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COLLEGIATE BOARD RESOLUTION - RDC No. 594, OF DECEMBER 28, 2021
(Rectified in DOU No. 246, of December 30, 2021)

It provides for the requirements for the grouping of implantable materials in orthopedics for registration purposes and provides other measures.

The Collegiate Board of the National Health Surveillance Agency, in the use of the attribution conferred on it by art. 15, III and IV, allied to art. 7, III, and IV, of Law No. 9,782, of January 26, 1999, and to art. 187, VI, §§ 1 and 3 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution of the Board of Executive Officers, as resolved at a meeting held on December 21, 2021, and I, the Chief Executive Officer, Substitute, determine its publication.

CHAPTER I
OF THE INITIAL PROVISIONS

Section I
Purpose and Scope

Art. 1 This Resolution defines the requirements for grouping implantable materials in orthopedics for registration purposes.

Single paragraph. Excluded from this Resolution are tailor-made medical devices emulated by Collegiate Board Resolution - RDC No. 305, of September 24, 2019.

Art. 2 This Resolution is applicable when requesting the registration of implantable arterials in orthopedics, its changes, and revalidations in accordance with the requirements set forth in the Collegiate Board Resolution - RDC No. 185, of October 22, 2001 or regulation that may replace it.

Section II
Definitions

Art. 3 For the purposes of this Resolution, the following definitions shall be considered:

I - accessory of implantable material in orthopedics: implantable component, complementary and exclusive use to a product, which may or may not be used during the implantation procedure;

II. - ancillary component: implantable component not object of the registry that necessarily must be implanted with the implantable material in orthopedics, and must be regularized in process separately;

III. - set: form of presentation of implantable materials in orthopedics with exclusive and single-use non-implantable materials, from the same manufacturer or manufacturing group, presented for consumption in the same packaging, and must be included in the risk class of the most critical product or component in terms of intrinsic risk;

IV. - Implant Constitution: refers to the manufacturing material of the implant components, being monocomponent those composed of manufacturing material of the same nature, and conjugated those composed of two or more materials of distinct and compatible natures;

V. - non-conventional endoprostheses: they are those with special characteristics due to the anatomical particularities of the patients and lesions associated with the implantation site, in

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addition to their application in specific cases, since they are usually used for substitutions where there is no anatomical standard for their placement;

VI. - Traceability label: complementary document to be provided with the permanent implant in the form of adhesive labels, containing the following information in Portuguese:

a) the trade name of the product and its respective code, in the case of a single product, or the name of the commercial model of the component and its respective code;

b) identification of the manufacturer's business name, and in the case of imported products the importer's business name;

c) lot number; and

d) registration number at ANVISA.

I - Legal Manufacturer: legal entity, public or private, with responsibility for the design, manufacture, packaging and labeling of a product, with the intention of making it available for use under its name, these operations being carried out by the company itself or by third parties on its behalf;

II - family of orthopedic implants: grouping of similar products, from the same manufacturer or manufacturing group, structured according to the criteria established in this regulation;

1. - form of presentation: all the ways in which implantable materials in orthopedics are presented for consumption, including a description of the form of packaging, the packaging specifications and the quantity of each product or accessory in the packaging;

III - form of fixation: refers to the way in which the implant is fixed to the body (being cemented or not cemented for joint replacement implants) or the way in which the components of a system attach to each other (being blocked or not blocked for implants for bone synthesis);

IV - Functionality: refers to the characteristic of the implantable material in orthopedics indicated for use in articulation of the skeletal system and is related to the level of maintenance of the degrees of joint freedom (total or partial loss or absence of loss of joint movement) in the different anatomical planes through intrinsic mechanisms;

V - degree of freedom: whether or not there is movement between surfaces of components of a system;

VI - permanent implant: implantable product intended for the definitive replacement of part or function of the normal structures of the body, such as implants for arthroplasty and spine, having no indication of withdrawal due to the function it performs;

VII - Implantable material in orthopedics: implantable medical device indicated for use in orthopedics, for the purpose of treating or correcting deformities, diseases or injuries of the skeletal system, its joints or associated structures;

VIII - Commercial model: implantable material in orthopedics that is part of a family;

IX - modularity: the ability of a system to accept combinations of components of different sizes, provided that there are functional and raw material compatibilities;

X - Nature of the material: refers to the classification of the manufacturing material into metallic, polymeric and ceramic, being absorbable or non-absorbable;

XI - Single composite product: product consisting of two or more elements with a single purpose, which maintains a relationship of interdependence to obtain the functionality and performance for which it is intended, non-interchangeable, supplied in the same package, and may suffer only dimensional variation;

XII - Fixation stiffness: refers to the resistance of the implant to the movement between the components or with the region of the human body that will be fixed, due to the presence of design elements;

XIII - System of implantable materials in orthopedics: grouping of implantable components, from the same manufacturer or manufacturing group, complementary and compatible with each other, and characterized according to criteria for specific structuring;

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XIV - Manufacturing unit: place where the manufacture of one or more manufacturing steps occurs, which may be the legal manufacturer itself, contracted manufacturer or original manufacturer of product.

CHAPTER II
OF THE GUIDELINES

Section I
Guidelines for grouping

Art. 4 For the purposes of this Resolution, implantable materials in orthopedics may be grouped as a family or system, and must be included in the risk class of the most critical product or component in terms of intrinsic risk.

§ 1 - Families and systems must consist of products, components and accessories from the same legal manufacturer or manufacturing group.

§ 2 - The concept of family is applicable to single composite products, but not extendable to systems.

§ 3 - The independent registration of accessories is not allowed, and must be regularized in the registration of the product to which they confer complementary characteristic.

§ 4 - The grouping of systems is defined according to the various structuring criteria applicable to each component established in this regulation.

§ 5 In the case of incomplete system will be allowed the indication of ancillary component (s), regularized in different processes, and must include in the instructions for use, or document attached to it, information on the dimensional and material compatibility between the implants of the registry and their ancillaries.

§ 6 - The risk classification of the family or system must be the risk classification in which the most critical product or component of the respective registration process fits.

Art. 5 The dimensional variations of a family are considered commercial models.

Art. 6 The dimensional variation of the components of a system does not characterize the family.

Art. 7 The joint presentation of implantable materials in orthopedics with instruments is only allowed as long as they are exclusive and single-use.

Art. 8 The implantable materials in orthopedics, when presented for commercialization, already connected to the exclusive and single-use instruments, are considered as a single composite product.

Section II
Guidelines for packaging, labeling and instructions for use

Art. 9 All elements of a single composite product must necessarily be used, not interchangeable and supplied in a single package.

Art. 10. The consumable packaging of the assembly must include all the components.

§ 1 - It is not allowed to vary the commercial presentation of the set with the exclusion or addition of one or more components.

§ 2 - For replacement purposes, the materials of the set may be marketed in consumer packaging separately, provided that they are for exclusive use in this one.

§ 3 - The label and instructions for use of the replacement component of the assembly must include the commercial name of the assembly and the name of the replacement component, as informed in the registration process.

Art. 11. The instructions for use of ancillary components registered as a family or system should include dimensional and material compatibility tables.

Single paragraph. The compatibility between implantable materials in orthopedics is related, among other characteristics, to the appropriate combination of dimensions and manufacturing materials.

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Art. 12. Permanent implants must contain at least 3 (three) traceability labels with information in Portuguese for mandatory fixation: in the medical record, in the document to be delivered to the patient, and in the tax documentation that generates the charge.

Art. 13. The instructions for use of permanent implants should include a recommendation to affix a traceability label to the patient's medical record and to provide one of the other labels to the patient.

Section III
Guidelines for proving safety and efficacy

Art. 14. The proof of the safety and efficacy of the products contemplated in this regulation must meet the requirements of the Collegiate Board Resolution - RDC No. 546, of August 30, 2021, or regulation that replaces it, as well as compliance with applicable technical standards defined in the Risk Management of the products.

CHAPTER III
OF THE CRITERIA FOR GROUPING INTO A SYSTEM OR FAMILY

Art. 15. For the grouping of implantable materials in orthopedics in a system or family, the following criteria should be considered:

I - nature of the material;
II - constitution;
III- form of fixation;
IV- functionality;
V- intracomponent degree of freedom;
VI - Scope of implementation;
VII- level of interference in the epiphysis; and
VIII- association or not with pharmacological agent.

Single paragraph. Implantable materials in orthopedics that have types of coating of materials of different natures should be regularized in family records or different system.

Art. 16. In addition to compliance with the criteria established in article 15, the specific criteria of each type of implantable material in orthopedics must be observed for the purpose of grouping into a system or family.

Art. 17. The grouping of orthopedic implants for hip joint replacement, in system or family, should consider the criteria:

I- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II- constitution (monocomponent or conjugate);
III- modularity (head/rod/core or capsule/acetabular);
IV - form of fixation (cemented or uncemented);
V- functionality (compensation for the loss or not of extrinsic stabilization of the joint);
VI- intracomponent degree of freedom [centrality of the joint (monopolar or bipolar)];
VII- scope of implantation including or not acetabular arthroplasty (partial or total); and
VIII- level of interference in the epiphysis (integral or surface).

Single paragraph. Systems consisting of modulated rod components should be grouped into separate registers of non-modulated rods.

Art. 18. The grouping of orthopedic implants for knee joint replacement, in system or family, should consider the criteria:

I- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II- constitution (monocomponent or conjugate));
III - form of fixation (cemented or uncemented);

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IV- functionality (restricted or partially restricted or unrestricted);
V- scope of implementation (partial or total);
VI- Degree of freedom (fixed or mobile) - tibial platform; and
VII- Degree of compartmentalization of the system (unicompartmental or multicompartmental).

Art. 19. The grouping of orthopedic implants for ankle joint replacement, that is, the tibia-talus and fibulomaleolar interface, in system or family, should consider the criteria:
I- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II- constitution (monocomponent or conjugate); and III - form of fixation (cemented or uncemented)).

Art. 20. The grouping of orthopedic implants for shoulder joint replacement, in system or family, should consider the criteria:
I- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II- constitution (glenoid component: monocomponent or conjugate);
III- form of fixation (cemented or uncemented));
IV- modularity (modular or non-modular);
V- functionality (partial or unrestricted);
VI- degree of intracomponent freedom (centrality of joint: monopolar or bipolar);
VII- Scope of deployment (partial or total);
VIII- level of interference in the epiphysis (integral or surface); and
IX- structure of joint containment (contained directly or contained inverted or not contained).

Art. 21. The grouping of orthopedic implants for elbow joint replacement, in system or family, should consider the criteria:
I- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II- constitution (monocomponent or conjugate));
III - form of fixation (cemented or not cemented;);
IV - modularity (modular or non-modular);
V- functionality (restricted or partial or unrestricted);
VI- degree of intracomponent freedom (centrality of the radiohumeral joint: monopolar or bipolar);
VII- scope of implementation (partial or total); and
VIII- level of interference in the epiphysis (integral or surface).

Art. 22. The grouping of orthopedic implants for wrist joint replacement, in system or family, should consider the criteria:
I- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II- constitution (monocomponent or conjugate));
III - modularity (modular or non-modular);
IV- form of fixation (cemented or uncemented); and
V- degree of compartmentalization of the system [unicompartmental (radio-carpic) or muticompartmental (radio-carpal and distal radio-ulnar])].

Art. 23. The grouping of orthopedic implants for temporomandibular joint replacement, in system or family, should consider:
I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;
II.- constitution of the implant (monocomponent or conjugate); III - form of fixation (cemented or not cemented);
III.- modularity (condylar component);
IV.- rigidity as to the form of fixation (locked fixation or non-locked fixation); and

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V.- Scope of implementation (partial or total)).

Art. 24. The grouping of orthopedic implants in non-conventional stent systems should consider:

I - functionality (monoarticulated or biarticulated or non-articulated); and

II - anatomical indication (lower limbs or upper limbs).

Art. 25. The grouping into a system or family of plates for bone synthesis should consider:

I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;

II.- shape (straight or special or angled-tubular); and

III.- rigidity as to the form of fixation (rigid fixation or non-rigid fixation).

§ 1 - Special plates are those with special conformations or ends, in T, L or Y formats, angled in blade or nail, wedge type, support or support, snake type or mesh type.

§ 2 - The plates that simultaneously admit rigid and non-rigid fixations must be regularized as a rigid fixation system.

§ 2 - The plates that simultaneously admit rigid and non-rigid fixations must be regularized as a form of rigid fixation. (Corrected in DOU No. 28 of February 8, 2023)

Art. 26. Grouping into families of screws for bone synthesis should consider:

I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applied to all components;

II.- geometry (cannulated or non-cannulated); and

III.- function (osteosynthesis or ligamentoplasty).

Art. 27. The grouping into a system or family of intramedullary nails should consider:

I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable);

II.- rigidity associated with the structure (flexible or semi-rigid);

III.- rigidity as to the form of fixation (with or without blockage);

IV.- locking form (by internal expansive systems or exclusive by transverse or mixed screw); and

V.- application in the case of systems (femoral or tibial or humeral).

Art. 28. Grouping into families of orthopedic suture anchors should consider:

I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) applicable to anchor and sutures; and

II.- presence of insertion device (with or without device).

§ 1 - The insertion devices may only integrate the product if they are prohibited reprocessing and are delivered to the consumer in packaging whose contents include both the insertion device and the orthopedic suture anchor.

§ 2 - The single products composed of anchor and suture admit models with and without needle, and with and without suture.

Art. 29. The grouping into a system or family of graft-carrying intersomatic spacing devices shall consider:

I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable);

II.- constitution (monocomponent or conjugate);

III.- indication (disc replacement or body-disc replacement); and

IV. - architecture (expansive or non-expansive).

§ 1 - Intersomatic spacing devices are considered intervertebral spacers for replacement of vertebral discs and fusion cylinders for replacement of vertebral bodies and discs.

§ 2 - The grouping in system of intervertebral spacers for replacement of vertebral discs and fusion cylinders for replacement of vertebral bodies and discs shall only be allowed when in complete system.

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§ 3 - The intervertebral spacers for replacement of vertebral discs and the fusion cylinders for replacement of vertebral bodies and discs shall compose distinct registers, due to their application.

Art. 30. Grouping into orthopedic implant systems for spine synthesis should consider:

I.- nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable);

II.- rigidity associated with the structure (rigid or flexible);

III.- fixing structure (wires/plates and screws/rods/screws/hooks/connectors); and

IV.- Approach to the spine by way of implantation (Anterior and Anterolateral or Posterior and Posterolateral).

§ 1 - Implants for column synthesis of nature of different materials may compose the same system register, provided that they meet the dimensional compatibility and material nature.

§ 2 - The grouping into family of components of products for column synthesis is not allowed.

Art. 31. For the purposes of family grouping, the following shall be considered as single composite products:

I.- intersomatic spacing devices with intrinsic mobility;

II.- devices for halo-cranial fixation, composed of the metallic halo with threaded holes and the threaded metal pins for fixation in the halo;

III.- implants for arthroplasty totally restricted to elbow and knee;

IV.- implants for recomposition of the femoral surface of cemented hip;

V.- implants for recomposition of femoral surface of uncemented hip;

VI.- implants for total arthroplasty of contained shoulder;

VII.- implants for inverted contained total shoulder arthroplasty;

VIII.- implants for restricted total arthroplasty of the elbow, without polymeric insert of radio-ulnar conjugation;

IX.- implants for restricted total arthroplasty of the elbow, with polymeric insert of radio-ulnar conjugation;

X.- implants for interphalangeal total arthroplasty for hand;

XI. - implants for metacarpal-phalangeal total arthroplasty; and

XII. - implants for total metatarsalal-phalangeal arthroplasty of the hallux.

Art. 32. The grouping into families considering only the criterion nature of the material (metallic or polymeric or ceramic and absorbable or non-absorbable) is applicable to the following implantable materials in orthopedics:

I - staples for osteosynthesis;

II- Meniscus implants;

III- Flexible wires and cables for osteosynthesis;

IV- Rigid pins and wires for osteosynthesis;

V- Diaphyseal spacer baskets graft carriers;

VI - implantable mandibular fixators; and

VII- cranial fixators;

VIII- Viscoelastic solutions;

IX - bone cements; and

X - bone grafts.

§ 1 - The clamps mounted on an inserter device are considered a single composite product for registration purposes, admitting dimensional variation of the clamps.

§ 2 - The viscoelastic solutions for intra-articular lubrication, bone cements and bone grafts can be grouped in the family, provided that the raw materials are the same, being allowed only variation of concentration of the raw materials present in its formulation.

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CHAPTER IV
TRANSITIONAL AND FINAL PROVISIONS

Art. 33. The records granted during the period of validity of the Collegiate Board Resolution - RDC No. 59, of August 25, 2008 and RDC No. 542, of August 30
August 2021, must comply with this regulation when requesting their next revalidation.

§ 1 - Single product registrations may not be changed to family or system registration.

§ 2 - Products with system characteristics that were registered as a family before the validity of this Resolution must be framed as a system at the time of its revalidation.

Art. 34. The records filed during the period of validity of the Collegiate Board Resolution - RDC No. 59, of August 25, 2008 and Collegiate Board Resolution - RDC No. 542, of August 30, 2021, but which are still pending technical analysis, must be appropriate to the new regulation, and the company must petition ANVISA the subject addition, instructed with the necessary documentation for such adequacy.

Art. 35. The petition filed in disagreement with the grouping requirements contained in this Resolution shall not be subject to a technical requirement, leading to the summary rejection of the petition.

Art. 36. The Collegiate Board Resolution - RDC No. 59, of August 25, 2008 and Normative Instruction No. 1, of March 2, 2009, published, respectively, in the Official Gazette No. 164, of August 26, 2008, Section 1, p. 49, and Official Gazette No. 42, of March 4, 2009, are hereby revoked. Section 1, p. 67.

Art. 37. This Resolution takes effect as of January 4, 2022.

RÔMISON RODRIGUES MOTA
Deputy Chief Executive Officer