Northview Pacific Laboratories, Inc.

2800 Seventh Street □ Berkeley, California 94710 □ 415/548-8440

STERILIZATION VALIDATION STUDY

NVP REPORT NO. W4E011

June 20, 1984

Respectfully submitted:

Tom Spalding

Tom Spalding,
Operations Manager

Northview Pacific Laboratories, Inc.

2800 Seventh Street □ Berkeley, California 94710 □ 415/548-8440

REPORT OF STERILITY AUDIT

CLIENT:

NVP Report No: W4E011

DATE: 6-25-84

YOUR P.O. NUMBER: P4E005

CATALOGUE NUMBER: P4E007

LOT NUMBER:

STERILIZATION NUMBER:

DATE TESTED: 5-11-84

SAMPLE IDENTIFICATION:

Twenty-two Inoculated products plus eight spore strips (B. stearothermophilus)

TEST TYPE:

_X_ Product with Spore Strips

____ Product Only/Direct Inoculation

____ Inoculated Product

____ Product Only/Membrane Filtration

____ Other _____

RESULTS:

ITEM	NO. TESTED	MEDIA FTM	MEDIA SCDM	NO. DAYS INCUBATED	NO. CONTAMINATED FTM	NO. CONTAMINATED SCDM
Inoculated Product control	1		1	10		1/1
Spore strip control	1		1	10		1/1
Cycles 1 & 2	10		10	10		0/10
Cycles 3 & 4	10		10	10		0/10
Cycles 5 & 6	8		8	10		0/8

FTM – Fluid Thioglycollate Medium
SCDM – Soybean–Casein Digest Medium

____ These samples do not pass the test for sterility

_X_ These samples pass the test for sterility

It is the client's responsibility to have on file current test data indicating the bacteriostatic/fungistatic characteristics of the product.

PROCEDURE REFERENCE:

Test methods used on these samples are in accordance with USP XX guidelines and/or client procedures.

NORTHVIEW LABORATORIES, INC.

Maria A. Picchi

by: Maria A. Picchi
Microbiologist

F.D.A. Registration No. 29-14117

Northview Pacific Laboratories, Inc.

2800 Seventh Street □ Berkeley, California 94710 □ 415/548-8440

DATE: 6-25-84

N.V.P. Report Number: W4E011

Date Received: 5-11-84

Sample Identification:

One Sparco Instrument Tray
Twenty-two Surgical Forceps; Inoculated with 0.1 ml of a 10^6 suspension of B. stearothermophilis
Eight B. stearothermophilis spore strips (10^5/strip)

Tests Performed:

Sterilization Validation

Procedure:

The test was designed to challenge the sterilizability of surgical instruments submitted to flash autoclaving in the Sparco Instrument Tray. Twenty-two surgical forceps inoculated with 10^5 B. stearothermophilis organisms per sample plus eight B. stearothermophilis spore strips were used for the challenge. The autoclave was an Amsco Eagle series Flash Sterilizer. Autoclave cycles were run at 272° F for four minutes. One or two spore strips and three to four pairs of forceps were placed in the tray for each cycle. The top of the tray and the side steam vents were open during the cycle. When a cycle was completed, the samples were transferred to a sterile holding container to await culturing. A total of six cycles were run. Each was four minutes in duration. Samples from each successive pair of cycles were grouped together for purposes of culturing. Samples were cultured in Soybean Casein Digest Medium and incubated for ten days at 55° C.

Test Results:

See attached.

Conclusion:

Surgical instruments can be successfully sterilized in the Sparco Instrument Tray under the conditions described.

STERILIZATION
TECHNICAL
SERVICES, Inc.
7500 West Henrietta Rd. • P.O. Box 349 • Rush, New York 14543 • (716) 533-1672
Telefax: (716) 533-1796

STS Report No. M88-390

SPARCO, INCORPORATED

Evaluation of Reticulated Foam and Velcro Closure in 270°F Flash Sterilization

Prepared For:

Sparco, Incorporated
1930 Watson Way, Unit E
Vista, California 92083

Attention: Beverly Sparks

Prepared By:

Sterilization Technical Services, Inc.
7500 W. Henrietta Road
P.O. Box 349
Rush, New York 14543

Study Conducted By:

Anne E. Culp
Senior Microbiology Technician

Rita Collins
Technician, Sterility Testing

Study Approved By:

James Whitbourne
President

April 18, 1988

Sponsor: Sparco, Incorporated
1930 Watson Way, Unit E
Vista, California 92083

Test Facility: Sterilization Technical Services, Inc.
7500 W. Henrietta Road
Rush, New York 14543

Principal Investigator: Beverly Sparks

Study Director: James Whitbourne, President

Test Material: Reticulated Foam MGM-14 representations
Velcro Closures MGV-1
Sparco Flash Guard Container 2000L
S/S Flash Guard Basket 1800L

Materials: Gravity Displacement Steam Sterilizer, STS #8
Hemostats various sizes
Bacillus stearothermophilus suspension
Lot SC-16 (BI)
100 ml Difco Tryptic Soybean Casein Digest (TSB)
in appropriately sized sterile plastic bottles
7 ml TSB
Fluke datalogger and thermocouples
Tec Test Chemical Indicators (CI)
Laminar Flow Hood Classic

Procedure:

A. Inoculation and Preparation of Test Materials

0.1 ml of 10^6 spores/ml Bacillus stearothermophilus Lot SC-16, was inoculated onto each of six (6) hemostats at the scissor box lock (in the open position) and one (1) forcep at the closure (refer to Diagram I) and allowed to dry for 24 hours. Spore strips were inoculated and dried in the same manner and then packaged in glassine.

Three (3) hemostats in the open position were arranged such that two uninoculated ones were above and below one that had been inoculated. These three were wrapped with a 3" x 12" swatch of foam around the scissor opening and secured with 1.5" of Velcro. A BI was placed inside the foam but not touching the instruments. A 12" x 8" piece of foam which had one 2" slice made in each quadrant such

that an inoculated hemostat and an inoculated forcep could be secured within the foam was used. An inoculated spore strip was taped onto the foam.

The remaining inoculated hemostat was rolled in a 12" x 8" piece of foam along with a spore strip and chemical indicator and secured with a 2" piece of Velcro.

These were placed inside the container in the basket. The procedure was repeated and these same configurations were set outside the container.

B. **Thermocouple Profiles**

Thermocouples were located both inside and outside the container as follows:

1. Inside rolled 12" x 8" foam with Velcro closure - no instrument
2. Inside 3" x 12" rolled foam on hemostat opening
3. Inside the open foam
4. Sterilizer drain area - single TC only

The lid of the container was displaced 7" from the rear of the sterilizer and the purge valve (facing front) was opened. Additional BIs and CIs were adhered to the top inside of the lid and at the interior of the purge valve as a verification of steam penetration.

C. **Exposure**

The container was exposed to a gravity steam displacement cycle utilizing these paramaters:

Exposure Temperature	270°F -2, +5°F
Exposure Chamber Pressure	30-32 psig
Jacket Pressure	32-34 psig
Come up time	5 minutes max.
Exposure Interval	3 minutes
Exhaust	Fast (Instrument)

Immediately subsequent to the exposure phase, the lid was replaced, the purge valve closed, thermocouples removed and the container moved to the Laminar Flow Hood. The hemostats, forceps and spore strips were transferred to appropriate volumes of TSB. The bottles and tubes were incubated at 55°-57°C for 7 days. A positive was indicated by turbidity or sediment in the media while a negative remained clear.

Chemical indicators were visually examined to ascertain the degree of change and the temperature data has been presented in graphical form.

This process was repeated two more times for a total of three cycles.

Discussion:

This study of the foam material and the Velcro fasteners demonstrated that in the configuration used steam sterilization was successful. This configuration tested was found to permit sterilization when tested inside the Sparco Flash Guard container as well as separately not in a container.

Results:

Cycle	Location	Inoculated Instrument and Biological Indicators			Biological Indicators		Chemical Indicators		
		Hemostat in 3" swatch	Hemostat in rolled foam	Hemostat & Forcep in open foam	Under Lid	At Purge valve	Under Lid	At Purge valve	In Rolled Foam
1	Inside	0/1	0/1	0/2	0/1	0/1	0/1	0/1	0/1
	Outside	0/1	0/1	0/2					0/1
1	Inside	0/1	0/1	0/2	0/1	0/1	0/1	0/1	0/1
	Outside	0/1	0/1	0/2					0/1
3	Inside	0/1	0/1	0/2	0/1	0/1	0/1	0/1	0/1
	Outside	0/1	0/1	0/2					

*Inside Flash Guard Container
**Outside Flash Guard Container

Observations:

After repeated cycles, the foam:

1. Stretches out of shape
2. discolors
3. loses its resiliency

There was no visible change of the Velcro closure

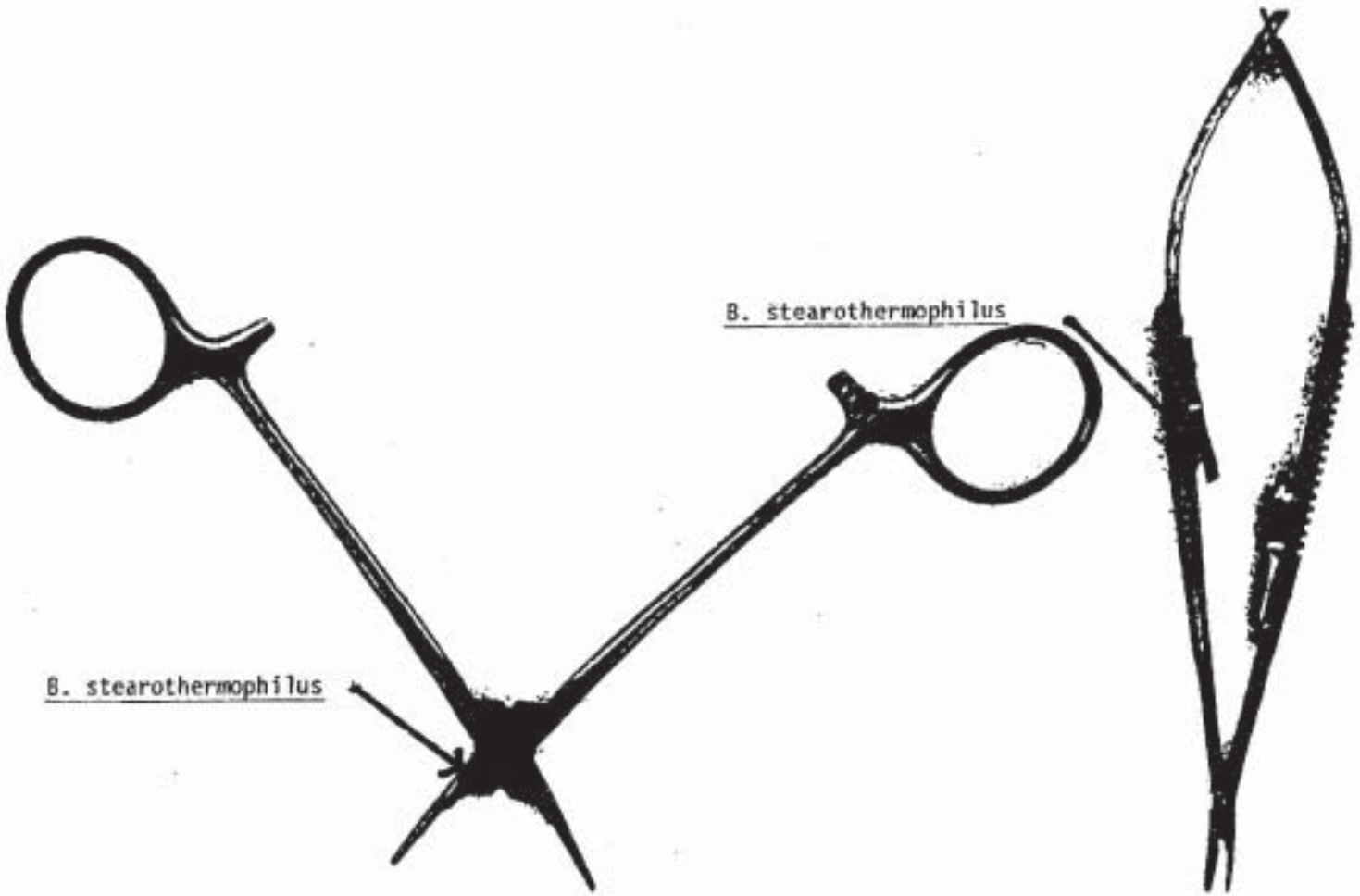
SPARCO, INCORPORATED

FLASH GUARD CONTAINER
REPEATED CYCLES OF 12"x8" ROLLED FOAM

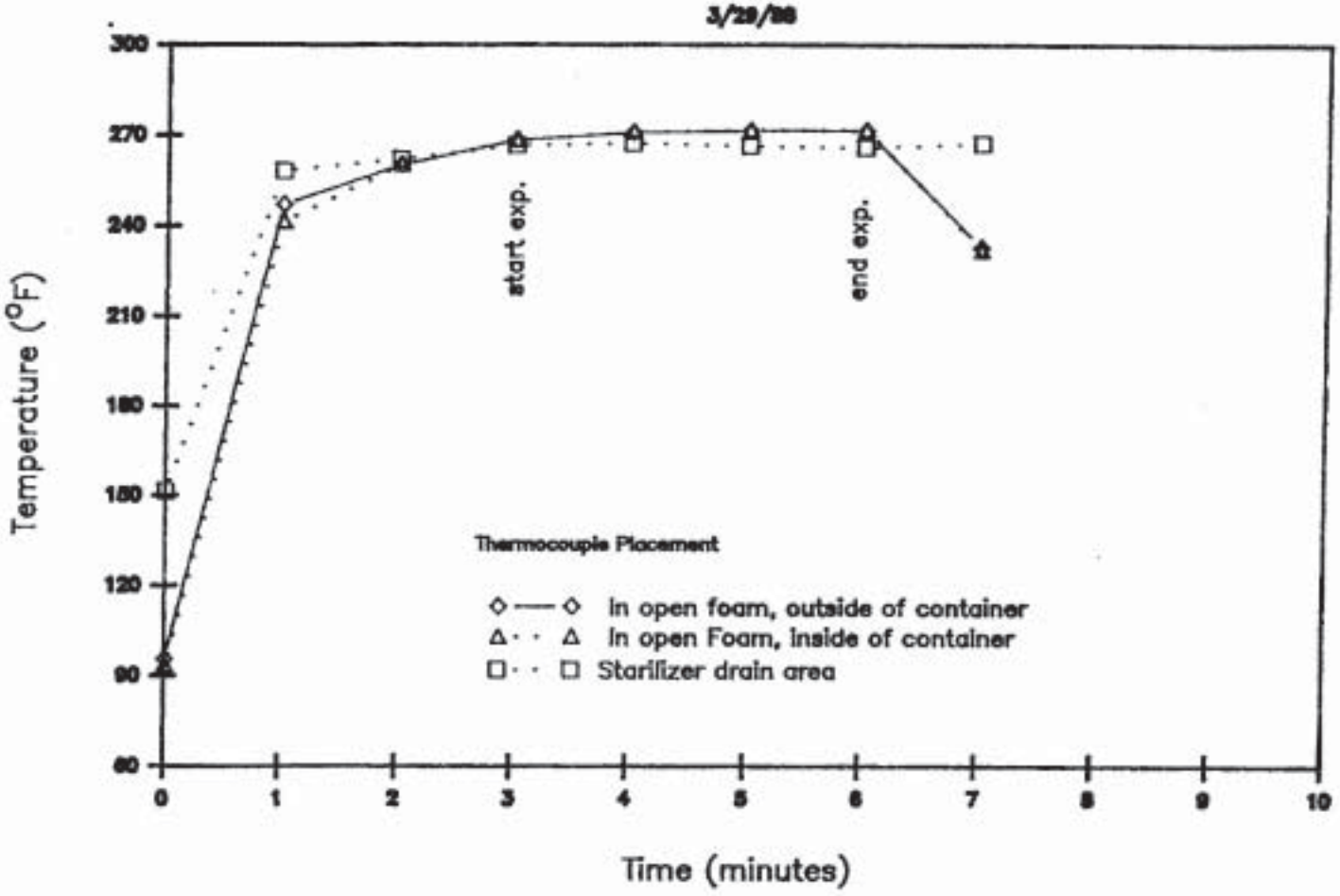
Position	Cycle No.	Sterigage	Tec Test
In Rolled Foam In Container	1	Past Accept	Complete
	2	Past Accept	Complete
	3	Past Accept	Complete
In Rolled Foam Outside Container	1	Complete	Complete
	2	Complete	Complete
	3	Complete	Complete
In Container Basket	1	Past Accept	Complete
	2	Past Accept	Complete
	3	Past Accept	Complete

DIAGRAM I

Product Inoculation



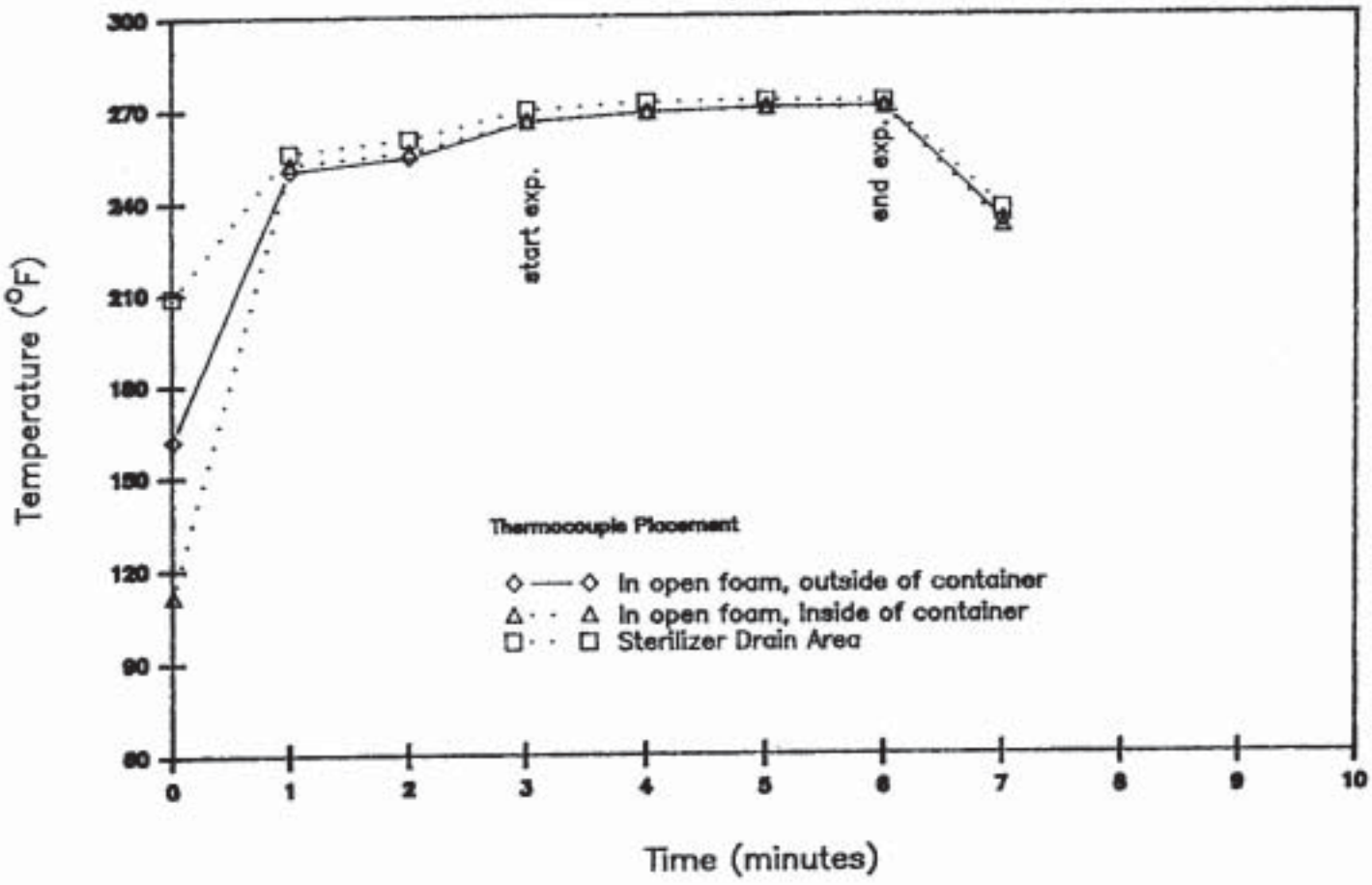
Sparco
Flash Guard Container and foam
3 min., 270°F Cycle 2
TC in open Foam
3/29/88



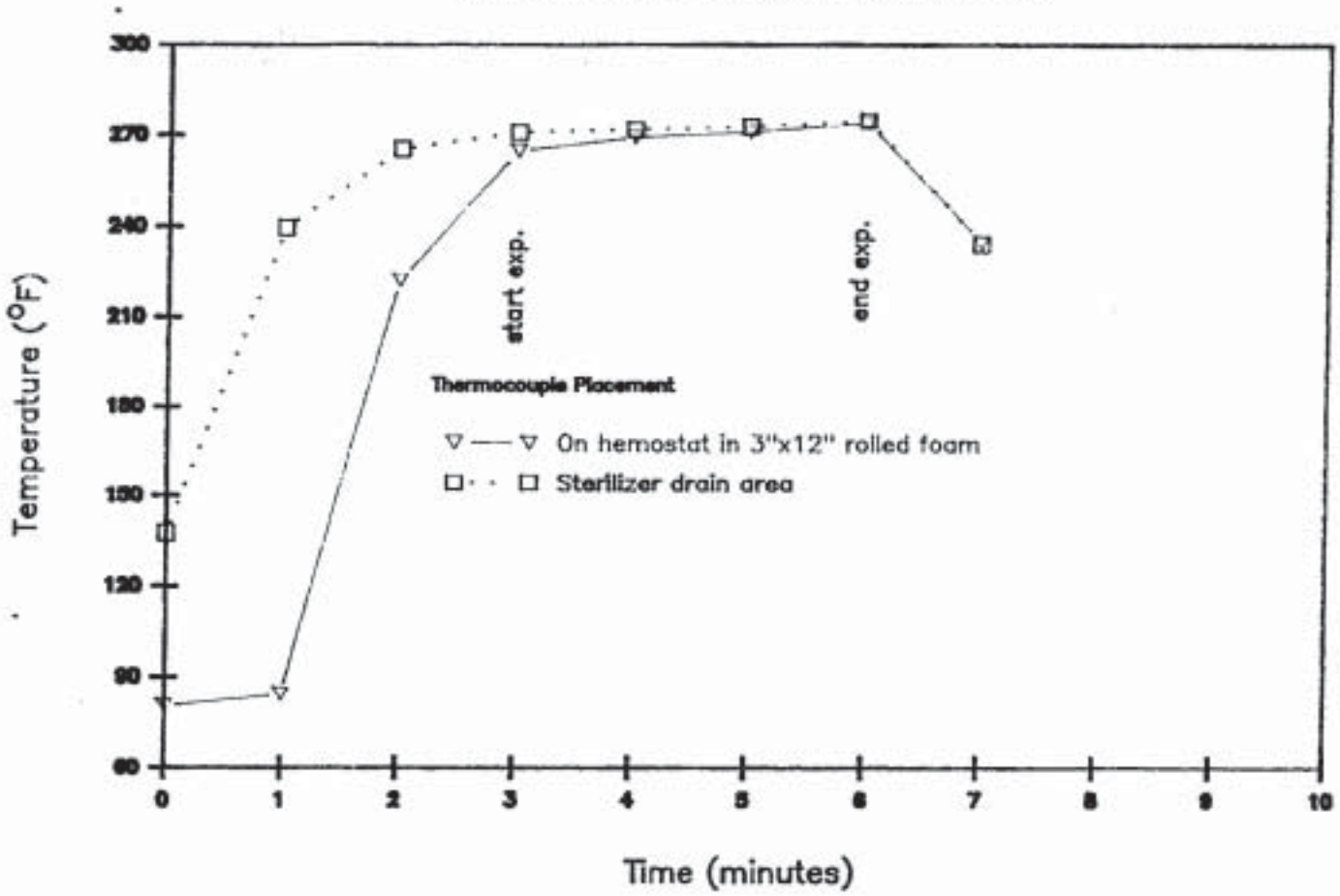
Sparco
Flash Guard Container
3 min., 270°F Cycle 1

TC in Open Foam

3/29/88



Sparco
Flash Guard Container
3 min., 270°F Cycle 3
TC on Hemostat in 3"x12" Rolled Foam



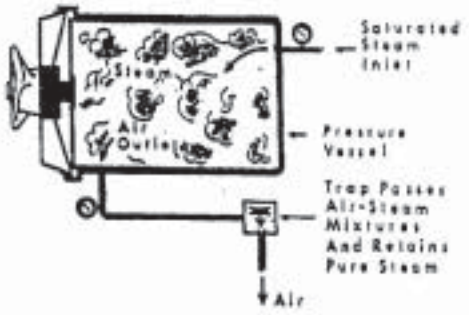
FLASH-GUARD STERILIZATION MONITORING

Air entrapment adversely effects steam sterilization. Unless steam is able to displace all of the air within the sterilizer, Flash-Guard and contents, the temperature will be cooler where air is present, with a high probability of sterilization failure.

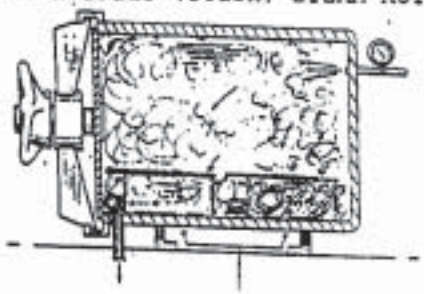
Gravity displacement high speed (flash) steam autoclaves rely upon the pressure of steam to displace all of the air down and out of sterilizer exhaust opening in the front bottom of the chamber. The trap passes air-steam mixtures and retains the pure steam, when working properly. If the trap malfunctions and closes prior to complete air evacuation, this situation is best identified by placing the integrator directly in close proximity to the sterilizer air outlet.

The Flash-Guard operates exactly in synchronization with the autoclave. If the sterilizer malfunctions and entraps air, the Flash-Guard will also. This is the reason for placing an integrator just inside of the Flash-Guard exhaust port to achieve the most valid test. If the integrator shows a cycle failure, the test indicates trapped air within the autoclave. This can be verified with placement of integrators in both the Flash-Guard and sterilizer exhausts. Both integrators indicating sterilization failure is diagnostic of retained air.

GRAVITY DISPLACEMENT HIGH SPEED (flash) STEAM AUTOCLAVE



GRAVITY DISPLACEMENT HIGH SPEED (flash) STEAM AUTOCLAVE WITH FLASH-GUARDS



Always have the Flash-Guard exhaust port open and facing the front of the sterilizer. The lid displaced forward to be even with the open exhaust door, as in the diagram. A sterilization integrator should be placed into the Flash-guard exhaust port, and read prior to removal of the Flash-Guard from the autoclave. It is highly recommended that the monitoring strip be placed on top of the Flash-Guard lid to provide sterilization process validation for the end user. Room member, case number, surgeon, time and date may be written on the back to assure confirmation of the appropriate destination.