
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

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Dimensions	2
4.1 General	2
4.2 Trocar pin and trocar sleeve	2
4.3 Endotherapy device for use through a trocar sleeve	4
4.3.1 Not dismountable endotherapy devices	5
4.3.2 Dismountable endotherapy devices	5
4.4 Endotherapy device with spring handle for use through a trocar sleeve	6
5 Material	8
6 Marking	8
Bibliography	9

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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).

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For an explanation of 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172 *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This first edition cancels and replaces the first edition of ISO/TS 18340:2015.

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

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

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

1 Scope

This document specifies the design, testing and labelling of trocar sleeves and trocar pins that are universally interchangeable and reusable.

It also specifies the design, testing and labelling of endotherapy devices which are inserted through these trocar sleeves and are also universally interchangeable and reusable.

This document specifies 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, *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, typically assembled and used together with a compatible trocar sleeve filling its lumen which allow the introduction of this assembly, used to puncture body cavities

3.3

trocar sleeve

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

3.4

puncture point

tip of a trocar pin

Note 1 to entry: It may have various 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
mentioned diameter 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.

4 Dimensions

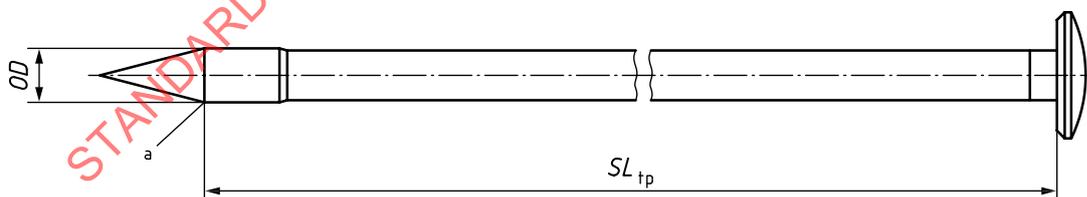
4.1 General

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

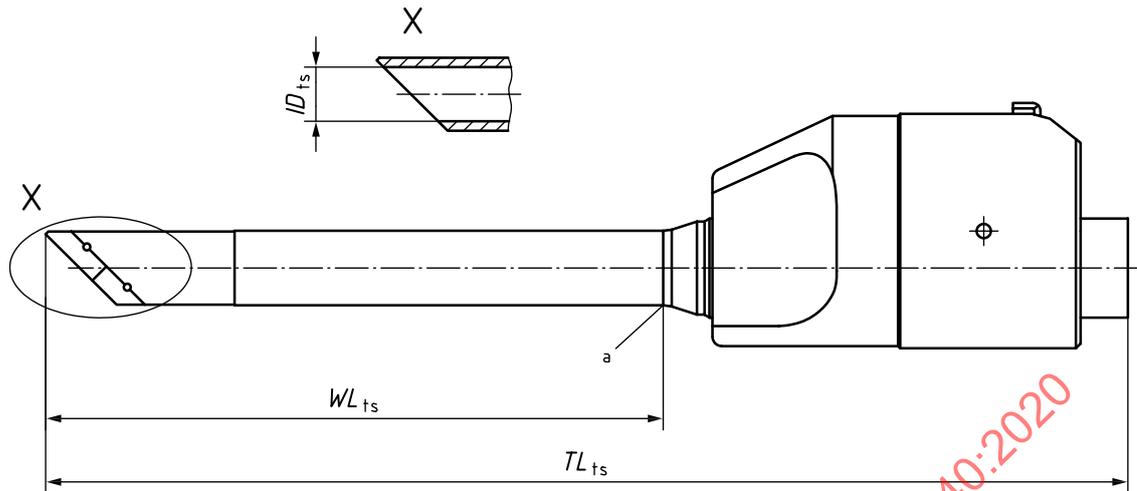
SL_{tp} shaft length of the trocar pin

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

^a Distal reference of SL_{tp} depends on the point where *OD* is circumferentially completed (e.g. asymmetrical trocar pins or chamfered edges).

NOTE Free choice of length.

Figure 1 — Trocar pin

**Key**

TL_{ts} total length of the trocar sleeve

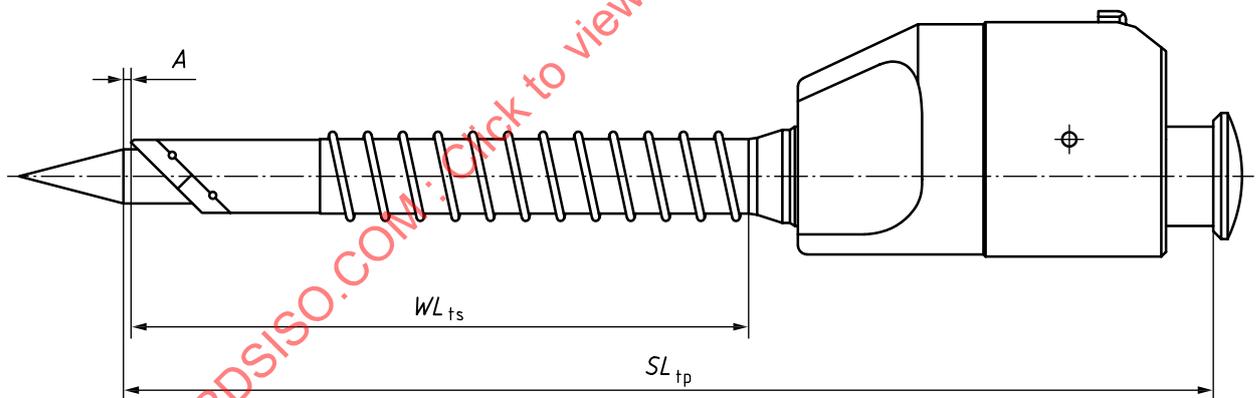
WL_{ts} working length of the trocar sleeve

ID_{ts} inner diameter of the trocar sleeve

^a Proximal reference of WL_{ts} depends on the point where the diameter exceeds OD.

NOTE Free choice of intermediate sizes.

Figure 2 — Trocar sleeve without trocar pin (schematic)

**Key**

A shortest visible length of the cylindrical part of trocar pin ≥ 0

WL_{ts} working length of the trocar sleeve

SL_{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 at least 0,05 mm larger. If the nominal diameter is ≥ 5 mm the inner diameter shall be at least 0,1 mm larger. See [Table 1](#) for details.

Table 1 — Dimensions

Dimensions in millimetres

Nominal diameter <i>ND</i>	Minimum inner diameter <i>ID_{ts,min}</i>
<5	$\geq ND + 0,05$
≥ 5	$\geq ND + 0,1$

4.3 Endotherapy device for use through a trocar sleeve

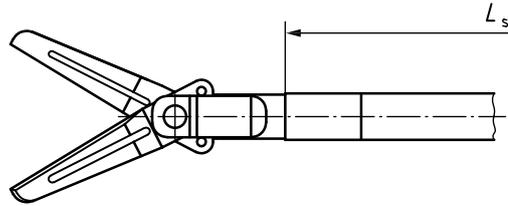


Figure 4 — Open distal part

Due to design of endotherapy devices moving parts may protrude. Sheath length shall not cover them. See [Figure 6](#).

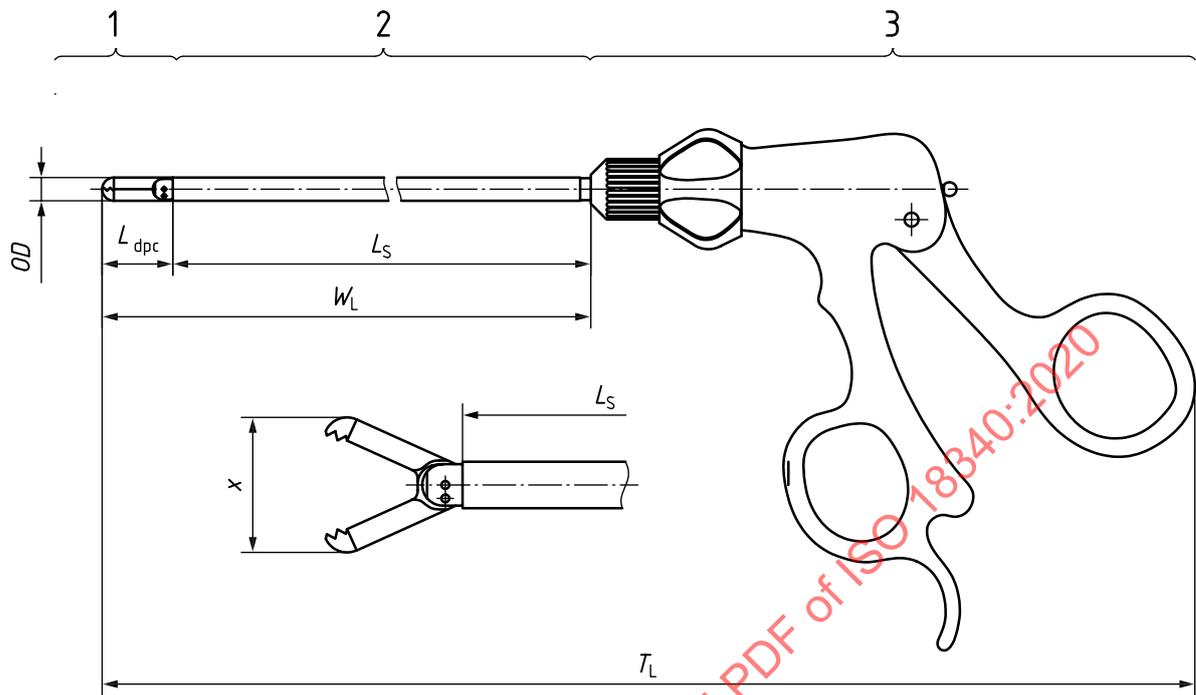
The maximum insertion portion width *OD* of the device shall fit to the minimum inner diameter of the trocar sleeve *ID_{ts,min}*

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

There are two different types of endotherapy devices available. The type of devices which are not dismantlable (see [Figure 5](#)) and the type of devices which are dismantlable (see [Figure 6](#)).

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4.3.1 Not dismountable endotherapy devices



Key

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

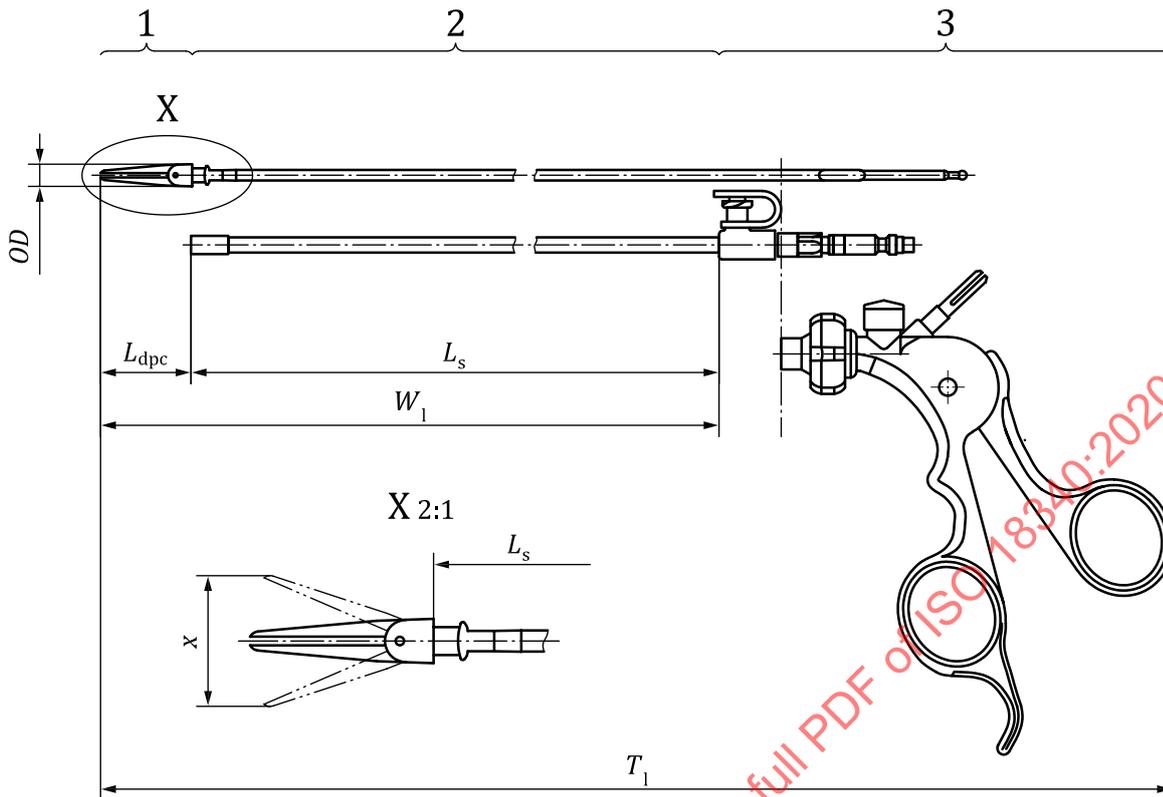
The sheath length L_S shall be longer than the total length of the trocar sleeve TL_{ts} .

NOTE Free choice of length.

Figure 5 — Not dismountable endotherapy device for use through a trocar sleeve (schematic)

4.3.2 Dismountable endotherapy devices

For dismountable endotherapy devices the length of the distal part L_{dps} varies depending on the type of jaws used in the current combination. Therefore the working length W_L varies about the same value.



Key

1	distal part	OD	maximum insertion portion width
2	sheath	W_l	working length
3	handle	L_s	sheath length (length without distal part)
1 and 2	insertion part	T_l	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 TL_{ts} .

NOTE Free choice of length.

Figure 6 — Dismountable endotherapy device for use through a trocar sleeve (schematic)

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 7](#). 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 issue is the maximum opening of the branches, which is smaller compared to the branches with joint.

The length of closed branches L_{bc} is shorter than the length with open branches L_{bo} .