

About ASTM International

ASTM International is one of the largest standards development and delivery systems in the world. ASTM standards are voluntary consensus documents that guide research, design, manufacturing, marketing and trade. For more than a century, ASTM has met the technical needs of commerce by providing standards that are accepted and used around the world.

ASTM's market relevance is evident in more than 100 industrial and management sectors ranging from construction materials and environmental assessment to medical devices and consumer products. More than 130 nations are represented in ASTM.

ASTM standards are developed by technical experts who are the members of ASTM International. Membership is open to all who have an interest in the standards affecting business and industry. You too can join the 30,000 individuals and institutions who set the standard for the rest of the world in ASTM International.

ASTM International meets the World Trade Organization principles for the development of international standards: coherence, consensus, development dimension, effectiveness, impartiality, openness, relevance and transparency.

You can contribute to ASTM's standards development process. For more information on ASTM membership, please contact Ileana Smith, manager of member promotion and academic outreach, at 610-832-9552 or ismith@astm.org.

To join on the web go to www.astm.org/JOIN.



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Developing Standards for Healthcare and Medical Technology with ASTM International

Advancing Human Health





Standards for Medical and Surgical Materials and Devices

As healthcare worldwide continues to evolve, so do available therapies and technologies. ASTM Committee F04 on Medical and Surgical Materials and Devices, as it has since its organization in 1962, represents a collaboration among close to 900 practitioners, faculty members, industry representatives and federal agencies — from 29 countries — on standards for materials, devices, testing and medical/surgical instruments.

At its beginnings, the committee concentrated on material and design aspects of implant device systems, with resulting standards often used for industrial quality control and analysis. Since that time F04's activities have evolved along with the discipline. Today, F04 technical subcommittees address standards related to ceramics, metals and polymers as well as biocompatibility and magnetic resonance imaging; methods and practices for osteosynthesis, arthroplasty and spinal devices; medical and surgical devices used in cardiology, neurology, audiology, gastroenterology and plastic surgery; computer-assisted orthopaedic surgical systems and tissue engineered medical products.

TEMPS, which use biological components alone or in combination with synthetic components to restore human tissue through regeneration, and their potential for enhancing human health, are the focus of F04.04, Division IV – Tissue Engineered Medical Products. F04.04 focuses on classifications and terminology, biomaterials and biomolecules, cells and tissue engineered constructs, assessment, adventitious agent safety and cell signaling.

Among the many F04 standards already available in this area is the recent F2027, Guide for Characterization and Testing of Raw or Starting Biomaterials for Tissue-Engineered Medical Products. Many more are under way.

Additional important consensus standards from F04 include:

- ▶ F899, Specification for Wrought Stainless Steels for Surgical Instruments, which covers the chemistry requirements for these metals used in manufacturing surgical instruments;
- ▶ F2103, Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications, an approach to evaluate chitosan salts suitable for TEMPs and other applications;
- ▶ F2150, Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products, a resource to characterize compositional and structural aspects of biomaterial scaffolds used to develop and manufacture TEMPs; and
- ▶ F2193, Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System, a comprehensive reference for spinal implant construct parts.

The F04 committee complements its standards work through symposia and workshops that promote the exchange of technical information about ongoing advances in the medical field. Some examples include arthroplasty standards, explant shipping and fatigue/fracture of metallic materials.



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Standards for Packaging and Labeling

ASTM Committee D10 on Packaging, which formed in 1914, possesses a long history of responding to the needs of the marketplace, including applications within the medical field. In addition, ASTM Committee F02 on Flexible Barrier Packaging, which has celebrated more than 50 years of standards development and the publication of more than 50 standards, provides documents used in the medical field.

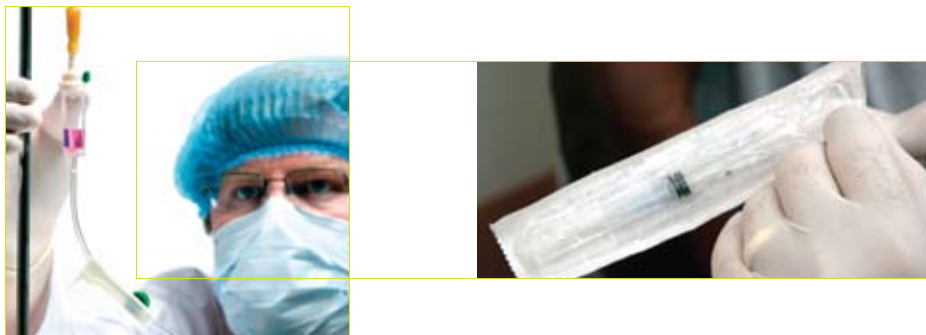
D10, a committee of some 350 members responsible for 135 standards, is geared toward medical applications in its Subcommittee D10.32 on Consumer, Pharmaceutical and Medical Packaging, which maintains standards for user-applied drug labels in anesthesiology, identification and configuration of drug syringes, and enhancing drug labeling. One of its significant standards is D4267, Specification for Labels for Small-Volume (100 mL or Less) Parenteral Drug Containers, which delineates orientation, type size and copy contrast to facilitate correct drug identification.

Collaboration between government, academia and packaging company professionals meets in the work of Committee F02. The 150-member strong F02 committee, which has jurisdiction over more than 50 standards, develops standards that ensure package integrity. Their standards include:

- ▶ F88, Test Method for Seal Strength of Flexible Barrier Materials, one of the committee's top standards, which covers techniques to measure seal strength and thus provide process validation, control and capability;
- ▶ F1140, Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages, which details how to determine the ability of packages to withstand internal pressurization;
- ▶ F1929, Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration, a procedure for locating leaks in medical package seals;
- ▶ F1980, Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, which gives direction to developing protocols for the rapid determination any effects of the passage of time on sterile barrier system integrity; and
- ▶ F2097, Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products, which provides a road map to the many standards in this area.



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Standards for Healthcare Informatics

The CCR or Continuity of Care Record is a dataset to be transferred to the next healthcare provider when a patient goes to different clinicians, hospitals and other medical providers – a simple yet powerful tool to reduce errors and enhance care while maintaining information security. The standard, E2369, Specification for Continuity of Care Record, is being used around the world, and Microsoft HealthVault and Google Health use the CCR as the basis for their products.

The responsible committee, ASTM E31 on Healthcare Informatics, also collaborated on AIIM/ASTM-BP-01-08, Portable Document Format-Healthcare (PDF) A Best Practices Guide. The guide, developed with AIIM, describes how to use PDF to capture, exchange, preserve and protect healthcare information.

E31 has been working on consensus standards since its organization in 1970. With representation from 17 countries in its membership of more than 300, the E31 committee develops standards for the architecture, content, storage and communication of information used within healthcare,

including patient-specific information and medical knowledge as well as integrity and confidentiality.

The group has also produced these benchmark documents:

- ▶ E1384, Practice for Content and Structure of the Electronic Health Record (EHR), a comprehensive structure for data collected in patient care records that draws on specialty disciplines and particularly integrates clinical laboratory data with other patient information;
- ▶ E1633, Specification for Coded Values Used in the Electronic Health Record, which gives details about value sets for explicit data attributes in E1384;
- ▶ E1869, Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records, which covers the protection of individual healthcare data but also abstracted data used for research or administrative purposes; and
- ▶ E2553, Guide for Implementation of a Voluntary Universal Healthcare Identification System, a system to enable unambiguous identification of individuals to facilitate healthcare delivery.



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Standards for Medical Applications of Nanotechnology

The burgeoning field of nanotechnology has created a need for standards, and ASTM has responded with several, including a recently published trio of methods for nanoparticle biocompatibility testing to aid in research that will help pave the way for commercial nano-scale cancer drugs. ASTM Committee E56 on Nanotechnology, organized in 2005, includes approximately 225 professionals working in the field.

The three methods are:

- ▶ E2524, Test Method for Analysis of Hemolytic Properties of Nanoparticles, is a protocol for examining the destruction of red blood cells (hemolysis) that can lead to anemia, jaundice and other issues. All intravenously administered drugs must be examined to determine potential for hemolysis.

- ▶ E2525, Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies, describes a method for evaluating nanoparticle stimulation or inhibition of the maturation of certain bone marrow cells (macrophages). A common side effect of anti-cancer drugs is inhibition of this process, and bone marrow cells may be particularly sensitive to nano-scale material.
- ▶ E2526, Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials on Porcine Kidney Cells and Human Hepatocarcinoma Cells, enables the nanomaterial toxicity evaluation by examining effects on kidney and cancerous liver cells. Because studies have indicated that many nanoparticles are cleared from the body through the kidney or liver, these organs are good choices for target organ toxicity evaluation.



E56 has also developed a terminology standard as well as E2535, Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings, and is working on several preparation and evaluation practices.

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Standards for Pharmaceutical Processes

The processes to produce pharmaceuticals have been the focus of ASTM Committee E55 on Manufacture of Pharmaceutical Products since its organization in 2003. E55 looks at process control, design and performance as well as quality assurance tests, in addition to current pharmaceutical end product testing in its standards work. With the participation of 330 representatives internationally from industry, academia, trade associations, financial organizations and the U.S. Food and Drug Administration as well as other federal agencies, E55 has developed several standards and is developing more related to process analytical technology.

E2537, Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing, is a recent standard from the committee; it describes an approach to verify that a process consistently produces products meeting predetermined attributes.



Additional key documents from E55 are:

- ▶ E2500, Standard Guide for Specification, Design and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment,
- ▶ E2503, Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus,
- ▶ E2474, Standard Practice for Pharmaceutical Process Design Utilizing Process Analytical Technology, and
- ▶ E2363, Standard Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry.

E2537, Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing, is a recent standard from the committee; it describes an approach to verify that a process consistently produces products meeting predetermined attributes.





Standards for Services

Quality emergency medical service is the shared goal of the almost 100 stakeholders in ASTM Committee F30 on Emergency Medical Services, which has published more than 50 standards and continues on several others. Documents and the responsible subcommittees cover:

- ▶ Immobilization devices, ground vehicles and air ambulances from Subcommittee F30.01 on EMS Equipment;
- ▶ Training and performance of emergency medical technicians and first responders from Subcommittee F30.02 on Personnel, Training and Education;
- ▶ EMS system structure, evaluation, transportation financing, and more from Subcommittee F30.03 on Organization/Management;

- ▶ Medical dispatch and dispatch management, reports and interagency communication exchange from Subcommittee F30.04 on Communications; and
- ▶ EMS definitions from Subcommittee F30.06 on Terminology.



And, in the event of an emergency, E2413, Guide for Hospital Preparedness and Response, from ASTM Committee E54 on Homeland Security Applications, provides a standard for a hospital to measure its readiness to operate in the face of such situations.



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Standards for Medical Gloves

ASTM Committee D11 on Rubber, which began its work in 1912, has a long productive history of promulgating standards. Technical subcommittees of D11, a group of some 315 members with jurisdiction over 215 standards, take in three primary areas: testing and analysis, raw materials and rubber products.

Subcommittee D11.40 on Consumer Rubber Products, among other rubber goods, specifically addresses gloves used in the medical sector — their performance and safety, materials and manufacture.

Significant standards in this area include the following:

- ▶ D3577, Specification for Rubber Surgical Gloves,
- ▶ D3578, Specification for Rubber Examination Gloves,
- ▶ D5151, Test Method for Detection of Holes in Medical Gloves,
- ▶ D6319, Specification for Nitrile Examination Gloves for Medical Application, and
- ▶ D7160, Practice for Determination of Expiration Dating for Medical Gloves.



Related ASTM International Publications

Bone Graft Substitutes encompasses contributions by more than 35 recognized experts writing about clinical and scientific aspects of bone grafting as well as the practical issues of bringing promising new graft materials to market. The monograph is edited by Cato T. Laurencin and co-published by ASTM International and the American Academy of Orthopedic Surgeons.

ASTM Standards on Medical Transcription incorporates seven standards vital for healthcare documentation, ones that ensure accuracy, security, and patient confidentiality during information maintenance, transmission, storage and retrieval.

STP 1481, Fatigue and Fracture of Medical Metallic Materials and Devices, includes 11 peer-reviewed papers on the thermal and mechanical properties of shape memory alloys and metallic medical materials and devices.