
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

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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*.

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.

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.