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

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

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 18340:2015



STANDARDSISO.COM : Click to view the full PDF of ISO/TS 18340:2015



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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
4.4 Endotherapy device with spring handle for use through a trocar sleeve	6
5 Material	7
6 Finish	7
7 Marking	7
Bibliography	8

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 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 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 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.

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 18340:2015

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 18340:2015

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

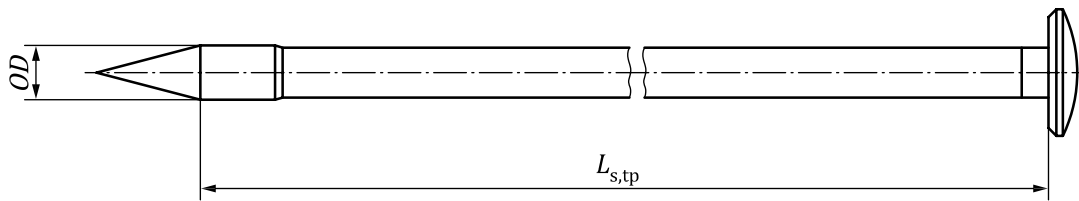
4.1 General

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.

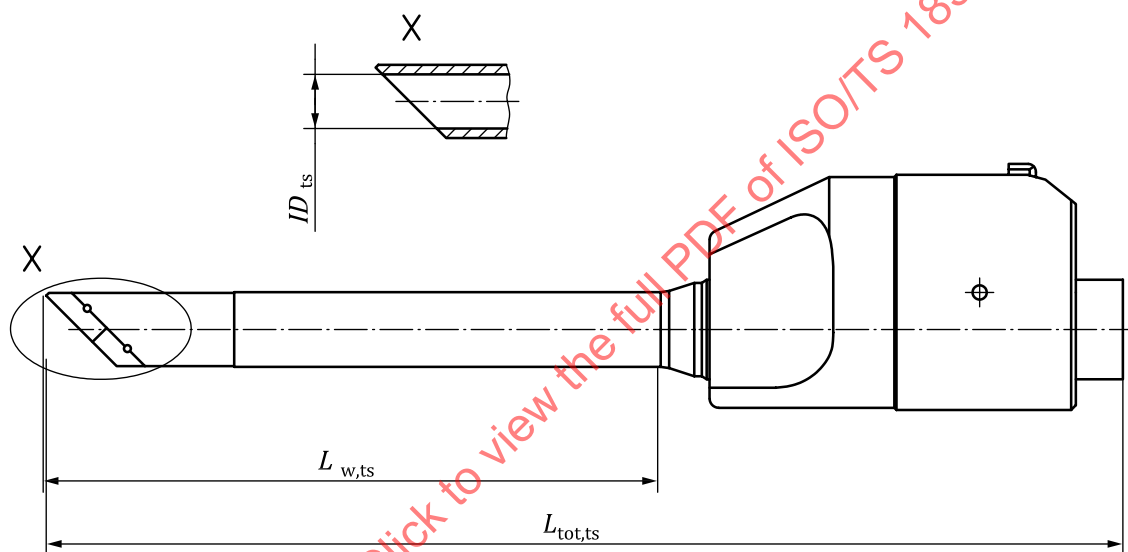
4.2 Trocar pin and trocar sleeve

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

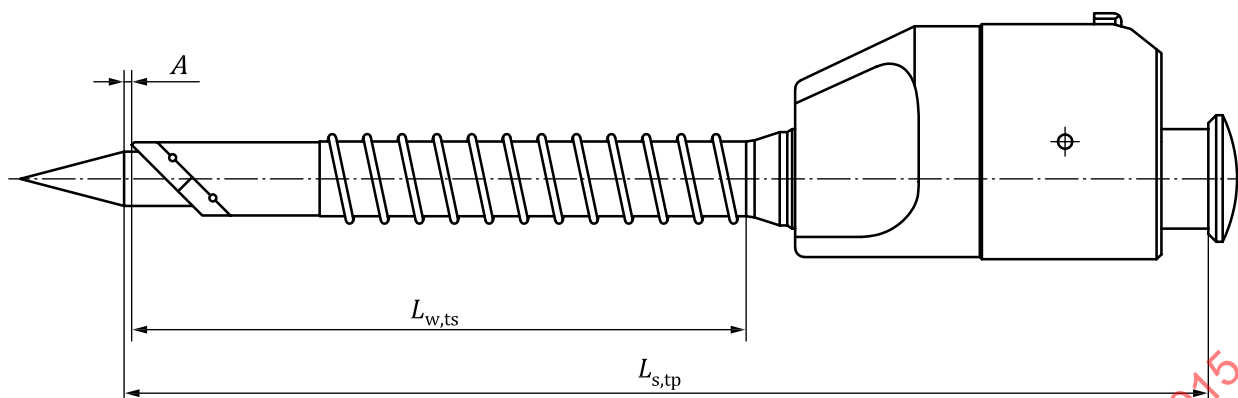
OD maximum insertion portion width (outer diameter) of trocar pin

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.

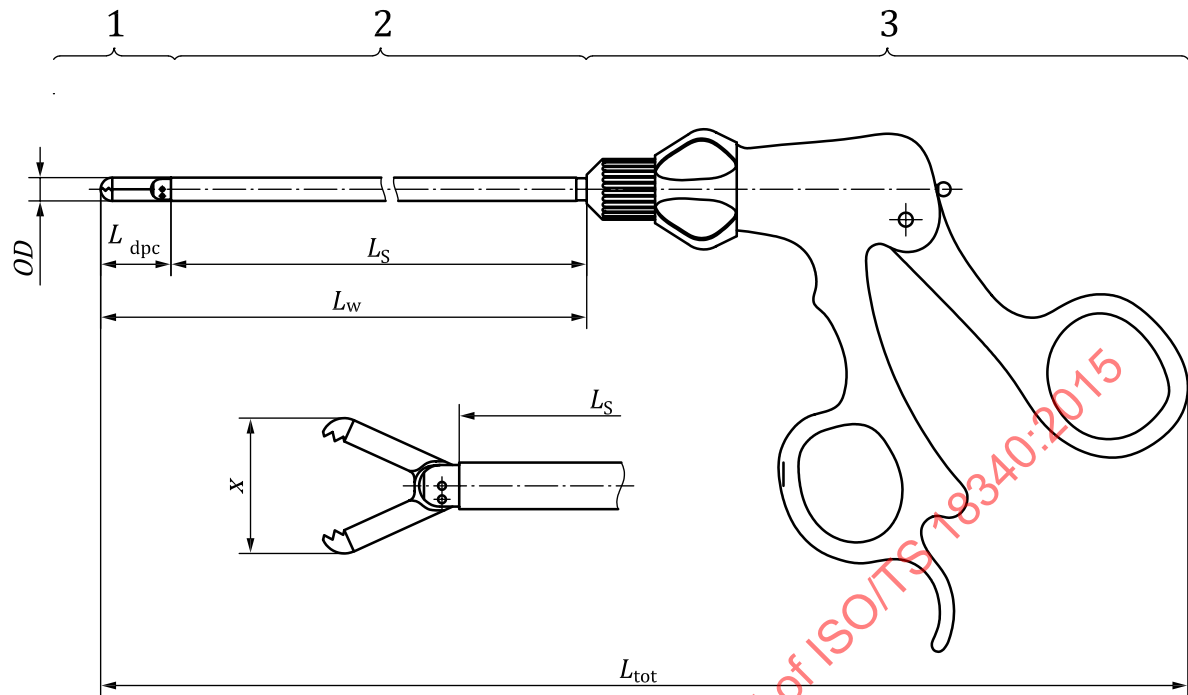
Table 1 — Dimensions

Dimensions in millimetres

Nominal diameter	Minimum inner diameter
<i>ND</i>	<i>ID_{ts,min}</i>
< 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)

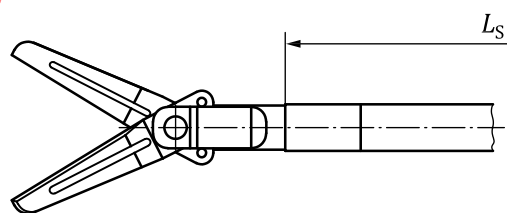


Figure 5 — Open distal part

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

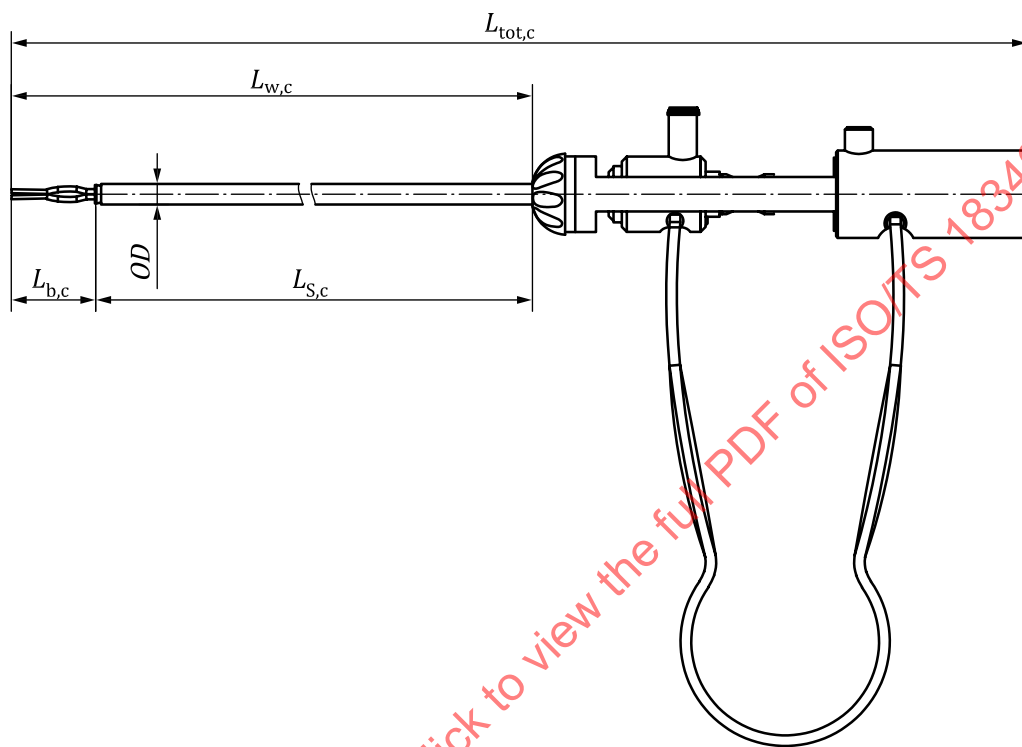
The maximum insertion portion width OD of the device shall fit to the minimal inner diameter of the trocar sleeve $ID_{ts, min}$

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