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**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*



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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](http://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](http://www.iso.org/patents)).

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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](http://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](http://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 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