Every day around the globe, ASTM International standards make a vital contribution in the healthcare field. Proven ASTM standards advance human health by improving care delivery, supporting medical research and drug development, enhancing product manufacturing and much more. Developed by leading healthcare practitioners, engineering professionals and other technical experts, ASTM standards drive the science and innovation that bring about a healthier and safer way of life.
Committee F04: Global Agenda for Medical Device Standards

Since 1962, F04 has played an important role in developing standards for medical and surgical instruments, orthopedic devices, implant systems and more that assist manufacturers and support quality patient care. Today, F04 addresses standards for a range of important uses:
- Ceramics, metals and polymers;
- Biocompatibility and magnetic resonance imaging;
- Osteosynthesis and spinal devices;
- Cardiology, neurology, audiology, gastroenterology and plastic surgery;
- Cell signaling;
- Computer-assisted orthopedic surgical systems; and
- Tissue engineered medical products.

With its dynamic focus and a broad global membership of more than 900 professionals from 31 countries, ASTM International Committee F04 on Medical and Surgical Materials and Devices delivers over 300 standards that make an impact around the world.

Tissue engineered medical products, commonly referred to as TEMPS, use biological components alone or in combination with synthetic components to restore human tissue through regeneration. To support continued progress in this field and its role in enhancing human health, F04 has subcommittees focused on TEMPS, including groups for classification and terminology, biomaterials and biomolecules, cells and tissue engineered constructs, assessment, adventitious agent safety and cell signaling.

F04 standards in this area include:
- F2900 for characterization of hydrogels used in regenerative medicine, which covers attributes such as biological properties, kinetics of formation, degradation and agent release, stability and mass transport capabilities; and
- F2150 for characterization and testing of biomaterial scaffolds used in TEMPS, including metallic, ceramic, polymeric, natural or composite materials.

Advancing the Science of TEMPS
Magnetic resonance imaging technology has grown dramatically since its debut in the 1980s. MR scanners use magnetic signals to create images of the human body, helping physicians to study nerves, muscles, ligaments, bones and other tissues and to diagnose injuries and disease.

F2503: Promoting the Safe Use of MRI

Within the MR environment, potential safety hazards pose concern for patients, MR technologists and other medical professionals. Implants such as pacemakers and metal joint replacements can interact with the MR scanner’s magnets and pulses, resulting in device damage, malfunction and overheating that may lead to serious patient injury and death. There is also the risk of projectile accidents caused when other medical devices and metallic items are pulled into the bore of the MR system. To mitigate technologist confusion and facilitate patient safety, F04 developed F2503 for marking medical devices for safety in the magnetic resonance environment. Recognized in U.S. Food and Drug Administration guidance, F2503 provides a uniform marking system to indicate what MR conditions have been determined to be acceptable for a medical device or other item. F2503 provides MR labeling terms and associated visual icons intended to reduce injuries when potentially hazardous items are brought into the MR environment.

Innovation in Medical Device Manufacturing

Another ASTM International committee that is making an impact on the medical device sector is F42 on Additive Manufacturing Technologies. Commonly known as 3D printing, additive manufacturing is the process of building a product or part by applying material or powder in very thin layers until the final product has been built. In the medical device field, additive manufacturing processes help to improve the design, test and manufacture of many new products, such as hearing aids, dental crowns and surgical implants.

ASTM Committee F42 is helping to support innovation in medical device manufacturing through additive manufacturing standards that cover the production of alloys potentially applicable for medical parts. Among these standards developed by Subcommittee F42.05 on Materials and Processes are F3001 for additive manufacturing titanium; F3055 for additive manufacturing nickel alloy; and F3049 for metal powders used for additive manufacturing processes.

Orthopedic Implant Labeling

Subcommittee F04.22 on Angioplasty recently released a standard to address labeling requirements for the orthopedic implant field. F2943 on end user labeling information for musculoskeletal implants presents a universal label format of content and relative location of information necessary for final implant selection within an implant’s overall package labeling. The guide identifies high priority label content and indicates a specific section of an implant’s labeling where this crucial information is to be placed. F2943 offers manufacturers a vehicle for labeling consistency across products and brands while supporting an implant delivery system that is optimized to ensure the correct selection of an implant for a specific patient.
Two of ASTM International’s most enduring committees, D10 on Packaging and F02 on Flexible Barrier Packaging, have long cooperated in developing standards that fulfill health and safety needs. D10 and F02 medical packaging standards respond to the needs of regulators and manufacturers both in the United States and internationally, and find broad use in primary packages, which maintain the sterility of the device, as well as their secondary shipping containers, which further protect the contents.

Committee D10, formed in 1914, has a portfolio of more than 150 standards, many geared toward critical medical applications. Highlighting these efforts is the work of Subcommittee D10.32 on Consumer, Pharmaceutical, Medical and Child Resistant Packaging.

- D3475 on child resistant packages, updated in 2014, defines the types of motions, skills or tools required for a particular type of child-resistant package and provides examples of current packaging within that type.

Committee F02 was established in 1957 and today is responsible for more than 50 standards. Notable F02 standards that support medical packaging integrity include:

- F88 on seal strength of flexible barrier materials, which covers techniques to measure seal strength and thus provide process validation, control and capability; and
- F2096 for detecting gross leaks in packaging. Referred to as the “bubble leak” test, F2096 is used in laboratory testing for visually inspecting medical packaging for bubble streams caused by a defect in the packaging/sterile barrier system.

Ensuring Safety in Pharmaceutical and Medical Product Packaging
E31: Improving Accuracy and Timeliness of Patient Information

As the nation's healthcare system continues to transform itself to improve quality of care, providers are increasingly embracing electronic health records to enable more reliable patient information exchange. EHRs are a critical component in the continued progress of healthcare that can strengthen the relationship between patients and their doctors. By improving the accuracy and availability of medical records, EHRs can reduce errors, speed treatment and care delivery, and keep patients better informed.

A major focus of ASTM International Committee E31 on Healthcare Informatics is the development of standards that help doctors and healthcare practitioners preserve and transfer patient information using EHR technologies. E31 has been collaborating on consensus standards since its organization in 1970.

Significant E31 standards include E2369 for continuity of care record (CCR). The CCR defines a core set of information to be sent to the next healthcare provider whenever a patient is referred, transferred or uses different medical facilities or providers. For both doctors and patients, the CCR facilitates better coordination and improved medical care. In the United States, the Office of the National Coordinator for Health Information Technology, part of the U.S. Department of Health and Human Services, has included the use of E2369 in its formal certification criteria for EHR technologies.

Two other benchmark E31 documents also provide utility in the EHR area. These standards are:
- E1384 for content and structure of the electronic health record, 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; and
- E1633 for coded values used in the electronic health record, which details value sets for explicit data attributes in E1384.

E56 Nanotech Standards Support Cancer Research

The battle against cancer is getting a boost from several breakthrough test methods under the jurisdiction of ASTM Committee E56 on Nanotechnology. E56, organized in 2005, is supporting cutting-edge research efforts that could pave the way for commercially available nanoscale cancer drugs.

The standards that have been developed include:
- E2524 for analysis of hemolytic properties of nanoparticles, a protocol to examine the destruction of red blood cells (hemolysis) that can lead to anemia and other issues;
- E2525 for evaluating the effect of nanoparticle materials, a method for evaluating nanoparticle stimulation or inhibition of the maturation of certain bone marrow cells (macrophages); and
- E2526 for evaluation of cytotoxicity of nanoparticulate materials by examining effects on kidney and cancerous liver cells.

Users of E56 tests include nanotech drug developers; scientists in the pharmaceutical, cancer research and nanotechnology fields; regulatory agencies; and agencies evaluating the environmental health and safety risks associated with nanoparticles.
Another emphasis of E31’s standards development activities is the dynamic and evolving area of universal patient identification. Issues related to UPI have been the focus of much discussion since the signing of the Health Insurance Portability and Accountability Act of 1996. Incorrectly identifying a patient continues to be a major area of concern in the healthcare environment and has serious unwanted consequences, including adverse drug events, unnecessary and duplicate testing, clinical complications, prolonged hospital stays and patient dissatisfaction.

A UPI approach would help reduce errors, improve patient safety, and enhance the interoperability and efficiency of health information networks.

- E2553 for implementation of a voluntary universal healthcare identification system describes the principles needed to create such a system, addressing issues of privacy, security and cost-effectiveness.
- Similar utility is found in E1714 for properties of a universal healthcare identifier (UHID).

Building a New Road Map for Pharmaceutical Manufacturing

When it comes to pharmaceutical manufacturing, a global industry whose products can literally mean the difference between life and death, quality and efficiency are major concerns.

Committee E55 on Manufacture of Pharmaceutical Products was born from an expansion of the Process Analytical Technology (PAT) initiative, a program developed by the FDA to overhaul pharmaceutical manufacturing processes to ensure good, safe and reliable products for consumers. E55’s first standards were focused on furthering the goals of the PAT framework throughout the pharmaceutical industry. These include E2363 on terminology relating to process analytical technology and E2474 for pharmaceutical process design.

Subcommittee E55.03 on General Pharmaceutical Standards has released several standards to facilitate purity testing of pharmaceutical water, the most common component or ingredient used in pharmaceutical and biopharmaceutical manufacturing.

Notable among these is E265 for real-time release testing of pharmaceutical water and E2810 for uniformity of dosage units, which is a valuable tool in drug content uniformity and dissolution testing.

Most recently added to the committee is Subcommittee E55.04 on General Biopharmaceutical Standards, which has developed numerous standards that support the manufacture of biopharmaceutical products. An important new thrust within E55.04 is standards for single use systems and raw materials pharmaceutical development and manufacturing, notably biotechnology. Among the new standards underway are a practice for testing integrity of single-use systems and a related practice for characterizing particulates burden from single-use systems.
Additional ASTM committees are involved in standards work that enhances healthcare products and services for people worldwide. These committees include the following:

- ASTM Committee F30 on Emergency Medical Services focuses on such topics as EMS equipment, including immobilization devices and air ambulances; emergency medical technicians and first responder training; EMS system structure; and medical dispatch management and communications. Notable among the committee’s more than 50 standards is F2020 for design, construction and procurement of emergency medical services systems ambulances.

- Subcommittee D11.40 on Consumer Rubber Products, which is part of Committee D11 on Rubber, has an extensive array of standards that impacts the quality, performance and safety of healthcare products such as medical gloves, condoms and drainage tubes. Among its widely used standards is D3577 for rubber surgical gloves and D7866 for radiation attenuating protective gloves. D11.40 also has several proposed standards under development, including a method for evaluating microbial contact transfer for antimicrobial treated gloves. The standard will help measure how well an exam glove can reduce skin-to-surface contact transfer of a known population of bacteria.

- With a membership of approximately 40 professionals, ASTM Committee F29 on Anesthetic and Respiratory Equipment develops standards for medical systems such as gas monitors, ventilators and other systems. Notable F29 standards include: F2726 for fixation devices for tracheal tubes and other airway devices and F2761 on medical devices and medical systems, which addresses the interconnectivity of medical devices in the clinical environment.

As healthcare needs evolve and expand around the globe, ASTM standards will continue to drive the scientific and medical advancements that support healthier and longer lives.

The ASTM technical committees highlighted in this piece include:

D10 on Packaging
D11 on Rubber
E31 on Healthcare Informatics
E55 on Manufacture of Pharmaceutical Products
E56 on Nanotechnology
F02 on Flexible Barrier Packaging
F04 on Medical and Surgical Materials and Devices
F29 on Anesthetic and Respiratory Equipment
F30 on Emergency Medical Services
F42 on Additive Manufacturing Technologies
Over 12,000 ASTM standards operate globally. Defined and set by us, they improve the lives of millions every day.

Combined with our innovative business services, they enhance performance and help everyone have confidence in the things they buy and use – from the toy in a child’s hand to the aircraft overhead.

Working across borders, disciplines and industries we harness the expertise of over 30,000 members to create consensus and improve performance in manufacturing and materials, products and processes, systems and services.

Understanding commercial needs and consumer priorities, we touch every part of everyday life: helping our world work better.