SLOVENSKI STANDARD

SIST-TS CEN/TS 15277:2006

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Neaktivni kirurški vsadki (implantati) - Vsadki za paranteralne farmacevtske oblike

Non-active surgical implants - Injectable implants

Nichtaktive chirurgische Implantate - Injizierbare Implantate

Implants chirurgicaux non actifs - Implants injectables

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

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TECHNICAL SPECIFICATION

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Non-active surgical implants - Injectable implants

Nichtaktive chirurgische Implantate - Injizierbare Implantate

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Foreword

This document (CEN/TS 15277:2006) has been prepared by Technical Committee CEN/TC 285 “Non-active surgical implants”, the secretariat of which is held by NEN.

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Introduction

This Technical Specification has been written because injectable implants are not covered by any standard.

1 Scope

This Technical Specification gives characteristics of medical devices that are injectable implants, such as lifetime, migration, displacement, unintended degradation, impurity, infections, bio-incompatibility and clinical incompatibility.

Pharmaceuticals, e.g. Botulinum-toxin, are not covered by the present document.

2 Normative references

The following referenced documents are indispensable for the application 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.

EN ISO 10993, *Biological evaluation of medical devices (all parts)*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects – Part 1: General requirements (ISO 14155-1:2003)*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans (ISO 14155-2:2003)*

EN ISO 14630:1997, *Non-active surgical implants – General requirements (ISO 14630:1997)*

EN ISO 14971 *Medical devices - Application of risk management to medical devices (ISO 14971:2000)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
biocompatibility
ability of a material to perform with an appropriate host response in a specific application.

NOTE This would be restricted to in vitro tests etc.]

3.2
clinical compatibility
Absence of unacceptable risk due to the implant as documented during pre-market and post-market evaluation

NOTE For acceptability of risk see EN ISO 14971

3.3
degradation
decomposition of an injectable implant in vivo into smaller chemical or physical components

3.4
displacement
undesired dislocation of the implant due to mechanical forces or gravity

3.5
impurity
unacceptable levels of substances from the production process and/or of other substances in injectable implants

3.6
injectable implant
implant material which is intended to be introduced by injection into the human body and which is supposed to remain in place after the procedure

3.7
harm
physical injury or damage to the health of people, or damage to property or environment

[ISO/IEC Guide 51:1999, definition 3.1]

3.8
hazard
potential source of harm

[ISO/IEC Guide 51:1999, definition 3.5]

3.10
migration
active or passive transport of the implant material from the intended place of administration

3.11
permanent injectable implants
injectable implants which are not intended to be totally degraded or resorbed

NOTE There are injectable implants composed of both temporary and permanent materials.

3.12
resorption
elimination and excretion of an injectable implant by the body

3.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51:1999, definition 3.2]

3.14
temporary injectable implants
injectable implants which are intended to be totally degraded or resorbed

NOTE There are injectable implants composed of both temporary and permanent materials.

4 Characteristics of injectable implants

4.1 General

General requirements for non-active surgical implants are given in EN ISO 14630.

Requirements for the biocompatibility of injectable implants are given in the EN ISO 10993 series of standards. Requirements for the risk management of injectable implants are given in EN ISO 14971.

All injectable implants shall be used in accordance with the instructions for use.

Once the implant is in place it is usually difficult to retrieve the implant completely.

4.2 Lifetime

4.2.1 General

The lifetime of injectable implants can vary depending on the type of material used and/or on the site of injection.

The manufacturer shall provide information, if applicable, on the expected duration of performance of the device as intended, preferably expressed as percentage of implant survivorship in accordance with the Kaplan Meier method or other appropriate statistical methods. Such relevant information includes the indication of factors which could have a significant influence on the actual lifetime of an individual implant.

4.2.2 Temporary injectable implants

Tables A.1 and A.2 give an overview of examples of temporary injectable implants, their possible indications for use and their related possible hazards. In Table 1 the animal derived materials are listed, in Table 2 the non-animal derived materials are listed.

NOTE The tables listed in Annex A are not intended to be complete.

4.2.3 Permanent injectable implants

Table A.3 gives an overview of examples of permanent injectable implants for non-animal derived materials, their possible indications for use and their related possible hazards.

NOTE 1 Animal derived materials intended as permanent injectable implants do not yet exist

NOTE 2 The tables listed in Annex A are not intended to be complete.

4.2.4 Injectable implants composed of both temporary and permanent materials

Table A.4 gives an overview of examples of injectable implants composes of both temporary and permanent materials, their possible indications for use and their related possible hazards.

NOTE The tables listed in Annex A are not intended to be complete.

4.3 Clinical Compatibility

The requirements of clause 7.3 of EN ISO 14630:1997 apply.

In case of clinical investigation the requirements of EN ISO 14155-1 and EN ISO 14155-2 shall apply.

The criteria for acceptance (i.e. safety and effectiveness) of clinical evaluation shall be clearly identified in order to allow a risk/benefit assessment and to provide evidence of the safety and the performance of the implant.

The main questions regarding the clinical compatibility of dermal and soft-tissue implants are:

— rates of infection;

— rate of granulomatous skin reactions;

— rate of any other adverse device effect.

The purpose of the clinical safety evaluation is to estimate the frequency and rate at which adverse device effects, in particular infections and granulomatous reactions, occur after the application of the injectable implant