FINAL STUDY REPORT

STUDY TITLE:	**Steam Sterilization Dry Time Validation - Reusable Device – 132°C, 4-minute Pre-Vacuum Cycle**
PROTOCOL NUMBER:	RCA082618STM.01
PRODUCT:	SteriBest® Instrument Trays
CLIENT:	RICA Surgical Products, Inc. 9207 Ivanhoe Street Schiller Park, IL 60176
PERFORMING LABORATORY:	WuXi AppTec, Inc. 1265 Kennestone Circle Marietta, GA 30066
FINAL REPORT NUMBER:	RCA082618STM.01F
RESULT SUMMARY:	**PASS**

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1.0 PURPOSE / SCOPE

The purpose of this study was to determine an effective dry time to be used in conjunction with the 4-minute, 132 °C, pre-vacuum steam sterilization cycle that is specified by RICA Surgical Products, Inc. for sterilization of the SteriBest® Instrument Trays in health care facilities. These reusable devices are manufactured by RICA Surgical Products, Inc. and are supplied non-sterile, without instruments, to the user.

2.0 CLIENT:

RICA Surgical Products, Inc. (RICA)
9207 Ivanhoe Street
Schiller Park, IL 60176

3.0 TEST FACILITY:

WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066

4.0 SCHEDULING

DATE SAMPLES RECEIVED:	April 17, 2018
PROTOCOL SIGNATURE COMPLETE:	August 30, 2018
STUDY INITIATION DATE:	September 06, 2018
STUDY COMPLETION DATE:	September 14, 2018

5.0 TEST ARTICLE IDENTIFICATION / TEST ARTICLE CHARACTERIZATION

The test articles were two (2) sets of six (6) different sizes of SteriBest® Instrument Trays, which were loaded with instruments by RICA to simulate usage of the trays in a clinical setting. One set of trays were individually packaged for sterilization by double wrapping in standard central supply. The other set of trays were individually placed in a single sterilization pouch. The six (6) sizes of the pre-loaded trays are listed in Table 1 and are shown in Figures 1 through 8.

Table 1: SteriBest® Instrument Trays

Tray #	Item Number	Dimensions	Contents (without instruments)	Qty.
1	CP614-SB	6.0 x 2.5 x 0.75 in	Base, Lid, Mat	2
2	CP778-SB	7.5 x 2.5 x 0.75 in	Base, Lid, Mat	2
3	CP634-SB	6.5 x 4.0 x 0.75 in	Base, Lid, Mat	2
4	CP471S-SB	7.5 x 4.0 x 0.75 in	Base, Lid, Mat	2
5	CP1038S-SB	10.0 x 6.0 x 0.75 in	Base, Lid, Mat	2
6	CP1038D2-SB	10.0 x 6.0 x 1.5 in	Base, Lid, Mat, Insert Tray, Insert Mat	2

Figure 1: Loaded SteriBest® Instrument Trays

Figure 2: Tray 1 (CP614-SB)

Figure 3: Tray 2 (CP778-SB)

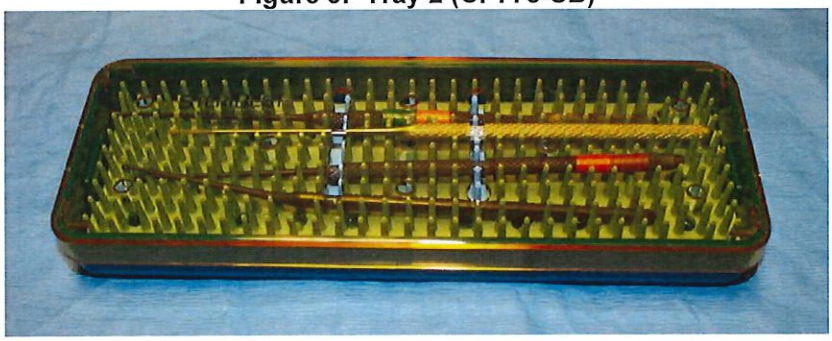

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Figure 4: Tray 3 (CP634-SB)

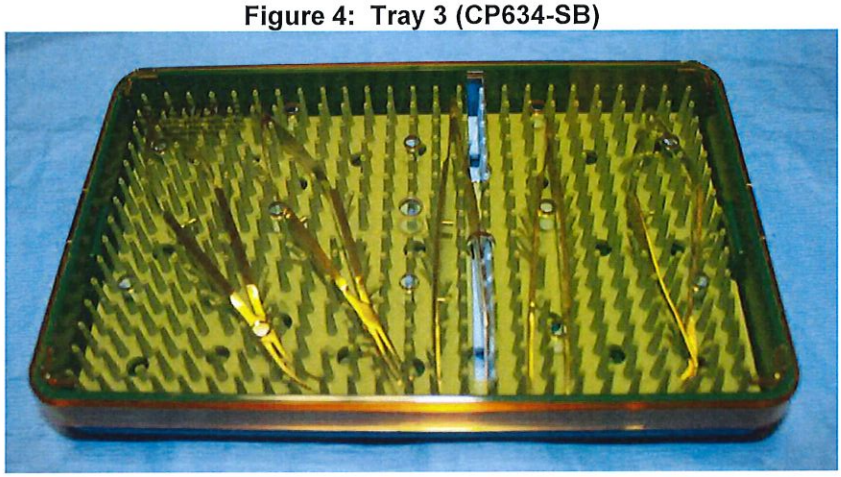


Figure 5: Tray 4 (CP471S-SB)

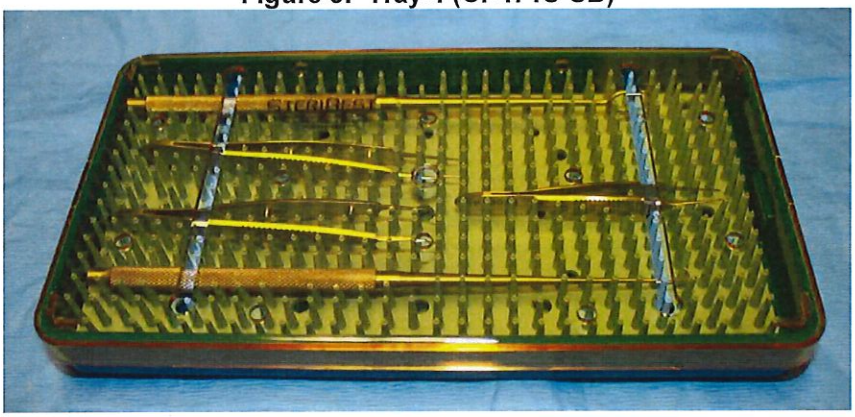


Figure 6: Tray 5 (CP1038S-SB)

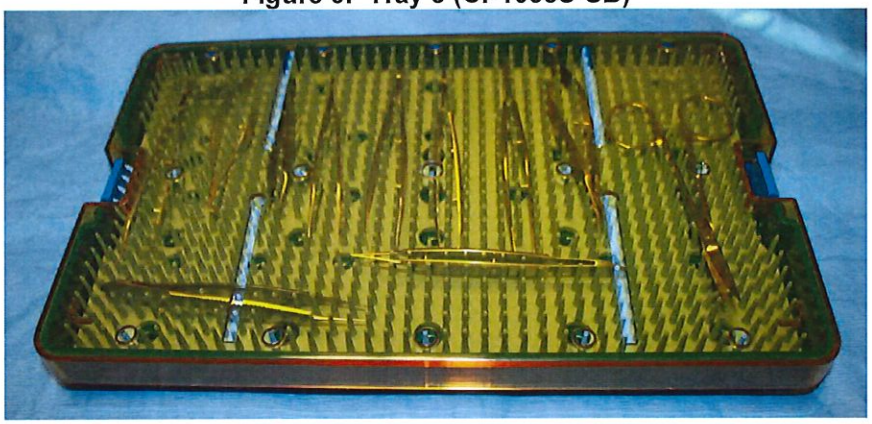


Figure 7: Tray 6 (CP1038D2-SB) – Top Level

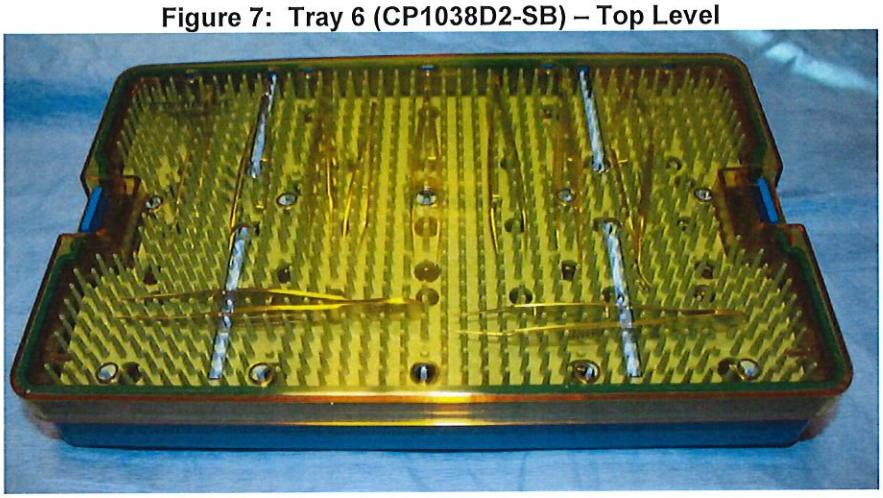
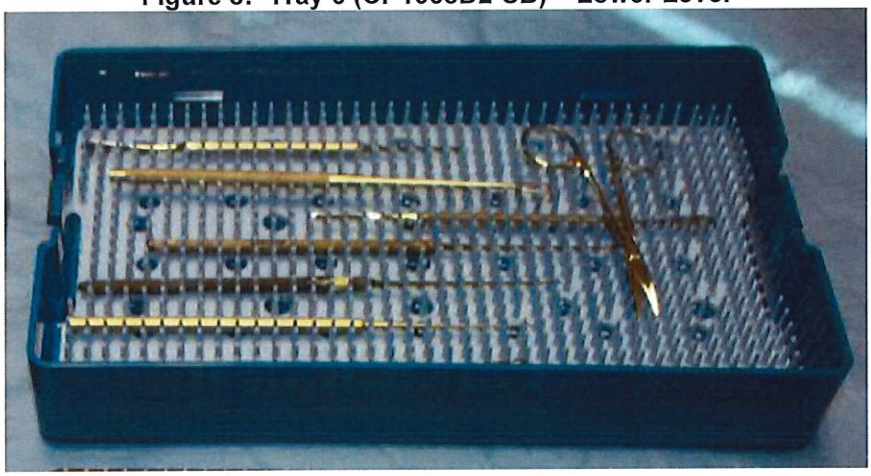


Figure 8: Tray 6 (CP1038D2-SB) – Lower Level



6.0 EXPERIMENTAL DESIGN

The dry time validation was based on the standard, full cycle steam sterilization cycle parameters as specified by RICA. At the conclusion of the sterilization cycle, the SteriBest® Instrument Trays were exposed to a specified dry time for the evaluation of the effectiveness of that time to remove all residual moisture from the trays as well as the packaging.

7.0 MATERIALS / EQUIPMENT

7.1 Processing

7.1.1 Packaging materials for steam sterilization were provided by WuXi AppTec, Inc.

7.1.1.1 Cardinal Health Convertors® Bio-Shield® Regular Sterilization Wrap, 40" x 40", Lot Number: 17KDDNA011

7.1.1.2 Propper STRATE-LINE® Autoclave Indicator Tape, ¾ in x 60 yd., Lot Number: 216507

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7.1.1.3 Fisherbrand Sterilization Pouch, 5 1/4" x 10", Lot Number: 2018-0212, Exp. Date: 2021-02-12

7.1.1.4 Cardinal Health Sterilization Pouch, 7.5" x 13", Lot Number: 170501-SS, Exp. Date: 2022-04-30

7.1.1.5 Fisherbrand Sterilization Pouch, 12" x 18", Lot Number: 2017-1121, Exp. Date: 2020-11-21

7.1.2 The steam sterilization cycles were conducted at WuXi AppTec, Inc. in a steam autoclave that is operated and calibrated following WuXi AppTec, Inc. SOPs.

7.1.2.1 Steris LAB 250 Autoclave (Chamber Dimensions: 20 x 20 x 38 inches), Serial # 0332809-19, Calibrated 02-20-18

Note: A Steris LAB 250 steam sterilizer was used for the cycle runs. The Steris LAB 250 sterilizer series are Century Steam Sterilizers modified to serve the life sciences industry. The Steris LAB 250 sterilizer provides the same time-proven, safe, reliable chamber and stand assembly as the Steris Century Steam Sterilizer offered to the healthcare and life sciences markets, while allowing more flexibility in cycle control.

7.1.3 The pre-sterilization and post-sterilization weights were determined at WuXi AppTec, Inc. using scales that are operated and calibrated following WuXi AppTec, Inc. SOPs.

7.1.3.1 OHAUS Washdown Checkweighing Scale Model CK30L55, ID # BAL0018, Calibrated 07-25-18

Note: An Ohaus Washdown Checkweighing Scale Model CK30L55 is used for determining the weight of large instrument trays and has an enhanced readability of five (5) grams.

7.1.3.2 Mettler Toledo PL303, ID # BAL0016, Calibrated 07-25-18

8.0 PROCEDURE

8.1. The pre-sterilization weights were determined as follows:

8.1.1 Prior to packaging for sterilization, the trays were weighed and that weight recorded.

8.1.2 The weight of the sterilization packaging used for each tray was determined separately and recorded.

8.1.3 The weights determined in 8.1.1 and 8.1.2 yielded the individual pre-sterilization weights for each tray and its respective packaging.

8.2 The trays were individually packaged and positioned in the autoclave as specified in Table 2. Photographs depicting the packaging and autoclave placement are in Figures 9 and 10 respectively. Both autoclave shelves were utilized to ensure that the packaged trays were not stacked or overlapped.

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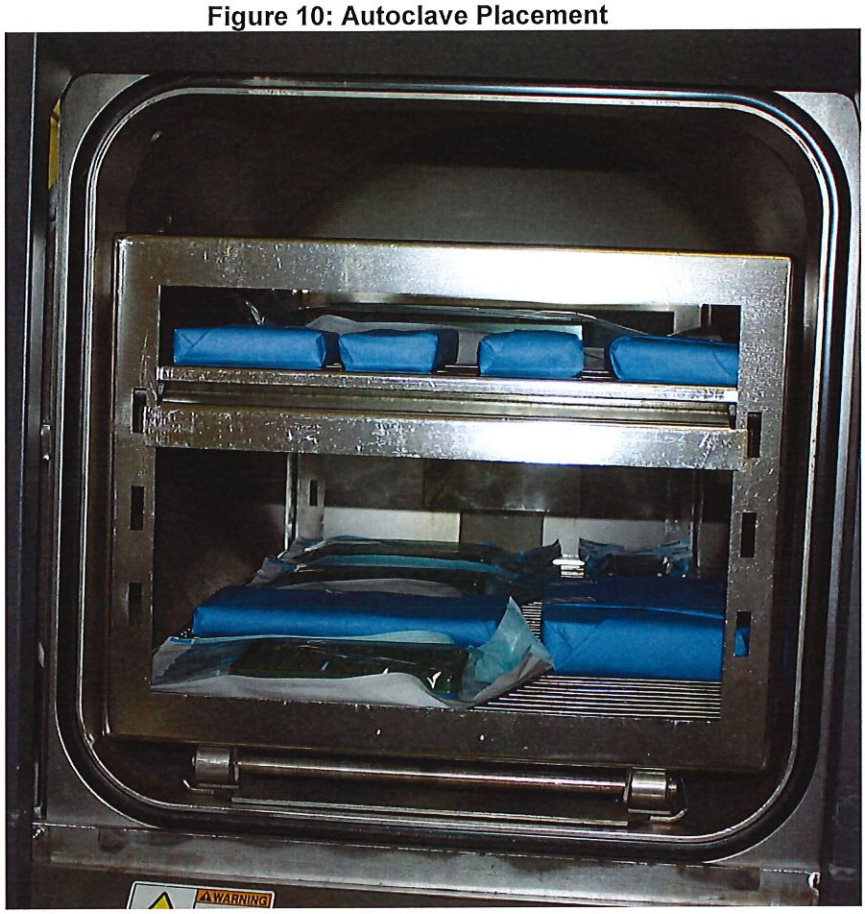
Table 2: Sample Requirements

Tray #	Item Number	Dimensions	Packaging	Autoclave Configuration
1	CP614-SB	6.0 x 2.5 x 0.75 in	Double Wrapped in standard central supply wrap	Lay Flat on Top Shelf of Autoclave
2	CP778-SB	7.5 x 2.5 x 0.75 in		Lay Flat on Top Shelf of Autoclave
3	CP634-SB	7.5 x 4.0 x 0.75 in		Lay Flat on Top Shelf of Autoclave
4	CP471S-SB	6.5 x 4.0 x 0.75 in		Lay Flat on Top Shelf of Autoclave
5	CP1038S-SB	10.0 x 6.0 x 0.75 in		Lay Flat on Bottom Shelf of Autoclave
6	CP1038D2-SB	10.0 x 6.0 x 1.5 in		Lay Flat on Bottom Shelf of Autoclave
7	CP614-SB	6.0 x 2.5 x 0.75 in	Placed in Single Sterilization Pouch	Lay Flat on Bottom Shelf of Autoclave
8	CP778-SB	7.5 x 2.5 x 0.75 in		Lay Flat on Bottom Shelf of Autoclave
9*	CP634-SB	7.5 x 4.0 x 0.75 in		Lay Flat on Bottom Shelf of Autoclave
10*	CP471S-SB	6.5 x 4.0 x 0.75 in		Lay Flat on Bottom Shelf of Autoclave
11*	CP1038S-SB	10.0 x 6.0 x 0.75 in		Lay Flat on Top Shelf of Autoclave
12*	CP1038D2-SB	10.0 x 6.0 x 1.5 in		Lay Flat on Top Shelf of Autoclave

* **Note**: See section 13.0 of this report for clarification.

Figure 9: Packaged Trays

Figure 10: Autoclave Placement



8.3 The autoclave cycle was initiated and the 4-minute timing for the full cycle began when the autoclave reached 132 °C. The temperature during the cycle was within + 3 °C.

8.4 When the 4-minute timing was complete, the selected dry time of 30 minutes began. The autoclave cycle parameters achieved are detailed in Table 3.

Table 3: Full Cycle Data

Parameter	Cycle 1	Cycle 2	Cycle 3
Temperature	132.0 – 133.9 °C	132.0 – 133.7 °C	132.0 – 133.6 °C
Dwell time	4 minutes	4 minutes	4 minutes
Dry Time	30 minutes	30 minutes	30 minutes
Status of cycle	Acceptable	Acceptable	Acceptable

8.5 Upon completion of the specified dry time, the trays were removed from the autoclave.

8.6 A visual inspection was performed for any wetness on the packaging or within the trays.

8.6.1 Each tray was carefully unwrapped from its respective packaging and the packaging was inspected.

8.6.1.1 Both layers of the sterilization wrap for each of the six (6) individual trays were inspected for moisture. No visible moisture was observed on either layer of the sterilization wrap.

8.6.1.2 The sterilization pouch for each of the six (6) individual trays were inspected for moisture. No visible moisture was observed on each of the sterilization pouch.

8.6.2 Each tray was individually inspected for visible moisture.

8.6.2.1 Each tray was lifted from its respective packaging and visibly inspected for residual moisture on the outside of the tray. No visible moisture was observed on the outside of the tray.

8.6.2.2 The lid was removed and the inside of the tray was visibly inspected for residual moisture. The silicone mat(s) was also removed and visibly inspected for moisture. No visible moisture was observed on the inside of the tray or on the silicone mat(s).

8.7 The post-sterilization weights were determined as follows:

8.7.1 The trays were individually unpackaged and weighed without the sterilization packaging and that weight was recorded.

8.7.2 The sterilization packaging used for each tray was weighed separately and recorded.

8.7.3 The individual weights determined in 8.7.1 and 8.7.2 yielded the post-sterilization weights for each tray and its respective packaging.

8.8 An initial dry time of 30 minutes was conducted which met the acceptance criteria as detailed in Section 12.0 of the protocol.

8.9 Steps 8.1 through 8.8 were repeated two additional times for a total of three cycles at the 30 minute dry time that was found to produce successful results. The pre-sterilization and post-sterilization weights are shown in Tables 4 and 5.

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Table 4: Sterilization Weight of the Trays – 30 Minute Dry Time

Cycle	Tray	Pre-sterilization Weight	Post sterilization Weight	Percent Difference in Weight
1	1	150 g	150 g	0.000 %
	2	195 g	195 g	0.000 %
	3	235 g	235 g	0.000 %
	4	280 g	280 g	0.000 %
	5	550 g	550 g	0.000 %
	6	995 g	995 g	0.000 %
	7	140 g	140 g	0.000 %
	8	195 g	195 g	0.000 %
	9	225 g	225 g	0.000 %
	10	265 g	265 g	0.000 %
	11	550 g	550 g	0.000 %
	12	985 g	985 g	0.000 %
2	1	150 g	150 g	0.000 %
	2	195 g	195 g	0.000 %
	3	235 g	235 g	0.000 %
	4	280 g	280 g	0.000 %
	5	550 g	550 g	0.000 %
	6	995 g	995 g	0.000 %
	7	140 g	140 g	0.000 %
	8	195 g	195 g	0.000 %
	9	225 g	225 g	0.000 %
	10	265 g	265 g	0.000 %
	11	550 g	550 g	0.000 %
	12	985 g	985 g	0.000 %
3	1	150 g	150 g	0.000 %
	2	195 g	195 g	0.000 %
	3	225 g	225 g	0.000 %
	4	265 g	265 g	0.000 %
	5	550 g	550 g	0.000 %
	6	985 g	985 g	0.000 %
	7	140 g	140 g	0.000 %
	8	195 g	195 g	0.000 %
	9	235 g	235 g	0.000 %
	10	280 g	280 g	0.000 %
	11	550 g	550 g	0.000 %
	12	995 g	995 g	0.000 %

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Table 5: Sterilization Weight of the Packaging – 30 Minute Dry Time

Cycle	Tray	Pre-sterilization Weight	Post sterilization Weight	Percent Difference in Weight
1	1	10.024 g	9.580 g	- 4.429 %
	2	7.453 g	7.119 g	- 4.481 %
	3	12.410 g	11.878 g	- 4.287 %
	4	14.491 g	13.845 g	- 4.458 %
	5	22.715 g	21.754 g	- 4.231 %
	6	34.131 g	32.805 g	- 3.885 %
	7	4.250 g	4.129 g	- 2.847 %
	8	7.855 g	7.649 g	- 2.623 %
	9	7.874 g	7.679 g	- 2.477 %
	10	7.825 g	7.617 g	- 2.658 %
	11	16.663 g	16.246 g	- 2.503 %
	12	16.675 g	16.261 g	- 2.483 %
2	1	8.871 g	8.471 g	- 4.509 %
	2	7.824 g	7.455 g	- 4.716 %
	3	12.505 g	11.934 g	- 4.566 %
	4	13.384 g	12.825 g	- 4.177 %
	5	25.061 g	23.996 g	- 4.250 %
	6	35.907 g	34.758 g	- 3.200 %
	7	4.211 g	4.116 g	- 2.256 %
	8	7.865 g	7.685 g	- 2.289 %
	9	7.829 g	7.644 g	- 2.363 %
	10	7.850 g	7.665 g	- 2.357 %
	11	16.567 g	16.227 g	- 2.052 %
	12	16.513 g	16.172 g	- 2.065 %
3	1	9.296 g	8.826 g	- 5.056 %
	2	7.761 g	7.361 g	- 5.154 %
	3	12.565 g	11.925 g	- 5.094 %
	4	14.213 g	13.469 g	- 5.235 %
	5	24.456 g	23.334 g	- 4.588 %
	6	34.700 g	33.240 g	- 4.207 %
	7	4.224 g	4.112 g	- 2.652 %
	8	7.779 g	7.584 g	- 2.507 %
	9	7.683 g	7.483 g	- 2.603 %
	10	7.742 g	7.554 g	- 2.428 %
	11	16.555 g	16.178 g	- 2.277 %
	12	16.535 g	16.129 g	- 2.455 %

8.10 An initial dry time of 30 minutes was conducted which met the acceptance criteria as detailed in section 12.0 of the protocol. No visible moisture was observed on each of the trays and its respective packaging. Based on these results, RICA Surgical Products elected to continue testing with a shorter drying time of 25 minutes for the SteriBest® trays as described in Section 11.8 of the study protocol.

8.11 The trays were allowed to completely dry. The trays were then re-weighed according to Section 8.1 of this report.

8.12 The trays were individually packaged with new packaging materials and positioned in the autoclave as specified in Table 2 of this report. Both autoclave shelves were utilized to ensure that the packaged trays were not stacked or overlapped.

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8.13 The autoclave cycle was initiated using the 4-minute full cycle and the 25-minute dry time. The full cycle began when the autoclave reached 132 °C. The temperature during the cycle was within + 3 °C.

8.14 When the 4-minute timing was complete, the 25-minute dry time began. The autoclave cycle parameters achieved are detailed in Table 6.

Table 6: Full Cycle Data

Parameter	Cycle 1	Cycle 2	Cycle 3
Temperature	132.0 – 133.7 °C	132.0 – 133.9 °C	132.0 – 133.6 °C
Dwell time	4 minutes	4 minutes	4 minutes
Dry Time	25 minutes	25 minutes	25 minutes
Status of cycle	Acceptable	Acceptable	Acceptable

8.15 Upon completion of the specified dry time, the trays were removed from the autoclave.

8.16 A visual inspection was performed for any wetness on the packaging or within the trays.

8.16.1 Each tray was carefully unwrapped from its respective packaging and the packaging was inspected.

8.16.1.1 Both layers of the sterilization wrap for each of the six (6) individual trays were inspected for moisture. No visible moisture was observed on either layer of the sterilization wrap.

8.16.1.2 The sterilization pouch for each of the six (6) individual trays were inspected for moisture. No visible moisture was observed on each of the sterilization pouch.

8.16.2 Each tray was individually inspected for visible moisture.

8.16.2.1 Each tray was lifted from its respective packaging and visibly inspected for residual moisture on the outside of the tray. No visible moisture was observed on the outside of the tray.

8.16.2.2 The lid was removed and the inside of the tray was visibly inspected for residual moisture. The silicone mat(s) was also removed and visibly inspected for moisture. No visible moisture was observed on the inside of the tray or on the silicone mat(s).

8.17 The post-sterilization weights were determined per Section 8.7 of this report.

8.18 Steps 8.11 through 8.17 were repeated two additional times for a total of three cycles at the 25 minute dry time that was found to produce successful results. The pre-sterilization and post-sterilization weights are shown in Tables 7 and 8.

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Table 7: Sterilization Weight of the Trays – 25 Minute Dry Time

Cycle	Tray	Pre-sterilization Weight	Post sterilization Weight	Percent Difference in Weight
1	1	150 g	150 g	0.000 %
	2	195 g	195 g	0.000 %
	3	235 g	235 g	0.000 %
	4	280 g	280 g	0.000 %
	5	550 g	550 g	0.000 %
	6	995 g	995 g	0.000 %
	7	140 g	140 g	0.000 %
	8	195 g	195 g	0.000 %
	9	230 g	225 g	- 2.174 %
	10	265 g	260 g	- 1.887 %
	11	550 g	550 g	0.000 %
	12	985 g	985 g	0.000 %
2	1	150 g	150 g	0.000 %
	2	195 g	195 g	0.000 %
	3	235 g	235 g	0.000 %
	4	275 g	275 g	0.000 %
	5	550 g	550 g	0.000 %
	6	995 g	995 g	0.000 %
	7	140 g	140 g	0.000 %
	8	195 g	195 g	0.000 %
	9	225 g	225 g	0.000 %
	10	265 g	260 g	- 1.887 %
	11	550 g	550 g	0.000 %
	12	985 g	985 g	0.000 %
3	1	150 g	150 g	0.000 %
	2	195 g	195 g	0.000 %
	3	235 g	235 g	0.000 %
	4	275 g	275 g	0.000 %
	5	550 g	550 g	0.000 %
	6	995 g	995 g	0.000 %
	7	140 g	140 g	0.000 %
	8	195 g	195 g	0.000 %
	9	225 g	225 g	0.000 %
	10	265 g	265 g	0.000 %
	11	550 g	550 g	0.000 %
	12	985 g	985 g	0.000 %

Table 8: Sterilization Weight of the Packaging – 25 Minute Dry Time

Cycle	Tray	Pre-sterilization Weight	Post sterilization Weight	Percent Difference in Weight
1	1	8.895 g	8.550 g	- 3.879 %
	2	8.656 g	8.257 g	- 4.610 %
	3	12.398 g	11.830 g	- 4.581 %
	4	13.644 g	13.017 g	- 4.595 %
	5	25.089 g	23.927 g	- 4.632 %
	6	28.160 g	26.999 g	- 4.123 %
	7	4.259 g	4.141 g	- 2.771 %
	8	7.879 g	7.668 g	- 2.678 %
	9	7.951 g	7.737 g	- 2.691 %
	10	7.864 g	7.645 g	- 2.785 %
	11	16.631 g	16.231 g	- 2.405 %
	12	16.643 g	16.223 g	- 2.524 %
2	1	9.947 g	9.524 g	- 4.253 %
	2	9.170 g	8.762 g	- 4.449 %
	3	12.859 g	12.246 g	- 4.767 %
	4	14.221 g	13.570 g	- 4.578 %
	5	23.669 g	22.606 g	- 4.491 %
	6	26.180 g	25.090 g	- 4.163 %
	7	4.226 g	4.115 g	- 2.627 %
	8	7.887 g	7.677 g	- 2.663 %
	9	7.833 g	7.631 g	- 2.579 %
	10	7.834 g	7.626 g	- 2.655 %
	11	16.612 g	16.208 g	- 2.432 %
	12	16.510 g	16.107 g	- 2.441 %
3	1	9.440 g	8.983 g	- 4.841 %
	2	8.808 g	8.375 g	- 4.916 %
	3	13.039 g	12.411 g	- 4.816 %
	4	14.213 g	13.495 g	- 5.052 %
	5	26.241 g	24.916 g	- 5.050 %
	6	27.512 g	26.299 g	- 4.409 %
	7	4.246 g	4.129 g	- 2.756 %
	8	7.791 g	7.575 g	- 2.772 %
	9	7.772 g	7.550 g	- 2.856 %
	10	7.774 g	7.545 g	- 2.946 %
	11	16.540 g	16.132 g	- 2.467 %
	12	16.535 g	16.122 g	- 2.498 %

9.0 RESULTS

9.1 This dry time validation was successful in determining effective dry times of 30 minutes and 25 minutes for the specified cycle parameters. All acceptance criteria as specified in Section 12.0 of the protocol were met during the course of this study, as shown in Tables 9 and 10. Reference Attachments A, B, C, D, E, and F for the individual cycle reports.

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Table 9: Acceptance Criteria – 30 Minute Drying Time

Acceptance criteria	Cycle 1	Cycle 2	Cycle 3
Autoclave data showing the appropriate dwell time at 132 °C (+3 °C) with the specified dry time for each full cycle	Criteria met	Criteria met	Criteria met
Confirmation of the absence of moisture for each tray and its respective packaging.	Criteria met	Criteria met	Criteria met
No more than a 3% increase in weight prior to and after sterilization for each tray	Criteria met	Criteria met	Criteria met
No more than a 3% increase in weight prior to and after sterilization for the packaging from each tray	Criteria met	Criteria met	Criteria met

Table 10: Acceptance Criteria – 25 Minute Drying Time

Acceptance criteria	Cycle 1	Cycle 2	Cycle 3
Autoclave data showing the appropriate dwell time at 132 °C (+3 °C) with the specified dry time for each full cycle	Criteria met	Criteria met	Criteria met
Confirmation of the absence of moisture for each tray and its respective packaging.	Criteria met	Criteria met	Criteria met
No more than a 3% increase in weight prior to and after sterilization for each tray	Criteria met	Criteria met	Criteria met
No more than a 3% increase in weight prior to and after sterilization for the packaging from each tray	Criteria met	Criteria met	Criteria met

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10.0 CONCLUSION

The results shown in Section 9.0 provide evidence that RICA Surgical Products, Inc.'s SteriBest® Trays can be completely dried using a 30-minute dry time and a 25-minute dry time when used in conjunction with the full cycle parameters shown in Table 11.

Table 11: Summary

	Cycle Parameters		
Cycle Type	**Sterilization Temperature**	**Sterilization Time – Full Cycle**	**Validated Dry Time**
Pre-vacuum	132 °C	4 minutes	30 minutes
Pre-vacuum	132 °C	4 minutes	25 minutes

11.0 LIST OF ATTACHMENTS

Attachment A Cycle 1 report – 30-minute dry time
Attachment B Cycle 2 report – 30-minute dry time
Attachment C Cycle 3 report – 30-minute dry time
Attachment D Cycle 1 report – 25-minute dry time
Attachment E Cycle 2 report – 25-minute dry time
Attachment F Cycle 3 report – 25-minute dry time

12.0 AMENDMENTS / DEVIATIONS

No amendments or deviations from the protocol were encountered during this study.

13.0 OBSERVATIONS/COMMENTS

13.1 Two (2) discrepancies were noted in Table 3 of the study protocol (RCA082618STM.01).

13.1.1 The item number listed for trays # 9 and # 10 are reversed. The item numbers for trays # 9 and #10 are CP634-SB and CP471S-SB respectively, as shown in Table 2, section 8.2 of this report.

13.1.2 Item numbers CP1038D2-SB and CP1038S-SB are listed as Tray numbers 11 and 12, respectively, in Table 3 of the study protocol. However, the study was executed with items numbers CP1038D2-SB and CP1038S-SB as Tray numbers 12 and 11, respectively, as shown in Table 2 of this final study report.

13.2 The discrepancies stated in 13.1 have no impact to the validity of this study.

14.0 RECORD RETENTION

An official copy of all documents associated with this study and the raw data pertinent to the study will be retained according to WuXi AppTec, Inc. standard operating procedures for archival.

15.0 INFORMATIVE REFERENCES

15.1 AAMI TIR 12: 2010, *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers* (AAMI TIR 12)

15.2 ANSI / AAMI ST 79: 2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (AAMI ST 79)

15.3 ISO 17665-1: 2006, *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* (ISO 17665-1: 2006)

15.4 Guidance for Industry and Food and Drug Administration Staff, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling (2017)

15.5 AAMI TLay FlatIR 39: 2009, *Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices*

15.6 USP / NF, I. S. Pharmacopia, current version (USP)

15.7 WuXi AppTec, Inc. SOP-00630, "*Performing Steam Sterilization Cycles*", current version

15.8 WuXi AppTec, Inc. SOP-00640, *"AMSCO Lab 250 and AMSCO Century SV-120 Sterilizer Operation"*, current version

15.9 WuXi AppTec, Inc. SOP-00569, *" Mettler Toledo Precision Balance Model PL303",* current version

15.10 WuXi AppTec, Inc. SOP-00573, *" Ohaus Washdown Checkweighing Scale, Model CK30L55",* current version

16.0 COMPLIANCE

The study was performed in accordance with applicable Good Manufacturing Practices.

17.0 TEST ARTICLE DISPOSITION

All test articles will be returned to the client after study completion unless otherwise requested by the Client.

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18.0 APPROVALS / SIGNATURES

WUXI APPTEC, INC.:

NAME: Michelle Eppes TITLE: Laboratory Coordinator

SIGNATURE: Michelle Eppes DATE: 10-09-18

NAME: Daniel Fowler TITLE: Principal Scientist

SIGNATURE: _____ DATE: _____

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