ASTM International
Technical Committee F04 on Medical and Surgical Materials and Devices

Established: 1962
Number of Members: 900+
Number of Standards: 280+
Global Participation: 31 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

SUBCOMMITTEES:

- F04.01 Division I - Resources
- F04.11 Polymeric Materials
- F04.12 Metallurgical Materials
- F04.13 Ceramic Materials
- F04.15 Material Test Methods
- F04.15.11 MR Standards
- F04.16 Biocompatibility Test Methods
- F04.18 Device Retrieval Analysis
- F04.02 Division II - Orthopaedic Devices
- F04.21 Osteosynthesis
- F04.22 Arthroplasty
- F04.25 Spinal Devices
- F04.03 Division III - Medical/Surgical Devices
- F04.30 Cardiovascular Standards
- F04.31 Neurosurgical Standards
- F04.32 Plastic and Reconstructive Surgery
- 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
- F04.04 Division lV - Tissue Engineered Medical Products
- 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
- F04.05 Computer Assisted Orthopaedic Surgical Systems
- F04.90 Executive
- 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

Visit the ASTM Committee F04 Webpage:
http://www.astm.org/COMMIT/F04.htm

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.

Committee Manager:

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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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