



Designation: F 370 – 94 (Reapproved 1999)

Standard Specification for Proximal Femoral Endoprosthesis¹

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1. Scope

1.1 This specification covers the materials, functional dimensions, and tolerances for single piece, metallic proximal femoral endoprosthesis.

1.2 In recognition of many broad and varied uses of such prostheses, many options are included. A variety, but not necessarily all, of the options are illustrated in Fig. 1.

1.3 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 ASTM Standards:

F 55 Specification for Stainless Steel Bar and Wire for Surgical Implants²

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications²

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications²

F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)²

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants²

F 620 Specification for Titanium 6A1-4V ELI Alloy Forgings for Surgical Implants²

F 621 Specification for Stainless Steel Forgings for Surgical Implants²

F 629 Practice for Radiography of Cast Metallic Surgical Implants²

F 983 Practice for Permanent Marking of Orthopedic Implant Components²

F 1108 Specification for Cast Titanium 6A1-4V Alloy for Surgical Implants²

2.2 ASQC Standard:

C1-1985 Specification of General Requirements for a Quality Control Program³

3. Materials

3.1 Proximal femoral endoprosthesis conforming to this specification shall be made of a material conforming to one of the following Specifications: F 55, F 75, F 136, F 138, or F 1108.

3.2 Proximal femoral endoprostheses made from stainless steel or titanium alloy forgings shall conform to one of the following, as applicable; Specifications F 620 or F 621.

4. Dimensions

4.1 Proximal femoral endoprosthesis conforming to this specification shall be fabricated in accordance with the tolerances indicated for specific dimensions illustrated in Fig. 2 of this specification. Where tolerances are not indicated for dimensions the following tolerances shall apply:

Fractional dimensions	± 1/64 in. (0.40 mm)
Decimal dimensions	± 0.005 in. (0.13 mm)
Angles	± 2°
Metric dimensions	± 0.5 mm (0.019 in.)

5. Finish and Marking

5.1 Proximal femoral endoprosthesis conforming to this specification shall be finished in accordance with Practice F 86.

5.2 Permanent identification marking on proximal femoral endoprostheses conforming to this specification shall be in accordance with F 983. Such markings shall include the following:

- 5.2.1 Head size (spherical diameter)
- 5.2.2 Stem length
- 5.2.3 Manufacturer's name and/or logo
- 5.2.4 Lot number or serial number
- 5.2.5 Catalogue number

6. Quality Program Requirements

6.1 The manufacturer shall maintain a quality program, such as, for example, is defined in the ASQC C1-1985.

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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² Annual Book of ASTM Standards, Vol 13.01.

³ Available from American Society of Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

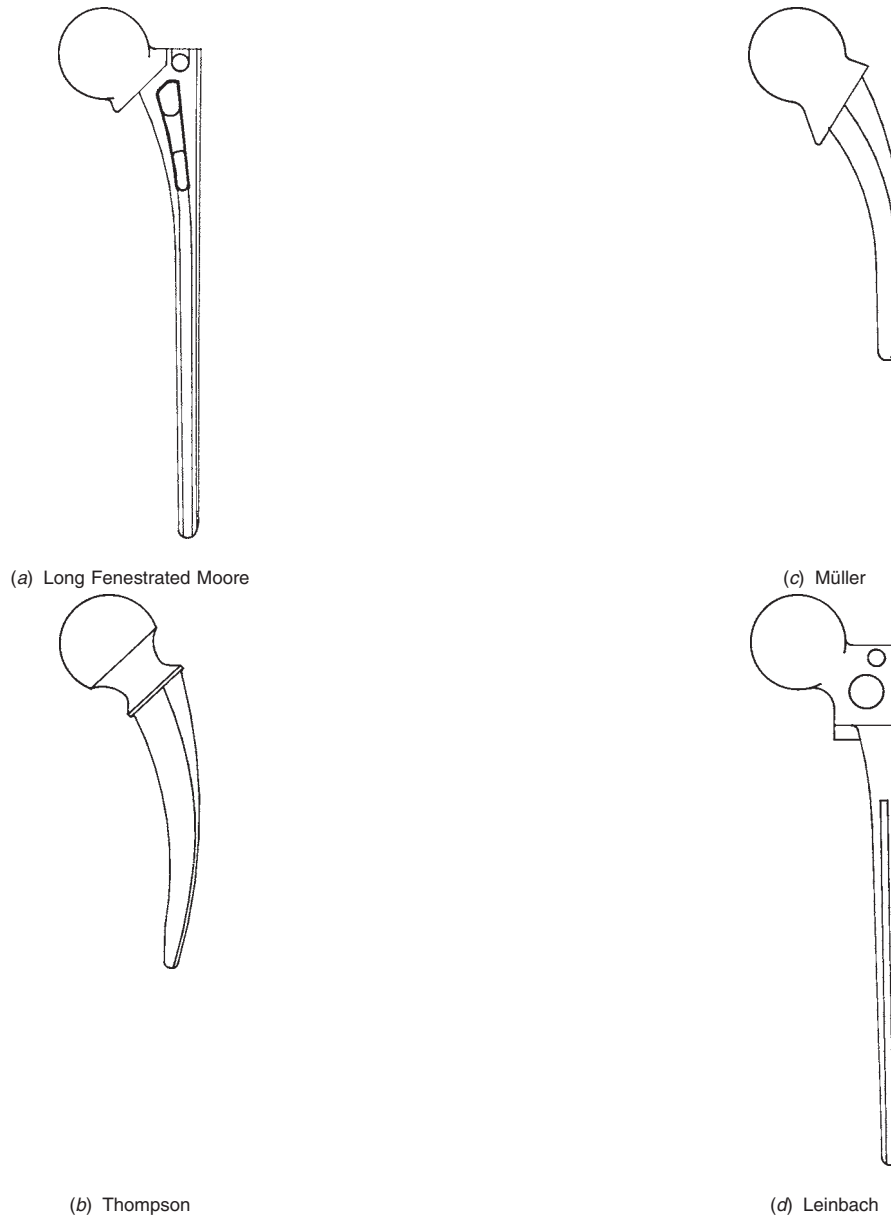


FIG. 1 Proximal Femoral Endoprosthesis—Typical Examples

6.2 Nondestructive inspection, as appropriate to the method of manufacturer, shall be used to ensure prostheses quality. Fluorescent penetrant inspection and radiography, when used,

shall be in accordance with Practices F 601 and F 629 respectively.