
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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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 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*.

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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.

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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.

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

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4 Dimensions

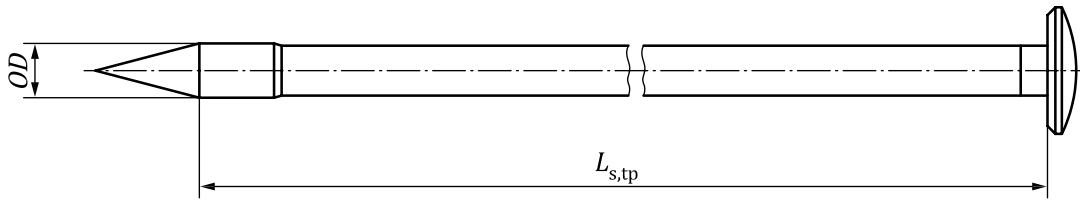
4.1 General

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](#).



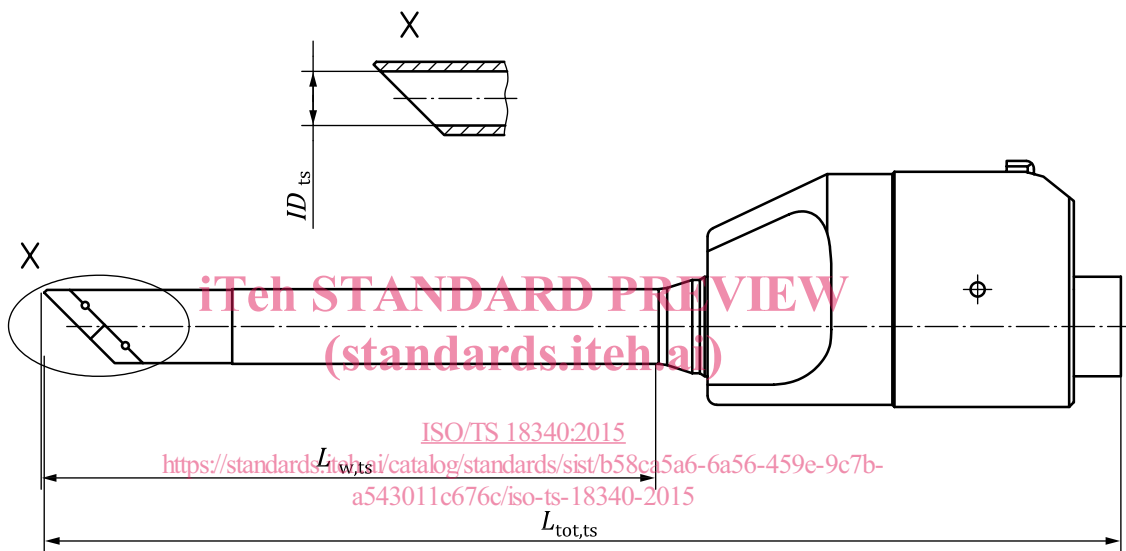
Key

$L_{s,tp}$ 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)