



ASTM International Committee F04 on  
Medical and Surgical Materials and Devices

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**Tissue Engineered Medical Products (TEMPs)  
Standardization Meeting**

When: 27 & 28 October 2008 (open to any interested party)

Where: Teddington, Middlesex, UK– Hosted by the [National Physical Laboratory](#)

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**TEMPs AND ADVANCED MATERIALS STANDARDIZATION**

The future of Tissue Engineered Medical Products (TEMPs), is being road mapped through the standards developed in ASTM International [Committee F04 on Medical and Surgical Materials and Devices](#) – some of which have been [recognized by the US FDA's Center for Devices and Radiological Health](#). With members from dozens of countries participating on F04, these standards are used to assist in review processes and product development around the world. In Europe, the current [Recast of the Medical Device Directive](#) noted that gaps in information and expertise exist around emerging technologies such as tissue engineering –gaps that need to be addressed to support regulatory frameworks.

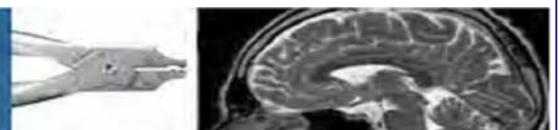
*These International TEMPs standards are developed in a global, open forum where YOU can participate* with producers, suppliers, clinicians, academics and regulators who come together to agree on their content. You are invited to attend the ASTM International TEMPs standardization meetings in October, scheduled for the UK to help engage the developing TEMPs industry in the EU.

**TECHNICAL PROGRAM OVERVIEW / AGENDA**

[F04 Tissue Engineered Medical Products \(TEMPs\) Standard Meeting  
October 27-28, 2008 / National Physical Laboratory, Teddington, Middlesex, UK](#)  
(The link provides details on location, directions, and hotel blocks)

The meeting will include discussion on the development/revision of the following standards:

- [F2311-06 \(WK11281\)](#): Standard Guide for Classification of Skin Substitutes
- [WK15152](#): Standard Practice for Characterization of Ceramic and Mineral Based Scaffolds Used for Tissue Engineered Medical Products (TEMPs) and as Medical Devices for Surgical Implant Applications
- [WK11381](#): Standard Guide for Assessment of Surface Roughness and Contact Angles of Biomaterials
- [WK11468](#): Standard guide for in situ visualization/quantification of mineralized matrix formed by mesenchymal cell culture
- [WK3551](#): Standard Guide for the Assessment of Bone Inductive Materials
- [WK8032](#): Standard Guide for Pre-Clinical in vivo Evaluation of Critical Size Segmental Bone Defects
- [WK8033](#): Standard Guide for Characterization of Tendons and Ligaments for TEMPs.
- [WK17626](#): A Standard Test Method for Quantifying the Spread Area of Cells on a Material Substrate



For more information on the full F04 TEMP's workflow, visit the F04 Homepage at <http://www.astm.org/COMMIT/COMMITTEE/F04.htm>, and select "Tissue Engineering Initiative Activity Structure." To join F04, visit [www.astm.org/joinF04.html](http://www.astm.org/joinF04.html). For only \$75 a year, member benefits include complimentary copies of the entire suite of some 250 medical device standards and access to other critical documentation, communication avenues to key industry contacts, and the ability to influence standards development. Become a member of Committee F04 and take part in these standards initiatives.

There is no fee to attend F04 meetings, and ASTM International membership is not required. There are no other forums so advanced in the standardization of Tissue Engineered Medical Products. Don't miss this opportunity to position yourself on the leading edge of industry standardization that will set the stage for product development and approval.

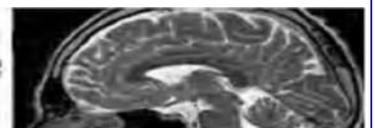
Please feel free to contact me with any questions. We look forward to seeing you there.

Thank you  
Daniel Schultz, ASTM Staff  
+1 610 832 9716  
dschultz@astm.org

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*ASTM International is one of the largest voluntary standards development organizations in the world - a trusted source for technical standards for materials, products, systems, and services. Known for their high technical quality, market relevancy, and time-to-market, ASTM International standards have an important role in the information infrastructure that guides design, manufacturing and trade in the global economy.*

*More about ASTM International, upcoming F04 meetings, and membership follows.*



### **More on F04 Standardization**

Recognized for the highest technical quality of its documentation, and for rapidly standardizing the most advanced areas in medicine, ASTM International's Committee F04 on *Medical and Surgical Materials and Devices* is the leader in these consensus standards efforts. F04 regularly conducts standardization meetings, workshops and symposium, providing a forum for discussing current topics for standardization. F04 standardization events are always open to any interested and affected party, and offer the essential opportunity to network with key regulators and industry colleagues who are setting the bar for device performance and acceptance.

### **In addition to the TEMPs Meeting in the UK... You are invited to the F04 Main Committee Meeting & Workshops**

[November 18 - 21 / La Fountain Bleu Hotel and Resort, Miami Florida, USA](#)

Standardization topics will include materials (metallurgical, ceramic and polymeric), arthroplasty, spinal devices, methods for MRI, and more. At this venue, F04 will hold two workshops: “[The Future of Arthroplasty Standards: Planning for the Next Five Years](#)” and “[Explant Shipping: the black hole between explantation and analysis](#)”. Topics will include the clinical and engineering perspective on current standards for hip, knee, and spine and where or additional standards are needed. In addition, device retrieval (from hospital to lab) will be discussed including topics of retrieval, packaging and shipping.

### **Notes on Ease of Participation and Benefits like Complimentary Standards:**

Today I invite you to become a member of Committee F04 and take part in this initiative. Log on to [www.astm.org/joinF04.htm](http://www.astm.org/joinF04.htm) and join today!

Members can participate from anywhere in the world because of ASTM's customized web-based systems. As a member you can contribute by participating in task group activities that interest you (both virtually and in person), and by voting/providing feedback on standards actions. Membership in ASTM will expand your career objectives and advance your organization's interests on issues that impact business practices and market acceptance.

The annual fee for ASTM Membership is \$75 and here are some of the benefits:

- FREE - Volume 13.01 Medical and Surgical Materials and Devices; Anesthetic and Respiratory Equipment; Manufacture of Pharmaceutical Products (print, CD or online version) in addition to a 10% discount on other publications
- Vote and influence decisions – be the first to know when changes occur
- Reduced fees for symposium and workshops
- Subscription to ASTM's *Standardization News* magazine

