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# Dentistry — Minimal dental implant data set for clinical use

*Médecine bucco-dentaire — Informations cliniques minimales requises pour les porteurs d'implants dentaires*

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. www.iso.org/directives

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The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

# Introduction

Dental implant treatment is a widely employed therapeutic procedure using endosseous devices which have a service life of many decades, although the restorations that they stabilize not infrequently require maintenance during this period. Uniquely, for such an extensively utilized technique, procedures are largely dependent upon the availability of pre-manufactured precision components. These are typically device-specific and frequently subject to design changes as manufacturers develop their products. Treatment of a patient who has had a dental implant body or bodies placed in their jaw(s) requires the availability of accurate information concerning the implants and any connecting components and adjunctive devices that have been utilized. This standard describes a minimum data set for meeting this requirement. The data may also have research, forensic and medico-legal benefits.

This minimal data set is intended to facilitate the care of patients who have been treated with dental implants by recording the relevant details of the inserted device(s) and any associated connecting components and adjunctive devices. It does not define the totality of the information that should be collected in connection with any such treatment, which is the responsibility of the relevant clinician(s).

# Dentistry — Minimal dental implant data set for clinical use

## 1 Scope

This International Standard specifies the minimal data set to be recorded for a patient receiving dental implant treatment. This will comprise the locations and types of dental implant bodies, connecting components and adjunctive devices, including grafting materials, placed in a patient's jaw(s).

This information will be recorded by the responsible clinician in the patient's file and should be made available to the patient by the clinician(s) who provided the care.

## 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 1942, *Dentistry — Vocabulary*

ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

## 3 Terms and definitions

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

**3.1**
**data set**
specification of linked data elements that comprise a unique relationship

**3.2**
**dental implant**
device especially designed to be placed surgically within, through or upon the bones of the craniofacial complex, the primary purposes of which are to support a dental prosthesis and to resist its displacement

[SOURCE: ISO 1942:2009, 2.71, modified — terminology has changed.]

**3.3**
**connecting components**
individual parts or components that can be joined to the implant body to provide support for the function of the implant

[SOURCE: ISO 1942:2009, 2.72, modified — term and definition have changed.]

**3.4**
**grafting materials**
material of allogenic, alloplastic, xenographic or autogenic origin which is implanted or transplanted to replace or repair defective or damaged human tissue

## 4 General information

### 4.1 Patient's identification

— patient's name;

— patient's date of birth.

## 4.2 Clinician's identification

— clinician's name;

— clinician's national registration number or license number.

## 4.3 Implant bodies

### 4.3.1 General

For each dental implant body, the dentist shall record:

— manufacturer;

— implant type, material used and dimensions;

— batch code, lot number and/or serial number;

— implantation date in accordance with ISO 8601;

— location of implant placement in accordance with ISO 3950;

— operation protocol (including insertion torque);

— name and national registration number of the clinician responsible for the placement of the implant body, if different from the clinician identified according to 4.2.

### 4.3.2 Pre-manufactured implant bodies

Record the commercial name of each dental implant body, name and address of manufacturer or of the official sales agent for the country in which the component was purchased, manufacturer's unique part number.

### 4.3.3 Patient-specific implant bodies

— information described in 4.3.1 plus modifications that would make the implant body unique;

— include dimensions if known;

— minimum data necessary to fabricate connecting components;

— describe implant body coating at the time of manufacture (if any) and if so, the material and technique used.

## 4.4 Connecting components

### 4.4.1 General

The clinician shall record:

— the name and national registration number of the clinician responsible for the treatment with this implant;

— the placement date of a connecting component;

— location of implant body's placement in accordance with ISO 3950;

— type of connection of the connecting part to prosthesis(e.g. cementation, screw connection);

— the mechanism for linking the connecting component to the implant body and the mechanism for linking the connecting component to a prosthetic suprastructure (e.g. screw fixation, taper fit, cementation);

— details of screw head configuration (e.g. hexagonal, square);

— screw composition (e.g. gold alloy or titanium alloy).

#### 4.4.2 Prefabricated connecting components

— the commercial name of each connecting component, name and address of manufacturer or of the authorized representative for the country in which the component was purchased, manufacturer's unique part number;

— type and all specific dimensions of the implant component;

— lot number and/or serial number.

#### 4.4.3 Patient-specific connecting components

— the name and address of the laboratory/manufacturer or of the authorized representative for the country in which the component was purchased, manufacturer's unique part number;

— unique construction details as prescribed by the clinician.

### 4.5 Adjunctive devices

#### 4.5.1 General

— the name and national registration number of the clinician responsible for the placement of the adjunctive device;

— the name and address of the manufacturer or of the authorized representative for the country in which the adjunctive device was purchased;

— lot number and/or serial number.

— approximate quantity of material;

— the date of placement of the adjunctive device;

— location of the adjunctive device.

#### 4.5.2 Autografts

— source of autograft;

— location of placement;

— date in accordance with ISO 8601.

### 4.6 Suprastructure

#### 4.6.1 General

— connecting parts specifications, if applicable (see 4.4);

— the name and address of the manufacturer/laboratory or of the authorized representative for the country in which the prosthesis was purchased;

— type, dimensions and material used;

— batch code (if available).

### 4.6.2 Dental/oral prosthesis

— manufacturer;

— manufacturing date;

— type and design;

— material(s) used with their lot number or serial number (if available);

— date of placement.

# Bibliography

[1] ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

[2] ISO/TR 13668, *Digital coding of oral health and care*

[3] ISO 16059, *Dentistry — Required elements for codification used in data exchange*

[4] ISO/TR 15599, *Digital codification of dental laboratory procedures*

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