Examination report

PB-Nr. 242-09

DAP-PL-3692.00

Examination laboratory accredited by the DAP, the German Accreditation System for Testing, according to: DIN EN ISO/IEC 17025:2008
The accreditation is valid for all the examination procedures listed on the diploma.

This report comprises 7 pages.

Client:	Argon Medical Mr. Richard Donaca Mainzer Str. 346 55411 Bingen am Rhein
Date of order:	10.11.2009
Concern:	**Examination of a subtractive surface**
Specimen designation client:	**K3pro Implant** **Osteoactive Surface** **4,5 x 11 mm**

Specimen receipt:	10.11.2009
Order number IGMHS:	**439-09**
Specimen designation IGMHS:	as client
Date of examination:	10.11.2009
Testing specification:	***QM-AA 5.09-20*** „Display of specimen surfaces via secondary electrons (SE) as well as measurement of lengths of particles in compact specimens including grindings, powders and separates- scanning electron microscopical procedure (SEM)“ **ASTM E 1508-98** “Standard Guide for Quantitative Analysis by energy-dispersive spectroscopy” **QM-AA 5.09-03** „Recording of spectrums of compact specimens, powders and separates via energy dispersive microanalysis (EDX)“ **QM-AA 5.09-41** „Standardless quantitative evaluation of EDX-spectra“
Examination results:	see page 2 and the following pages

The scope of accreditation does not contain the interpretation of the test results!

Head of laboratory (SEM)

Rostock, 11.11.2009

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Dr.-Ing. G. Horn-Samodelkin

1. Facts of the case

The IGMHS received a postal consignment containing a factory sealed implant in order to perform examinations according to the correspondance from 10.11.2009 zu. In **figure 1a-e** different views of the packaging and the unpacked Implant are displayed.

Figure 1a: upper side packaging

Figure 1b: lower side packaging

Figure 1c: lower side inner packaging

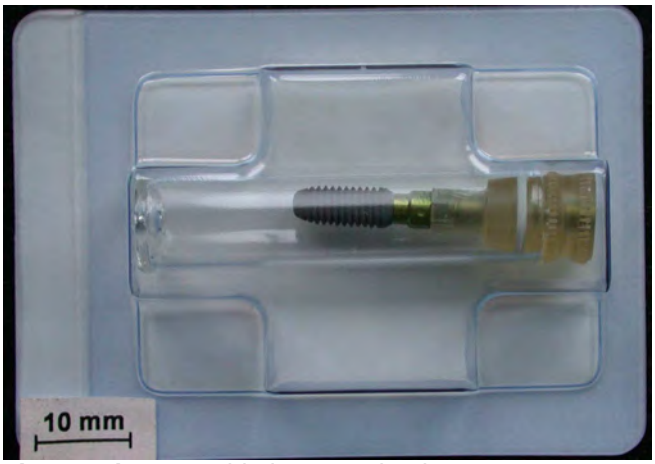


Figure 1d: upper side inner packaging

Figure 1e: view of implant in glas tube

2. Examination procedure

The examinations were carried out with SEM of the type Leitz “AMR 1600T” with an electronical upgrade done by the company point electronic. The primary voltage amounted to 20 keV . The documentation of the pictures was done via a secondary electron detector (SE- pictures) and a digital interface with the measuring computer. Therefore the Point-programm DIPS 32 was applied. The determination of the chemical composition of the implant surfaces was done with an X-Flash-EDX-detector of the company Bruker. The EDX-detector is equipped with a light- element window which allows the detection of elements with an ordinal >= 5 (Boron). The recording of spectra was done in field-mode (300s MZ, 3kcps rate of incoming impulses).

Notice:

EDX is a procedure of microanalysis. Beside the advantage of being able to carry out location dependent examinations of very small surface areas, there are the following disadvantages that should be taken into consideration when examining the spectra and interpreting the results:

a) **overlapping of lines** (in the designation of the spectrum peaks the operator of the instrument individually decided in favour of the element that was more likely to be present, by personal experience. However there is a possibility that one or more of the other potential elements are present in very low concentrations!)
b) **detection limit** (In consideration of the atomic number of the element, the excitation voltage during the examination and other factors, the detection of low element concentrations, approx. <0,3%, is possible.)
c) **conditions of excitation** (Altough the EDX is a procedure of surface analysis (µm-range), very small particles can be „shoot through“ by the excitation beam, so that the results of the analysis as the case may be, derive from the particles’ neighbourhood.)
d) **quantification** (A standard less quantification is being carried out following a physical base model, where elements such as C and O are being determined in a difference to 100%. The quantification of rough, heterogeneous surfaces is highly afflicted with faults.)

3. Ergebnisse

The examined specimen had an etched surface.

Following, the examination results of a measuring point in the upper area of the angular running shoulder, a second measuring point in the middle of the implant on a screw mountain and a third measuring point in the middle of the implant in a screw valley are displayed.

3.1 Measuring point shoulder

Figure 2a displayes the examined area on the shoulder, the attribution of the location on the implant is displayed in **figure 2b**.

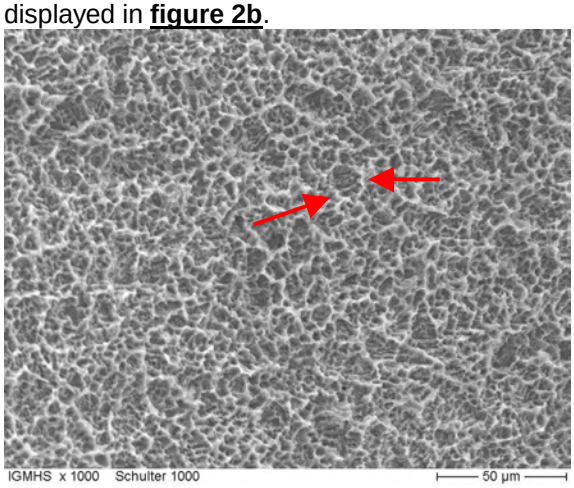


Figure 2a: measuring point on the shoulder

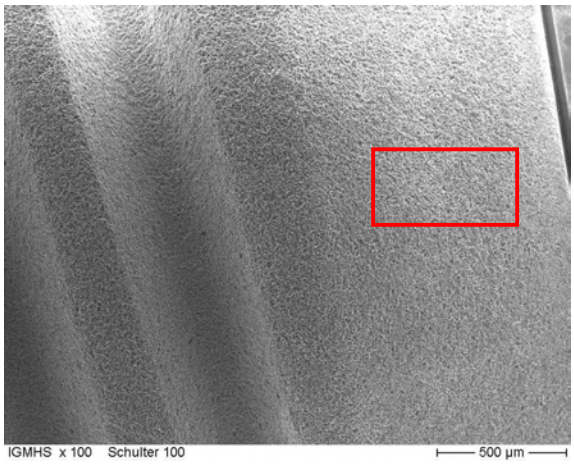


Figure 2b: marked measuring point on the shoulder

The diameters of the 5 single cavities (lacunae) in **figure 2c** measured in this area range between **1,8** and **4,3 µm**, mean: **3,0 µm**. The lacunae-clusters (in **figure 2a** one cluster of lacunae is marked by two red arrows) range between **20,7** and **39,7** µm, mean: **26,6 µm**.

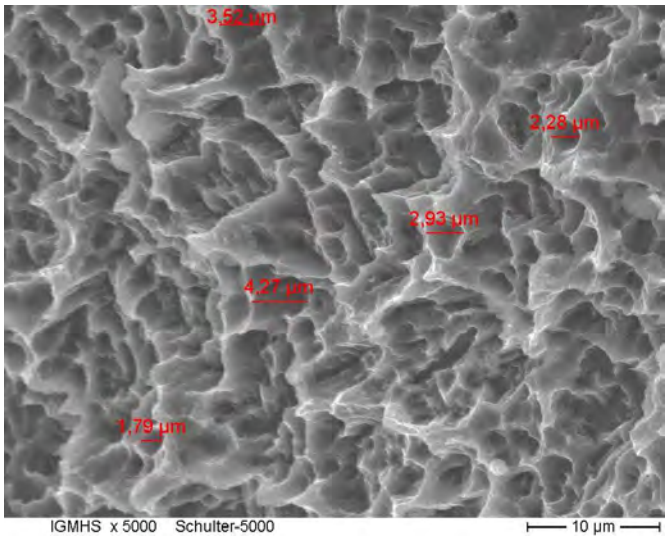


Figure 2c: measuring point on the shoulder, magnified

Figure 3 shows the EDX-spectrum belonging to **figure 2a**. In due consideration of the limit of detection of the EDX no contaminations were found.

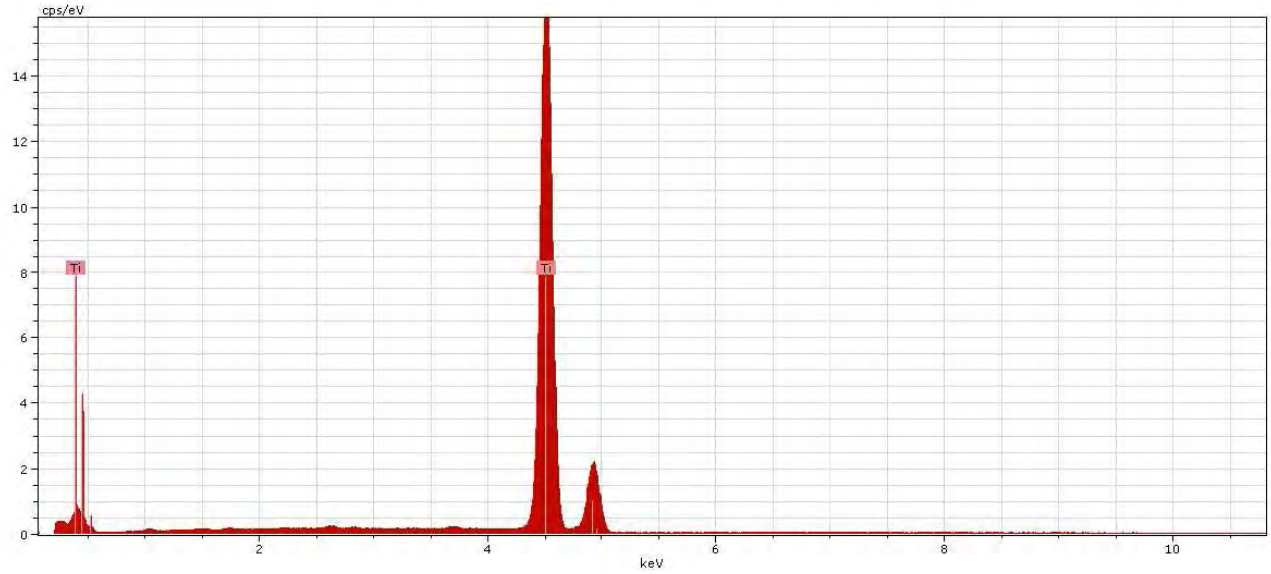


Figure 3: EDX-spectrum of an area on the shoulder of the implant

3.2 Measuring point in the middle of the implant, on a screw mountain

Figure 4a displayes the examined area in the middle of the implant on a screw mountain, the attribution of the location on the implant is displayed in **figure 4b**.

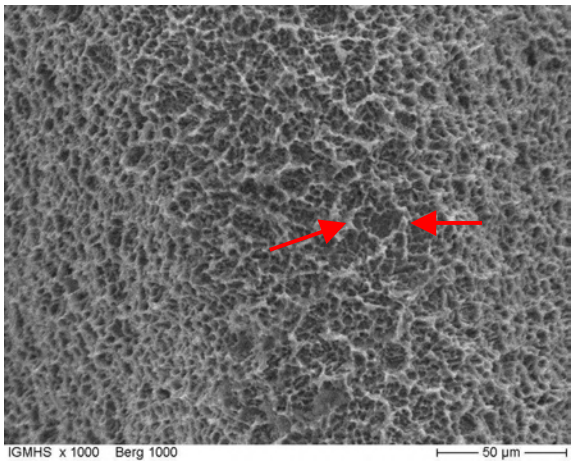


Figure 4a: measuring point on a screw mountain

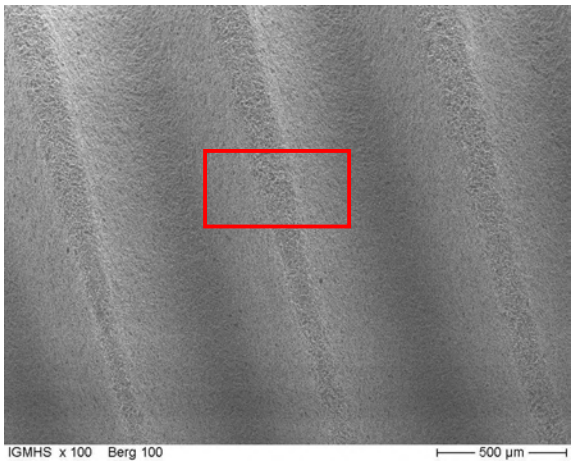


Figure 4b: marked measuring point in the middle of the implant, screw mountain

The diameters of the 5 single cavities (lacunae) in **figure 4c** measured in this area range between **2,2** and **3,3 µm**, mean: **2,9 µm**. The lacunae-clusters (in **figure 4a** one cluster of lacunae is marked by two red arrows) range between **14,7** and **24,3** µm, mean: **18,2 µm**.

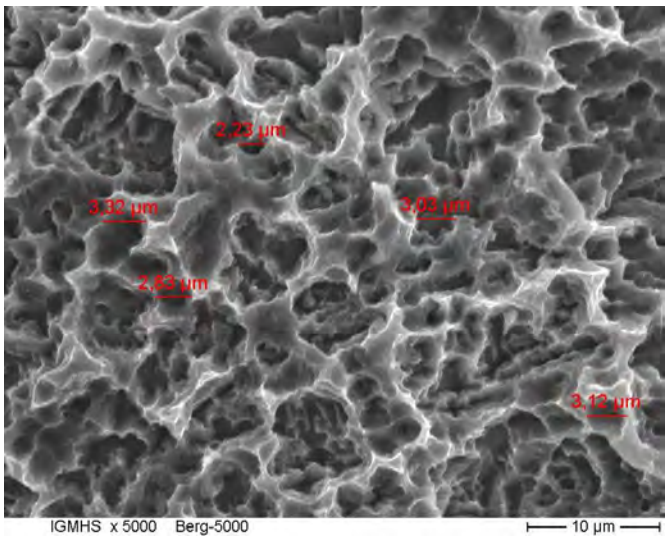


Figure 4c: measuring point on a screw mountain in the middle of the implant, magnified

3.3 measuring point in the middle of the implant in a screw valley

Figure 5a displayes the examined area in the middle of the implant in a screw valley, the attribution of the location on the implant is displayed in **figure 5b**.

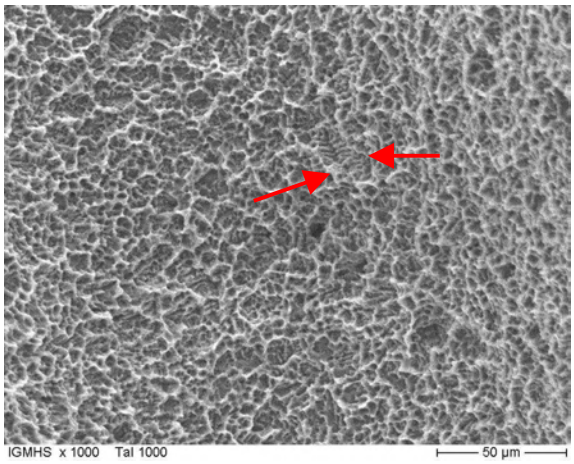


Figure 5a: measuring point on a screw valley

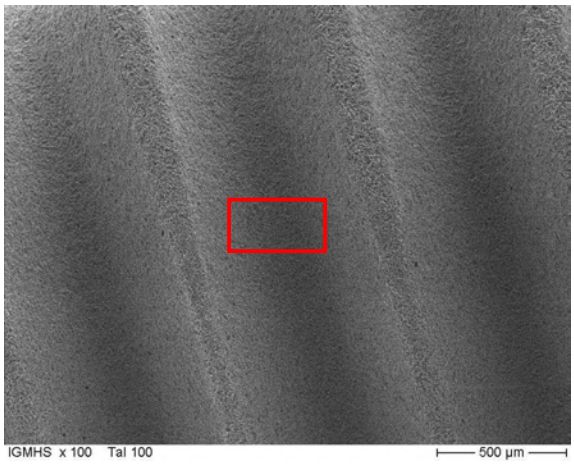


Figure 5b: marked measuring point in the middle of the implant, screw valley

The diameters of the 5 single cavities (lacunae) in **figure 5c** measured in this area range between **1,8** and **4,3 µm**, mean: **3,1 µm**. The lacunae-clusters (in **figure 5a** one cluster of lacunae is marked by two red arrows) range between **13,5** and **26,2** µm, mean: **19,1 µm**.

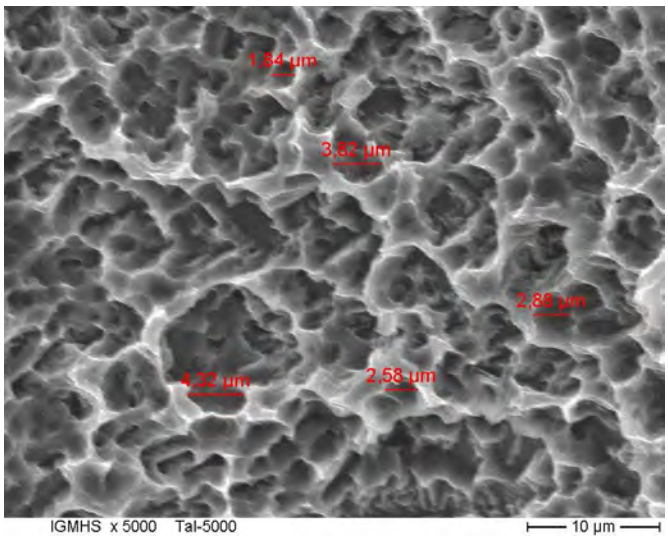


Figure 5c: measuring point in a screw valley in the middle of the implant, magnified

Figure 6 shows the EDX-spectrum belonging to **figure 5a**. In due consideration of the limit of detection of the EDX no contaminations were found.

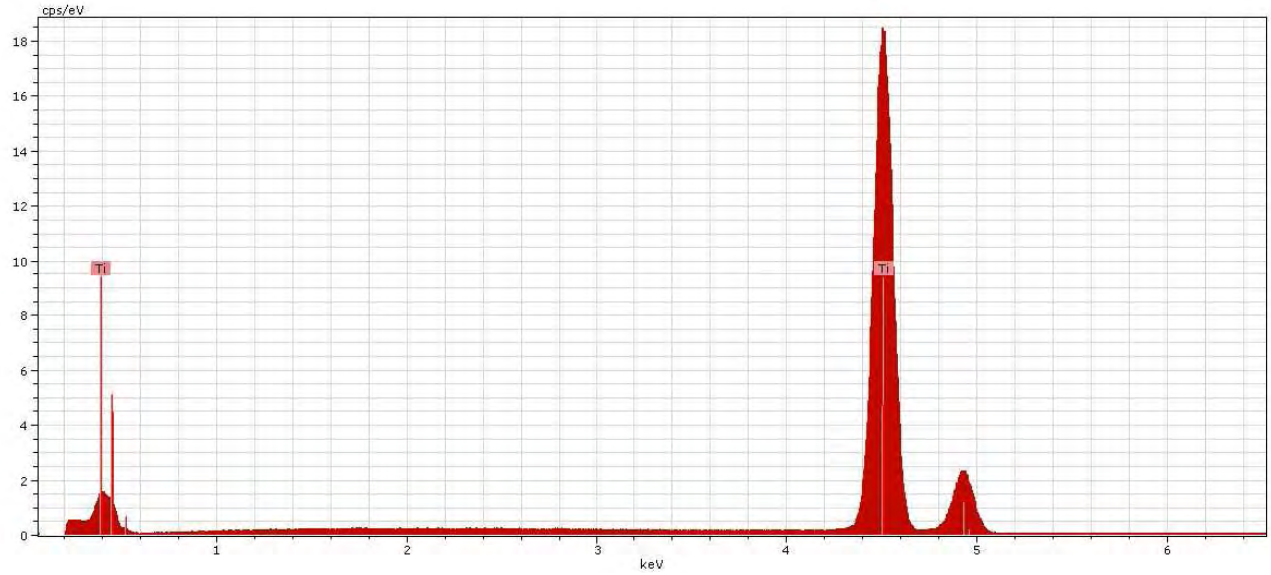
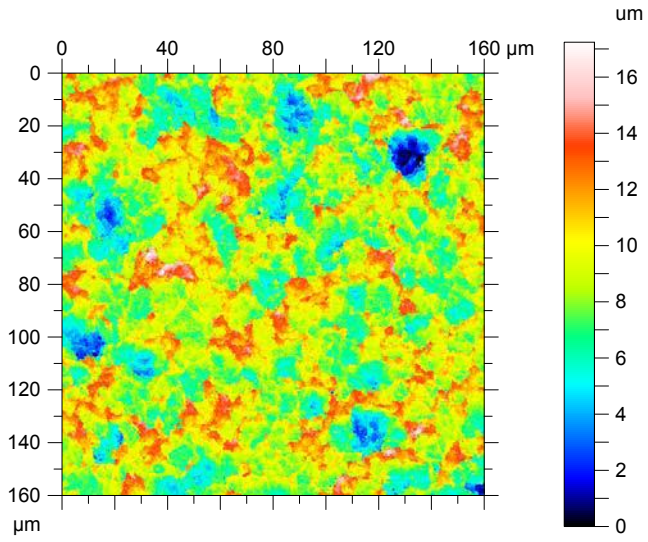


Figure 6: EDX-spectrum of an area in a screw valley in the middle of the implant

upper area of the implant



Pseudo-colour Image: heights are coded using colours

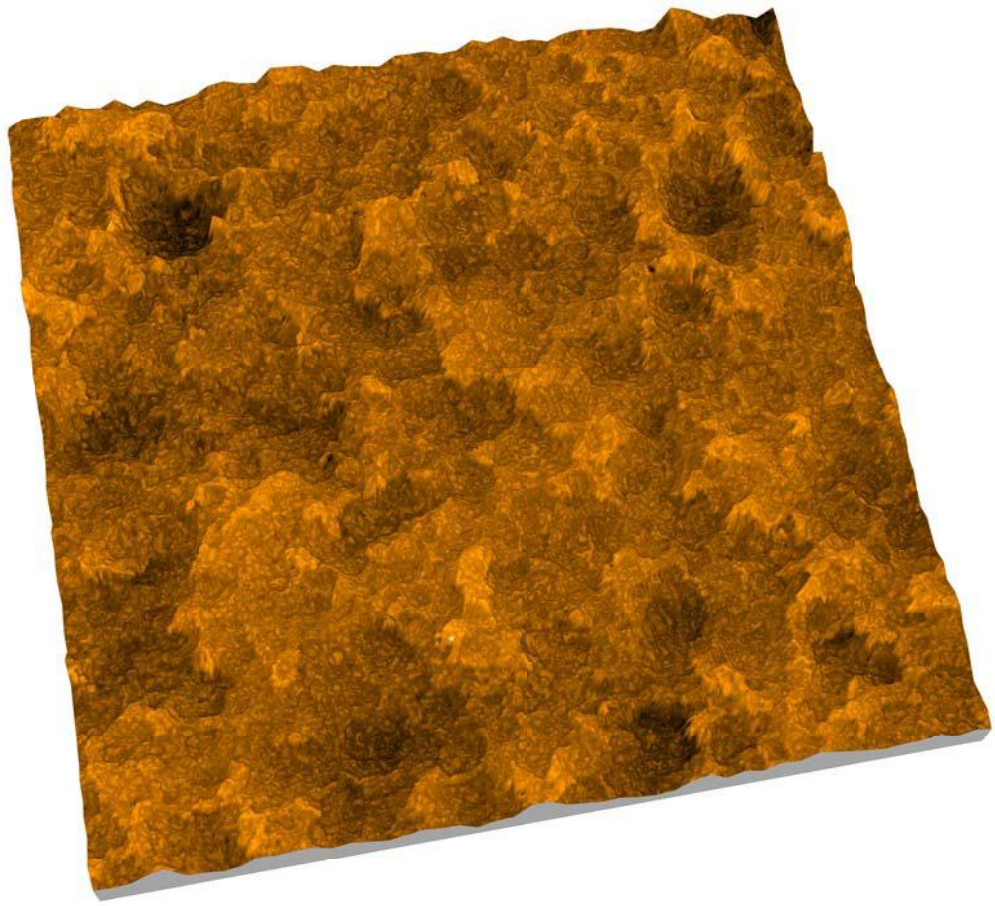
Identity card

Name: K3pro Implant Osteoactive Surface 4.5x11 mm_Oberer Bereich

Axis: X
- Length: 160 µm
- Size: 512 points
- Spacing: 0.313 µm

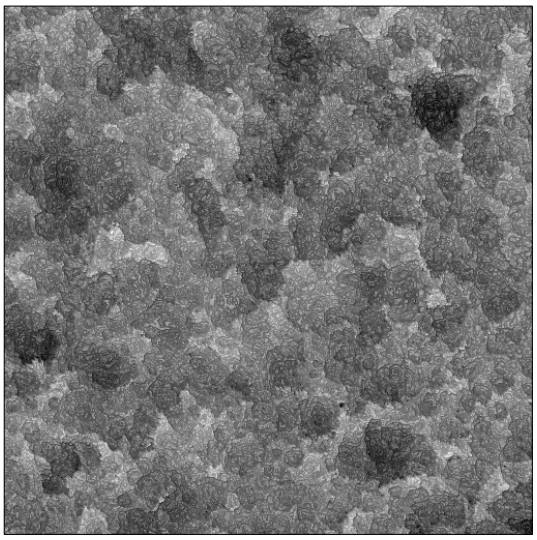
Axis: Y
- Length: 160 µm
- Size: 512 lines
- Spacing: 0.313 µm

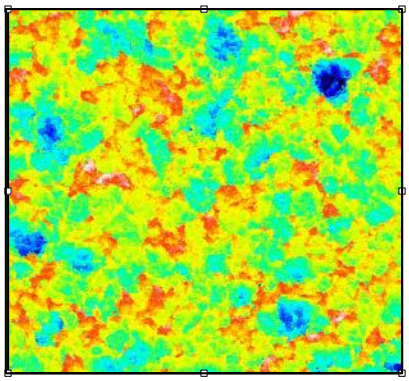
Axis: Z
- Length: 72.3 um



3D View: Displays the studiable within an interactive 3d visualization

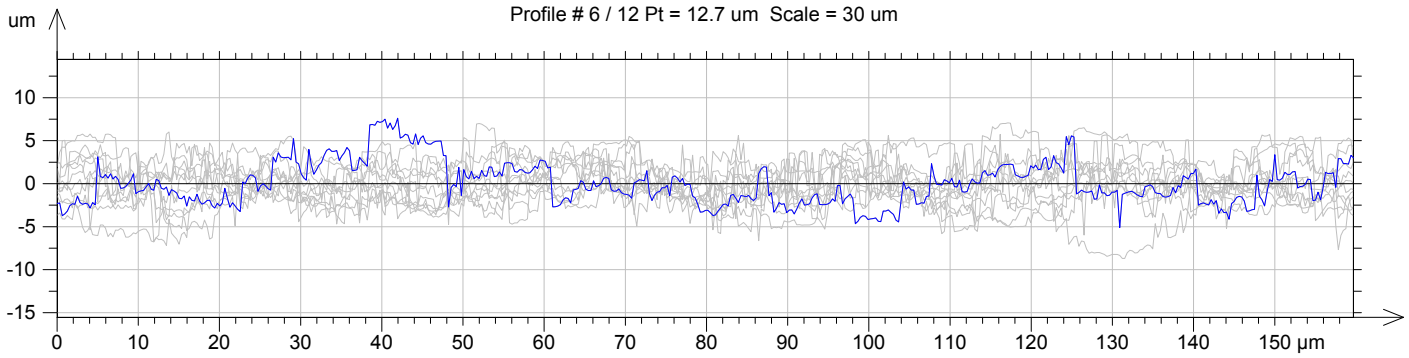
Photo Simulation: Displays a 2D photo simulation





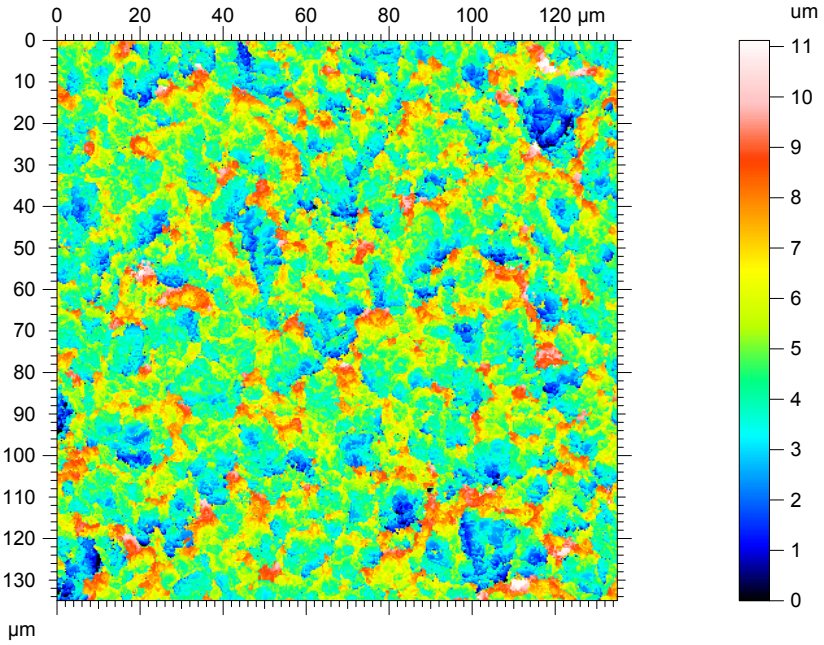
Converted to a series

Series of profile curves



ISO 4287

		Context	Mean	Std dev	Min	Max
Amplitude parameters - Roughness profile						
Ra	um	*Gaussian filter, 0.025 mm*	1.04	0.0851	0.899	1.15
Rz	um	*Gaussian filter, 0.025 mm*	5.76	0.424	4.95	6.38

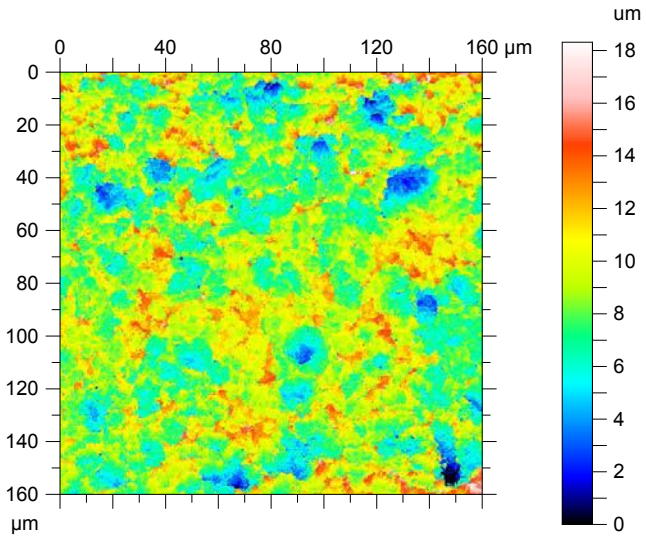


3D roughness parameters

ISO 25178

Height Parameters		
Sa	1.4	um
Sz	11.1	um

valley in the thread



Pseudo-colour Image: heights are coded using colours

Identity card

Name: K3pro Implant Osteoactive Surface 4.5x11mm_Gew indetal

Axis: X
- Length: 160 µm
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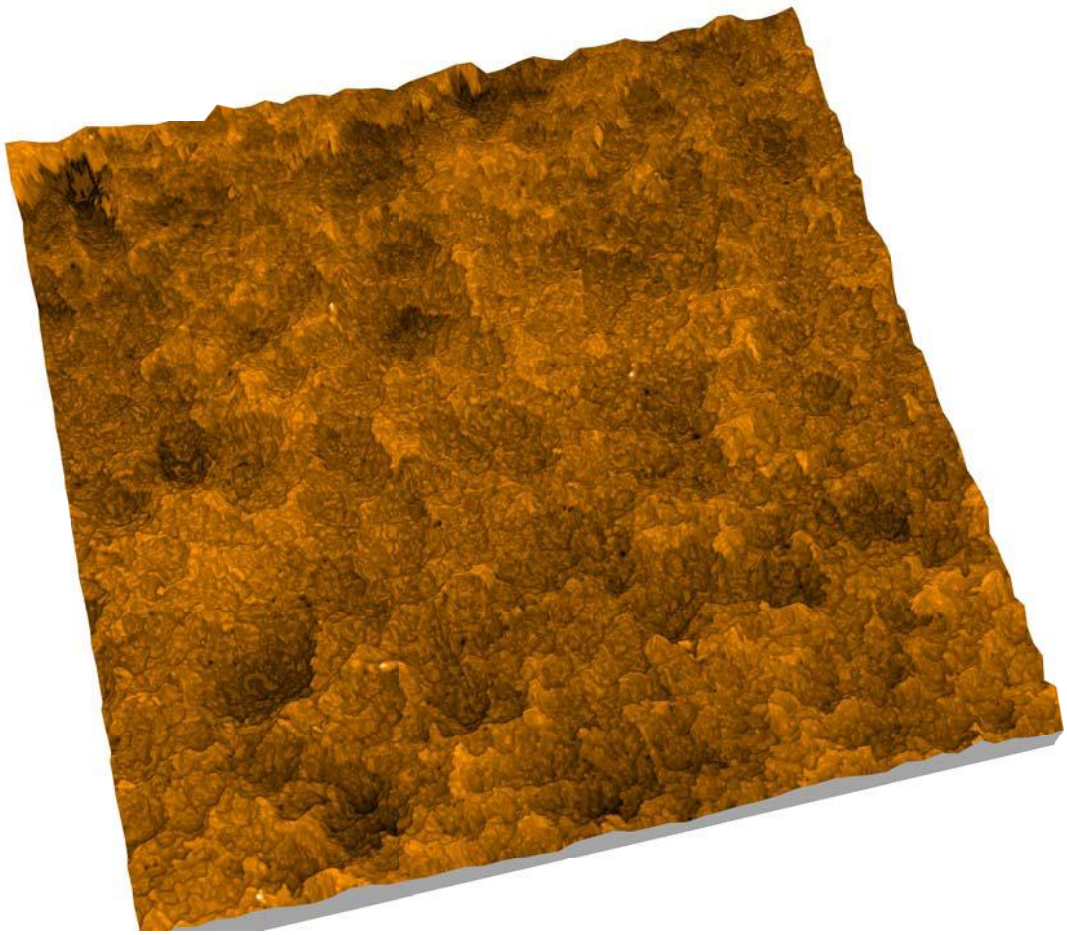
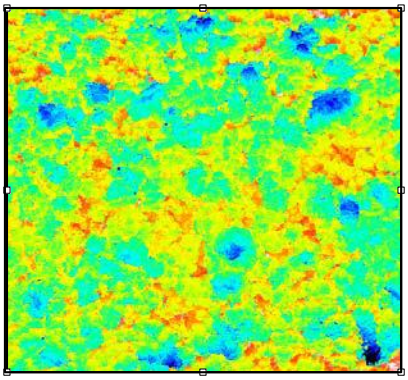
Axis: Y
- Length: 160 µm
- Size: 512 lines
- Spacing: 0.313 µm

Axis: Z
- Length: 74.1 um



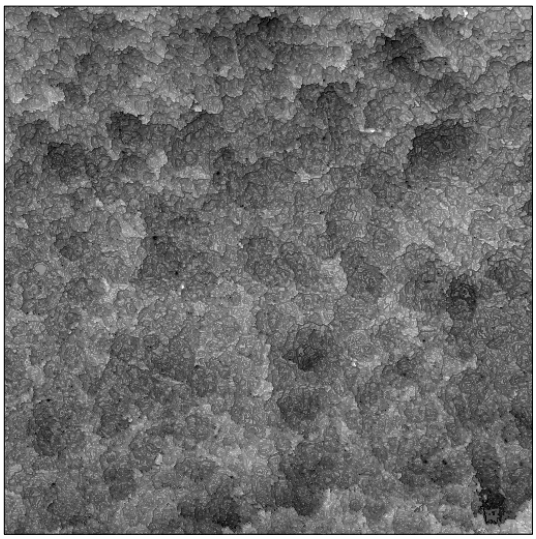
3D View: Displays the studiable within an interactive 3d visualization

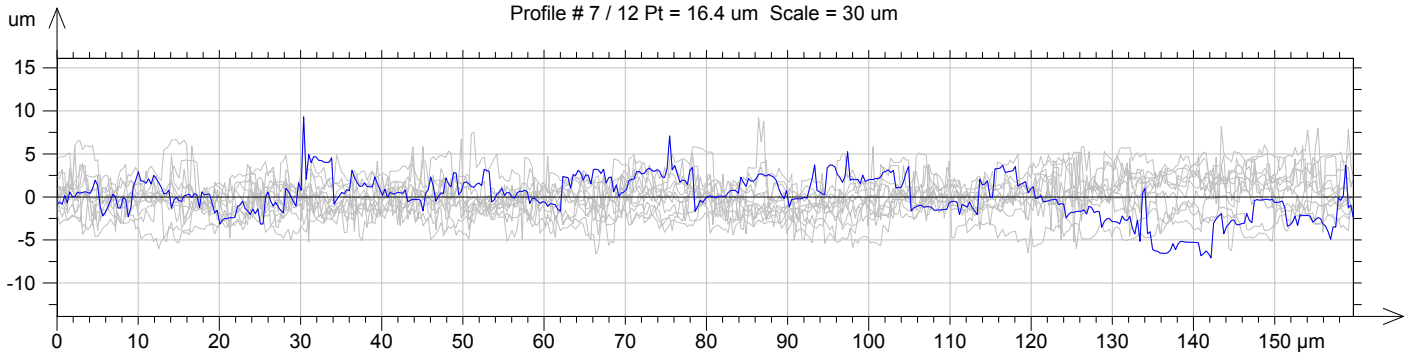
Photo Simulation: Displays a 2D photo simulation



Converted to a series

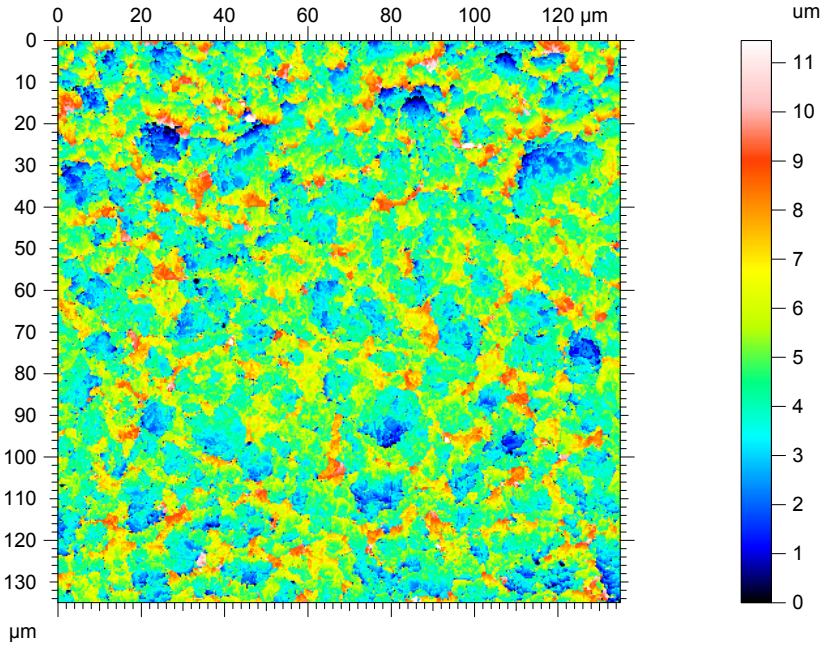
Series of profile curves





ISO 4287

		Context	Mean	Std dev	Min	Max
Amplitude parameters - Roughness profile						
Ra	um	*Gaussian filter, 0.025 mm*	0.993	0.14	0.671	1.26
Rz	um	*Gaussian filter, 0.025 mm*	5.82	0.96	3.98	7.58



3D roughness parameters

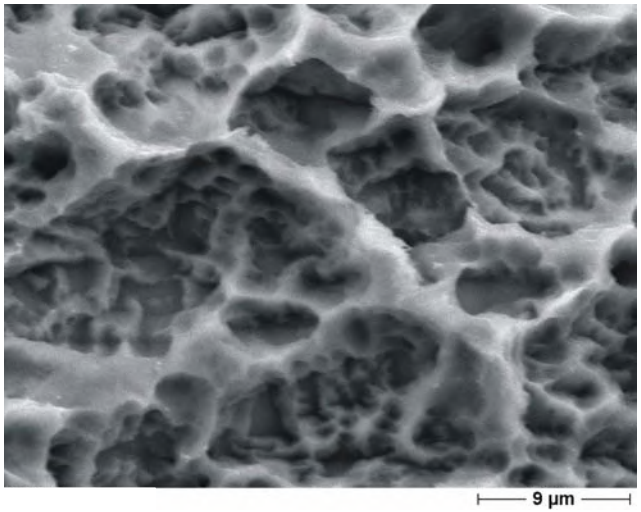
ISO 25178

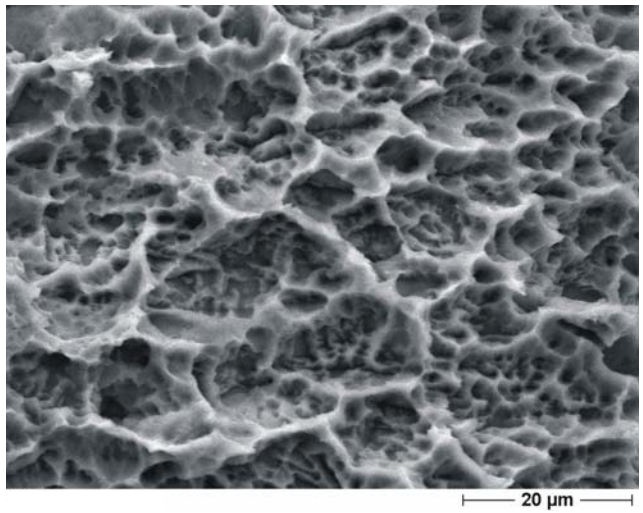
Height Parameters		
Sa	1.33	um
Sz	11.5	um

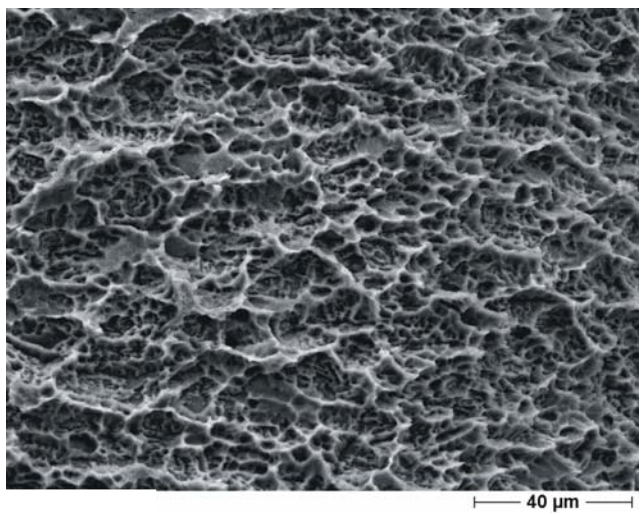
OsteoActive™

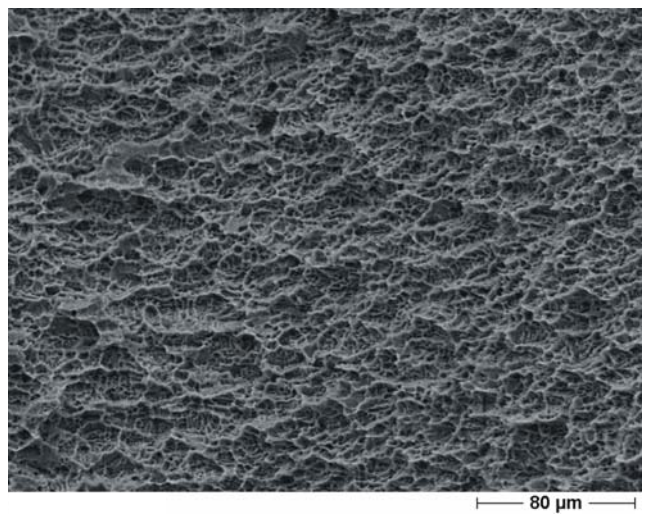
OsteoActive®
(subtractive method)

OsteoActive® (subtractive method)

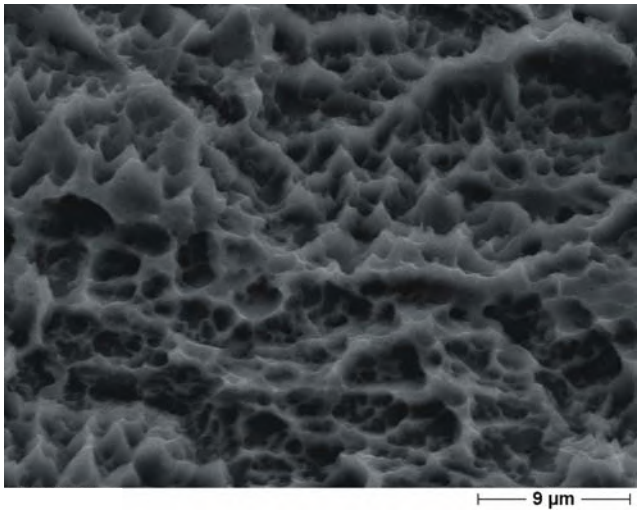


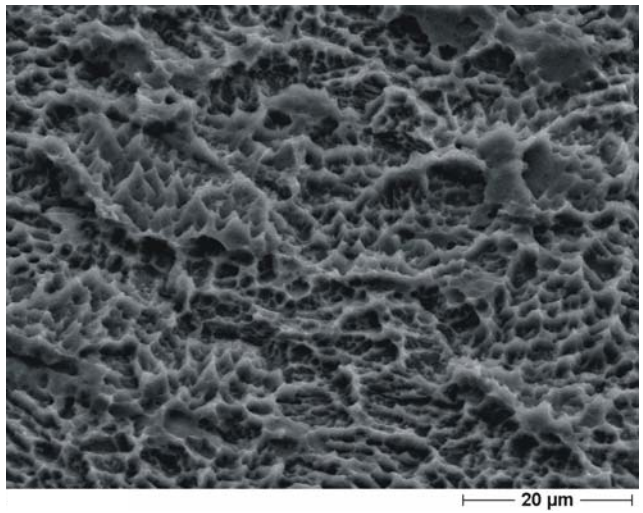


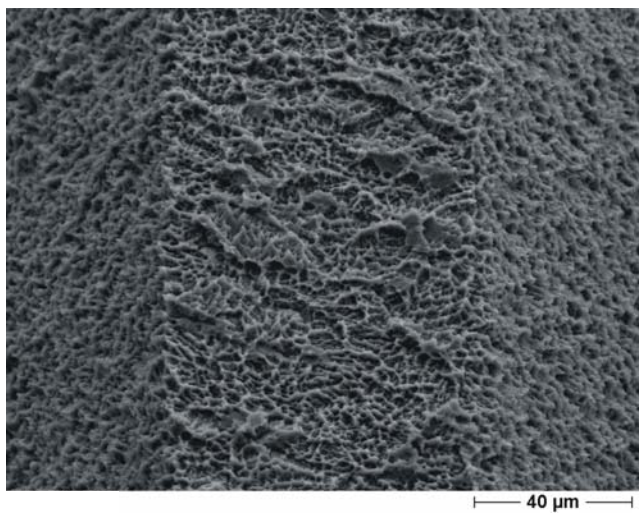


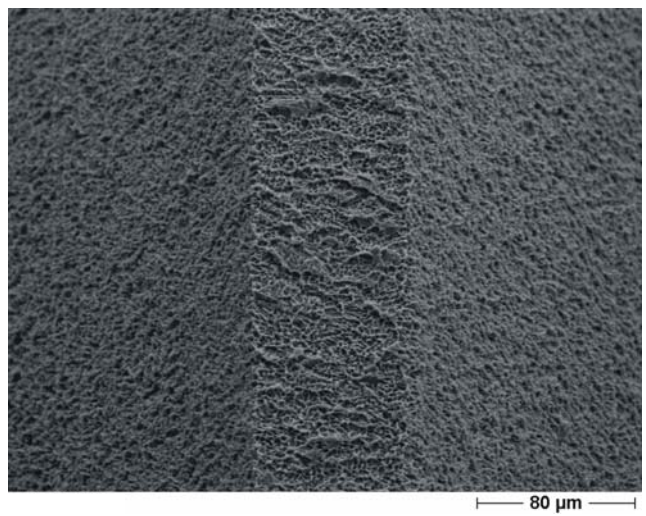


OsteoActive® (subtractive method)

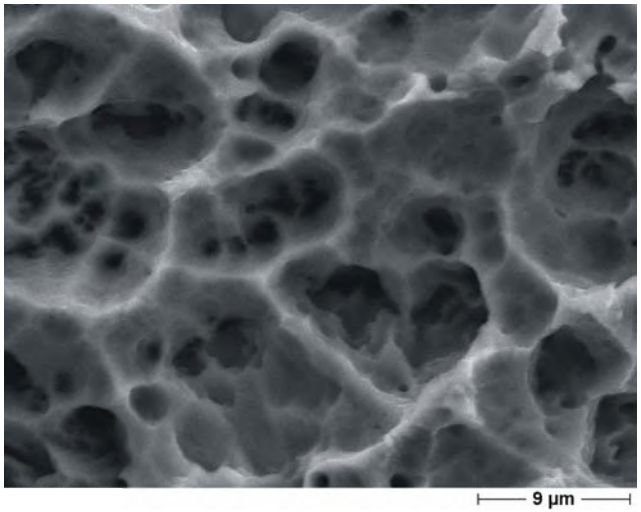


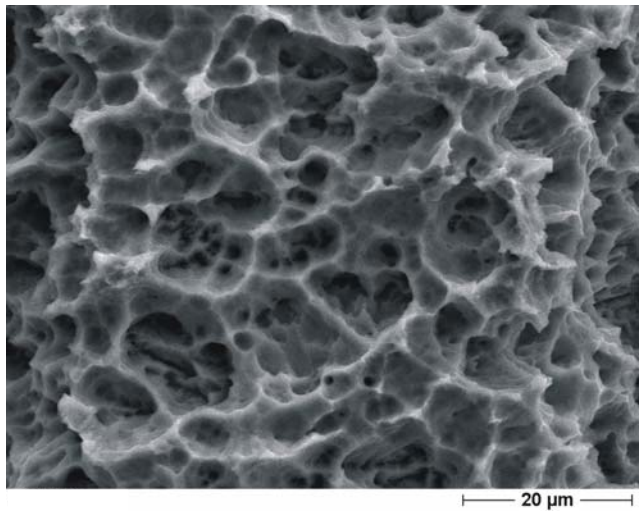


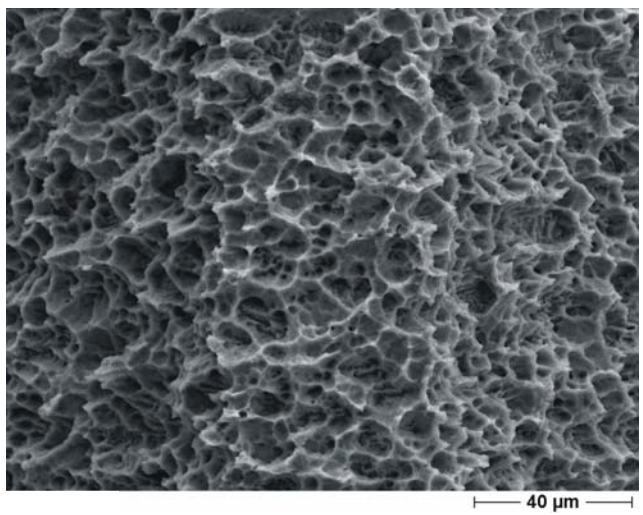


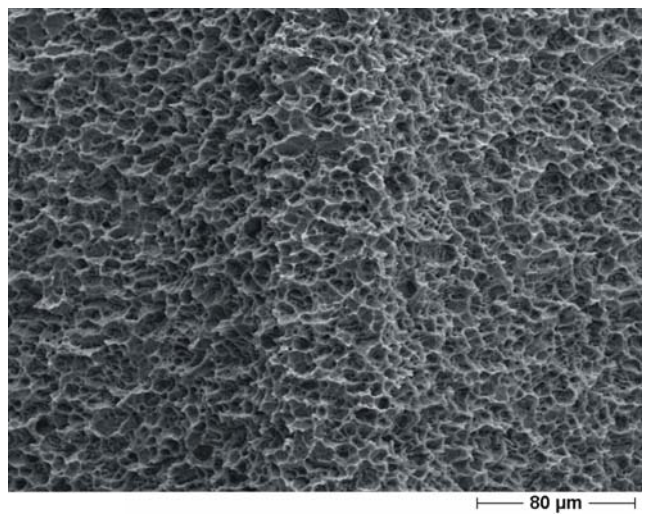


OsteoActive® (subtractive method)

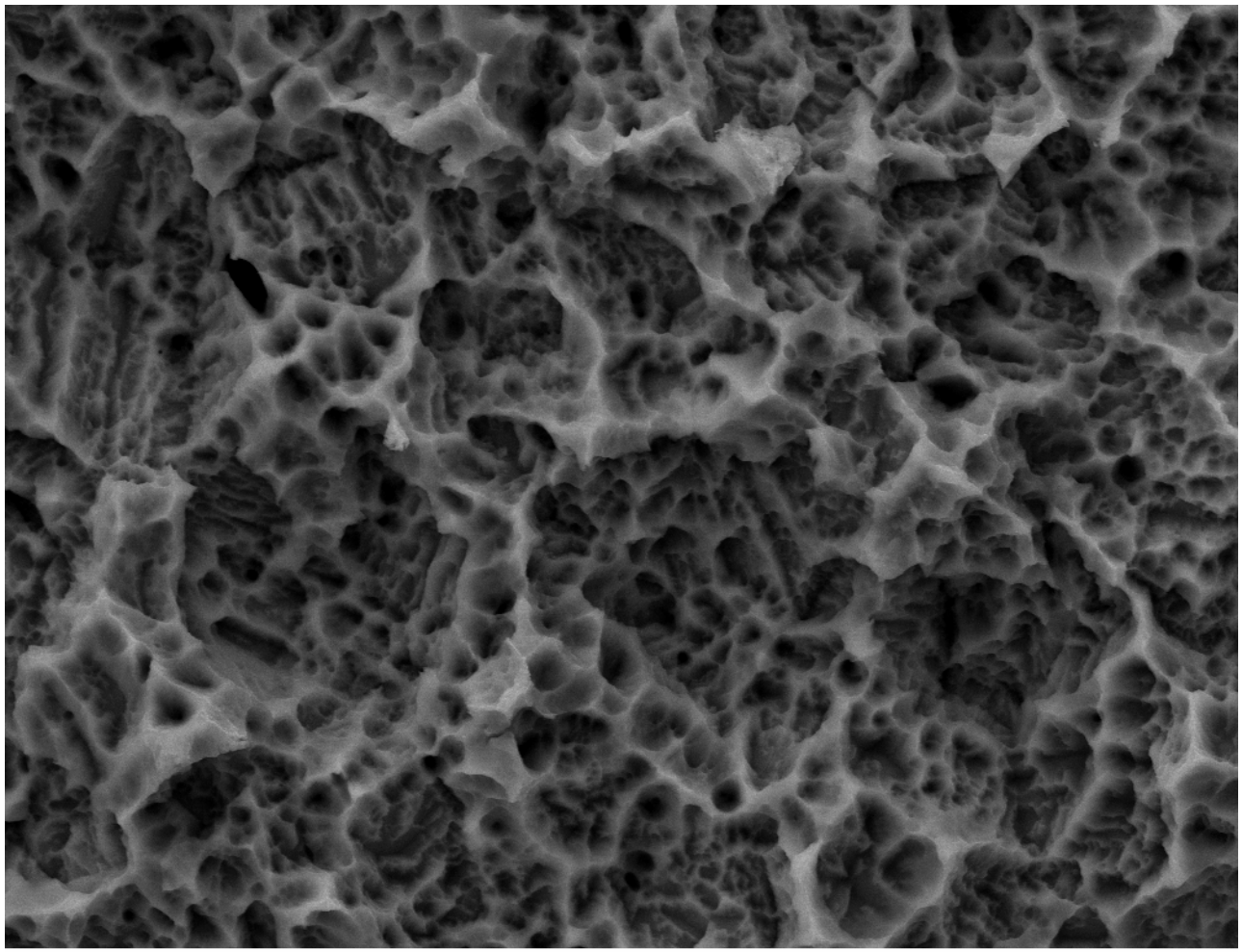








OsteoActive® (subtractive method)



OsteoActive® (subtractive method)