
Endotherapy devices — Eyepiece cap and light guide connector

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



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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).

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).

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

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.

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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.