



ASTM International Committee F04 on Medical and Surgical Materials and Devices

Scope

The scope of the Committee shall be the development of standardized nomenclature and definitions of terms, test methods, recommended practices, guides, specifications and performance standards for medical and surgical materials and devices. The Committee will encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests.

Technical Subcommittees

- F04.01 Division I - Resources
- F04.02 Division II - Orthopaedic Devices
- F04.03 Division III - Medical/ Surgical Devices
- F04.04 Division IV - Tissue Engineered Medical Products
- 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 TEMPs
- F04.42 Biomaterials and Biomolecules for TEMPs
- F04.43 Cells and Tissue Engineered Constructs for TEMPs
- F04.44 Assessment for TEMPs
- F04.45 Adventitious Agents Safety
- F04.46 Cell Signaling
- F04.90 Executive
 - F04.90.01 Strategic Planning
 - F04.90.02 Absorbable Metals
- F04.91 Awards
- F04.92 Planning
- F04.93 US TAG ISO/TC 150 - Implants for Surgery
- F04.94 Finance
- F04.95 US TAG ISO/TC 168 - Prosthetics and Orthotics
- F04.97 Editorial and Terminology



Quick Facts

Established 1962
Number of Members 940
Number of Standards 320
Global Participation
30 Countries represented
The standards are available in
Volumes 13.01 and 13.02 in the
Annual Book of ASTM Standards
Meetings F04 meets twice each
year, in May and November

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Learn more about Committee F04
www.astm.org/COMMIT/F04

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Liaison With Key Organizations

F04 has working relationships with many associations, such as the American Academy of Orthopaedic Surgeons (AAOS), the Orthopaedic Surgical Manufacturers Association (OSMA), the American Association of Blood Banks (AABB), and the Association for the Advancement of Medical Instrumentation (AAMI). AAOS and ASTM often work together to ensure that practitioners are in attendance at meetings of the Committee, and that issues of importance to the surgical community are integrated into developing standards. Similarly, OSMA supports F04 to ensure the Committee is able to coordinate global standards efforts that provide for transparency in trade for the manufacturing community. AABB, as a reference in various standards, is becoming more of an integral player in the registry of tissue for TEMPs-related issues. Finally, AAMI and AMS (American Metallurgical Society) are responsible for other medically related standards work also utilized in the medical and surgical device community. Standards developers work together to avoid overlap and they often share resources. The list of affiliated organizations goes on, but these are some of the key associations that have relationships with the Committee.

Activities, Products, and Services

The technical subcommittees of F04 collectively encompass five primary areas: resources, orthopaedic devices, medical and surgical devices, tissue engineered products, and computer-assisted surgical systems.

The resources area addresses standards for materials such as ceramics, metals, and polymers; it also includes standards to address needed fundamental information on biocompatibility, test methodology, and magnetic resonance imaging. The orthopaedic devices area focuses on methods and practices for osteosynthesis, arthroplasty, and spinal devices. Standards under the medical and surgical device category pertain mostly to cardiology, neurology, audiology, gastroenterology, and plastic surgery. Tissue engineered medical products (TEMPs) standards focus on materials needed in, and practices and methods for, the development and application of TEMPs technologies. Lastly, a division on computer assisted surgical systems includes a subcommittee on computer-assisted orthopaedic surgical systems (CAOS), which is writing standards for system accuracy.



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