

GUARANTEE AND EXCHANGE POLICY, THEIR RESPECTIVE FGM BRAND COMPONENTS AND INSTRUMENTS MANUFACTURED BY DENTSCARE LTDA.

1. IDENTIFICATION OF THE MANUFACTURER

1.1. The present Term of Guarantee and Implant Exchange Policy is provided by **DENTSCARE LTDA** ., A legal entity under private law, enrolled with the CNPJ under no. 05.106.945 / 0001-06, headquartered at Av. Edgar Nelson Meister, 474, Industrial District, Joinville Municipality, State of Santa Catarina, Brazil, CEP 89219-501, with respect to the products of its manufacture of the Arcsys - FGM line, hereinafter referred to as simply "**MANUFACTURER**"

2. CONTACT INFORMATION

2.1. If the dentist needs any information, clarification or assistance regarding this Product Exchange and Return Policy, the MANUFACTURER makes available the following means to receive all the communications that the professional wishes to do: (i) SAC: 0800 644 6100; (ii) electronic address: fgm@fgm.ind.br ; and (iii) postal correspondence: Av. Edgar Nelson Meister, 474, Industrial District, Joinville Municipality, State of Santa Catarina, Brazil, CEP 89219-501.

3. PURPOSE OF THE WARRANTY

3.1. The MANUFACTURER warrants to the dental surgeon the replacement of the above-mentioned manufacturing products (implants, surgical instruments and prosthetic components installed in the patient) that present a defect or an adverse event, for the periods stated in clause 5 of this Instrument, observing that:

3.1.1. The product(s) to be replaced shall have been purchased by the dental surgeon in the original form of the MANUFACTURER;

3.1.2. The dentist must comply with the instructions for use of the product, and there is no claim for a product used / handled incorrectly by the dentist and/or patient;

3.1.3. The guarantee object of this instrument refers only to the products of the MANUFACTURER, not extending to the possible costs associated with the treatment.

3.2. This warranty is valid and will apply only to the end user of the product, i.e. it will not be valid in case of purchase of the product for resale.

3.3. This guarantee also presupposes:

3.3.1. The legitimate acquisition of original products MANUFACTURER by the dentist, without the combination of products with other brands;

3.3.2. The careful selection of the patient with clinical indication for treatment with dental implant and the appropriate use of this therapy;

3.3.3. The informed consent of the patient, with proper guidance and clarification by the dental surgeon regarding treatment options, risks and benefits;

3.3.4. That the patient does not present any contraindications, described in the instructions for use before, during or after implant installation;

3.3.5. That the use of the product has been carried out in strict accordance with the guidelines and recommendations contained in the instructions for use of each product;

3.3.6. The observance of care before and after surgery, as well as proper oral and regular hygiene by the patient;

3.3.7. Duly documented follow-up consultations;

3.3.8. That the prosthesis installed on the implant (or to be replaced) allows the balanced intercuspation between arches.

3.3.9. That the IMPLANTS EXCHANGE FORM (Annex 1) AND/OR INSTRUMENT AND COMPONENT REPLACEMENT FORM (Annexe 2) for guarantee request be forwarded, fully filled to the MANUFACTURER, within 30 (thirty) days after the occurrence.

3.4. The warranty is exclusive to the professional dental surgeon, expressly excluding any right to third parties, patients, distributors or intermediary suppliers.

4. USING THE WARRANTY

4.1. In order for the dental surgeon to have the right to use this guarantee, strictly follow the instructions below:

4.1.1. If the product is not functioning as guaranteed, during the guarantee period, contact the Relationship Center - CR, through the information provided in clause 2.1. of this instrument;

4.1.2. When contacting the CR, the dental surgeon must have the invoice of purchase of the product, as well as information about the model, lot number, place, date of purchase and name of the company where the product was purchased.

4.1.3. Any transportation charges will be the sole responsibility of the dental surgeon, making sure that the MANUFACTURER is not responsible for the risks of transportation, as well as refuse the product if the transport is not previously paid.

4.1.4. The surgeon-dentist, in order to carry out the correct transport of the products, must pack them in self-sealing packaging of surgical grade paper with laminated film, after subjecting it to the sterilization process by autoclaving, with confirmation of this procedure.

4.1.5. All products must be sent to the MANUFACTURER duly sanitized and sterilized, accompanied by the following documents: (i) Copy of the purchase invoice of the product; (ii) IMPLANT EXCHANGE FORM (Annex 1) AND / OR INSTRUMENT AND COMPONENT EXCHANGE FORM (Annex 2) duly completed, with all requested data; (iii) Copy of the clinical record of the patient; (iv) pre and post-operative complementary examinations (radiographic and / or tomographic images, laboratory tests, study models) containing patient consent, being returned to the professional after analysis by the MANUFACTURER.

4.1.6. Products that are not cleaned, sterilized and with a completed sterilization statement will not be received for analysis and will be returned to the dental surgeon without being evaluated, as well as, the warranty assessment request will be terminated.

4.1.7. Take all necessary care before, during and after using the MANUFACTURER's products, as well as ensuring that the patient has taken them.

4.1.8. Observe the indications and contraindications of each patient and follow the recommendations provided in the instructions for use of the Product.

4.1.9. Ensure that adequate oral hygiene was provided by the patient and that consultations were regularly completed and documented.

4.2. The product will only be analyzed by the MANUFACTURER upon receipt of the IMPLANT EXCHANGE FORM (Annex 1) AND / OR FORM OF EXCHANGE OF INSTRUMENTS AND COMPONENTS (Annex 2), duly completed, within a period of thirty (30) days date of the occurrence, according to medical records.

4.3. Replacement of the product will only occur upon receipt and analysis of the documentation provided in clause 4.1.5. and within the period described above.

5. WARRANTY TERM

5.1. The term of this warranty for implants and prosthetic components is:

5.1.1. 30 (thirty) days for metallic pillars, non-customizable and non-provisional (replacement by an equal metallic component), counting from the date that was learned of the event; within a maximum period of ten (10) years from its acquisition;

5.1.2. 30 (thirty) days for implants (replacement by implant equivalent or equivalent and an equivalent pillar, when necessary), from the date that was learned of the event, in an avital way since its acquisition;

5.2. Included in this warranty are prosthetic components made of STM 18Cr14Ni2.5Mo stainless steel in accordance with ASTM F138-13a, and not subject to any changes, in addition to the angulation of the component according to the instruction manual, in those that allow this customization and which are not provisional use.

5.3. The warranty periods provided for in this clause are valid only for products purchased from an AUTHORIZED DISTRIBUTOR and used in the same location. The MANUFACTURER is authorized to offer different warranty periods for products purchased from its subsidiaries and distributors located in other countries.

TERM OF WARRANTY AND POLICY OF EXCHANGE AND RETURN OF

5.4. This warranty does not cover intermediate components, which are customizable and/or have been customized in addition to the angulation of the component according to the instruction manual, in those that allow this customization, provisional prosthetic components and other provisional use items. In the case of these items, the company offers only the guarantees provided by Law.

6. THE CAUSES OF EXCLUSION

6.1. This warranty does not apply to:

- 6.1.1.** misuse or misuse of the product or use of the product in disagreement with the guidelines for use of this MANUFACTURER;
- 6.1.2.** natural wear and tear of the products, because they have not been correctly followed, and in full, the instructions for use and maintenance;
- 6.1.3.** malfunctions suffered in the transport of the products, performed by the dental surgeon;
- 6.1.4.** neglect or omission in the recommendations of use and placement;
- 6.1.5.** malfunctions caused by items not original MANUFACTURER, coupled by the dentist, patient or by unauthorized third parties, including accessories, components, parts and materials not provided by DENSTCARE;
- 6.1.6.** contamination by the professional or third parties;
- 6.1.7.** modification or combination with third party products not manufactured by the MANUFACTURER;
- 6.1.8.** contraindications mentioned in the instructions for use;
- 6.1.9.** incorrect handling of the product by the professional dental surgeon or dental technician;
- 6.1.10.** customizable and / or provisional prosthetic components;
- 6.1.11.** failure or defect of the product caused by accident, trauma or any cause of responsibility of the patient, the professional or third parties;
- 6.1.12.** products that undergo modifications made by dental surgeon and / or third;
- 6.1.13.** acts of God or force majeure;
- 6.1.14.** use of the product by unauthorized person.

6.2. This warranty does not include maintenance for the suitability of the product for any statement that has been made by a third party about its suitability for a specific use that has not been acknowledged in writing by the MANUFACTURER.

6.3. The guarantee will also be excluded in the following cases:

- 6.3.1.** if it is found that the products have undergone any intervention of an unauthorized person;
- 6.3.2.** if handling of the products is identified;
- 6.3.3.** if the invoice for the purchase of the product is not presented, the completed guarantee form, containing all the requested data; a copy of the patient's clinical file, pre and post-operative complementary examinations (radiographic and / or tomographic images, laboratory tests, study models); together with this certificate;
- 6.3.4.** the products are not sent to the MANUFACTURER completely sanitized and sterilized, accompanied by the respective declaration;

6.4. The warranty specified in this document is the only warranty granted by the MANUFACTURER.

6.5. The MANUFACTURER does not assume any responsibility in relation to the professional dental surgeon for loss of business, income, or lost profits and recognizes that the only relationship between them is commercial, resulting from the purchase and sale of products manufactured by the MANUFACTURER, emphasizing that the products of the MANUFACTURER constitute an input to the activity of the professional surgeon-dentist.

6.6. The MANUFACTURER is not responsible for the compliance or not of the dental practice recognized in the scientific literature, nor is it responsible for damages that are directly related to such practices.

7. EVENTUAL INDEMNIFICATION

7.1. The amount of any indemnity to be paid by the MANUFACTURER for direct or indirect damages caused to the dental surgeon shall be limited to the amount paid for the product. The products have been developed for generic use, not to serve the specific purposes of each consumer.

TERM OF WARRANTY AND POLICY OF EXCHANGE AND RETURN OF

7.2. The MANUFACTURER does not guarantee that the products will serve the specific purposes of each consumer, but rather those purposes foreseen in the User Manual.

8. ANNUENCE

8.1. Acquiring the implants of the MANUFACTURER and participating in the guarantee program, the professional dental surgeon accepts the terms and conditions contained therein.

9. TECHNICAL ASSISTANCE

9.1. In order to request a technical report, the products purchased from the MANUFACTURER in Brazil and for use in Brazil must be sent to Av. Edgar Nelson Meister, 474, CEP 89219-501 - Joinville / SC - Brazil.

9.2. In the case of products purchased from authorized distributors in another location for use in another location, the technical report must be requested and the products sent **exclusively** to the care of the AUTHORIZED DISTRIBUTOR, which will be sent to the Technical Department of the MANUFACTURER for analysis.

9.3. The preparation of the technical report by the MANUFACTURER shall be made within the period of 45 (forty-five) days, provided that all the conditions described herein are met.

9.4. The MANUFACTURER assures the confidentiality of the information that appears in the patient's medical record and other tests available.

10. MODIFICATION OF THE WARRANTY

10.1. The MANUFACTURER reserves the right to change warranty periods at any time, in whole or in part. Changing the terms of this Warranty Policy will not affect products installed prior to the date of change of the same.

11. DURATION

11.1. This GUARANTEE AND EXCHANGE POLICY, THEIR RESPECTIVE FGM BRAND COMPONENTS AND INSTRUMENTS MANUFACTURED BY THE MANUFACTURER shall become effective on the date of its availability on the institutional site of the MANUFACTURER, that is, on 10/17/2016, covering all installed products from this date.

ANNEXE 01
IMPLANT EXCHANGE FORM

In accordance with clauses 3.3.9., 4.1.5. and 4.2. of the WARRANTY TERM AND POLICY OF EXCHANGE AND RETURN OF PRODUCTS from the manufacturer DENTSCARE LTDA, below is the form that must be filled by the dentist, for each product to be analyzed, with the maximum amount of information and details of the patient, containing the signature and stamp of the professional:

1. DENTIST / PROSTHETIC SURGEO INFORMATION

Name of professional: _____ CRO / UF: _____
 Address: _____
 Nº _____ Complement: _____ Neighborhood: _____
 ZipCode: _____ - _____ City: _____ State: _____
 Parents: _____
 Phone: _____ E-mail: _____

2. INFORMATIONS ABOUT THE PRODUCT

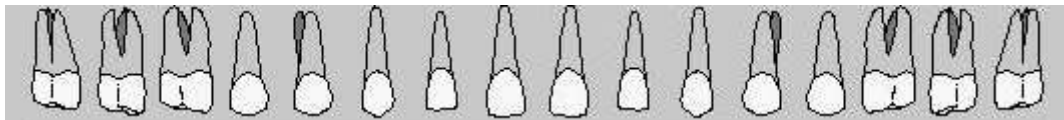
Part code	Product's name	Lot nº	Amount
Click here to type	Click here to type	Click here to type	Click here to type

3. PATIENT INFORMATION

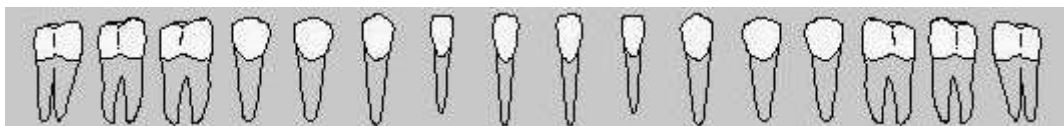
a) Name and identification code: _____
 Date of birth ___/___/_____ Sex: F() M() Weight: _____

b) According to the odontogram, mark with an "X" the region where the implant was installed:

·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
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---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---



c) Clinical History:

- () Diabetes Mellitus;
- () Radiotherapy - head / neck;
- () Allergy / hypersensitivity;
- () Chemotherapy;
- () Hypertension;



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ANNEXE 01
IMPLANT EXCHANGE FORM

- () Xerostomia;
- () Smoking;
- () Immune deficiency;
- Oral hygiene: () Good () Fair () Poor
- Alcoholism: () None () Low () Average () Common
- () Medication. Which? _____;
- () Other diseases. Which? _____;

4. SURGERY INFORMATION

a) General data:

- Date of implant installation: ___/___/_____
- Primary stability achieved (touch) _____ n.cm
- Was the implant cover (submerged) installed? Yes () No ()
- Has the multifunctional scar been installed? Yes () No ()
- Date of implant removal: ___/___/_____
- Was the installation of a new implant performed in the same surgical procedure? Yes () No ()

b) Surgical intervention data:

- What is the bone density found? Bone type: I () II () III () IV ()
- Was an immediate implant (post-extraction) performed? Yes () No ()
- Have you seen any infection / injury? Yes () No ()
- Which drill(s) were used? **2.4**() **2.9**() **3,4**() **3.9**() **4.6**() **5.6**()
others()
- Was there some kind of fenestration? Yes () No ()
- Was bone graft performed on site? Yes () No ()
- If yes, what material used (Particulate / block)? _____
- Was immediate loading and / or immediate provisioning performed? Yes () No ()
- If yes, what prosthetic component is used? _____

5. DESCRIPTION OF THE OCCURRENCE

6. RELEVANT INFORMATION

a) Factors that influenced the occurrence:

- () Trauma;
- () Poor oral hygiene;
- () Insufficient bone quality / quantity;
- () Sinus membrane perforation;
- () Infection;
- () Immediate loading;
- () Periimplantite;



ANNEXE 01
IMPLANT EXCHANGE FORM

- () Bone overheating;
- () Implant fracture;
- () Biomechanical overload and / or occlusal trauma;
- () Bruxism;
- () Does not make use of myorelaxant plate;
- () Pre-existing diseases: _____
- () Others: _____

b) Loss of the implant was accompanied by the following events:

- () Pain / edema;
- () Bleeding;
- () Instability;
- () Infection;
- () Fistula;
- () Swelling;
- () Others: _____
- () There was no symptom.

c) Other relevant data:

- When was the prosthetic component installed? ___/___/_____
- Which _____ component _____ was _____ installed:

- Date of installation of provisional crown: ___/___/_____
- Date of installation of the final crown: ___/___/_____
- Date of removal of the prosthetic component: ___/___/_____
- Control consultations were carried out: Yes() No ()
- Did the patient receive information about pre and post-operative care and signed a corresponding document (consent form)? Yes() No ()

ANNEXE 01
IMPLANT EXCHANGE FORM

TERM OF COMMITMENT

I _____, hereby, duly qualified in item 1 of this instrument, declare, under the penalties of law, that the above information is true and in keeping with the patient's medical records.

Cidade/UF, ____ de _____ de _____.

(Nome do cirurgião dentista e assinatura)

STERELIZATION DECLARATION

By this, I _____, CPF number ____-____-____, declares under penalty of law, that the product now sent, described in item 2 of this instrument has been properly sterilized according to ideal standards - 121 ° C temperature, the pressure of 1 atm and cycle time is 30 minutes, before sending for the preparation of a technical report, according to the information below:

- Sterilization method: _____;
- The biological indicator batch number (*Bacillus stearothermophilus*): _____;
- Result of the biological indicator:
 - () Satisfactory - absence of biological indicator growth;
 - () Unsatisfactory - presence of biological indicator growth;
- Date of sterilization: ____/____/____

City/State, ____ of _____ of _____.

(Name of person responsible and signature)



ANNEXE 01
IMPLANT EXCHANGE FORM

IMPORTANT INSTRUCTIONS (!)

How to send products for analysis

1. Failure to complete the form will result in the return of the product, with the transportation costs being borne by the professional dental surgeon;
2. For the request of technical report, the form duly filled and signed and the product must be sent to the following address: Av. Edgar Nelson Meister, 474, CEP 89219-501 - Joinville / SC – Brazil or to the AUTHORIZED DISTRIBUTOR;
3. For analysis of the product it is necessary that the material is sent to DENTSCARE LTDA or to the AUTHORIZED DISTRIBUTOR properly packed in self-sealing packaging of surgical grade paper with laminated film, with confirmation of sterilization by means of specific tapes for autoclaving;
4. All products must be sent to DENTSCARE LTDA or to the AUTHORIZED DISTRIBUTOR completely sanitized and sterilized, accompanied by this completed Warranty Form and with the respective documents:
 - a) Copy of the purchase invoice of the product;
 - b) Completed guarantee form, containing all requested data;
 - c) Copy of the clinical file of the patient;
 - d) Periapical or panoramic x-rays, being returned to the professional after analysis by DENTSCARE LTDA.
5. Products that are not cleaned, sterilized and with the respective declaration of sterilization filled in, will not be received and accepted for analysis, being discarded upon receipt;
6. The dental surgeon assumes full responsibility for the costs of contracting outsourced companies for the sterilization of products sent without observance of the above items with prior authorization;
7. The preparation of the technical report by DENTSCARE LTDA will be done within a period of 45 (forty-five) days, upon receipt at the manufacturer's head office, provided that all the conditions described herein are met, pursuant to clause 7.3. of the WARRANTY TERM AND POLICY OF EXCHANGE AND RETURN OF PRODUCTS;
8. If you have any questions, please contact the DENTSCARE LTDA Relationship Center - CR at 0800 644 6100.

City/State, _____ of _____ of _____.

(Name of the dentist and signature)



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ANNEXE 02
INSTRUMENT AND COMPONENT EXCHANGE FORM

In accordance with clauses 3.3.9., 4.1.5. and 4.2. of the WARRANTY TERM AND POLICY OF EXCHANGE AND RETURN OF PRODUCTS from the manufacturer DENTSCARE LTDA, below is the form that must be filled by the dentist, for each product to be analyzed, with the maximum information and details of the patient, containing the signature and stamp of the professional:

1. DENTIST / PROSTHETIC SURGEON INFORMATION

Name of professional: _____ CRO / UF: _____

Address: _____

Nº _____ Complement: _____ Neighborhood: _____

Zip Code: _____ - _____ City: _____ State: _____

Parents: _____

Phone: _____ E-mail: _____

2. INFORMATION ABOUT THE PRODUCT

Part code	Product's name	Lot nº	Amount
Click here to type	Click here to type	Click here to type	Click here to type

3. PATIENT INFORMATION

a) Name and identification code: _____
Date of birth ___ / ___ / _____ Sex: F() M() Weight: _____

4. DESCRIPTION OF THE OCCURRENCE

5. RELEVANT INFORMATION

a) Occurrences:

- Problem encountered?
 - () Attachment / Attachment
 - () Oxidation
 - () Deformation
 - () Fracture
 - () Machas
 - () Packing / label
 - () Others. Which are? _____

- Frequency of use?
 - () New
 - () Already used. ___ number of times.



ANNEXE 02
INSTRUMENT AND COMPONENT EXCHANGE FORM

b) Oxidation cases (for instrument return):

- What is the product used for cleaning?

Enzyme detergent
 Chlorhexidine 2%
 Glutaraldehyde
 Saline
 Alcohol 70%
 Hydrogen peroxide
 Others: _____

- Medium used?

Manual
 Ultrasound

- What material used for asepsis?

Nylon brushes
 Multipurpose sponge
 Steel brush
 Steel sponge

c) Cases of fracture / deformation (for component return):

- Was it used martelete?

Yes. _____ Number of drives
 Do not. Which instrument used? _____

- Was ratcheting torque (for screw M1.8) used?

Yes _____ N.CM.
 Do not. Which instrument used? _____

- Was there any difficulty in using the instrument?

Yes. What?

 No

- What difficulties were encountered?

Little inter-occlusal space
 Difficulty fitting / fitting the connection
 Position / Implant Angle
 Difficulty removing component.
 Others:

ANNEXE 02
INSTRUMENT AND COMPONENT EXCHANGE FORM

TERM OF COMMITMENT

I _____, hereby, duly qualified in item 1 of this instrument, declare, under the penalties of law, that the above information is true and in keeping with the patient's medical records.

City/State, _____ of _____ of _____.

(Name of dentist and signature)

STERILIZATION DECLARATION

By this, I _____, CPF number _____-_____, declare under penalty of law, that the product now sent, described in item 2 of this instrument has been properly sterilized according to ideal standards - 121 ° C temperature, the pressure of 1 atm and cycle time of 30 minutes, before sending for the preparation of a technical report, according to the information below:

- Sterilization method: _____ ;
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- Date of sterilization: ____/____/_____

City/State, _____ of _____ of _____.

(Name of person responsible and signature)



ANNEXE 02
INSTRUMENT AND COMPONENT EXCHANGE FORM

IMPORTANT INSTRUCTIONS (!)

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3. For analysis of the product it is necessary that the material is sent to DENTSCARE LTDA or to the AUTHORIZED DISTRIBUTOR properly packed in self-sealing packaging of surgical grade paper with laminated film, with confirmation of sterilization by means of specific tapes for autoclaving;
4. All products must be sent to DENTSCARE LTDA or to the AUTHORIZED DISTRIBUTOR completely sanitized and sterilized, accompanied by this completed Warranty Form and with the respective documents:
 - a) Copy of the purchase invoice of the product;
 - b) Completed guarantee form, containing all requested data;
 - c) Copy of the clinical file of the patient;
 - d) Periapical or panoramic x-rays, being returned to the professional after analysis by DENTSCARE LTDA.
5. Products that are not cleaned, sterilized and with the respective declaration of sterilization filled in, will not be received and accepted for analysis, being discarded upon receipt;
6. The dental surgeon assumes full responsibility for the costs of contracting outsourced companies for the sterilization of products sent without observance of the above items with prior authorization;
7. The preparation of the technical report by DENTSCARE LTDA will be done within a period of 45 (forty-five) days, upon receipt at the manufacturer's head office, provided that all the conditions described herein are met, pursuant to clause 7.3. of the WARRANTY TERM AND POLICY OF EXCHANGE AND RETURN OF PRODUCTS;
8. If you have any questions, please contact the DENTSCARE LTDA Relationship Center - CR at 0800 644 6100.

City/State, _____ of _____ of _____.

Understood, _____

(Name of dentist and signature)



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