BS EN ISO 16061:2015

BSI Standards Publication

Instrumentation for use in association with non-active surgical implants — General requirements

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National foreword

This British Standard is the UK implementation of EN ISO 16061:2015. It supersedes BS EN ISO 16061:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150, Implants for surgery.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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EUROPEAN STANDARD

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English Version

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2015)

Instrumentation à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2015)

Instrumente die in Verbindung mit nichtaktiven chirurgischen Implantaten verwendet werden - Allgemeine Anforderungen (ISO 16061:2015)

This European Standard was approved by CEN on 12 March 2015.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 16061:2015) has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by November 2015, and conflicting national standards shall be withdrawn at the latest by November 2015.

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

This document supersedes EN ISO 16061:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16061:2015 has been approved by CEN as EN ISO 16061:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
7.3	6a	
6	7.1, 1. indent	
6	7.1, 2. indent	
10.1	7.2	In respect of packaging only
6	7.3	
5 i)	7.5	
5 i)	7.6	
5 b) and 6	8.1	
10.2	8.3	In respect of packaging only
9.1	8.4	
5 b)	8.5	
10.1	8.6	
9.1, 9.2, 10.2 and 11.3 i)	8.7	
11.3 f) and 11.5	9.1	
5 f) and 7.1	9.2, 1. indent	
7.1	9.2, 2. indent	
11.2	10.1	
11.1, 11.4 and 11.5	13.1	
11.1	13.2	
11.2 b)	13.3 (a)	The part of ER 13.3 (a) concerning the information on the manufacturer's authorized representative in the European Community is not addressed in this European Standard
11.2 c)	13.3 (b)	

11.2 e)	13.3 (c)	This European Standard is not applicable to power-driven systems, so ER 13.3 (l) is not applicable.
11.2 c)	13.3 (d)	
11.2 g) and 11.1	13.3 (e)	
11.2 h) 11.7	13.3 (f)	ER: 13.3 (f) is only partially addressed in this European Standard. The safety issue is addressed, but not the regulatory requirement that the manufacturer's indication of single use must be consistent across the European community.
11.2 i)	13.3 (i)	
11.2 j)	13.3 (j)	
11.2 e)	13.3 (m)	
11.2 d) and 11.3 d)	13.4	
113 b), 11.3 c), 11.3 h), 11.3 k), 13.3 n)	13.6 (a)	The part of ER 13.6 (a) concerning the information on the manufacturer's authorized representative in the European Community is not addressed in this European Standard. The part of ER 13.6 (a) concerning the regulatory requirement that the manufacturer's indication of single use must be consistent across the European community is not addressed in this European Standard.
11.3 e)	13.6 (b)	
11.3 f)	13.6 (c)	
11.3 g)	13.6 (d)	
13.3 j)	13.6 (g)	
11.3 k)	13.6 (h)	
11.3 m)	13.6 (i)	
11.3 a)	13.6 (j)	
11.3 k)	13.6 (k)	
11.3 o)	13.6 (l)	
11.3 r)	13.6 (m)	
11.3 q)	13.6 (n)	
11.3 r)	13.6(o)	
11.4	13.6 (p)	
11.3 s)	13.6 (q)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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 150, *Implants for surgery*.

This third edition cancels and replaces the second edition (ISO 16061:2008), which has been technically revised.

INTERNATIONAL STANDARD **ISO 16061:2015(E)**

Instrumentation for use in association with non-active surgical implants — General requirements

1 Scope

This International Standard specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment.

This International Standard also applies to instruments which may be connected to power-driven systems, but does not apply to the power-driven systems themselves.

With regard to safety, this International Standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the manufacturer.

This International Standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants, and ophthalmic implants.

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 80000-1, *Quantities and units — Part 1: General*

3 Terms and definitions

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

3.1
associated implant
specific non-active surgical implant in association with which a specific surgical instrument is intended to be used during a surgical procedure

3.2
instrument
non-active medical device intended for use during surgical procedures related to a specific non-active surgical implant

3.3
resupplied instrument
instrument or set of instruments that has been returned to the manufacturer and has been re-issued

4 Intended performance

The intended performance of an instrument shall be described and documented by addressing the following, with particular regard to safety:

a) functional characteristics; and

b) intended conditions of use.

Account should be taken of:

— published standards;

— published clinical and scientific literature;

— validated test results.

The extent to which the intended performance of an instrument has been achieved shall be determined (see Clause 7).

5 Design attributes

The development of the design attributes of an instrument to meet the performance intended by the manufacturer shall take into account at least the following:

a) physical, mechanical, and chemical properties of the instrument materials (see Clauses 6 and 7);

b) microbiological and particulate contamination levels (see Clauses 7, 9, and 10);

c) ease of use, cleaning, and maintenance (see Clause 7);

d) potential deterioration of the material characteristics due to sterilization and storage (see Clauses 6, 7, and 8);

e) effects of contact between the instrument and body, the implant, and other instruments (see Clause 7);

f) shape and dimensions of the instrument, including their possible effects on the body (see Clause 7);

g) wear characteristics of materials and the effect of wear and wear products on the instrument and the body (see Clauses 6 and 7);

h) insertion, removal, and interconnection of parts (see Clause 7);

i) extent of fluid leakage and/or diffusion of substances into or out of instruments (see Clauses 6 and 7);

j) accuracy and stability of instruments with a measuring function (see Clauses 7 and 8);

k) ability of the instrument or fragment of instrument to be located by means of an external imaging device (see 11.3 p); and

l) compatibility with any medicinal substances incorporated into or used with the instrument.

6 Selection of materials

Materials for the manufacture of instruments shall be selected with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization, and storage, as well as any treatment (chemical, electro-chemical, thermal, mechanical, etc.) applied to the surface or a part of the surface of the instrument in order to modify its properties. Possible reactions of instrument materials with human tissues and body fluids shall be considered (see Clause 7).

The suitability of a given material for a particular application shall be demonstrated by either

a) documented assessment in accordance with ISO 10993-1, or

b) selection from the materials found suitable by proven clinical use in similar applications.

NOTE Annex A lists some of the materials that have been found acceptable in certain applications.

7 Design evaluation

7.1 General

Instruments shall be evaluated in association with the implant they are designed for, in order to demonstrate that the intended performance is achieved (see Clause 4). Safety shall be demonstrated by pre-clinical evaluation and by carrying out a risk analysis in accordance with ISO 14971.

7.2 Pre-clinical evaluation

If pre-clinical testing of instruments is required, the testing shall simulate conditions of intended use.

7.3 Clinical evaluation

If a clinical evaluation is required, it shall be based on the following:

a) critical evaluation of the relevant scientific and clinical literature relating to the safety, performance, design characteristics, and intended use of the instrument or demonstrably similar instruments; or

b) critical evaluation of the results of all clinical investigations conducted using the associated implant under the intended conditions of use; or

c) combination of the clinical data provided in a) and b) above.

Where a clinical investigation is carried out, it shall be managed in accordance with ISO 14155.

8 Manufacture

Instruments shall be manufactured to specifications in accordance with the required design attributes (see Clause 5).

9 Sterilization

9.1 Products supplied sterile

For terminally sterilized instruments to be designated “STERILE”, the theoretical probability of there being a viable microorganism present on or in the instrument shall be equal to or less than 1×10^{-6}.

Manufacturers may use other sterility assurance levels, provided that this is justified by a documented risk assessment.

If instruments are to be sterilized by ethylene oxide, it shall be done according to ISO 11135.

If instruments are to be sterilized by irradiation, it shall be done according to ISO 11137-1, ISO 11137-2, and ISO 11137-3.

If instruments are to be sterilized by moist heat, it shall be done according to ISO 17665-1.

9.2 Products provided non-sterile

For instruments that are supplied non-sterile, the manufacturer shall specify at least one appropriate sterilization method such that the functional safety of the product is not adversely affected. If multiple sterilizations are not allowed, this shall be stated.

For instruments that are supplied non-sterile or claimed to be resterilizable, the manufacturer shall provide information on the processing of these instruments in accordance with ISO 17664.

10 Packaging

10.1 Protection from damage in storage and transport

For each instrument, the packaging shall be designed so that, under conditions specified by the manufacturer for storage, transport, and handling (including control of temperature, humidity, and ambient pressure, if applicable), the instrument is protected against damage and deterioration and the packaging does not adversely affect the intended performance of the instrument.

NOTE Possible test methods are specified in IEC 60068–2-27, IEC 60068–2-31, and/or IEC 60068–2-47.

10.2 Maintenance of sterility in transit

Instruments labelled “STERILE” shall be packaged such that they remain sterile under normal storage, transport, and handling conditions, unless the protective package is damaged or opened.

The packaging shall comply with ISO 11607-1 and ISO 11607-2.

11 Information supplied by the manufacturer

11.1 General

Information supplied by the manufacturer and intended for direct visual recognition shall be legible when viewed under illumination of 215 lx using normal vision, corrected if necessary, at a distance that takes into account the form and size of the individual instrument.

If there is insufficient space on each instrument’s individual packaging, the relevant information may be given on an insert, accompanying document, or on the next layer of packaging, as applicable.

The recognition of certain markings on small or specialized instruments might require the use of methods other than visual, e.g. electronic methods.

When appropriate, symbols, abbreviations, and identification colour may be used in the markings and accompanying documents of an instrument. Any symbols, abbreviations, and identification colours used shall conform to published International Standards (e.g. ISO 15223-1). Where no such standards exist, the manufacturer shall describe the symbols, abbreviations, or identification colours used in the documentation supplied with the instrument.

The information supplied by the manufacturer shall not be presented in such a manner that it can be confused with other essential information and shall be understandable by the intended user and/or other persons, where appropriate.

Any units of measurement shall be expressed in SI units complying with ISO 80000-1. Equivalent units may be stated in parentheses.

As far as practicable and appropriate, the information needed to use the instrument safely shall be set out on the instrument itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information shall be set out in the leaflet supplied with each instrument or package.

When applicable, instruments with user adjustable controls shall have their function clearly specified.

Any detachable components, intended by the manufacturer to be used separately from the original instrument, shall be identified by their batch code or by other appropriate means.

Any date shall be expressed in the format YYYY-MM-DD, or YYYY-MM, or YYYY, in accordance with ISO 8601.

11.2 Labelling

The label shall bear the following information:

a) if the packaging contains any radioactive substance, it shall have markings that state the type and activity of the radioactive substance;

b) name and address of the manufacturer, including at least the city and the country;

c) description of the instrument, the model designation of the instrument, and, if applicable, the batch number or the serial number of the instrument preceded by an appropriate identification;

EXAMPLE “LOT”, “SN”, or the lot, or serial number symbols ISO 7000-2492 and ISO 7000-2498, respectively. See ISO 15223-1:2012, 5.14 and 5.16.

d) if the intended purpose of the instrument is not obvious to the user, a clear statement of the intended purpose;

e) if the instrument is terminally-sterilized, an indication that the contents of the package are sterile and the method of sterilization (see 9.1);

EXAMPLE The word “STERILE” or the sterile symbol ISO 7000-2499, or one of the “sterilized using…” symbols ISO 7000-2500, ISO 7000-2501, ISO 7000-2502, or ISO 7000-2503. See ISO 15223-1:2012, 5.20 or 5.21, 5.22, 5.23, and 5.24.

f) if identical or similar instruments are sold in both sterile and non-sterile condition, a clear indication that the contents of the particular package are non-sterile, when applicable;

EXAMPLE The “non-sterile” symbol ISO 7000-2609. See ISO 15223-1:2012, 5.26.

g) if applicable, the “use by date”, expressed as year and month;

EXAMPLE The “use by date” symbol ISO 7000-2607. See ISO 15223-1:2012, 5.12

h) if the instrument is intended for single use, an appropriate indication;

EXAMPLE The “do not re-use” symbol ISO 7000-1051. See ISO 15223-1:2012, 5.2.

i) any special storage and/or handling conditions;

j) any special operating instructions;

k) any warnings or precautions relating to use.

11.3 Instructions for use

If applicable, the instructions for use shall contain the following information:

a) if the packaging contains any radioactive substance, the type and activity of the radioactive substance;

b) name and address of the manufacturer, including at least the city, and the country, and a telephone number;

c) description of the instrument and the model designation of the instrument;

d) if the intended purpose of the instrument is not obvious to the user, a clear statement of the intended purpose;

e) the intended performance described in Clause 4 and, if appropriate, any undesirable side-effects;

f) information allowing the user to select a suitable instrument (including a correct size), its accessories, and related devices, in order to obtain a safe combination;

g) if applicable, any information needed to verify that the instrument is functioning correctly and safely;

h) if the instrument is terminally-sterilized, an indication that the contents of the package are sterile and the method of sterilization used;

EXAMPLE The word "STERILE" or the sterile symbol ISO 7000-2499, or one of the "sterilized using…" symbols ISO 7000-2500, ISO 7000-2501, ISO 7000-2502, or ISO 7000-2503. See ISO 15223-1:2012, 5.20 or 5.21, 5.22, 5.23, and 5.24.

i) if identical or similar instruments are sold in both sterile and non-sterile condition, an instruction, when applicable, that the contents shall be sterilized;

j) instructions on the method of sterilization with its appropriate cycle parameters for an instrument that is delivered non-sterile, or for dealing with the contents of a sterile package that has been damaged or has been previously opened, and maximum number of re-sterilization cycles that may be performed;

k) if the instrument is intended to be reused, instructions on appropriate processing before reuse including cleaning, disinfection packaging, and, where appropriate, the method(s) of sterilization with its appropriate cycle parameters, and any restriction on the number of reuses;

l) if the instrument is intended for single use, an appropriate indication;

EXAMPLE The "do not re-use" symbol ISO 7000-1051. See ISO 15223-1:2012, 5.2.

m) details of any treatment or handling needed before the instrument can be used;

EXAMPLE Final assembly, cleaning, sterilization, etc.

n) any special storage and/or handling conditions;

o) warnings or precautions relating to use, including limitations on chemicals (e.g. alcohol) or other environmental conditions to which the instrument might reasonably be exposed in the clinical setting;

p) if appropriate, an indication of whether the instrument or any fragment, thereof, can be located by means of an external imaging device, and with what kind of such device;

q) instructions for the proper disposal of the instrument, if there are special or unusual risks;

r) if applicable, information on any medicinal products incorporated into or used with the instrument (see Clause 5).

s) date of issue or the latest revision of the instructions for use, if applicable.

11.4 Instruments with measuring function

The limits of accuracy of instruments having a measuring function shall be indicated by a marking on the instrument and/or label, and in the instructions for use.

This requirement does not apply to gauges used for component size selection and GO/NO GO determination.

11.5 Restrictions in combinations

If the instrument is intended to be used in combination with other instruments, devices, or equipment, restrictions in the use of the combination shall be indicated on the label or in the instruction for use.

11.6 Marking on instruments

Instruments shall be marked with the following:

— manufacturer's name or trademark;

— batch code or serial number, where appropriate;

— catalogue/article number, where appropriate, and/or size indication, if needed for safe selection or use.

If the marking would affect the intended performance or the instrument is too small to be legibly marked, the information required shall be given on the label.

11.7 Instruments intended for single use

If the instrument bears an indication that it is for single use only, the instructions for use shall contain information on known characteristics and technical factors known to the manufacturer that could pose a risk if the instrument was to be re-used.

Annex A
(informative)

Examples of typical instrument applications, together with materials found acceptable for instrument manufacture

A.1 Invasive applications

A.1.1 Instruments with cutting edges

— scissors;

— needles;

— knives;

— cannulae;

— chisels;

— drill bits;

— gouges;

— broaches;

— curettes;

— sawblades;

— burrs;

— reamers;

— trepans.

A.1.2 Instruments used as guides

— cannulae;

— saw guides;

— drill guides;

— aiming devices.

A.1.3 Instruments having implant contact

— punches;

— extractors;

— introducers;

— impactors;

— pullers;

— trial implants;

— drive connections.

A.1.4 Instruments having passive contact

— retractors;

— location guides;

— spreaders;

— sizers;

— forceps;

— measuring devices;

— holders;

— trial implants;

— location pins.

A.1.5 Miscellaneous

— vents;

— brushes;

— restrictors.

A.2 Non-invasive applications

— external alignment guides;

— handles.

A.3 Materials for invasive applications

A.3.1 Instruments with cutting edges

A.3.1.1 Stainless steels

See Tables A.1, A.2, A.3, and A.4.

See ISO 5832-1 and ISO 5832-9.

A.3.1.2 Cobalt/chromium alloys

See ISO 5832-4, ISO 5832-5, ISO 5832-6, ISO 5832-7, ISO 5832-8, and ISO 5832-12.

A.3.1.3 Non-metallic

— silicon carbide;

— tungsten carbide.

A.3.1.4 Coatings

— titanium nitride;

— titanium carbide;

— silicon carbide.

A.3.2 Instruments used as guides

A.3.2.1 Stainless steels

See A.3.1.1.

A.3.2.2 Cobalt/chromium alloys

See A.3.1.2.

A.3.2.3 Titanium/titanium alloys

See ISO 5832-2, ISO 5832-3, and ISO 5832-11

A.3.3 Instruments having implant contact

A.3.3.1 Stainless steels

See A.3.1.1.

A.3.3.2 Cobalt/chromium alloys

See A.3.1.2.

A.3.3.3 Titanium/titanium alloys

See A.3.2.3.

A.3.3.4 Polymers

— polyacetal [Delrin, Celcon[1)]];

— polyetheramide [Ultem[1)]];

— oxide resins;

— polycarbonate (see NOTE 1);

— polyester resins;

— polysulfone (see NOTE 1);

— silicone rubbers;

— polyethylene (see NOTE 2);

— polyurethane;

— polypropylene;

— polyamides (e.g. nylon);

1) Delrin, Celcon and Ultem are examples of suitable products available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of these products.

— polyaryletherketone (PAEK);

— cotton-reinforced phenolformaldehyde [Canvesit[2)]].

NOTE 1 These polymers can exhibit cracking if exposed to lipids.

NOTE 2 Some methods of resterilization of polyethylene can affect mechanical properties and dimensional stability.

A.3.4 Instruments having passive tissue contact

A.3.4.1 Stainless steels

See A.3.1.1.

A.3.4.2 Cobalt/chromium alloys

See A.3.1.2.

A.3.4.3 Titanium/titanium alloys

See A.3.2.3.

A.3.4.4 Aluminium alloys

All aluminium components should be anodized.

A.3.4.5 Polymers

See A.3.3.4.

A.3.5 Miscellaneous

A.3.5.1 Vents

— plasticized PVC.

A.3.5.2 Brushes

— polyamide (e.g. nylon).

A.3.5.3 Restrictors

— polyethylene (see NOTE 2 under A.3.3.4);

— polypropylene;

— polyurethanes.

A.4 Materials for non-invasive applications

A.4.1 Stainless steels

See A.3.1.1.

2) Canvesit is an example of a suitable product available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of these products.

A.4.2 Cobalt/chromium alloys

See A.3.1.2.

A.4.3 Titanium/titanium alloys

See A.3.2.3.

A.4.4 Aluminium alloys

See A.3.4.4.

A.4.5 Polymers

See A.3.3.4.

Table A.1 — Austenitic stainless steels

Steel grade in accordance with:			Chemical composition %							
ISO 7153-1 ref. letter	ISO 4957	AISI	**C** max.	**Si** max.	**Mn** max.	**P** max.	**S**	**Cr**	**Mo**	**Ni**
M	—	304	0,07	1	2	0,045	0,03 max.	17 to 19	—	8 to 11
N	—	303	0,12	1	2	0,060	0,15 to 0,35	17 to 19	0,7	8 to 10
O	—	—	0,15	1	2	0,045	0,03 max.	16 to 18	—	6 to 8
P	—	316	0,07	1	2	0,045	0,03 max.	16,5 to 18,5	2 to 2,5	10,5 to 13,5
—	—	316L	0,03	1	2	0,045	0,03 max	16,5 to 18,5	2,50 to 3,0	10,50 to 13,0

Table A.2 — Martensitic stainless steels

Steel grade in accordance with:			Chemical composition %								
ISO 7153-1 ref. letter	ISO 4957	AISI	**C**	**Si** max.	**Mn** max.	**P** max.	**S**	**Cr**	**Mo**	**Ni**	**Other elements**
A	—	410	0,09 to 0,15	1	1	0,04	0,030 max.	11,5 to 13,5	—	1 max.	—
B	27	420 A	0,16 to 0,25	1	1	0,04	0,030 max.	12 to 14	—	1 max.	—
C	28	420 B	0,26 to 0,35	1	1	0,04	0,030 max.	12 to 14	—	1 max.	—
D	—	420 C	0,42 to 0,50	1	1	0,04	0,030 max.	12,5 to 14,5	—	1 max.	—
E	—	—	0,47 to 0,57	0,5	1	0,030	0,030 max.	13,7 to 15,2	—	0,5 max.	—
F	—	—	0,60 to 0,70	0,5	1	0,030	0,030 max.	12 to 13,5	—	0,5 max.	—
G	—	—	0,65 to 0,75	1	1	0,04	0,030 max.	12 to 14	0,5 max.	1 max.	—
H	—	—	0,35 to 0,40	1	1	0,045	0,030 max.	14 to 15	0,4 to 0,6	—	V 0,1 to 0,15
I	—	—	0,42 to 0,55	1	1	0,045	0,030 max.	12 to 15	0,45 to 0,90	—	V 0,1 to 0,15
K	30	—	0,33 to 0,43	1	1	0,03	0,030 max.	15 to 17	1,0 to 1,5	1 max.	—
—	—	431	0,20 max.	1	1	0,04	0,030 max.	15 to 17	—	1,0 to 1,5	—
R	—	440 B	0,85 to 0,95	1	1	0,045	0,030 max.	17 to 19	0,9 to 1,3	—	V 0,07 to 0,12
—	—	440 A	0,60 to 0,75	1	1	0,040	0,030 max.	16 to 18	0,75 max.	—	—
—	—	440 F	0,95 to 1,20	1	1,25	0,06	0,15 to 0,27	16 to 18	—	0,5 max.	Cu 0,6 max.
—	—	—	0,33 to 0,43	1	1	0,03	0,030 max.	12,5 to 14,5	0,8 to 1,2	1 max.	—
—	—	420 Mod	0,35 to 0,50	1	1	0,04	0,015 max	14,0 to 16,0	1,0 to 2,5	0,5 max	V: 1,5 max N : 0,10 to 0,30

Table A.3 — Precipitation-hardening stainless steels

Steel grade in accordance with:			Chemical composition %										
ISO 7153-1 ref. letter	ISO 4957	AISI	**C** max.	**Si** max.	**Mn** max.	**P** max.	**S** max.	**Cr**	**Mo**	**Ni**	**Cu**	**Nb + Ta**	**Other elements**
—	—	—	0,030	0,7	1	0,03	0,015	11 to 13	3 to 5	8 to 10	1,5 to 3,5	—	Al 0,15 to 0,50 Ti 0,5 to 1,2
—	—	630	0,07	1	1	0,04	0,03	15 to 17	—	3 to 5	3 to 5	0,15 to 0,45	—
—	—	631	0,09	1	1	0,04	0,03	16 to 18	—	6,5 to 7,75	—	—	Al 0,75 to 1,50
—	—	XM16	0,03	0,5	0,5	0,02	0,015	11,0 to 12,5	0,5 max	7,5 to 9,5	1,5 to 2,5	0,10 to 0,5	Ti 0,9 to 1,4
—	—	New grade	0,02	0,25	0,25	0,015	0,010	11,0 to 12,5	1,7 to 2,3	10,2 to 11,3	—	—	Al 1,3 to 2,3 Ti 0,2 to 0,5

Table A.4 — Ferritic stainless steel

Steel grade in accordance with:			Chemical composition %							
ISO 7153-1 ref. letter	ISO 4957	AISI	**C** max.	**Si** max.	**Mn** max.	**P** max.	**S**	**Cr**	**Mo** max.	**Ni** max.
L	—	430 F	0,08	1	1,5	0,06	0,15 to 0,35	16 to 18	0,6	1

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