CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 021 **Date of Recognition:** 04/04/2023

SDO Name/Designation: ASTM F3259 **Year of Publication:** 2017

Title: Standard Guide for Micro-computed Tomography of Tissue Engineered Scaffolds

Scope:
1.1 This guide is a resource for conducting micro-computed tomography (microCT) imaging and analysis of porous scaffolds for tissue engineering applications. Considerations are provided for sample preparation, image acquisition parameter selection, post-processing, and data interpretation.
1.2 The information in this guide is intended to be applicable to products that include a porous scaffold component and are designed for tissue engineering repair strategies. The scaffolds may be fabricated from synthetic polymers (e.g., absorbable polyesters) or natural materials (e.g., calcium phosphates), mammalian or human derived materials (e.g., demineralized bone) or combinations of these. While some considerations are provided for imaging of materials that are of moderate to high radiodensity, specific guidelines are not provided for imaging metallic scaffolds.
1.3 Applicability of the guidelines herein will depend on scaffold material type and the user's application (e.g., experimental design, as manufactured characterization) as appropriate. The guidelines for microCT discussed herein are most suitable for specimen scanning in vitro. Specific guidelines relevant to direct in vivo imaging of scaffolds are not included because the imaging parameters will be dependent on the implantation site, animal size, breathing etc. In addition, consensus recommendations for in vivo imaging are provided in Bouxsein et al 2010.
1.4 While the specific imaging parameters and processing recommendations discussed in Bouxsein et al are specific to bone imaging, many of the considerations and precautions are also applicable for in vivo scaffold imaging.
1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.
1.6 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.
1.7 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Extent of Recognition: Complete Recognition

Rational for Recognition: The standard is scientifically sound and does not conflict with regulations or FDA guidance.
Standard Development Organization: https://www.astm.org/

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.