Designation: F3212 – 16

Standard Test Method for Coring Testing of Huber Needles[1]

This standard is issued under the fixed designation F3212; 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

1.1 This test method covers the qualitative measurement of Huber-type needles' potential to remove septum material during implantable port access (1)[2].

1.2 This test method does not address other issues that may include, but are not limited to, force measurement during the perforation/withdrawal, septum integrity, and any safety issues.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

D2240 Test Method for Rubber Property—Durometer Hardness

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *bevel, n*—the slanted part of a needle that creates a sharp pointed tip.

3.1.2 *cannula, n*—the tubular part of a needle through which fluids pass.

3.1.3 *core, n*—a sliver of septum material that may be produced when a needle perforates a septum.

3.1.4 *heel, n*—the rear cutting edge of the needle bevel.

3.1.5 *Huber needle, n*—a needle whose tip is angles such that the bevel opening is parallel to the main axis of the cannula. Its special shape slices rather than perforates the septum, reducing the chance of leakage due to coring. It is also known as a non-coring needed. See Fig. 1.

3.1.6 *implantable port, n*—a reservoir placed under the skin (and usually attached to a catheter) that is made to receive a needle through a septum; it is often used to deliver medication. See Fig. 2.

3.1.7 *lumen, n*—the inside surface of the cannula.

3.1.8 *septum, n*—a feature of an implantable port that allows repeated access by a port-access needle, generally composed of an elastomeric material. See Fig. 2, Item 1.

3.1.9 *stylet, n*—a device, preferably metallic, inserted into the lumen to remove a core.

4. Summary of Test Method

4.1 A silicone elastomeric disk (surrogate septum or just septum thereafter) is clamped into a specifically designed septum holder. The test operator accesses the septum with a Huber needle in accordance with the needle manufacturer's instructions for use, as if the septum was an implantable port. The lumen at the bevel is examined for the existence of a core, preferably before the needle is withdrawn. This is categorized as a pass/fail test. Existence of a core in the needle's cannula is a failed result.

5. Significance and Use

5.1 This test method determines whether Huber needles are designed and manufactured such that they will not produce a core during simulated implantable port access.

5.2 If a needle produces a core during actual use, leaking of the implantable port may occur. Also, the core may be flushed into the port's reservoir and subsequently into the patient's body.

6. Apparatus

6.1 *Clamping Test Fixture,* a clamping device which can hold a septum with nominal dimensions of 0.70 in. in diameter and 0.25 in. thick. The clamping device is such that it restrains radial expansion of the septum under axial compression. The compression force is specified when the compression plates are in contact. The distance between the two compressive surfaces of the fixture plates after the clamping will be 0.213 in. which results in nominal 15 % compression. See Figs. 3-13.

6.1.1 The clamping test fixture consists of 6 parts (See Figs. 3-13.). The septum (Fig. 8) is placed on the opening of the septum restrictor (Fig. 6). The septum restrictor with the

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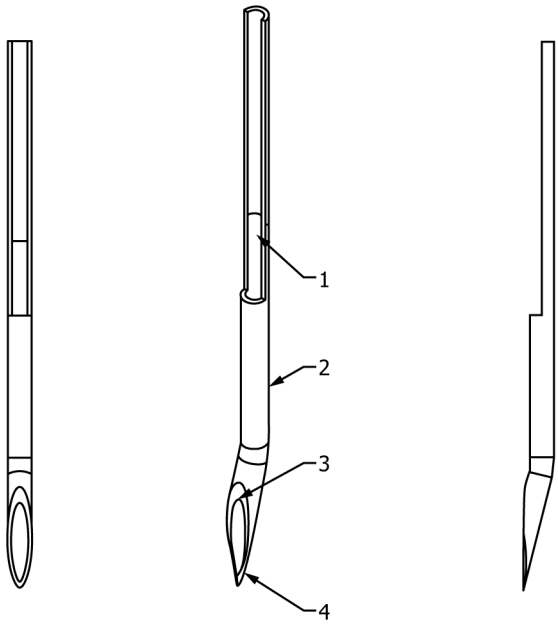
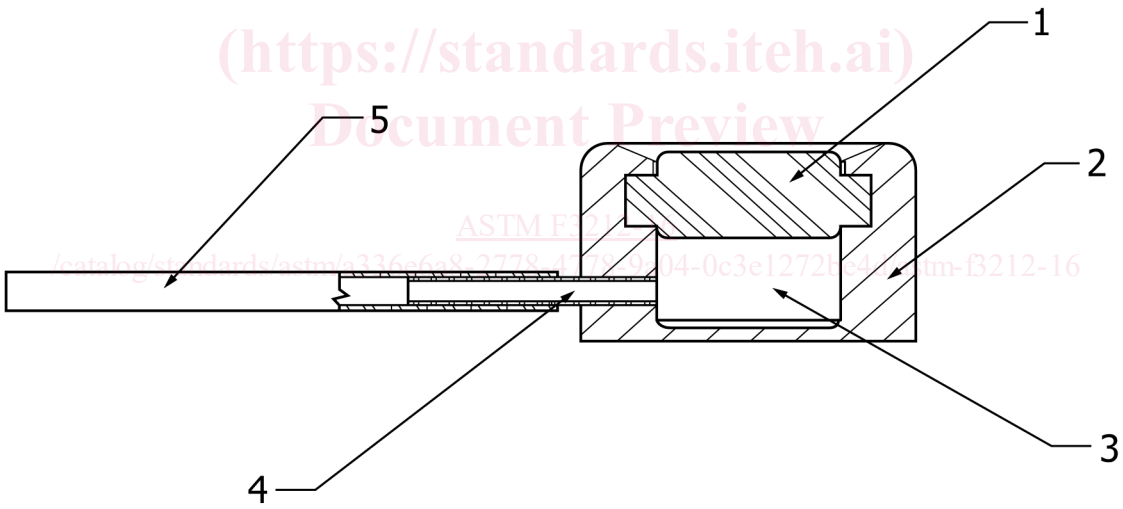
[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.

[3] 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.



1. Lumen 2. Cannula 3. Heel 4. Bevel

FIG. 1 Example of a Huber Needle (partial section through cannula)



1. Septum 2. Housing/Body 3. Reservoir 4. Outlet Tube 5. Catheter

FIG. 2 Example of an Implantable Port (section)

septum is held between two clamps (Fig. 4, Fig. 5 and Fig. 7) with three screws (Fig. 11 and Fig. 12). The screws must be tightened completely. A polycarbonate cylinder (Fig. 9) holds the clamping setup at a height that enables needle penetration while protecting the tester from any potential needle sticks. Parts 6a, 6b, and 6c (Fig. 10) are three possible versions of the guide template.

6.2 *Septum (*Fig. 8*),* a silicone disk 0.70 ± 0.01 in. in diameter and 0.25 ± 0.01 in. thick. The flat surfaces should be smooth with neither tool marks nor voids visible to the naked eye. The septum is made of molded LSR (silicone) elastomeric material with a durometer hardness of 55 ± 5A (Test Method D2240).