

ASTM COMMITTEE F04 ON MEDICAL AND SURGICAL MATERIALS AND DEVICES
SCOPES

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.

DIVISION I - RESOURCES

Scope: To define and determine the properties and characteristics of materials in order to develop standard specifications, test methods, classifications and performance requirements for medical and surgical materials and devices.

F04.11 on Polymeric Materials

Scope: To define and determine the properties and characteristics of polymeric materials in order to develop standard specifications, test methods, classifications and performance requirements for medical and surgical materials and devices.

F04.12 on Metallurgical Materials

Scope: To define and determine the properties and characteristics of metallurgical materials in order to develop standard specifications, test methods, classifications and performance requirements for medical and surgical materials and devices.

F04.13 on Ceramic Materials

Scope: To define and determine the properties and characteristics of ceramic materials in order to develop standard specifications, test methods, classifications and performance requirements for medical and surgical materials and devices.

F04.15 on Material Test Methods

Scope: The development of standard methods of test and recommended practices for evaluating the properties and performance of materials, components, and processes used in the manufacture of medical and surgical devices.

F04.16 on Biocompatibility

Scope:

1. The preparation of standards relating to the determination of biocompatibility of materials.
2. The preparation of appropriate sections for standards, both generic and specific, under consideration by other Sections within F-4. These sections will include information on:
 - a) Methods of determination of biocompatibility.
 - b) The biocompatibility status of the subject of the standard.
 - c) The limitations on the scope and applicability of the standard that may be imposed by biocompatibility considerations.
3. The assembly, maintenance, and continuing updating of information concerning the biocompatibility of materials that are the subjects of standards under the jurisdiction of F-4.

F04.18 on Device Retrieval Analysis

Scope: Development of recommended practices for the retrieval and analysis of surgical implants.

DIVISION II - ORTHOPAEDIC DEVICES

F04.21 on Osteosynthesis

Scope: Development of standard specifications, classifications and performance requirements for orthopaedic devices.

F04.22 on Arthroplasty

No SCOPE

F04.25 on Spinal Devices

NO SCOPE

DIVISION III - MEDICAL/SURGICAL DEVICES

F04.30 on Cardiovascular Standards

Scope: Development of standard specifications, methods of test, practices, classifications and performance requirements for cardiovascular devices.

F04.31 on Neurosurgical Standards

Scope: Development of standard specifications, test methods, practices, classifications and performance requirements for neurosurgical materials and devices. To coordinate its activities through the Joint Committee on Materials and Devices of the Congress of Neurological Surgeons and American Association of Neurological Surgeons and other ASTM committees and outside organizations.

F04.32 on Plastic & Reconstructive Surgery

Scope: To develop standard specifications, test methods and definitions for devices used in plastic and re-constructive surgery.

F04.33 Medical/Surgical Instruments

Scope: To develop performance standards, test methods, practices and definitions for medical/surgical instruments where there is a need established by such considerations as risk to the patient, interchangeability or regulatory requirements.

F04.34 on Urological Materials & Devices

No SCOPE

F04.35 on GI Endoscopes

NO SCOPE

F04.36 Cotton Products for Medical Use

NO SCOPE

DIVISION IV - TISSUE ENGINEERED MEDICAL PRODUCTS

Scope: The development of standards and promotion of related materials for tissue engineered medical Products focusing on components of combination medical products intended to repair, replace Or regenerate human tissue. They comprise the biological components such as the cells, Tissue, cellular products, and/or the bimolecular and the biomaterials components used in Combination, including biologic, biomimetic, and/or synthetic materials. This division will work

With other committees within ASTM and other organization having mutual interests.

F04.41 on Classification and Terminology for TEMPs

Scope: To develop classification of areas and standard definitions of terminology used for tissue engineered medical products.

F04.42 on Biomaterials and Biomolecules

Scope: To develop standard that identify the normal biological functional characteristics that would be required of a tissue-engineered medical product.

F04.43 on Cells and Tissue Engineered Constructs

Scope: To develop standards for the structural and mechanical characterization of a tissue engineered medical product.

F04.44 on Assessment

Scope: To develop standards for the biomaterials used in tissue engineered medical products.

F04.45 on Safety

Scope: To develop standards for the biomolecules, natural and/or recombinant, used in tissue engineered medical products.

DIVISION IX - ADMINISTRATIVE

F04.90 Executive

Scope: To provide executive direction to the subcommittees under Committee F04.

F04.91 Awards

NO SCOPE

F04.92 Planning

NO SCOPE

F04.93 ISO TAG/TC 150

NO SCOPE

F04.94 on Finance

NO SCOPE

F04.95 ISO/TC 168

NO SCOPE

F04.96 ISO/TC 194

NO SCOPE