



SLOVENSKI STANDARD
oSIST prEN ISO 22569:2019
01-julij-2019

Zobozdravstvo - Večnamenski ročni pripomočki (ISO/DIS 22569:2019)

Dentistry - Multifunction handpieces (ISO/DIS 22569:2019)

Zahnheilkunde - Mehrfunktionshandstücke (ISO/DIS 22569:2019)

Médecine bucco-dentaire - Pièces à main multifonctionale (ISO/DIS 22569:2019)

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Médecine bucco-dentaire — Pièces à main multifonctionale

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Foreword

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

ISO/DIS 22569:2019(E)**Introduction**

For many years, dental multifunction handpieces (colloquially called “syringes”) have been used in the field of dentistry to carry out treatment in the oral cavity of the patient.

Technological progress enables continual development of improved and new handpieces with simplified handling and extended range of applications.

These handpieces are produced by the dental industry as high-quality medical devices under application of quality management methods.

This document describes the applicable technical properties of products in order to maintain this high level of quality.

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Dentistry — Multifunction handpieces

1 Scope

This document specifies requirements, test methods, instructions for use and marking for multifunction handpieces (colloquially called “syringes”) intended to be used in the oral cavity of the patient. The multifunction handpieces are connected to dental units and provide the user with water, air and spray for treatment purposes. Some multifunction handpieces provide also illumination of the situs.

This document does not apply to dental handpieces and motors, dental turbines, intraoral cameras, contra angels, dental polymerisation lamps, powered scalers, powder jet handpieces, prophylaxis handpieces, suction cannulas and saliva ejectors.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 7494-1, *Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

ISO 21531, *Dentistry — Graphical symbols for dental instruments*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

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3.1 multifunction handpiece

handpiece, which is supplied with air and water and transfers the water and air directly or as air water mixture (spray) in the cold and/or the warm state into the oral cavity of the patient

Note 1 to entry: Multifunction handpieces may be additionally equipped with a light function.

Note 2 to entry: Multifunction handpieces may be called as multi-way syringe or multifunction syringe.

4 Classification

4.1 Shape

Multifunction handpieces are classified according to their geometry (as shown in Figure 1 to Figure 3) as follows:

- angled handpieces;
- straight handpieces;
- curved handpieces.

4.2 Number of functions

The number of transferable fluids such as air, water and spray as well as fluid heating is indicated with a numerical designation:

Examples

3-function handpiece: water, air, and spray.

6-function handpiece: water, air, spray, warm water, warm air, and warm spray.

In addition the lighting equipment is also indicated if applicable.

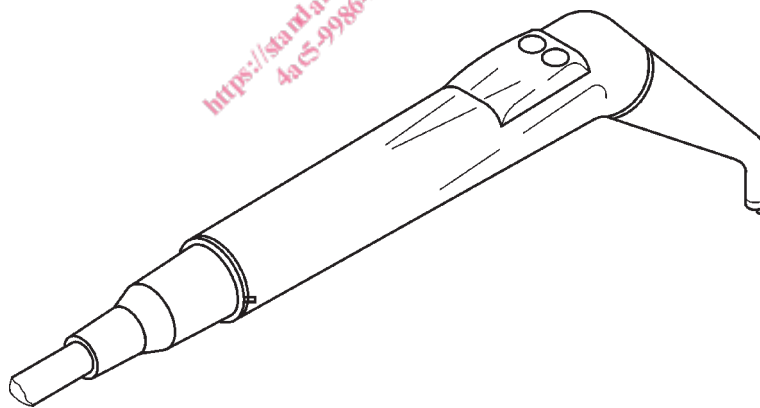


Figure 1 — Angled multifunction handpiece