INTERNATIONAL STANDARD

ISO 18340

First edition
2020-07

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
ISO 18340:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

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 (see 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 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.

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

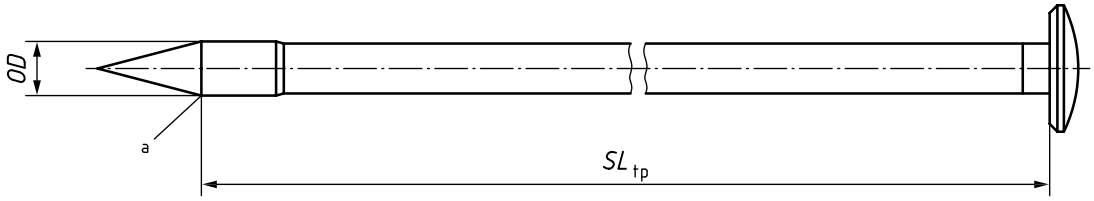
4.1 General

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.

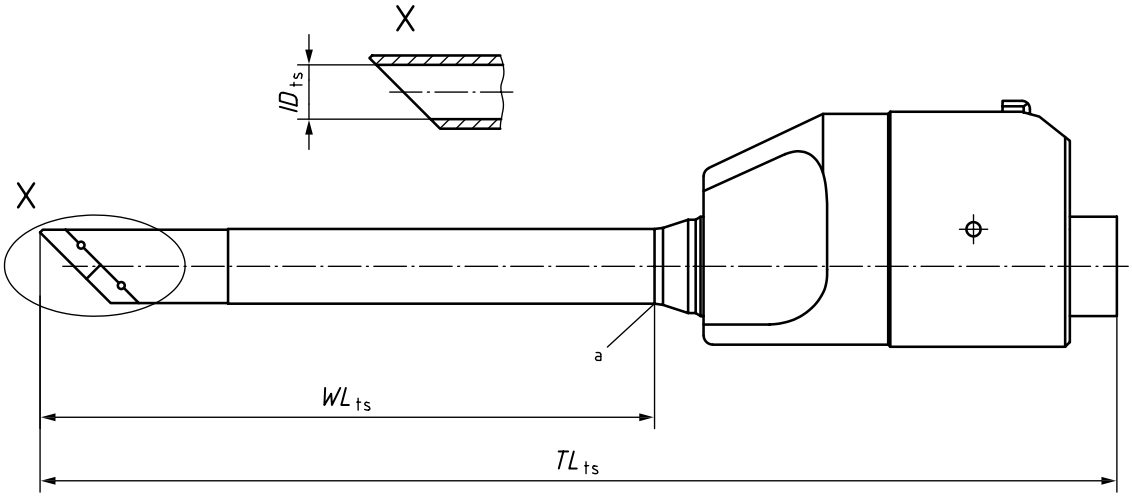


Key

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

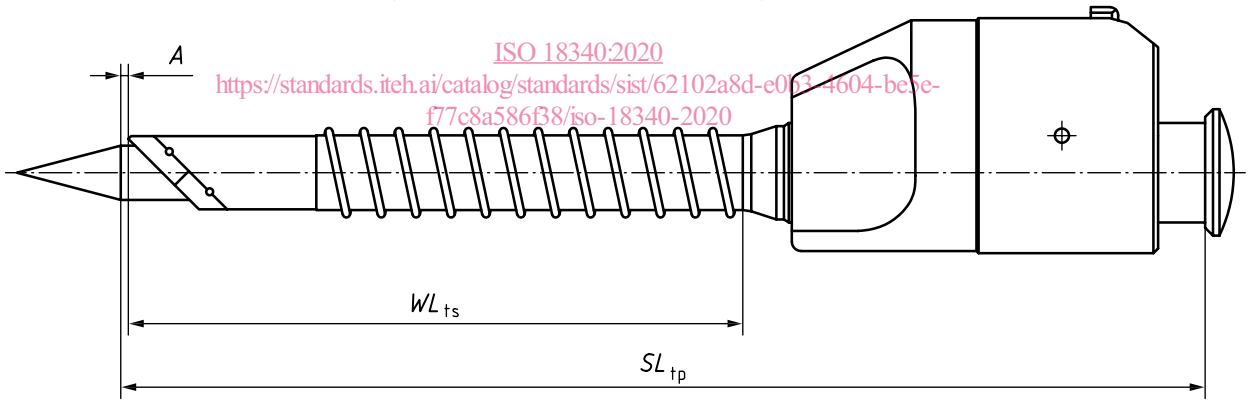


Key

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.