TECHNICAL SPECIFICATION

ISO/TS 18339

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Endotherapy devices — Eyepiece cap and light guide connector

Dispositifs d'endothérapie — Bouchon d'oculaire et raccord de guide de lumière

Reference number
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Foreword

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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).

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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

To carry out minimal invasive diagnostic or therapy not only endoscopes are required, but also some additional components like light guide cable, light source, and video-camera.

Sometimes these components are not from the same manufacturer. This Technical Specification is a recommendation to ensure the mechanical compatibility with these components.

If items are not from the same manufacturer, this kind of combination might not generate best results, but it allows the user to be able to work.

Endotherapy devices — Eyepiece cap and light guide connector

IMPORTANT — Joint applications of different products are only permissible if the intended use and the relevant technical data are the same (working length, diameter, etc.). Injuries to the patient, user, or others, as well as damage to the products, are possible if the combination is not correct.

1 Scope

This Technical Specification specifies the design of eyepiece cap and light guide connector of an endoscope to enable the combination of products from different manufacturers. The products intended only for limited combination are out of the scope. It is a mechanical connection; it might not generate best results, but it allows the user to be able to work.

This Technical Specification supports manufacturers of components in the design of interfaces.

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 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 8600-6, *Optics and photonics — Medical endoscopes and endotherapy devices — Part 6: Vocabulary*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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
eyepiece cap
part located at the proximal end to which a photographic or video camera can be attached

3.2
light guide connector
part located at the proximal end which is designed to allow the connection of a *light guide cable* (3.3)

3.3
light guide cable
part which connects the endoscope to a light source for transmitting illumination

4 Dimensions

4.1 Eyepiece cap

4.1.1 Eyepiece cap with straight edges

If the proximal image output is provided in the form of an eyepiece cap, it shall be designed in accordance to the details shown in Figure 1. These are the minimum requirements in terms of shape and design.

Dimensions in millimetres

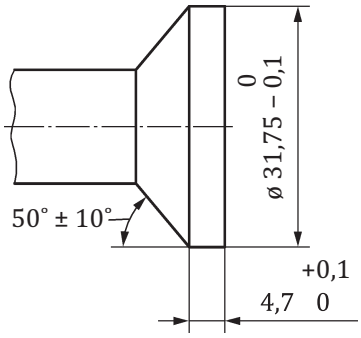
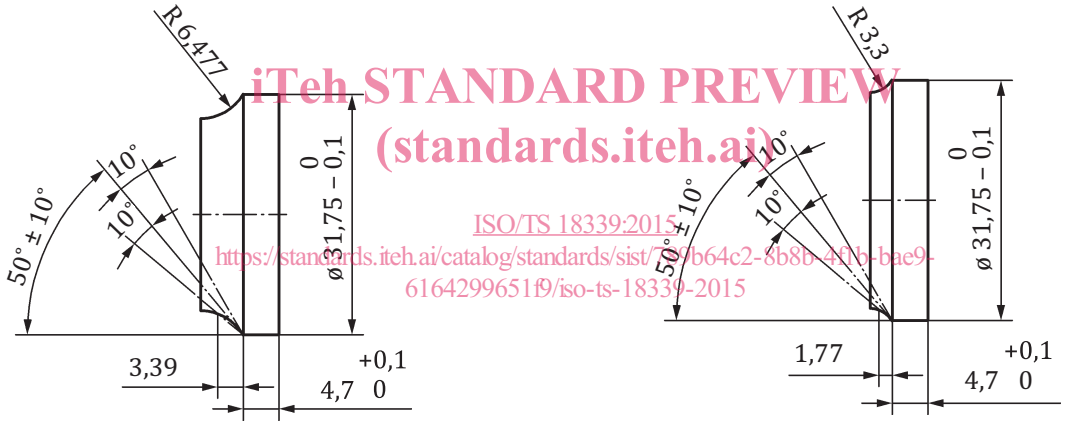


Figure 1 — Eyepiece cap with straight edges

4.1.2 Eyepiece cap with curved edges

Even if the eyepiece cap is designed with a radius, it will fit into the dimensions of this Technical Specification. See Figure 2.

Dimensions in millimetres



a) Form 1 b) Form 2

NOTE This information is provided in order to assure the correct mechanical interface to any kind of camera couplers.

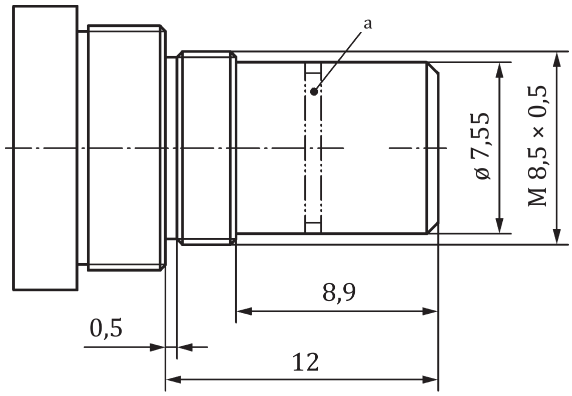
Figure 2 — Eyepiece cap with radius

4.2 Light guide connector

To assure mechanical connection of the light guide cable to an endoscope with detachable light guide connector. The design shall be considered in accordance with Figure 3.

NOTE For future light guide connectors, only the smaller thread size could be applicable.

Dimensions in millimetres



Key

a Nut optional.

Figure 3 — Light guide connector

The tolerance class in Figure 3 should be in accordance with ISO 2768-1.

To connect the light guide cable, it can be necessary to use manufacturer specified adapter available on the market. For safety aspects, a risk management shall be carried out in accordance with ISO 14971.

To achieve optimum light transmission, the fibre bundle diameters of the endoscope and fibre light cable shall match.

The instruction manuals of the products used in conjunction with these products shall be considered.

The possible consequences if the identification does not match are as follows.

— The fibre light cables with excessively large fibre bundle diameter (cross-section) cause excessive heating at the coupling point with the endoscope.

— In the case of unfavourable combinations, temperature increases can occur at the coupling point or at the light exit point of the endoscope. Burns of the patient, user, and others, as well as damage to endoscope, are possible. Reduce the light output or choose a fibre light cable with suitable diameter.

— The fibre light cables with excessively small fibre bundle diameter (cross-section) cause reduced light output.

