



Standard Guide for Clinical Trial Design for Hip Replacement Systems (HRSs)¹

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1. Scope

1.1 This guide is intended as a resource for individuals and organizations involved in designing clinical trials of hip replacement systems (HRSs) including metal/polymer, metal/metal, metal/composite, metal/ceramic/polymer, metal/polymer/metal, and ceramic/ceramic bearing surfaces; semi-constrained and constrained designs; and cemented, nonporous uncemented, and porous-coated uncemented fixation.

1.2 In this guide, methods to measure the efficacy, effectiveness, and safety of HRS devices through standardizing outcomes measures are provided for designing, reviewing, and accepting human clinical trial protocols.

1.3 This guide is intended to provide consistency in study design, review, regulatory approval, and coverage approval for hip replacement systems to the health care market.

1.4 For the purpose of this guide, an HRS is any device that is intended to replace the hip joint, in part or in total, as a treatment for joint disease, trauma, or dysfunction, where long-term functional restoration and pain relief without major adverse events are the desired outcomes.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F2809 Terminology Relating to Medical and Surgical Materials and Devices

F2978 Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.39 on Human Clinical Trials.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

Devices using Magnetic Resonance Imaging
F2979 Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses

2.2 ISO Standards³

ISO 12891-1 Retrieval and analysis of surgical implants – Part 1: Retrieval and handling

ISO 12891-2 Retrieval and analysis of surgical implants – Part 2: Analysis of retrieved surgical implants

ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice

ISO 14971 Medical devices – Application of risk management to medical devices

3. Terminology

3.1 Unless provided in 3.2.1 – 3.2.5, definitions shall be in conformance with Terminology **F2809**.

3.2 Definitions:

3.2.1 *coverage, n*—insurance decision to reimburse for a device and/or procedure.

3.2.2 *effectiveness, n*—extent to which medical interventions achieve health improvements in real practice settings.

3.2.3 *efficacy, n*—extent to which medical interventions achieve health improvements under ideal circumstances.

3.2.4 *level of evidence*—strength of clinical evidence for evidence-based medicine (1)⁴.

3.2.5 *safety*—the condition of being protected from or unlikely to cause risk or injury. See **Appendix X1** for a tabulated list of adverse events reported for hip replacement systems (2).

3.3 Acronyms:

AJRR—American Joint Replacement Registry

ASA—American Society of Anesthesiologists

DVT—Deep Vein Thrombosis

EQ-5D—European Quality of Life – 5 Domains

FDA—Food and Drug Administration

HHS—Harris Hip Score

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁴ The boldface numbers in parentheses refer to a list of references at the end of this standard.