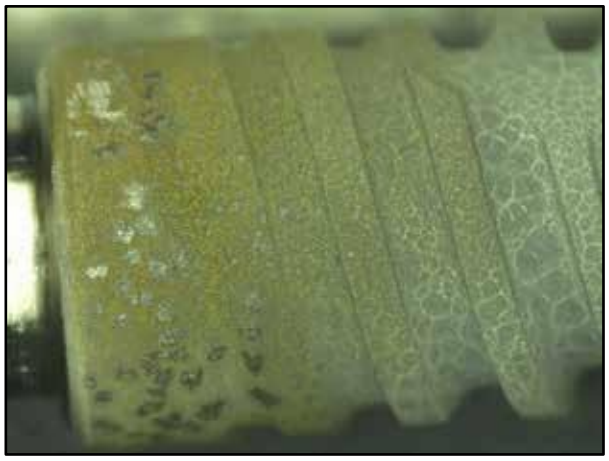
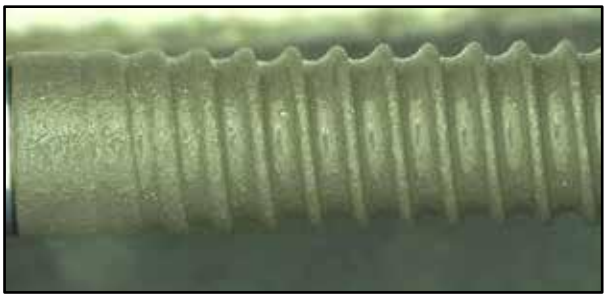
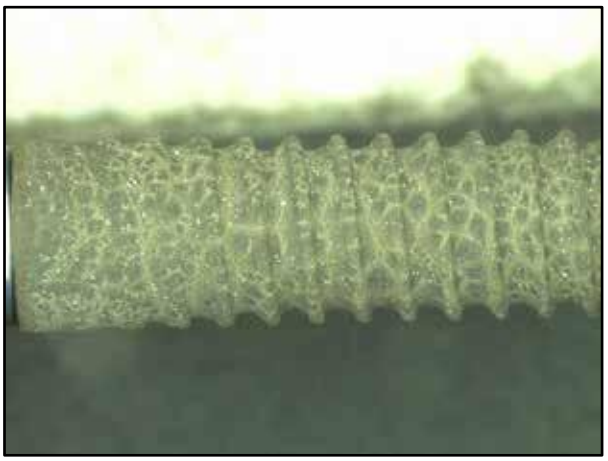
Note on discoloration on the surface of ICX-ACTIVE LIQUID implants.

ICX-Active Liquid® LAC-425125



Similar implant Competitor





The discoloration visible on the ICX-Active Liquid®implant LAC-425125 and a similar implant from a competitor (see image below left and right: dried implants) is visually noticeable but harmless!

This discoloration **occurs** not only with ICX-Active Liquid®implants from medentis medical GmbH, but also with similarly stored/manufactured implants from **competitors (see images top right).**

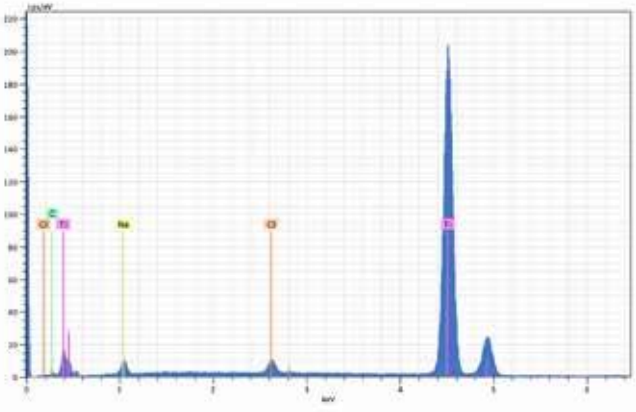
Further tests conducted by medentis medical GmbH on February 2, 2021 yielded the following results:

The glass vials for storing and transporting ICX-Active Liquid®implants are filled with liquid (physiological saline solution) and implants in a clean room, blister-packed, and then gamma sterilized. The concentration of the liquid (0.9% NaCl) was chosen because the osmotic pressure of this solution corresponds to the osmotic pressure of a human cell. Common areas of application for physiological saline solution include: rinsing solution for cleaning during surgical procedures, for cleaning wounds and burns.

Analysis of the discoloration on the surface of the dried ICX-Active Liquid®implants using scanning electron microscopy-energy dispersive X-ray spectroscopy (SEM-EDX) shows, in addition to the implant material titanium (Ti) and system-dependent impurities with

Application Note

Company / Department



Spektrum: Zeiss REM-EDX Analyse

El	OZ	Serie	unn. C [Gew.%]	norm. C [Gew.%]	C Atom. [At.%]	C Fehler (1 Sigma) [Gew.%]
Ti	22	K-Serie	92,13	94,63	89,39	2,58
Na	11	K-Serie	2,75	2,83	5,57	0,22
Cl	17	K-Serie	1,78	1,82	2,33	0,09
C	6	K-Serie	0,70	0,72	2,72	0,30
Summe:			97,36	100,00	100,00	

carbon (C), as expected, it also shows elemental residues of sodium (Na) and chlorine (Cl), which can be attributed to the physiological saline solution in the glass vials.

Conclusion: The discoloration or stains on ICX-Active Liquid®implants are physiologically harmless.

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