
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.

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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