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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 (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 the standard.

2. Referenced Documents

2.1 ASTM Standards: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 Steel and Heat-Resisting Steel Plate, Sheet, and Strip

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

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

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

F 899 Specification for 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 of Terms Specific to This Standard:

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

4.1 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 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. 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,

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.