~~Designation:F1611–95~~

~~Standard Terminology for Sizing of IMFDs for Application to Reamed Diaphyseal Bone and Associated Instrumentation~~Designation: F 1611 – 00 (Reapproved 2009)

Standard Specification for Intramedullary Reamers[1]

This standard is issued under the fixed designation F 1611; 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

~~1.1This terminology defines basic terms and considerations related to diameter measurement and designation specifications for reamers, reamed holes, and intramedullary fixation devices (IMFDs) for application in the medullary canal prepared by reaming.~~

~~1.2The values stated in SI units are to be regarded as the standard.~~

1.1 This specification provides requirements for material, dimensions and tolerances, finish and marking, and care and handling for reamers intended to cut a cylindrical path along the medullary canal of diaphyseal bone.

1.2 Intramedullary reamers are commonly used to prepare the medullary canal for the insertion of intramedullary fixation devices (IMFD). As such, the relationship between the intramedullary reamer diameter and the IMFD's diameter are considered.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

2. Referenced Documents

2.1 *ASTM Standards:*

~~F86Practice for Surface Preparation and Marking of Metallic Surgical Implants~~

~~F138Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[2]~~

~~F139Specification for Stainless Steel Sheet and Strip for Surgical Implants (Special Quality)[2]~~ [2]

A 564/A 564M Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

A 693 Specification for Precipitation-Hardening Stainless and Heat-Resisting Steel Plate, Sheet, and Strip

A 705/A 705M Specification for Age-Hardening Stainless Steel Forgings

~~F339Specification for Cloverleaf Intramedullary Pins[2]~~

~~F899Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments[2]~~ 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F 565 Practice for Care and Handling of Orthopedic Implants and Instruments

F 899 Specification for Wrought Stainless Steels for Surgical Instruments

F 983 Practice for Permanent Marking of Orthopaedic Implant Components

F 1264 Specification and Test Methods for Intramedullary Fixation Devices

3. Terminology

~~3.1*Definitions:*~~

~~**IMFD diameter**—the diameter of the circumscribed circle of the IMFD's uniform cross section, intended to fit in the reamed portion of the diaphyseal bone (see Specification F339, Dimension A).~~

~~**IMFD for reamed application**—any IMFD that is recommended for use in the medullary canal of a diaphyseal bone that has been prepared by reaming.~~

~~**IMFD reamer diameter**—the diameter of the circumscribed circle of the cutting portion of the reamer's cross section.~~

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[1] This ~~terminology~~specification is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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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* ~~, Vol 13.01.~~volume information, refer to the standard's Document Summary page on the ASTM website.

~~**reamed diameter**—the diameter of the hole cut by the reamer.~~

~~3.2~~

3.1 *Definitions of Terms Specific to This Standard:* ~~tolerance—the dimensional standard met by the reamer at the time of manufacture.~~

3.1.1 *cutting head*, *n*—the portion of the reamer, which consists of flutes, or edges, which cut the bone.

3.1.2 *reamer diameter*, *n*—the diameter of the circumscribed circle of the cutting head's cross-section (shown in Fig. 1).

3.1.3 *reamer shaft diameter*, *n*—the diameter of the circumscribed circle of the long portion of the reamer, which connects the cutting portion of the reamer to the drill.

4. Classification

~~4.1Types of considerations covered by this terminology are as follows:~~

~~4.1.1Measurement of standard dimensions, and~~

~~4.1.2Meaning of designated sizes.~~

4.1 In general, intramedullary reamers consist of two types:

4.1.1 *One-piece reamer*—A design where the reamer shaft and cutting head are permanently attached to each other.

4.1.2 *Modular Reamer*—A design where the reamer shaft and cutting head are two separate components, fixed to each other temporarily at the time of use via a geometric connection, for example, dovetail joint.

5. ~~Ordering Information~~

~~5.1The diameter of the reamer should be designated by the diameter of the hole that it is intended to make, or the reamed diameter as defined in .~~ Dimensions and Tolerances

5.1 The reamer diameter shall be measured at the largest portion of the cutting head's cross section and reported to the nearest 0.2 mm. The reamer diameter shall be measured using a micrometer or an appropriate ring gage. When using a micrometer to measure reamers with an odd number of flutes, a V-anvil micrometer (with the appropriate angle, based on the number of flutes) will be used to accurately determine the reamer diameter.

5.2 The tolerance of a reamer diameter shall be no more than ±0.075 mm.

6. ~~Significance and Use~~

~~6.1This terminology is intended to provide a simple means of establishing useful, consistent, and reproducible information on the function and application of reamers for IMFDs and the relationship of the reamer size designation to the size designation of the IMFDs. The surgeon can better determine the proper instruments and the proper IMFD for each application by predicting the size of the reamed hole without respect to reamer design and knowing the real meaning of the size designation of the IMFD.~~ Material Requirements

6.1 The reamer's shaft and cutting head shall be fabricated from materials with suitable strength, hardness, and corrosion resistance. The materials described in Specifications A 564/A 564M A 693, A 705/A 705M and F 899 have been found to be suitable for this use.

7. Finish and Marking

7.1 The shaft and cutting head shall be free from burrs, nicks, dents, and scratches when examined in accordance with Practice F 86.

7.2 The flutes of the cutting head will be of the appropriate geometry to perform the intended use of reaming bone.

7.3 When space permits, the following information should be legibly marked on the reamer (in order of preference):

7.3.1 Reamer diameter,

7.3.2 Manufacturer's name or logo,

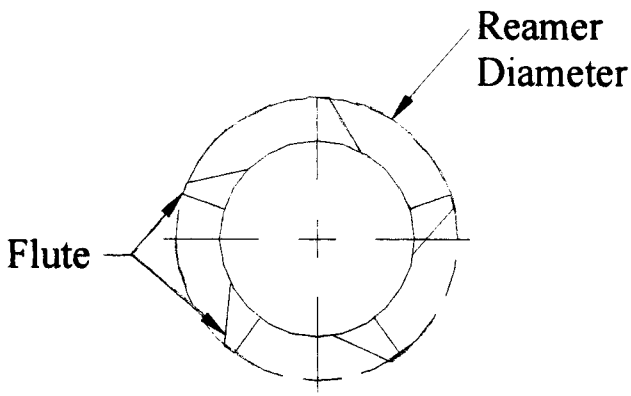

FIG. 1 Reamer Cutting Head