

Product Information

Ref:

Description:

Lot:

SPACE FOR PRODUCT TAG

SPACE FOR RADIOGRAPHY

Customer Information

Name/Corporate name:

ID Number:

CNES:

Address:

City:

State:

Phone:

Cel Phone:

E-mail:

Patient Information

Name/ID:

Age:

Gender: Male

Female

Clinical history:

Diabetes Mellitus

Hypertension

Xerostomia

Bruxism

Smoking

Allergy or Hypersensitivity

Immune Deficiency

Chemotherapy

Another disease:

Surgery Information

Reason of return:

Packaging

Failure in osseointegration

Lack of primary stability

Impossible to install

Fracture

Others (describe):

Date:

Fill in all the fields below in case of Failure in osseointegration/Lack of primary stability.

Implant date:

Bone type:

I

II

III

IV

Immediate loading implant: Yes

No

Removal date:

Fill in all the fields below in case of Instrumental.

Used instrumental S.I.N.? Yes

No

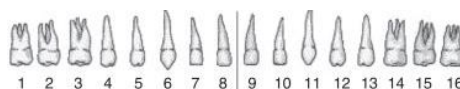
If so, what sequence of borers were used?

Was a bone graft performed at the site? Yes

No

If so, what material was used?

Intraoral implantation region:



Dear Dentist,

Any occurrence related to our products is of the utmost importance to us. Therefore, we ask that the completion and submission of information for our analysis be done thoroughly. This information will be essential for a detailed analysis of the occurrence.

PREMISE

1. Warranty Scope

S.I.N Implant System guarantees to all dental institutions that have acquired, provided that they are original products, that the instructions for use have been respected, as well as the following described situations:

- 1.1 The legitimate acquisition of products by the dental institution;
- 1.2 The careful selection of the patient with clinical indication for treatment and appropriate application of the technique;
- 1.3 Informed and signed consent by the patient, with proper guidance from the dentist;
- 1.4 That the patient does not present any contraindications described in the instructions for use;
- 1.5 That the use of the product has been carried out in strict compliance with the guidance and recommendations described in the instructions for use of each product.

2. Warranty Exclusions

The warranty **DOES NOT COVER** products that are sent without the following documents:

- 2.1 Fully completed (original) Product Evaluation Form;
- 2.3 Implant radiographs.

We remind you that S.I.N.'s quality is recognized by the most important certifications in the segment, such as ISO 13485/2016, ISO 9001/2015, RDC 665/2022, and MDD 93/42/EEC and MDR 745/2017, which enables marketing in Europe. In addition to these, other certificates received over the past more than 20 years attest to the continuous improvement of our work.

Still, for your greater satisfaction, we have a direct channel with a scientific dental consultant in the product research and development area, whom you can call to ask questions or even clarify this and other cases further.

Declaration of Truthfulness

I, _____, declare that the information provided in this document is true.

Date: _____

Signature and stamp of the dental professional: _____

Quality Control Form Completion

Customer SAP

Occurrence

Order

Analysis Report