

Introduction to Biomaterials

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LEC (5)

Test Hierarchies (for blood-contacting device)

- Cell culture, cytotoxicity (Mouse L929 cell line)
- Hemolysis (rabbit or human blood)
- Mutagenicity (Ames test)
- Systemic injection, acute toxicity (Mouse)
- Sensitization (Guinea pig)
- Pyrogenicity (Rabbit)
- Intramuscular implantation (Rat, rabbit)
- Blood compatibility
- Long-term implantation.

Standards

- Test methods
- Materials standards
- Device standards
- Procedure standards

ISO 10993 and EN 30993

- ISO 10993-1: guidance on selection of tests
- ISO 10993-2: Animal welfare requirements
- ISO 10993-3: Test for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4: Selection of tests for interactions with blood
- ISO 10993-5: Tests for cytotoxicity: In vitro methods
- ISO 10993-6: Test for local effects after implantation
- ISO 10993-7: Ethylene oxide sterilization residuals
- ISO 10993-8: Clinical investigation
- ISO 10993-9: Degradation of materials related to biological testing
- ISO 10993-10: Tests for irritation and sensitization
- ISO 10993-11: Tests for systemic toxicity
- ISO 10993-12: Sample preparation and reference materials
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Testing of Biomaterials

- Physical and mechanical

- Biological

 - In vitro assessment

 - in vivo assessment

 - Functional assessment

 - Clinical assessment