

Overview of ASTM Subcommittee F04.15 on Material Test Methods

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FDA Center for Devices & Radiological Health**

**PERU Workshop on Medical Device Regulation and Standards:
Policy and Technical Aspects
January 25, 2017**



Committee F04 Structure

- **F04.01 Division I - Resources**
- **F04.02 Division II - Orthopaedic Devices**
- **F04.03 Division III - Medical/Surgical Devices**
- **F04.04 Division IV - TEMPs**
- **F04.05 Division V - Computer Assisted Orthopaedic Surgical Systems**

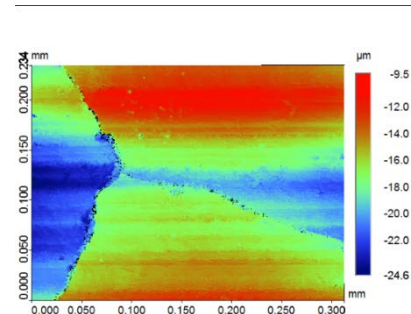
Committee F04 Structure

F04.01: Division I on Resources - Terry Woods

- F04.11 Polymeric Materials - Jon Moseley/Steve Kurtz
- F04.12 Metallurgical Materials - Rod McMillan
- F04.13 Ceramic Materials - Gary Fischman
- F04.15 Material Test Methods - Terry Woods
- F04.16 Biocompatibility - Anita Sawyer

F04.02: Division II on Orthopaedic Devices - Mark Melkerson

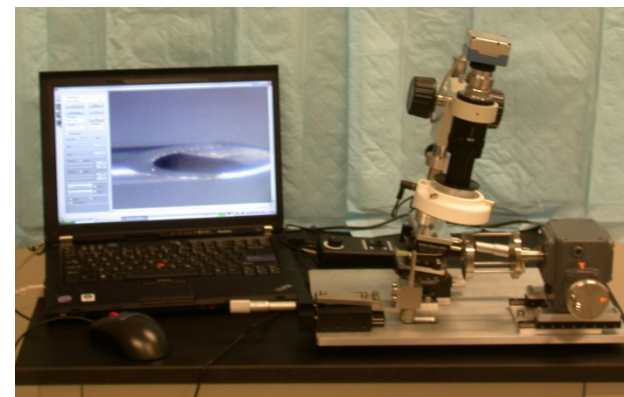
- F04.21 Osteosynthesis - Roger Kenyon/Greg Brown
- F04.22 Arthroplasty - John Goode /Les Gilbertson
- F04.25 Spinal Devices - Jove Graham/Dave Spenciner



Committee F04 Structure

F04.03: Division III Medical/Surgical Standards

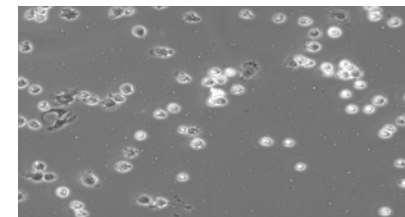
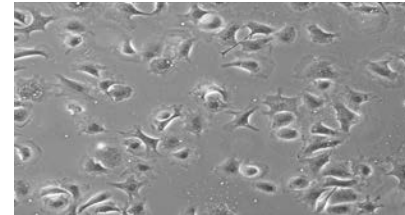
- F04.30 Cardiovascular Standards
- F04.31 Neurosurgical Standards
- F04.32 Plastic & Reconstructive Surgery
- F04.33 Medical & Surgical Instruments
- F04.34 Urological Materials & Devices
- F04.35 Gastroenterology Applications
- F04.37 Implantable Hearing Devices
- F04.38 Computer Assisted Orthopaedic Surgical Systems
- F04.39 Human Clinical Trials



Committee F04 Structure

F04.04: Division IV on Tissue Engineered Medical Products

- F04.40 Administration
- F04.41 Classification & Terminology
- F04.42 Biomaterial & Biomolecules
- F04.43 Cells & Tissue Engineering Constructs
- F04.44 Assessment
- F04.45 Microbiological Safety
- F04.46 Cell Signaling

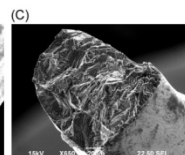
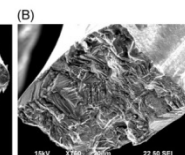
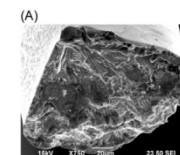
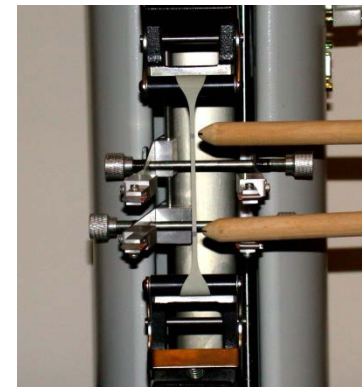
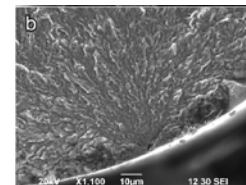
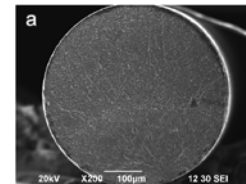
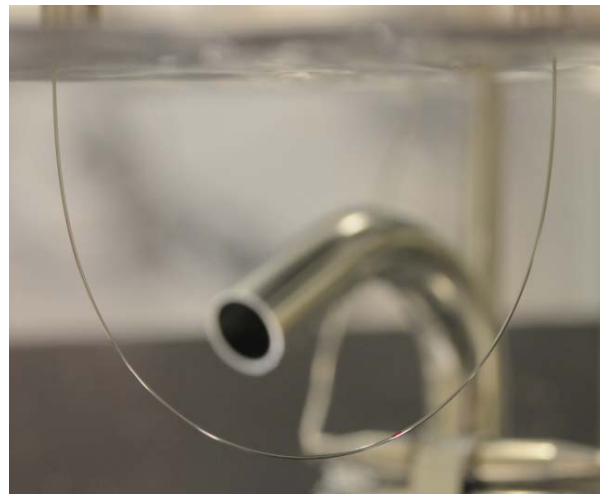
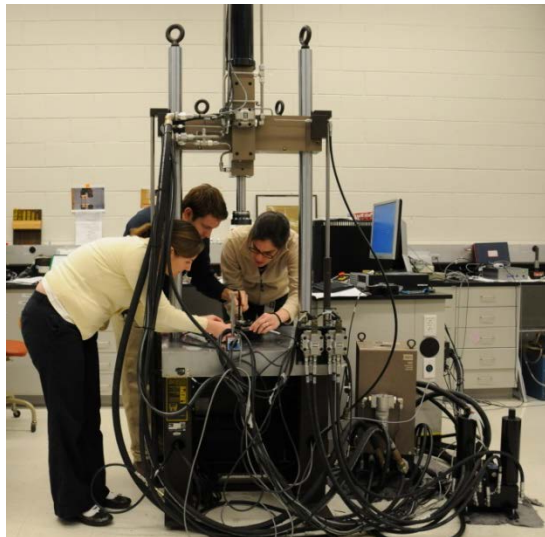


F04.05: Division V on Computer Assisted Orthopaedic Surgical Systems



F04.15 Material Test Methods

- **Scope: the broad spectrum of Material Test Methods needed to characterize & assess materials used in medical devices**
- **Approximately 50 standards**
 - 5-10 under development at any time
- **Approximately 20 task groups**
 - covering testing of materials (not specific devices)



F04.15 Material Test Methods



F04.15.02 Polymer Wear Testing

- F732-00(2011) Standard Test Method for **Wear Testing** of Polymeric Materials Used in Total Joint Prostheses

F04.15.04 Transducer Calibration

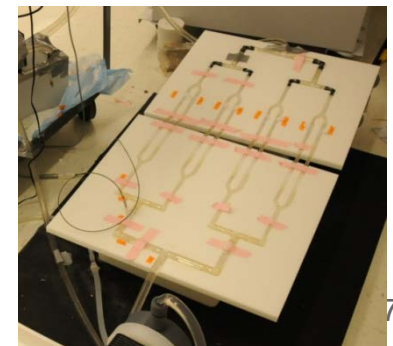
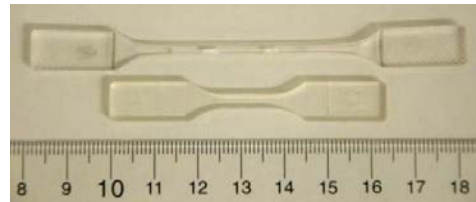
- F2537-06(2011) Standard Practice for **Calibration of Linear Displacement Sensor Systems** Used to Measure Micromotion

F04.15.05 Stereology of Porous Coatings - Les Gilbertson

- F1854-15 Standard Test Method for **Stereological Evaluation** of Porous Coatings on Medical Implants

F04.15.07 Absorbable Polymer Test Methods – J. Moseley/B. Hayes

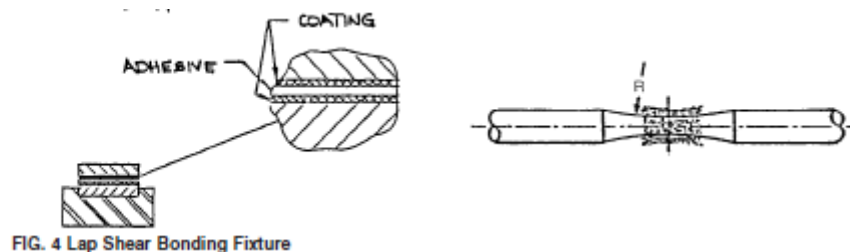
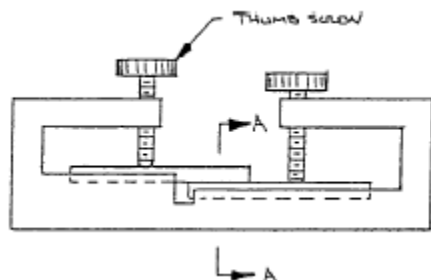
- F1635-11 Standard Test Method for in vitro **Degradation** Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants



F04.15 Material Test Methods

F04.15.08 Coatings Test Methods - Parimel Bapat

- F1044-05(2011)e1 Standard Test Method for **Shear Testing** of Calcium Phosphate Coatings and Metallic Coatings
- F1147-05(2011) Standard Test Method for **Tension Testing** of Calcium Phosphate and Metallic Coatings
- F1160-14 Standard Test Method for **Shear and Bending Fatigue Testing** of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- F1978-12 Standard Test Method for Measuring **Abrasion Resistance** of Metallic Thermal Spray Coatings by Using the Taber Abraser



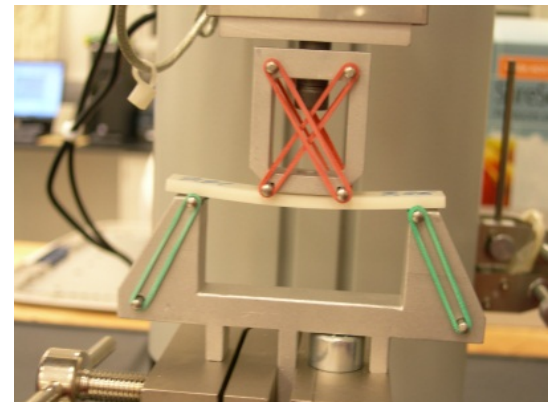
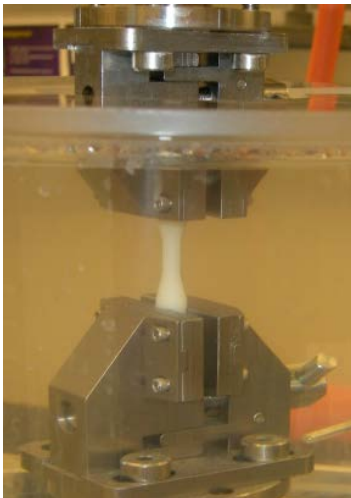
F04.15 Material Test Methods

F04.15.09 Biomechanics Force Measurement - Cindy Samaan/ Howard Hillstrom

- F3109-16 Standard Test Method for **Verification of Multi-Axis Force Measuring Platforms**

F04.15.10 Mechanical Testing of Bone Cement - Hany Demian

- F2118-14 Standard Test Method for Constant Amplitude of Force Controlled **Fatigue Testing** of Acrylic Bone Cement Materials



F04.15 Material Test Methods

F04.15.11 MRI Compatibility Testing - Terry Woods

- F2052-15 Standard Test Method for Measurement of Magnetically Induced **Displacement Force** on Medical Devices in the Magnetic Resonance Environment
- F2119-07(2013) Standard Test Method for Evaluation of **MR Image Artifacts** from Passive Implants
- F2182-11a Standard Test Method for Measurement of **Radio Frequency Induced Heating** On or Near Passive Implants During Magnetic Resonance Imaging
- F2213-06(2011) Standard Test Method for Measurement of Magnetically Induced **Torque** on Medical Devices in the Magnetic Resonance Environment
- F2503-13 Standard Practice for **Marking** Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

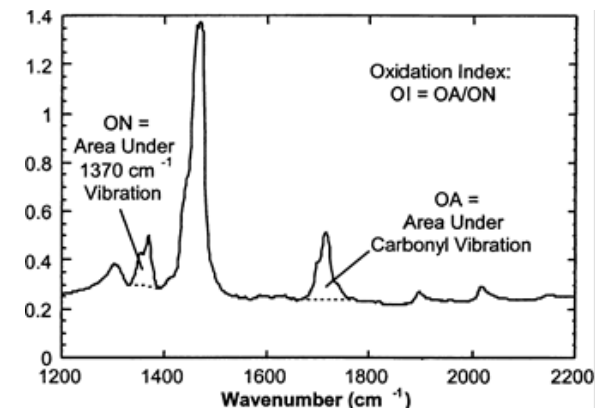


F04.15 Material Test Methods



F04.15.12 UHMWPE Characterization - Steve Kurtz

- F2003-02(2015) Standard Practice for **Accelerated Aging** of Ultra-High Molecular Weight Polyethylene (UHMWPE) after **Gamma Irradiation** in Air
- F2102-13 Standard Guide for Evaluating the **Extent of Oxidation** in Polyethylene Fabricated Forms Intended for Surgical Implants
- F2214-16 Standard Test Method for **In Situ Determination of Network Parameters of Crosslinked UHMWPE**
- F2381-10 Standard Test Method for Evaluating **Trans-Vinylene Yield** in **Irradiated UHMWPE** Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy
- F2625-10(2016) Standard Test Method for **Measurement of Enthalpy of Fusion, Percent Crystallinity, and Melting Point** of UHMWPE by Means of Differential Scanning Calorimetry
- F2977-13 Standard Test Method for **Small Punch Testing** of Polymeric Biomaterials Used in Surgical Implants



F04.15 Material Test Methods



F04.15.14 Corrosion Testing - Spiro Megremis

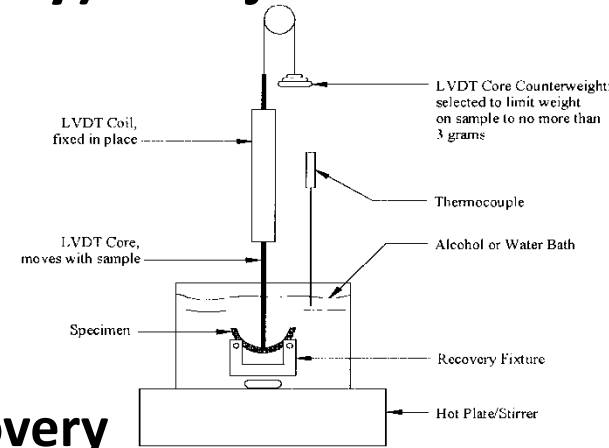
- F746-04(2014) Standard Test Method for **Pitting or Crevice Corrosion** of Metallic Surgical Implant Materials
- F897-02(2013) Standard Test Method for Measuring **Fretting Corrosion** of Osteosynthesis Plates and Screws
- F1089-10 Standard Test Method for **Corrosion** of Surgical Instruments
- F1801-97(2014) Standard Practice for **Corrosion Fatigue** Testing of Metallic Implant Materials
- F1875-98(2014) Standard Practice for **Fretting Corrosion** Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
- F2129-15 Standard Test Method for Conducting **Cyclic Potentiodynamic Polarization** Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
- F3044-14 Test Method for Standard Test Method for Evaluating the Potential for **Galvanic Corrosion** for Medical Implants
- WK52215 * **Ion Release** Evaluation of Medical Implants



F04.15 Material Test Methods

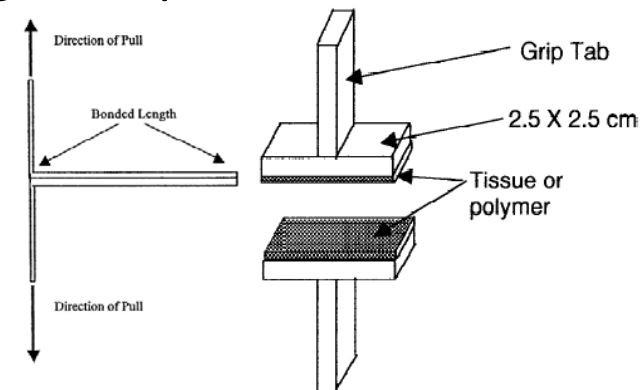
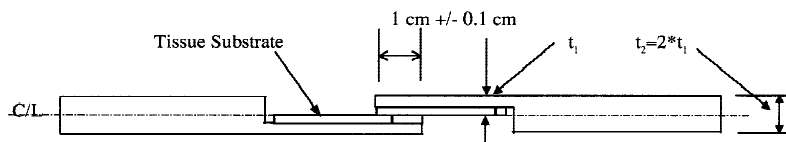
F04.15.15 Nitinol Test Methods - R. M. (Maddy) Manjeri

- F2004-05(2010) Standard Test Method for **Transformation Temperature of NiTi Alloys by Thermal Analysis**
- F2082/F2082M-16 Standard Test Method for Determination of **Transformation Temperature of NiTi Shape Memory Alloys by Bend and Free Recovery**
- F2516-14 Standard Test Method for **Tension Testing of Superelastic NiTi**



F04.15.16 Tissue Adhesive Test Methods – J. Moseley/D. Sierra

- F2255-05(2015) Standard Test Method for Strength Properties of Tissue Adhesives in **Lap-Shear by Tension Loading**
- F2256-05(2015) ... in **T-Peel by Tension Loading**
- F2258-05(2015) ... in **Tension**

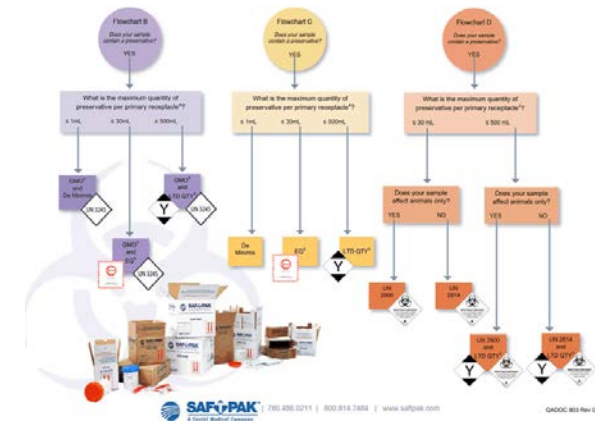


F04.15 Material Test Methods



F04.15.17 Device Cleanliness Validation – S. Spiegelberg/Ralph Basile

- F2459-12 Standard Test Method for **Extracting Residue** from Metallic Medical Components and Quantifying via **Gravimetric Analysis**
- F2847-10 Standard Practice for **Reporting and Assessment of Residues** on Single Use Implants
- F2995-13 Standard Guide for **Shipping Possibly Infectious Materials, Tissues, and Fluids**
- F3127-16 Standard Guide for **Validating Cleaning Processes** Used During the **Manufacture** of Medical Devices
- F3208-17 Standard Guide for Selecting **Test Soils** for **Validation of Cleaning** Methods for Reusable Medical Devices
- WK53082 Characterizing the **Cleaning Performance of Brushes** Designed to Clean the Internal Channel of a Medical Device
- WK57049 Using a Force Tester to **Evaluate the Performance of a Brush Part** Designed to Clean the External Surfaces of a Medical Device

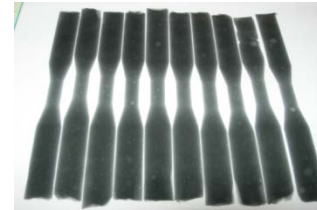


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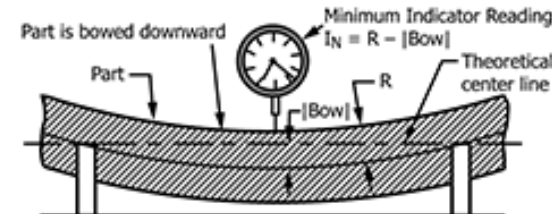
F04.15.18 Radiopacity Testing - Pamela Kramer-Brown

- F640-12 Standard Test Methods for Determining **Radiopacity** for Medical Use



F04.15.19 Wire Characterization - Jim Carlson

- F2754/F2754M-09(2013) Standard Test Method for Measurement of **Camber, Cast, Helix and Direction of Helix of Coiled Wire**
- F2819-10(2015)e1 Standard Test Methods for Measurement of **Straightness of Bar, Rod, Tubing and Wire** to be used for Medical Devices



F04.15.22 PEEK Characterization - Steve Kurtz

- F2778-09(2015) Standard Test Method for Measurement of **Percent Crystallinity of Polyetheretherketone (PEEK)** Polymers by Means of Specular Reflectance Fourier Transform Infrared Spectroscopy (**R-FTIR**)

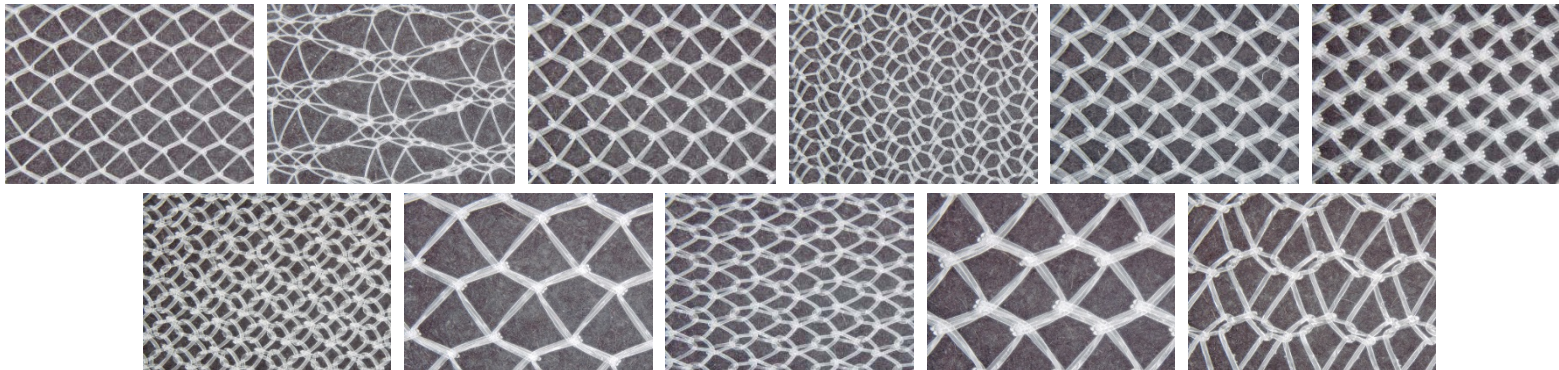
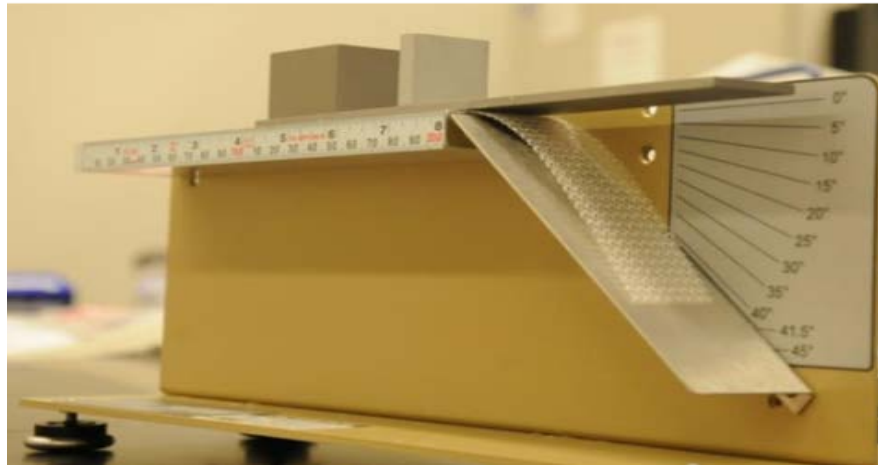
F04.15.23 Device Retrieval - Fabrizio Billi/Harry McKellop

- F561-13 Standard Practice for **Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids**

F04.15 Material Test Methods

Additional New Standards

- WK52640 In-Vitro Degradation Testing of **Absorbable Metals**
- WK54249 Flexural Stiffness of **Medical Textiles**



Summary

- **F04.15 covers the broad spectrum of Material Test Methods needed to characterize & assess materials used in medical devices**
- **The next talk shares details of the workings of our task group on corrosion testing**
- **Followed by perspectives from stakeholders in the medical devices industry representing**
 - Professional Organizations
 - Contract Test Companies
 - Medical Device Manufacturers
- **In the key areas of**
 - Corrosion
 - Orthopedic Device Performance
 - Cardiovascular Device Performance
 - Device Cleanliness

Thank You!

FDA

