



### ISO/FDIS 4631:2023(E)

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<u>ISO 4631</u>

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### ISO/FDIS 4631:2023(E)

## Introduction

Ti alloys such as Ti-6Al-4V are considered to be the most promising biomedical materials. Due to a unique combination of high strength, low modulus, lower density, and outstanding corrosion resistance, their applications have become more widespread in a wide range of industries, e.g. aerospace, automobile, marine and biomedical fields. Especially the medical grade Ti alloys are implanted in patients worldwide every year and also have a significantly higher strength to weight ratio than competing stainless steels. It has well established that Ti alloys are excellent corrosion resistance by all body fluids and tissue and are thus completely biocompatible. These Ti alloys are conventionally produced by wrought or cast processes which are the subtractive manufacturing (SM) methods, but recently the new additive manufacturing (AM) method is emerging, called "3D printing". This new methodology has gained worldwide attention as a way to cut costs and improve efficiency. Comparing SM with AM, the ratio of the mass of the starting, raw material to the mass of the final, finished part can be as high as 20:1. In terms of mechanical view point, both strength and ductility of Ti alloys such as Ti-6Al-4V fabricated by AM are comparable to or above their properties made by conventional manufacturing methods, because of their unique microstructure. However, the resistance to corrosion of Ti alloys produced by AM is still unknown, whether it is comparable to those of the conventionally manufactured Ti alloys or not, because of their defects such as porosity, the formation of martensite phase resulting from the rapid solidification, and directional difference with the stacking. Therefore, the new standards should be made how to evaluate the resistance to localized corrosion on the stacked alloys produced by AM methods. For this use, the measurement method such as electrochemical critical localized corrosion temperature (E-CLCT) has been adopted as ISO 22910<del>:2020</del>. However, at the normal ranges of pH and temperatures corresponding to human body, the use of E-CLCT measurement method should be limited because of the temperature scan during testing. Therefore, electrochemical critical localized corrosion potential (E-CLCP) is newly introduced and proposed as a new criterion for the evaluation on the resistance to the localized corrosion on the biomedical AM Ti alloys in humane body environments. This new test method is controlled by Potentiostatpotentiostat through potentiodynamic -galvanostatic-potentiostatic polarization processes and electrochemical polarization cell is used in the artificial physiological fluids.

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