

WARRANTY POLICY



PRODUCT WARRANTY POLICY

Implacil Osstem Material Odontológico S.A.

Implacil Osstem Material Odontológico S.A., enrolled with CNPJ/ME under No. 05.741.680/0001-18, headquartered at Rua Vicente de Carvalho, nº 178, and 182, Cambuci, São Paulo – SP, CEP [Zip Code] 01.521.020 (“Implacil”), offers its customers and consumers (herein referred to as “Customers”) products of the highest quality, marketed and shipped through adequate packaging to ensure the safety and quality of such products.

In order to serve its Customers with good faith, transparency, and efficiency, Implacil discloses this Product Warranty Policy (“Policy”), with the objective of guiding Customers in the solution of potential problems with Implacil products and procedures.

Other information can be obtained through the “Instructions for Use of the Products”, which are available on the website www.implacil.com.br. All information is subject to change without prior notice.

We highlight that any modification or inappropriate or unauthorized use of our products, in addition to voiding their warranty, may affect their functioning or performance, consequently threatening the safety of your patient.

A) WARRANTY COVERAGE PERIOD

1. The following warranty periods shall be observed:

(i) Prosthetic components and surgical instruments

Regarding durable products, Implacil offers the legal warranty to its Customers for the replacement of its prosthetic components and surgical instruments, whenever a manufacturing defect is found in these products, within a period of ninety (90) days, counted:

- From the delivery of the products, in the case of apparent defects or those of easy verification;
- From the moment the defect becomes evident, in the case of a latent defect or one of difficult verification.

(ii) Dental Implants

Implacil also offers its Customers the contractual warranty of replacement of any original implant placed in their patients. This warranty (valid only for osseointegratable implants) is lifetime, provided that the Customer follows all warranty procedures provided in this Policy and all information available in the “Instructions for Use of the Products”. For the exercise of the warranty, the Customer must send the information previously requested by the Customer Service – SAC of Implacil.

2. After the complete filling of the Customer complaint report (available on the website www.implacil.com.br or with one of our consultants) and sending of the sterilized product to Implacil, an investigative analysis will be carried out by Implacil's technical department to verify the report and take appropriate measures.

3. In the absence of any of the requirements demanded by this Policy, the analysis will be cancelled and the product will be returned to the Customer, with the freight charges being borne by the latter and, consequently, the non-replacement of the implant in question.

B) WARRANTY BENEFICIARY

1. The warranty obligation is exclusively issued in favor of the Customer who purchased the product directly from Implacil, it being incumbent upon the latter, therefore, to be responsible before third parties with whom they contract, such as, for example, their patients or intermediate suppliers.

C) WARRANTY LIMITS

1. The warranty offered by Implacil shall cover only cases occurring within the coverage periods cited above, in which manufacturing defects of the product are verified.
2. The warranty offered by Implacil regarding osseointegratable implants shall cover, in addition to cases of manufacturing defect, the non-osseointegration of the implant, provided that the conditions provided in this Policy and in the Instructions for Use of the Products are respected.
3. Implacil guarantees the replacement of the product with another equivalent one. Thus, this warranty shall not cover any type of consequential damage and shall not create any liability regarding the extension/abandonment of the treatment by the professional or the patient, such as, for example: actual damages, lost profits, additional fees and/or indemnities charged by the patient.

D) WARRANTY CONDITIONS

1. All warranty presupposes the appropriate use of the products in patients fit to be rehabilitated with the use of dental implants. Thus, the Customer shall be entitled to the warranties provided in this Policy provided that the following conditions are respected:

- (I) The patient must not present any of the contraindications described in the Instructions for Use of the Products;
- (II) The product was used following the guidelines and recommendations contained in the Instructions for Use of the Products available on the website www.implacil.com.br and/or eventually sent by Implacil to Customers;
- (III) The patient was selected in a criterious manner and provenly received guidance and clarifications from the Customer regarding treatment options, risks, and benefits;
- (IV) The instructions on the care to be taken before and after surgery, in addition to being correctly explained to the patient, were also duly documented;
- (V) Adequate and regular oral hygiene by the patient was ensured, with follow-up appointments duly performed and documented;
- (VI) The product to be covered by the warranty was sent sterilized and accompanied by the following documents:
 - Customer complaint record, duly filled out and signed;
 - Copy of the patient's clinical file (medical record) proving the date of installation of the implant through the traceability label, if requested;
 - Periapical or panoramic radiographs of the region in question, taken before the removal of the implant. If it is not possible to take the radiograph prior to the removal of the implant, a radiograph of the implant site, provided it is taken within a period of up to fifteen (15) days after the removal of the implant, may be attached.

2. **ATTENTION:** Non-compliance with the items above will make the analysis of the case impossible. Consequently, the return of the product to the Customer will occur, with transport charges being at the Customer's expense.

3. The product to be analyzed must be sent together with the required documentation, within a maximum period of ninety (90) calendar days, after the occurrence that generated the activation of the warranty.



E) LOSS OF WARRANTY

1. The Customer shall lose the right to the warranty if:
 - (I) The products are not used in accordance with their Instructions for Use of the Products or if surgical instruments or other products manufactured by third parties are used in them;
 - (II) The products are altered, custom-made, or modified specifically for a patient;
 - (III) There is the existence of contraindications mentioned in the Instructions for Use of the Products;
 - (IV) The failure of an implant occurs due to an accident, a trauma, or any other damage caused by the patient themselves or third parties, or, further, due to deficient execution by the Customer's professional;
 - (V) It is verified that the failure of the product resulted from the use of damaged, worn, or improperly handled surgical instruments;
 - (VI) There are overdue debts owed by the Customer to Implacil.
2. If the product sent does not fit the terms and conditions of the warranty, it will be returned to the Customer, accompanied by an explanatory letterhead and/or technical report when necessary, with transport charges being borne by the Customer.
3. If the non-osseointegration of the implant is verified, respecting the conditions of the items above, or the manufacturing defect, Implacil will proceed with the replacement of the product with another of the same kind. Implacil will not perform exchanges for currency or credit on account.

F) PROCEDURES FOR WARRANTY REQUEST

1. The failure in the functioning of the product may or may not be caused by a manufacturing defect. If any irregularity is found during your procedure, so that the existence of the manufacturing defect is verified, the following recommendations must be adopted:
 - (I) Pack and sterilize the product to be returned:
 - (II) Completely fill out the customer complaint record, not failing to fill out the mandatory fields and the sterilization declaration present therein;
 - (III) Stamp and sign the customer complaint record. Do not forget that the customer complaint record is a document that will allow or not the benefit of the warranty;
 - (IV) Pack in a way to avoid loss or damage during transport, preferably in padded bags. For Customers residing abroad, the products must be sent to the commercial representative of the country of residence, and the shipment to Brazil must be done by the commercial representative. And for customers residing in Brazil, the product in question must be sent to the address below:

IMPLACIL OSSTEM MATERIAL ODONTOLÓGICO S.A.

C/O QUALITY ASSURANCE

Rua Cesário Ramalho, 821 – CEP 01521-000 - São Paulo – SP/Brasil

G) FINAL PROVISIONS

1. Whenever this Policy is altered, as Implacil deems necessary at any time, without prior notice, the new version will be published on the website www.implacil.com.br.
2. In case of doubts about this Policy, or for interaction with Implacil regarding matters involving its terms, please contact us through the following channels:
0800-7790011
contato@implacil.com.br
3. Upon acquisition of Implacil products, the Customer accepts the terms and conditions stipulated herein.

Update: June 21, 2021.

IMPLACIL OSSTEM MATERIAL ODONTOLÓGICO S.A.



