



Designation: F1611 – 20

Standard Specification for Intramedullary Reamers¹

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1. Scope

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 (IMFDs). As such, the relationship between the intramedullary reamer diameter and the IMFD's diameter are considered.

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

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- A564/A564M Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- A693 Specification for Precipitation-Hardening Stainless and Heat-Resisting Steel Plate, Sheet, and Strip
- A705/A705M Specification for Age-Hardening Stainless Steel Forgings
- F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants
- F565 Practice for Care and Handling of Orthopedic Implants and Instruments
- F899 Specification for Wrought Stainless Steels for Surgical Instruments

¹ This specification is under the jurisdiction of ASTM Committee 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* volume information, refer to the standard's Document Summary page on the ASTM website.

- F983 Practice for Permanent Marking of Orthopaedic Implant Components
- F1264 Specification and Test Methods for Intramedullary Fixation Devices

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

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

4.1 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. 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 gauge. 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) shall 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. Material Requirements

6.1 Reamers shall be fabricated from a material intended for surgical applications. In addition, the materials shall be biocompatible for the intended application. Materials should be chosen based on the design requirements of the particular device. ASTM Committee F04 on Medical and Surgical Materials and Devices maintains a number of specifications for