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Standard Specification for Intramedullary Reamers[1]

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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 standard. No other units of measurement are included in this standard.

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

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 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 A564/A564M, A693, A705/A705M, and F899 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 F86.

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsiblitiy 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.

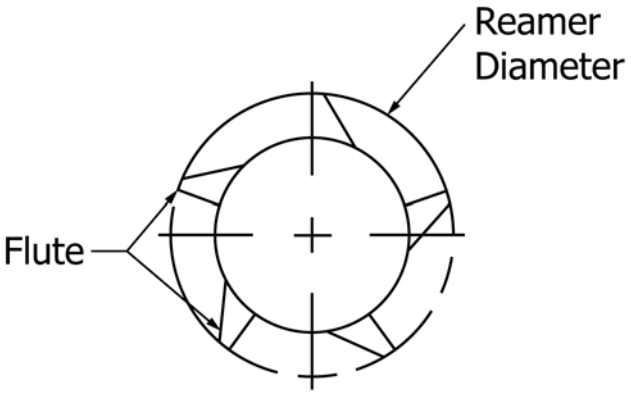

FIG. 1 Reamer Cutting Head

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,

7.3.3 Catalog number,

7.3.4 Reamer shaft diameter, if the shaft diameter is not uniform along its length, for example, a tapered shaft, then the maximum and minimum diameters should be given.

7.3.5 Manufacturing lot number.

7.4 Reamers shall be marked in accordance with Practice F983 when practical, unless otherwise specified in 7.3.

8. Care and Handling

8.1 The reamer should be cared for and handled in accordance with Practice F565, as appropriate.

8.2 The flutes of the cutting head should be checked periodically for damage or wear. Reamers that are considered to be performing inadequately should be removed from service.

NOTE 1—No standards exist for the measurement of "sharpness." Reamer performance is the most reliable method for assessing reamer sharpness.

9. Keywords

9.1 intramedullary fixation device; orthopaedic medical device; reamer; surgical instruments

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Intramedullary reamers commonly are used to prepare the medullary canal for the subsequent insertion of an IMFD. The relationship between the diameter of the hole prepared by the reamer and the IMFD's diameter are important in relation to the fit achieved by the implant in the bone and the avoidance of surgical complications. If the fit is too loose, the initial fixation may be inadequate to control the translation of the fragments. If the fit is too tight, it may be impossible to drive the IMFD into the bone, the bone fragments may burst, the IMFD may migrate out through the side of the bone, and so forth. It is important that the designation for the reamer size or diameter be related to the diameter of the reamer's cutting flutes so that instruments and IMFDs of different designs and manufacturers can be interchanged during use. Using the reamer diameter specified here and the IMFD diameter specified in Specification F1264, the surgeon may have confidence in achieving the correct reamer/IMFD geometric relationship.

X1.2 The reamer shaft diameter may be an important dimension in the clinical use of the intramedullary reamer. Laboratory studies have suggested that larger reamer shaft diameters result in greater intramedullary pressure.[3,4,5]

[3] Muller, C.A., Schavan, R., Frigg, R., Perren, S.M., and Pfister, U., "Intramedullary Pressure Increase for Different Commercial and Experimental Reaming Systems: An Experimental Investigation," *Journal of Orthopaedic Trauma*, Vol 12, No. 8, pp. 540–46, 1998.

[4] Peter, R.E., Selz, T., and Koesti, A., "Influence of the Reamer Shape on Intraosseous Pessure During Closed Intramedullary Nailing of the Unbroken Femur: A Preliminary Report," *Injury*, Vol 24, Suppl. 3, pp. S48–55, 1993.

[5] Muller, C.A., Frigg, R., and Pfister, U., "Can Modifications to Reamer and Flexible Shaft Design Decrease Intramedullary Pressure During Reaming? An Experimental Investigation," *Techniques in Orthopaedics*, Vol 11, No. 1, pp. 18–27, 1996.