SCIOGRAFT

Mineralized Cortical Cancellous Allograft

TECHNICAL DOSSIER

SCIOGRAFT
Mineralized Cortical Cancellous Allograft

A sterile biocompatible anorganic porous bone mineral for use in periodontal, oral and maxillofacial surgery.

Description

SCIOGRAFT is a porous bone mineral matrix. It is produced by removal of organic components from bovine bone. SCIOGRAFT provides a supportive structure for osteoconduction. The presence of pores in SCIOGRAFT is of great importance for repearing bone defects. It is available in cancellous (spongiosa) granules and block.

Properties/actions

The anorganic bone matrix of SCIOGRAFT has macro and microcopic structures that mimics human bone. The formation and ingrowth of new bone at implantation site of SCIOGRAFT is favoured, due to its trabecular architecture, interconnecting macro and micro pores. The use of SCIOGRAFT may be considered when autogenous bone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure.

Indications and usage

SCIOGRAFT is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridges.
- Filling of infrabony periodontal defects
- Filing of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filing of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of per-implant defects in conjunction with products intended for Guided
- Bone Regeneration (GBR)

Instructions for use

- After exposure of the bony defect with a mucoperiosteal flap, all granulation tissue must be carefully removed
- SCIOGRAFT can be mixed with sterile standard saline. If large maxillofacial defects are present, SCIOGRAFT should be mixed with autogenous bone in a ratio of approximately 1:1
- In order to assure the formation of new bone SCIOGRAFT should only be placed in direct contact with well vascularized surface.
- Loosely pack SCIOGRAFT granules into osseous defect using a sterile instrument. The use of excessive force will result in compression of the particles and loss of trabecular architecture.
- Overfilling of the defects should be avoided.
- Mucoperiosteal flaps should be sutured to achieve primary closure, if possible.
- If primary wound closure can not be achieved completely, further immobilization of the flap (e.g., by incision through the periosteum) should be performed and/or a bioabsorbable membrane should be placed over the bone graft site

Contraindications

Contraindications customary to the use of bone grafts should be observed. SCIOGRAFT should not be used in patients with:

- Acute or chronic infection (osteomyelitis) at the surgical site
- Metabolic diseases (diabetes, hyperpara thyroidism, osteomalacia)
- Severe renal dysfunction.
- Severe liver disease.
- High dose corticosteroid therapy.
- Vascular impairment at the implant site.
- Osteoporosis.

Precautions

In order to facilitate the formation of new bone SCIOGRAFT should only be implanted in direct contact with a well vascularized bone tissue. Drilling may be recommended to facilitate bleeding from cortical bone.
In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
Excessive flap tension or rough handling of flaps may result in flap sloughing and loss of the implant.

Implantology

The placement of titanium fixtures should not take place until 6 months after implantation of SCIOGRAFT. For sinus floor elevation, typically 9-12 months should be allowed after implantation of bone graft material before placement of the titanium fixtures.
X-rays should be taken to confirm the bone integrity prior to dental implant placement.

Periodontology

The filling of periodontal defects with SCIOGRAFT requires (along with plaque control) the successful local treatment of the periodontal lesion (e.g. root planning, debridement of granular tissue) prior to implantation.

Caution

Federal law restricts this device to sale by or on the order of a licensed dentist.

Adverse reactions

No adverse reactions have been reported.

How supplied

SCIOGRAFT is supplied sterile, non bacterial endotoxin, and for single use only. SCIOGRAFT is delivered in the following sizes and configurations:
SCIOGRAFT cancellous-bone granulate:

Granule size: 0.840 mm – 2.0 mm
Vials of 0.5 grams and 2.0 grams
Granule size: 0.350 mm – 0.840 mm
Vials of 0.25 grams, 0.5 grams, and 2.0 grams
SCIOGRAFT cancellous -bone block
Double-blister pack with 1 block
Block size: 1 cm x 1 cm x 2 cm.

The proper mixing ration and the wetting time

The proper mixing ratio for a 0.5 grams dose of SCIOGRAFT Granule: 0.840 to 2.0 mm is between 0.35 – 0.40 ml of saline.
The proper mixing ratio for a 0.5 grams dose of SCIOGRAFT Granule: 350 to 840 is between 0.50 – 0.55 ml of saline.
For both granules the wetting time is around 5 seconds.

Storage

Store at room temperature.

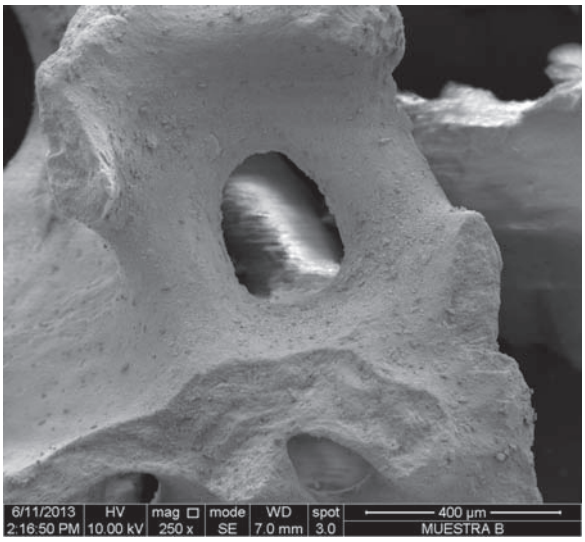
Manufacturer

ODONTIT S.A.
KALOS BIOMEDICAL LLC

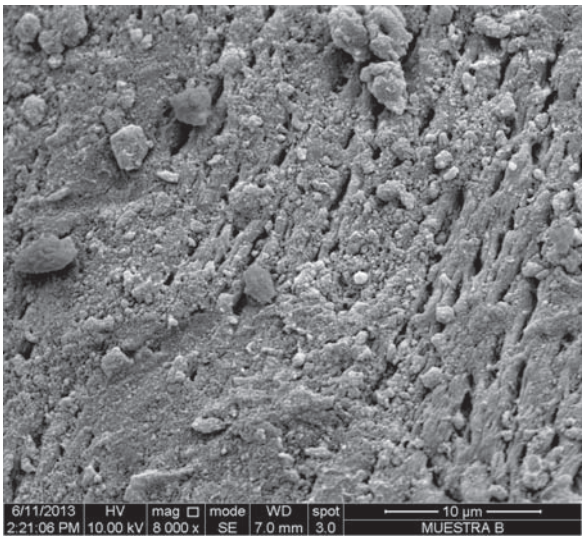
El producto SCIOGRAFT, que se fabrica a partir de hueso bovino, presenta macro y micro poros interconectados que son similares a los que se reportan para el Bio-Oss. Esta propiedad permite utilizar al producto SCIOGRAFT como material de relleno óseo. Las imágenes SEM de la muestra Bio-Oss, denominada B y las de SCIOGRAFT denominada: Lote H1306007 fueron obtenidas utilizando un microscopio electrónico de barrido (FEI QUANTA FEG 250). Ambos productos mostraron una distribución son causadas por elestructura porosa, donde eltamaño, forma y proceso de fabricación. SCIOGRAFT tiene un sistema deporos interconectados. El tamaño de los mismos sonsimilares a la estructura que presenta Bio-Oss.

BIO OSS

The following SEM image corresponds to Bio - Oss. Pores between of 242.5 µm x 310 µm



Magnification 250X

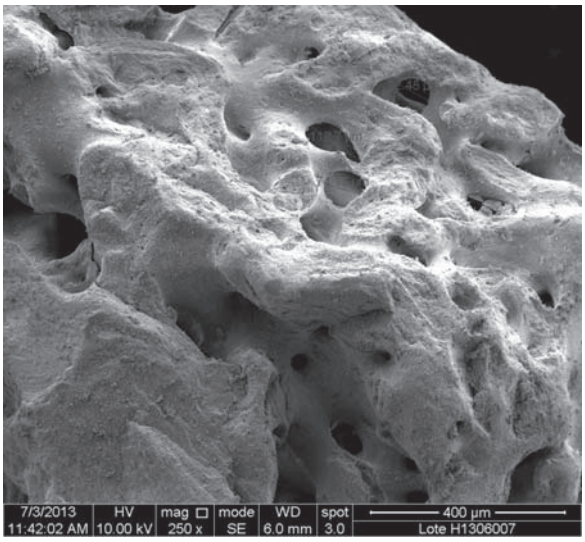


Magnification 8000X

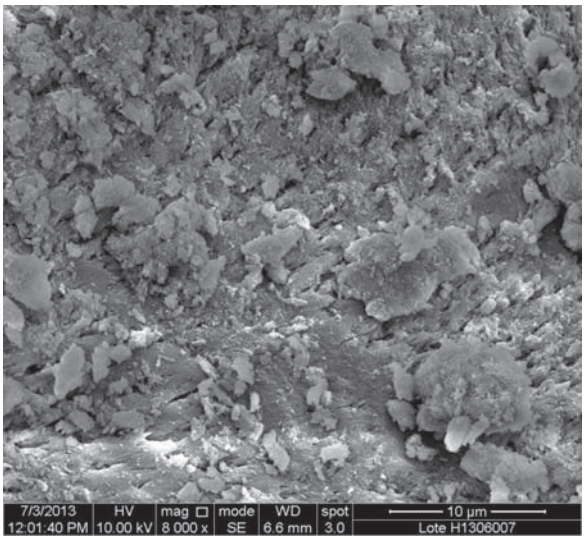
SCIOGRAFT product, which is manufactured from bovine bone, presents macro and micro interconnected pores which are similar to those reported for Bio-Oss. This property allows to use the product as bone grafting material.
SEM images for Bio-Oss, sample B and SCIOGRAFT sample Lote H1306007 were obtained using a scanning electron microscope (FEI Quanta 250 FEG). Both products showed a porous structure, where the size, shape and distribution are caused by manufacturing process. SCIOGRAFT has interconnected pores with a pore size similar to Bio-Oss.

SCIOGRAFT

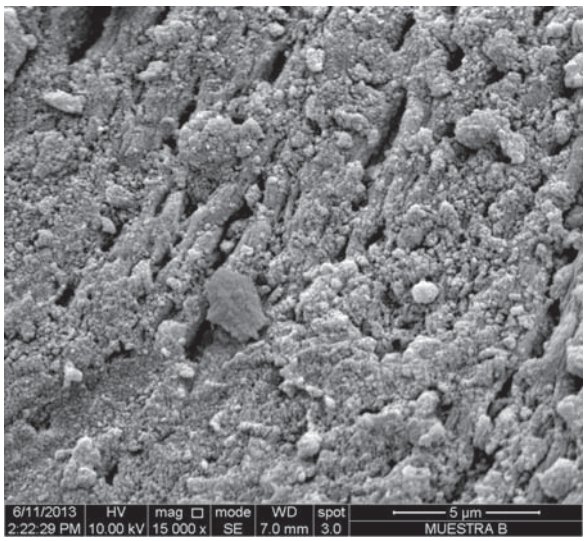
The following SEM image corresponds to SCIOGRAFT. Pores between 118 and 410 µm



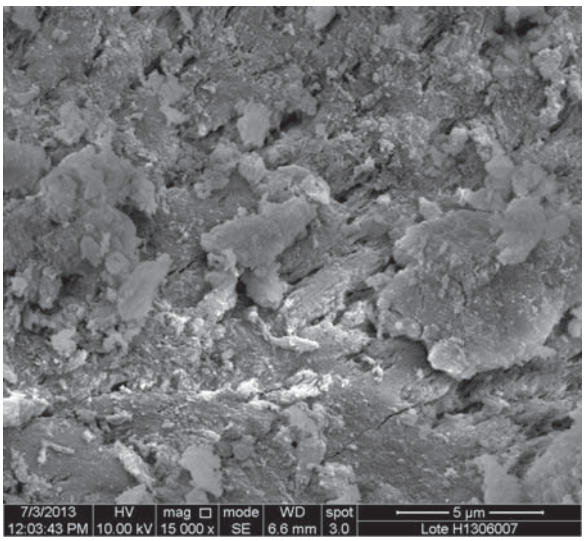
Magnification 250X



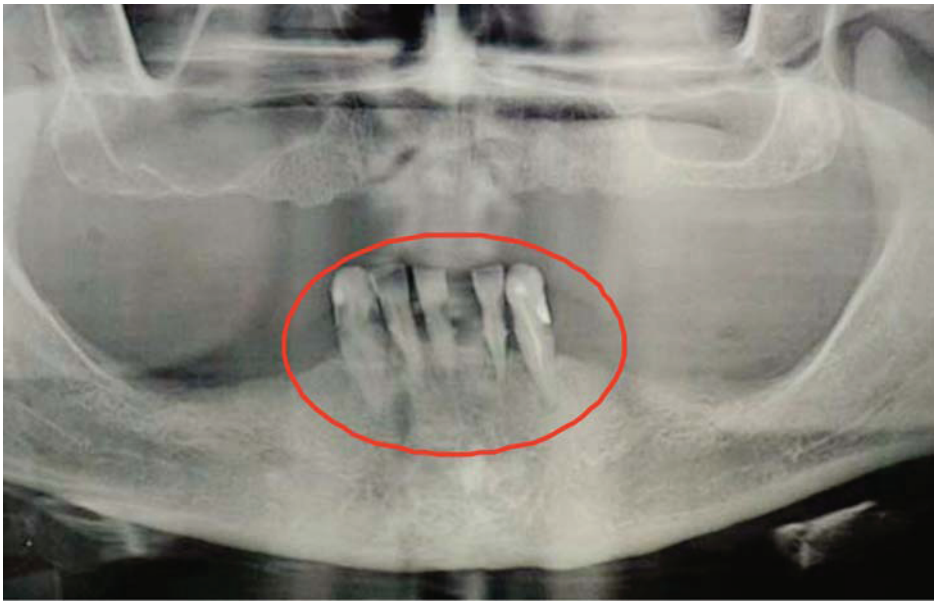
Magnification 8000X



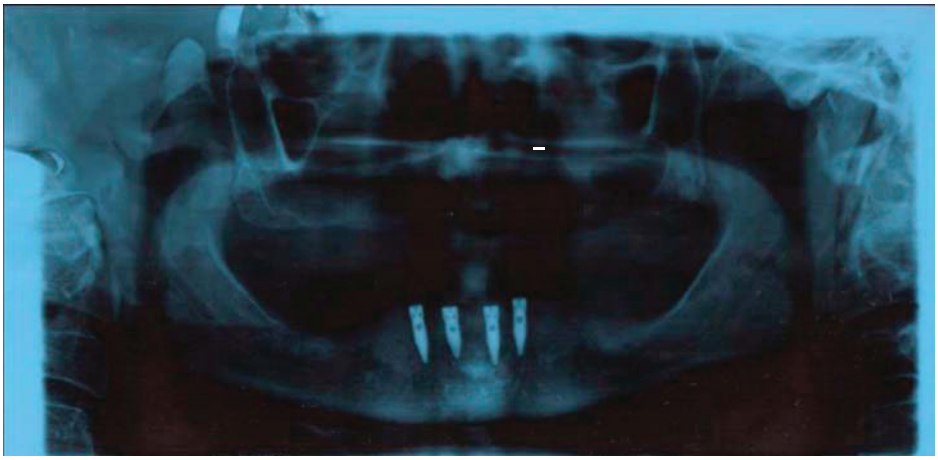
Magnification 15000X



Magnification 15000X

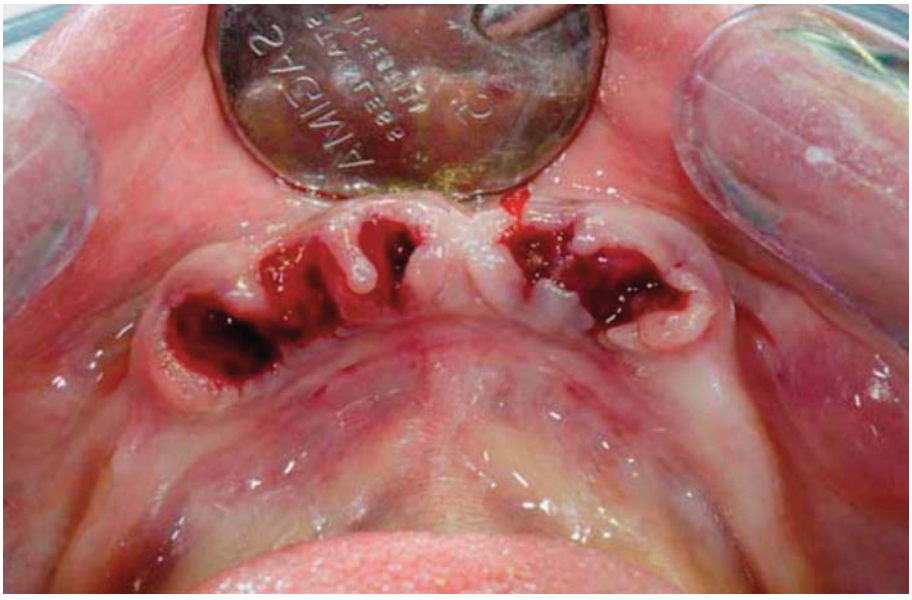


Panoramic Xr pre-surgical. Circle indicates the surgical area.



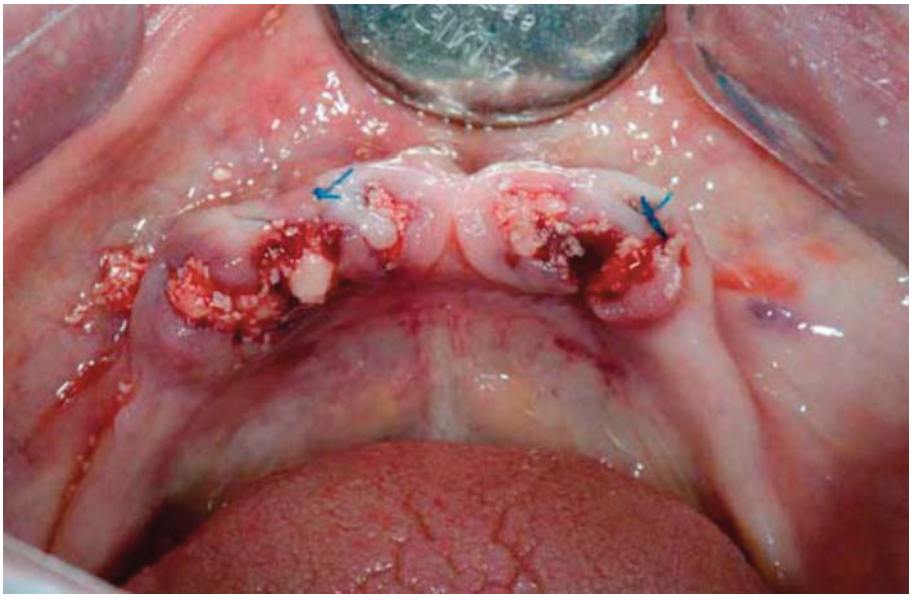
Panoramic Xr, post surgical with implants in place.

Pre surgical photography. Lower teeth to be extracted.



Post extraction sockets.

SCIOGRAFT bovine bone grafting material.



Sockets filled with SCIOGRAFT and suture in place.

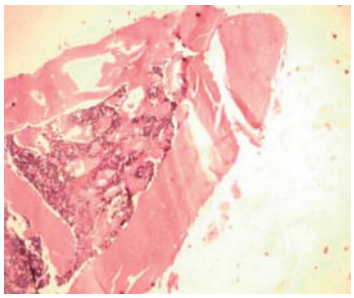
Summary Table

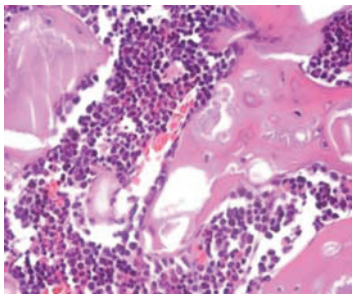
Analyzed Parameter	Granule Size 350-840 microns	Granule Size 840-2000 microns	SCIOGRAFT Block
PH	7.0	7.0	7.0
Pore Distribution	0.7 – 50 µm	0.7 – 50 µm	0.7 – 50 µm
Surface Area	93,0 m^2/g +/-2 m^2/g	99,5 m^2/g +/-2 m^2/g	107 m^2/g +/-2 m^2/g
External Surface Area	93,0 m^2/g	95,0 m^2/g	109,0 m^2/g
Mesopore surface area	140 m^2/g	116,0 m^2/g	151,0 m^2/g
Pore Size	0.0154 µm	0.0144 µm	0.0120 µm
Total Pores Volume	0,36 cm^3/g	0,36 cm^3/g	0,32 cm^3/g
Interconnectivity	100%	100 %	100%
% Open Porosity	53%		
% Total Porosity	48%		
Obteined Density	3.42 g/cm^3 +/-0.1 g/cm^3.		

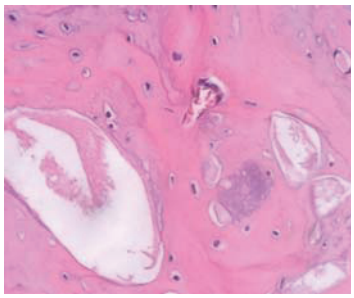
EXPERIMENTAL STUDIES

1) Rats

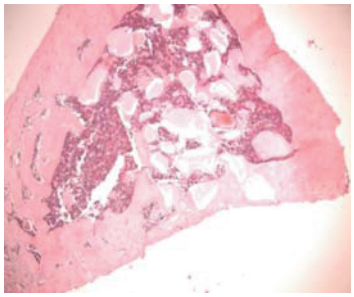
SCIOGRAFT

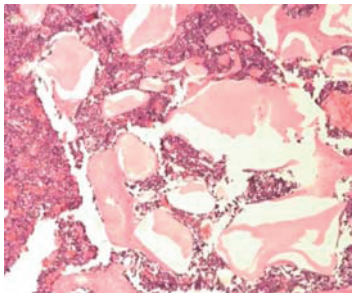

A

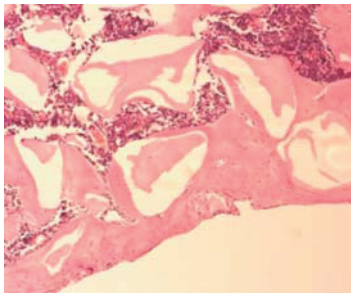

B


C

BIO OSS


D


E


F

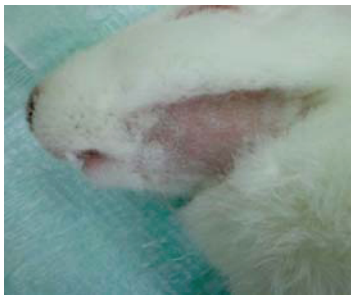
Histological observations of bone defects filled with SCIOGRAFT (A, B and C) and Bio-Oss (D, E, and F).
A and D. Cortical and medullary section.
B and E. bone marrow. Arrows indicate the presence of SCIOGRAFT/ bio-oss
C and F. Cortical. Arrows indicate negative images that where occupied with SCIOGRAFT (B and C) and Bio-Oss (E and F) and the laminar bone tissue surrounding them.

Cross-sections of tibiae shows negative images of different sizes in the thickness of cortical bone, where the deffect was made to incorporate each biomaterial, integrating to the process of bone healing.

Multiple negative images of different shapes and sizes surrounded by laminar bone tissue can be observed in the medullary space which indicates that the both bone substitutes are osteoconductive.

No signs of inflammation were observed which indicates biological acceptability (Figure 5 A, B, C, D, E and F).

2) Rabbits



A

B

C

D

E

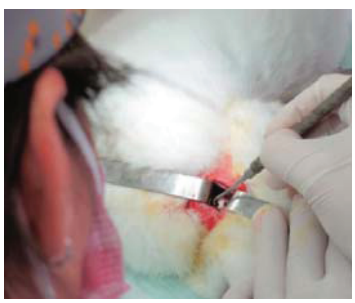
F

G

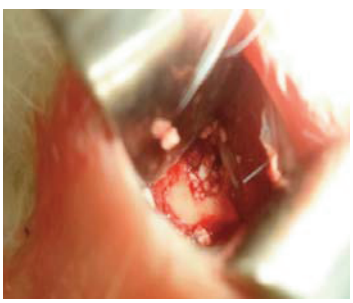
H

I

J

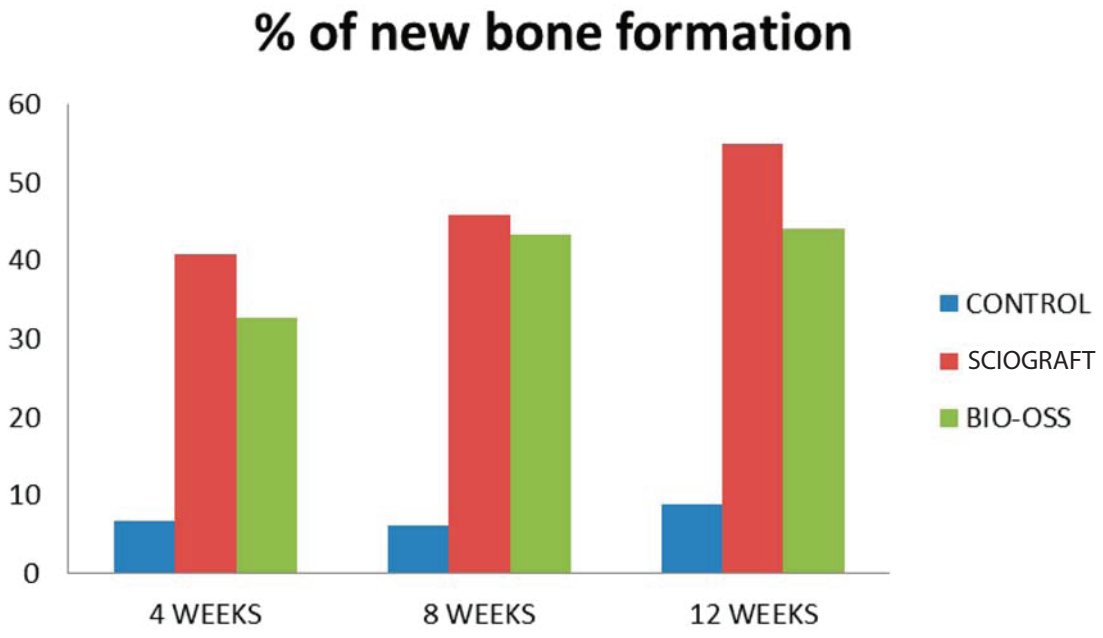


K

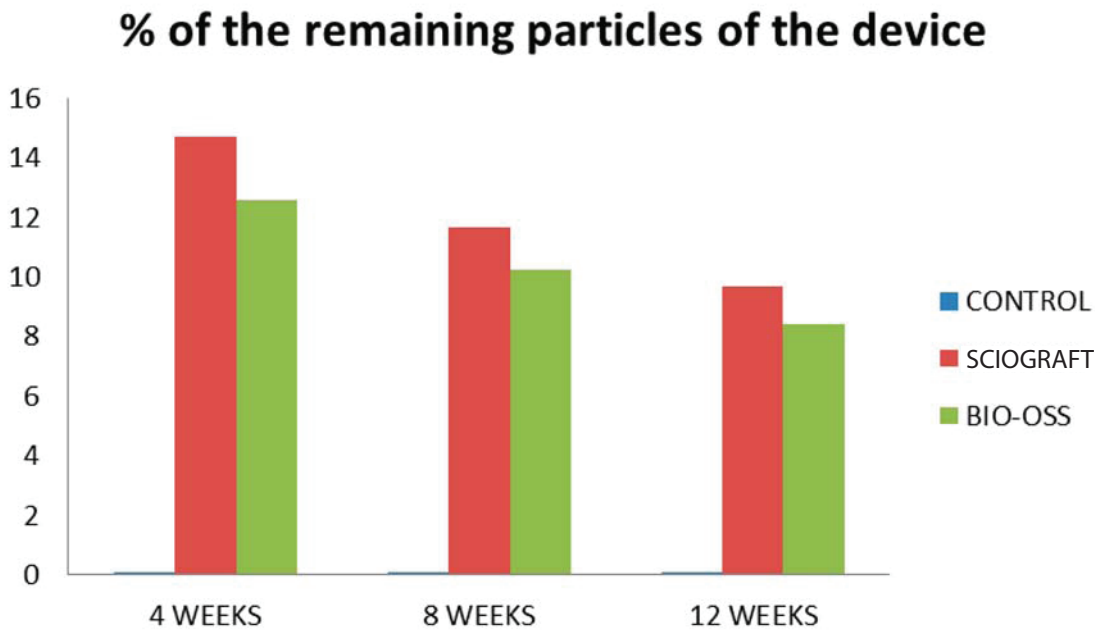


L

HISTOMORPHOMETRIC RESULTS



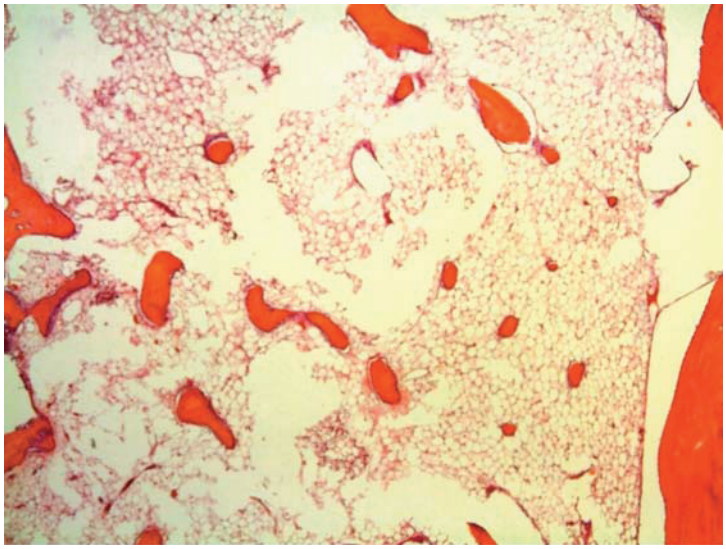
New bone formation plot for SCIOGRAFT and Bio-Oss at different end-points.



Remaining of the particle of the bone grafts (SCIOGRAFT and Bio-Oss) at different end-points.

For both SCIOGRAFT and Bio-Oss, a trend was observed to increase bone volume as a function of time.

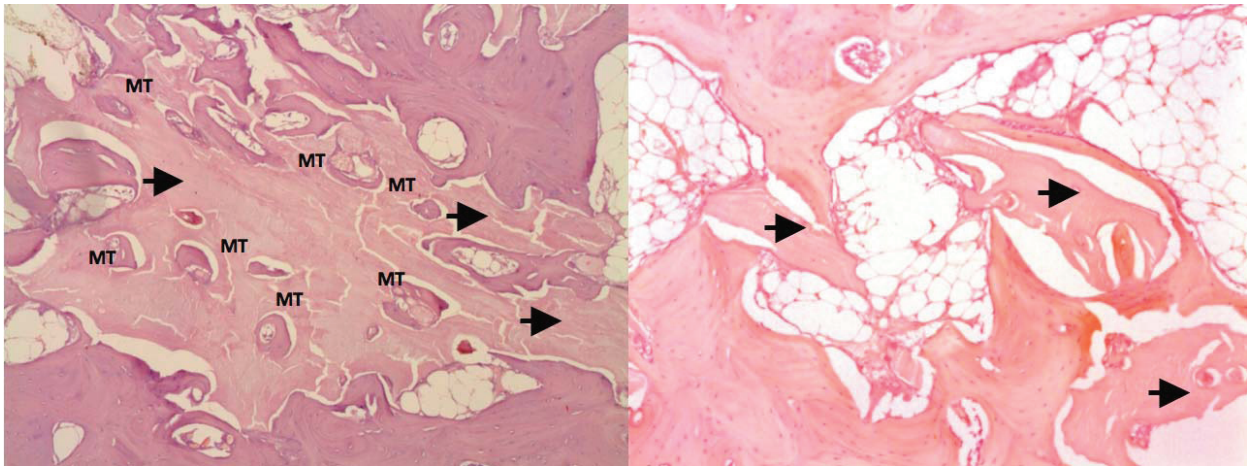
CONTROL



Control bone deffect. Magnification: 4x, (H-E)

4 WEEKS

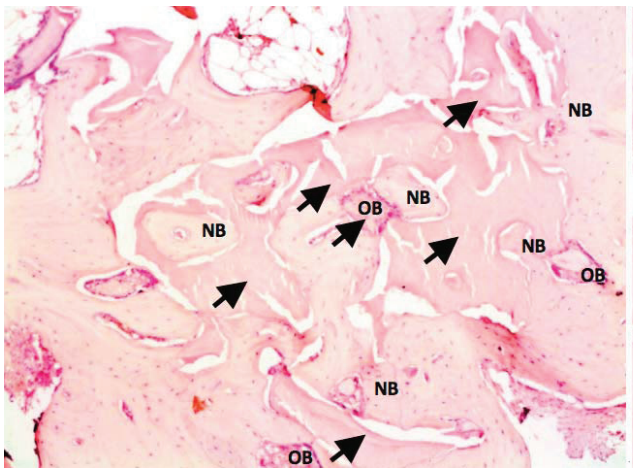
SCIOGRAFT BIO-OSS



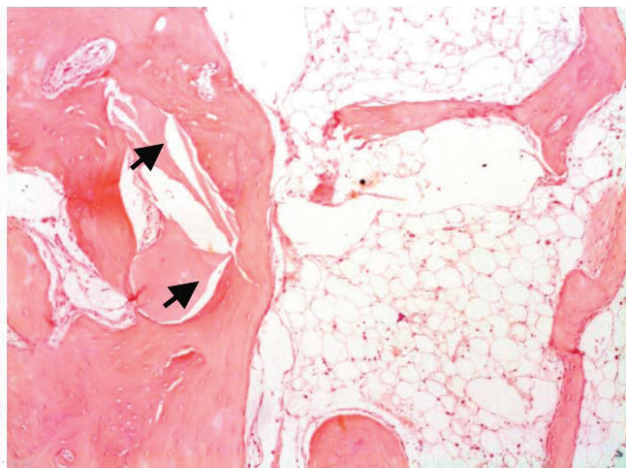
S: Arrows indicate SCIOGRAFT bovine bone graft particles. Newly formed bone micro trabeculae (MT). (10x, H-E)
B: Arrows indicate Bio-Oss bovine bone graft particles. Newly formed bone micro trabeculae (MT). (10x, H-E)

8 WEEKS

SCIOGRAFT



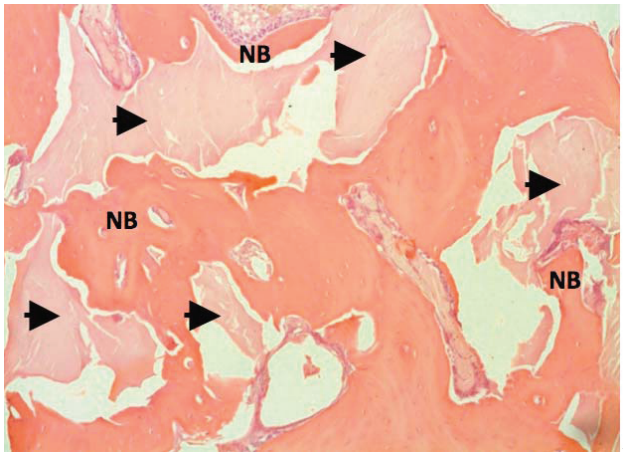
BIO-OSS



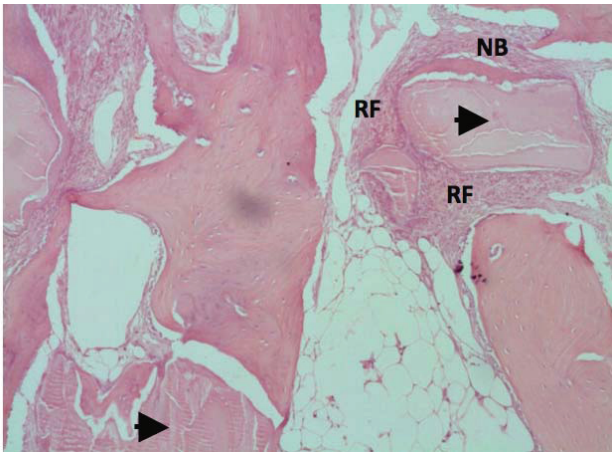
S: Arrows indicate SCIOGRAFT particles. NB: new bone formation foci, OB: osteoblasts. (10x, H-E).
B: Arrows indicate Bio-Oss particles. (10x, H-E).

12 WEEKS

SCIOGRAFT



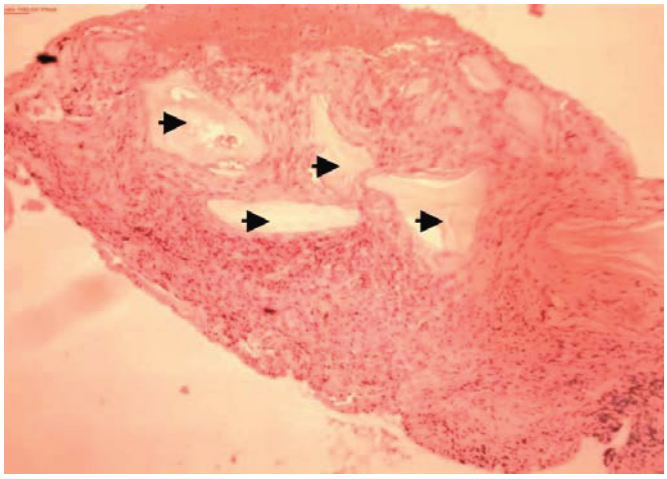
BIO-OSS



S: Arrows indicate SCIOGRAFT. Newly formed bone trabeculae (NB). (10x, H-E)
B: Arrows indicate Bio-Oss. Presence of reparative fibrous tissue (RF) . Newly formed bone trabeculae (NB). (10x, H-E)

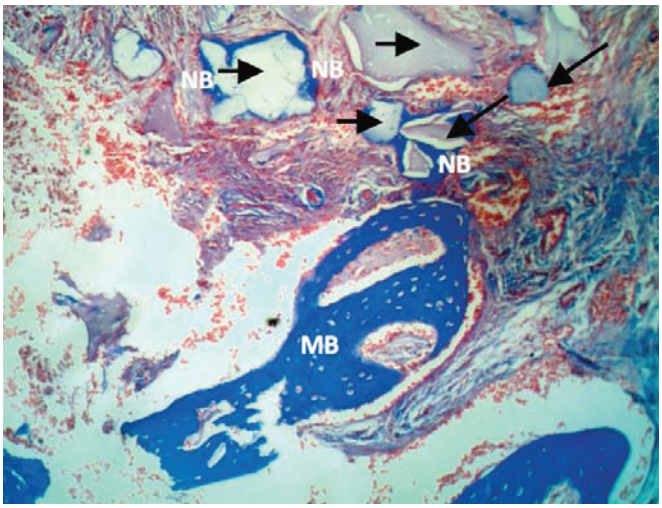
HUMAN CLINICAL CASES AND BIOPSIES

Clinical case I - 15 days



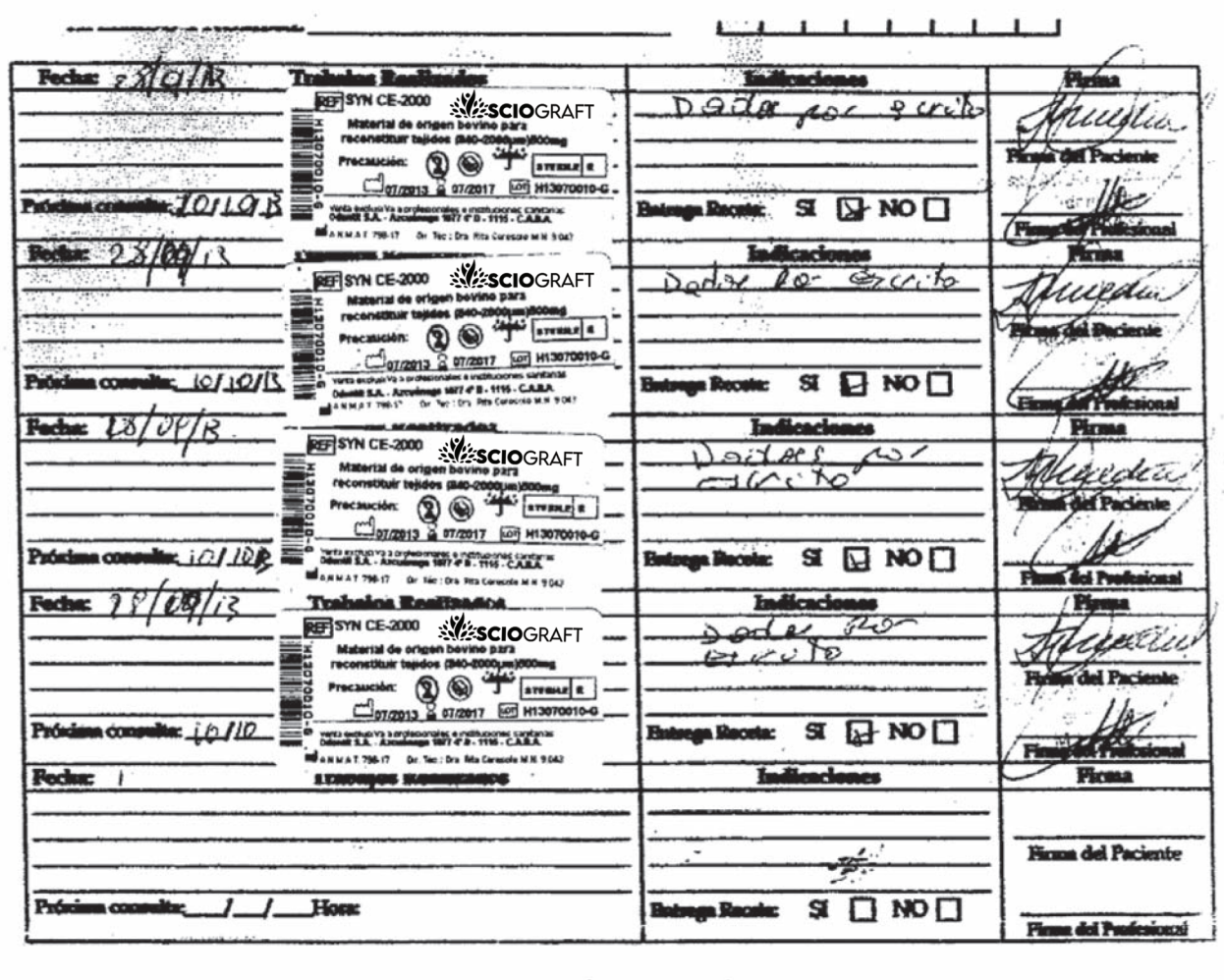
Photomicrography of a post-extraction socket filled with SCIOGRAFT. Cross-setional cut. Magnification: 10xHematoxilin- eosin. SCIOGRAFT deposit (Arrows).

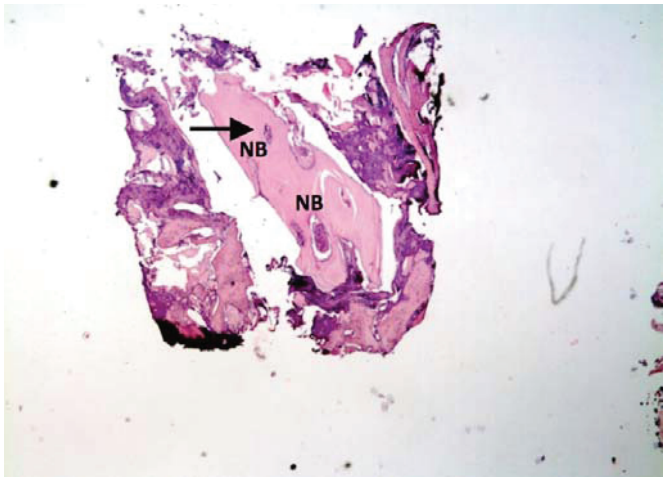
Clinical Case II - 90 days



Photomicrography of peri-implant defect filled with SCIOGRAFT. Cross-setional cut. Magnification: 10x, Masson´s trichrome and anilin blue. Presence of bone neotrabeculae (NB). SCIOGRAFT deposit (Arrows) and mature trabecular bone (MB).

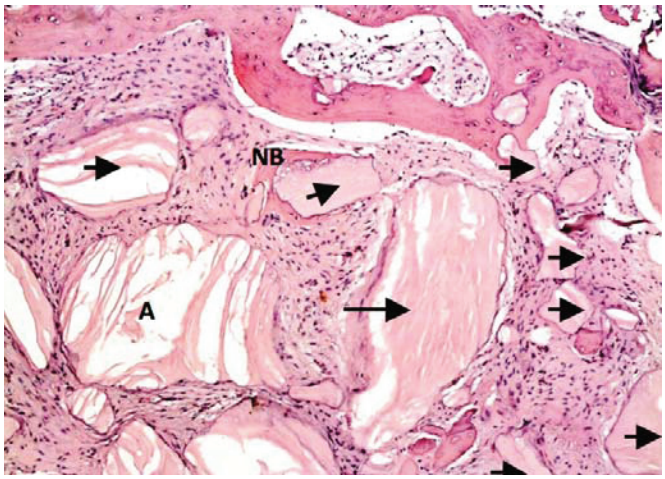
Clinical Case III - 110 days



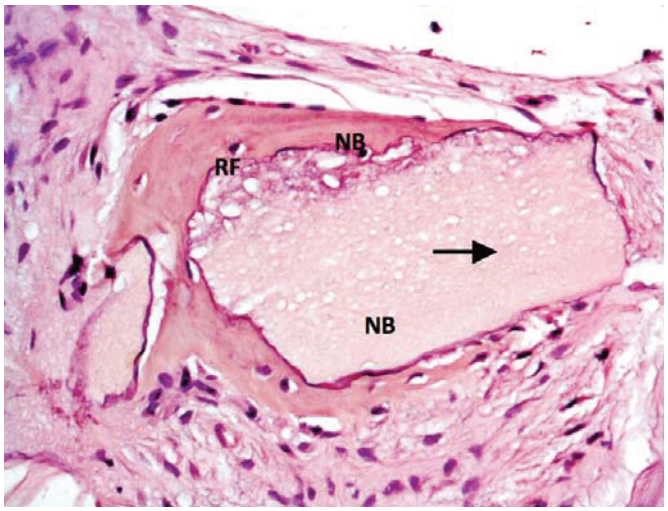


Arrows indicate SCIOGRAFT graft and NB the presence of neoformation foci. (4x, H-E).

P.32

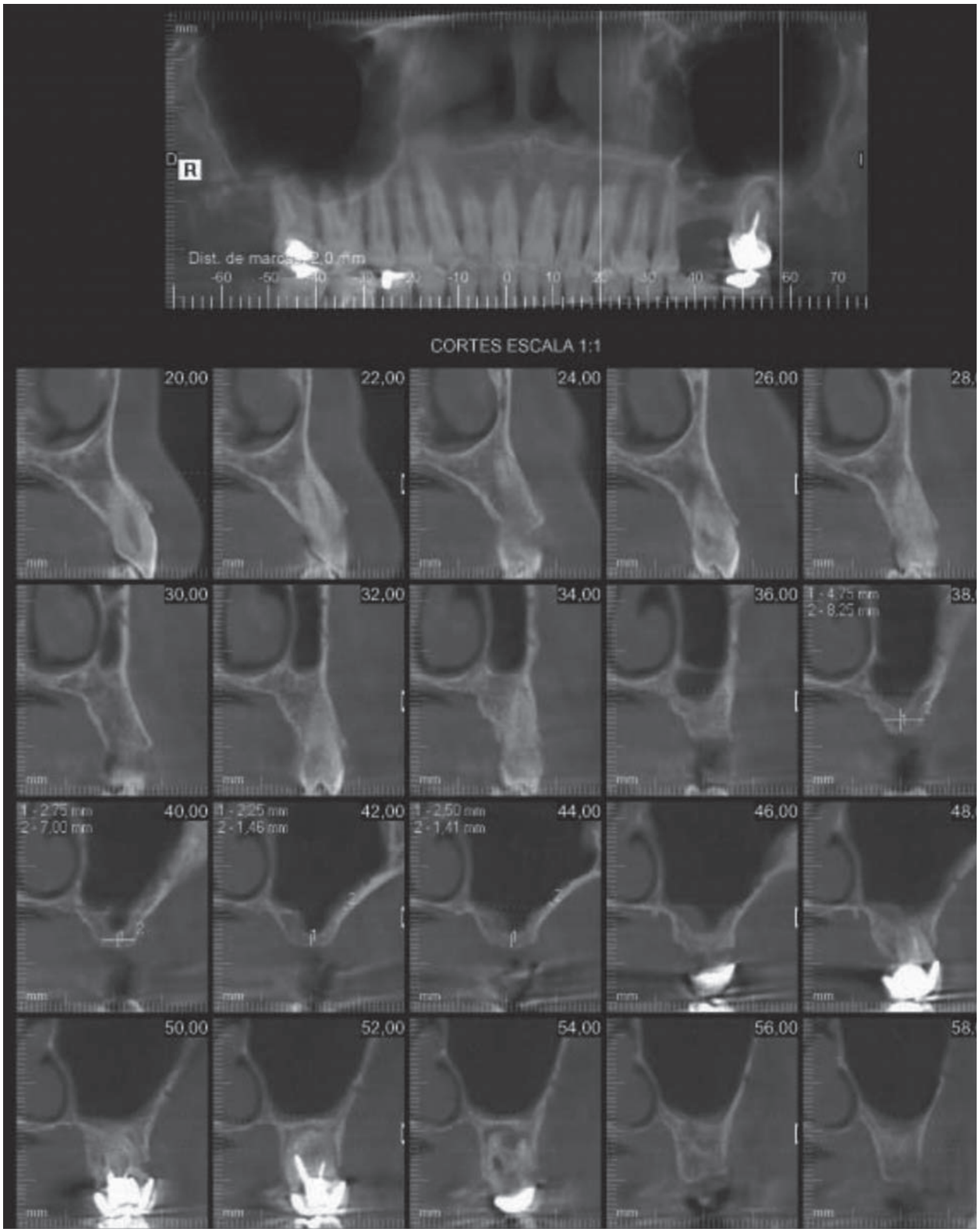


Arrows indicate SCIOGRAFT graft. Presence of new bone trabecula (NB), SCIOGRAFT deposit witn lamellar artifact (A). 10X, H-E.

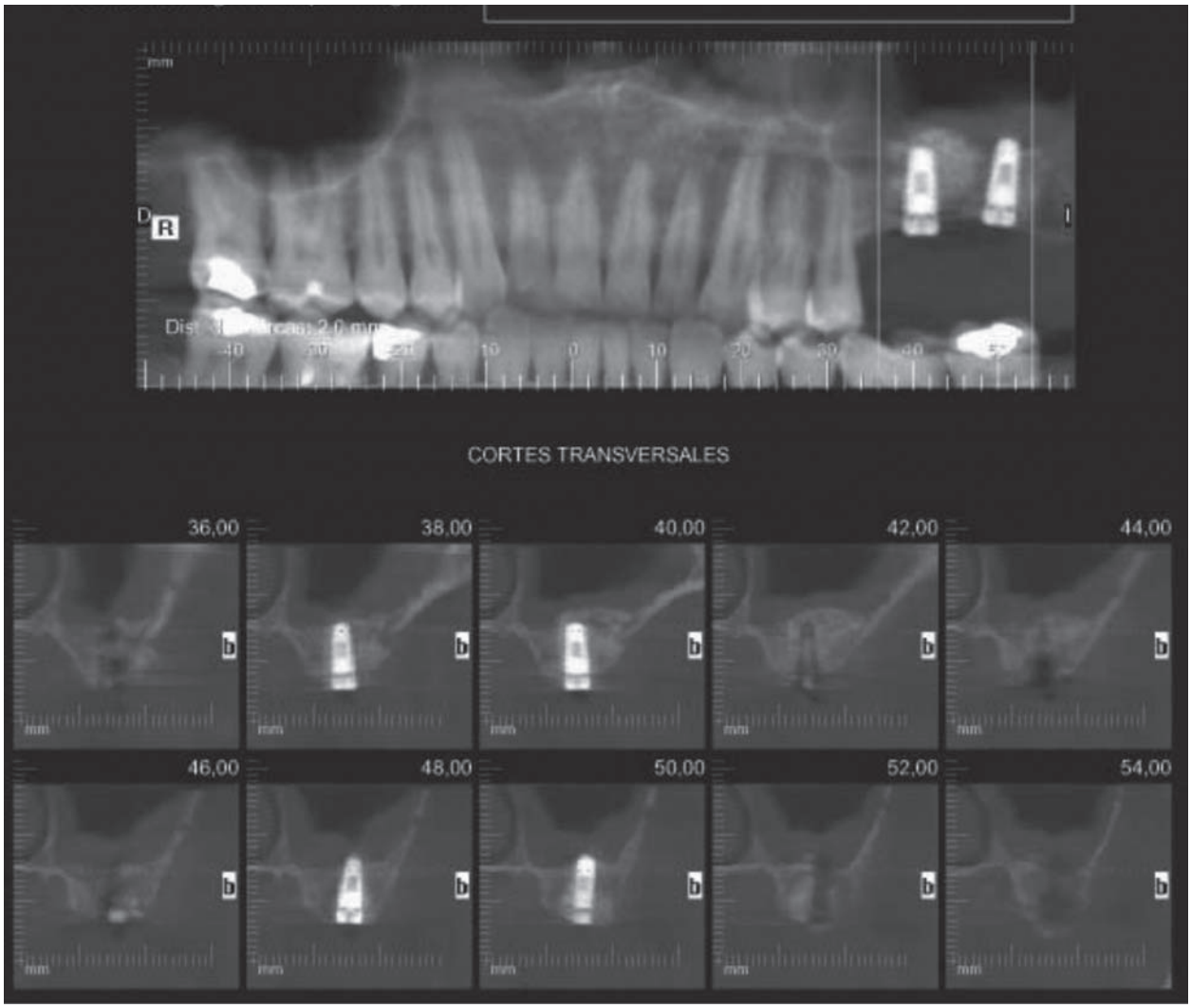


Photomicrography of the previous image. (40x, H-E). Arrows indicate SCIOGRAFT graft. Presence of new bone trabecula (NB), Residual fibrosis area (RF).

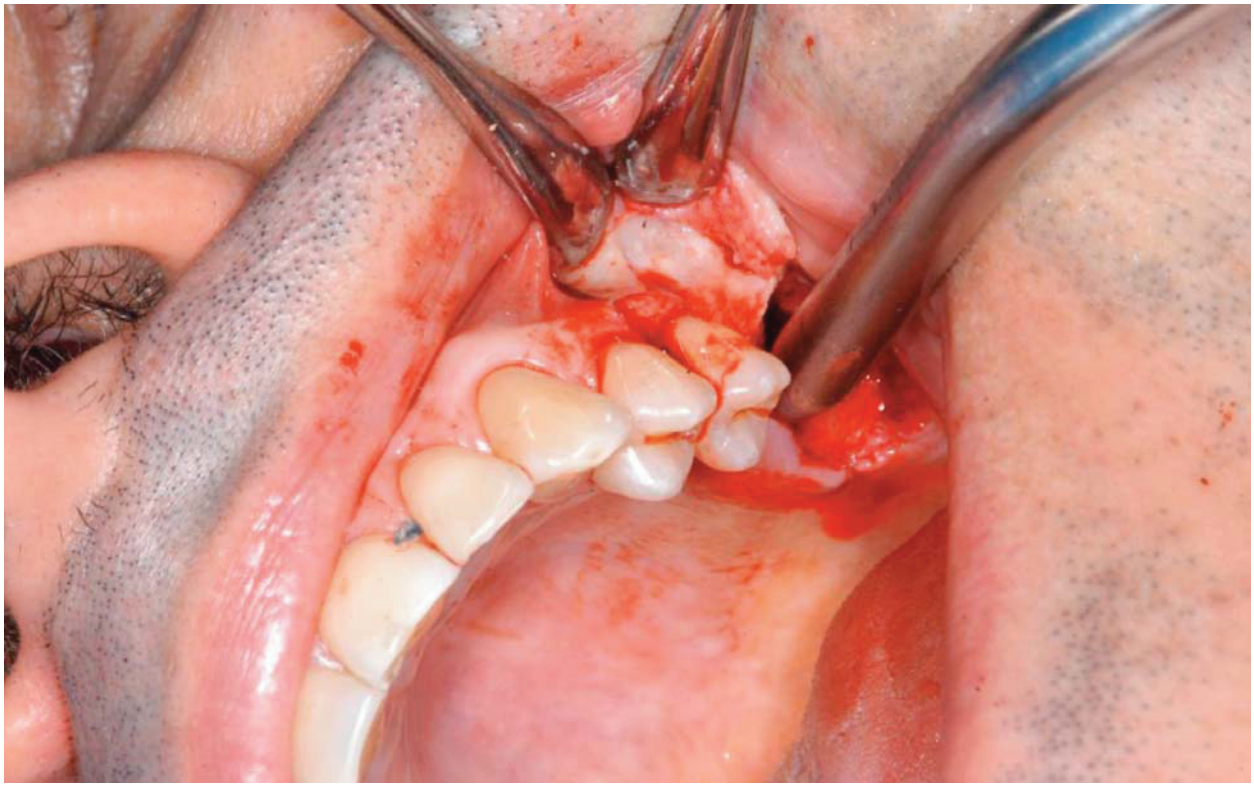
Climical Case IV - 120 days

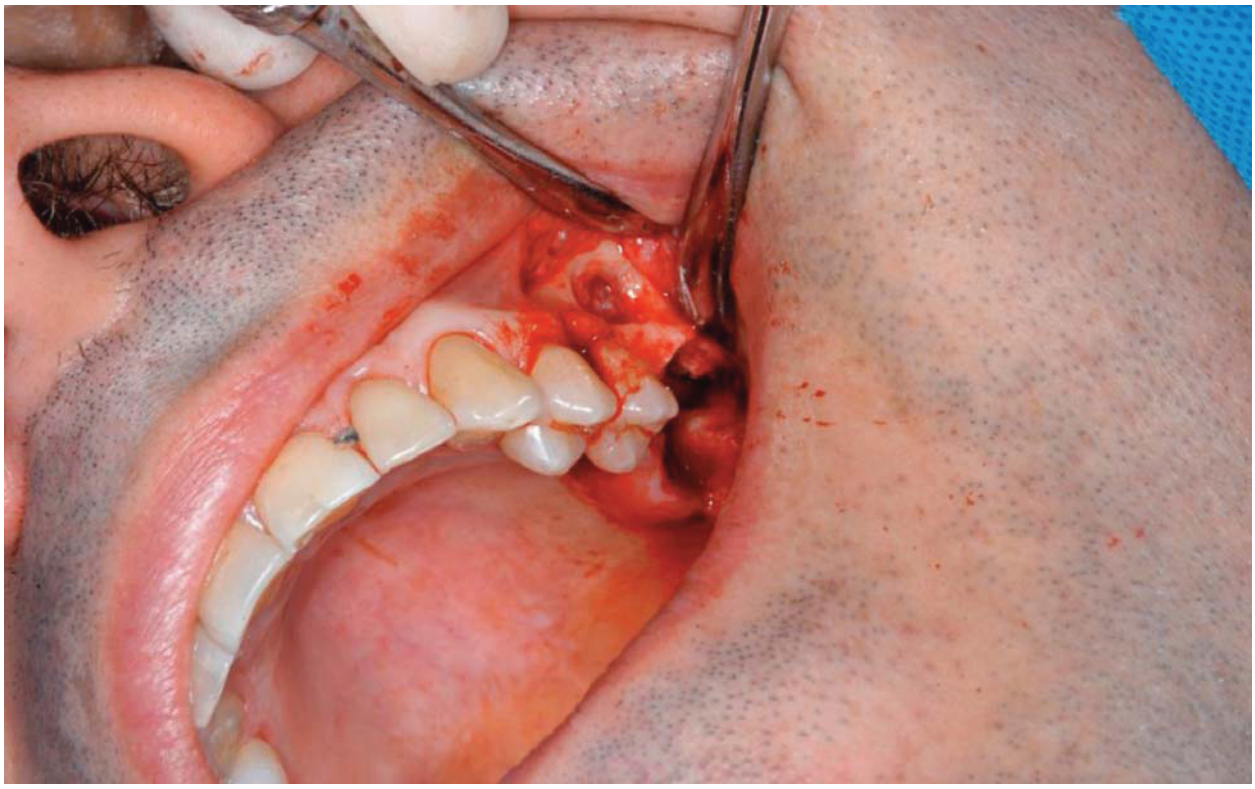


Pre surgical CAT. Circles indicates implantation area.

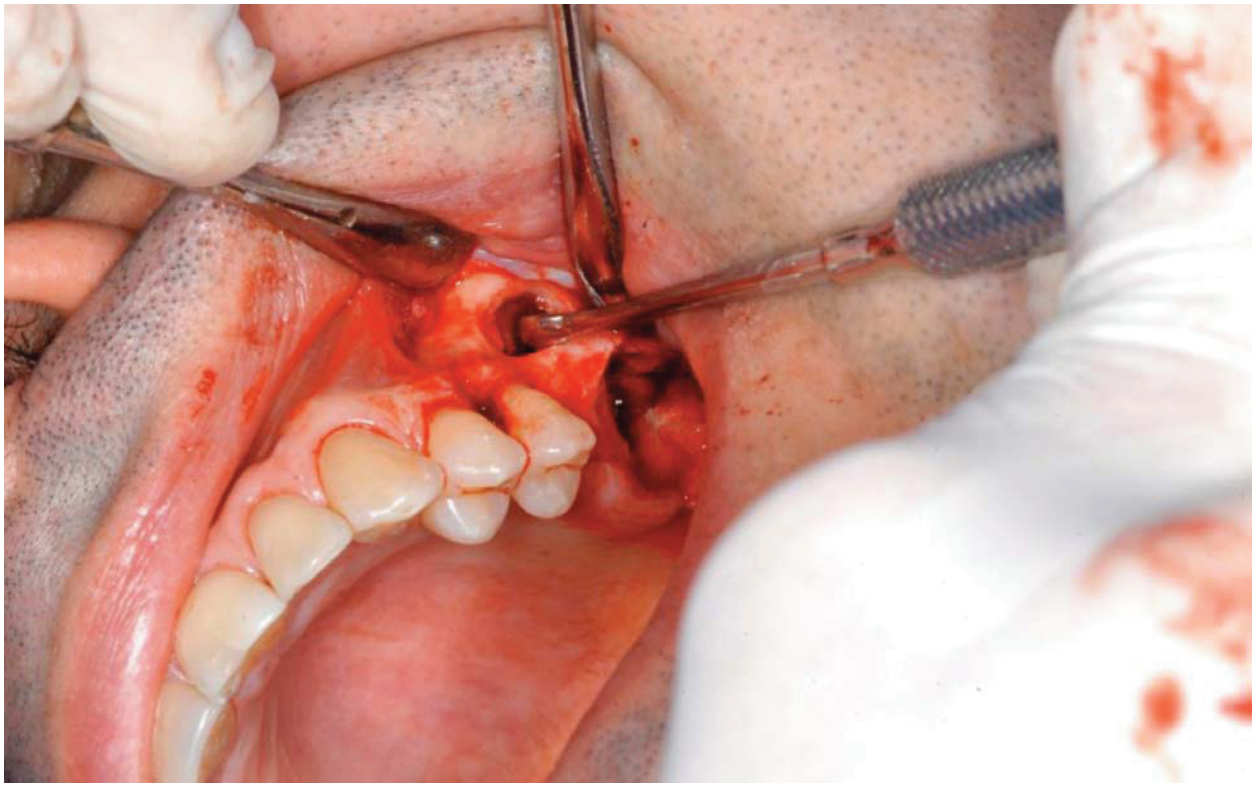


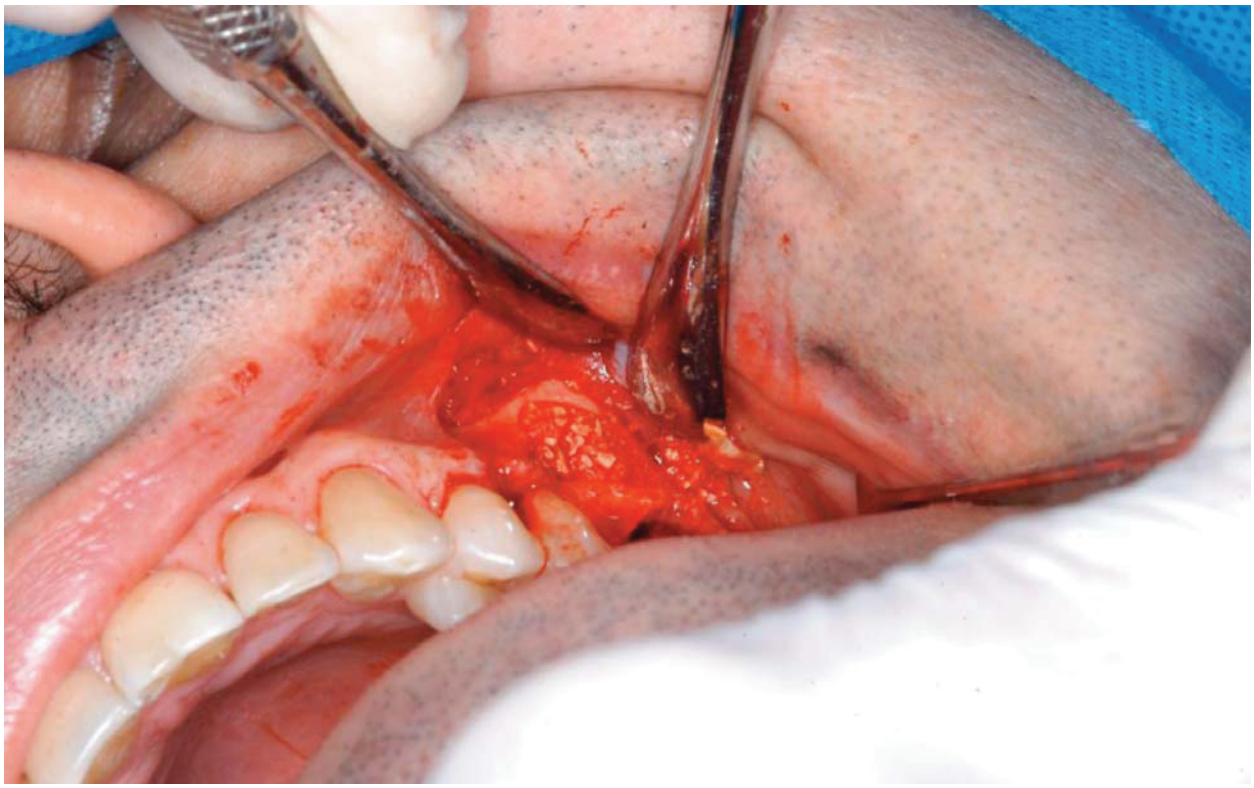
Post surgical CAT showing sinus elevation (left side) and implants placement. Arrows indicates the presence of SCIOGRAFT.



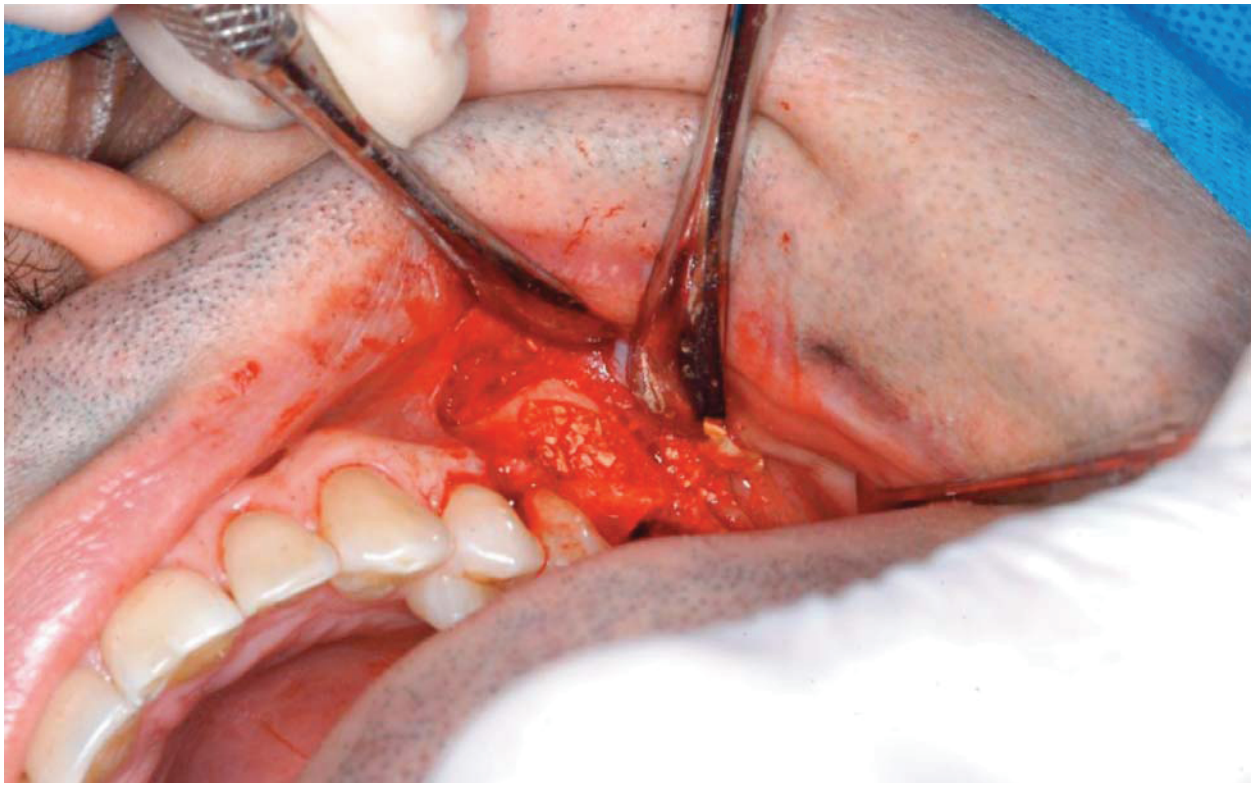


Sinus lifting surgery.

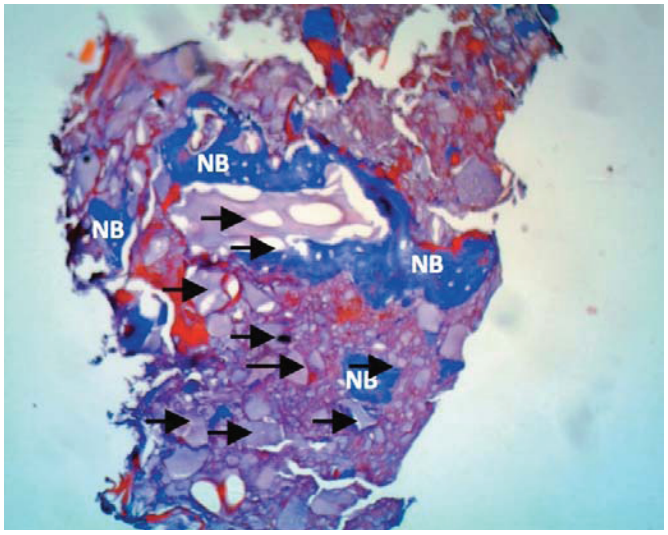




Sinus elevation with SCIOGRAFT grafting material.



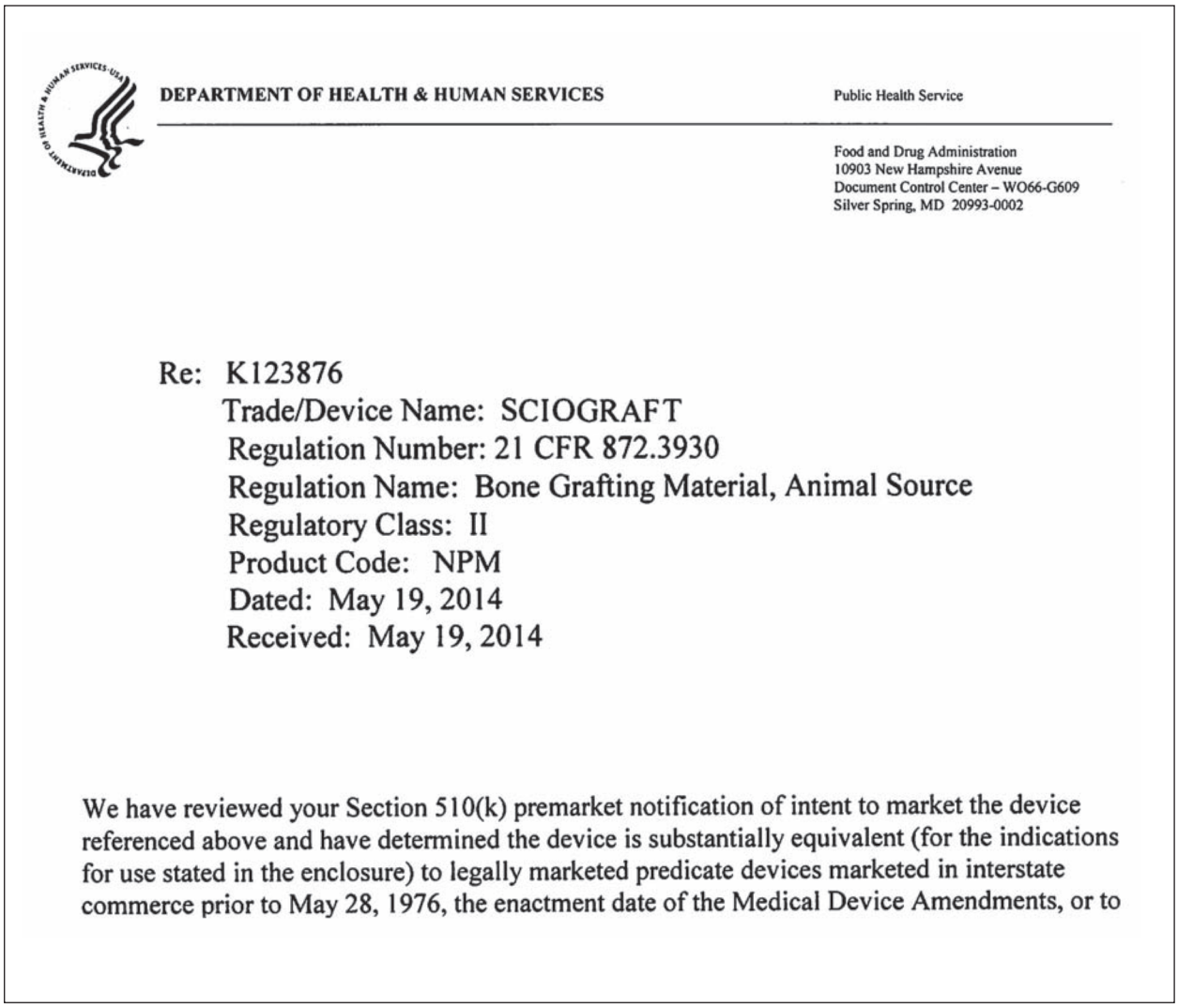
Sinus elevation with SCIOGRAFT grafting material.



Photomicrography of right sinus floor elevation with SCIOGRAFT. Cross-setional cut. (4x, Masson´s trichrome and anilin blue). Arrows indicate SCIOGRAFT deposit. Presence of trabecular bone neoformation (NB).

SUBSTANTIALLY EQUIVALENT

Based upon comparison of the intended use, biocompatibility, sterility, physical and chemical testing, and the performance evaluation of the subject and predicate device in an anatomically relevant animal model, and the results of clinical cases, Odontit concludes that SCIOGRAFT is substantially equivalent to the predicate devices Bio-Oss™ and Equimatrix™.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Re: K123876
Trade/Device Name: SCIOGRAFT
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material, Animal Source
Regulatory Class: II
Product Code: NPM
Dated: May 19, 2014
Received: May 19, 2014

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to

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Date ended: May 2014
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