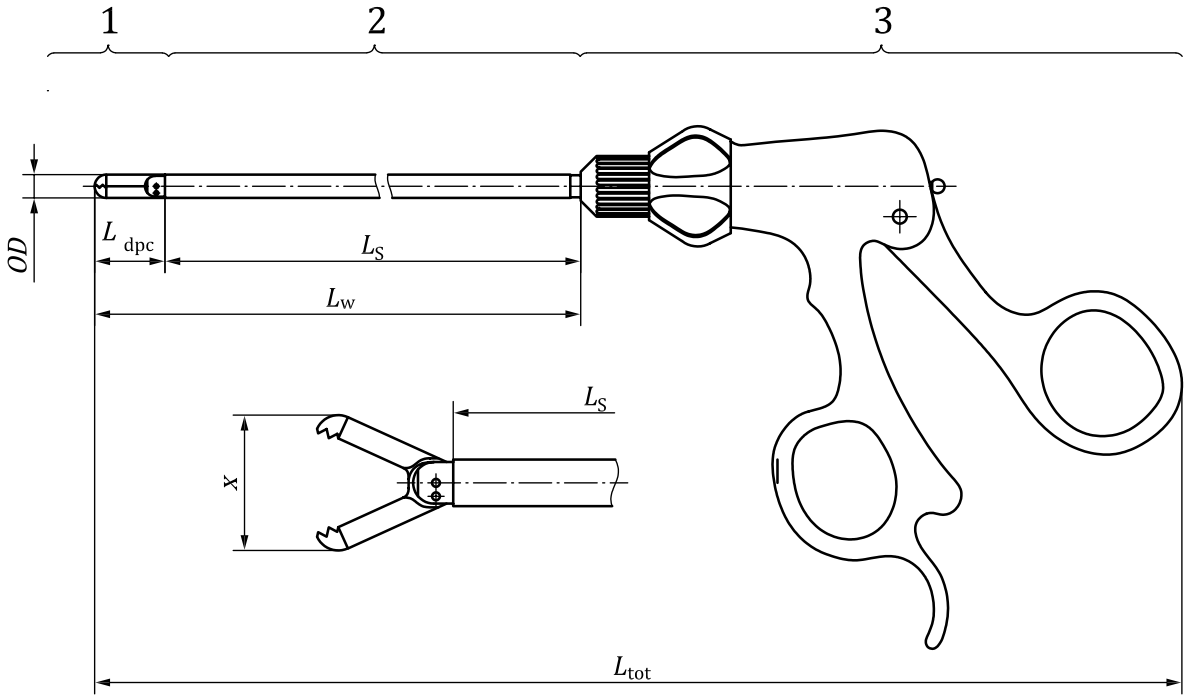
Table 1 — Dimensions

Dimensions in millimetres

Nominal diameter ND	Minimum inner diameter $ID_{ts,min}$
< 5	ND + 0,05
≥ 5	ND + 0,1

4.3 Endotherapy device for use through a trocar sleeve

See Figure 4.



Key

1	distal part	*OD*	maximum insertion portion width
2	sheath	L_w	working length
3	handle	L_S	sheath length (length without distal part)
1 and 2	insertion part	L_{tot}	total length
x	maximum size with opened branches	L_{dpc}	length of ***closed*** distal part

The sheath length L_S shall be longer than the total length of the trocar sleeve $L_{tot,ts}$.

NOTE Free choice of length.

Figure 4 — Endotherapy device for use through a trocar sleeve (schematic)

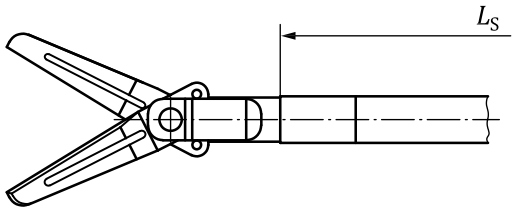


Figure 5 — Open distal part

Due to design of endotherapy devices moving parts may protrude. Sheath length shall not cover them. See Figure 5.

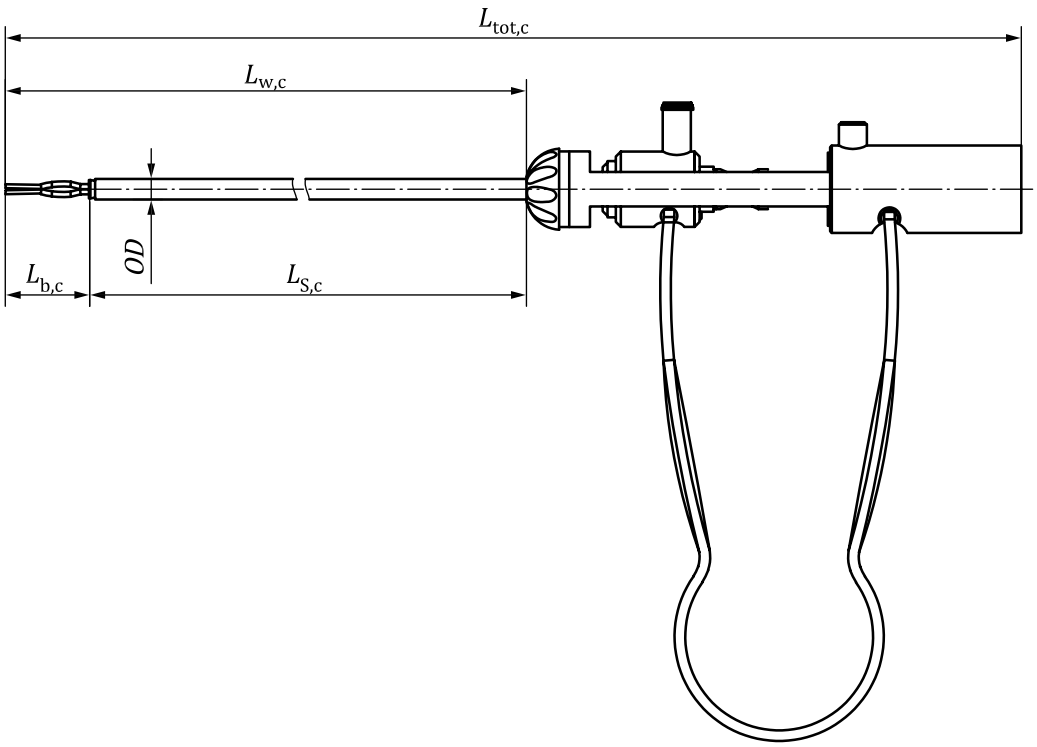
The maximum insertion portion width *OD* of the device shall fit to the minimal inner diameter of the trocar sleeve $ID_{ts,\,min}$

To ensure the compatibility to a trocar sleeve the maximum insertion portion width shall not be larger than the nominal diameter.

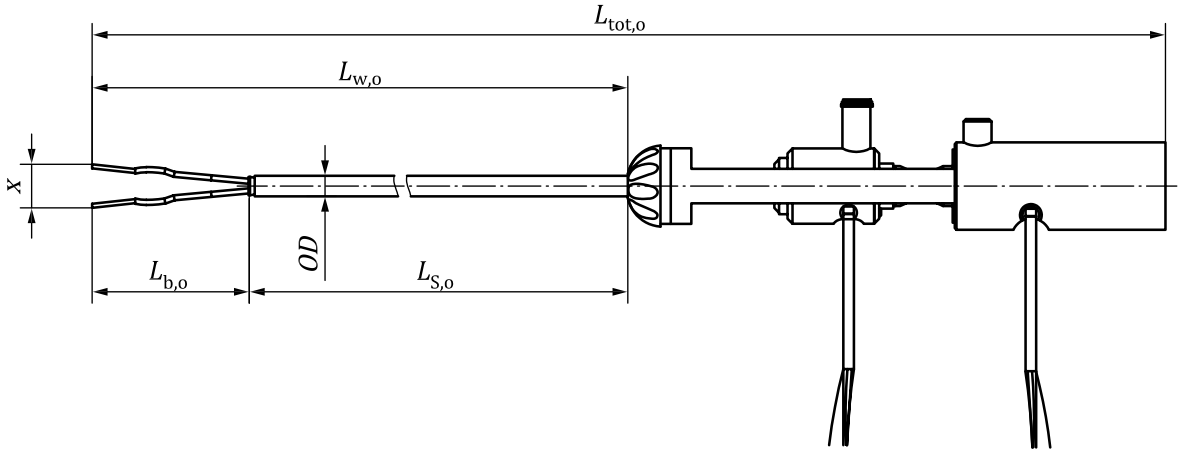
4.4 Endotherapy device with spring handle for use through a trocar sleeve

There are also devices (forceps etc.) with "spring handle" available. These devices have branches without joint, see Figure 6. In this case the inner part has to be moved forward within the sheath to open the branches, or the sheath has to be moved backwards for opening. This means, the user has to take care of the relative movement of the distal part. Another disadvantage is the maximum opening of the branches, which is smaller compared to the branches with joint.

The length of closed branches $L_{b,c}$ is shorter than the length with open branches $L_{b,o}$.



a) Closed



b) Opened

Key

OD	maximum outer diameter of the insertion part		
$L_{tot,o}$	total length of the device, opened	$L_{tot,c}$	total length of the device, closed
$L_{w,o}$	working length of the device, opened	$L_{S,o}$	sheath length, opened
$L_{w,c}$	working length of the device, closed	$L_{S,c}$	sheath length, closed
$L_{b,o}$	length of the branches, opened	$L_{b,c}$	length of the branches, closed

NOTE $L_{S,o} \neq L_{S,c}$; $L_{tot,o} = L_{tot,c}$, $\Delta L = L_{b,o} - L_{b,c}$

Figure 6 — Variability of lengths on forceps in closed a) and opened b) state

5 Material

Metallic, non-metallic or combination of both materials can be used.

The material shall meet the requirements of medical devices.

6 Finish

The endotherapy devices shall be free of burrs, pores, cracks, groves and production residues.

These requirements shall be proved without visual aids.

7 Marking

The marking shall be in accordance with ISO 8600-1:2013, Clause 6.

Bibliography

[1] ISO 10993 (all parts), *Biological evaluation of medical devices*

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