Over a Century of Openness

How We Work

- Worldwide acceptance and trust comes from the principle of openness
- Experts, individuals, organizations, academia, governments, trade associations, consultants and consumers come together
- Over 33,000 members from 150 countries
- Exchanging expertise and knowledge
- Participating in a transparent process – open to anyone, anywhere
- Timely and relevant. Fully representative of sectors. An aid to innovation, not a hurdle to overcome
- Complying with WTO/TBT Principles for International Standards

147 main committees with over 12,700 technical standards
Universal Equality of Opportunity

Operating Globally

– ASTM is one of the world’s largest Standards Developing Organizations, with global reach and influence
– Working across political, cultural and geographic borders
– Trusted for market relevance and technical quality
– Our MoU program provides resources and tools to facilitate standards development that can be applied in regulation
ASTM Standards
Building the Bridge from Innovation to Market

RESEARCH
Technology

Basic Manufacturing Research

ASTM
Smoothing the Road
Standards

Proof of Concept

MARKET
Compliance

Capacity to Produce Prototype

Demonstration of Production Rates

Production in Laboratory

Capability in Production Environment
Access ASTM Anywhere in the World

Electronic Tools

- Participation
  - WebEx virtual meetings
  - Personal “My ASTM” web page
    - Committee update
    - Balloting
    - Draft document development/collaboration

- Communications/Engagement
  - Standardization News
  - E-News
  - Social media
  - Standards Tracker Tool

- Services
  - Proficiency Testing Programs
  - Certification and Declaration Programs
  - E-Learning
Technical Committee Structure: Organization of Volunteer Members

Main Committee

- Subcommittee .01
- Subcommittee .02
- Subcommittee .03

Technical Committees
Address specific industry subjects

Subcommittees
Address subsets of specialized subject matter

Task Groups
Organized by subcommittees: standards get drafted, revised, and developed at this level
Applying ASTM International Medical Device Standards in Latin America

30 Standards
From 7 subcommittees:
- Metallurgical Materials
- Materials Testing
- Osteosynthesis
- Arthroplasty
- Spinal Devices
- Cardiovascular Standards
- Medical/Surgical Devices

5 Nations
In Latin America cite ASTM F04 standards:
- Chile
- Colombia
- Ecuador
- Nicaragua
- Peru

32 Citations
of Committee F04 standards including adoptions, consultations, and use as the basis of a national standard
ASTM Committee F04 on Medical and Surgical Devices

- Organized in 1962
- Includes over 950 members from 31 countries
  - Argentina, Canada, Brazil, Germany, India, Italy, Japan, Mexico, Peru, Spain, United Kingdom, United States etc.
- Meets twice a year with about 180 members in attendance
- 24 technical subcommittees
- 320 active standards and 57 draft proposed new standards
- Organized into 4 Divisions:
  - **Division I** – Resources
  - **Division II** – Orthopaedic Devices
  - **Division III** – Medical/Surgical Devices
  - **Division IV** – Tissue Engineered Medical Products
# F04 Technical Subcommittees

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<td>F04.46 Cell Signaling</td>
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Division IV – Tissue Engineered Medical Products (TEMPS)

Division Scope

The development of standards and promotion of related materials for tissue engineered medical products focusing on components of combination medical products intended to repair, replace or regenerate human tissue. They comprise the biological components such as the cells, tissue, cellular products, and/or the bimolecular and the biomaterials components used in combination, including biologic, biomimetic, and/or synthetic materials.
Developed by Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs

Originally approved in 2000

The physico-chemical characteristics of the raw or starting material used in regenerative medicine scaffolds carries significant potential to affect product performance by influencing cell behavior and/or the release of bioactive molecules or drugs.

This standard provides guidance on writing a materials specifications or characterizations of raw or starting materials to ensure reproducibility prior to their fabrication into implantable tissue engineering scaffolds for growth, support, or delivery of cells and/or biomolecules.
F2212 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)

- Developed by Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs
- Originally approved in 2002
- Guidance in the characterization of Type I collagen, which is the most abundant collagen in mammals, especially in skin and bone.
- The collagen covered by this guide may be used in a broad range of applications, forms, or medical products, for example medical devices, tissue engineered medical products (TEMPs) or cell, drug, or DNA delivery devices for implantation.
- This guide for characterizing collagen-containing biomaterials is intended to provide characteristics, properties, and test methods to more clearly identify the specific collagen materials used.
Includes general requirements, a model and framework for integrating equipment to create an Integrated Clinical Environment (ICE)

Specifies the characteristics necessary for the safe integration of medical devices via an electronic interface, from different manufacturers into a single medical system for the care of a single high acuity patient

Establishes requirements for a medical system that is intended to have greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices
US FDA asks industry for information demonstrating MR safety for finished devices.

Needed test methods did not exist.

US FDA requested ASTM consider developing MR safety/compatibility standards.

Recognized by FDA-CDRH
F2052 – Test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment

F2119 – Test method for evaluation of MR Image artifacts from passive implants

F2182 – Test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging

F2213 – Test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment

F2503 – Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
Proposed New Standards

– WK51697 Testing and Characterization of Alginate Foam Scaffolds Used in Tissue Engineered Medical Products (TEMPs)

– WK57514 Evaluating Biomaterial Decellularization Processes

Approved New Standards

F3259-18 New Guide for Micro Computed Tomography of Tissue Engineered Scaffolds

5 Year Review of Standards

– F2212-11 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)
ASTM Committee F42 on Additive Manufacturing
- Standards directly relevant to Medical Devices

- Organized in 2009
  - PSDO with ISO signed 2011 (ISO/ASTM Standards)
  - Meets twice a year (US/Non-US locales) with ~120 attending
- Includes over 600 members from 28 countries (177 members Int’l)
  Andorra, Australia, Belgium, Brazil, Canada, China, Czech Republic, France, Germany, India, Ireland, Israel, Italy, Japan, Korea, Mexico, Nigeria, Norway, Russian Federation, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, United Kingdom, United States

- 6 technical subcommittees
  - F42.01 Test Methods
  - F42.04 Design
  - F42.05 Materials and Processes (F42.05.01 – Metals, F42.05.02 – Polymers, F42.05.03 – Medical Applications, F42.05.04 Aerospace Applications, F42.06 Environment, Health, and Safety)
  - F42.90.05 Research and Innovation
  - F42.91 Terminology
  - F42.95 US TAG to ISO TC 261

- 23 active standards and 15 draft proposed new standards
- The next few slides summarize some of the approved/draft standards that indirectly support the medical device community for additive manufacturing.
F42.01 Test Methods

Approved (3)
F2971 Practice for Reporting Data for Test Specimens Prepared by AM
F3122 Guide for Evaluating Mechanical Properties of Metal Materials Made via AM Processes

ISO/ASTM52921 Terminology for AM-Coordinate Systems and Test Methodologies

Under Development (4)
WK56649 / JG 60 - Practice for Intentionally Seeding Flaws in (AM) Parts
WK49229 / JG 61 - Orientation and Location Dependence Mechanical Testing for Metal AM
WK55297 / JG 52 - General Principles -- Standard Test Artefacts for AM
WK55610 / JG 63 - Characterization of Powder Flow Properties

Joint Groups (7)
JG59: NDT for AM
JG62: Guide for Conducting Round Robin Studies
JG66: Technical specification on metal powders

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F42.04 Design

Approved (2)
ISO/ASTM52910-17 Standard Guidelines for Design for Additive Manufacturing

Under Development (3)
WK48549 New Specification for AMF Support for Solid Modeling: Voxel Information, Constructive Solid Geometry Representations and Solid Texturing
F42.05 Materials and Processes

Approved (12)
- F3049-14 Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
- F3056-14e1 Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
- F3184-16 Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion
- F3187-16 Standard Guide for Directed Energy Deposition of Metals

Under Development (8)
- WK53423 Additive Manufacturing - Finished Part Properties-Standard Specification for AlSi10Mg via Powder Bed Fusion
- WK58233 Additive Manufacturing - Post Thermal Processing of Metal Powder Bed Fusion Parts

331 Stakeholders
Supporting Innovation in Health and Medicine

Every day, ASTM International standards advance health by improving care delivery, supporting R&D, enhancing manufacturing, and more.

Top medical practitioners, engineers, academics, and others work through ASTM International to drive the science and services that lead to longer, fuller lives.

www.astm.org/industry/healthcare
Core Program – ASTM MoU Program

Memorandum of Understanding

**ASTM**
- Full collection of ASTM Standards (reference, adoption, use as basis of national standards)
- Membership at no cost to participant
- Information, training and partnership

**National Standards Body Partner**
- Access to ASTM standards in its Information Center
- Annual Report on use of ASTM standards
- Utilization of ASTM standards where relevant and appropriate

110 MoU partners worldwide

7900+ citations of ASTM standards in 75 nations
## ASTM Memorandums of Understanding

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Six Ways to Adopt and Reference ASTM

Available to all Public and Private Standards’ Users
- Referenced in Regulations
- Normative Reference
- Code Reference

Available Only to MoU Partners
- Identical Adoption
- Equivalent Adoption
- Used as the Basis of a National Standard or Consulted

- Simple Ways to Adopt or Reference ASTM International Standards
  - Equivalent Adoption
  - Used as the Basis of National Standard or Consulted
  - Reference in Regulation
  - Normative Reference
  - Code Reference

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Key Training Programs for MoU Partners

- **Standards Expert Program**
  - 2-4 weeks
  - On-site at ASTM International Headquarters
  - Training on various aspects of ASTM operations: technical committees, virtual tools, Committee Week, etc.
  - Fully sponsored by ASTM

- **Technical Visitor Grant Program**
  - 4-6 weeks
  - Educational program on ASTM standards within an industry sector
  - Candidates compete for two positions available annually
  - ASTM funds up to 50% of the program cost to a limit of $5,000

- **Intensive Training Programs**
  - Delegations of 6-12 individuals
  - Focused on a specific topic, industry, or set of standards
  - Generally requested by an industry, institute, government ministry or university
  - Tailored program includes site visits, technical discussions, and meetings with other related organizations
  - ASTM facilitates all planning; staff accompanies delegation at no charge; delegation fees fully sponsored by requesting entity

- **Virtual Training**
  - Interactive web-based training on technical and procedural topics
  - Accommodate for time differences and languages
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