Designation: F3212 – 16 (Reapproved 2023)

# 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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:*[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 angled 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

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.33 on Medical/Surgical Instruments.

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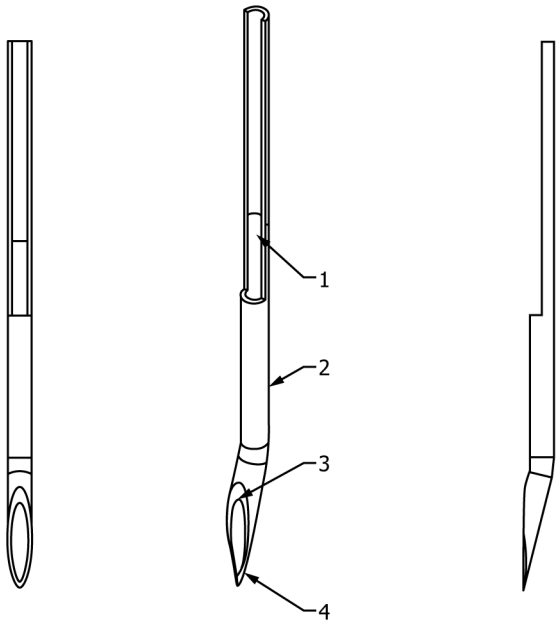
[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.

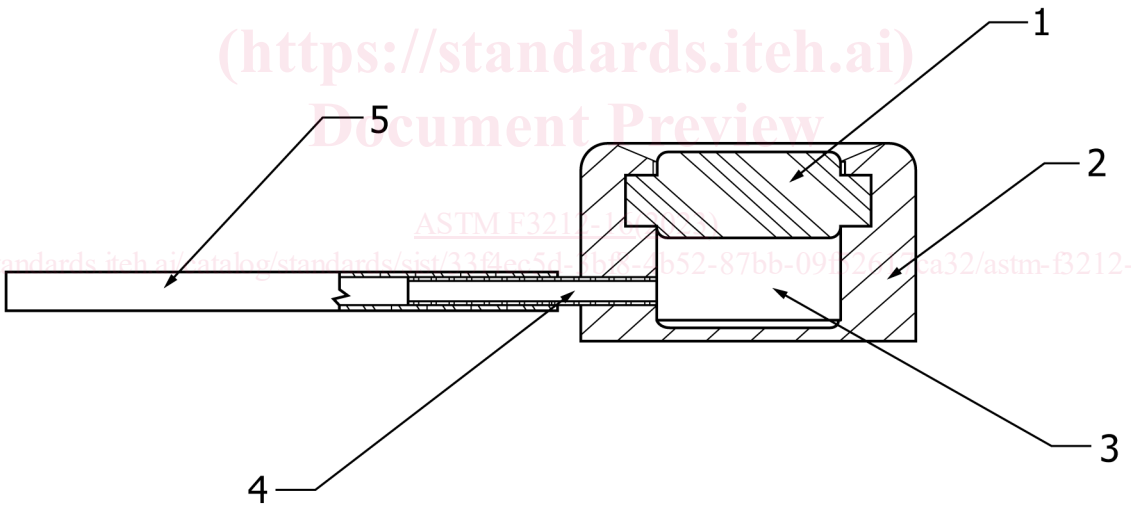
[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.




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)**

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 six 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 septum is held between two clamps (Fig. 4, Fig. 5, and Fig. 7) with three screws (Figs. 11 and 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.

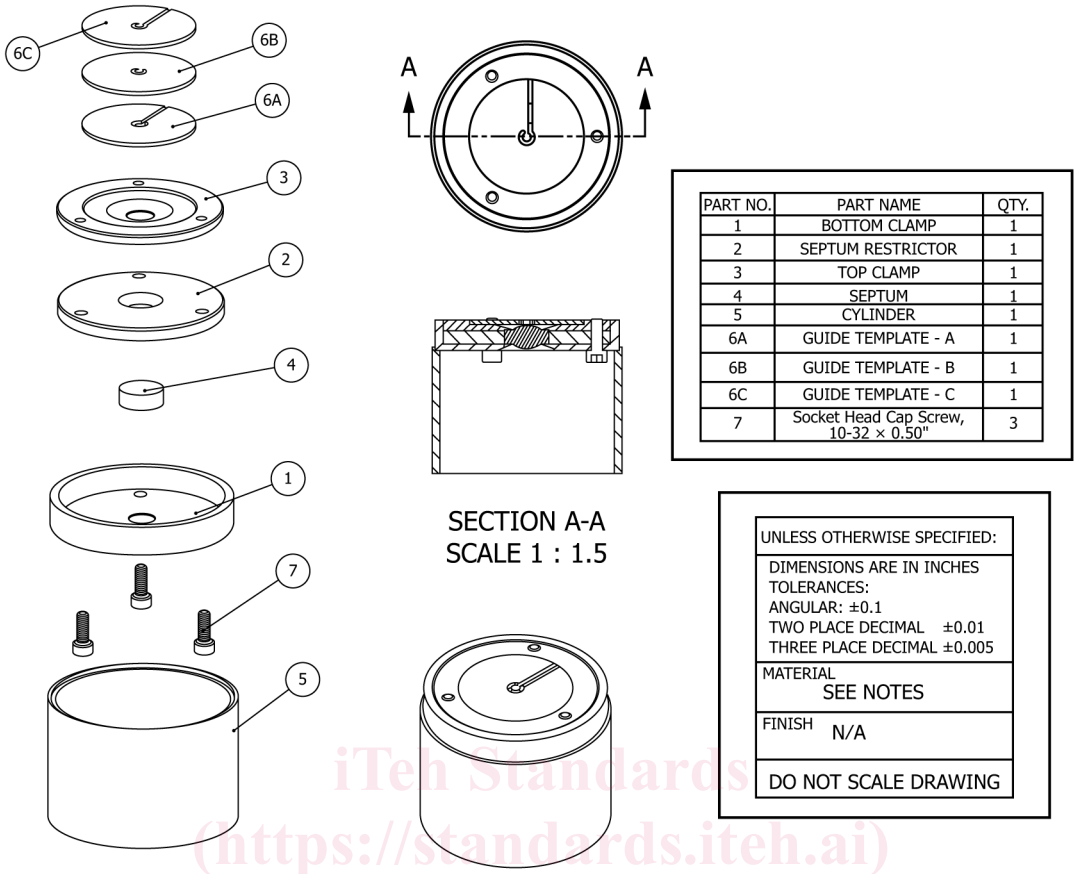
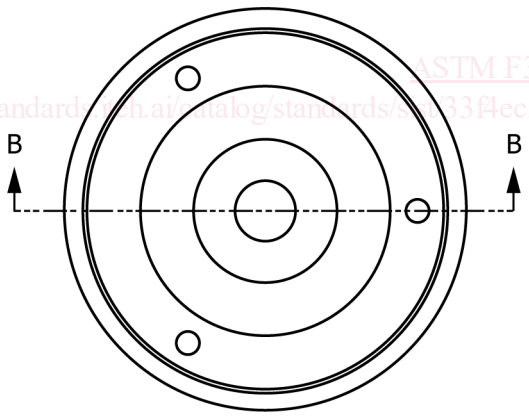



FIG. 3 Clamping Test Fixture Layout





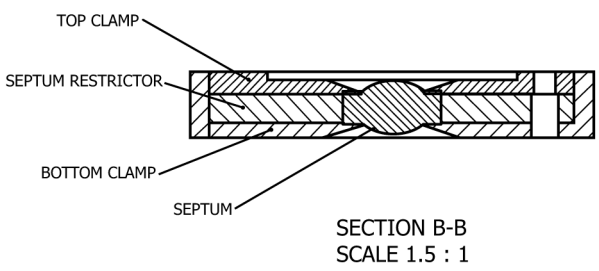




FIG. 4 Cross-Section of Clamping Device with Septum

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).

6.3 *Optical Microscope,* capable of an optical magnification of at least 20×.

6.4 *Stylet,* a wire, not less than 70 % of inner diameter of the cannula, used to push through the needle to force out a possible core within the lumen.

## 7. Test Specimens and Test Units

7.1 Test specimens are production-equivalent Huber needles in their original packaging.

## 8. Procedure

8.1 Remove the needle from its package (if applicable). Each needle should be tested only once.

8.2 Clamp the septum into the test fixture (Figs. 11 and 12) in accordance with 6.1.1.

8.3 Fasten the test fixture on top of the cylinder and then place the guide template on top of the test fixture (Fig. 13).

8.4 Insert the needle into the clamped septum along the outer edge of the circular opening of the guide template with the bevel oriented in the circumferential direction (Fig. 14).

PART 1: BOTTOM CLAMP
MATERIAL: 300 SERIES STAINLESS STEEL

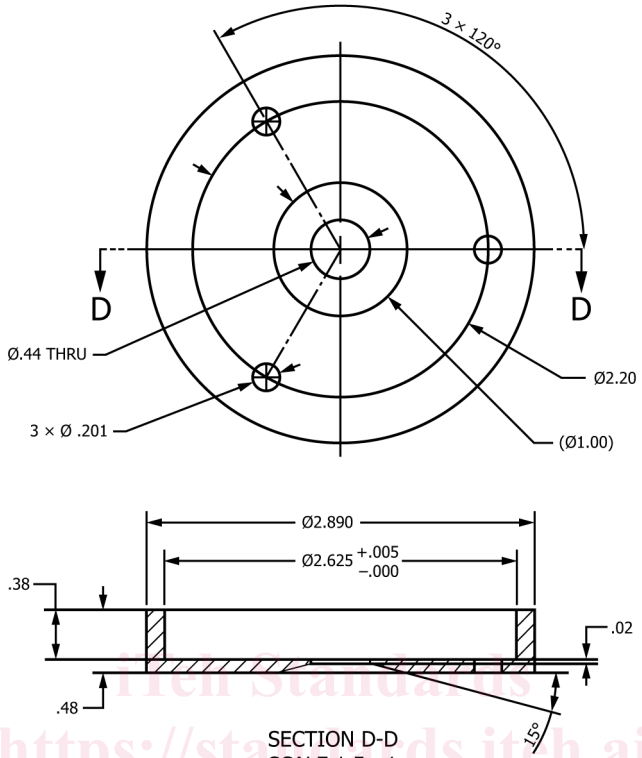



**FIG. 5 Bottom Clamp**



Perforate the septum with only one needle at a time. Carefully avoid any previous penetration sites. Ensure that the needle is handled and penetrates in accordance with the instructions for use from the needle manufacturer except that the needle is to be tested dry, even if the manufacturer's instructions require that the needle be flushed before use. Do not insert the needle into the 0.125 in. diameter central area of the septum (**2**).

8.5 Determine whether coring has occurred. The method to determine whether a core is present may be developed by each testing facility, and appropriately validated. The following techniques can potentially be used to identify a core:

*(a)* Flip the clamping test fixture over to expose the bevel. Observe the cannula lumen at the bevel, area around the penetration and under the penetration using an optical microscope with 20× magnification for the presence of a core. If coring has occurred, a sliver of the septum should be observed in the needle cannula. Use a stainless steel stylet, coil spring-type guide wire, or polyamide tubing to confirm the absence of a core in the cannula lumen. Note existence or absence of a core or any foreign particles (Figs. 15 and 16).

*(b)* For 90° bent needles, cut the needle to remove the bent part and be able to use a stylet in the straight part to remove the core.

*(c)* Directly observe the inside of the lumen with a microscope by orienting the deflected tip of the needle with the microscope's line of sight.

*(d)* Attach a syringe to the needle and flush the needle with water. Ensure that the discharged water passes through filter paper to collect any existing core.

8.6 Remove the needle from the septum and mark the location of the perforation with a permanent fine tip marker.

8.7 Repeat steps 8.1 – 8.6 for each needle tested by moving along the circumference of the guide template. Replace the test fixture with a new septum once twelve needles have been tested or after five cores are observed, whichever occurs first.

## 9. Report

9.1 Report the following information:

9.1.1 Name of testing laboratory.

9.1.2 Name of person performing test.

9.1.3 Date and time of testing and testing conditions.

9.1.4 Identify septum holder used.

9.1.5 Identify septum: materials, manufacturer, lot number, and actual hardness.

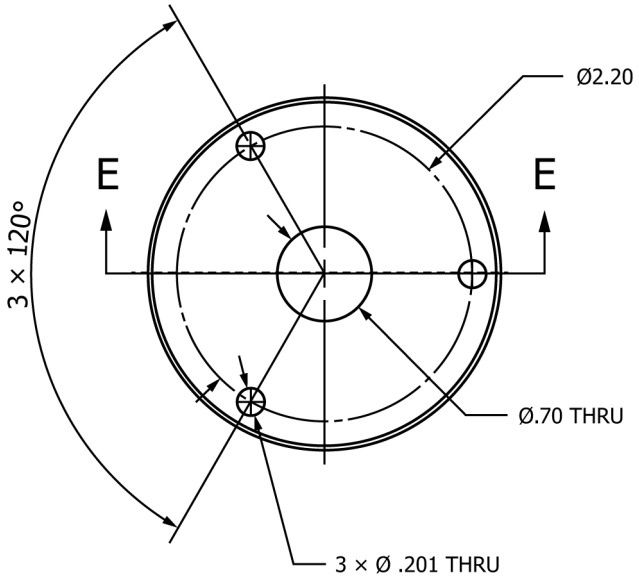
9.1.6 Identify needle: manufacturer and/or supplier, model, size, lot number.

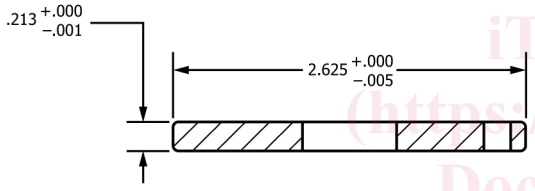
9.1.7 Brief description of core identifying procedure and magnification used.

9.1.8 Existence or absence of core or other foreign particles.

9.1.9 If a core is found, explain any specific observations that were made.

PART 2: SEPTUM RESTRICTOR
MATERIAL: 300 SERIES STAINLESS STEEL



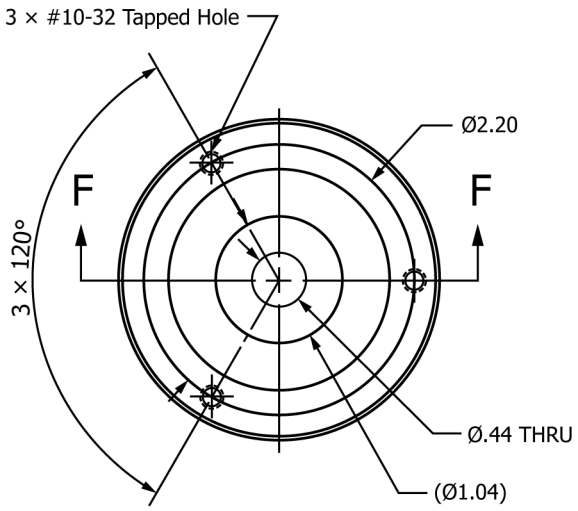



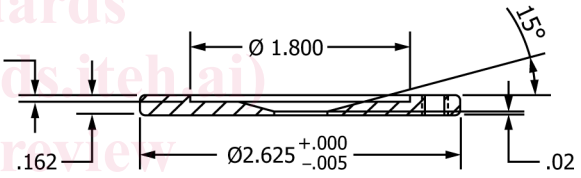

SECTION E-E

**FIG. 6 Septum Restrictor**

Note: Brake sharp edges, not to exceed 0.02 in. by 45°.

PART 3: TOP CLAMP
MATERIAL: 300 SERIES STAINLESS STEEL




SECTION F-F

**FIG. 7 Top Clamp**



9.1.10 Provide photographic documentation, if available.

## 10. Precision and Bias

10.1 The precision of this test method is based on an interlaboratory study of F3212, Standard Test Method for Coring Testing of Huber Needles, conducted in 2015. Nine laboratories participated in this study, with seven labs submitting suable data. Six labs received 100 individually identified Huber needles (25 defective and 75 non-defective) and one lab tested 125 needles (100 non-defective and 25 defective). Every "test result" reported represents an individual coring determination. The details of this study are recorded in ASTM Research Report No. RR:F04-1015.[4]

10.1.1 Intentionally defective Huber needles were properly identified 96.6 % of the time when the test method was performed as written.

10.1.2 Non-defective Huber needles were identified 99.8 % of the time when the test method was performed as written.

10.2 *Bias*—At the time of the study, there was no accepted reference material suitable for determining the bias for this test method; therefore, no statement of bias is being made.

10.3 The precision statement was determined through statistical examination of 725 test results, from seven laboratories, on both intentionally defective and standard Huber needles.

## 11. Keywords

11.1 core; Huber needle; medical device; non-coring needle

[4] Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:F04-1015. Contact ASTM Customer Service at service@astm.org.

PART 4: SEPTUM
MATERIAL: SILICONE ELASTOMER

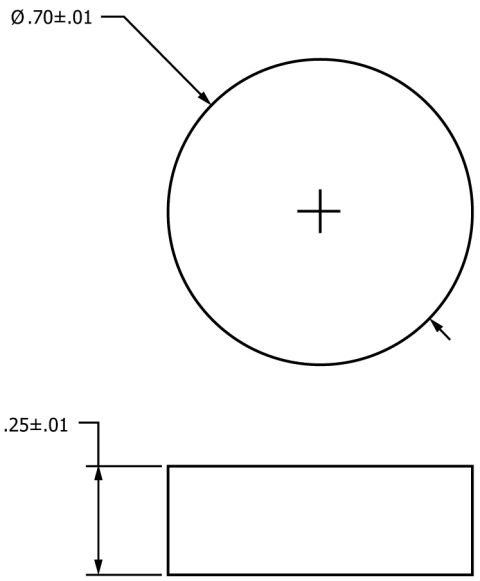
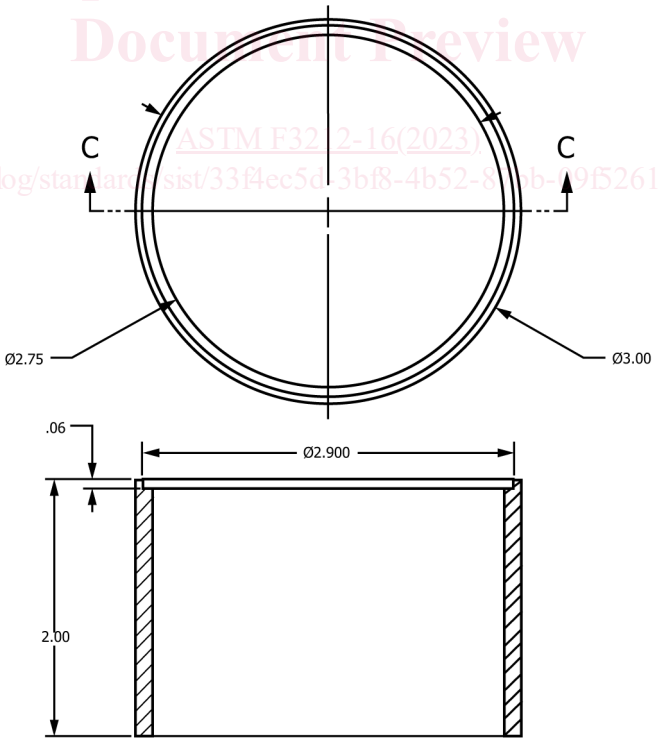



**FIG. 8 Septum**



PART 5: CYLINDER
MATERIAL: POLYCARBONATE




SECTION C-C
SCALE 1.5 : 1

**FIG. 9 Cylinder**

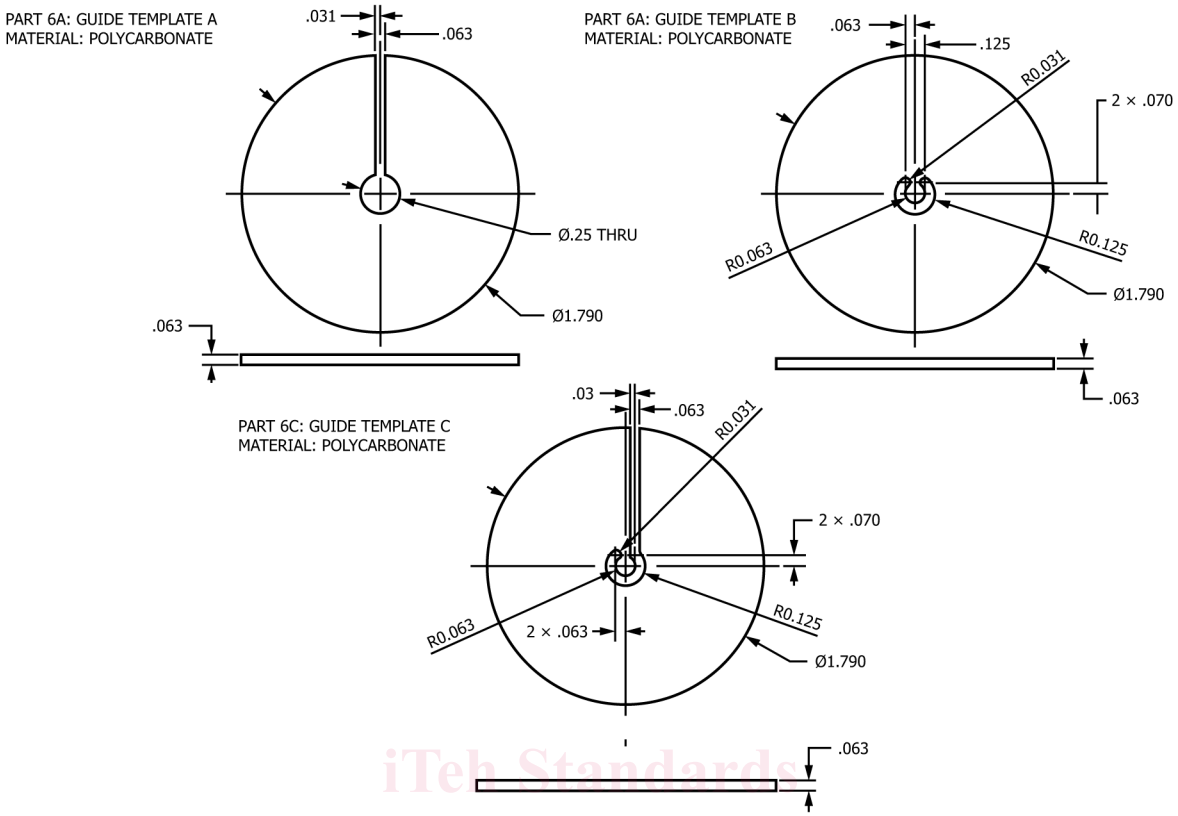



FIG. 10 Guide Template (three possible designs)



FIG. 11 Stainless Steel Clamping Top and Bottom Along with Septum and Septum Restrictor

FIG. 12 Clamped Septum with Guide Template and Cylinder