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Standard Specification for Total Knee Prosthesis¹

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1. Scope

1.1 This specification covers total knee replacement (TKR) prostheses used to provide functioning articulation by employing femoral and tibial components. Although a patellar component may be considered an integral part of a TKR, the detailed description of this component is excluded here since it is provided in Specification F 1672.

1.2 Included within the scope of this specification are replaceable components of modular designs, for example, tibial articulating surfaces and all components labeled for or capable of being used with cement, regardless of whether the same components can also be used without cement. This includes primary and revision prostheses and also covers fixed and mobile bearing knee designs.

1.3 This standard specification is intended to provide basic descriptions of material and prosthesis geometry. Additionally, those characteristics determined to be important to *in-vivo* performance of the prosthesis are defined.

1.4 Excluded from the scope are hemiarthroplasty devices that replace only the femoral or tibial surface, but not both; unicompartmental designs, which replace the articulating surfaces of only one condyle; and patellofemoral prostheses. Also excluded are devices designed for custom applications.

2. Referenced Documents

2.1 ASTM Standards:

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700) for Surgical Implant Applications

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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