SLOVENSKI STANDARD
SIST EN ISO 21917:2023

01-april-2023

Anestezijska in dihalna oprema - Govorne proteze (ISO 21917:2021)

Anaesthetic and respiratory equipment - Voice prostheses (ISO 21917:2021)

Anästhesie- und Beatmungsgeräte - Stimmprothesen (ISO 21917:2021)

Matériel d'anesthésie et de réanimation respiratoire - Implants phonatoires (ISO 21917:2021)

Ta slovenski standard je istoveten z: **EN ISO 21917:2022**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 21917:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21917

December 2022

ICS 11.040.10; 11.040.40

English Version

Anaesthetic and respiratory equipment - Voice prostheses (ISO 21917:2021)

Matériel d'anesthésie et de réanimation respiratoire - Implants phonatoires (ISO 21917:2021)

Anästhesie- und Beatmungsgeräte - Stimmprothesen (ISO 21917:2021)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

The text of ISO 21917:2021 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21917:2022 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 21917:2021 has been approved by CEN as EN ISO 21917:2022 without any modification.

INTERNATIONAL STANDARD

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Anaesthetic and respiratory equipment — Voice prostheses

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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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment* and is written following the format of ISO 18190 *General standard for airways and related equipment*. The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard.

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Introduction

Voice prostheses are used to restore voice in patients after total laryngectomy. They are placed into a surgically created tracheoesophageal puncture (TEP). The placement can be performed during the laryngectomy (primary placement), later after healing as an endoscopic procedure (secondary placement) or in order to replace a *voice prosthesis* (replacement procedure). There exist different prosthesis specific placement tools to insert a *voice prosthesis* into the TEP. Placement of the *voice prosthesis* can be performed via the tracheostoma (anterograde), via the mouth (retrograde) and via the surgical wound (intraoperative).

Voice prostheses have three essential functions:

— they prevent spontaneous closure of the TEP;

— they allow airflow into the pharynx for the creation of speech;

— they seal the TEP during swallowing.

Safe retention of the *voice prosthesis* is achieved by the oesophageal and tracheal flanges. The oesophageal flange is placed into the oesophagus, the tracheal flange is placed in the trachea. In order to prevent leakage of food and saliva into the trachea *voice prostheses* have a one-way valve that opens in the direction of the oesophagus.

Voice prostheses have a limited service life and have to be replaced if they start leaking or if they are overgrown with a biofilm.

There are two groups of *voice prostheses*:

— indwelling *voice prostheses*, and

— non-indwelling *voice prostheses.*

Indwelling *voice prostheses* are placed by a professional (e.g., speech-language pathologist, physician) and left in the TEP until they fail. They are then replaced.

Non-indwelling *voice prostheses* are replaced by the patient himself after a certain training period.

The following three most common test methods have been included to determine:

a) *Leakage*, which provides information about the basic one-way function of the *voice prosthesis* valve.

b) The valve *opening pressure*, which evaluates the ability of the valve to withstand phenomena that can cause leaking/aspiration during swallowing and inspiration.

c) *Characteristic curve*, which allows an assessment of the air flow resistance of the *voice prosthesis* during speech.

Annex A contains rationale statements for some of the requirements of this document and recommendations that have been incorporated into this document. It is considered that knowledge of the reasons for the requirements and recommendations will not only facilitate the proper application of this document but will expedite any subsequent revisions.

Throughout this document the following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples and references: smaller type.

— *Terms defined in Clause 3: italic type.*