EXCERPT REPORT ON THE BIOCOMPATIBILITY OF ZIRCONIA (Zirconium Oxide)

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1. Identification of the product

Ceramic products made by sintering of powder of Zirconia (ZrO_2) to be used as dental prosthesis.

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5. Presence of radioactive impurities

Uranium dioxide and Zirconia show a wide field of miscibility [1] since Uranium and Thorium are associated with Zirconium in granitic rocks [2].
Even if powder manufacturing processes provide for an efficient separation of such elements, Uranium, Thorium, and some of their decay products can be present as impurities in Zirconia powders with a different concentration according to the level of purification of the material and of the powder manufacturing process.
In the case of the tested powders, available data are as follows:

	U (ppm)	Th (ppm)
n=1	0.19	1.3
n=2	0.19	1.3
Average	0.19	1.3

Testing method: ICP mass spectrometry (SEIKO SPQ6500)

The attention to the content of Zirconia radioactive impurities in biomedical applications was triggered by the publication of Höpf et al. [3, 4].

These studies concluded that, regarding radioactivity, TZP is adequate for clinical use.

During the third International Symposium of Medicine Ceramics, data related to in vivo carcinogenity tests (Ames test) and to teratogenicity (aberration of cell chromosomes in cell cultures) on ZrO_2 + Y_2O_3 plus 0.5 ppm of ^{235}U were introduced [5].
Both tests have shown negative results.

The differences of Gamma activities among various powders on the market or being developed have been object of study by various authors [6, 7] who have shown that even though the level of radionuclides can reach high levels in not purified materials.

High purity powders can have specific activity equal or inferior to the one of the human bone.

A method for the calculation of the equivalent dose of periimplant tissues starts from measures of specific Gamma activities and from Alpha flow density [8]. On the base of the tested outcome, it is possible to state that, even if TZP ceramic biomaterials show higher specific activities than Alumina, Titanium alloys, and Chrome-Cobalt alloys, their prolonged use bears for patients doses that are within the average limits of exposure due to the natural base and to medicinal doses, in compliance with the recommendations of the International Commission on Radiological Protection [9, 10]. Radioactive analysis data related to the tested powders obtained at the Toray Research Center Inc. are shown here:

α ray Total

α ray Density	
(α / cm² – h)	***(mBq / cm²)***
0.73 ± 0.013	0.203 ± 0.004

Test method: Low level α-ray measurement (2π-Gas Flow Counter).

β ray Total

β ray total
(Bq / g)
< 0.5

Test method: GM Counter (Aloka GP-14).

Ray spectrum_:

Not assessable.

Data are in compliance with UNI EN ISO 6872 international standards.

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