Standard Specification for Fixation Pins and Wires¹

This standard is issued under the fixed designation F 366; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope

- 1.1 This specification covers functional dimensions for fixation pins and wires.
- 1.2 In recognition of many broad and varied uses of such pins and wires, many options are included. A variety, but not necessarily all, of the options are illustrated in Figs. 1-3.
- 1.3 The values stated in inch-pound units are to be regarded as the standard.
- 1.4 The values given in parentheses are provided for information only.

2. Referenced Documents

- 2.1 ASTM Standards:
- F 55 Specification for Stainless Steel Bar and Wire for Surgical Implants²
- F 67 Specification for Unalloyed Titanium for Surgical Implant Applications³
- F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants³
- F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications³
- F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications³
- F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)³
- F 562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications³
- F 563 Specification for Wrought Cobalt-Nickel-Chromium-

Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications³

3. Materials

3.1 Fixation pins and wires shall be fabricated from material conforming to one of the following ASTM Specifications: F 55, F 67, F 90, F 136, F 138, F 562, or F 563.

4. Performance Requirements

4.1 Factors considered to be important, but for which values and test methods have not been established, are bending strength, fatigue strength, breaking strength (Knowles Type only), torsion strength, and ductility.

5. Dimensions and Characteristics

- 5.1 Fixation pins and wires shall be fabricated in accordance with the dimensions illustrated in Figs. 1-4.
- 5.2 Fixation pins and wires shall have surfaces prepared and marked in accordance with Practice F 86.
- 5.2.1 Optional marking on the fixation pins and wires shall identify the manufacturer or distributor.

6. Packaging and Labeling

- 6.1 Packaging shall be adequate to protect the fixation pins and wires during shipment.
 - 6.2 Labeling for fixation pins and wires shall include:
 - 6.2.1 Product name,
 - 6.2.2 Size, on the immediate container,
 - 6.2.2.1 Length,
- 6.2.2.2 Diameter (if round) or cross-sectional size (if square of hexagonal), that is, $\frac{1}{4}$ in. (6.4 mm) square, and
 - 6.2.3 ASTM material specification Designation number.

7. Keywords

7.1 fixation materials; flexible surgical wire; orthopaedic medical devices; wire-surgical implants

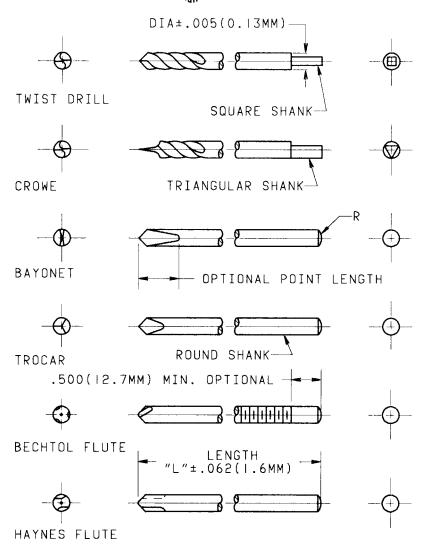
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² Discontinued—See 1991 Annual Book of ASTM Standards, Vol 13.01.

³ Annual Book of ASTM Standards, Vol 13.01.

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Note 1-Pins and wires may be smooth shank or threaded.

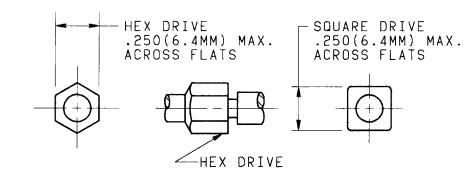
Note 2—Point angle and helix angle, where applicable, is as specified by manufacturer.

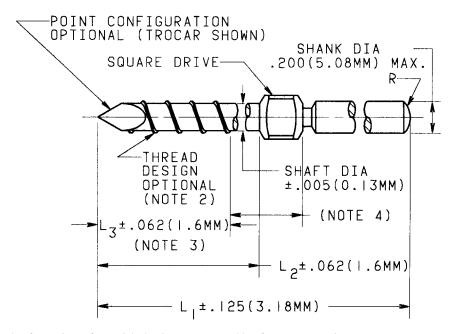
Note 3—On square or triangular shanks, flats are equal and corners are on the same circumference as the pin diameter. Shank diameters on pins larger than 1/8 in. (3.2 mm) may be reduced.

Note 4—Optional designs, both ends pointed or point with suture hole.

FIG. 1 Fixation Pins and Wires

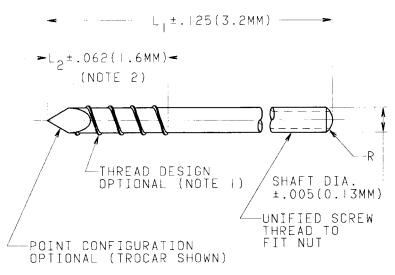
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- Note 1—Shall be made of one piece of material; that is, not an assembly of two or more pieces.
- $\ensuremath{\text{Note}}\xspace$ 2—Thread major diameter may be the same or larger than the shaft diameter.
- Note 3—Thread length shall be optional to suit intended medical application.
- Note 4—Optional marking in this location.

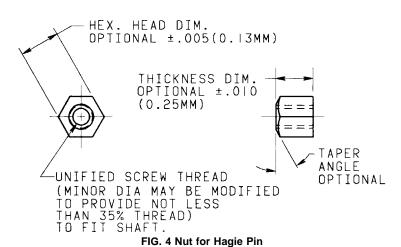
FIG. 2 Fixation Pin-Knowles Type



Note 1—Thread major diameter may be the same or larger than the shaft diameter.

Note 2—Thread length shall be optional to suit intended medical application.

FIG. 3 Fixation Pin-Hagie Type



APPENDIX

(Nonmandatory Information)

X1. RATIONALE

- X1.1 The primary reasons for the revision of this standard are:
- X1.1.1 To characterize fixation pins and wires used in the treatment of fractures or disease of the skeletal system.
- X1.1.2 To incorporate fixation pins—Knowles and Hagie types (F 368).
 - X1.1.3 To specify marking nomenclature.
- X1.1.4 To add performance requirements in accordance with Performance Section's request.
 - X1.1.5 To add packaging and labeling.
 - X1.1.6 To remove the dimensions on the Crowe since the

- dimensions are not essential.
- X1.1.7 Specific surface finish was considered, however, not included, since test data to confirm what the requirement should be or what effect it has upon performance was not available.
- X1.2 Designs listed enable the surgeon to select from a variety of fixation pins and wires.
- X1.3 The materials listed represent the current usage and have demonstrated clinical acceptance in these devices.



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