ARGON
MEDICAL DEVICES & DENTAL IMPLANTS

Scientific Research

Summary of Research Studies

Argon K3Pro™ Dental Implants

QUALITY & DESIGN
MADE IN GERMANY

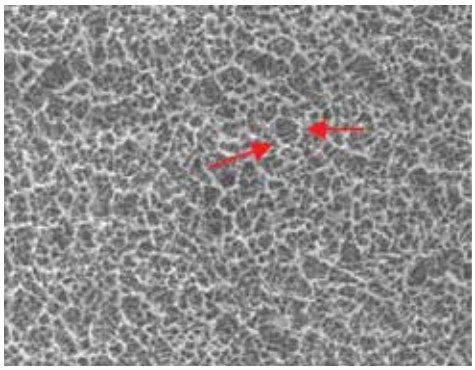
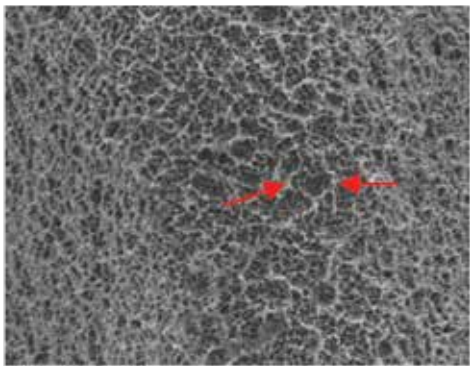
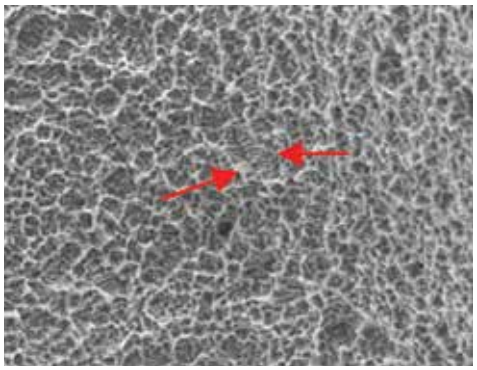
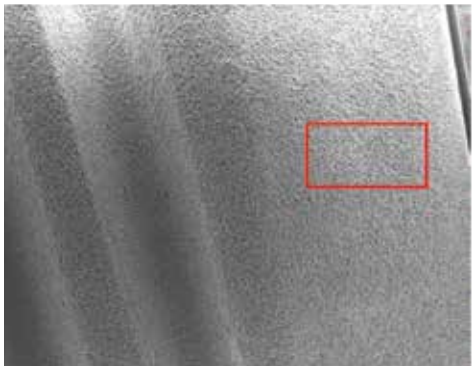
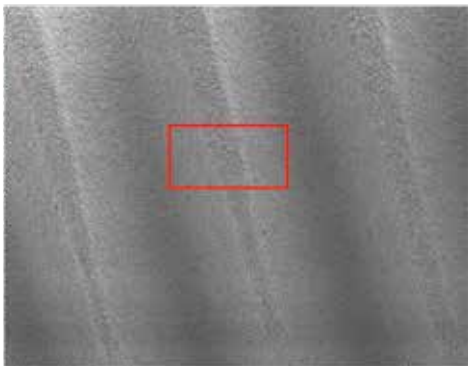
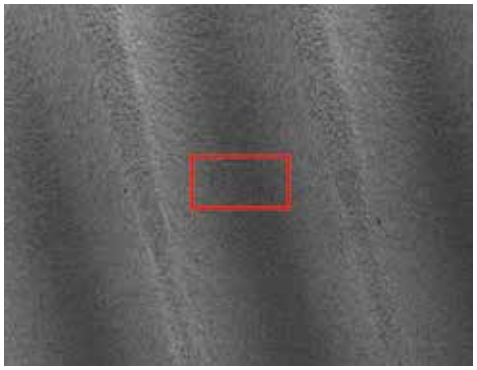
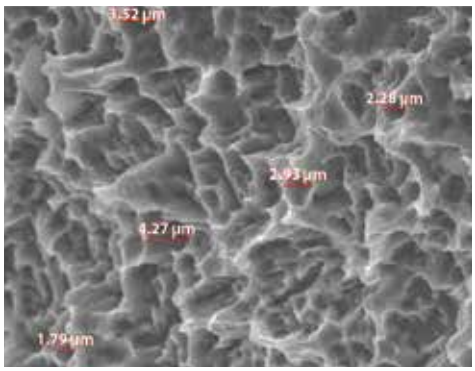
Examining the K3Pro™ Osteoactive Surface[1]

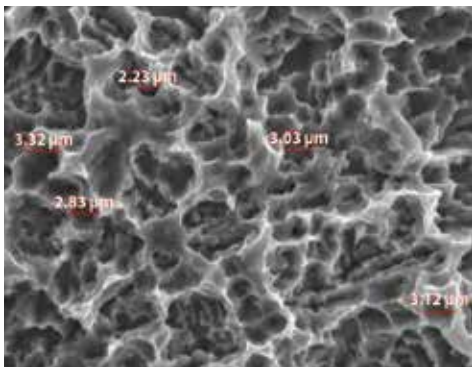
An independent study was completed by the DAP, the German Accreditation System for testing according to DIN EN ISO/IEC 17025:2008.

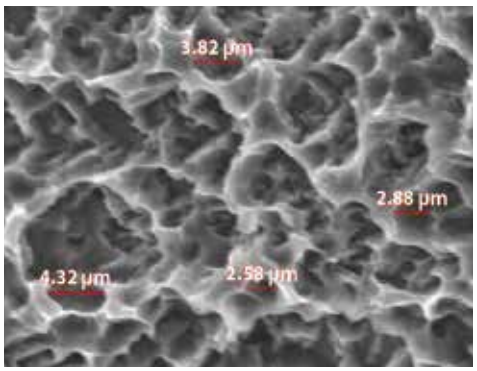
Using a Leitz AMR 1600T Scan Electronic Microscope (SEM) with a voltage of 20 keV, the IGMHS (Examination Laboratory Accredited by the DAP) completed a micro-analysis study of a factory sealed K3Pro™ implant. The chemical composition of the implant surface was analyzed using a Bruker X-Flash-EDX detector which was equipped with a light-element window that allows the detection of elements within an ordinal >=5 (boron). The spectra recording was done in field mode (300s Mz, 3kcps rate of incoming impulses). The pictures were documented using a secondary electron detector.

The implant was examined in three different areas to include:

- Upper area of the angular shoulder
- Middle of the implant on a screw mountain
- Middle of the implant in a screw valley

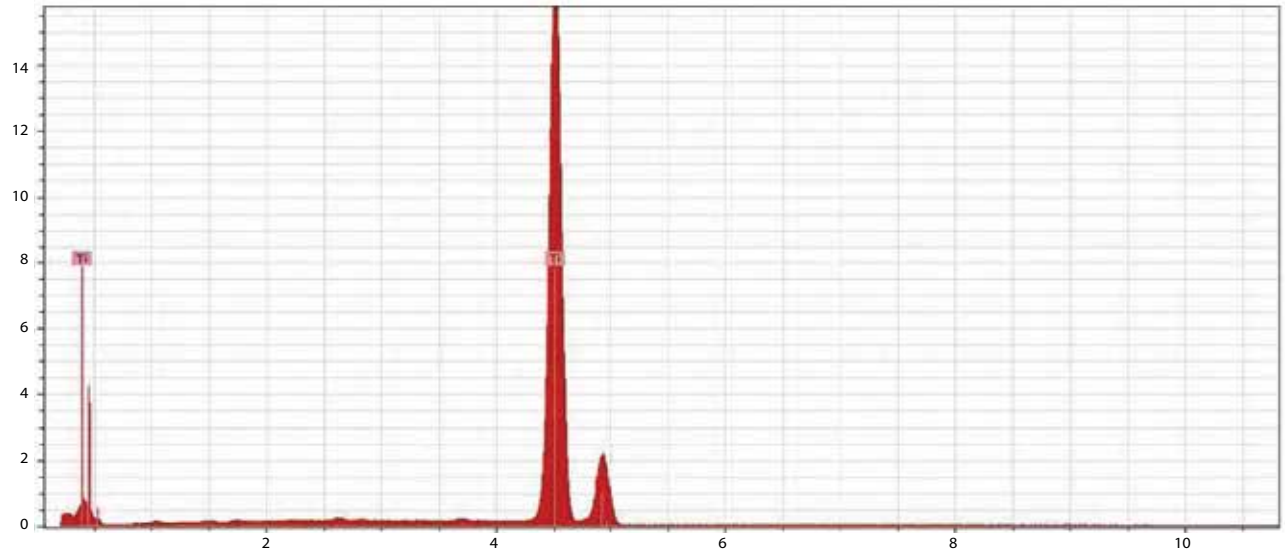




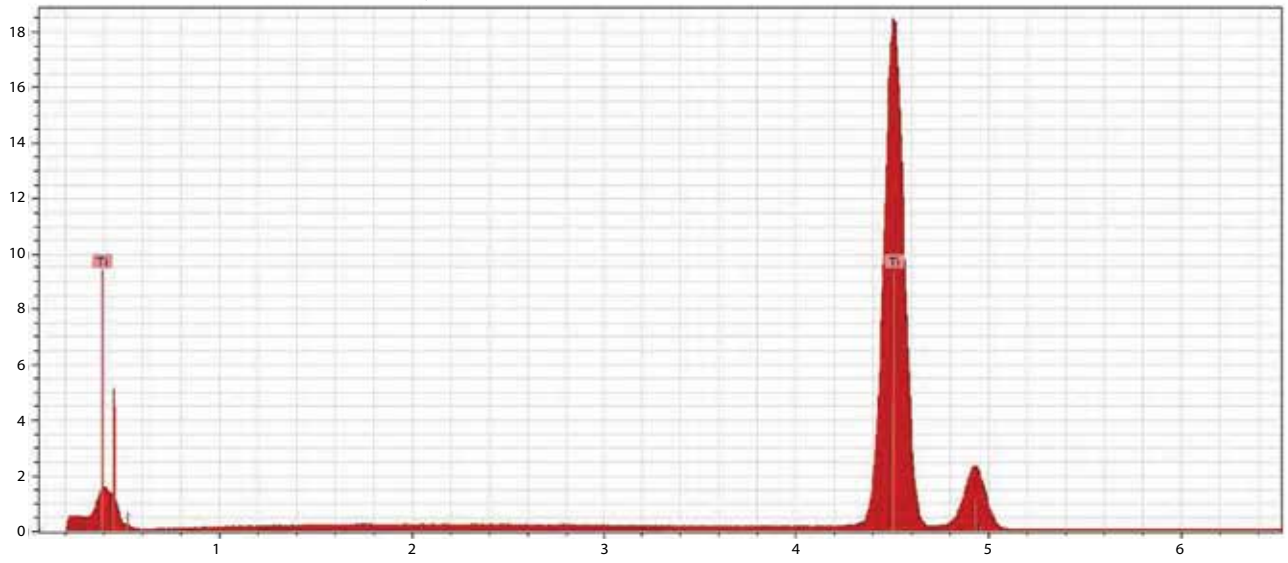
RESULTS

The results of the EDX micro-analysis testing showed that within the ranges of study, no contaminations were found.

EDX - spectrum of an area on the shoulder of the implant



EDX - spectrum of an area in a screw valley in the middle of the implant



1- BEM Implant Study (2014-2015) Quantitative and Qualitative Element-Analysis of Implant-Surfaces by SEM/EDX, Dr. Dirk U. Duddeck, Department of Oral Surgery and Implantology, University of Cologne, Germany. To view the comprehensive study, visit www.argondentalusa.com.

Micro-movement and Micro-pump Effect Analysis of the Implant Abutment Connection [2]

The University of Frankfurt and Main conducted a test analyzing the micro-movement and micro-pump effect for the K3Pro™ implant and abutment. The analysis consisted of simulating implant support molar crowns in the upper jaw, where the abutments were fixed to the implant following the manufacturers requirements. Polyether impression material was then used to duplicate a patient's mucous membrane and placed at the implant-abutment-interface. An opening was created inside the simulated membrane, where x-ray contrast medium was inserted. An x-ray device constantly radiated the sample while the two-dimensional chewing simulator was testing the sample under loads of 25N, 50N, 75N, 100N, 125N, 150N, 175N, and 200N, reporting the results using the following formula: F(t) = i(t) x I x B.

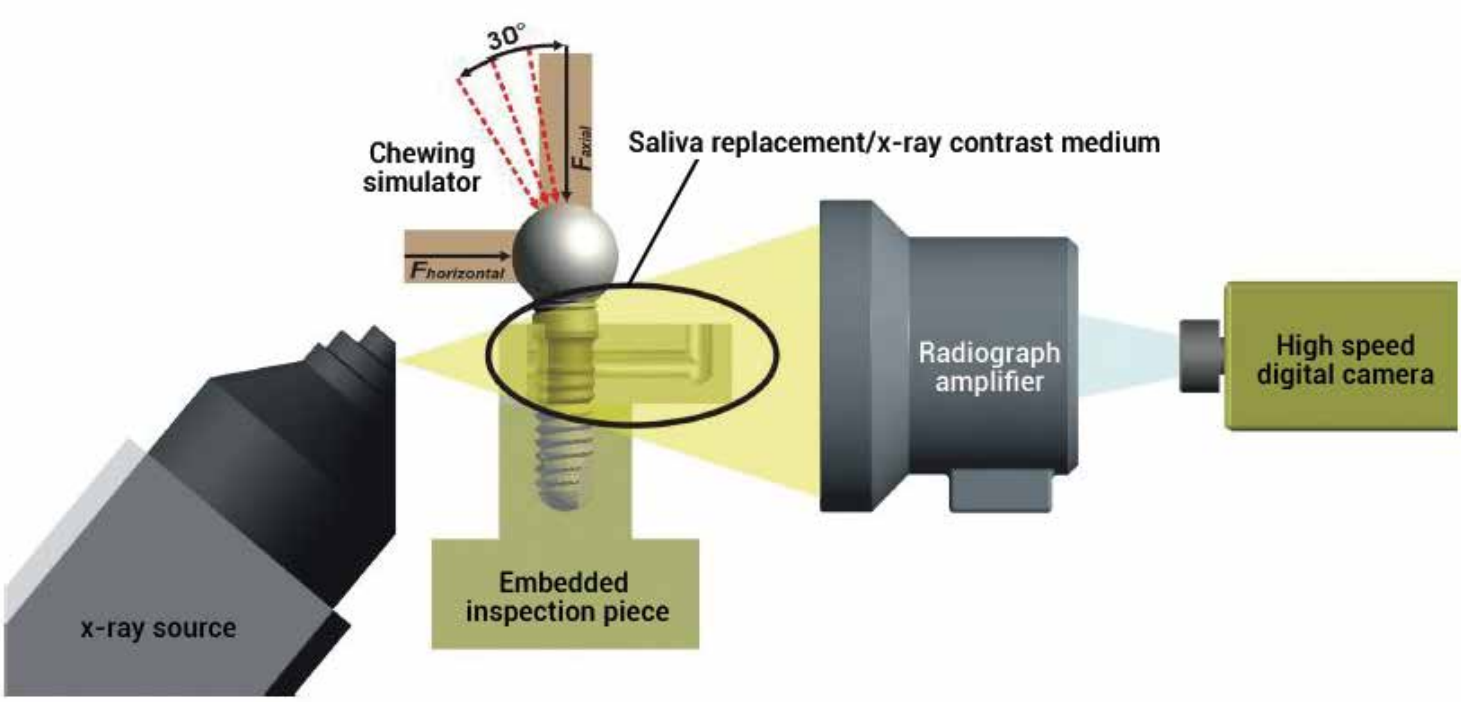
Values:

F(t) = time-independent Force (Lorenz Force)

I (t) - temporarily changeable river [A}

I = effective leader length [mm] B = magnetic flow density [C]

X-ray videos recorded the transformation of the x-ray into visible light.



RESULTS

This process was repeated five times, testing the implant under various loads. The results of the in vitro study show that between the tested implant and abutment, no micro-gap and micro-pump effect exists.

Micro-gap Konus K3Pro®					
Load	Inspection piece 1	Inspection piece 2	Inspection piece 3	Inspection piece 4	Inspection piece 5
25N	no space 550	no space 560	no space 555	no space 550	no space 545
50N	no space 760	no space 765	no space 760	no space 770	no space 760
75N	no space 995	no space 995	no space 940	no space 960	no space 950
100N	no space 1050	no space 1060	no space 1055	no space 1060	no space 1060
125N	no space 1190	no space 1185	no space 1195	no space 1185	no space 1180
150N	no space 1385	no space 1380	no space 1390	no space 1380	no space 1380
175N	no space 1590	no space 1580	no space 1595	no space 1590	no space 1590
200N	no space 1745	no space 1745	no space 1780	no space 1760	no space 1765

Micro-pump effect Konus K3Pro®					
Load	Inspection piece 1	Inspection piece 2	Inspection piece 3	Inspection piece 4	Inspection piece 5
25N	no micro-pump-effect 545	no micro-pump-effect 565	no micro-pump-effect fect 550	no micro-pump-effect 555	no micro-pump-effect 560
50N	no micro-pump-effect 770	no micro-pump-effect 755	no micro-pump-effect 760	no micro-pump-effect 750	no micro-pump-effect 750
75N	no micro-pump-effect 965	no micro-pump-effect 945	no micro-pump-effect 960	no micro-pump-effect 955	no micro-pump-effect 950
100N	no micro-pump-effect 1060	no micro-pump-effect 1065	no micro-pump-effect 1050	no micro-pump-effect 1045	no micro-pump-effect 1055
125N	no micro-pump-effect 1180	no micro-pump-effect 1195	no micro-pump-effect 1180	no micro-pump-effect 1185	no micro-pump-effect 1190
150N	no micro-pump-effect 1385	no micro-pump-effect 1375	no micro-pump-effect 1385	no micro-pump-effect 1390	no micro-pump-effect 1385
175N	no micro-pump-effect 1580	no micro-pump-effect 1570	no micro-pump-effect 1585	no micro-pump-effect 1575	no micro-pump-effect 1580
200N	no micro-pump-effect 1740	no micro-pump-effect 1760	no micro-pump-effect 1775	no micro-pump-effect 1750	no micro-pump-effect 1760

2- Examination Report PB-Nr. 242-09 (2009) Examination of a Subtractive Surface K3Pro Implant Osteoactive Surface 4.5 x 11mm, Dr. –Ing. G. Horn-Samodelkin, Examination laboratory accredited by the DAP, German Accreditation System for Testing according to DIN EN ISO/IEC 17025:2008. - To view the comprehensive study, visit www.argondentalusa.com.

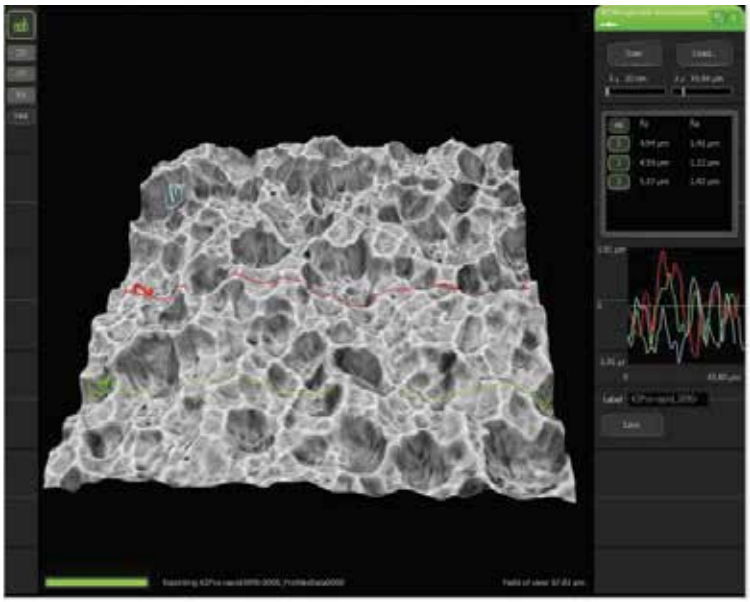
Quantitative and Qualitative Element-Analysis of Implant-Surfaces by SEM and EDX[3]

In 2008, The University of Cologne, Germany and the European Association of Dental Implantology performed a study on 23 different titanium implant systems, testing the implant surfaces of several manufacturers to ensure the manufacturing quality of a product. The tested implants showed isolated and/or extensive deposits. Depending on the manufacturing process, accumulations of organic material (carbon) or inorganic material like aluminum, silicon, phosphor, sulfur, chlorine, potassium and calcium were found.

In 2011-2012, they repeated the same process testing 57 dental implants, some of which had been tested in 2008. Although some manufacturers have made substantial improvements since the first survey in 2008, the 2011-2012 study singled out a few implants with larger areas of surface blasting residue and selective organic impurities.

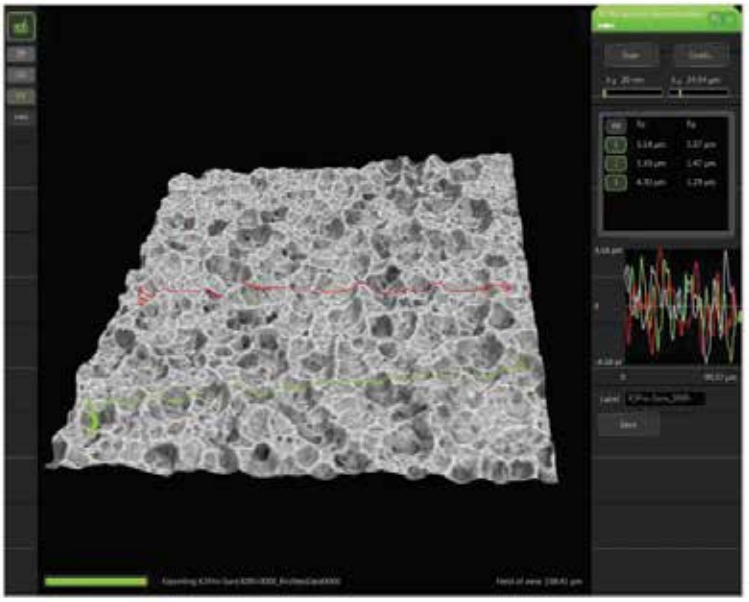
In 2014-2015, the Argon K3Pro™ Rapid and Sure implants were tested. Each tested implant was taken out of the implant package with a sterile forceps and was tested using a scanning electron microscopy (SEM) and energy dispersive x-ray spectroscopy (EDX). The SEM evaluates the topical implant surface by generating images in compositional and topographical mode to a magnification of 20.000x. The Energy Dispersive X-ray Spectroscopy (EDX) analyzes the X-rays generated by the electrons of the electron beam while they are interacting with the sample, producing specific X-ray peaks.

Argon - Konus K3Pro™ RAPID (R-line) Implant



3D Roughness Reconstruction

Argon - Konus K3Pro™ SURE (S-line) Implant

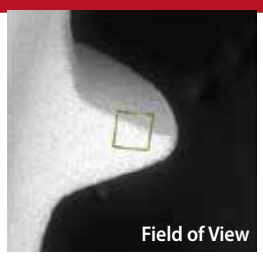


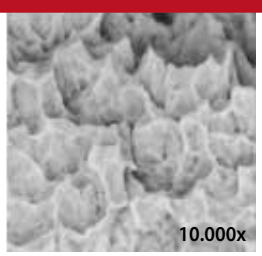
3D Roughness Reconstruction

Surface Topography

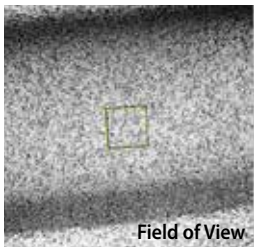
K3PRO™ RAPID

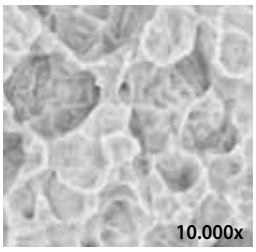
Thread



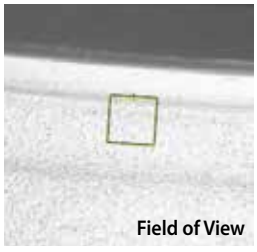


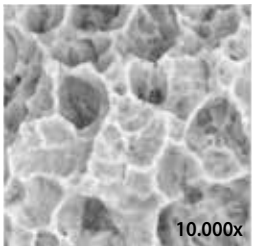
Body





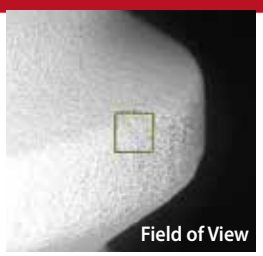
Shoulder

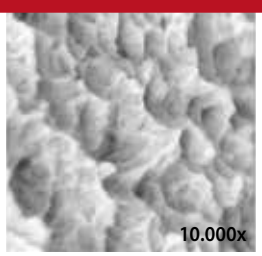




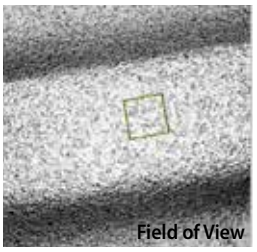
K3PRO™ SURE

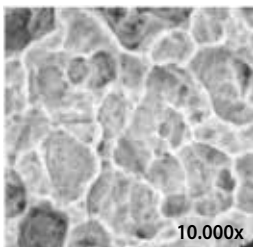
Thread



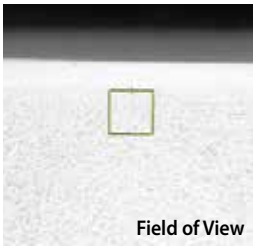


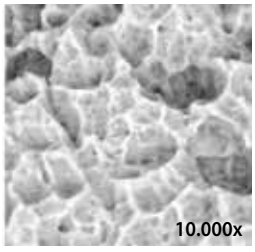
Body





Shoulder



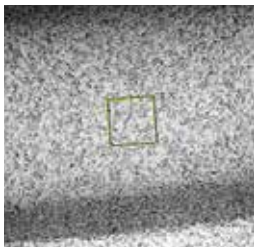


RESULTS

The Konus K3Pro® "Rapid" and "Sure" Implants show no significant traces of inorganic or organic residues.

K3PRO® RAPID

EDX Area Analysis

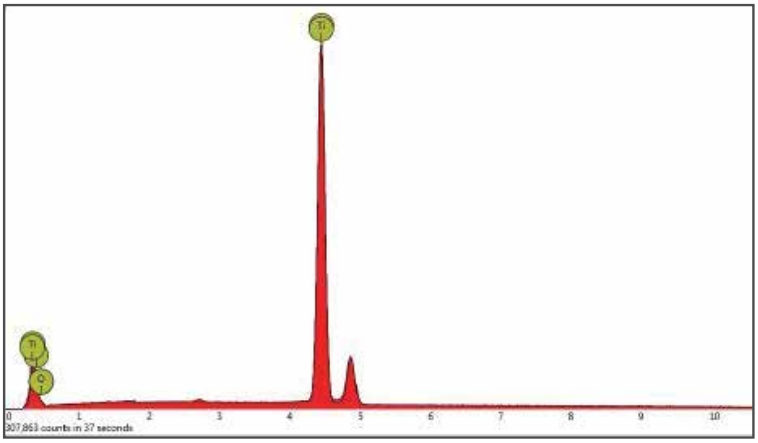


Field of View

Quantitative Elemental Analysis

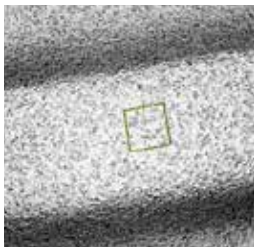
	Atomic percentage	Certainty
Ti	75.0 %	1.00
O	25.0 %	0.96

Qualitative Elemental Analysis



K3PRO® SURE

EDX Area Analysis

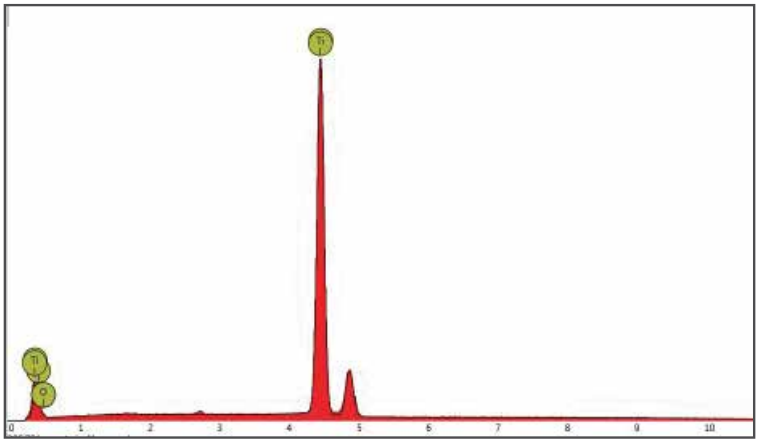


Field of View

Quantitative Elemental Analysis

	Atomic percentage	Certainty
Ti	77.5 %	1.00
O	22.5 %	0.96

Qualitative Elemental Analysis



3- Micro-movements and micro-pump-effect of implant-abutment-connection Test Report for Konus K3Pro Dental Implants (2010), Prof. Dr. H.-Ch. Lauer, Department of Prosthetic Dentistry at J.W. Goethe-University Frankfurt am Main - To view the comprehensive study, visit www.argondentalusa.com.

Case Example - Maintain Bone with K3Pro™

2011 - Implant X-ray
at placement

2015 - X-ray showing bone
integration after 5 years

2010 - Before implant is placed

2011 - Implant is placed

2011 - Results at placement

2015 - Cosmetic results after 5 years

Case Example - Maintain Bone with K3Pro™

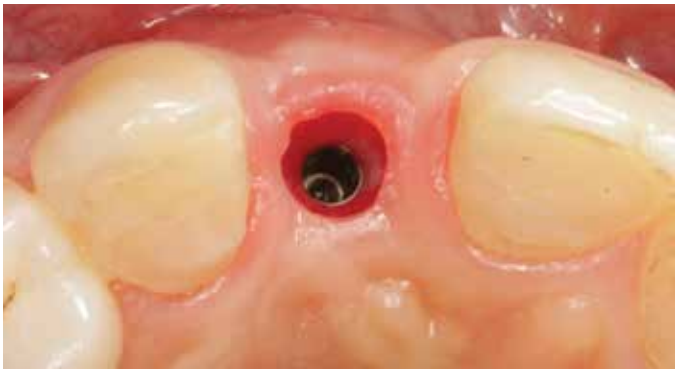
Dr. Frank Michael Meir

2013 - Implant placement

2013 - Implant X-ray at placement

2015 - Implant X-ray 2 years post placement

2017 - X-ray showing no bone loss after 4 years



2013 - 2 months after placement

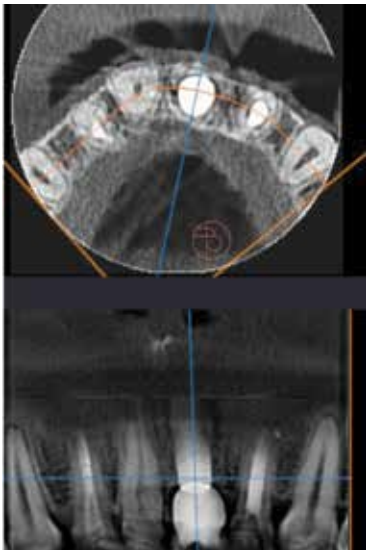
2014 - Cosmetic results

Case Example - Maintain Bone with K3Pro™

Dr. Bogdan Baldea

2011 - X-ray before placement

2011 - Implant X-ray at placement



2018 - X-ray showing bone integration after 7 years

2018 - X-ray showing bone integration after 7 years

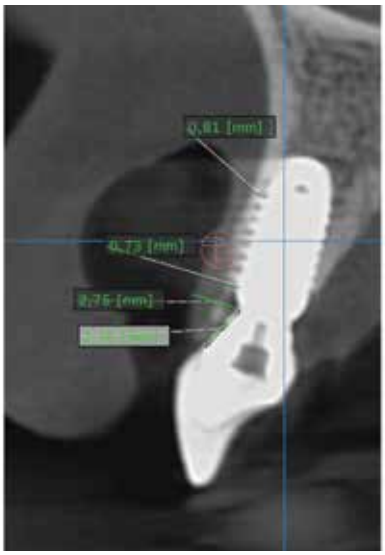
2011 - Before implant is placed

2018 - Cosmetic result after 7 years

Case Example - Maintain Bone with K3Pro™

Dr. Bogdan Baldea

2012 - Implant X-ray at placement



2017 - X-ray showing bone integration after 5 years

2012 - Before implant is placed

2017 - Cosmetic result after 5 years

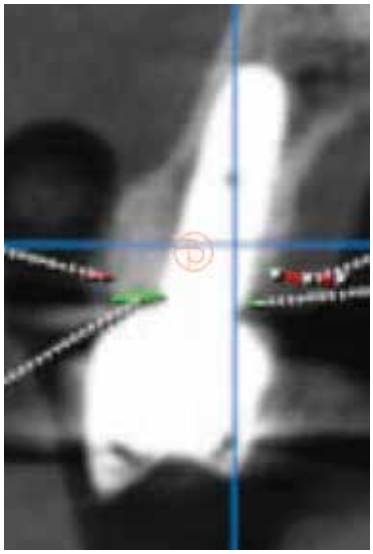
Case Example - Maintain Bone with K3Pro™

Dr. Bogdan Baldea

2013 - X-ray before placement

2013 - Implant X-ray at placement

2015 - X-ray showing bone integration after 2 years



2018 - X-ray showing bone integration after 5 years

2013 - Before implant is placed

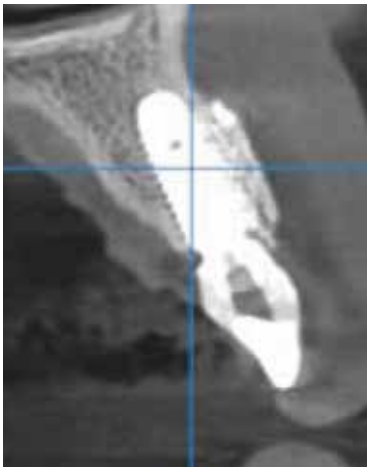
2018 - Cosmetic result after 5 years

Case Example - Maintain Bone with K3Pro™

Dr. Bogdan Baldea

2010 - Implant X-ray at placement

2011 - Implant X-ray 9 months after placement



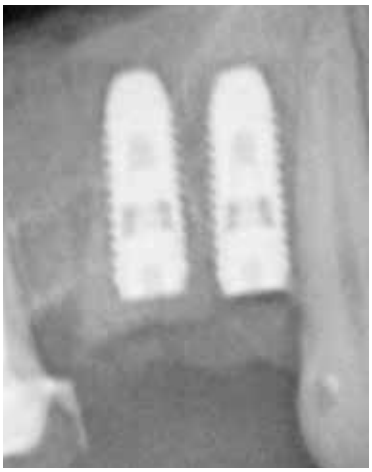
2018 - Implant X-ray 8 years after placement

2010 - Before implant is placed

2018 - Cosmetic result after 8 years

Case Example - Maintain Bone with K3Pro™

Dr. Bogdan Baldea



Implant X-ray at placement

Implant X-ray 9 months after placement

Implant X-ray 1 year after placement

Implant X-ray 2 years after placement

Before implant is placed

Initial Placement

9 months after placement

Cosmetic result after 2 years

Case Example - Maintain Bone with K3Pro™

Dr. Bogdan Baldea

2014 - Implant X-ray before placement

2014 - Implant X-ray at placement

2015 - Implant X-ray 1 year after placement

2017 - Implant X-ray 3 years after placement

2014 - Before implant is placed

2016 - Cosmetic result after 2 years

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