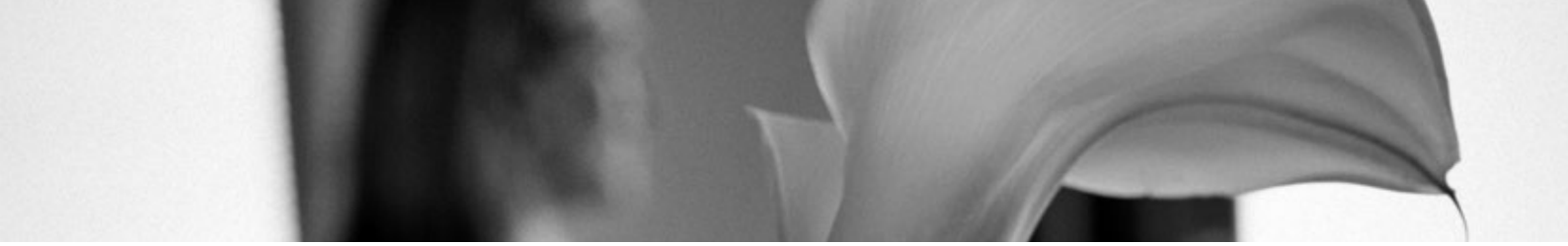


Radioactivity of Ceramic Implants

RADIOACTIVITY IS ALL AROUND US...

In our daily life, we are constantly exposed to radioactive substances like

- dust particles in the air
- trace elements in food
- cosmic radiation
- external terrestrial radiation (mountains/earth)
- sunshine

Radioactivity can be quantified in different units:

- Bequerel (Bq, decay/second) is the measuring unit for the activity of a radioactive material/substance.
- Sievert (Sv, energy/kg) is the measuring unit for the biological effect of a radiation dose absorbed by tissue.

Each year, we are naturally exposed to radiation levels between 1 and 10 mSv, with an average of 2.4 mSv[1]. Besides this natural exposure, additional radiation is generated through other sources. For example, a transatlantic flight exposes travelers to higher levels of cosmic radiation because of the thinner atmosphere providing less protection. Therefore, during an airplane flight from Frankfurt to San Francisco, a body will absorb an additional radiation dose of 0.16 mSv[2].

RADIOACTIVITY IS PART OF OUR BODIES

The human body accumulates radioactivity during its whole lifetime. This represents a mass activity of approximately 130 Bq/kg, which is more than twice the mass activity of 1 kg of implant material*.

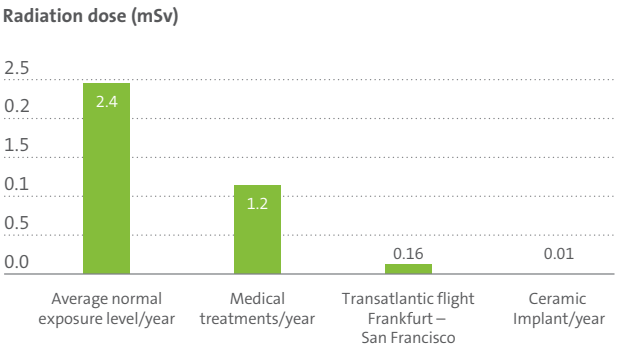
*1 kg is the equivalent of about 500 implants. The mass activity of a ceramic implant is about 20–50 Bq/kg.

CERAMIC IMPLANTS AND RADIOACTIVITY

Straumann® PURE Ceramic Implants are made from Yttria-stabilized zirconia (Y-TZP). This material is made from natural ores that contain traces of radioactive elements (226 Ra and 228 Th). After the purification process, these traces are reduced to very low levels.

Similar materials have been successfully used for many years in the production of femoral heads of hip implants. A femoral head made from ceramics with a typical weight of about 100 g emits a radiation dose of 0.13–0.53 mSv per year[3]. Dental implants made from ceramics weigh less than 2 g (a fiftieth of a femoral head made from ceramics). Compared to a femoral head of about 100 g, this results in a radiation dose of 0.01 mSv per year for a dental implant.

Yearly doses from medical treatments are typically 1.2 mSv (overall medical) for countries with more than 1 physician per 1000 people of a population. One CT scan of the head typically results in 2.3 mSv[4].



straumann
simply doing more

STRAUMANN® PURE CERAMIC IMPLANTS: MORE THAN COMPLIANT TO INTERNATIONAL SAFETY STANDARDS

International standards specify the limits for radioactivity:

- ISO 13356[5]: specifies the properties of Y-TZP zirconia ceramics for implants and limits the mass activity to below 200 Bq/kg. The Y-TZP used for the Straumann® PURE Ceramic Implant shows a value of 20 – 50 Bq/kg, which is clearly below this benchmark.
- The International Commission on Radiological Protection (ICRP) specifies a dose limit of 1 mSv/year in addition to the natural exposure for the public[6]. The dose of one single Straumann® PURE Ceramic Implant is 0.01 mSv/year, which accounts for only 1% of the ICRP limit.

CONCLUSION

The Straumann® PURE Ceramic Implant shows very low radioactivity levels which are insignificant compared to the natural yearly dose.

The values fulfil all safety standards. Therefore, it can be concluded that the very low amount of additional radioactivity bears no risk to the patient.

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