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

Catalog of Regulatory Science Tools to Help Assess New Medical Devices

Technical Description

This tool provides protocols to evaluate the mechanical strength and leakage integrity of tissue containment systems (TCS) and its component materials.

In the appendix section of the tool, protocols for conducting the following preclinical tests are provided for TCS materials.

Table 1: Summary of preclinical test methods for TCSs

Evaluation Type	Preclinical Testing	Outcome/Metric	Rationale
Mechanical Strength Evaluation	• Tensile testing • Burst testing • Puncture testing	• Ultimate tensile strength • Toughness • Burst pressure • Full puncture force	To evaluate strength of the containment system when subjected to tensile, radial, and puncture forces.
Leakage Integrity (or Material Impermeability) Evaluation	• Dye penetration testing • Microbiological penetration testing • Dye penetration testing after partial puncture.	• Leakage pressure • Leakage integrity • Minimum puncture force that caused leakage without puncturing the bag (i.e., partial TCS damage)	To understand the ability of the TCS material to remain impermeable under clinically relevant forces

Intended Purpose

The test methods in this tool are intended to evaluate the mechanical strength and leakage integrity of TCSs and its materials. These tests are designed to complement testing recommendations in the "Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures" Guidance document issued in May 2023, specifically the special controls outlined in 21 CFR 884.4050(b)(4) [Product Code PMU] and 21 CFR 878.4825(b)(4) [Product Code PZQ].

Testing

The adequacy of all the test methods listed in Table 1 were evaluated using 7 different tissue containment systems.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.GOV

See the following publications for details:

- Herman, A., Duraiswamy, N., Nandy, P., Myers, M. R., Price, V., Gibeily, G., & Hariharan, P. (2020). In Vitro Leakage Testing of Tissue Containment Bags When Subjected to Power Morcellation Forces. *Journal of minimally invasive gynecology*, *27*(3), 655–664. https://doi.org/10.1016/j.jmig.2019.05.006
- Herman, A., Duraiswamy, N., Nandy, P., Price, V., Gibeily, G., & Hariharan, P. (2023). Mechanical and leakage integrity testing considerations for evaluating the performance of tissue containment systems. *Scientific reports*, *13*(1), 5104. https://doi.org/10.1038/s41598-023-31847-7

Limitations

- These protocols are not applicable to testing of the TCS bag as a whole but only to assess the materials used to manufacture TCS. Additional test methods are needed to evaluate the mechanical and leakage integrity of the full TCS bag.
- Additional simulated use methods may be needed to evaluate all aspects of device performance.

Supporting Documentation

- Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures Final Guidance
- ASTM F1670
- ISO 16603
- ASTM F1671
- ASTM D882
- ASTM D412
- ASTM D2240
- Herman, A., Duraiswamy, N., Nandy, P., Myers, M. R., Price, V., Gibeily, G., & Hariharan, P. (2020). In Vitro Leakage Testing of Tissue Containment Bags When Subjected to Power Morcellation Forces. *Journal of minimally invasive gynecology*, *27*(3), 655–664. https://doi.org/10.1016/j.jmig.2019.05.006
- Herman, A., Duraiswamy, N., Nandy, P., Price, V., Gibeily, G., & Hariharan, P. (2023). Mechanical and leakage integrity testing considerations for evaluating the performance of tissue containment systems. *Scientific reports*, *13*(1), 5104. https://doi.org/10.1038/s41598-023-31847-7

Contact

- RST_CDRH@fda.hhs.gov

Tool Reference

In addition to citing relevant publications please reference the use of this tool using DOI:

10.5281/zenodo.8380160

For more information:

- Catalog of Regulatory Science Tools to Help Assess New Medical Devices

Appendix

This Appendix 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.

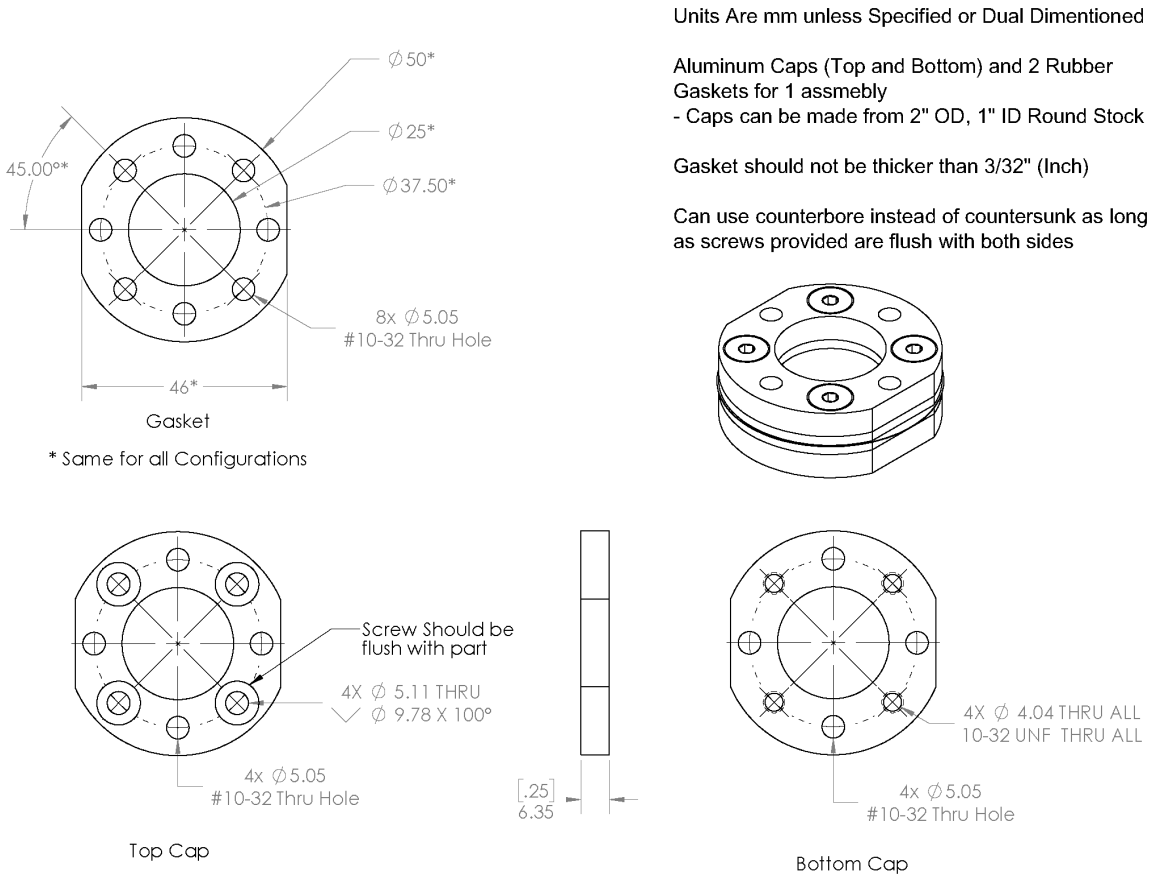

Figure 1: CAD Drawing of the Sandwich Assembly Used in the Puncture Test and Partial Puncture/Dye Test Setup

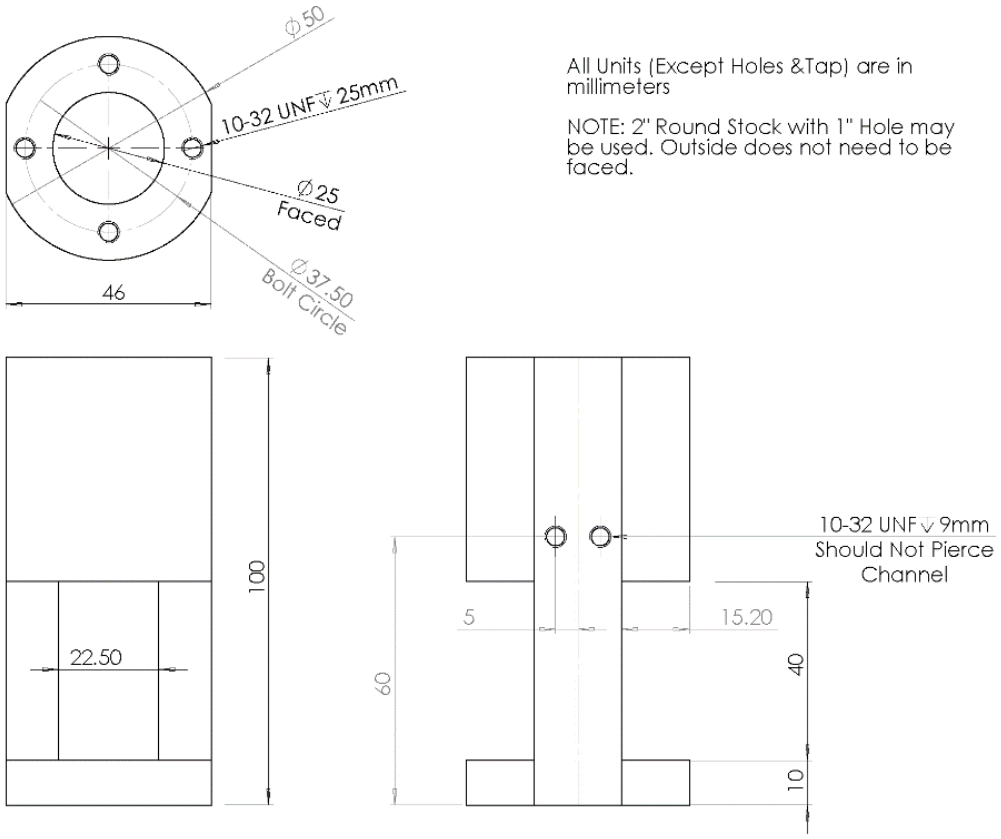

Figure 2: CAD Drawing of the Puncture Rig Setup Base

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.

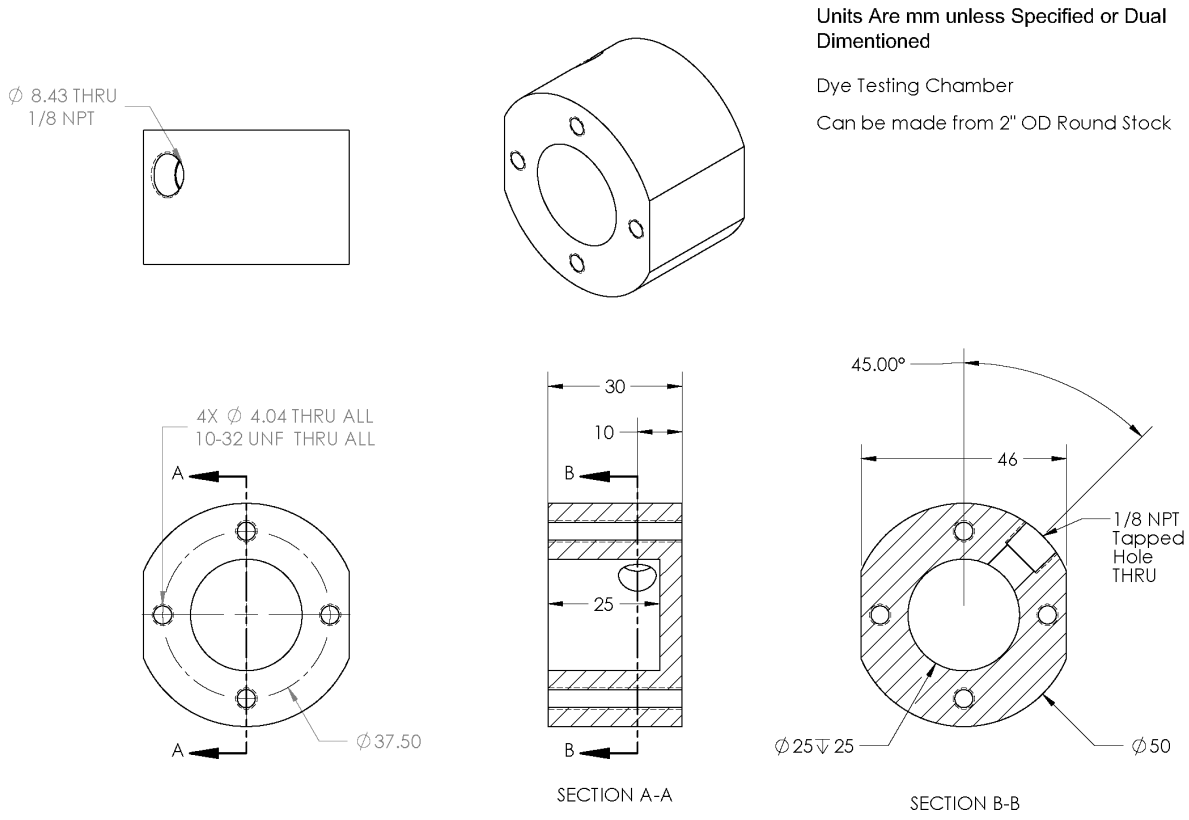

Figure 3: CAD Drawing of the Modified Dye Testing Cell to be Used in the Partial Puncture and Dye Testing.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.GOV

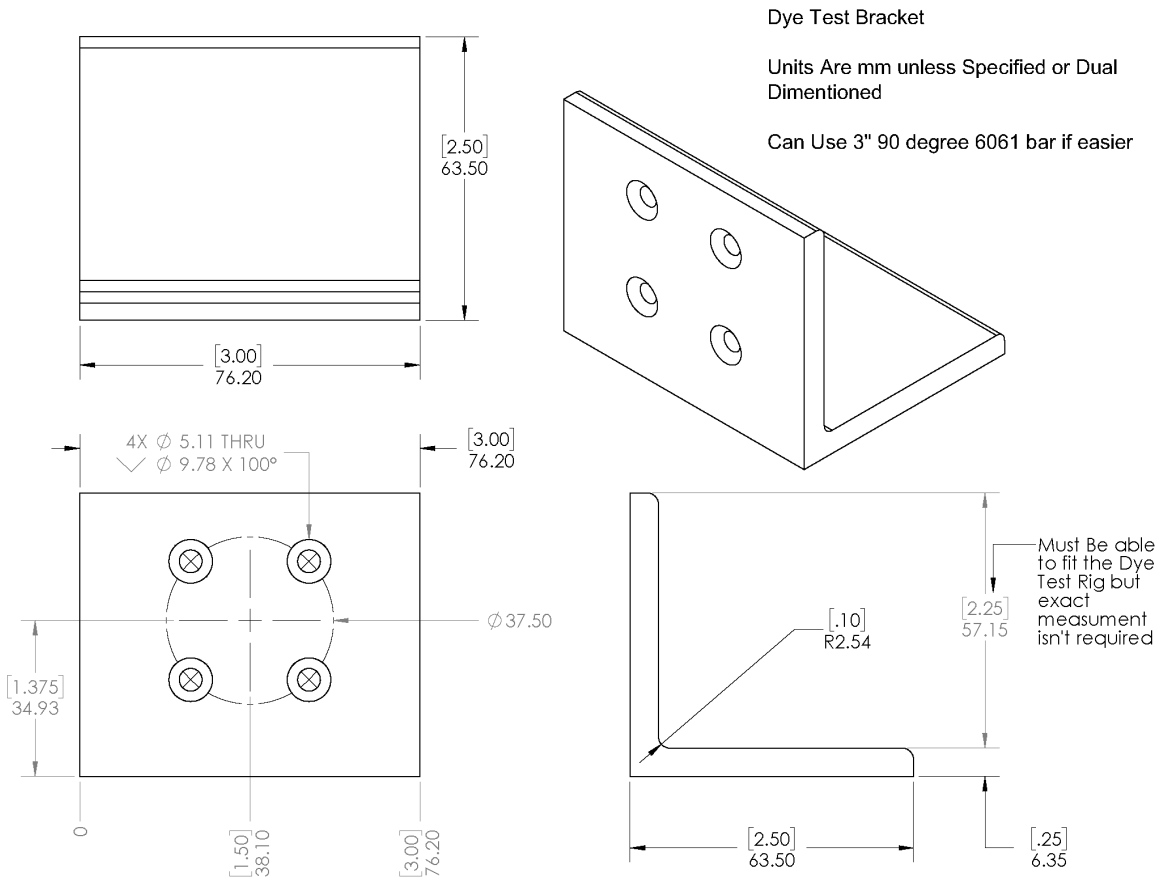

Figure 4: CAD Drawing of the Mounting Bracket for Modified Dye Testing Cell