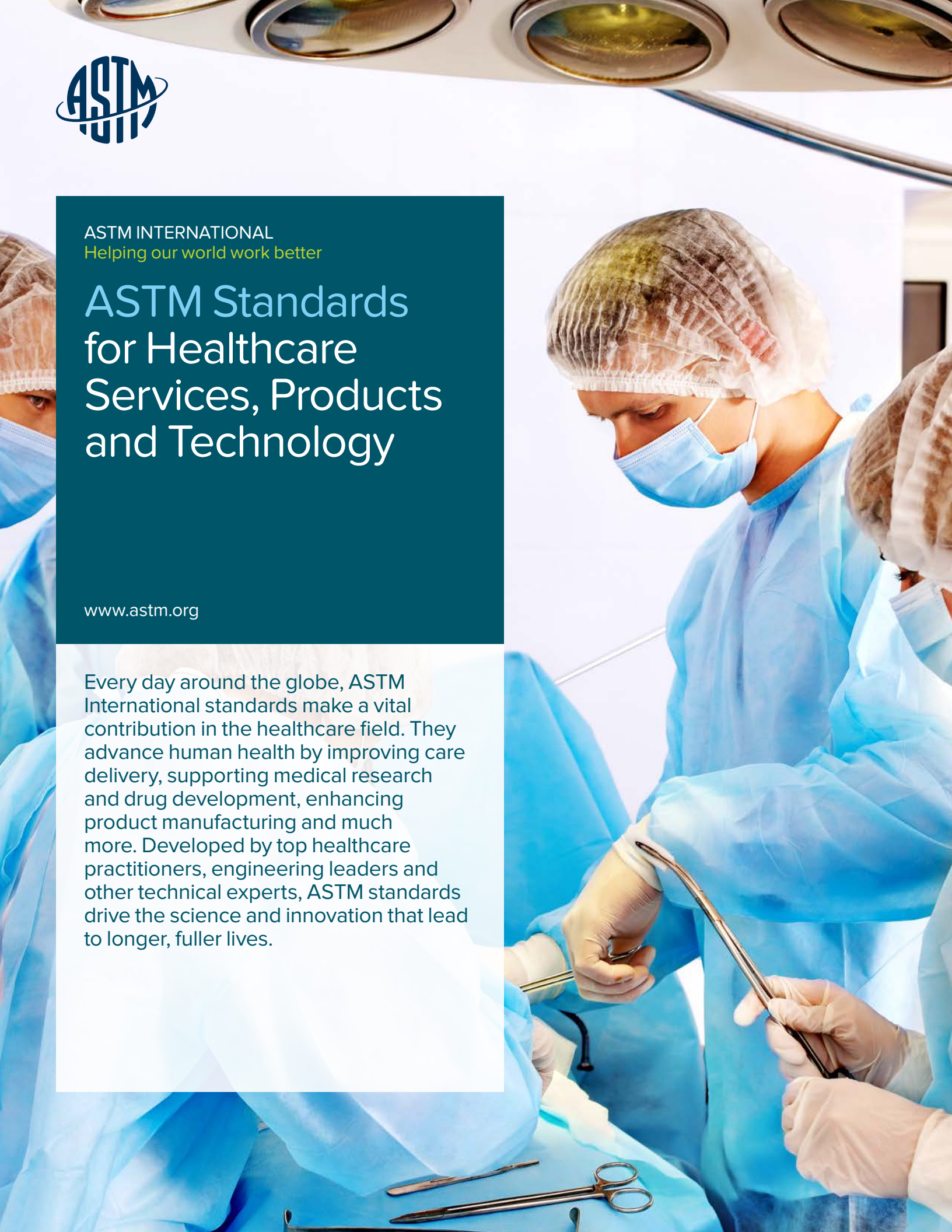

ASTM INTERNATIONAL
Helping our world work better

ASTM Standards for Healthcare Services, Products and Technology

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Every day around the globe, ASTM International standards make a vital contribution in the healthcare field. They advance human health by improving care delivery, supporting medical research and drug development, enhancing product manufacturing and much more. Developed by top healthcare practitioners, engineering leaders and other technical experts, ASTM standards drive the science and innovation that lead to longer, fuller lives.

Standards Drive Global Innovation through Committee F04

With a broad membership of more than 900 professionals from 31 countries, Committee F04 on Medical and Surgical Materials and Devices delivers over 300 standards that help bring life-saving breakthroughs to patients worldwide.

F04 plays an important role in developing standards that help manufacturers and support quality patient care. Today, F04 addresses standards for medical and surgical instruments, orthopedic devices, implant systems and more:

- 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.

Advancing the Science of TEMPs

Tissue engineered medical products (TEMPs) use biological components alone or with synthetic components to regenerate human tissue. To support continued progress in this field and enhance human health, F04 TEMPs subcommittees focus on classification and terminology, biomaterials and biomolecules, cells and tissue engineered constructs, assessment, adventitious agent safety and cell signaling.

F04 standards in this cutting-edge area include:

- F2900 for characterizing hydrogels used in regenerative medicine, including attributes such as biological properties, kinetics of formation, degradation and agent release, stability and mass transport capabilities; and
- F2150 for characterizing and testing TEMPs biomaterial scaffolds, including metallic, ceramic, polymeric, natural and composite materials.

Advances in magnetic resonance imaging (MRI) technology have grown dramatically since the 1980s. MR scanners help physicians study nerves, muscles, ligaments, bones and other tissues, helping to diagnose and treat injuries and disease.

F2503: Promoting the Safe Use of MRI

In the magnetic resonance environment, potential safety hazards exist for patients, technologists and other medical professionals. Scanner magnets and pulses can damage Implants such as pacemakers, potentially causing serious patient injury. Projectile accidents may also occur if medical devices and metallic items are pulled into the bore. To help ensure patient safety and reduce technologist confusion, standard F2503 covers marking medical devices for safety. Recognized in U.S. Food and Drug Administration guidance, the F2503 system indicates what conditions are acceptable for a specific medical device or other item. F2503 labeling terms and associated visual icons help prevent injuries when potentially hazardous items are brought into the environment.

3D Printing Standards Transform Manufacturing

Committee F42 on Additive Manufacturing Technologies is making a powerful impact on the medical device industry. 3D printing builds products and parts by applying material or powder in very thin layers. These processes improve the design, testing and manufacturing of many patient-specific medical devices such as hearing aids, dental crowns and surgical implants.

Committee F42 standards support innovation in producing alloys used for medical devices. Among these are standards (developed by Subcommittee F42.05 on Materials and Processes) on titanium (F3001) and nickel alloys (F3055 and F3056) for powder bed fusion, and metal powders (F3049) used for additive manufacturing.

Orthopedic Implant Labeling

Subcommittee F04.22 on Arthroplasty addresses orthopedic implant labeling requirements with F2943. The standard details content for a universal label format and indicates where crucial information is to be placed. The standard provides manufacturers with a consistent labeling approach that also supports correct implant selection.

Ensuring Safety in Pharmaceutical and Medical Product Packaging

Two of ASTM's long-standing committees, D10 on Packaging and F02 on Flexible Barrier Packaging, cooperate in developing medical packaging standards, which help meet the needs of regulators and manufacturers around the world. The standards address packages that maintain the sterility of the device as well as shipping containers that protect the contents.

Committee D10 has a portfolio of more than 150 standards, many geared toward critical medical products. Subcommittee D10.32 on Consumer, Pharmaceutical, Medical and Child Resistant Packaging (part of D10), is responsible for:

- D3475, which defines the motions, skills or tools required for a particular type of child-resistant package, and
- D4774 for drug labels used in anesthesiology, which addresses label size, color and pattern, and type used on labels to better identify the drug content.

Committee F02 is responsible for more than 60 standards, including some that support medical packaging integrity:

- F88 on seal strength of flexible barrier materials, which covers measurement techniques that provide process validation, control and capability; and
- F2096 for detecting gross leaks in packaging. (Referred to as the "bubble leak" test, F2096 is used to visually inspect medical packaging for any bubble streams caused by packaging/sterile barrier system defects.)

E31: Improving Accuracy and Timeliness of Patient Information

Healthcare providers are increasingly embracing electronic health records (EHRs) to enable more reliable patient information exchange. EHRs can reduce errors, speed treatment and care delivery, and keep patients better informed, which can strengthen the relationship between patients and their healthcare teams.

Committee E31 on Healthcare Informatics develops standards to help practitioners preserve and transfer accurate patient information using EHR technologies.

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 leads to 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, includes E2369 in formal EHR technology certification criteria.

Two other benchmark E31 documents also provide utility in the EHR area:

- E1384 for EHR content and structure, which provides a comprehensive structure for data collected in patient care records that draws on specialty disciplines and integrates clinical laboratory with other patient information; and
- E1633 for coded values used in the EHR, which outlines value sets for explicit data attributes in E1384.

E56 Nanotech Standards Support Cancer Research

The battle against cancer is getting a boost from breakthrough test methods from Committee E56 on Nanotechnology. E56 supports cutting-edge research efforts that could pave the way for commercially available nanoscale cancer drugs.

Crucial standards in this area include:

- E2524 for analyzing the hemolytic properties of nanoparticles, a protocol to examine the destruction of red blood cells (hemolysis), which can lead to anemia and other issues;
- E2525 for evaluating the effect of nanoparticulate materials, a method for evaluating nanoparticle stimulation or inhibition of the maturation of certain bone marrow cells (macrophages); and
- E2526 for evaluating the 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.

ASTM Standards and Universal Patient Identification

E31 standards also address the dynamic and evolving area of universal patient identification (UPI). 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 and prolonged hospital stays.

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

E31 standards in this area include:

- E2553 for implementation of a voluntary universal healthcare identification system describes the principles needed to create a system that addresses issues of privacy, security and cost-effectiveness, and
- E1714, which details requirements for a universal healthcare identifier (UHID) system.

Building a New Road Map for Pharmaceutical Manufacturing

When it comes to pharmaceutical manufacturing, quality and efficiency are major concerns.

Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products was born from an expansion of the Process Analytical Technology (PAT) initiative, developed by the U.S. Food and Drug Administration to overhaul drug manufacturing processes and help ensure safe and reliable consumer products. E55's first standards focused on furthering the goals of the PAT framework throughout the industry. These include E2363 on PAT terminology and E2474 for pharmaceutical process design.

Subcommittee E55.03 on General Pharmaceutical Standards has released several standards to support purity testing of pharmaceutical water, the most common ingredient used in pharmaceutical and biopharmaceutical manufacturing. This includes E2656 for real-time release testing of pharmaceutical water and E2810 for uniformity of dosage units, a valuable tool in drug content uniformity and dissolution testing.

Subcommittee E55.04 on General Biopharmaceutical Standards develops standards that support biopharmaceutical product manufacturing. E55.04 is working on standards for single-use systems and raw materials pharmaceutical development and manufacturing, notably biotechnology. Among the standards underway are a practice for testing system integrity and a related practice for characterizing particulates burden.

Supporting the Entire Healthcare System

Many more ASTM committees are involved in standards work that enhances healthcare products and services for people worldwide:

- Committee F30 on Emergency Medical Services focuses on areas such 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 30 standards is F2020 for the design, construction and procurement of EMS systems ambulances.
- Subcommittee D11.40 on Consumer Rubber Products (part of Committee D11 on Rubber) has an extensive array of standards that support 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 is also developing standards such as a method for measuring how well exam gloves reduce skin-to-surface contact bacteria transfer.
- Committee E61 on Radiation Processing, responsible for more than 30 standards, looks at ionizing radiation processing and dosimetry for medical products, pharmaceuticals and other goods. The committee has been focusing on sterilizing medical devices and developing dosimetry standards. One standard guides how to select and calibrate dosimetry systems for radiation processing (ISO/ASTM 51261) and another describes the use of the equipment while another describes making absorbed dose measurements according to E61 standards (ISO/ASTM 52628).

The ASTM technical committees highlighted in this piece include:

- D10 on Packaging
- D11 on Rubber
- E31 on Healthcare Informatics
- E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products
- E56 on Nanotechnology
- E61 on Radiation Processing
- F02 on Flexible Barrier Packaging
- F04 on Medical and Surgical Materials and Devices
- F30 on Emergency Medical Services
- F42 on Additive Manufacturing Technologies

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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.

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