Designation: F 370 – 94 (Reapproved 1999)

Standard Specification for Proximal Femoral Endoprosthesis[1]

This standard is issued under the fixed designation F 370; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 Implants[2]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[2]

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[2]

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 Implants[2]

F 620 Specification for Titanium 6A1-4V ELI Alloy Forgings for Surgical Implants[2]

F 621 Specification for Stainless Steel Forgings for Surgical Implants[2]

F 629 Practice for Radiography of Cast Metallic Surgical Implants[2]

F 983 Practice for Permanent Marking of Orthopedic Implant Components[2]

F 1108 Specification for Cast Titanium 6A1-4V Alloy for Surgical Implants[2]

2.2 *ASQC Standard:*

C1-1985 Specification of General Requirements for a Quality Control Program[3]

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	±1⁄64in. (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.

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.

[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.

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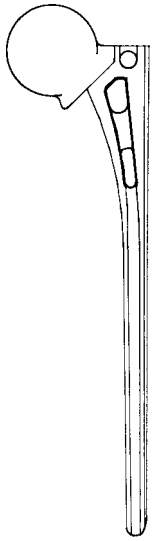
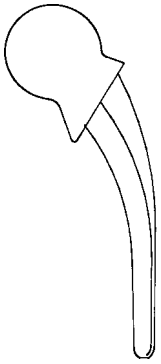
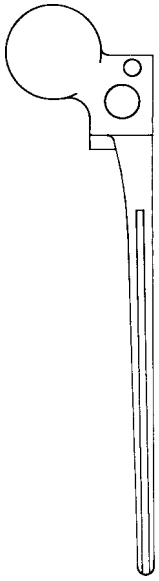


(*a*) Long Fenestrated Moore



(*c*) Müller

(*b*) Thompson



(*d*) Leinbach

FIG. 1 Proximal Femoral Endoprosthesis—Typical Examples

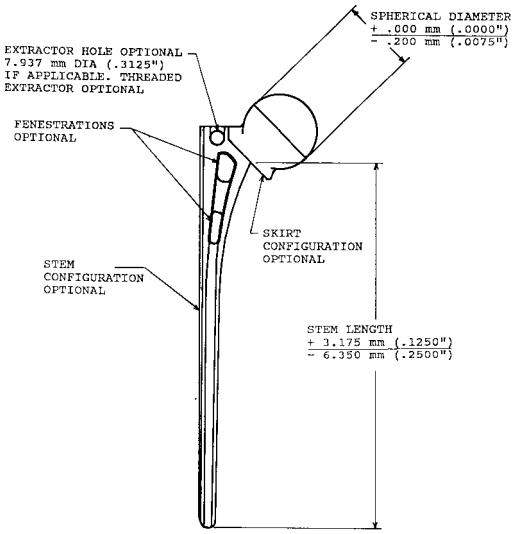


FIG. 2 Typical Features and Tolerances for Proximal Femoral Endoprostheses

APPENDIX

(Nonmandatory Information)

X1. (RATIONALE)

X1.1 This standard specification describes the basic features of classic femoral prostheses used for hemiarthroplasty of the hip (commonly termed endoprostheses). This specification applies to prostheses of fixed head construction only.

X1.2 More detailed requirements for this class of hip implant, including those of modular and bi-polar construction, are currently under development as part of comprehensive physical and performance standards for all hip prostheses. This revision of F 370 is intended to reflect current industry practice and to include reference to relevant ASTM standards passed since its last revision. In accordance with reflecting industry practice for this class of prostheses, primary dimensions are listed in inch-pound units.

X1.3 This standard is not meant to be perfect but to serve until the comprehensive standards are ready. When the comprehensive standards for hip prostheses are complete, F 370 will be balloted for withdrawal.

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