

PIMENTA NA LÍNGUA

FIZ-ME ACASO VOSSO INIMIGO, DIZENDO A VERDADE?

GÁLATAS 4:16

“Aquele que vende muito gato por lebre, quando tiver lebre para vender, não encontrará comprador”

Josemar Bosi



Dr. João Pimenta, Académico Honorário da Academia Brasileira de Odontologia.



Dr. Dirk U. Duddeck, DDS. Managing director and head of research of the CLEANIMPLANT FOUNDATION.

Já escrevi alguns artigos sobre contaminação de implantes dentários. Todas as imagens que mostrei eram de implantes com o rótulo de Conformidade Europeia (CE).

Até 26 de Maio de 2025 os implantes dentários com a certificação CE podem ser comercializados, sendo que após essa data têm que obedecer às Medical Device Regulation (MDR 2017/745) como material médico da classe IIB, o que significa pertencerem à classe de médio/alto risco.

Consideramos desde há uns anos que um implante certificado e estéril pode não ser um implante limpo e livre de contaminantes de superfície.

Ultimamente, analisámos dois implantes da mesma marca, à venda em Portugal. Uma das análises foi feita na Universidade do Minho e a outra em Berlim.

Como as imagens e relatórios falam por si, sendo coincidentes, resolvemos publicar o relatório do MMRI.BERLIN, que é um laboratório acreditado, para evidenciar que é absolutamente fundamental que os colegas entendam, em definitivo, que um implante estéril pode não ser um implante limpo...

E, por conseguinte, o paciente poderá correr sérios riscos, e o profissional também...

Em 2019, Duddeck, Albertsson, Wenneberg e colaboradores publicaram um artigo no Journal of Clinical Medicine, com o título “On the Cleanliness of Different Oral Implant Systems: a Pilot Study”, em que compararam implantes das marcas Dentsply, Nobelbiocare e Straumann com três marcas que fabricavam cópias. A conclusão é deveras interessante: *“In contrast to the original implants of market-leading manufacturers, the analyzed look-alike implants showed significant impurities, underlining the need for periodic reviews of sterile packaged medical devices and their clinical documentation”*.

A maior parte dessas impurezas eram resíduos orgânicos, tal como os observados nos implantes que analisamos.

Já em março deste ano, Mtanis, Biadsee e Ormanier publicaram, no Journal of Functional Biomaterials, um estudo chamado “Assessing the Cleanliness of Dental Implants Using Scanning Electron Microscopy and Energy-Dispersive X-ray Spectroscopy Analysis – A SEM and EDS In Vitro Study”, em que concluíram que havia uma alta contaminação dos implantes analisados (*“Most of the implants studied were contaminated. Particle distribution patterns vary with the manufacturer. The wider and outer areas of the implant have a higher probability of contamination”*).

O assunto é muito sério, e a falta de controlo analítico, que deveria ser feito ou por uma unidade europeia independente, sem conflito de interesses, ou por entidades nacionais, poderá vir a ser de futuro fonte de conflitos judiciais... Além de que é a saúde dos pacientes, e também a reputação de profissionais, que estará em jogo...

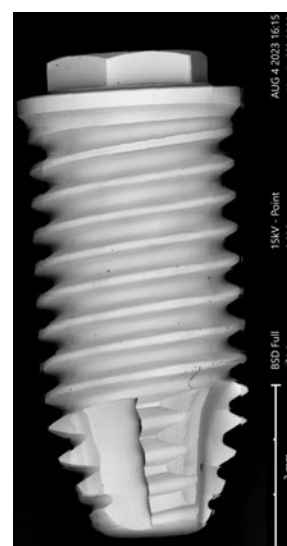
file: FB_19 version: 02 valid from: 01.01.2021	mmri.berlin medical materials research institute berlin Office: Zum See 9 14542 Wuster (Havel) Test-Laboratory: Max-Planck-Str. 3 12489 Berlin (Germany)
Test-Report according to DIN ISO 22309:2015-11	
page: 1 / 20	

order number: 23-00035-001, [redacted] date: 2023-08-12

client: Prof. Dr. Joao Pimenta, Barcelos, Portugal
 sample collection: laboratory client
 name of examiner: Dr Dirk Duddeck
 sample received: 2023-07-26
 sample tested: 2023-08-04
 manufacturer/brand: [redacted]
 sample type/material: [redacted] Titanium
 production-/valid-date: [redacted]
 sample identifier: [redacted]
 test method: scanning electron microscopic (SEM), energy dispersive X-ray spectroscopic (EDS) tests by means of imaging entangements according to DIN ISO 22309:2015-11
 testing instrument: Phenom Pro X, Desktop-SEM
 software: Phenom ProSuite / element identification, version 3.8.4
 calibration method: Software
 operating conditions: Laminar-flow-cabin, clean room ISO class 5 (DIN EN ISO 14644-1), normal room temperature
 validation: standard-free analysis reference materials
 impartiality ensured:

Exclusion of liability uncertainty of measurement:
 The analysis results given below, which have been normalized to 100 (mass %), are based on an estimate that does not reflect the validity of the total. This is reflected in the value of the stated uncertainty.

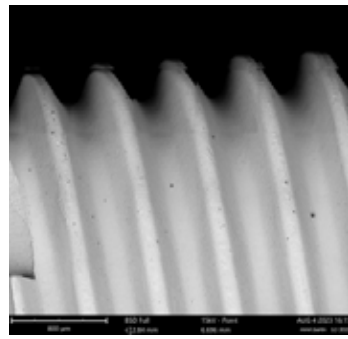
Accredited test laboratory according to DIN EN ISO/IEC 17025:2018:
 Registration Number (DAKS): D-PL-21029-01-00
 The accreditation is valid for the scope specified in the deed annex.



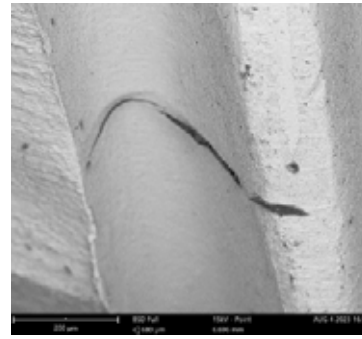
FSHR-SEM image (digitally composed, approx. 500x).



Sample mounted on the sample holder.



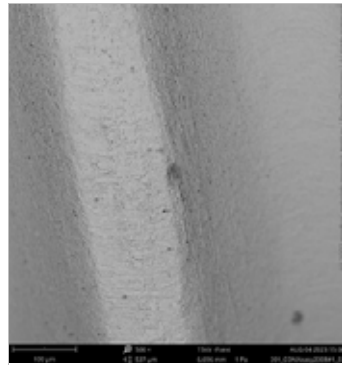
Sem mapping #1.



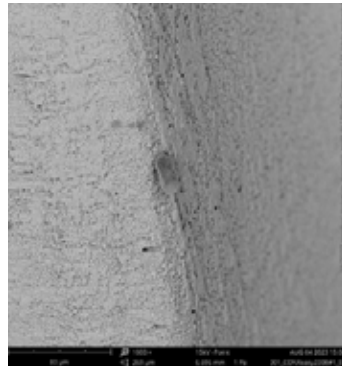
Sem mapping #2.



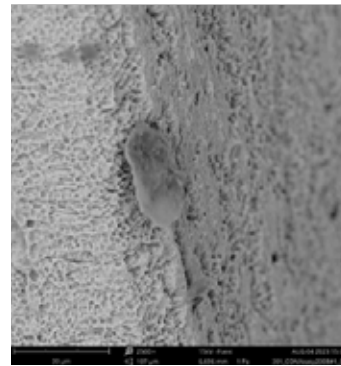
Phenom camera.



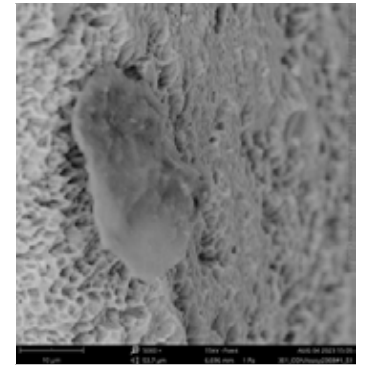
500x.



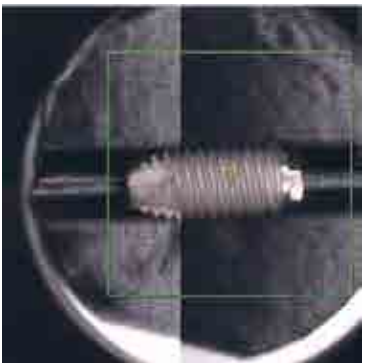
1,000x.



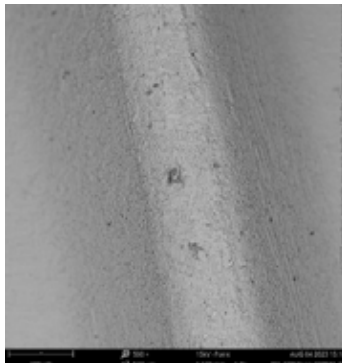
2,500x.



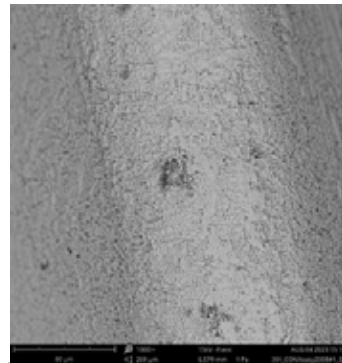
5,000x.



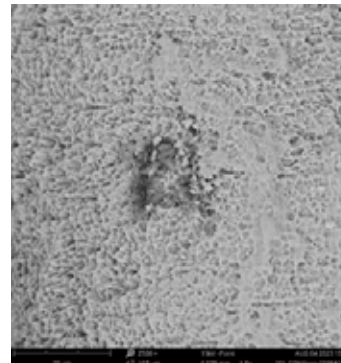
Phenom camera.



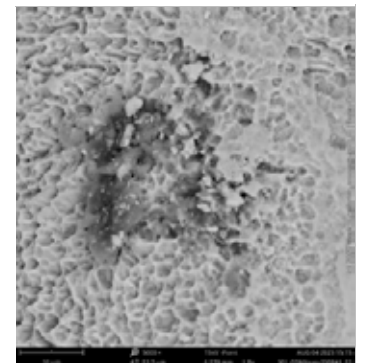
500x.



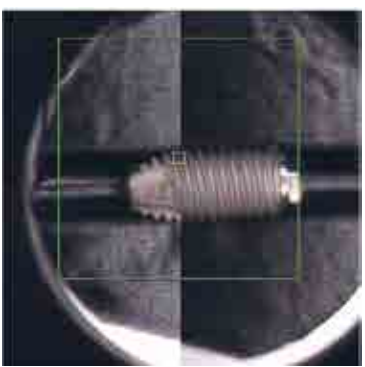
1,000x.



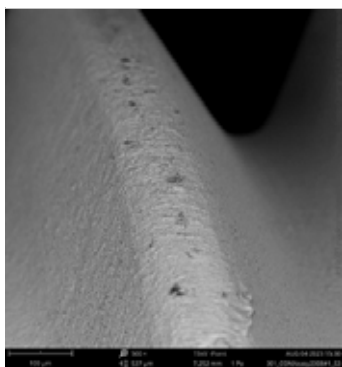
2,500x.



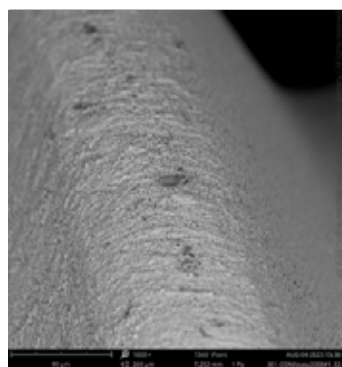
5,000x.



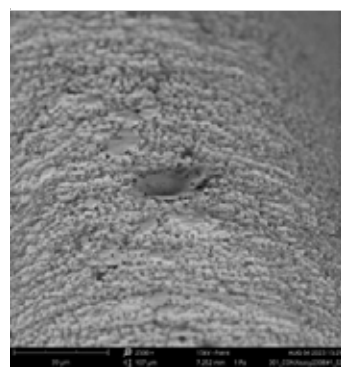
Phenom camera.



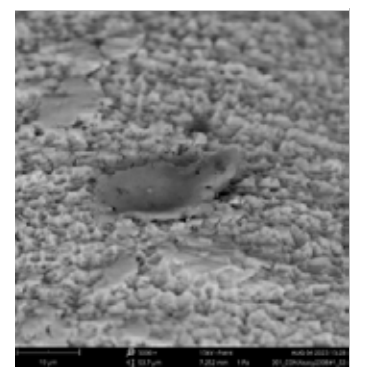
500x.



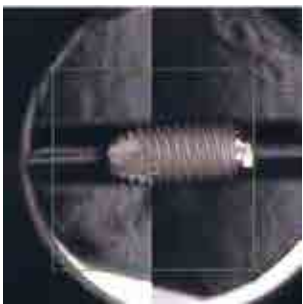
1,000x.



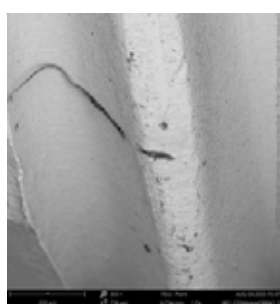
2,500x.



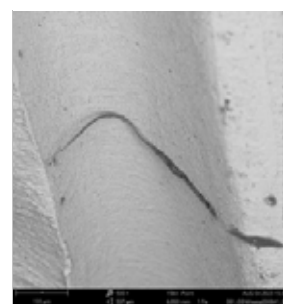
5,000x.



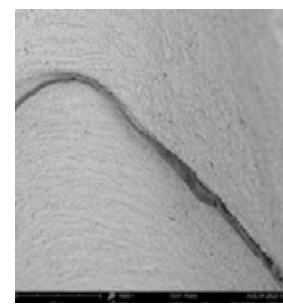
Phenom camera.



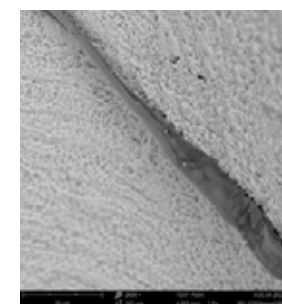
360x.



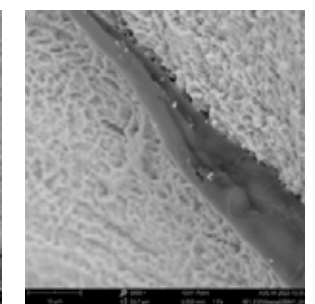
500x.



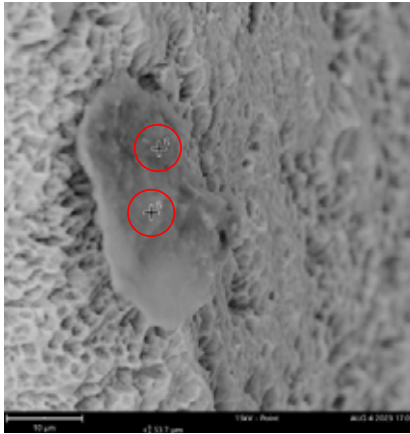
1,000x.



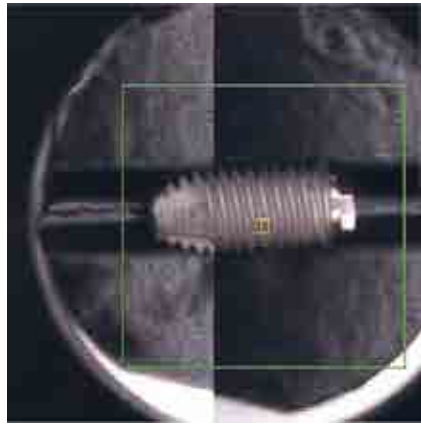
2,500x.



5,000x.



EDS Analysis Spot_1 (Overview).



Phenom camera.



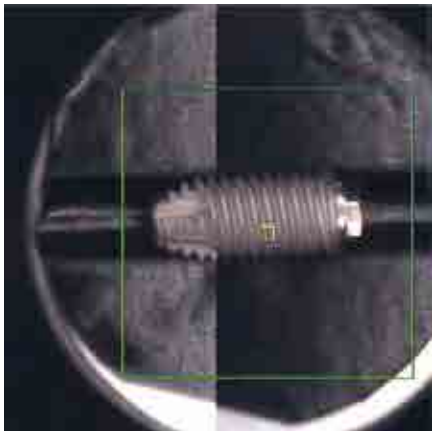
Spot reading #1.



Quantitative elemental analysis.



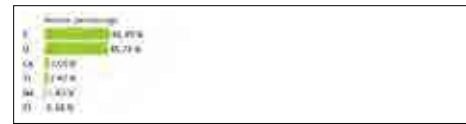
Qualitative elemental analysis.



Phenom camera.



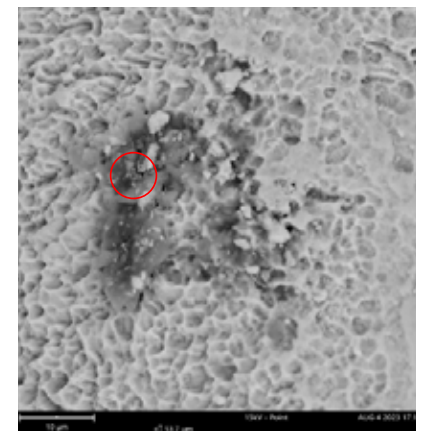
Spot reading #2.



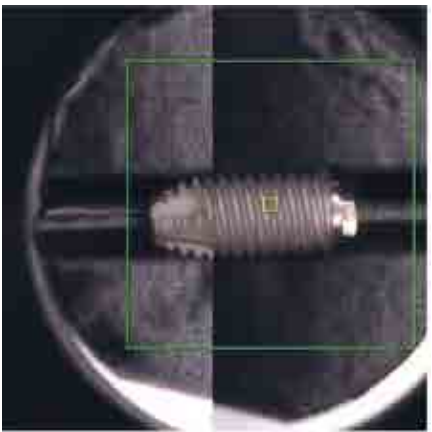
Quantitative elemental analysis.



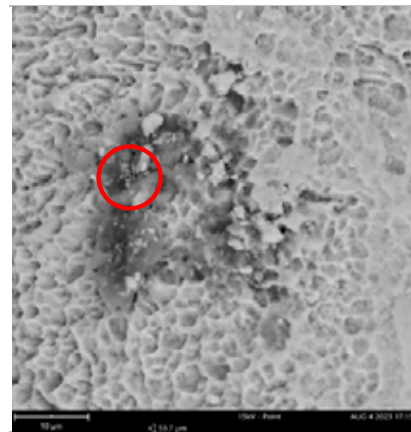
Qualitative elemental analysis.



EDS Analysis Spot_2 (Overview).



Phenom camera.



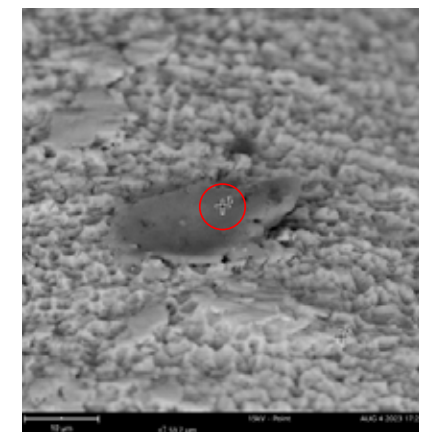
Spot reading #3.



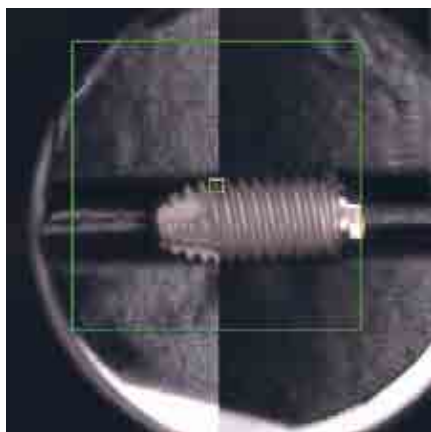
Quantitative elemental analysis.



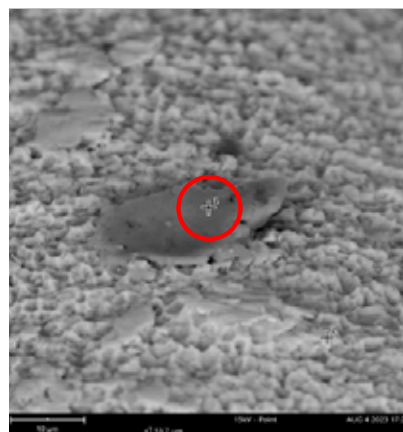
Qualitative elemental analysis.



EDS Analysis Spot_3 (Overview).



Phenom camera.



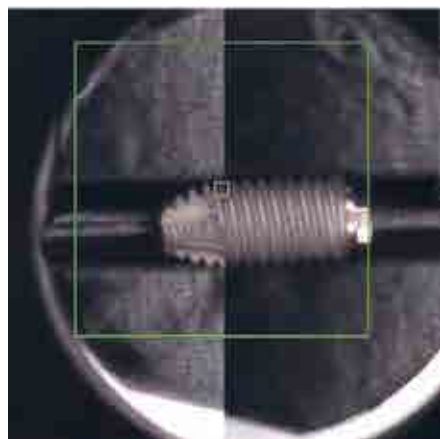
Spot reading #1.



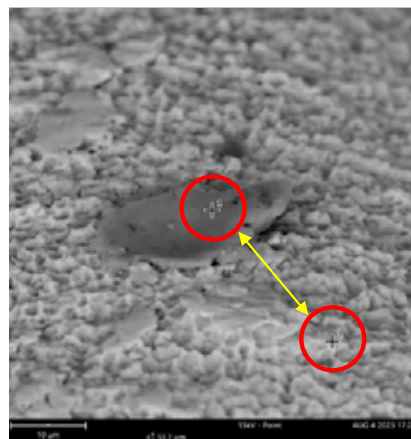
Quantitative elemental analysis.



Qualitative elemental analysis.



Phenom camera.



Differential spectrum #1 - #2.



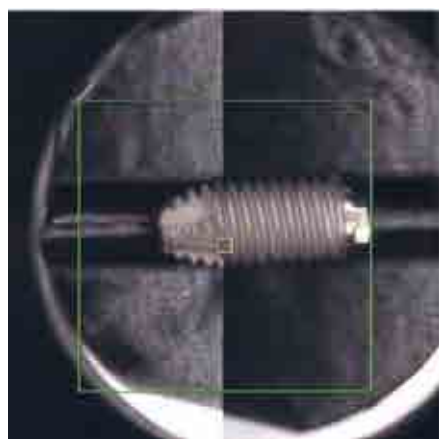
Quantitative elemental analysis (differential spectrum #1 - #2).



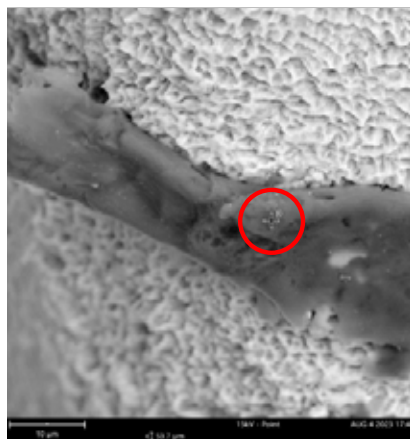
Qualitative elemental analysis (differential spectrum #1 - #2).



EDS Analysis Spot_4 (Overview).



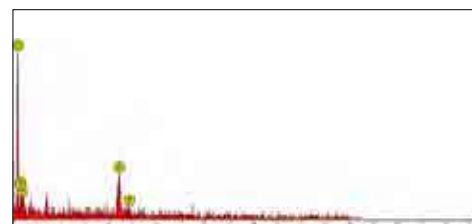
Phenom camera.



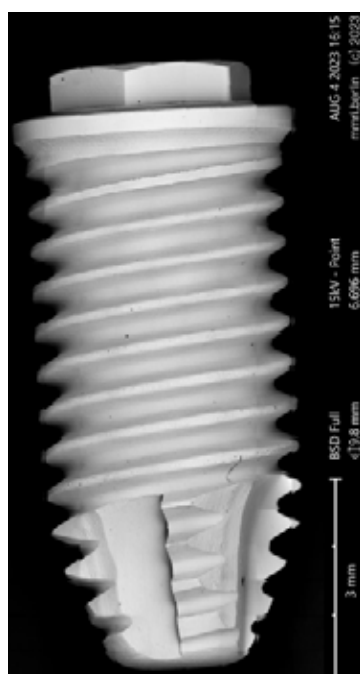
Spot reading #3.



Quantitative elemental analysis.



Qualitative elemental analysis.



SEM Mapping (overview).

report number: 23-00035-001 page: 20 / 20

TEST RESULTS

The implant sample showed numerous carbonaceous particles. One particle exceeded the length of 400µm. Elemental analysis of other, smaller particles demonstrated additional signals of calcium [2-3 At.-%] and minor traces of sodium [<2 At.-%].

test report, examined: date: 2023.08.11 signature examiner: *M. Silva*

approval: date: 2023.08.12 signature laboratory manager: *J. J.*

Interpretation of results:

The FSHR [Full-Size High-Resolution] SEM mapping image is electronically composed of up to 400 single SEM frames in a magnification of 500x and shows the complete implant from shoulder to apex in a viewing angle of approx.120°. The tested sample demonstrated significant contamination with organic, i.e., carbonaceous particles (> 50 particles in the viewing angle of 120°) with no pattern of distribution.

note: The report contains data on concentrations of elements with an atomic number < 2 less than 11, such as oxygen; the specified norm has only limited applicability here since there is no accepted standard for an exact quantitative EDS analysis of light elements. The software utilizes various methods also listed in the relevant norm, such as direct analysis (e.g., for carbon) or by calculation using stoichiometry, e.g., for oxygen in combination with elements of higher atomic number. However, since materials can exist in several oxide states or are not completely oxidized, quantitative data on the concentration of oxygen in the individual analyses are to be understood as approximate values.

The interpretation of results and possible deductions on chemical compounds and material classes or causes of particulate and thin-film impurities are not covered by the specified norm and - therefore - solely reflect the investigator's conclusions and opinion.

legal indication: The test report is only valid as a complete document. The test results refer exclusively to the tested specimen. Parts of the report may not be reproduced or published without the written approval of the testing laboratory.

E no final, como de costume,
AGORA PENSEM!...