Ziacom®

INFORMATION ON METAL ALLERGIES IN ORAL IMPLANTOLOGY AND THE COMPOSITION OF RAW MATERIALS

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THE FOLLOWING MATERIALS ARE USED IN THE MANUFACTURE OF ZIACOM® PRODUCTS:

- Ziacom® **implants** are manufactured from commercially pure Grade IV titanium, in accordance with ASTM F67 and UNE-EN ISO 5832-2 standards, as well as Grade 5 titanium alloy (Ti-6Al-4V ELI), in accordance with ASTM F136 and UNE-EN ISO 5832-3 standards, depending on the product design and intended application.

  Both materials are widely used in the manufacture of medical implants and have demonstrated biocompatibility in accordance with the referenced standards:

Grade IV Titanium Chemical Composition Table	
Element	Composition limits (% by mass)
Nitrogen (N)	≤ 0,05
Carbon (C)	≤ 0,10
Hydrogen (H)	≤ 0,012
Iron (Fe)	≤ 0,50
Oxygen (O)	≤ 0,40
Titanium (Ti)	Balance

Chemical Composition Table – Grade 5 Titanium (Ti-6Al-4V ELI)	
Element	Composition limits (% by mass)
Aluminum (Al)	5,50 – 6,75
Vanadium (V)	3,50 – 4,50
Iron (Fe)	≤ 0,25
Oxygen (O)	≤ 0,13
Carbon (C)	≤ 0,08
Nitrogen (N)	≤ 0,05
Hydrogen (H)	≤ 0,012
Titanium (Ti)	Balance

- Ziacom® **prosthetic components** are primarily manufactured from Grade 5 titanium alloy (Ti-6Al-4V ELI), in accordance with ASTM F136-08 and UNE-EN ISO 5832-3 standards.

  PEEK (polyether ether ketone) is also used in the manufacture of prosthetic components.

  Additionally, certain components are made from other metallic materials, such as:

  - Cobalt-chromium alloy (Co-Cr), used for its high mechanical strength and biocompatibility in implantable applications.
  - AISI 303 stainless steel, used in non-implantable or auxiliary components, characterized by its good machinability, corrosion resistance, and widespread use in medical applications.

The materials used in the manufacture of prosthetic components have demonstrated biocompatibility through compliance with specific standards for medical-grade materials or through evaluation in accordance with the ISO 10993 series of standards, as applicable.

- **Instrumentation:** Ziacom® surgical instruments are manufactured from a specific grade of stainless steel depending on the type of instrument and its intended function, ensuring suitability for the intended use.

  Instruments intended to come into contact with the patient are manufactured from AISI 440B stainless steel and AISI 303 stainless steel, selected for their mechanical properties, corrosion resistance, and suitability for use in medical devices.

  The materials used have demonstrated biocompatibility, supported by the applicable standards for medical-grade materials and/or by evaluation in accordance with the ISO 10993 series of standards, as applicable.

TITANIUM ALLERGY

Titanium is one of the most widely used materials in dental implantology due to its excellent biocompatibility, corrosion resistance, and ability to integrate with bone. For this reason, titanium dental implants have been successfully used in millions of patients worldwide.

Hypersensitivity or allergic reactions to titanium are uncommon. However, as with any material used in medicine, isolated cases have been reported in the scientific literature.

As with other metals, titanium may release very small amounts of particles or ions as a result of wear or corrosion processes. In certain susceptible individuals, these may trigger an immune response.

Identifying a possible titanium allergy can be challenging, as the symptoms are not specific and may be related to other causes. If a patient has a history of metal allergy or develops persistent symptoms after placement of a dental implant, they should consult their dentist or oral surgeon, who will assess the clinical situation and, if considered necessary, request the appropriate diagnostic tests.

How is a possible titanium allergy diagnosed?

The diagnosis of possible titanium hypersensitivity should be made by a healthcare professional, taking into account the patient's medical history, clinical examination, and, when considered necessary, additional diagnostic tests.

At present, there is no single diagnostic test considered the gold standard for confirming titanium allergy; therefore, the assessment should be carried out on an individual basis.

Symptoms associated with metal hypersensitivity

The most common metal hypersensitivity reaction is contact dermatitis, particularly associated with nickel. In the case of implantable medical devices, reactions to titanium and other metal alloys are uncommon, but they may occur in patients with individual sensitivity.

Manifestations reported in cases of metal hypersensitivity may include:

- Skin reactions such as dermatitis or skin irritation.
- Local reactions in the oral cavity or surrounding soft tissues.
- Persistent inflammation or discomfort at the implant site.

In some cases, symptoms may be nonspecific, such as localized discomfort or a prolonged sensation of irritation. The presence of these signs does not necessarily indicate an allergy, as they may be related to multiple clinical factors that should be evaluated by a healthcare professional.

CONCLUSION

Some individuals may have sensitivity or hypersensitivity reactions to certain metals present in medical devices, dental restorations, or other products used in healthcare.

In rare cases, the presence of metallic materials may be associated with nonspecific local or systemic signs or symptoms. However, these manifestations may have multiple causes and therefore require appropriate clinical evaluation to determine their origin.

If a patient has a history of metal allergy or develops persistent symptoms without a clear explanation following the placement of a medical device, consultation with a healthcare professional is recommended for further evaluation.

The diagnosis of possible metal hypersensitivity should be based on the patient's medical history, clinical examination, and the healthcare professional's clinical judgment. At present, there is no single diagnostic test universally accepted as the reference standard for all cases.

WARNINGS AND LEGAL CONSIDERATIONS

Ziacom® is a manufacturer of medical devices, specifically dental implants and related medical-surgical products. It also acts as the official distributor in Spain and as an Authorized Representative within the European Union.

The products marketed by Ziacom® are intended exclusively for use by properly trained and qualified healthcare professionals. Their purchase and use are restricted to such professionals, and resale is not permitted.

Ziacom® does not practice clinical medicine or provide recommendations regarding surgical techniques or treatment decisions. Accordingly, it does not guarantee specific outcomes or particular benefits arising from the use of its products and cannot assume responsibility for the interpretation or application of the information contained in its documentation.

Any testimony, opinion, or instruction attributed to physicians, clinicians, researchers, or other experts represents the views of those third parties and does not necessarily reflect the position of Ziacom®. Consequently, Ziacom® accepts no responsibility for such statements.

Ziacom® and its personnel shall not be liable for any damages, consequences, or incidents arising from the use of its products, whether used alone or in combination with other devices or materials.

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