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ISO 10993-6:1994, Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation



Synopsis

Specifies test methods for the assessment of the local effects of an implant material on living tissue, at both the macroscopic and microscopic level. The local effects are evaluated by a comparison of the tissue response caused by a test specimen to that caused by materials used in medical devices whose clinical acceptability has been established. The test methods for local effects after implantation are used to assess subchronic effects (short-term, up to 12 weeks), or chronic effects (long-term, longer than 12 weeks). This title may contain less than 24 pages of technical content.

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