User Manual: Mechanical and Leakage Integrity Testing Protocols for Evaluating the Performance of Tissue Containment Systems Used During Power Morcellation Procedures

Tool Reference

RST Reference Number: RST24PM01.01

Date of Publication: 09/24/2023

Recommended Citation: U.S. Food and Drug Administration. (2023). *Mechanical and Leakage Integrity Testing Protocols for Evaluating the Performance of Tissue Containment Systems Used During Power Morcellation Procedures* (RST24PM01.01). https://cdrh-rst.fda.gov/mechanical-and-leakage-integrity-testing-protocols-evaluating-performance-tissue-containment

For more information

Catalog of Regulatory Science Tools to Help Assess New Medical Devices

Disclaimer

About the Catalog of Regulatory Science Tools

The enclosed tool is part of the Catalog of Regulatory Science Tools, which provides a peer-reviewed resource for stakeholders to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as Medical Device Development Tools and the FDA has not evaluated the suitability of these tools within any specific context of use. You may request feedback or meetings for medical device submissions as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email RST_CDRH@fda.hhs.gov.

Mechanical and Leakage Integrity Testing Protocols for Evaluating the Performance of Tissue Containment Systems Used During Power Morcellation Procedures

This user manual lists protocols for the test methods listed in Table 1 to evaluate mechanical strength and leakage potential of the TCS materials

Tensile Testing

The tensile testing protocol is based on the following standards:

Standard	Aspects of Standard Used/Incorporated
ASTM D412	Section 10.1: Die – Type C Dye
ASTM D882	All with the Exception of Section 6

The majority of the test procedure is derived from ASTM D882. However, in place of section 6 of ASTM D882 this standard, test samples should be cut using an ASTM D412 Type C (25 mm × 115 mm) dumbbell shaped die.

Additional information for the tensile testing can be obtained from Herman et al. [2023].

Burst Testing

Information for the burst testing can be obtained from Herman et al. [2023]. SolidWorks® files of the test rig can be downloaded here.

Puncture Testing

Resistance to puncture for each containment system was obtained by measuring the force required to cause a standardized puncture pin to completely penetrate through the thickness of the specimen. A 50mm circular coupon is sandwiched between two circular specimen holders with an internal test diameter of 25 mm using four screws (Figure 1). The specimen holder is then secured to a puncture test fixture (Figure 2) which is designed to be secured on top of a 50 mm compression plate. For the puncture pins, one of the two standard durometers pins, Type OO and Type D from ASTM D2240 are used. The pin is moved uniformly downwards with a speed of 25 mm/min until it punctured through the thickness of the containment system while the force-displacement data was recorded. The threshold force at which the pin traversed through the full thickness of the TCS (i.e., fully punctured) was called the full-puncture force ($F_{puncture}$).

Additional Information for the puncture testing can be obtained from Herman et al. [2023]. SolidWorks® files of the sample sandwich, puncture rig stand, and bracket can be found here.

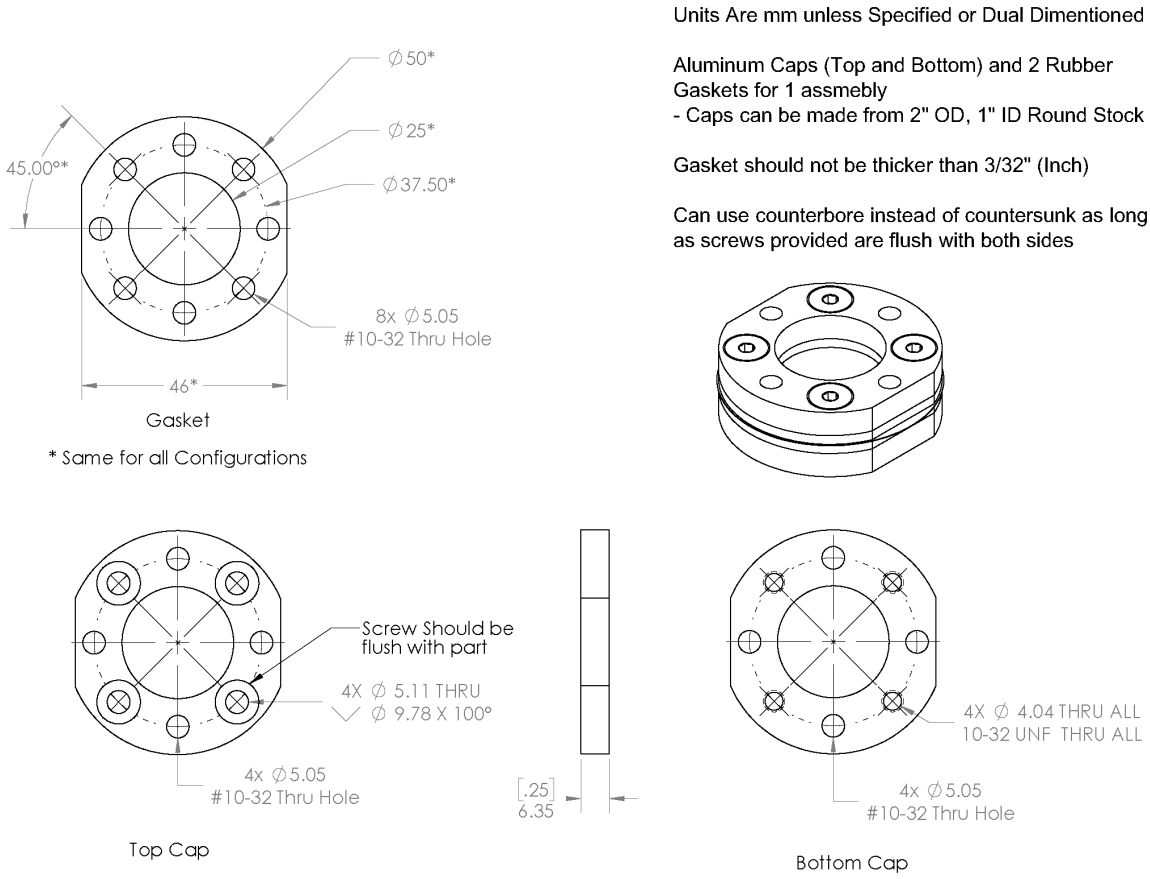

Figure 1: CAD Drawing of the Sandwich Assembly Used in the Puncture Test and Partial Puncture/Dye Test Setup

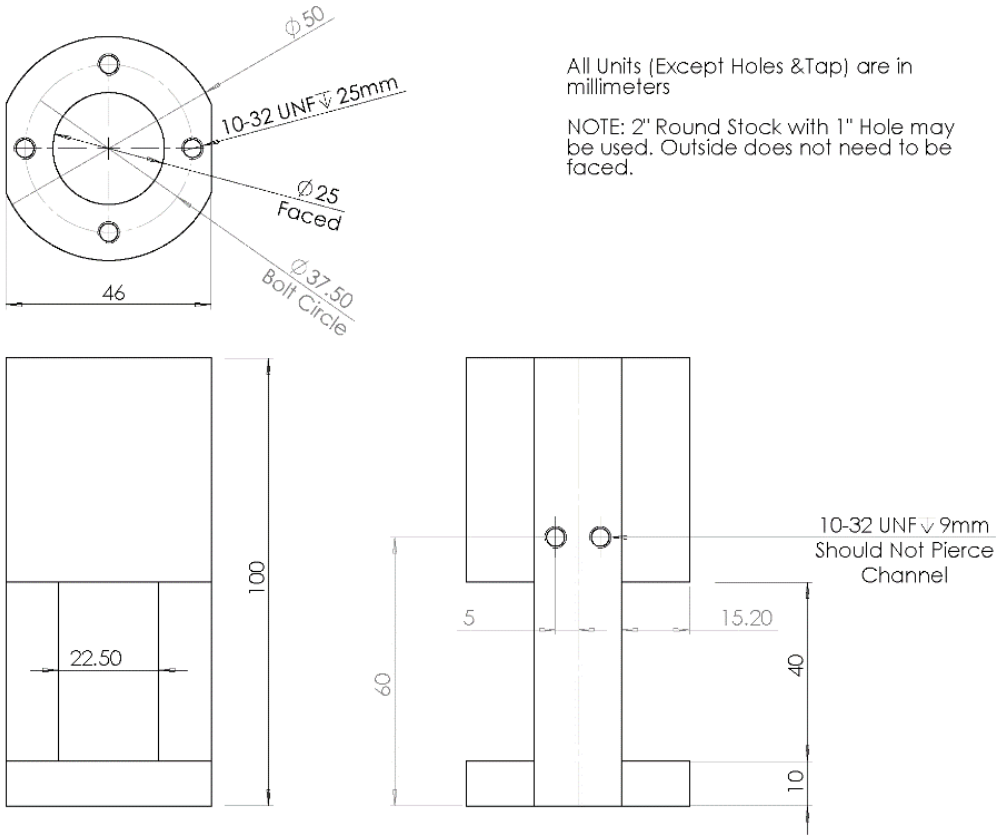

Figure 2: CAD Drawing of the Puncture Rig Setup Base

Dye Testing

The protocol for dye testing has been adopted from ASTM F1670. All sections with the exception of Section 7: Reagents from ASTM F1670 are applicable here. Annex A of ISO 16603 may be used in place of Section 7 from ASTM F1670 for artificial blood soil. Herman et al. [2020] also provides additional information about dye testing.

Bacteriophage Testing

The protocol for bacteriophage testing has been adopted from the protocol outlined in ASTM F1671. All sections are applicable for the Bacteriophage Testing procedure for this RST. Herman et al. [2020] also provides additional information about bacteriophage testing.

Partial Puncture / Dye Testing

Information for the partial puncture testing can be obtained from Herman et al. [2023]. SolidWorks® files of the modified dye testing cell, and mounting plate can be found here.

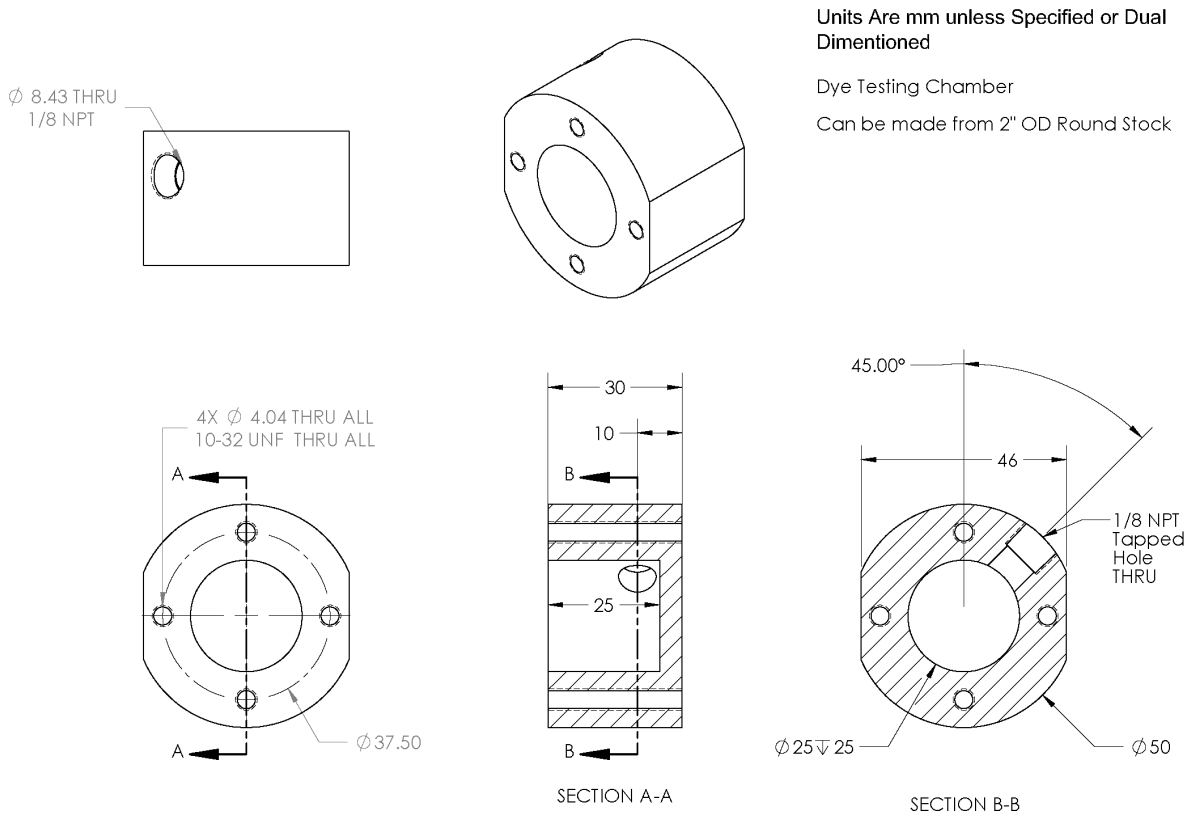

Figure 3: CAD Drawing of the Modified Dye Testing Cell to be Used in the Partial Puncture and Dye Testing.

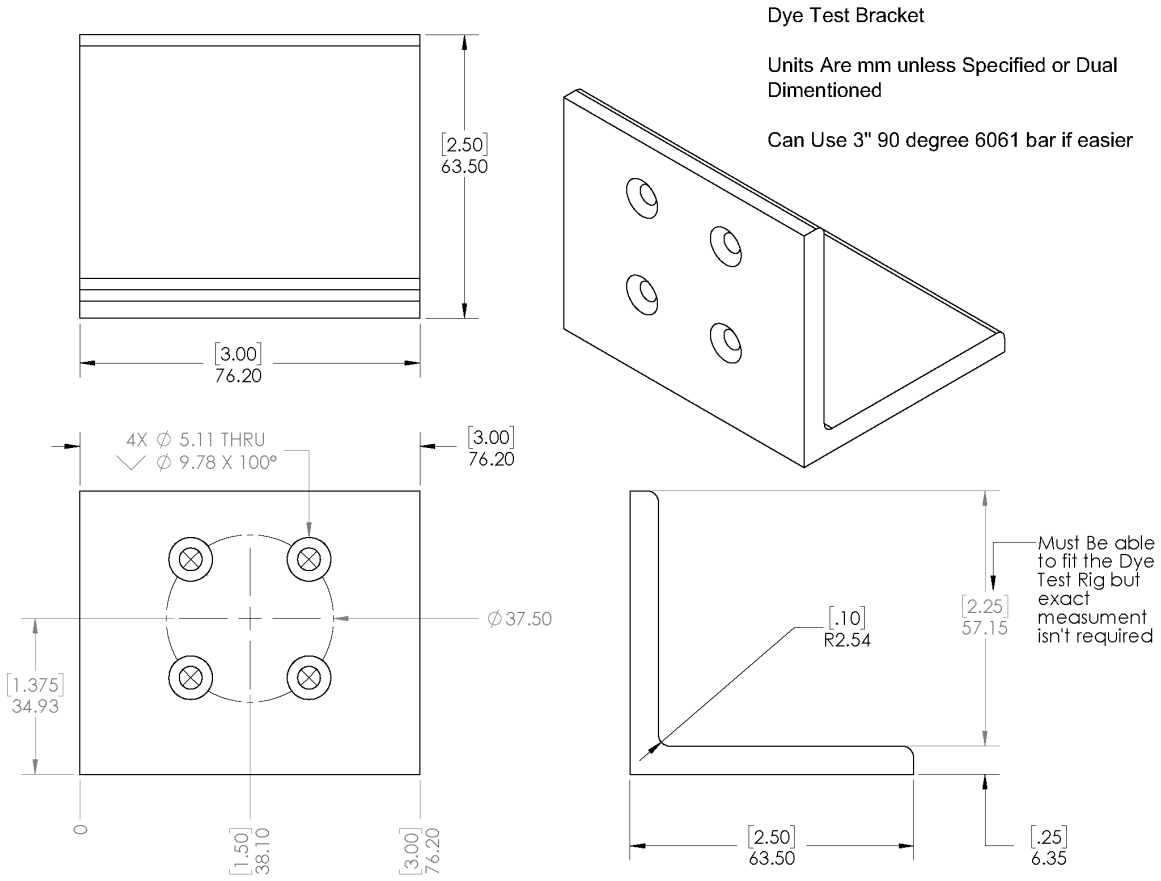

Figure 4: CAD Drawing of the Mounting Bracket for Modified Dye Testing Cell