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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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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.

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 reuseable.

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

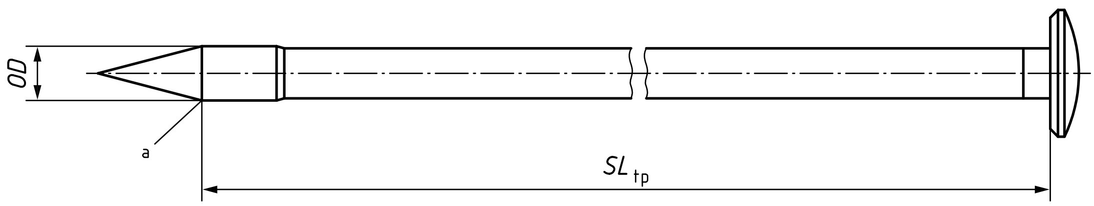
4.1 General

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

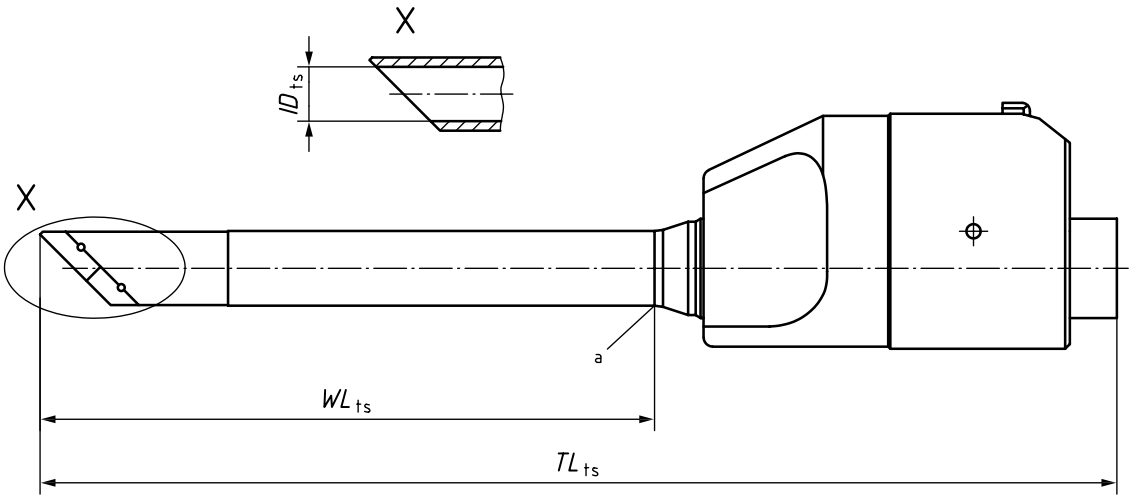
SL_{tp} shaft length of the trocar pin

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

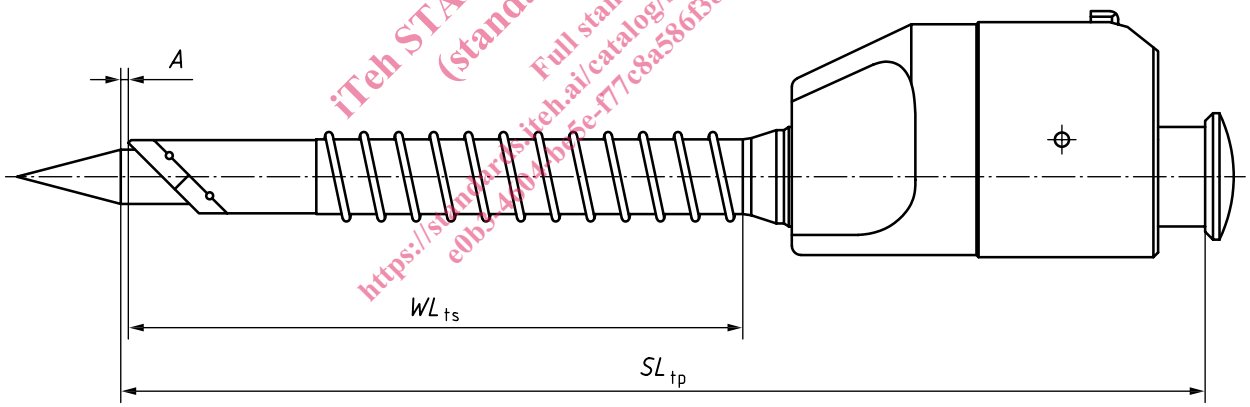


Key

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.