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## Effect of thermomechanical pre-treatment on Ni release from electropolished NiTi wires

Assessment of NiTi devices for medical applications requires careful consideration of Ni ion release. For addressing specific release behavior of NiTi alloys, the standard ISO 10993-15 was updated, extending the immersion time from one week to twelve weeks. This revision points out that NiTi exhibits a rather complex Ni release behavior with fundamental aspects requiring further investigation. This study focuses on the effects of thermomechanical pre-treatment on short-term and long-term Ni ion release from electropolished and heat-treated NiTi wires. The wires were subject to a single cycle of pseudoelastic deformation and immersed in Ringer's solution according to ISO 10993-15. The quantification of Ni release was measured using inductively coupled plasma mass spectrometry with a detection limit of  $0.02 \mu\text{g/L}$ .

Microscopic analysis showed that the surfaces were smooth and uniform before deformation. Pseudoelastic deformation caused a characteristic formation of cracks and localized flaking of oxide, which correlated with increased Ni release. An initial increase in Ni release was observed for all conditions. Long-term Ni release was below  $\sim 30 \text{ ng} \cdot \text{cm}^{-2} \cdot \text{d}^{-1}$  for all conditions, meeting the requirements of EU regulations. The Ni release is discussed regarding pre-deformation, oxide layer integrity and specific aspects of the Ni-rich layer that formed below the Ti-rich oxide. The conditions exhibiting the highest Ni release correlate with the conditions in which metastable phases form beneath the oxide layer, indicating towards an aspect that requires more detailed consideration in future work.