



# Medical Engineering Technologies Ltd



*Technical and Scientific  
Solutions*




# Medical Engineering Technologies Ltd



**MET specialise exclusively in being a one-stop resource for engineers working in the medical device and pharmaceutical industries.**

# Stent Testing



**Class III medical device  
Active Implant  
Delivery device included**

# What is a Medical Device

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‘any instrument, apparatus, appliance or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of

diagnosis, prevention, monitoring, treatment or alleviation of disease,

diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap,

Investigation, replacement or modification of the anatomy or of a physiological process,

Control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.’

# Who Defines a Medical Device

- ◆ **Two Organisations**
- ◆ **FDA**
  - ❖ Classification Database
  - ❖ PMN (510K), PMA
- ◆ **EU Medical Device Directive**
  - ❖ CE Marking
  - ❖ Self Classification


# Area For Testing

- ◆ **Functional Testing**
- ◆ **Biological Safety Testing**
- ◆ **Packaging Validation**
- ◆ **Clinical Testing**

# Biological Testing

- **Biological evaluation should be considered in terms of the toxicological risk to patients, drawing on the nature of the materials, the literature, the biological data and the clinical purpose and environment. Toxicological risk assessment should be performed in accordance with the guidance provided in ISO 14971. This can be applied to reduce the amount of biological testing required if a predicate device exists or the material(s) have a documented history of use in other medical devices.**

# ISO 10993

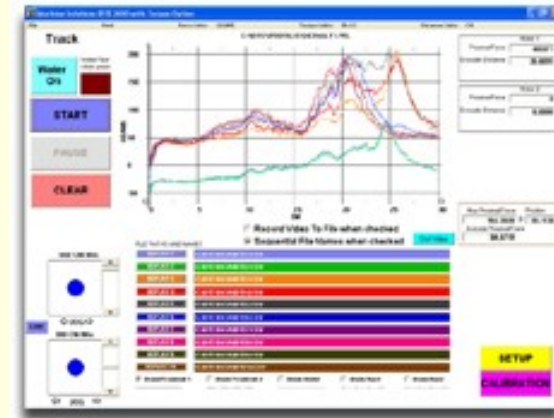


**The guidance provided in the ISO 10993<sup>ref 3</sup> series (Biological Evaluation of Medical Devices) is broadly accepted worldwide. ISO 10993 Part 1 details the types of test that should be considered, but manufacturers intending to market in the USA (where requirements can be more stringent) should also be aware of the useful guidance provided in ASTM F748-04.**

# Testing Requirements

- **ISO 25539-1:2003 - Cardiovascular implants -- Endovascular devices**
- **ISO 25539-2:2008 - Cardiovascular implants -- Endovascular devices -- Part 2: Vascular stents**
- **Design Verification**

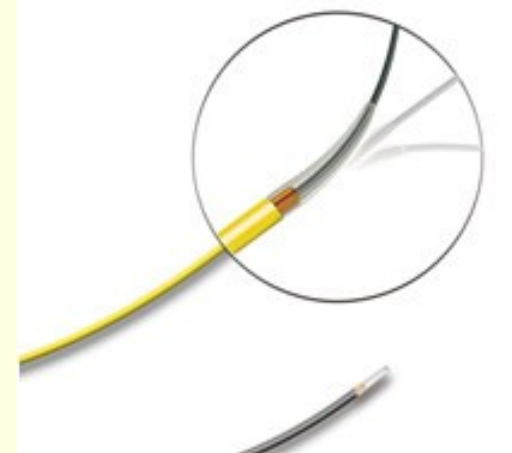
# Delivery System Testing



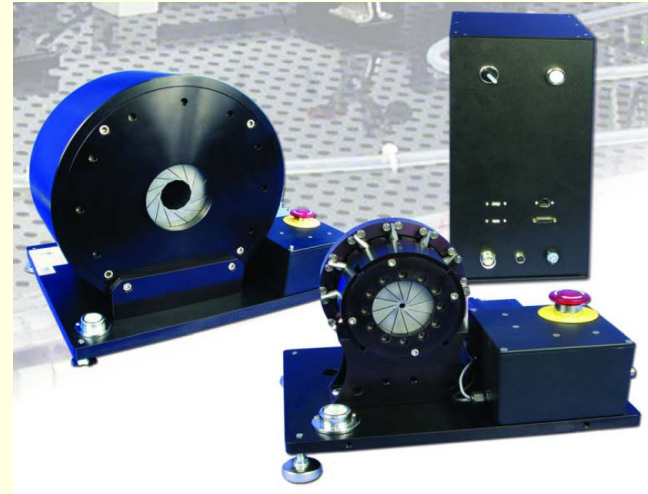
# Delivery System Tests

<b>Dimensional verification</b>	<b>Pressure vs. flow characterization</b>
<b>Catheter body tensile strength</b>	<b>Catheter burst pressure</b>
<b>Tubing to connector bond strength</b>	<b>Leakage between lumena</b>
<b>Catheter elongation</b>	<b>Leakage at hub</b>
<b>Tip attachment strength</b>	<b>Balloon inflation /deflation time</b>
<b>Catheter stiffness</b>	<b>Balloon related burst pressure</b>
<b>Catheter flexural fatigue</b>	<b>Balloon fatigue</b>
<b>Insertion and removal forces</b>	<b>Torque transmission</b>
<b>Coating performance and stability</b>	

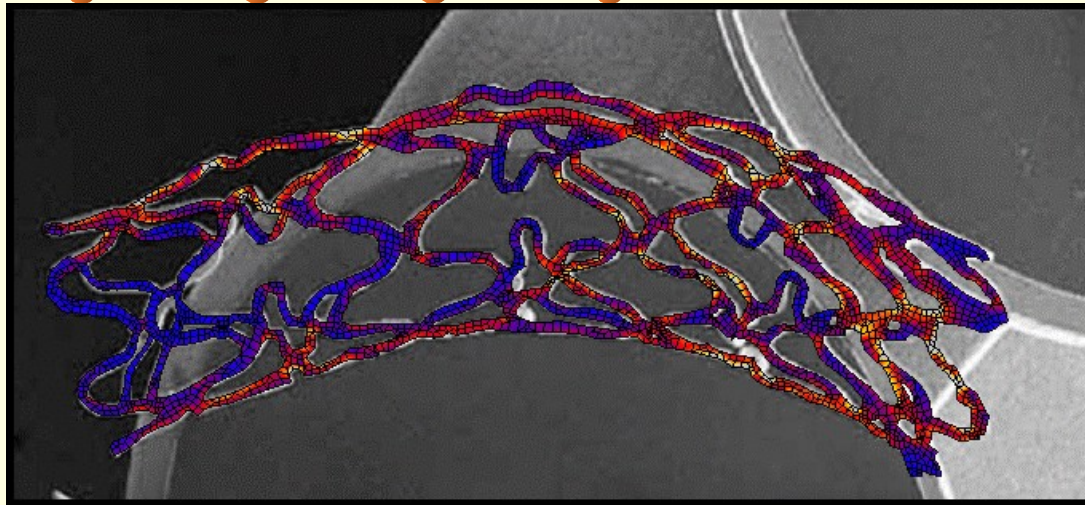
# Delivery System Tests



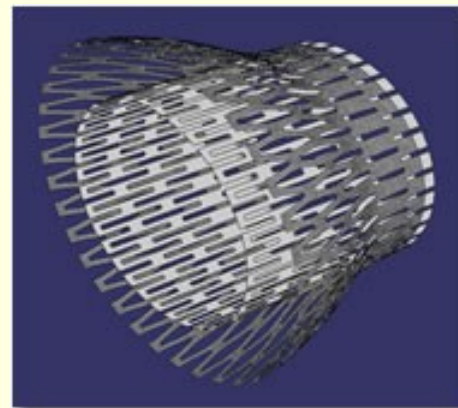
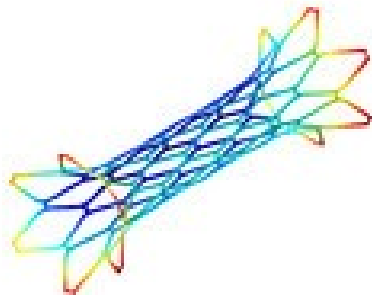
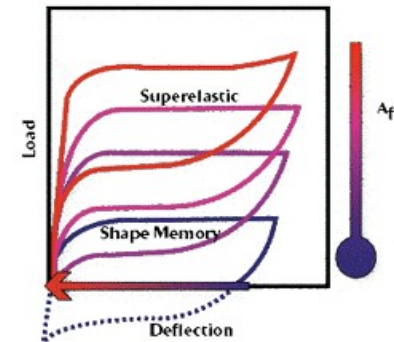
# Stent Testing Equipment



# FEA Analysis



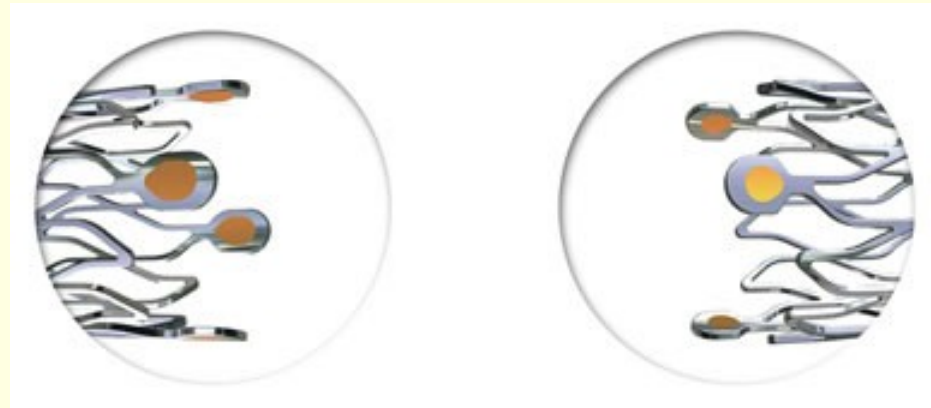
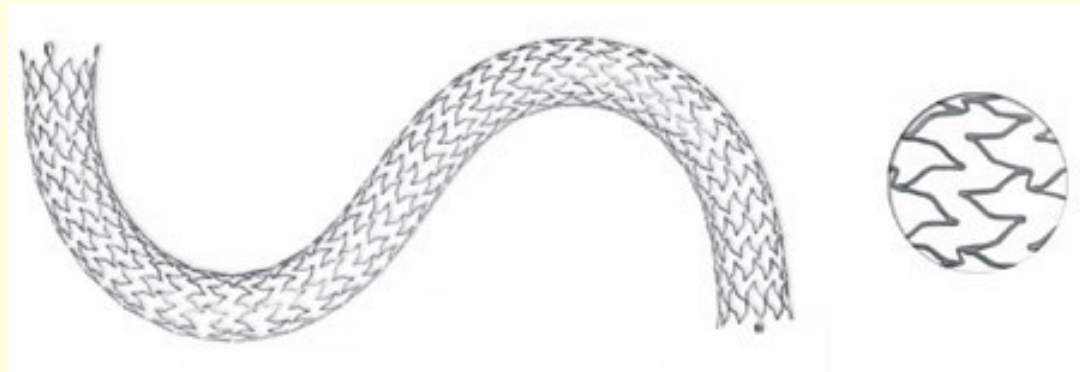
**Nitinol Stress - Strain**  
Influence of Temperature





# Stent Tests

<b>Dimensional Verification (including vessel contact area)</b>	<b>Radial stiffness and strength (crush and kink resistance)</b>
<b>Corrosion resistance</b>	<b>Retention force – stent securement</b>
<b>Behaviour of any memory metals</b>	<b>Stability and function of any coatings</b>
<b>Stent integrity</b>	
<b>Dimensional Verifications</b>	
<b>Physical dimensions contracted and expanded.</b>	<b>Stent diameter vs balloon inflation pressure.</b>
<b>Vessel contact area</b>	<b>Crossing profile / diameter</b>
<b>Foreshortening</b>	<b>Recoil</b>

# Stent Tests



# Guidance



- **FDA: Guidance for Industry and FDA Staff. Non-Clinical Tests and Recommended Labelling for Intravascular Stents and Associated Delivery Systems, 1 January 2005**

**Guidance for Industry: Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies, March 27, 2008**

# Some of the Standards ISO

ISO 10993 - Biological evaluation of medical devices

ISO 14971 Application of risk management to medical devices

ISO 25539-1:2003 - Cardiovascular implants -- Endovascular devices --  
Part 1: Endovascular prostheses

ISO 25539-2:2008 Cardiovascular implants -- Endovascular devices -- Part  
2: Vascular stents

ISO 7198:1998 Cardiovascular implants -- Tubular vascular prostheses

# Standards ASTM Corrosion

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**ASTM F 2004 Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis**

**ASTM F 2082-02 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery**

**ASTM F746 - 04 Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials**

**ASTM F2129-06, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices**

# Standards ASTM MRI

**ASTM F2213 - 06 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment**

**ASTM F2052 - 06e1 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment**

**ASTM F2119 - 07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants**

# Yet More Standards

**ISO 11070:1998 Sterile, single-use intravascular catheter introducers**

**ISO 7198:1998 Cardiovascular implants -- Tubular vascular prostheses**

**ASTM F 2081 Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents**

**ASTM F2477 - 07 Standard Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents**

# Summary

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**Testing requirements are dictated by the product claims and risk analysis.**

**Functional and biological evaluation - plan early**

**History of the materials in medical devices**

**Discuss your strategy with your regulatory agency**

**Use a risk based approach**

**Toxicological risk assessment.**

**Fatigue testing for implants is essential as are a large range of dimensional and build quality tests.**



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