PD ISO/TS 18340:2015

BSI Standards Publication

Endoscopes — Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves

bsi.

...making excellence a habit.™

National foreword

This Published Document is the UK implementation of ISO/TS 18340:2015.

The UK participation in its preparation was entrusted to Technical Committee CPW/172, Optics and Photonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2015

ISBN 978 0 580 80648 3
ICS 11.040.55

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 October 2015.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 18340:2015

TECHNICAL SPECIFICATION

ISO/TS 18340

First edition
2015-10-15

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/TS 18340:2015(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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 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 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 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.