



ASTM INTERNATIONAL  
Helping our world work better

# ASTM International, Medical Device Standards, and Latin America

[www.astm.org](http://www.astm.org)

# 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

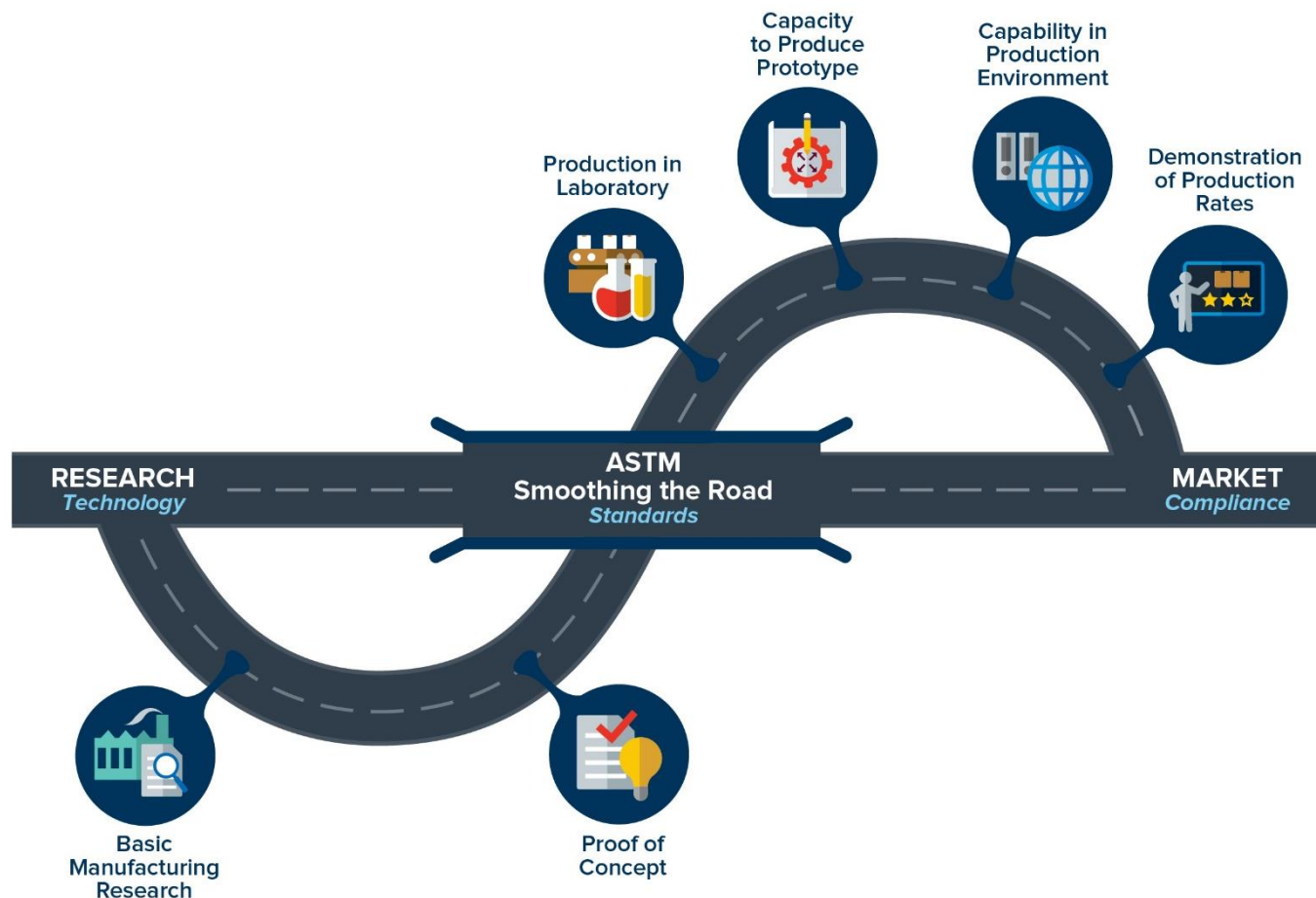


# 110

Memoranda of Understanding

# ASTM Standards

## Building the Bridge from Innovation to Market





# Access ASTM Anywhere in the World



## Electronic Tools

### – Participation

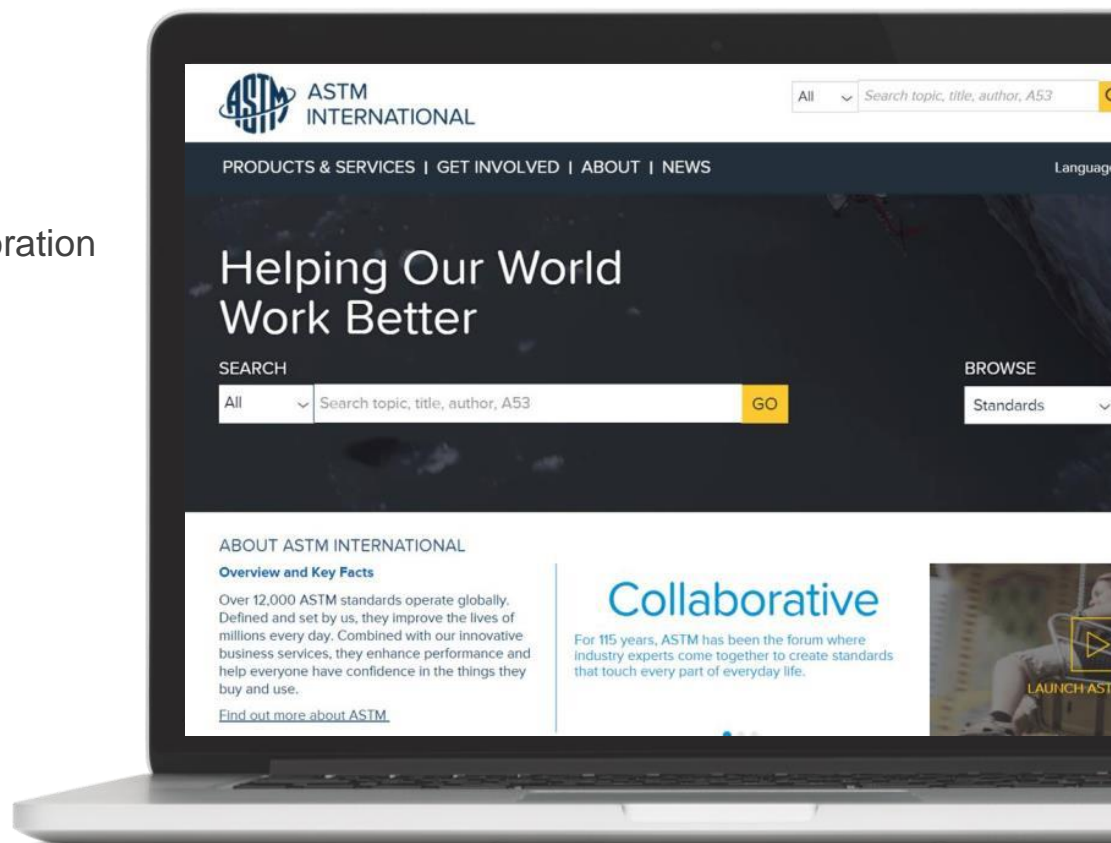
- WebEx virtual meetings
- Personal “My ASTM” web page
  - Committee update
  - Balloting
  - Draft document development/collaboration

### – Communications/Engagement

- Standardization News
- E-News
- Social media
- Standards Tracker Tool

### – Services

- Proficiency Testing Programs
- Certification and Declaration Programs
- E-Learning

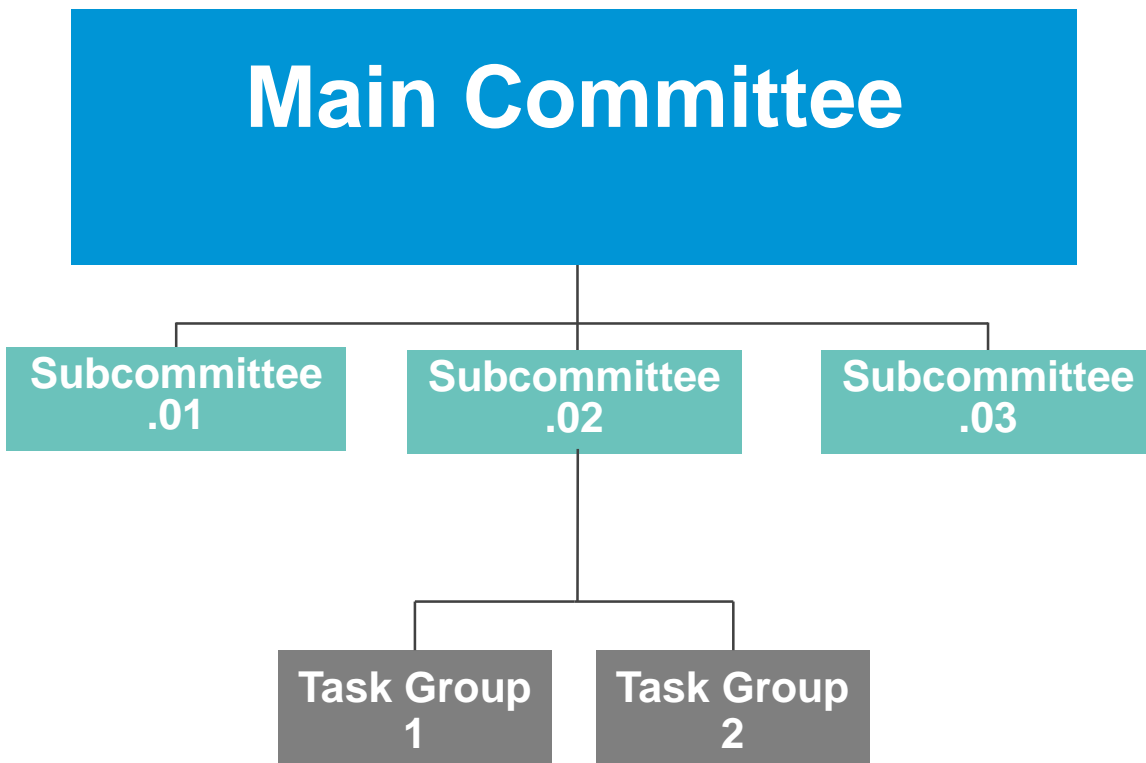


# Technical Committee Structure:

## Organization of Volunteer Members



### Main Committee



### 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

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- 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



F04.11 Polymeric Materials  
F04.12 Metallurgical Materials  
F04.13 Ceramic Materials  
F04.15 Material Test Methods  
F04.16 Biocompatibility Test Methods  
F04.21 Osteosynthesis  
F04.22 Arthroplasty  
F04.25 Spinal Devices  
F04.30 Cardiovascular Standards  
F04.31 Neurosurgical Standards  
F04.32 Plastic and Reconstructive  
Surgery  
F04.32.01 Mammary Implants  
F04.33 Medical/Surgical Instruments

F04.34 Urological Materials and Devices  
F04.35 GI Applications  
F04.37 Implantable Hearing Devices (IHDs)  
F04.38 Computer Assisted Orthopaedic Surgical  
Systems  
F04.39 Human Clinical Trials  
F04.41 Classification and Terminology for TEMP  
F04.42 Biomaterials and Biomolecules for TEMP  
F04.43 Cells and Tissue Engineered Constructs for  
TEMP  
F04.44 Assessment for TEMP  
F04.45 Adventitious Agents Safety  
F04.46 Cell Signaling

# Division IV – Tissue Engineered Medical Products (TEMPs)



## Division Scope

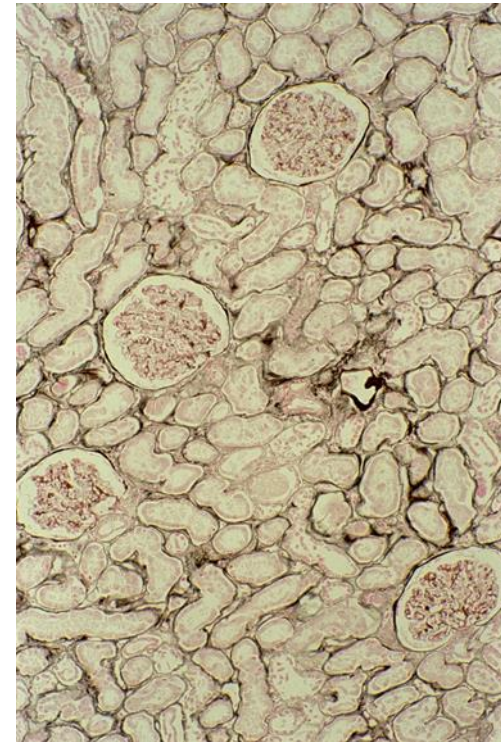
The development of standards and promotion of related materials for tissue engineered medical products focusing on components of combination medical products intended to repair, replace or regenerate human tissue. They comprise the biological components such as the cells, tissue, cellular products, and/or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



## F2027 Standard Guide for Characterization and Testing of Raw or Starting Materials for Tissue-Engineered Medical Products



- Developed by Subcommittee F04.42 on Biomaterials and Biomolecules for TEMP
- 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.



## F2761 Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model



- 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

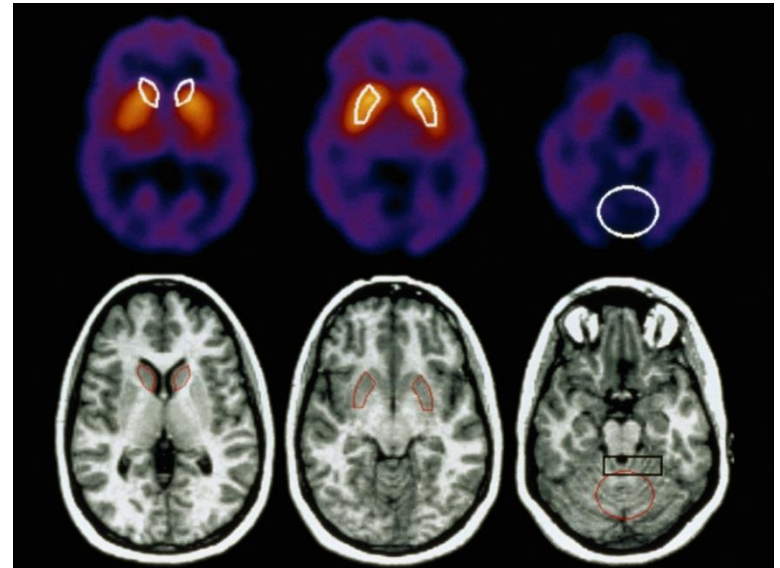




# F04 Advanced Standards Initiatives – MRI



- 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





# F04 Advanced Standards Initiatives – MRI



**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

# Current Activity in Subcommittee F04.42



## Proposed New Standards

- [WK51697](#) Testing and Characterization of Alginate Foam Scaffolds Used in Tissue Engineered Medical Products (TEMPs)

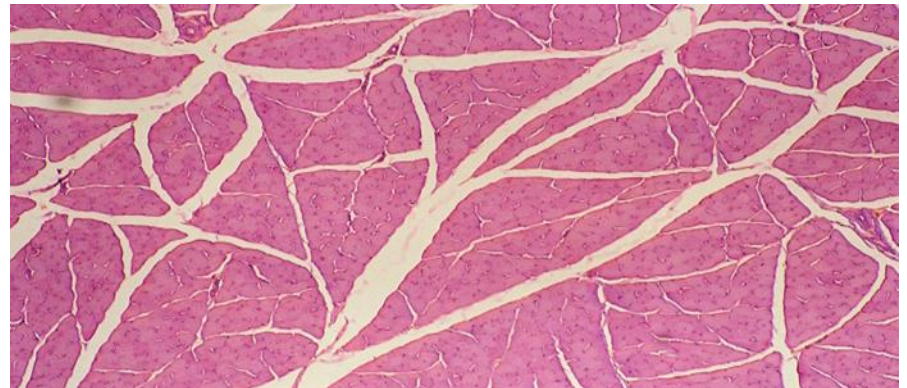
[WK57514](#) Evaluating Biomaterial Decellularization Processes

## 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

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- 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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Stakeholders

## Approved (2)

[ISO/ASTM52915-16 Standard Specification for Additive Manufacturing File Format \(AMF\) Version 1.2](#)

[ISO/ASTM52910-17 Standard Guidelines for Design for Additive Manufacturing](#)

[F3280-17 Standard for Additive manufacturing, Technical Design Guideline for Powder Bed Fusion, Part 2: Laser-based Powder Bed Fusion of Polymers](#)

[F3281-17 Standard for Additive manufacturing, Technical Design Guideline for Powder Bed Fusion, Part 1: Laser-based Powder Bed Fusion of Metals](#)

## Under Development (3)

[WK48549](#) New Specification for AMF Support for Solid Modeling: Voxel Information, Constructive Solid Geometry Representations and Solid Texturing

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Stakeholders

# F42.05 Materials and Processes



## Approved (12)

[F2924-14 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion](#)

[F3049-14 Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes](#)

[F3055-14a Standard Specification for Additive Manufacturing Nickel Alloy \(UNS N07718\) with Powder Bed Fusion](#)

[F3056-14e1 Standard Specification for Additive Manufacturing Nickel Alloy \(UNS N06625\) with Powder Bed Fusion](#)

[F3091/F3091M-14 Standard Specification for Powder Bed Fusion of Plastic Materials](#)

[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](#)

[ISO/ASTM52901-16 Standard Guide for Additive Manufacturing – General Principles – Requirements for Purchased AM Parts](#)

## Under Development (8)

[WK60906](#) Additive Manufacturing - Process Characteristics and Performance - Metal Powder Bed Fusion Process to Meet Critical Applications

[WK53878](#) Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials

[WK58219](#) Additive Manufacturing - Feedstock Materials-Creating Feedstock Specifications for Metal Powder Bed Fusion

[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

[WK60552](#) Additive Manufacturing-Finished Part Properties-Standard Specification for Additive Manufacturing Titanium Alloys via Powder Bed Fusion

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Stakeholders

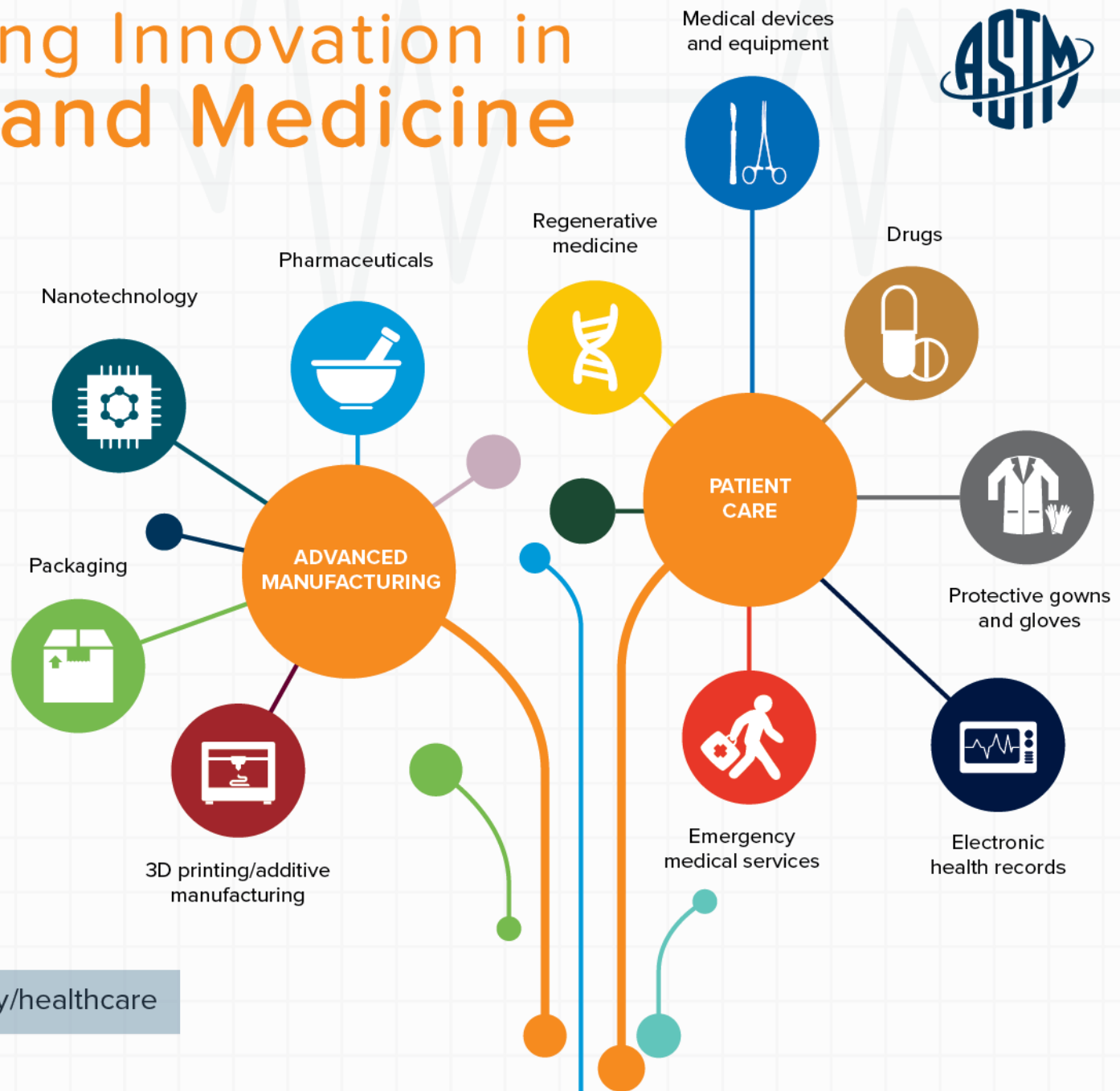


# Supporting Innovation in Health and Medicine

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](http://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



ASIA	EUROPE	CENTRAL & SOUTH AMERICA	CARIBBEAN	MIDDLE EAST & NORTH AFRICA	EASTERN, WESTERN & CENTRAL AFRICA	SOUTHERN AFRICA
BANGLADESH	ALBANIA	BOLIVIA	ANTIGUA AND BARBUDA	AFGHANISTAN	ARSO	ANGOLA
BHUTAN	ARMENIA	CHILE	BAHAMAS	BAHRAIN	BURUNDI	BOTSWANA
BRUNEI DARUSSALAM	AZERBAIJAN	COLOMBIA	BARBADOS	EGYPT	CAMEROON	MALAWI
CAMBODIA	BOSNIA	COSTA RICA	BELIZE	GSO	COTE d'IVOIRE	MAURITIUS
CHINA	BULGARIA	ECUADOR	CROSQ	IRAQ	DEM.REP. CONGO	NAMIBIA
INDONESIA	CROATIA	EL SALVADOR	DOMINICA	ISRAEL	ETHIOPIA	SEYCHELLES
KOREA	EASC	GUATEMALA	DOMINICAN REPUBLIC	JORDAN	GAMBIA	SADC
LAO	GEORGIA	HONDURAS	GRENADA	KUWAIT	GHANA	SOUTH AFRICA
MALAYSIA	KAZAKHSTAN	NICARAGUA	GUYANA	MOROCCO	KENYA	SWAZILAND
MONGOLIA	KOSOVO	PANAMA	HAITI	OMAN	MOZAMBIQUE	ZAMBIA
MYANMAR	MOLDOVA	PARAGUAY	JAMAICA	PALESTINE	NIGERIA	ZIMBABWE
NEPAL	MONTENEGRO	PERU	MONTSERRAT	QATAR	RWANDA	
PAKISTAN	ROMANIA*	URUGUAY	ST. KITTS-NEVIS	SAUDI ARABIA	SIERRA LEONE	
PAPUA NEW GUINEA	RUSSIA		ST. LUCIA	TUNISIA	SENEGAL	
PHILIPPINES	SERBIA		ST. VINCENT - GRENADINES	TURKEY	TANZANIA	
SINGAPORE	UKRAINE		SURINAME	U.A.E.	UGANDA	
SRI LANKA			TRINIDAD & TOBAGO	YEMEN		
TAIWAN						
THAILAND						
VIETNAM						

# Six Ways to Adopt and Reference ASTM

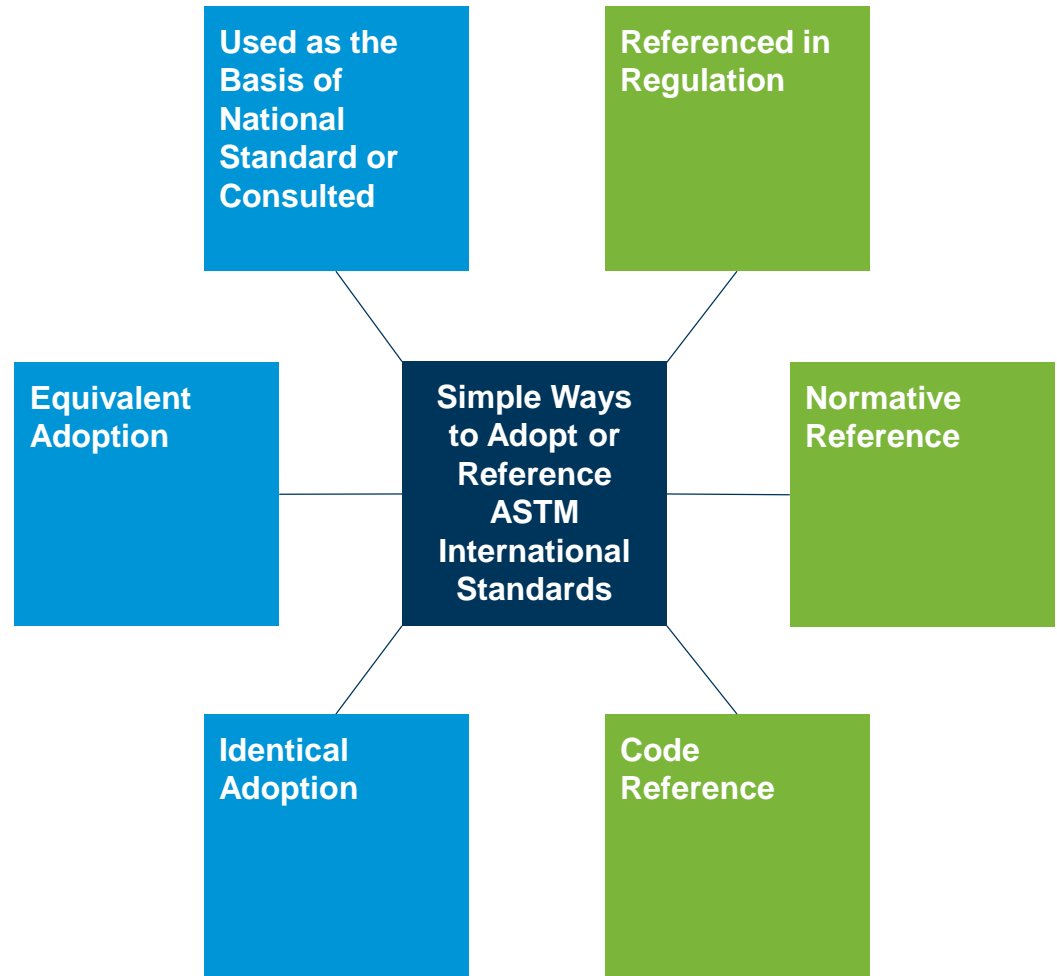


## Available to all Public and Private Standards' Users

- 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



# 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 a 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

# Contacts

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