

1. Purpose

- 1.1. The purpose of this document is to report the tissue capture test results for comparing the capability of simulated sample capture of the Cook Medical Tao Brush I.U.M.C. Endometrial (“Tao Brush”) to the TechMed Ventures Utepreva Endometrial Sampler (“Utepreva”, MM PN 027329).

2. Product Description and Intended Use

- 2.1. The Tao Brush is an endometrial sampling device comprised of a 9Fr plastic sheath and 3.5cm long interior brush. It is indicated for use in evaluation of the endometrium.
- 2.2. The Utepreva is an endometrial sampling device comprised of an 11.5Fr plastic sheath and 3.175cm long brush. The Utepreva includes a plunger on the brush assembly which supports fluid capture. Additionally, a foam tip at the end of the brush is incorporated for further fluid and tissue capture. The Utepreva is indicated for use in evaluation of the endometrium.

3. Scope

- 3.1. This testing report applies to comparative testing of the Tao Brush and Utepreva devices to evaluate their respective capabilities to capture simulated endometrial tissue samples.

4. Responsibility

- 4.1. Medical Murray is responsible for proper documentation of the test results.
- 4.2. Medical Murray Engineering and Quality Assurance, and TechMed Ventures are responsible for review and approval of the report.
- 4.3. TechMed Ventures is responsible for interpretation of the test results.

5. References

- 5.1. 510(k) Number K941298 – Tao Brush I.U.M.C Endometrial
- 5.2. 510(k) Number K240595 – Utepreva Endometrial Sampler
- 5.3. MM Doc 042637 Rev. A - Test Protocol – Comparison of Simulated Sample Capture of the Cook Medical Tao Brush to the TechMed Ventures Utepreva
- 5.4. MM Doc 027329 Rev. D – Packaged Utepreva Kit (MM Lot P009218)
 - 5.4.1. MM Doc 016426 Rev. D – Endometrial Biopsy Device

6. Equipment and Materials

- 6.1. Equipment and Gauges
 - 6.1.1. Calipers: Gauge # 11010, Calibration Due Date: 08/16/25
 - 6.1.2. Scale: Gauge # 697, Calibration Due Date: 07/29/25
- 6.2. Materials
 - 6.2.1. Johnson & Johnson Baby Soap
 - 6.2.2. Cow liver
 - 6.2.3. Ruler or calipers
 - 6.2.4. Razor blade or scalpel
 - 6.2.5. DI water
 - 6.2.6. Weight boat
 - 6.2.7. Wire cutters

7. Test Articles

- 7.1. Tao Brush I.U.M.C Endometrial
 - 7.1.1. Test Article Identification: Lot 16137446
- 7.2. Utepreva Endometrial Sampler
 - 7.2.1. All test articles were final finished products.
 - 7.2.2. All test articles underwent 1x sterilization with ethylene oxide (EO) at Sterilization Services of Georgia (SSG).
 - 7.2.3. Test Article Identification: MM Lot P009218
- 7.3. The sample size was n=22 for each device to mirror the sample size used for design verification testing based on a 90/90 confidence/reliability. As needed, test articles were cleaned and re-used as an additional sample, per MM Doc 042637: Tao Comparison Test Protocol.

8. Test Method

- 8.1. All articles underwent simulated tissue capture Testing per MM Doc 042637: Test Protocol – Comparison of Simulated Sample Capture of the Cook Medical Tao Brush to the TechMed Ventures Utepreva.

9. Deviations

- 9.1. N/A

10. Test Results

- 10.1. Simulated Tissue Capture Test
 - 10.1.1. The results from the Simulated Tissue Capture Test are depicted in Figure 4 below.

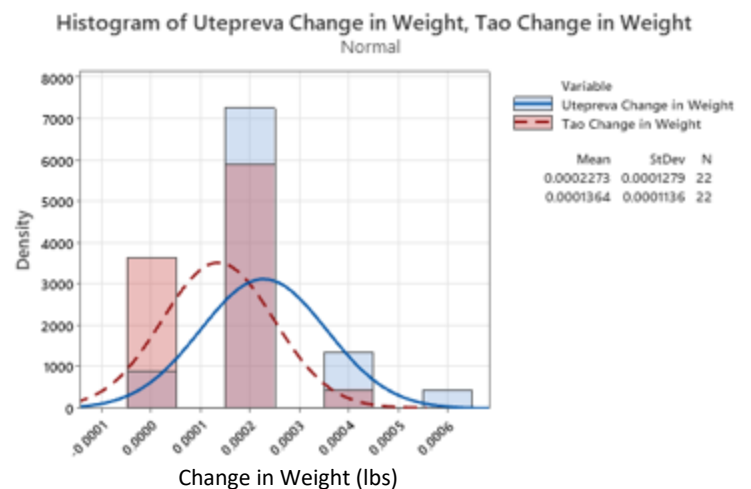


Figure 4: Simulated Tissue Capture – Change in Weight

- 10.1.2. The raw data can be found in Appendix 1 and 2, statistical analysis in Appendix 3, and testing images in Appendix 4.

11. Observations

- 11.1. Twenty-two devices were used to reach the minimum sample size for the Utepreva device. Fifteen Tao devices were used, seven of them undergoing cleaning and retesting to reach an n=22 sample size. Reused devices are denoted on the data sheets in Appendix 1 and 2.
- 11.2. It was observed the Utepreva device was able to capture tissue along the majority of the brush length for each sample. Images of this observation can be found in Appendix 4: Utepreva.

12. Discussion

12.1. Tissue Capture Test

- 12.1.1. Tissue Capture Testing was simulated by rotating the device in a sliced cow liver where the liver tissue was collected by the brush and tip only (brush removed from main body of device). The amount of tissue collected was represented by the change in weight of the device before and after collection. The Utepreva device statistically captured more liver tissue, resulting in an average weight change of 22.73×10^{-4} lbs compared to the Tao Brush average weight change of 13.64×10^{-4} lbs. The performance of the Utepreva device was statistically significant (p -value < 0.05) compared to the Tao Brush. The images in Appendix 4 capture the increased amount of tissue captured by the Utepreva brush compared to the Tao Brush.


13. Conclusion

- 13.1. The aim of this study was to evaluate the capabilities for capturing simulated endometrial tissue samples of the Tao Brush and Utepreva device. Simulated Tissue Capture testing was conducted on the two devices. The Utepreva device outperformed the Tao Brush for simulated tissue capture using cow liver tissue, resulting in a statistically significant difference. The Utepreva device also showed a more even distribution of the tissue collection throughout the length of the brush in comparison to the Tao brush.
- 13.2. For this comparison study, the suction ability of the Utepreva device was not investigated, as the Tao Brush does not include a design feature to pull vacuum. It is predicted the Utepreva device can capture a larger tissue sample than demonstrated in this study when utilizing this feature of the device. Design verification testing confirmed the Utepreva device can obtain and transfer a 0.4mL sample of fluid. Therefore, the full fluid capture capacity and capability of the Utepreva device is not encapsulated in this study.

14. Appendices

- 14.1. Appendix 1: Simulated Tissue Capture Test Data Sheet (Tao Brush)
- 14.2. Appendix 2: Simulated Tissue Capture Test Data Sheet (Utepreva)
- 14.3. Appendix 3: Statistical Analysis; Simulated Tissue Capture Test
- 14.4. Appendix 4: Simulated Tissue Capture Test Images

Appendix 1: Simulated Tissue Capture Test Data Sheet (Tao Brush)

 <p>Medical Murray™ Device Development & Contract Manufacturing</p>	Test Protocol – Comparison of Simulated Sample Capture of the Cook Medical Tao Brush to the TechMed Ventures Utepreva		
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Appendix 2: Simulated Tissue Capture Test Data Sheet

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Device Name: Tao Brush Endometrial Sampler Device Part Number: N/A Rev: N/A
 Lot Number: 16139446 Sample Size: 22
 EQ # / Gauge #: 11010, 097 11034 Calibration Due Date(s): 02/14/25, 07/29/25, 06/19/25
(calipers) (scale) (temp. probe) (EW 03/19/25)

water bath:
EQ #1991
EW 03/19/25

Δ 0.0056
EW 03/19/25

Sample	Initial Brush Weight (g) @ 10	Final Brush Weight (g) @ 10	Comments
1	0.0060	0.0062	
2	0.0058	0.0058	
3	0.0058	0.0058	
4	0.0060	0.0060	
5	0.0060	0.0062	
6	0.0056	0.0058	N/A
7	0.0062 Δ	0.0058	EW 03/19/25
8	0.0062	0.0062	
9	0.0054	0.0056	
10	0.0054	0.0056	
11	0.0056	0.0056	
12	0.0058	0.0060	
13	0.0056	0.0056	
14	0.0056	0.0058	
15	0.0060	0.0062	

Line Clearance: Alma Lopez Imy 03/19/25
Print Sign Date

Testing Performed By: Elayna Williams Elayna Williams 03/19/25
Print Sign Date

Reviewed By: Jenny Fuchs Jenny Fuchs 03/21/25
Print Sign Date



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Appendix 2: Simulated Tissue Capture Test Data Sheet

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Device Name: Tao Brush Endometrial Sampler Device Part Number: N/A Rev: N/A

Lot Number: 1x137416 Sample Size: 22

EQ # / Gauge #: 11010 1497 11034 Calibration Due Date(s): 08/16/25, 09/29/25, 04/19/25
(calipers) (scale) (temp. probe) © EW 03/19/25

Water bath:
EQ # 1941
EW 03/19/25

Sample	Initial Brush Weight (g) lb	Final Brush Weight (g) lb	Comments
16	0.0054	0.0056	cleaned/re-tested sample 1
17	0.0056	0.0058	cleaned/re-tested sample 2
18	0.0054	0.0054	cleaned/re-tested sample 3
19	0.0052	0.0054	cleaned/re-tested sample 4
20	0.0060	0.0062	cleaned/re-tested sample 5
21	0.0056	0.0060	cleaned/re-tested sample 6
22	0.0058	0.0058	cleaned/re-tested sample 7
N/A			
EW 03/19/25			

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Testing Performed By: Elayna Williams [Signature] 03/19/25
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Reviewed By: Jenny Fuchs [Signature] 03/21/25
Print Sign Date



Test Protocol – Comparison of Simulated Sample Capture of the Cook Medical
Tao Brush to the TechMed Ventures Utepreva


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Appendix 2: Simulated Tissue Capture Test Data Sheet (Utepreva)

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Appendix 2: Simulated Tissue Capture Test Data Sheet

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Device Name: Utepreva Endometrial Sampler Device Part Number: 027329 Rev: D

Lot Number: P009218 Sample Size: 22

EQ # / Gauge #: 11010 697 11034 Calibration Due Date(s): 03/16/25 07/29/25 08/19/25
(calipers) (scale) (temp. probe) EW 03/19/25

*water bath
EQ #1991
EW 03/19/25

Sample	Initial Brush Weight (g) lb	Final Brush Weight (g) lb	Comments
1	0.0056	0.0058	
2	0.0052	0.0054	
3	0.0054	0.0056	
4	0.0058	0.0060	
5	0.0052	0.0054	
6	0.0058	0.0058	N/A EW 03/19/25
7	0.0058	0.0062	
8	0.0054	0.0056	
9	0.0050	0.0056	
10	0.0056	0.0060	
11	0.0058	0.0060	
12	0.0054	0.0056	
13	0.0058	0.0058	
14	0.0060	0.0062	
15	0.0054	0.0056	

Line Clearance: Aimee Lopez err 03/19/25
 Print Sign Date

Testing Performed By: Elayna Williams Elayna Williams 03/19/25
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Reviewed By: Jonny Kuchs Jonny Kuchs 03/21/25
 Print Sign Date

Proprietary Information

Proprietary Information



Appendix 3: Statistical Analysis; Simulated Tissue Capture Test

Two-Sample T-Test and CI: Tissue Capture Utepreva Change in Weight, Tao Change in Weight

Method

μ_1 : population mean of Utepreva Change in Weight

μ_2 : population mean of Tao Change in Weight

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Utepreva Change in Weight	22	0.000227	0.000128	0.000027
Tao Change in Weight	22	0.000136	0.000114	0.000024

Estimation for Difference

Difference	95% CI for Difference
0.000091	(0.000017, 0.000165)

Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$

Alternative hypothesis $H_a: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
2.49	41	0.017



Appendix 4: Simulated Tissue Capture Test Images
Tao Brush





Utepreva

