U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K941507 - 303 pages
COMPANY:	SANESE MEDICAL CORP. (SANEMEDI)
PRODUCT:	LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES) (HET)
SUMMARY:	Product: THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC SYSTEM
DATE REQUESTED:	Oct 5, 2015
DATE PRINTED:	Oct 5, 2015
Note:	Printed

K941507

SECTION 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION FOR SMC'S THERMO-FLO SYSTEM 3 LAPAROSCOPIC/ HYSTEROSCOPIC IRRIGATION SYSTEM AND SANESE DISPOSABLE IRRIGATION/ASPIRATION PROBE AND TUBING

Pursuant to Section 12(a) of the Safe Medical Devices Act of 1990, 21 U.S.C. § 360c(i)(3)A and 21 C.F.R. § 807.92, the following summary of information concerning the safety and effectiveness of SMC's Thermo-Flo System 3 Laparoscopic/Hysteroscopic Irrigation System and Sanese Disposable Irrigation/Aspiration Probe and Tubing is hereby submitted.

1. Name and address of device manufacturer submitting 510(k) notification:

   Sanese Medical Corporation
   885 Northwest Boulevard
   Columbus, OH 43212
   (614) 291-8848

2. Regulatory correspondent.

   Christopher N. Sanese
   Sanese Medical Corporation
   885 Northwest Boulevard
   Columbus, OH 43212
   (614) 291-8848

3. Date summary was prepared: March 17, 1994

4. Names of Devices:

   (i) Proprietary Names:

   (a) Thermo-Flo System 3 Laparoscopic/ Hysteroscopic Irrigation System®
   (b) Sanese Disposable Irrigation/Aspiration Probe and Tubing™

   (ii) Common, usual names:

   (a) Laparoscopic irrigation pump system
   (b) Disposable aspiration/irrigation probe and tubing.

   (iii) Classification Names: Hysteroscope and Accessories and Gynecologic Laparoscope and Accessories, 21 C.F.R. §§ 880.1690 and 884.1720.

5. Predicate devices to which SMC is claiming substantial equivalence:

SMC claims substantial equivalence for purposes of section 510(k) only to:

A. Irrigation Pump System:

The Niagra™ High-Flow Irrigator System, 510(k) Number K924530 by Cabot Medical, 2021 Cabot Boulevard, West Langhorn, PA 19047 (800-523-6078).

B. Disposable Probe and Tubing:

(1) Probe:

Corson™ Disposable Suction Irrigation Probe by Cabot Medical, 2021 Cabot Boulevard, West Langhorn, PA 19047 (800-523-6078).

(2) Tubing:

Core Dynamics Inc. Disposable Irrigation/ Suction Tubing Set (510(k) Number K910246) by Core Dynamics, Inc., 9951 Atlantic Boulevard, Jacksonville, Florida 3225 (904-727-0910).

6. Description of the devices and primary principles of operation:

A. Description of irrigation pump system.

This device consists of a fabric enclosure (pressure envelope) in which a bag of irrigation fluid is placed. The fabric enclosure contains an inflatable bladder that is pneumatically inflated to pressurize the fluid in the irrigation fluid bag. Inflation of the bladder is provided by an air compressor which has a maximum voltage leakage current of 100 microamps. This complies with Underwriters Laboratory Standard 544.

The pressure envelope also contains a heating element to assist in maintaining the temperature of preheated irrigation solution while being used in the pressure envelope. There is also a thermal regulator to control the temperature of the heating element. The heating element and the thermal regulator are powered by an Underwriter Laboratory approved 24 volt electrical power supply.

The air compressor and heating element are controlled by a microcontroller. These components are controlled by the micro-controller through activating solid state switches which control electrical power to the pump, pump solenoids and the heater.

The pressurized preheated fluid is then introduced into the endoscopic surgery site through a medical grade plastic tube and probe that are discussed below.

B. Description of disposable probe and tubing:

The probe consists of a medical grade plastic, activation valve and metal shaft that will deliver and aspirate fluids to and from an operative site.

The tubing consists of two 15 foot length medical grade surgical tubing that are approximately 10 millimeters in diameter which would be connected to the probe and the irrigation solution bag and the pump when used for irrigation or to the probe and the suction unit when used for aspiration. The probe and tubing are made of medical grade plastic and metal that have been determined by FDA to be safe and effective for this intended usage.

C. Primary Principles of Operation:

(i) Irrigation Pump System:

The primary principles of operation are pressurization through an electrically powered pneumatic compressor for pressurized irrigation fluid flow and thermal transfer through an electrically-powered thermo-conducted heat transfer unit to maintain preheated fluid.

(ii) Probe and Tubing:

With respect to the aspiration/irrigation use of the probe and tubing, the principle operation is vacuum and pressurization.

7. Statement of the purpose for which the device will be recommended:

These devices are intended to be used for irrigation and aspiration during adult and pediatric hysteroscopic or laparoscopic (endoscopic) surgery.

8. Biocompatibility and effectiveness of the device:

(i) Biocompatibility:

The only aspect of the device that comes in contact with the patient is the distal end of the probe. The probe and the probe tubing have been subject to biocompatibility tests and are safe and effective for such usage. The irrigation pump has a maximum voltage

leakage current of 100 microamps in accordance with U.L. Standard 544. Performance tests of the pump demonstrate that it is safe and effective for its intended use. Also, all components of the pump meet U.L. Standards.

Respectfully submitted,

Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
(614) 291-8848

K941507/A3

RECEIVED ADD TO FILE

7 MAR 95 11 42

FDA/CDRH/ODE/DMC

SANESE MEDICAL®
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

March 3, 1995

Ms. Donna-Bea Tillman
FDA
9200 Corporate Boulevard
Rockville, Maryland 20850

RE:K941507 / A
Thermo-flo System 3
Dated: July 5, 1994
Received: July 6, 1994

VIA FAX & FEDEX
301-594-2339

Dear Donna,

Per our telephone conversation of today, I am forwarding the revised draft labeling you requested.

Thank you for your time and consideration.

Sincerely,

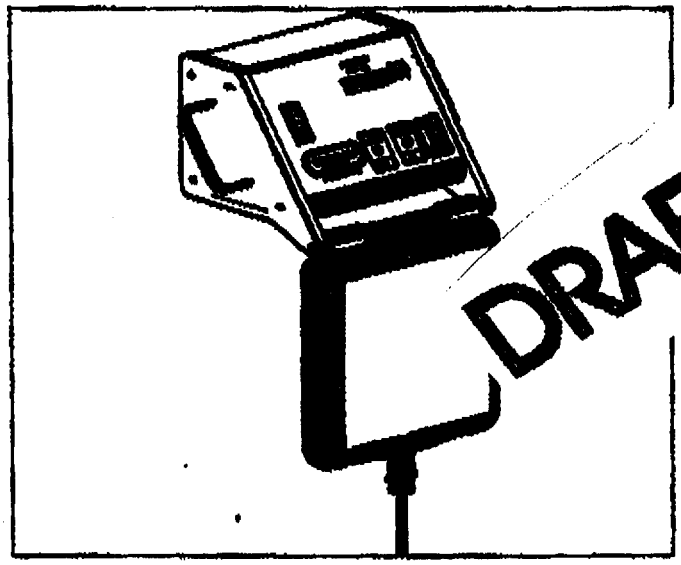
Christopher N. Sanese
Regulatory Corespondent
SANESE MEDICAL CORPORATION

ENC: 1
cs/CNS

cc: John Jevicky, Esq.
DINSMORE & SHOHL

THERMO-FLO
SYSTEM 3

OPERATION MANUAL



INDICATION FOR USE: INDICATED FOR IRRIGATION DURING LAPAROSCOPIC PROCEDURES.

CONTRA INDICATIONS: WHERE LAPAROSCOPIC SURGERY IS CONTRA INDICATED.

FEDERAL (USA) LAW restricts this device to sale by, or on the order of a physician. Recommended for Laparoscopic Irrigation in adult and pediatric surgery.

THIS PRODUCT TO BE USED FOR LAPAROSCOPIC IRRIGATION. DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

SANESE MEDICAL
CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 1995

Mr. Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, Ohio 43212

Re: K941507/B
Thermo-Flo System 3
Laparoscopic/Hysteroscopic
Irrigation System®
Sanese Disposable
Irrigation/Aspiration Probe
and Tubing™
Dated: January 13, 1995
Received: January 17, 1995
Regulatory class: II
21 CFR §884.1720/Procode: 85 HET

Dear Mr. Sanese:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

7a 1/24/95RR

510(K) ROUTE SLIP

510(k) NUMBER K941507 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC SYSTEM

COMMON NAME LAPAROSCOPIC IRRIGATION PUMP SYSTEM

PRODUCT CODE ___

APPLICANT SANESE MEDICAL CORPORATION
SHORT NAME SANEMEDI
CONTACT CHRISTOPHER N SANESE
DIVISION
ADDRESS 885 NORTHWEST BLVD.
COLUMBUS, OH 43212
PHONE NO. (614) 291-8848 FAX NO. (___) ___-____

MANUFACTURER SANESE MEDICAL CORPORATION REGISTRATION NO.

DATE ON SUBMISSION 16-MAR-94 DATE DUE TO 510(K) STAFF 12-JUN-94

DATE RECEIVED IN ODE 29-MAR-94 DATE DECISION DUE 27-JUN-94

DECISION ___ DECISION DATE MAR - 6 1995

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S002	13-JAN-95	17-JAN-95	02-APR-95	17-APR-95	
S001	05-JUL-94	06-JUL-94	19-SEP-94	04-OCT-94	17-NOV-94

CORRESPONDENCE	SENT	DUE BACK	
C001	06-JUN-94	06-JUL-94	HOLD LETTER
C002	17-NOV-94	17-FEB-95	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	10-AUG-94	15-AUG-94			
ADD-TO-FILE	15-OCT-94	19-OCT-94			

Date March 3, 1995

Memorandum

From REVIEWER(S) - NAME(S) Donna-Bea Tillman

Subject 510(k) NOTIFICATION K941507/S2

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

X (A) Is substantially equivalent to marketed devices.

___ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

___ (C) Requires more data.

___ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☒ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

___ No Confidentiality

X Confidentiality for 90 days

___ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:
85 HET Class II
884.1720

Additional Product Code(s) w/Panel (optional):

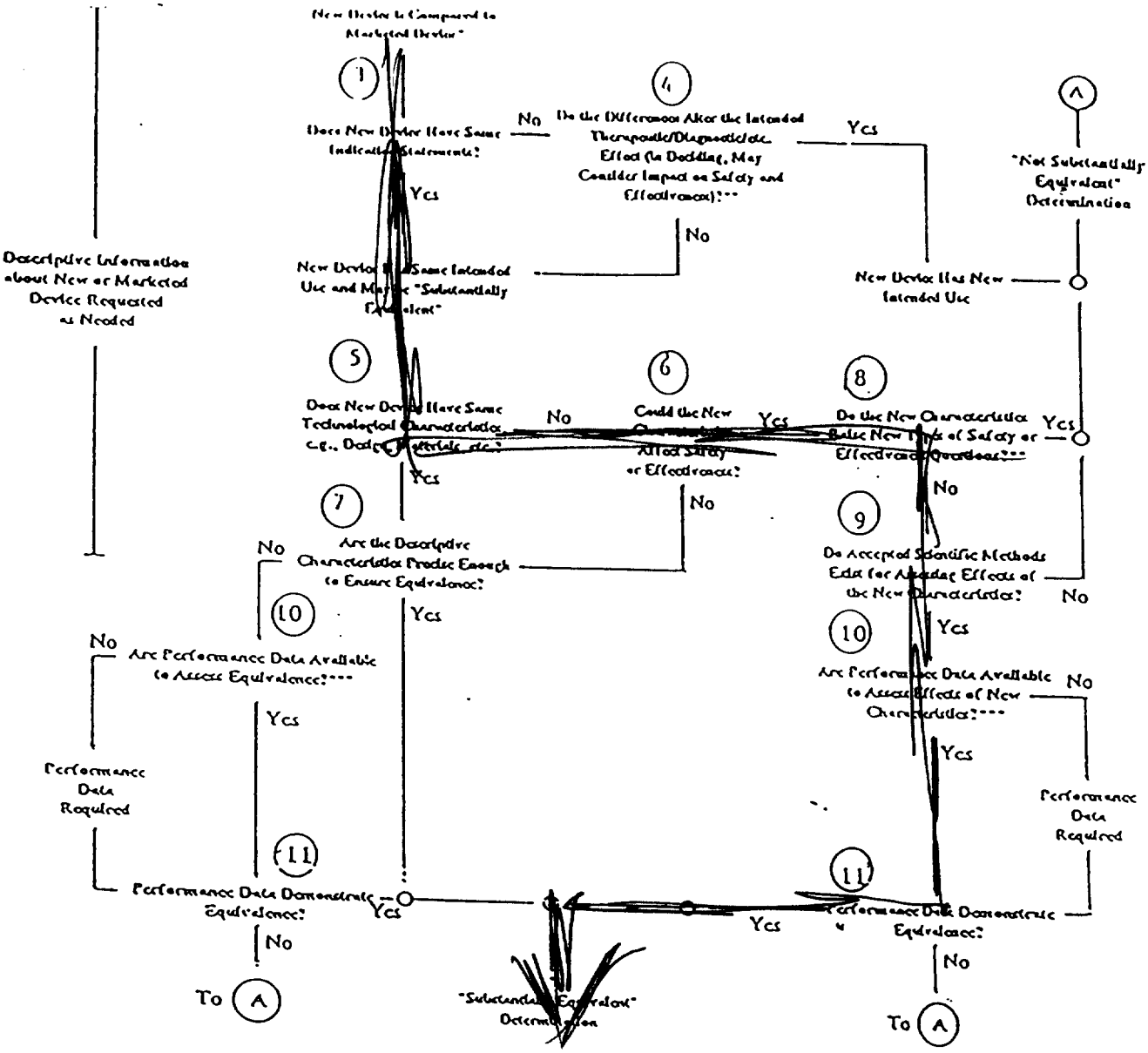
REVIEW: Colin M. Pollard (BRANCH CHIEF) 06DB (BRANCH CODE) 3/6/95 (DATE)

FINAL REVIEW: R. Scott Young for L. Lin (DIVISION DIRECTOR) 3/6/95 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)'s, the Center's classification files, or the literature.

OGDB

K941507/B

Reviewer: *Donna-Bea Tillman*
Biomedical Engineer

Division/Branch: DRAERD/ADOU/OGDB (HFZ-470)

Proprietary Trade Name: Thermo-Flow System 3
Common Name: Laparoscopic Irrigation and Aspiration

Product to which compared: Cabot Niagara High-Flow Irrigator (K924530)

Applicant: Sanese Medical Corporation
885 Northwest Blvd
Columbus, OH 43212

Contact: Christopher N. Sanese, Regulatory Correspondent
Phone: (614) 291-8848

DEVICE DESCRIPTION

1. *Intended Use:*

The Thermo-Flow System 3 is intended for irrigation/aspiration during laparoscopic surgery (Note: In a October 15, 1994, amendment, the firm withdrew its claims for hysteroscopy).

2. *Physical Description:*

	YES	NO
• Is the device life-supporting or life sustaining?	_	X
• Is the device implanted (short-term or long-term)?	_	X
• Does the device design use software?	X	_
• Is the device sterile?	_	X
• Is the device single use?	_	X
• Is the device home use?	_	X
• Is the device for prescription?	X	_
• Does the device contain a drug or biological product as a component?	_	X
• Is this device a kit?	_	X

(b)(4) Trade Secret Process - Product Specifications

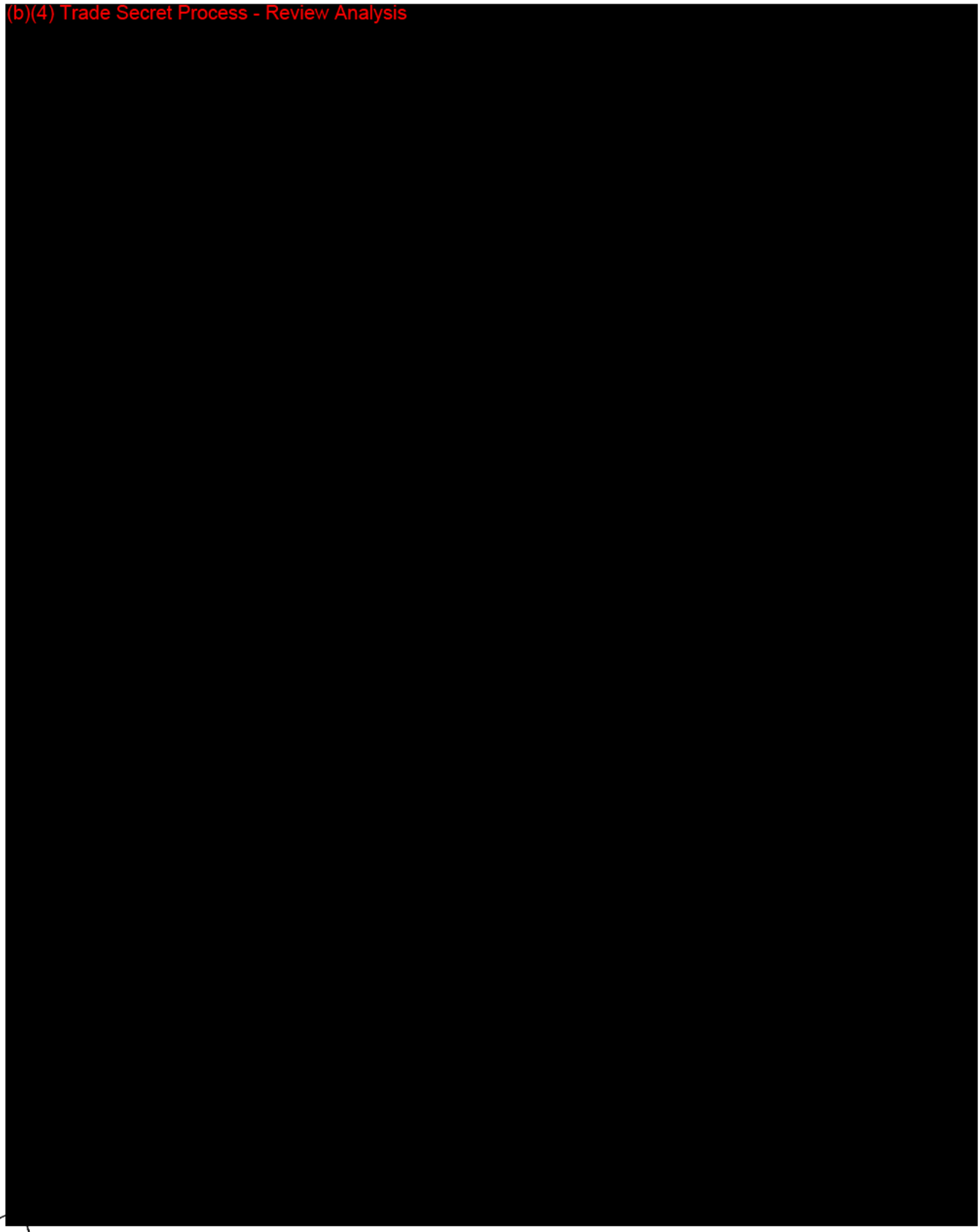
[redacted]

REVIEW ANALYSIS

(b)(4) Trade Secret Process - Review Analysis

[redacted]

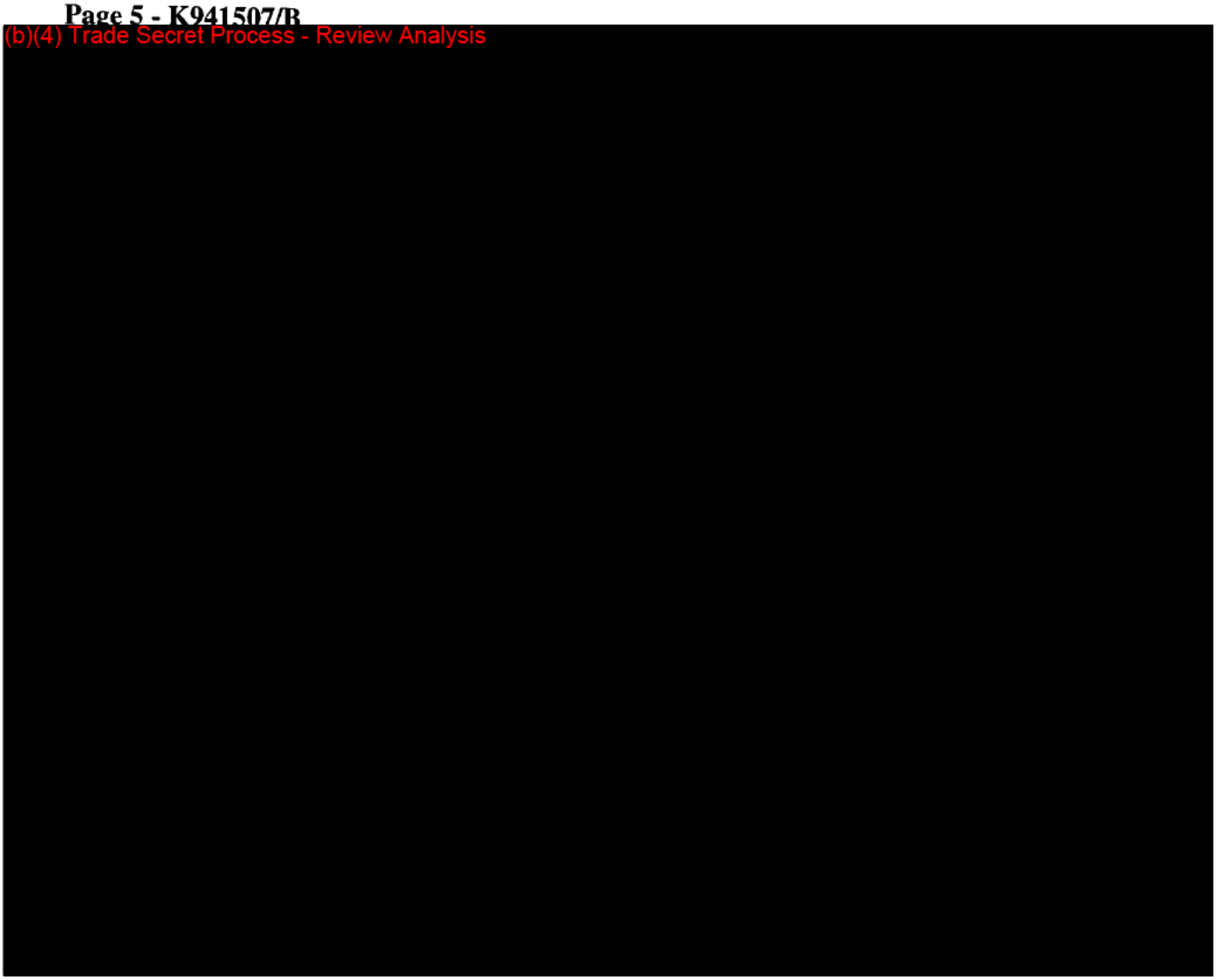
(b)(4) Trade Secret Process - Review Analysis



(b)(4) Trade Secret Process - Review Analysis

[redacted]

(b)(4) Trade Secret Process - Review Analysis



Substantial Equivalence (SE) Decision Making Documentation

		YES	NO	
1.	IS PRODUCT A DEVICE?	X	_	IF NO, STOP
2.	DEVICE SUBJECT TO 510(k)?	X	_	IF NO, STOP
3.	SAME INDICATION STATEMENT?	X	_	IF YES, GOTO 5
4.	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	_	_	IF YES,STOP->NSE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	_	X	IF YES, GOTO 7
6.	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	_	_	IF YES, GOTO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	_	X	IF YES, STOP->SE
8.	NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS?	_	X	IF YES, STOP->NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?	X	_	IF NO,STOP->NSE
10.	PERFORMANCE DATA AVAILABLE?	X	_	IF NO,REQ. DATA
11.	**DATA DEMONSTRATE EQUIVALENCE**	_	X	**IF YES, STOP->SE**

REVIEWER RECOMMENDATION

Substantially Equivalent

ProCode: 85 HET
Class: II
CFR #: 21 CFR §884.1720

Donna-Bea Tillman, Ph.D — 3/3/95 — Date

Concur

Colin M. Pollard — 3/6/95

Colin M. Pollard
Chief, Ob/Gyn Devices Branch — Date

/ ✓ Concur
/ / Do not concur.

Comments:

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SANESE MEDICAL®
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

DATE:March 3, 1995
TO: Ms. Donna-Bea Tillman
FIRM: FDA
TELECOPIER NO: 301-594-2339
FROM: Christopher N. Sanese

NO. OF PAGES (INCLUDING COVER SHEET) TRANSMITTED: X 3

IF THERE ARE ANY PROBLEMS IN RECEIVING THIS TRANSMISSION, PLEASE CALL (614)291-8848 IMMEDIATELY

THANK YOU,
TELECOPIER OPERATOR

SENT BY:_____
TIME SENT:_____
COMPLETED & LOGGED
NOTES & COMMENTS:

_____ *No original documents will follow unless requested*
_____ *Original document will follow by courier*
_____ *Original documents will follow by mail*

883 NORTHWEST BLVD., COLUMBUS, OHIO 43212 / (614) 291-0040 / FAX (614) 291-1389 / 800-873-7585

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SANESE MEDICAL®
CORPORATION
MANUFACTURER OF MEDICAL PRODUCTS

March 3, 1995

Ms. Donna-Bea Tillman
FDA
9200 Corporate Boulevard
Rockville, Maryland 20850

RE:K941507 / A
Thermo-flo System 3
Dated: July 5, 1994
Received: July 6, 1994

VIA FAX & FEDEX
301-594-2339

Dear Donna,

Per our telephone conversation of today, I am forwarding the revised draft labeling you requested.

Thank you for your time and consideration.

Sincerely,

Christopher N. Sanese
Regulatory Correspondent
SANESE MEDICAL CORPORATION

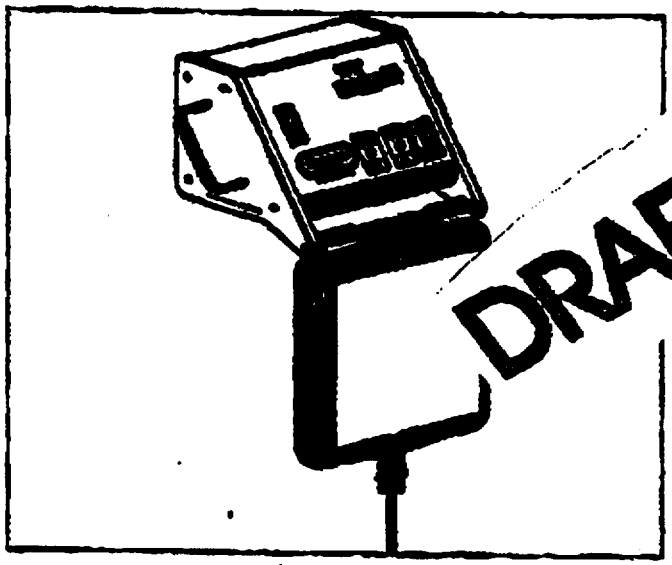
ENC: 1
cs/CNS

cc: John Jevicky, Esq.
DINSMORE & SHOHL

13

THERMO-FLO
SYSTEM 3

OPERATION MANUAL



INDICATION FOR USE: INDICATED FOR IRRIGATION DURING LAPAROSCOPIC PROCEDURES.

CONTRA INDICATIONS: WHERE LAPAROSCOPIC SURGERY IS CONTRA INDICATED.

FEDERAL (USA) LAW restricts this device to sale by, or on the order of a physician. Recommended for Laparoscopic irrigation in adult and pediatric surgery.

THIS PRODUCT TO BE USED FOR LAPAROSCOPIC IRRIGATION. DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

SANESE MEDICAL
CORPORATION

SANESE MEDICAL®
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

March 2, 1995

Ms. Donna-Bea Tillman
FDA
9200 Corporate Boulevard
Rockville, Maryland 20850

RE:K941507 / A
Thermo-flo System 3
Dated: July 5, 1994
Received: July 6

VIA FAX & FEDEX

301-594-2339

Dear Donna,

Per our telephone conversation of February 24, 1995 I am forwarding the draft labeling copy you requested; A) Operators Manual B) Reusable probe label.

Thank you for your time and consideration.
Sincerely,

Christopher N. Sanese
Regulatory Corespondent
SANESE MEDICAL CORPORATION

ENC: 9
cs/CNS

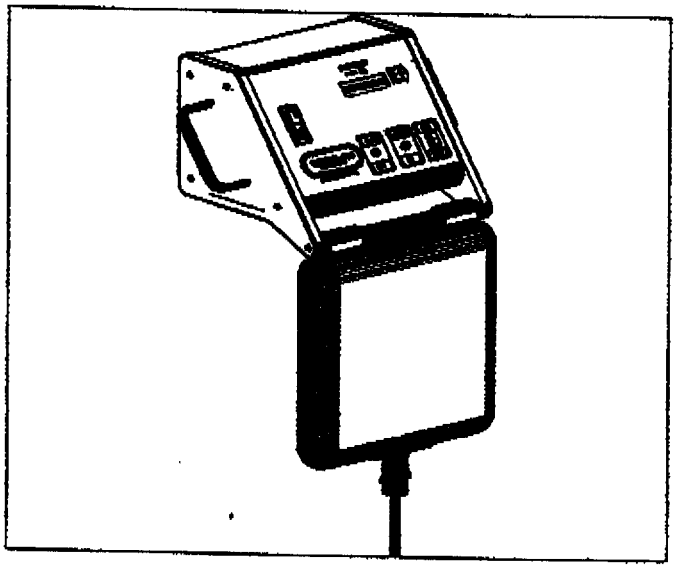
cc: John Jevicky, Esq.
DINSMORE & SHOHL

15

883 NORTHWEST BLVD., COLUMBUS, OHIO 43212 / (614) 291-8848 / FAX (614) 291-1389 / 800-873-7585

THERMO-FLO
SYSTEM 3

OPERATION MANUAL



DRAFT COPY

SANESE MEDICAL
CORPORATION

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THERMO-FLO
SYSTEMS

TABLE OF CONTENTS

SANESE MEDICAL
CORPORATION

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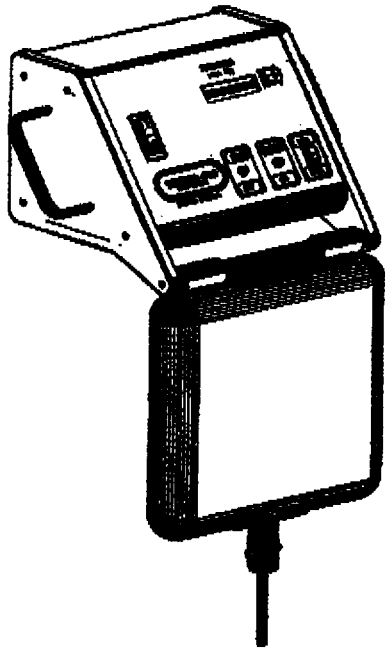
1.0 Product Description

The Thermo-Flo System 3 was developed to eliminate the major problems faced everyday by the surgeons and O.R. unit Mangers. These are cross contamination, inadvertent patient hypothermia, inadequate irrigation solution capacity , ease of set up, tube sets and disposable probes that leak, noise and physical space. Sanese Medical answers these problems with the Thermo-Flo System 3.



1) CROSS CONTAMINATION occurs when non sterile fluid enters the patient's abdominal cavity through the irrigation line. The Thermo - Flo System 3 eliminates cross contamination.

2) INADVERTENT PATIENT HYPOTHERMIA is the result of the combination of gas and fluids ranging in temperature from 65 to 72 degrees fahrenheit being introduced into the patient. The Thermo - Flo System can maintain the solution temperature at 100 degrees fahrenheit Though this system alone cannot prevent hypothermia, it will dramatically effect the reduction of the core temperature due to existing conditions of surgery.

3) SOLUTION CAPACITY / EASE OF SET UP
The Thermo - Flo System 3 meets the liter needs of the oday's and tomorrow's laparoscopic procedures. This amount provides less disruption of the procedure, by not replacing the solution , cap and tube inserts that promotes the inadvertent contamination by the person replacing the solution as often.

KEY ADVANTAGES OF THE THERMOL-FO SYSTEM 3
* Delivers a strong stream of irrigation fluid
*No capital equipment necessary
*Choice of disposable of reuseable probe
*Simplified O.R. set up / I.V.
*Avoids Equipment purchase
*Quite operation
*24 hour , 7 days a week service available

THERMO-FLOW SYSTEM 3 PRODUCT LINE

1) The Thermo-Flo System 3 Irrigation Pump.....TFS3 one per case

2) TFS3-3WP Tube Set with Dispoable Probe.....TFS3-3WP one per case

3) TFS3-3WOP Tube Set with out Probe .....TFS3-3WOP one per case

4) TFS3-N-3WP Tube Set with Disposable Probe.....TFS3-N-3WP 10 per case

5) TFS3-n-3WP Tube set with out Probe.....TFS3-N-3WOP 10 per case

6) TFS3- 3RPR Reusable Probe Set .....TFS3-N-3RPR one per case

All tube sets are 15' in length .

SANESE MEDICAL
CORPORATION

2.0 SAFETY

2.1 SYMBOL EXPLANATIONS

READ THE OPERATIONS MANUAL BEFORE OPERATING THIS UNIT.
FOR SALE BY, OR ON THE ORDER OF A HEALTH CARE PROFESSIONAL.

THIS UNIT CAN NOT BE OPERATED IN THE PRESENCE
OF AN EXPLOSIVE ANAESTHETIC MIXTURE WITH AIR, OXYGEN
OR NITROUS OXIDE.

Only qualified personnel should perform repair to this unit.
This unit requires a power input of - 110 VAC 60 HZ 1.0 AMP
This device is equipped with a "Hospital Grade" plug. Grounding
reliability can only be achieved when the equipment is connected
to an equivalent receptacle marked " Hospital Only" or "Hospital Grade".

2.2 SAFETY PRECAUTIONS

Use only with TFS 3 irrigation tube sets. These sets are equipped with
lock and pierce components for the safe operation of the device. Never
use parts from another manufacturer's unit even though they appear to fit.

Never service device while it is plugged into an outlet.

Never service device near water.

This device is designed to be operated from a power
indicated on the marking label.

Do not overload wall outlets or use extension cords.

Do not allow anything to rest on the power cord or locate
this product where the cord will abused by persons or
equipment moving on or near the cord.

Unplug the unit from the wall and refer servicing
to a qualified personnel under the following conditions:
-Damaged or frayed power cord
-If product has been dropped or case is damaged
-If a marked change in product performance is noted

2.3 SAFETY FEATURES

OVER PRESSURE - In the event over pressure occurs the unit cut power to the pump and air supply system.

OVER TEMPERATURE - In the event an over temperature condition occurs an independent hardware/software circuit will cut power to the heater.

LEAKAGE CURRENT- The leakage current of the pressure enclosure is less than 10 micro amps.

WATCHDOG TIMER- If the micro controller fails to execute code properly the watchdog timer will reset the Unit to the initial conditions.

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3.0 SPECIFICATIONS Model TFS3 *

Power

120 v ac 1 AMP or 220 V AC .5 AMP 50/60 Hz
(95 to 250 V AC to 63 Hz)

Weight

7 lbs. (with out stand)

Pressure Range

100 mm Hg to 800 mm Hg + or - 10 mm Hg

Heater Temperature

The heater is preset to 100 F° + or - 2 F°
Safety Shutdown Temperature- 105 F°.

Maximum Leakage Current

Control Unit - 100 micro amps. (per UL 544)
Pressure Enclosure - 10 micro amps. (per UL 544)

Maximum Ground Impedance - 0.1 ohm (per UL 544)

Fuse : Slow Blow 2.0 amp. (Located on the back of control unit)

Environmental Operating Conditions

40 F° to 150 F°, Humidity non-condensing

* U. S. and International patent pending
Specification subject to change without notice.

4.0 OPERATING THE SYSTEM

4.1 DESCRIPTION OF THE CONTROLS

Power Switch: The power switch is located on the front panel. It controls the power to unit.

Pressure Adjust Switch: Located to the right of the displays a three position rocker switch which is used to adjust the pressure. The center position is off . The top position (up arrow) and bottom position (down arrow) are momentary. Pressing the UP arrow increases the pressure. Pressing the bottom (down arrow) will decrease the pressure.

Load/Run Switch: This switch is a two position rocker. When the switch is set to the Load position the device will drop the air pressure in the Pressure Enclosure so the bag can be reloaded. When the switch is in the Run position the Pressure Enclosure will inflate to the set point on the display.

Display : The display is a 16 character single line LCD.

Low Fluid LED: The is a panel light on the front panel that indicates when the fluid level is low and prompts the user to prepare a new bag of solution.

Heater On LED: This is a panel light that indicates when the heater is on. If this light is not on the heater is not maintaining the Pre-set temperature of 100° F.

Air Connector: On the Back of panel of the unit a Colder Connector which plugs into a mating connector on the Pressure Enclosure.

Heater Electrical Connector: On the back panel of the controller is located a connector used to electrically connect the heater and the temperature sensor to the controller.

4.2 DESCRIPTION OF THE OPERATION

Plug the unit into a proper outlet according to the power requirements listed on the label at the back of the unit.

Turn on the power located on the front panel.

Set the Load/Run switch located on the front panel to the LOAD position.

Place a fresh preheated bag of solution into the Solution Carrier and insert this into the pressure enclosure.

The solution bag is connected to the Probe/Tubing set through stick fittings that protrude through an opening at the bottom of the pressure enclosure.

After the stick fitting has been plugged into the bag of solution. lock the piercing in locking collar at the bottom of the pressure enclosure.

Set the LOAD/RUN switch to the run position.

4.2 (continued)

Set the operating pressure setpoint with the switch located to the right of the LED display located on the front panel.

Pushing up on the switch will cause the pressure setting to go up. Pushing down on the switch will cause the setting to down.

After a setting has been set for more the 10 seconds the device will store as the last setting and will automatically go to this setting when the is powered up in the next session. Always check the setting before proceeding with procedure.

Temperature is automatically set to 100 F°. The heater is designed to maintain the temperature of the irrigation fluid.

When the user depresses the fluid control valve on the probe fluid will flow and provide irrigation.

When the irrigation fluid level gets low in the bag a FLUID LOW indicator light will come on indicating that level is low in the irrigation bag.

When the bag becomes empty set the LOAD/RUN switch to the LOAD position. This will cause the pressure to drop off in the pressure enclosure and a fresh bag of irrigation fluid can be installed.

The device will stored the last settings until they are changed by the user.

5.0 USAGE / CARE / WARRANTY

USAGE RECOMMENDATION

The ***THERMO-FLO SYSTEM*** *3*TM was designed for Laparoscopic surgery and is only to be used by licensed, certified surgical personnel.

RECOMMENDED CARE

Do not leave unit plugged in.
Do not use abrasive cleaning and disinfecting solutions.

LIMITED WARRANTY

Sanese Medical Corporation ("Sanese") warrants the **THERMO-FLO SYSTEM 3** TM to be free from defects in material and workmanship for a period of one (1) year from date of initial purchase. No warranty shall apply if the goods have been damaged by accident, abuse, misuse, or misapplication, or as a result of service or modification by other than a person authorized by Sanese. Sanese's liability under this warranty, and buyer's exclusive remedy is limited to the cost of materials and labor to repair defective goods, or to their replacement, and in no event shall exceed the purchase price. Repair or replacement of defective goods under warranty will be made only upon their return to Sanese after notice to Sanese and Buyer's receipt of shipping instructions. Upon receipt of goods returned under warranty, Sanese will inspect the goods, will notify buyer of the extent of repair or replacement which Sanese will perform under warranty, which shall be conclusive of Sanese's liability.

Sanese is not responsible for incidental consequential damages resulting from the breach of any expressed or implied warranty, including damage to property and to the extent permitted by law, damages for personal injury. The warranty contained herein is in lieu of all warranties, expressed or implied. No statement of any representative shall extend Sanese's liability as herein established or limited.

SANESE MEDICAL
CORPORATION
885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

LOT NO. 0500

THIS DEVICE IS NON-STRILE AND NEEDS TO BE STERILIZED AND CLEANED ACCORDING TO MANUFACTURING SPECIFICATIONS.

CONTENTS: MODEL NO. TFS3 - 3 RPR
1 - Reusable Probe Set

INDICATION FOR IRRIGATION
DURING LAPAROSCOPIC PROCEDURES

CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a physician.
Recommended for Laparoscopic Irrigation in adult and pediatric surgery.

THIS PRODUCT TO ONLY BE USED FOR LAPAROSCOPIC IRRIGATION. DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

Distributed by: SANESE MEDICAL CORPORATION

[redacted]

LABEL SIZE - 3.25 X 5.50
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE

ECN	REV	DESCRIPTION	DATE	DWN

SANESE MEDICAL	TITLE: TFS3 - 3 RPR PRODUCT LABEL		
	PART NUMBER: 10030	DWN	DATE
SHEET 1 OF 1 / SCALE: FULL	FILE: TFS33RPR.CDR	MDT	3/1/95

24

SANESE MEDICAL®
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

PREMARKET 510(k)
NOTIFICATION OF CLASS II
DEVICE. CLASSIFICATION
REQUESTED BY NOTIFICATION
85 HET (LAPAROSCOPE
ACCESSORY); REGULATION NO
21 C.F.R. § 884.1720

CONFIDENTIAL - 21 CFR § 807.95(b,c)
CLAIMS MADE
DO NOT LOG IN PUBLICLY
AVAILABLE LOG

February 22, 1995

Office of Device Evaluation
Centers for Devices and Radiological Health
Document Mail Center (HFZ-41)
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Second Submission of Additional Information in Support of Section 510(k) Notification of Sanese Medical Corporation's Intention to Market Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation Aspiration Probe and Tubing
510(k) No.: K941507/A

Dear Sir/Madam:

Enclosed is an original and two copies of Sanese Medical Corporation's second submission of additional information in support of its Section 510(k) notification of its intention to market its Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation/Aspiration Probe and Tubing.

Respectfully submitted,

Christopher N. Sanese
Regulatory Correspondence
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
Telephone: (614) 291-8848
Fax: (614) 291-1389

SANESE MEDICAL®
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

PREMARKET 510(k)
NOTIFICATION OF CLASS II
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REQUESTED BY NOTIFICATION
85 HET (LAPAROSCOPE
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February 22, 1995

Office of Device Evaluation
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9100 Corporate Boulevard
Rockville, MD 20850

Re: Second Submission of Additional Information in Support of Section 510(k) Notification of Sanese Medical Corporation's Intention to Market Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation/Aspiration Probe and Tubing.
510(k) No.: K941507/A

Dear Sir/Madam:

I.

Pursuant to 21 C.F.R. § 807.87(H) Sanese Medical Corporation (hereinafter "SMC") hereby submits additional information in support of its 510(k) submission under 510(k) No. K941075/A. The additional information provided through this second submission consists simply of promotional material of a predicate device which was inadvertently omitted from the first submission of additional information dated January 13, 1995.

II.

Additional Information

Attached as Exhibit F is a copy of promotional material from Level 1 Technologies Inc. concerning a heated irrigation system indicated for usage during laparoscopic surgery. The attached Exhibit F should be substituted for the present Exhibit F attached to the first submission of additional information in support of the SMC 510(k) notification dated January 13, 1995.

883 NORTHWEST BLVD., COLUMBUS, OHIO 43212 / (614) 291-8848 / FAX (614) 291-1389 / 800-873-7585

The current Exhibit F to the first submission while a similar product also marketed by Level 1 Technologies Inc. is not the same type of heated irrigation system as the SMC device and was erroneously attached to the first submission when it was sent in January 1995.

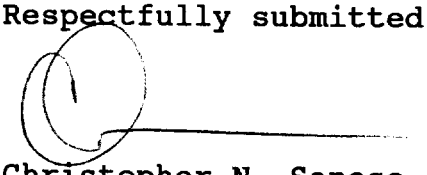
III.

CONCLUSION

SMC believes that with the second submission of the additional information described in II above and as supported with the Exhibit F attached hereto, its Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation/Aspiration Probe and Tubing are substantially equivalent in terms of their safety and effectiveness to the legally marketed predicate devices described in the original 510(k) submission and identified in first and second submissions of additional information. Accordingly, SMC requests that pursuant to 21 C.F.R. § 807.100, FDA issue an order granting SMC premarket clearance to market this device.

Should you have any questions concerning this additional information, please do not hesitate to call or write to me at the number and address set forth below.

Respectfully submitted,



Christopher N. Sanese
Regulatory Correspondence
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
Telephone: (614) 291-8848
Fax: (614) 291-1389

NEW EXHIBIT F

LEVEL 1®
TECHNOLOGIES INC

Thank you for requesting information on the LEVEL 1 Normothermic Irrigating System. The information has been enclosed.

Hypothermia is a major cause of complications. The Level 1 Normothermic Irrigating System provides a high flow supply of body temperature irrigating solution so your patient ***stays warm, safe and stable.***

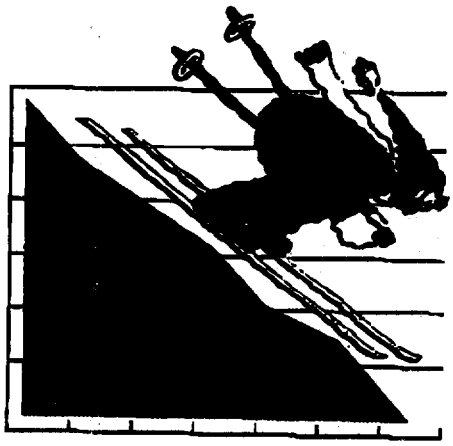
With Normothermic Irrigating your patients will benefit clinically and your hospital will benefit economically. Normothermic Irrigating makes sense in today's economically sensitive medical environment. A warm stable patient means a fast, uneventful recovery, minimizing valuable nursing time and therefore reducing the overall cost of care.

The Level 1 System is easy to use. It requires no change in your present protocol. The automatic air elimination system removes air bubbles, ensuring a clear, unobstructed field of vision. Our new Power Pole lifts up to 12 liters of fluid at the touch of a switch, facilitating bag changes and making flow rate adjustments fast, safe and easy.

Let us prove it! The enclosed literature describes the clinical benefits of Normothermic Irrigating in more detail, but you don't have to take our word for it. Try the system on a few cases. The Level 1 Normothermic Irrigating System makes sense, it's practical and your patients will feel the difference!

Call us at 1-800-5-LEVEL-1 (1-800-553-8351) to arrange an evaluation.

617-878-8011 160 Weymouth St., Rockland, MA 02370 FAX 617-878-8201



Hypothermia *is* a dangerous downhill run.

Now, the same system that kept tens of thousands of patients warm last year is available for ***all irrigating applications.***

- **Hysteroscopy**
- **Arthroscopy**
- **Cystoscopy**

In fact, *any* procedure that uses 3 liters or more of irrigating fluid.

The Level 1 Normothermic Irrigating System.

Making surgery safer by reducing the incidence of hypothermia.

LEVEL 1 TECHNOLOGIES INC

NORMOTHERMIC IRRIGATING

30

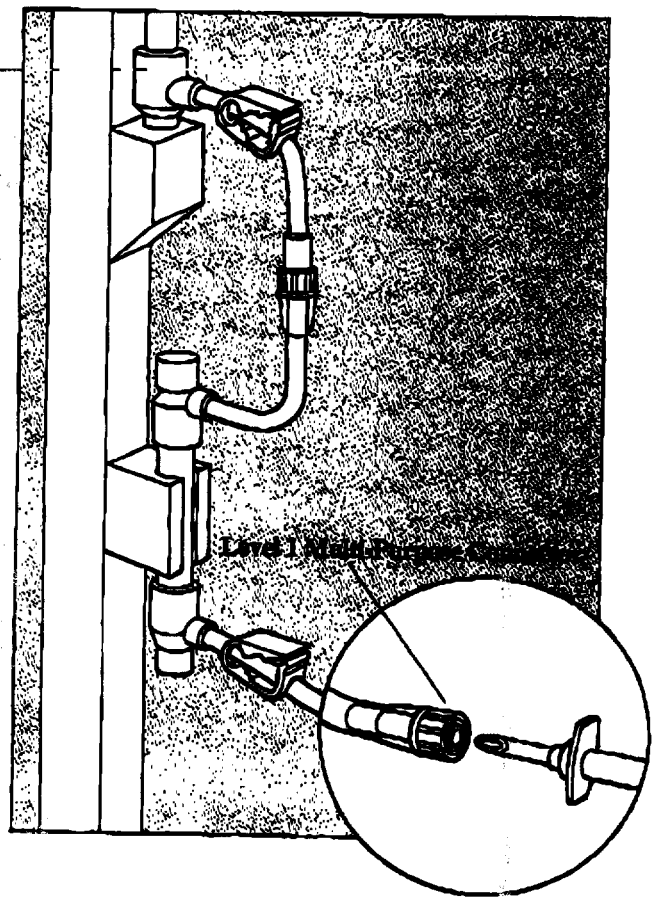
Adaptability.

Need to use a specialized pump for your irrigating procedures? With Level 1, it's easy as 1,2,3.

1. Set up and prime the Level 1 Normothermic Irrigating Set.

2. Spike your pump's tubing into the multi-purpose connector.

3. Prime your pump as always.



The Level 1 Normothermic Irrigating System. Adapts to all your needs.

Questions? Call 1 800 5 LEVEL 1 (1 800 553-8351)

LEVEL 1 TECHNOLOGIES INC
NORMOTHERMIC IRRIGATING

Level 1 Technologies, Inc., 160 Weymouth Street, Rockland, MA 02370
800 553-8351, 617 878-8011, FAX 617 878-8201

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SB 102

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 20, 1995

SANESE MEDICAL CORPORATION
885 NORTHWEST BLVD.
COLUMBUS, OH 43212
ATTN: CHRISTOPHER N. SANESE

510(k) Number: K941507
Product: THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K941507/S2

SANESE MEDICAL®
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

PREMARKET 510(k)
NOTIFICATION OF CLASS II
DEVICE. CLASSIFICATION
REQUESTED BY NOTIFICATION
80 HET: REGULATION NO. 21
C.F.R. § 884.1720

CONFIDENTIAL - 21 CFR § 807.95(b,c)
CLAIMS MADE
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FDA/CDRH/OSE/DMC

January 13, 1995

Office of Device Evaluation
Centers for Devices and Radiological Health
Document Mail Center (HFZ-41)
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Submission of Additional Information in Support of Section 510(k) Notification of Sanese Medical Corporation's Intention to Market Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation Aspiration Probe and Tubing
510(k) No.: K941507/A

Dear Sir/Madam:

Enclosed is an original and two copies of Sanese Medical Corporation's submission of additional information in support of its Section 510(k) notification of its intention to market its Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation/ Aspiration Probe and Tubing.

Respectfully submitted,

Christopher N. Sanese
Regulatory Correspondence
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
Telephone: (614) 291-8848
Fax: (614) 291-1389

PREMARKET 510(k)
NOTIFICATION OF CLASS II
DEVICE. CLASSIFICATION
REQUESTED BY NOTIFICATION
85 HET: REGULATION NO. 21
C.F.R. § 884.1720

CONFIDENTIAL - 21 CFR § 807.95(b,c)
CLAIMS MADE
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AVAILABLE LOG

January 13, 1995

Office of Device Evaluation
Centers for Devices and Radiological Health
Document Mail Center (HFZ-41)
Food and Drug Administration
9100 Corporate Boulevard
Rockville, MD 20850

Re: Submission of Additional Information in Support of Section 510(k) Notification of Sanese Medical Corporation's Intention to Market Thermo-Flow System 3 Laparoscopic Irrigation System and Irrigation/Aspiration Probe and Tubing.
510(k) No.: K941507/A

Dear Sir/Madam:

I.

Pursuant to the November 17, 1994 letter of Colin M. Pollard, Chief, Obstetrics/Gynecology Devices Branch, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Device, Office of Device Evaluation, Centers for Devices and Radiological Health (copy attached as Exhibit A), Sanese Medical Corporation (hereinafter "SMC") hereby submits pursuant to 21 C.F.R. § 807.87(H) additional information in support of its 510(k) submission under 510(k) No. K941075-A.[1/] The additional information provided through this submission consists of certain tests, some of which were in existence at the time of the original submission but were deemed unnecessary for inclusion in the notification, an amended summary of safety and effectiveness information, software validation results and modified labeling. To aid in understanding the submission, the requests for

---

[1/] Pursuant to SMC's written request, it was granted until February 17, 1995 to submit additional information in response to the request. (See Exhibit B.)

SANESE MEDICAL CORPORATION

additional information set forth in Mr. Pollard's November 17, 1994 letter are set out in their entirety with SMC's responses following each numbered request and/or its subpart.

II.

b(4)CCI

[redacted]

b(4)CCI

[redacted]

SANESE MEDICAL CORPORATION

b(4)CCI

[redacted]

SANESE MEDICAL
CORPORATION

b(4)CCI

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III.

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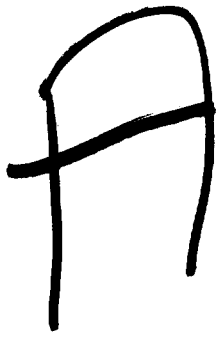
41



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Mr. Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, Ohio 43212

NOV 17 1994

Re: K941507/A
Thermo-Flo System 3
Dated: July 5, 1994
Received: July 6, 1994

Dear Mr. Sanese:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided.

(b)(4) Trade Secret Process - Product Specification

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(b)(4) Trade Secret Process - Product Specification

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If the information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Donna-Bea Tillman at (301) 594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Colin M. Pollard

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

95

bcc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

DBTillman
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Draft 11-15-94 ens

12-9-94

Colin M. Pallard
Food and Drug Administrarion
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RE:K941507 / A
Thermo - Flo System 3
Dated: July 5, 1994
Received: July 6

Dear Mr. Pallard,

This letter is to formally request a 60 day extension of our Decmber 17, delivery compliance as requested of your letter of November 17, 1994. This request was made verbally to Donna -Bea Tillman in our phone conversation of December 5, 1994.

Thank you very much for your consideration of this request.

Sincerely,

Christcher N. Sanese
Regulatory Corespondent
SANESE MEDICAL CORPORATION

ENC: 4 pages

CNS/lll

CC: John Jevicky, Esq.
DINSMORE & SHOHL

48

DEPARTMENT OF HEALTH AND HUMAN SERVICES | Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 15, 1994

SANESE MEDICAL CORPORATION
885 NORTHWEST BLVD.
COLUMBUS, OH 43212
ATTN: CHRISTOPHER N. SANESE

510(k) Number: K941507
Product: THERMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC

Extended Until: 17-FEB-95

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

49

C

SD

AMENDED SECTION 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION FOR SMC'S THERMO-FLOW SYSTEM 3 LAPAROSCOPIC IRRIGATION SYSTEM AND DISPOSABLE IRRIGATION/ASPIRATION PROBE AND TUBING

Pursuant to Section 12(a) of the Safe Medical Devices Act of 1990, 21 U.S.C. § 360c(i)(3)A and 21 C.F.R. § 807.92, the following amended summary of information concerning the safety and effectiveness of SMC's Thermo-Flow System 3 Laparoscopic Irrigation System and Disposable Irrigation/Aspiration Probe and Tubing is hereby submitted.

1. Name and address of device manufacturer submitting 510(k) notification:

   Sanese Medical Corporation
   885 Northwest Boulevard
   Columbus, OH 43212
   (614) 291-8848

2. Regulatory correspondent.

   Christopher N. Sanese
   Sanese Medical Corporation
   885 Northwest Boulevard
   Columbus, OH 43212
   (614) 291-8848

3. Date amended summary was prepared: January 10, 1995

4. Names of Devices:

   (i) Proprietary Names:

   (a) Thermo-Flow System 3 Laparoscopic Irrigation System®
   (b) Sanese Disposable Irrigation/Aspiration Probe and Tubing™

   (ii) Common, usual names:

   (a) Laparoscopic irrigation pump system
   (b) Disposable aspiration/irrigation probe and tubing.

   (iii) Classification Names: Gynecologic Laparoscope and Accessories, 80 HET: 21 C.F.R. § 884.1720.

5. Predicate devices to which SMC is claiming substantial equivalence:

S1

SMC claims substantial equivalence for purposes of section 510(k) only to:

A. Irrigation Pump System:

(1) The Niagra™ High-Flow Irrigator System, 510(k) Number K924530 by Cabot Medical, 2021 Cabot Boulevard, West Langhorn, PA 19047 (800-523-6078).

(2) Level One Technologies, Inc., Labroscopic Irrigation System, 160 Weymouth Street, Rockland, MA 02370 (800-553-8351).

B. Disposable Probe and Tubing:

(1) Probe:

Corson™ Disposable Suction Irrigation Probe by Cabot Medical, 2021 Cabot Boulevard, West Langhorn, PA 19047 (800-523-6078).

(2) Tubing:

Core Dynamics Inc. Disposable Irrigation/ Suction Tubing Set (510(k) Number K910246) by Core Dynamics, Inc., 9951 Atlantic Boulevard, Jacksonville, Florida 3225 (904-727-0910).

6. Description of the devices and primary principles of operation:

A. Description of irrigation pump system.

This device consists of a fabric enclosure (pressure envelope) in which a bag of irrigation fluid is placed. The fabric enclosure contains an inflatable bladder that is pneumatically inflated to pressurize the fluid in the irrigation fluid bag. Inflation of the bladder is provided by an air compressor which has a maximum voltage leakage current of 100 microamps. This complies with Underwriters Laboratory Standard 544.

The pressure envelope also contains a heating element to assist in maintaining the temperature of 100° F. of preheated irrigation solution while being used in the pressure envelope. There is also a thermal regulator to control the temperature of the heating element. The heating element and the thermal regulator are powered by an Underwriter Laboratory approved 24 volt electrical power supply.

SZ

The air compressor and heating element are controlled by a microcontroller. These components are controlled by the micro-controller through activating solid state switches which control electrical power to the pump, pump solenoids and the heater.

The pressurized preheated fluid is then introduced into the laparoscopic surgery site through a medical grade plastic tube and probe that are discussed below.

B. Description of disposable probe and tubing:

The probe consists of a medical grade plastic, activation valve and metal shaft that will deliver and aspirate fluids to and from an operative site.

The tubing consists of two 15 foot length medical grade surgical tubing that are approximately 10 millimeters in diameter which would be connected to the probe and the irrigation solution bag and the pump when used for irrigation or to the probe and the suction unit when used for aspiration. The probe and tubing are made of medical grade plastic and metal that have been determined by FDA to be safe and effective for this intended usage.

C. Primary Principles of Operation:

(i) Irrigation Pump System:

The primary principles of operation are pressurization through an electrically powered pneumatic compressor for pressurized irrigation fluid flow and thermal transfer through an electrically-powered thermo-conducted heat transfer unit to maintain preheated fluid.

(ii) Probe and Tubing:

With respect to the aspiration/irrigation use of the probe and tubing, the principles of operation are vacuum and pressurization.

7. Statement of the purpose for which the device will be recommended:

These devices are intended to be used accessories to laparoscopic surgical equipment by providing irrigation and aspiration during adult and pediatric laparoscopic surgery.

8. Biocompatibility and effectiveness of the device:

SS

(i) Biocompatibility:

The only aspect of the device that comes in contact with the patient is the distal end of the probe. The probe and the probe tubing have been subject to biocompatibility tests and are safe and effective for such usage. The irrigation pump has a maximum voltage leakage current of 100 microamps in accordance with U.L. Standard 544. Performance tests of the pump demonstrate that it is safe and effective for its intended use. Also, all components of the pump meet U.L. Standards.

Respectfully submitted,

Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
(614) 291-8848

S4

D

Preliminary Discussion:

b(4)Trade Secret Process-Product Specs

Conditions:

b(4)Trade Secret Process-Product Specs

Data:

b(4)Trade Secret Process-Product Specs

SP

Results:

b(4)Trade Secret Process-Product Specs

[redacted]

57

b(4)Trade Secret Process-Product Specs

[redacted]

4 Numerical Specifications

b(4)Trade Secret Process-Product Specs

[redacted]

5 User Interface

5.1 Description of Controls

b(4)Trade Secret Process-Product Specs

[redacted]

58

E

Sanese Medical Test Report:
Test Number: eo001-12 REV A
Subject : Testing of Machine Setting Accuracy
Written: Marc D. Taylor
Date: 12/12/94

12/12/94

Objective:

b(4)Trade Secret Process-Product Specs

Conditions:

b(4)Trade Secret Process-Product Specs

Results:

b(4)Trade Secret Process-Product Specs

Discussion:

b(4)Trade Secret Process-Product Specs

60

Sanese Medical Test Report:
Test Number: eo001-12 rev a
Subject: Testing of Machine Setting Accuracy
Written: Marc D. Taylor
Date: 12/12 /94
Page 2 of 2

Marc D Taylor 12/12/94

GRAPH OF AIR AND FLUID PRESSURES

b(4)Trade Secret Process-Product Specs

61

Sanese Medical Test Report:
Test Number: eo001-16 REV A
Subject : Flow Rate Test
Written: Marc D. Taylor
Date: 12/12/94

Objective:

[redacted]b(4)Trade [redacted]
S t

Conditions:

b(4)Trade Secret Process-Product Specs [redacted]

Test:

b(4)Trade Secret Process-Product Specs [redacted]

Results:

b(4)Trade Secret Process-Product Specs [redacted]

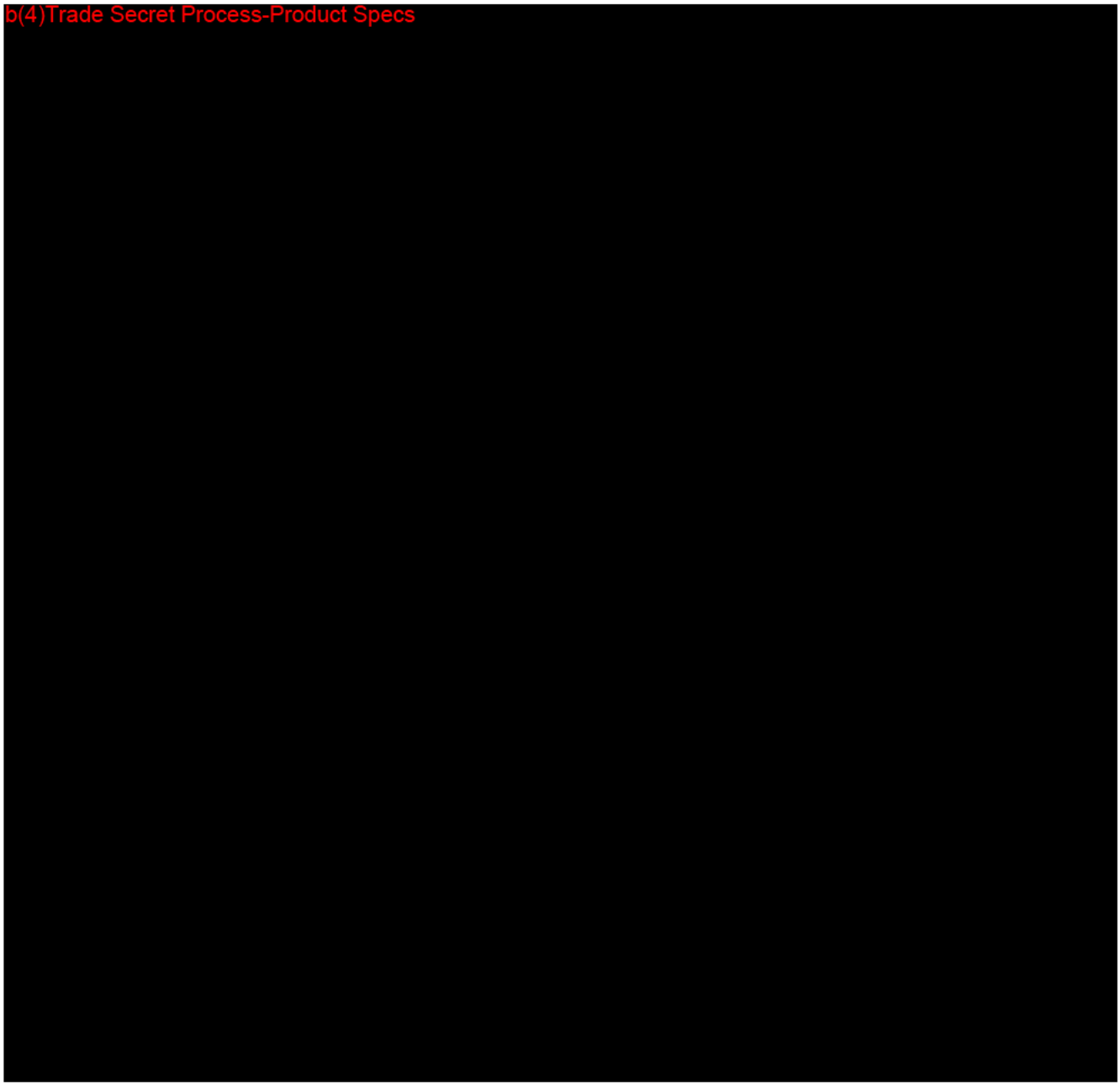
Discussion:

b(4)Trade Secret Process-Product Specs [redacted]

62

Sanese Medical Test Report
Test Report Number: eo001-16 revA
Written By: Marc D. Taylor
Date: 12/12/94

b(4)Trade Secret Process-Product Specs



63

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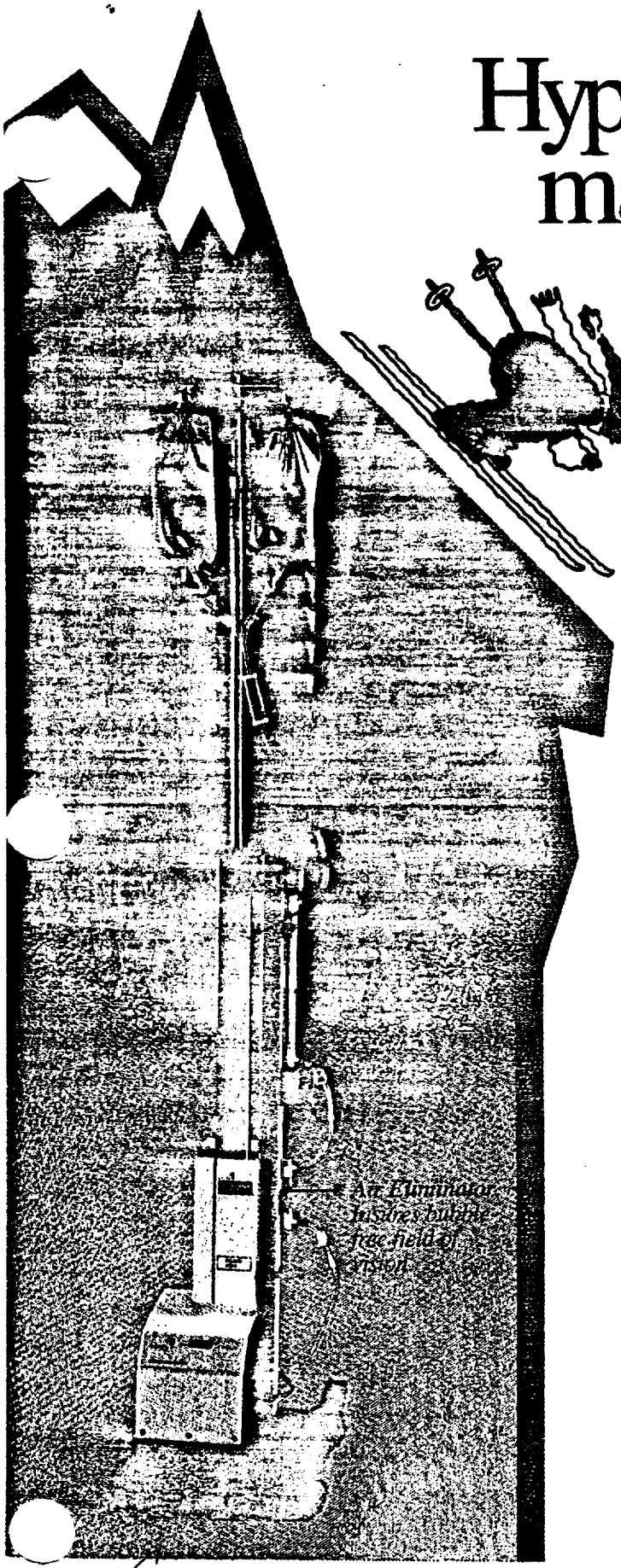
64

K911383 - DGRD

Hypothermia makes TURP a dangerous downhill run.



Ask your Recovery Room staff. TURP patients are cold!

Even *lukewarm* irrigating during TURP makes core temperature loss unavoidable. This is significant because hypothermia increases cardiac stress, elevates bleeding times and lengthens the recovery period.

Eliminate the risk of hypothermia.

Normothermic Irrigating lowers the risk of serious hypothermic complications, reduces bleeding and maintains stable cardiac function. With the Level 1 Normothermic Irrigating System, regardless of the length of the procedure or the volume of irrigant used, you can be confident your patient will leave your O.R. warm. *In fact, the more fluid used, the warmer your patient will stay!*

Specifically for Urology.

The H-600 Normothermic Irrigating System provides a continuous, high flow supply of body temperature irrigating fluid so your patient *stays* warm, safe and stable. An in-line **Air Eliminator** assures a clear, bubble-free field of vision. And, our exclusive **Power Pole™** lifts up to four three-liter bags at the touch of a switch... bag changes and height adjustments become quick, safe and easy.

Evaluate the H-600 Normothermic Irrigating System. Your patients will feel the difference!

LEVEL 1 TECHNOLOGIES INC.

NORMOTHERMIC IRRIGATING

Level 1 Technologies, Inc., 160 Weymouth Street, Rockland, MA 02370, 1 (800) 5 LEVEL 1, FAX 617 878 8201

K861477 - DCRND / K873435 - GU

LEVEL 1®

TECHNOLOGIES INC

NORMOTHERMIC IRRIGATING DURING TURP?

-Room temperature and lukewarm irrigating solutions cause a serious loss of core temperature.[1,2,3,4]

-This temperature loss causes significant cardiovascular stress[1,2,7] and increases the risk of additional hypothermic complications.[1,2,3,4,5,6,7]

-Normothermic irrigating maintains core temperature, reduces bleeding and maintains safe, stable cardiac function.[2,5,6]

The Level 1 Normothermic Irrigating System eliminates hypothermic complications and provides for *"a less stressful and safer operation"* [5]

NORMOTHERMIC IRRIGATING DURING TURP!

Call 800-5-LEVEL-1 to arrange an evaluation at your facility.

1. **Haemodynamic evidence for cardiac stress during transurethral prostatectomy,** J.W.H. Evans, et al, *British Medical Journal* 1992;304:666-671.
2. **Haemodynamic and cardiological responses to TURP, standard vs. isothermic techniques,** J.W.H. Evans, et al, *presented to the British Society of Urological Surgeons,* June, 1991
3. **Hypothermia during transurethral resection of the prostate,** Carpenter, *Urology,* 2/84
4. **Body temperature changes during prostatic resection as related to the temperature of the irrigating solution,** Allen, *The Journal of Urology,* 10/73
5. **The effect of warm irrigation on blood loss during transurethral prostatectomy under spinal anesthesia,** Heathcote and Dyer, *British Journal of Urology,* 4/86
6. **The effects of warm irrigating fluid during and after transurethral prostatectomy,** Ogura, et al, *Clinical Therapuetics/*Vol 10, special issue, 1988
7. **Hypothermia Is An Independent Predictor Of Postoperative Myocardial Ischemia,** S.M. Frank, et al, *Anesthesiology,* V77, No 3A, September, 1992

**Summaries of the above studies are attached. The complete articles are available in your library or on request from*

LEVEL 1 TECHNOLOGIES

617-878-8011 160 Weymouth St., Rockland, MA 02370 FAX 617-878-82(

aemodynamic evidence for cardiac stress during transurethral prostatectomy,

J. W. H. Evans, et al, *British Medical Journal* 1992;304: 666-671.

This paper examines changes in cardiac output, stroke volume, systemic vascular resistance, and core temperature between a group of patients undergoing routine TURP (intermittent flow technique) and a control group, undergoing either hernia repair or testicular exploration. The same anesthetic protocol was used in both groups. Both groups compare well in terms of age of patient and length of procedure.

RESULTS

CONTROL GROUP

- No significant changes in hemodynamic parameters measured
- Core temperature was stable

ROUTINE TURP GROUP

- Systemic vascular resistance rose significantly from baseline compared to the control group (+49% vs Control -10%)
- Cardiac output fell significantly (-21% vs Control +12%)
- Stroke volume also fell significantly (-16% vs Control +26%)
- Core temperature fell significantly compared to the control group

AUTHOR'S CONCLUSIONS

-"Important haemodynamic(sic) disturbances were identified during routine apparently uneventful transurethral prostatectomy but not during control procedures."

-"The heamodynamic differences between groups must be the result of a factor peculiar to transurethral prostatectomy which was present early in the procedure."

"The most remarkable difference between the two groups was the rapid central cooling during transurethral prostatectomy"

67

Haemodynamic and Cardiological Responses to TURP: Standard vs. Isothermic Techniques, J.W.H. Evans et al, presented to the British Society of Urological Surgeons, June, 1991.

This study compares cardiovascular and core temperature changes in patients undergoing TURP using room temperature irrigant, TURP using normothermic (body temperature) irrigant, and a control group undergoing non-endoscopic surgery. The same anesthetic protocil was used in all groups. The duration of surgery was comparable in all groups.

RESULTS

Non-endoscopic surgery (no bladder irrigation)

- No significant changes in heart rate, stroke volume, cardiac output, or vascular resistance
- Core temperature was stable

TURP with normothermic irrigant

- No significant changes in the above hemodynamic parameters or core temperature

TURP with room temperature irrigant

- Mean arterial pressure and vascular resistance rose significantly (over 55%)
- Stroke volume and cardiac output fell significantly (-20% and -25% respectively)
- Core Temperature dropped significantly
- 20% of the room temperature TURP group became hypothermic during surgery (core temperature $< 35°C$). [Previous study documents that core temperature continues to drop in recovery...Allen, The Journal of Urology, 10/73]

AUTHORS' CONCLUSION

- "The hemodynamic responses during standard TURP [room temperature irrigant] were the result of falls in core temperature..."
- "Iatrogenic falls in core temperature represent a cardiovascular stress to all TURP patients. Furthermore, low core temperatures have many other detrimental physiological and metabolic effects, especially in the elderly."
- "The prevention of falls in core temperature during TURP is a simple, practical, and effective preventative measure."

Hypothermia During Transurethal Resection of Prostate", Carpenter, Urology 2/84

Author reviews previous articles and conducts his own research on using room temperatures vs body temperature irrigating fluids.

Previous Study

Room temperature solutions drop body temperature 2oF per hour.

120 min. latter body temperature still dropping, the study was concluded at this time.

Warmed solutions: no drop in temperature; no increase in bleeding.

Carpenter's Results

Average operating time 90 minutes

Average patients temperature dropped for 180 minutes.

Temperatures returned to normal 7 hours after onset of anesthesia.

Several patients remained cold for up to 15 hours.

Comments

Elderly may have defective thermoregulation. This can result in a lack of shivering to protect core temperatures.

Cardiovascular system especially sensitive to hypothermia.

Hypothermic heart relatively unresponsive to atropine, electropacing or counter shock.

Turp with room temperature relatively safe procedure.

Geriatric group may have pre-existing cardiovascular disease thus possibility of complications is always present.

Authors Conclusions

"The concept that mild hypothermia is beneficial in regard to intraoperative blood loss would seem to be greatly outweighed by the potentially serious cardiovascular complications which might occur as a result of hypothermia."

"BODY TEMPERATURE CHANGES DURING PROSTATIC RESECTION AS RELATED TO THE TEMPERATURE OF THE IRRIGATING SOLUTION", Allen, The Journal of Urology, 10/79

This study looks at the effect on body temperature during TURP using irrigating solutions at three different temperatures;

1. Cool (68-84°F) - 2. Lukewarm (85-94°F) - 3. Warm (95-100°F)

Author's Observations

- Due to conventional O.R. temperatures patients tend to have a decline in body temperature even before resection has begun.
- This decline accelerates upon the institution of cool OR lukewarm irrigation of the bladder.
- The cooling effect was only *SLIGHTLY* less when the irrigant was lukewarm. There was an "invariable fall in body temperature when cool *OR* lukewarm irrigation solutions were used." (emphasis ours)
- In the warm series, no drop in body temperature occurred.
- A fall in body temperature of as little as 2/3°C may cause shivering.
- In the cardiac patient with ischemic heart disease, shivering may be sufficient to induce arrhythmias, angina or even myocardial infarction.

Author's Conclusions

"The use of warm irrigating solutions seemed to have considerable superiority over other methods of maintaining body temperature."

Use of warm solutions makes the patient and surgeon more comfortable.

No adverse effects were seen with the use of warm solutions, but cool solutions caused shivering in 16 per cent of the patients."

70

The effect of Warm Irrigation on Blood Loss during Transurethral Prostatectomy under Spinal Anesthesia, Heathcote and Dyer, British Journal of Urology, 4/86

This study describes the effect of warm irrigating fluid on blood loss during TURP.

Authors' comments:

- Hypothermia is a common problem during TURP.
- Hypothermia causes a risk of cardiovascular complications.
- Cold irrigating fluids cause discomfort for patient and operator.
- With cooled irrigating fluids, shivering and exaggerated temperature decrements up to 6°C have been reported.
- Warm irrigating fluids are more comfortable for the operator and the increased pliability of the tubing made the resectoscope easier to handle.

Authors' Conclusion:

"By using warmed irrigating fluids during TURP one can decrease heat loss and shivering in the patients. Warmed irrigating fluids do not increase blood loss during TURP and their use leads to a less stressful and safer operation."

The Effects of Warm Irrigating Fluid during and after Transurethral Prostatectomy, Ogura et al, Clinical Therapeutics/Vol 10, special issue,1988

This study compares warm (37°C) versus room temperature irrigation in TURP patients to determine effects on total blood loss.

Previous literature documents:

- Irrigation during TURP with room temperature fluids causes a decrease in core temperature.
- Intraoperative hypothermia can seriously affect the cardiovascular system in elderly patients.

This study shows:

- Normothermic Irrigating fluid group showed significantly less blood loss than the control group.
- Far less shivering during and after surgery was noted in the warmed-fluid group (8% vs. 35% in the room temperature group).

Authors' conclusions:

"The results of the present investigation demonstrate that transurethral resection is safer when irrigating fluid is warmed to body temperature (37°C). Warmed irrigating fluid appeared to reduce blood loss locally and prevented hypothermia and associated complications systemically."

HYPOTHERMIA IS AN INDEPENDENT PREDICTOR OF POSTOPERATIVE MYOCARDIAL ISCHEMIA

S.M. Frank, et al, *Anesthesiology*, V77, No 3A, September, 1992

It has been previously suggested that shivering may be detrimental in patients with coronary artery disease, but no documentation exists to support this hypothesis. This abstract is from a study conducted at Johns Hopkins Hospital. It examines the relationship between inadvertent hypothermia and cardiac morbidity.

METHODS

Patients' temperatures were recorded upon admission to the ICU (hypothermia <35°C, normothermia ≥35°C), shivering was determined by physical examination and ischemia was identified via 24 hour holter monitoring.

RESULTS

The incidence of myocardial ischemia was almost ***THREE TIMES GREATER*** in the hypothermic group (36% vs 13% for the normothermic group)

Shivering was ***not*** a predictor of ischemia, **"the only independent predictor of ischemia was temperature on arrival in the ICU."**

The odds of developing myocardial ischemia increased by *82% for each degree C decrease in core temperature.*

AUTHORS' CONCLUSIONS

"The incidence of postoperative myocardial ischemia was significantly greater in the hypothermic patients"

"Contrary to expectation, the incidence of ischemia was not related to shivering."

"... patients at risk for perioperative myocardial ischemia should receive special attention regarding the maintenance of body temperature."

G

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Objective:

b(4)Trade Secret Process-Product Specs

Conditions:

b(4)Trade Secret Process-Product Specs

Results:

b(4)Trade Secret Process-Product Specs

Discussion:

b(4)Trade Secret Process-Product Specs

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Sanese Medical Test Report:
Test Number: eo001-06 REV A
Subject : Production - Line Dielectric Voltage - Withstand Test
Production - Line Grounding - Continuity Test
Written: Marc D. Taylor
Date: 12/12/94
Page 1 of 1 Marc D. Taylor 12/12/94

Objective:

b(4)Trade Secret Process-Product Specs

Conditions:

b(4)Trade Secret Process-Product Specs

UL Code Table Reference:

b(4)Trade Secret Process-Product Specs

Results:

b(4)Trade Secret Process-Product Specs

Discussion:

b(4)Trade Secret Process-Product Specs

Sanese Medical Test Report:
Test Number: eo001-13 REV A
Subject : 35 LB Pull Test of Cord and Strain Relief (7.2.3.4 of the UL 544 Code)

Written: Marc D. Taylor
Date: 12/12/94
Page 1 of 1

Marc D Taylor 12/12/94

Objective:

[redacted] b(4)Trade S t

Conditions:

b(4)Trade Secret Process-Product Specs [redacted]

Test:

b(4)Trade Secret Process-Product Specs [redacted]

Results: b(4)Trade Secret Process-Product Specs [redacted]

Discussion: b(4)Trade Secret Process-Product Specs [redacted]

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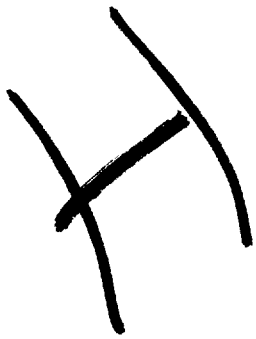

Descriptions of Functions: (Structure Chart on page 3)

b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

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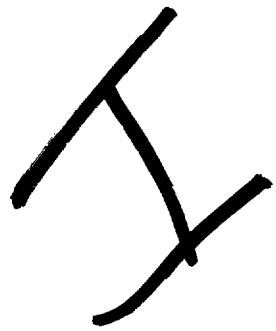

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0 Sub Documents

b(4)Trade Secret Process-Product Specs

1 Purpose

b(4)Trade Secret Process-Product Specs

2 System Overview

b(4)Trade Secret Process-Product Specs

3 Hardware Overview

b(4)Trade Secret Process-Product Specs

4 Software Requirements

4.1 Software Requirements for the User Interface

b(4)Trade Secret Process-Product Specs

[redacted]

4.2 Software Requirements for the Hardware Interface

b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

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5 Software Specifications:

b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

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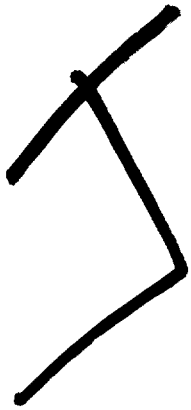

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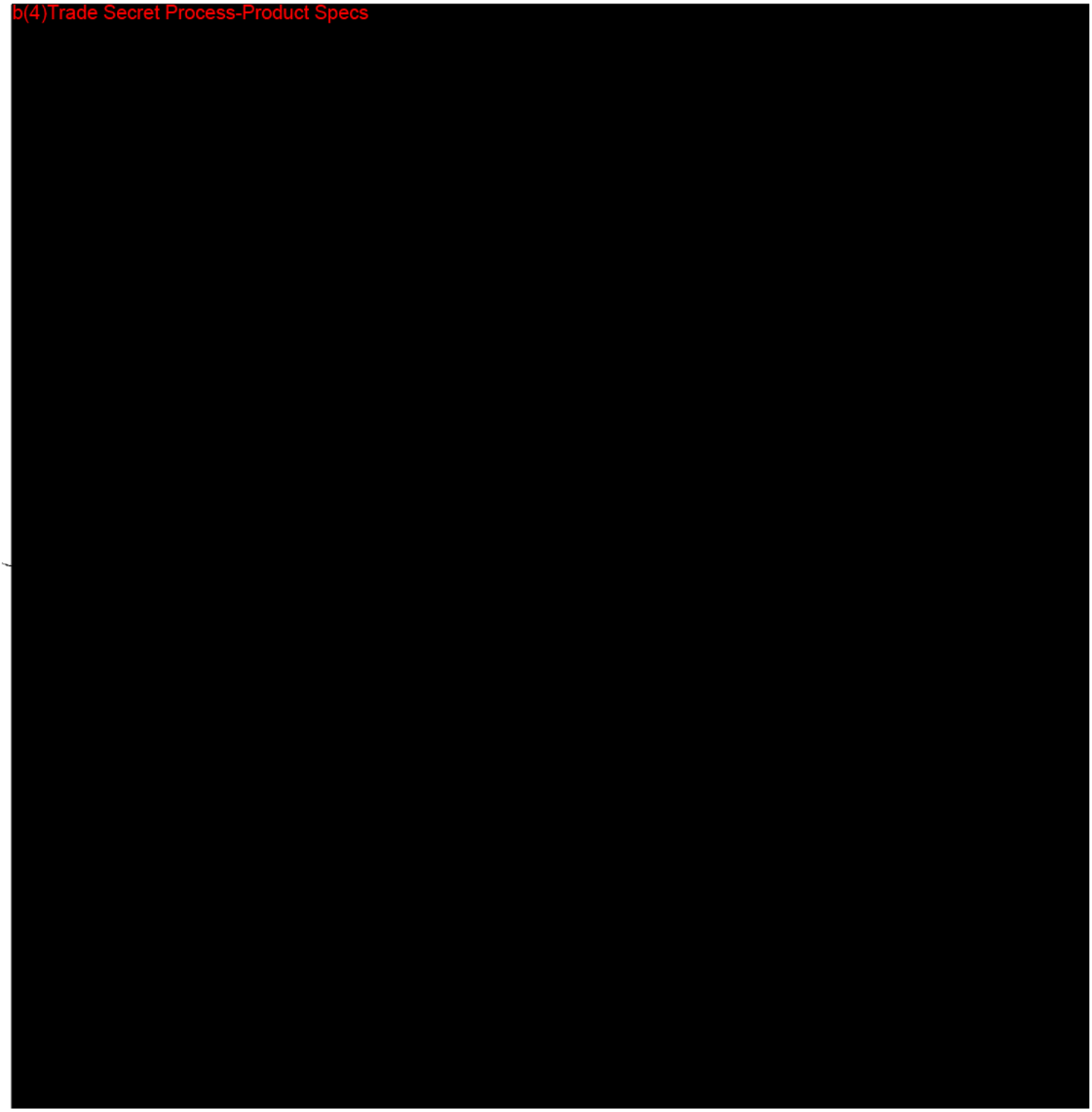

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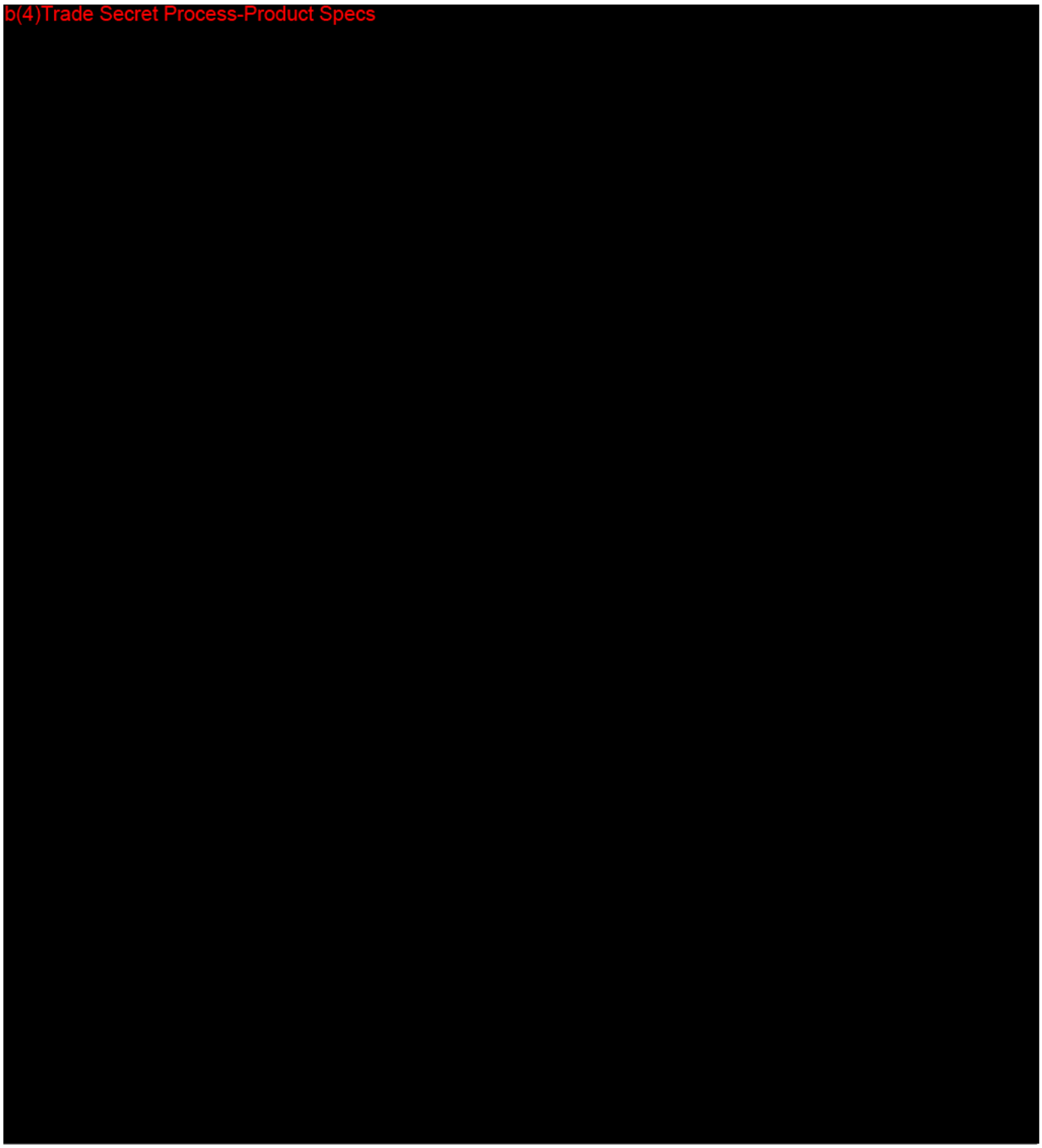
b(4)Trade Secret Process-Product Specs



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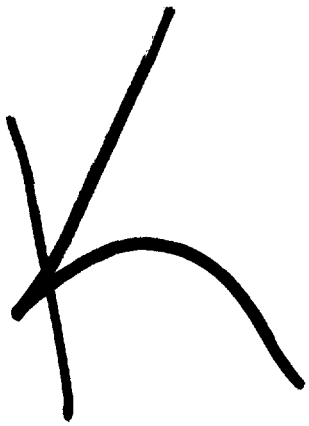

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b(4)Trade Secret Process-Product Specs

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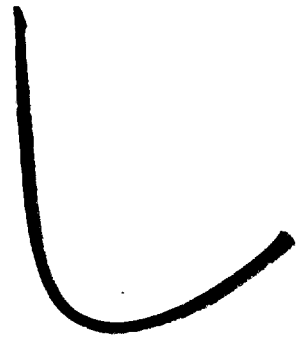

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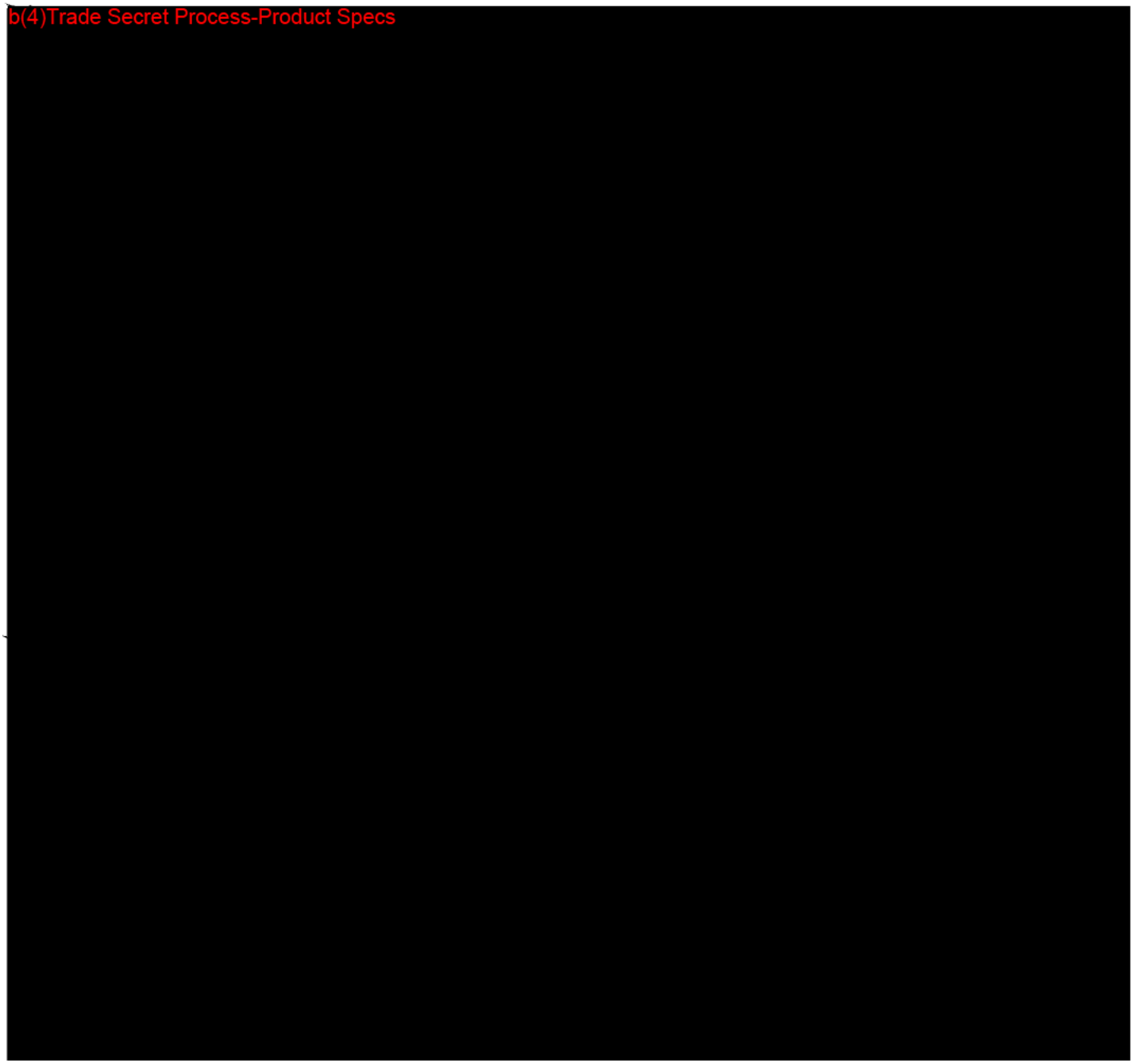
b(4)Trade Secret Process-Product Specs



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b(4)Trade Secret Process-Product Specs

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b(4)Trade Secret Process-Product Specs

[redacted]

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b(4)Trade Secret Process-Product Specs

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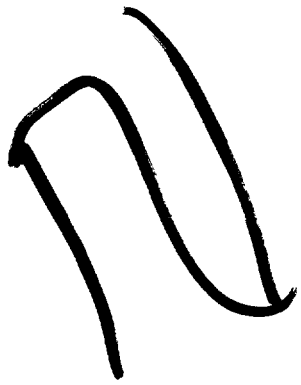


SANESE MEDICAL CORPORATION, INC.

REUSABLE PROBE STERILIZATION PROCEDURE

Preparation for cleaning

1- Dismantle.

a) Remove housing screws.
b) Remove valve gates.
c) Remove springs.
d) Remove seals.

2- Immerse housing screws, valve gates, springs and, seals in instrument disinfectant.

3- Wipe down the exterior with a lint free cloth soaked in instrument disinfectant.

4- Rinse interior of the probe by introducing the same disinfectant into the embodiment of the probe and allowing the disinfecting solution to run through the irrigation tube.

Manual cleaning

1- Completely immerse the dismantled probe into the disinfecting solution. Ensure that all of the air is forced out of the probe by tilting it slightly and moving it to and fro in the solution until all air bubbles have been removed.

2- Do not use abrasives for cleaning the probe. Use only swabs, soft bristle brushes or, cleaning guns on the probe.

3- Check the instrument for adhering protein prior to sterilization. If remnants of protein are discovered resoak in disinfecting solution and repeat step #4.

114

Probe Sterilization

Ultrasonic cleaning

1- This probe may be cleaned ultrasonically.

2- Check the instrument for adhering protein prior to sterilization. If remnants of protein are discovered reclean ultrasonically or soak the probe in a disinfecting solution and wipe with a swab or a soft bristle brush until the probe is free of protein and, repeat ultrasonic cleaning.

Autoclave sterilization

1- Autoclave using hospital standardized procedures. Normally autoclaving is performed with saturated steam at 134 degrees C.

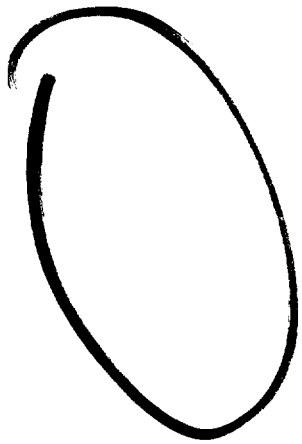
2- Steam used for sterilization must be free from any contamination and should neither impede the process nor damage the sterilizer or the probe. To guarantee this meet the recommendations of pr EN 285 regarding the quality of water in the tank as well as the condensate.

3- After autoclave sterilization the probes must be stored dry until ready for reuse.

Reassemble and test for leaks

a) Check seals for wear. If worn replace with new seals provided by the manufacturer. If seals show no signs of wear, proceed to "b."
b) Replace seals into probe housing.
c) Replace springs.
d) Replace valve gates.
e) Replace housing screws.

115



LOT NO. 0333

THERMO-FLO SYSTEMS

CONTENTS:

1 -MODEL TFS3 LAPAROSCOPIC IRRIGATION SYSTEM

CAUTION:

Federal (U.S.A.) Law restricts this device to sale by, or on the order of a physician.

Non - Sterile : Recommended for Laparoscopic Irrigation in adult and pediatric surgery

Distributed by:

SANESE MEDICAL CORPORATION

[redacted]

LABEL SIZE - 3.25 X 5.50
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE

ECN	REV	DESCRIPTION	DATE	DWN

SANESE MEDICAL		TITLE TFS3 PRODUCT LABEL		
		PART NUMBER 10020	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE TFS3.CDR	MDT	12/12/94

117

LOT NO. 0500
FOR SINGLE USE ONLY CONTENTS
IN UNOPEN, UNDAMGED PACKAGES

CONTENTS: MODEL NO. TFS3 - 3 WP
1 - Single use, disposable 15' irrigation / aspiration tube set with prode

INDICATION FOR IRRIGATION
DURING LAPAROSCOPIC PROCEDURES

CAUTION: Federal (U.S.A.) Law restricts this device to sale by,
or on the order of a physician.
Recommended for Laparoscopic Irrigation
In adult and pediatric surgery.

THIS PRODUCT TO ONLY BE USED FOR
LAPAROSCOPIC IRRIGATION. DO NOT
USE FOR HYSTEROSCOPIC DISTENTION.

Distributed by: SANESE MEDICAL CORPORATION
[illegible]

LABEL SIZE - 3.25 X 5.50
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE

ECN	REV	DESCRIPTION	DATE	DWN

SANESE MEDICAL		TITLE TFS3 - 3 WP PRODUCT LABEL		
		PART NUMBER 10021	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE TFS33WP .CDR	MDT	12/12/94

118

LOT NO. 0500
FOR SINGLE USE ONLY CONTENTS
IN UNOPEN, UNDAMGED PACKAGES

CONTENTS: MODEL NO. TFS3 - 3 WOP
1 - Single use, disposable 15' irrigation / aspiration tube set

INDICATION FOR IRRIGATION
DURING LAPAROSCOPIC PROCEDURES

CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a physician.
Recommended for Laparoscopic irrigation
In adult and pediatric surgery.

THIS PRODUCT TO ONLY BE USED FOR
LAPAROSCOPIC IRRIGATION. DO NOT
USE FOR HYSTEROSCOPIC DISTENTION.

Distributed by: SANESE MEDICAL
CORPORATION
[illegible]

LABEL SIZE - 3.25 X 5.50
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE

ECN	REV	DESCRIPTION	DATE	DWN
SANESE MEDICAL		TITLE TFS3 - 3 WOP PRODUCT LABEL		
		PART NUMBER 10022	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE TFS33WOP .CDR	MDI	12/12/94

119

LOT NO. 0500
FOR SINGLE USE ONLY CONTENTS
IN UNOPEN, UNDAMGED PACKAGES

CONTENTS: MODEL NO. TFS3 - N- 3 WOP
10 - Single use, disposable 15' irrigation / aspiration tube set
INDICATION FOR IRRIGATION
DURING LAPAROSCOPIC PROCEDURES

CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a physician.
Recommended for Laparoscopic irrigation in adult and pediatric surgery.

THIS PRODUCT TO ONLY BE USED FOR LAPAROSCOPIC IRRIGATION. DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

Distributed by: SANESE MEDICAL CORPORATION
[illegible]

LABEL SIZE - 3.25 X 5.50
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE

ECN	REV	DESCRIPTION	DATE	DWN
SANESE MEDICAL		TITLE TFS3 - N- 3 WOP CASE LABEL		
		PART NUMBER 10023	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE TFS3NWOP .CDR	MDT	12/12/94

120

LOT NO. 0500
FOR SINGLE USE ONLY CONTENTS
IN UNOPEN, UNDAMGED PACKAGES

CONTENTS: MODEL NO. TFS3 - N- 3 WP
10 - Single use, disposable 15' irrigation / aspiration tube set with probe
INDICATION FOR IRRIGATION
DURING LAPAROSCOPIC PROCEDURES

CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a physician.
Recommended for Laparoscopic irrigation in adult and pediatric surgery.

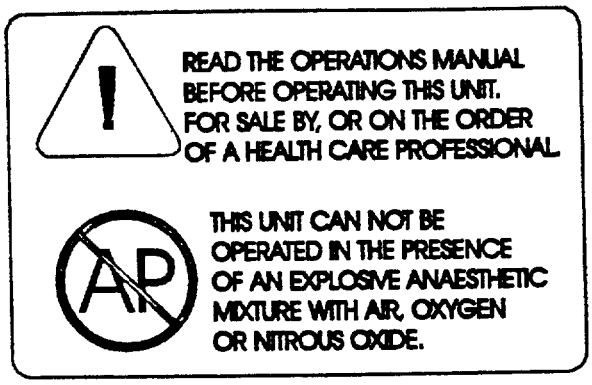
THIS PRODUCT TO ONLY BE USED FOR LAPAROSCOPIC IRRIGATION. DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

Distributed by: SANESE MEDICAL CORPORATION
[illegible] NORTHWEST BLVD. COLUMBUS, OHIO [illegible] (614) 291-[illegible] FAX (614) 291-[illegible]

LABEL SIZE - 3.25 X 5.50
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE

ECN	REV	DESCRIPTION	DATE	DWN
SANESE MEDICAL		TITLE TFS3 - N- 3 WP CASE LABEL		
		PART NUMBER 10024	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE TFS3NWP .CDR	MDT	12/12/94

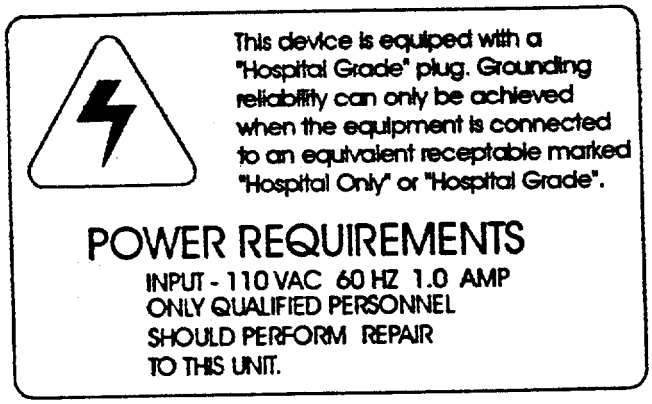
101



LABEL SIZE 1.90 X 3.00
CORNER RADII - .100
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACGROUND COLOR- WHITE
RED COLOR- PANTONE 032 RED
YELLOW COLOR - PANTONE YELLOW CV

ECN	REV	DESCRIPTION	DATE	DWN
SANESE MEDICAL		TITLE AP WARNING LABEL		
		PART NUMBER 10012	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE APWARN.CRD	MDT	12/12/94

100

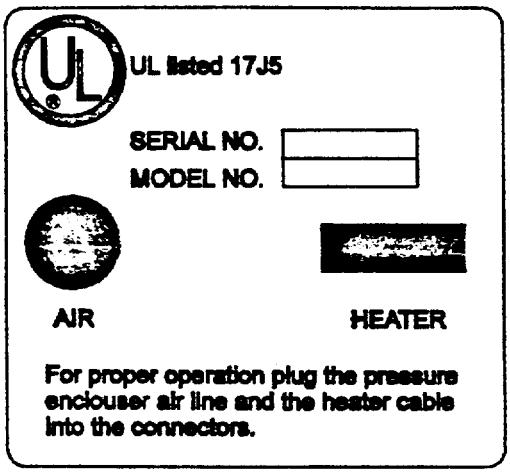


LABEL SIZE 2.00 x 3.60
CORNER RADII - .100
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE
YELLOW COLOR - PANTONE YELLOW CV

ECN	REV	DESCRIPTION	DATE	DWN

SANESE MEDICAL	TITLE: POWER CORD WARNING LABEL		
	PART NUMBER: 10013	DWN	DATE
SHEET 1 OF 1 / SCALE: FULL	FILE: POWER.CRD	MDT	12/12/94

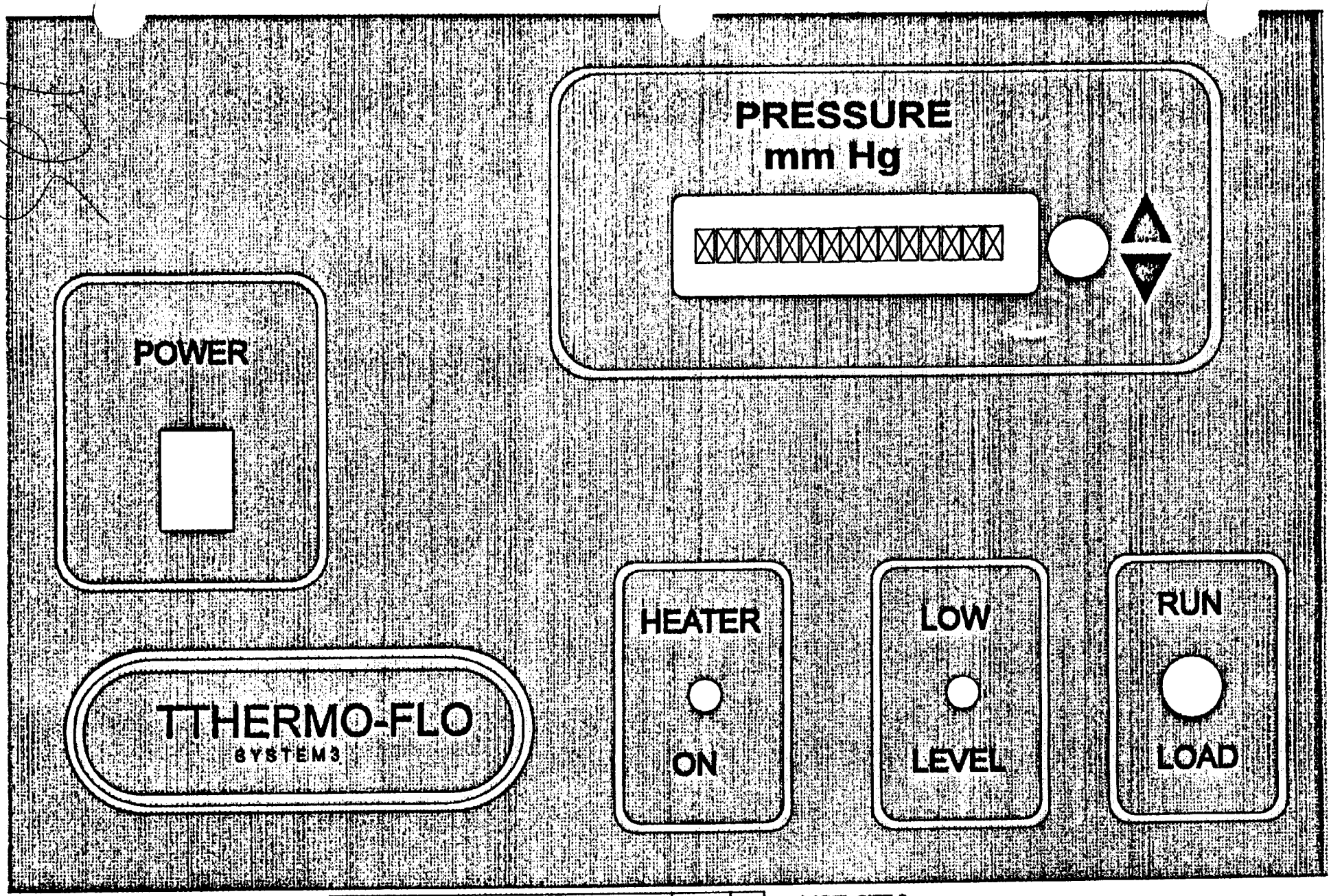
103



LABEL SIZE - 2.40 X 2.60
CORNER RADII - .100
UL PDQ2 SPECIFICATIONS
TEXT COLOR- BLACK
BACKGROUND COLOR- WHITE
RED - PANTONE S 73 -1

ECN	REV	DESCRIPTION	DATE	DWN

SANESE MEDICAL		TITLE CONNECTIONS LABEL		
		PART NUMBER 10025	DWN	DATE
SHEET 1 OF 1	SCALE FULL	FILE CONN .CDR	MDT	12/12/94



ECN	REV	DESCRIPTION	DATE	DWN

SANESE MEDICAL	TITLE: FRONT PANEL LABEL		
	PART NUMBER: 10014	DWN	DATE
SHEET 1 OF 1	SCALE: FULL	FILE: FRONT.CRD	MDT	12/12/94

LABEL SIZE 2
OFF-SET COLOR PROCESS
PDQ2 NOT REQUIRED
TEXT COLOR- BLACK
GREEN SHADES TBD PANTONE COLORS

Safety Precautions

Symbol Explanations

READ THE OPERATIONS MANUAL BEFORE OPERATING THIS UNIT.
FOR SALE BY, OR ON THE ORDER OF A HEALTH CARE PROFESSIONAL.

THIS UNIT CAN NOT BE OPERATED IN THE PRESENCE
OF AN EXPLOSIVE ANAESTHETIC MIXTURE WITH AIR, OXYGEN
OR NITROUS OXIDE.

Only qualified personnel should preform repair to this unit.
This unit requires a power input of - 110 VAC 60 HZ 1.0 AMP
This device is equiped with a "Hospital Grade" plug. Grounding
reliability can only be achieved when the equipment is connected
to an equivalent receptable marked"Hospital Only" or "Hospital Grade".

Use only with TFS 3 irrigation tube sets. These sets are equiped with
lock and pierce components for the safe operation of the device. Never
use parts from another manfacturer's unit even though they appear to fit.

Never sevice device while it is plugged into an outlet.

Never sevice device near water.

This device is designed to be operated from a power
indicated on the marking label.

Do not overload wall outlets or use extension cords.

Do not allow anything to rest on the power cord or locate
this product where the cord will abused by pearsons or
equipment moving on or near the cord.

This device is a Class II, Type B device.

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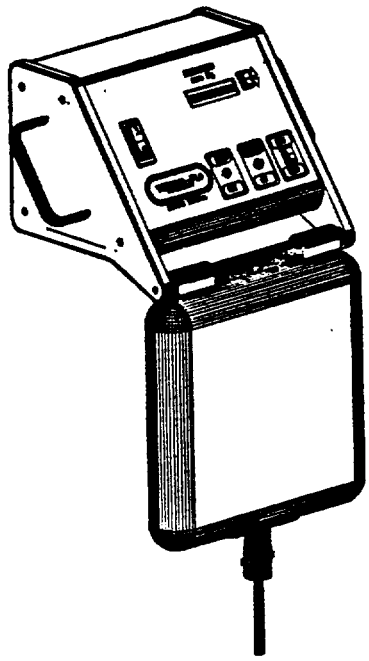
SANESE MEDICAL

THERMO-FLO SYSTEMS

IRRIGATION PUMP SYSTEM



The Thermo-Flo System 3 was developed to eliminate the major problems faced everyday by the surgeons and O.R. unit Mangers. These are cross contamination, indavertent patient hypothermia, inadequate irrigation solution capacity , ease of set up, tube sets and disposable probes that leak, noise and physical space. Sanese Medical anwers these problems with the Thermo-Flo System 3.

1) CROSS CONTAMINATION occures when non sterile fluid enters the patient's abdominal cavity through the irrigation line. The Thermo - Flo System 3 eliminates cross contamination.

2) INADVERTENT PATIENT HYPOTHERMIA is the result of the combination of gas and fluids ranging in temperature from 65 to 72 degrees farenhite being introduced into the patient. The Thermo - Flo System can maintian the solution temperature at 100 degress farenhite. Though this system alone cannot prevent hypothermia, it will dramatically effect the reduction of the core temperature due to existing conditions of surgery.

3) SOLUTION CAPACITY / EASE OF SET UP
The Thermol - Flo System 3 meets the liter needs of the todays and tomorrows laparoscopic procedures. This amount provides less disruption of the procedure, by not replacing the solution , cap and tube inserts that promotes the inadvertent contamination by the person replacing the solution as often.

KEY ADVANTAGES OF THE THERMOL-FO SYSTEM 3
* Delivers a strong stream of irrigation fluid
*No capital equipment necessary
*Choice of disposable of reuseable probe
*Simplified O.R. set up / I.V.
*Avoids Equipment purchase
*Quite operation
*24 hour , 7 days a week service available

THERMO-FLOW SYSTEM 3 PRODUCT LINE

1) The Thermo-Flo System 3 Irrigation Pump.....TFS3 - one per case

2) TFS3-3WP Tube Set with Dispoable Probe.....TFS3-3WP one per case

3) TFS3-3WOP Tube Set with out Probe .....TFS3-3WOP one per case

4) TFS3-N-3WP Tube Set with Disposable Probe.....TFS3-N-3WP 10 per case

5) TFS3-n-3WP Tube set with out Probe.....TFS3-N-3WOP 10 per case

All Tube Sets are 15' with Aspiration line included

SANESE MEDICAL
CORPORATION
[illegible]

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SPECIFICATIONS *Model TFS3 **

Power

120 v ac 1 AMP or 220 V AC .5 AMP 50/60 Hz
(95 to 250 V AC to 63 Hz)

Weight

7 lbs. (with out stand)

Pressure Range

100 mm Hg to 800 mm Hg + or - 10 mm Hg

Heater Temperature

The heater is preset to 100 F° + or - 2 F°
Safety Shutdown Temperature- 105 F°.

Maximum Leakage Current

Control Unit - 100 micro amps. (per UL 544)
Pressure Enclosure - 10 micro amps. (per UL 544)

Maximum Ground Impedance - 0.1 ohm (per UL 544)

Fuse : Slow Blow 2.0 amp. (Located on the back of control unit)

Environmental Operating Conditions

40 F° to 150 F°, Humidity non-condensing

* U. S. and International patent pending
Specification subject to change without notice.

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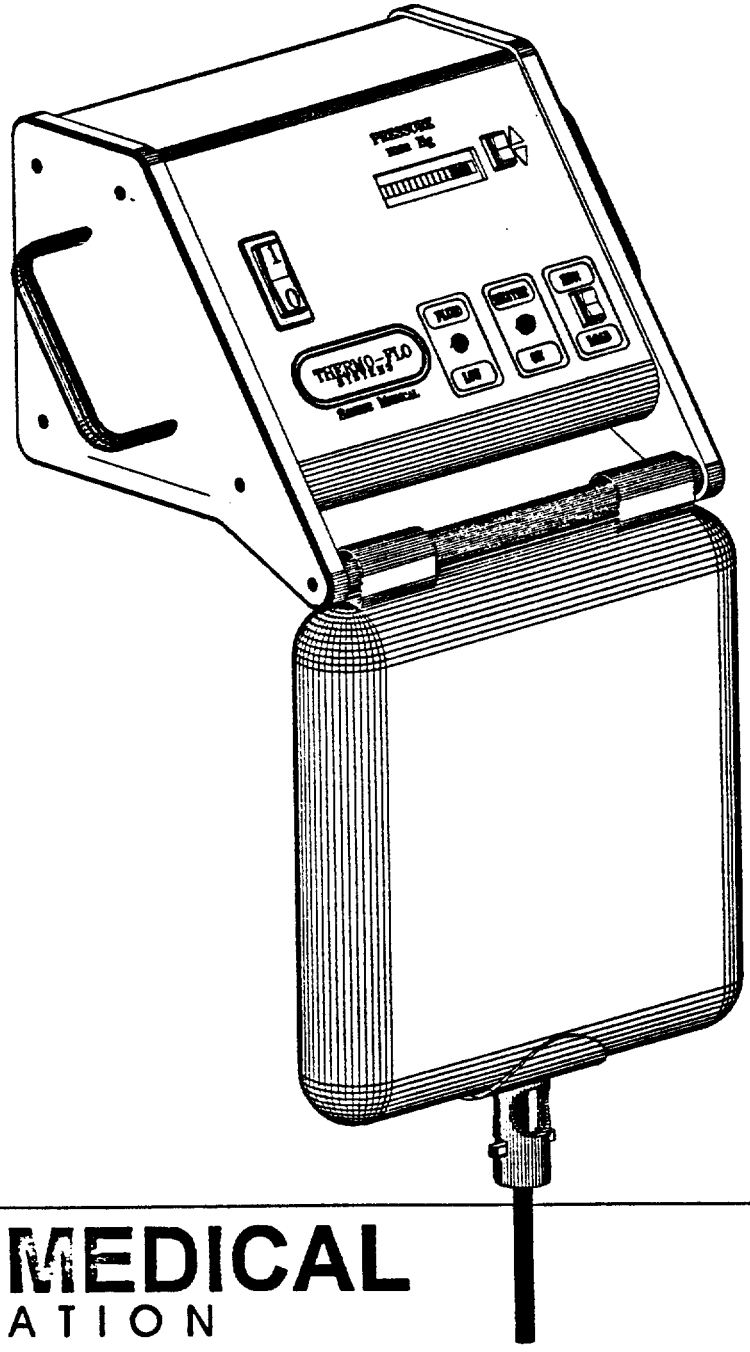
DESCRIPTION OF OPERATION

The controller is plugged into the wall outlet. The power switch is turned on and the LOAD/RUN switch is placed in the LOAD position. A fresh preheated bag of irrigation fluid is placed in the pressure enclosure.
The irrigation bag is connected to the tubing set/probe through the stick fittings which protrude through a opening in the bottom of the pressure enclosure. The LOAD/RUN switch is placed in the run position.
When the power is first turned on the pressure setpoint will need to be set. The heater automatically comes on and goes to a set temperature of 100 F°. The heater is design to maintain the temperature of the irrigation fluid.
The user then depresses the fluid control valve on the probe to obtain irrigation fluid. After a time the FLUID LOW light will come on indicating that the level is low in the irrigation fluid bag.
When the bag becomes empty move the LOAD/RUN switch load position and replace the empty bag with a fresh bag of irrigation fluid.
The machine will remain on the last settings until they are changed by the user.

IRRIGATION PUMP SYSTEM

THERMO-FLO

SYSTEM 3



SANESE MEDICAL

CORPORATION

The new Thermo-Flo System 3 was developed to eliminate the major problems faced everyday by the surgeon and the O.R. unit manger.

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OPERATING THE TFS3 IRRIGATION SYSTEM

DESCRIPTION OF THE CONTROLS

Power Switch: The power switch is located on the front panel. It contros the power to unit.

Pressure Adjust Switch: Located to the right of the displays a three position rocker switch which is used to adjust the pressure. The center position is off . The top position (up arrow) and bottom position (down arrow) are momentary. Pressing the UP arrow increases the pressure. Pressing the bottom (down arrow) will decrease the pressure.

Load/Run Switch: This switch is a two position rocker. When the switch is set to the Load position the device will drop the air pressure in the Pressure Enclosure so the bag can be reloaded. When the switch is in the Run position the Pressure Enclosure will inflate to the set point on the display.

Display : The display is a 16 character single line LCD.

Low Fluid LED: The is a panel light on the front panel that indicates when the fluid level is low and prompts the user to prepare a new bag of solution.

Heater On LED: This is a panel light that indicates when the heater is on. If this light is not on the heater is not maintaining the Pre-set temperature of 100° F.

Air Connector: On the Back of panel of the unit a Colder Connector which plugs into a mating connector on the Pressure Enclosure.

Heater Electrical Connector: On the back panel of the controller is located a connector used to electrically connect the heater and the temperature sensor to the controller.

DEPARTMENT OF HEALTH AND HUMAN SERVICES | Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 15, 1994

SANESE MEDICAL CORPORATION
885 NORTHWEST BLVD.
COLUMBUS, OH 43212
ATTN: CHRISTOPHER N. SANESE

510(k) Number: K941507
Product: THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC

Extended Until: 17-FEB-95

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

12-9-94

Colin M. Pollard
Food and Drug Administrarion
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RE:K941507 / A
Thermo - Flo System 3
Dated: July 5, 1994
Received: July 6

Dear Mr. Pollard,

This letter is to formally request a 60 day extension of our Decmber 17, delivery compliance as requested in your letter of November 17, 1994.

This letter is a follow up to the verbal request made of Donna -Bea Tillman in our phone conversation of December 5, 1994.

Thank you very much for your consideration of this request.

Sincerely,

Christoher N. Sanese
Regulatory Corespondent
SANESE MEDICAL CORPORATION

ENC: 4 pages

CNS/lll

CC: John Jevicky, Esq.
DINSMORE & SHOHL

1555

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848/FAX (614) 291-1389

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Mr. Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, Ohio 43212

NOV 17 1994

Re: K941507/A
Thermo-Flo System 3
Dated: July 5, 1994
Received: July 6, 1994

Dear Mr. Sanese:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided.

[redacted] (b)(4) [redacted]

(b)(4) Trade Secret Process - Product Specification

[redacted]

7514

(b)(4) Trade Secret Process - Product Specification

[redacted]

(b)(4) Trade Secret Process - Product Specification

[redacted]

136

bcc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

DBTillman
C:\WP51\FILES\K941507.AI
Draft 11-15-94 ens

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Mr. Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, Ohio 43212

Re: K941507/A
Thermo-Flo System 3
Dated: July 5, 1994
Received: July 6, 1994

Dear Mr. Sanese:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided.

(b)(4) Trade Secret Process - Product Specification [redacted] [redacted] [redacted]:

(b)(4) Trade Secret Process - Product Specification

[redacted]

138

(b)(4) Trade Secret Process - Product Specification

[redacted]

159

(b)(4) Trade Secret Process - Product Specification

[redacted]

140

bcc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

DBTillman
C:\WP51\FILES\K941507.AI
Draft 11-15-94 ens

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	Tillman	11/15/94						
Z-470	Pollard	11/16/94						

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: November 15, 1994

From: REVIEWER(S) - NAME(S) Donna-Bea Tillman

Subject: 510(k) NOTIFICATION K941507/S1

To: THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

__X__ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☒ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

__X__ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class: _____

Additional Product Code(s) w/Panel (optional): _____

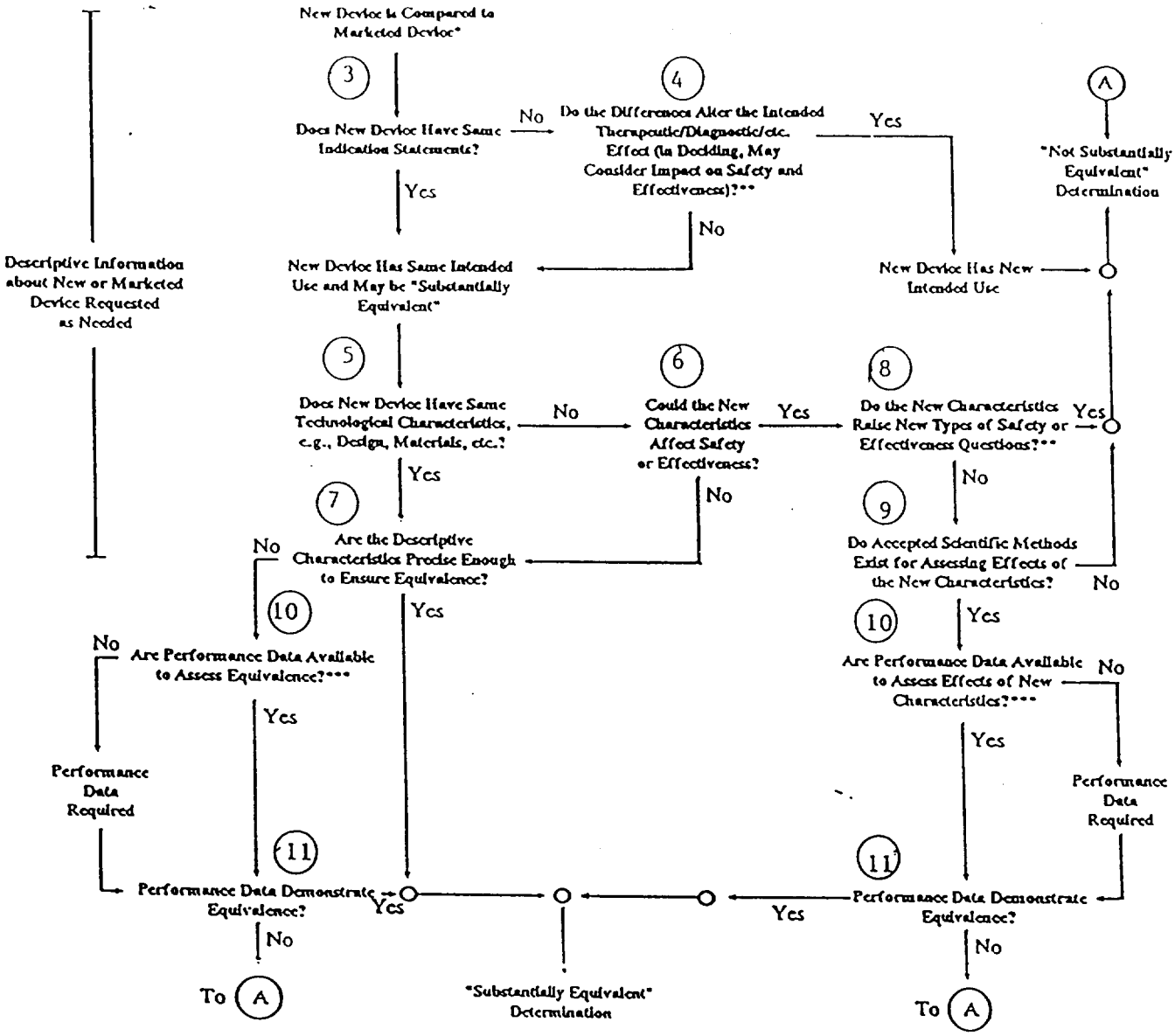
REVIEW: Colin M Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 11/16/94 (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) _____ (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

OGDB

K941507/A

Reviewer: *Donna-Bea Tillman*
Biomedical Engineer

Division/Branch: DRAERD/ADOU/OGDB (HFZ-470)

Proprietary Trade Name: Thermo-Flo System 3
Common Name: Laparoscopic Irrigator

Product to which compared: Cabot Niagra High-Flow Irrigator (K924530)

Applicant: Sanese Medical Corporation
885 Northwest Blvd
Columbus, OH 43212

Contact: Christopher N. Sanese, Regulatory Correspondent
Phone: (614) 291-8848

DEVICE DESCRIPTION

1. *Intended Use:*

The Thermo-Flo System 3 is intended for irrigation/aspiration during laparoscopic surgery (Note: In a October 15, 1994, amendment, the firm withdrew its claims for hysteroscopy).

2. *Physical Description:*

	YES	NO
· Is the device life-supporting or life sustaining?	—	X
· Is the device implanted (short-term or long-term)?	—	X
· Does the device design use software?	X	—
· Is the device sterile?	—	X
· Is the device single use?	—	X
· Is the device home use?	—	X
· Is the device for prescription?	X	—
· Does the device contain a drug or biological product as a component?	—	X
· Is this device a kit?	—	X

(b)(4) Trade Secret Process - Product Specification

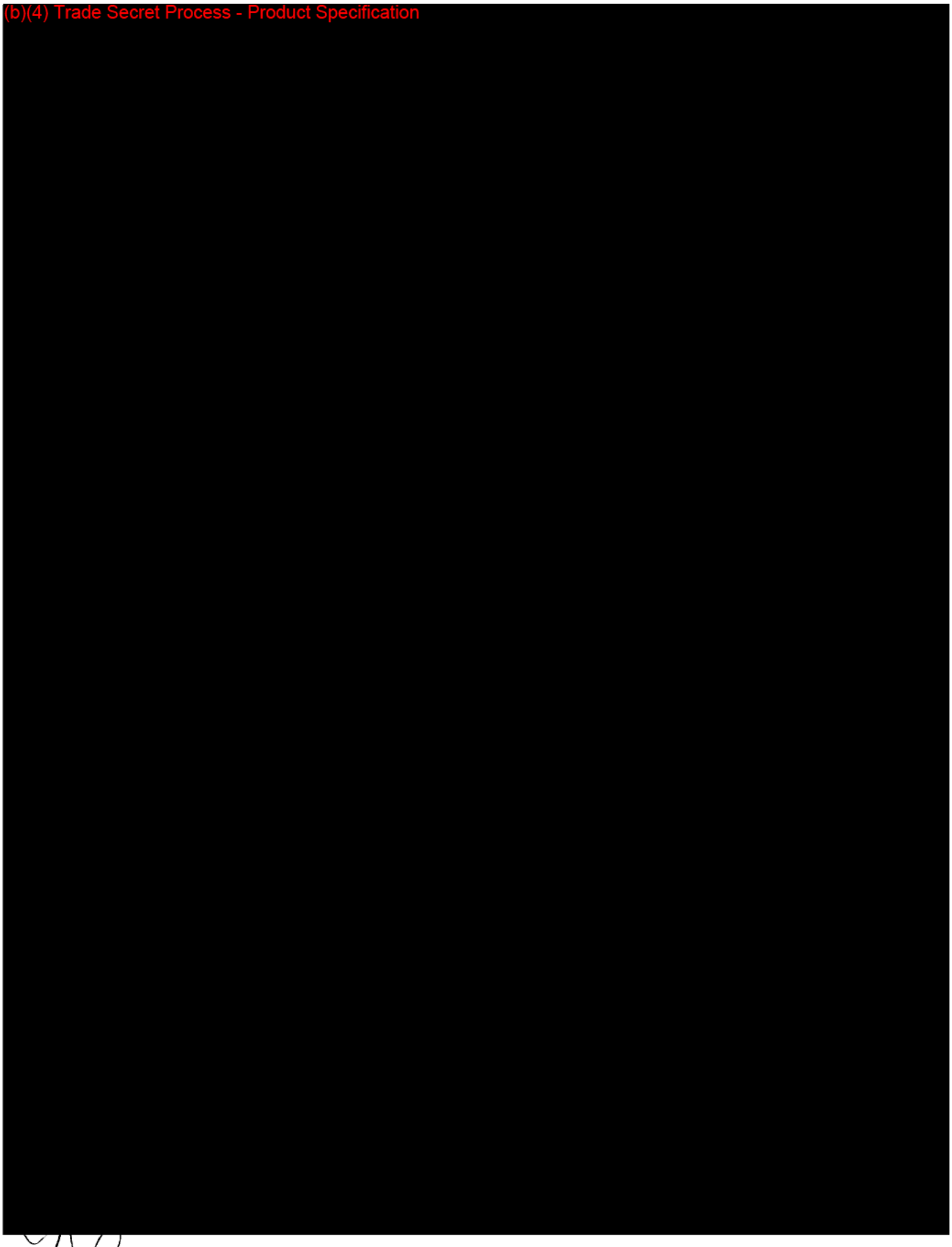
[redacted]

REVIEW ANALYSIS

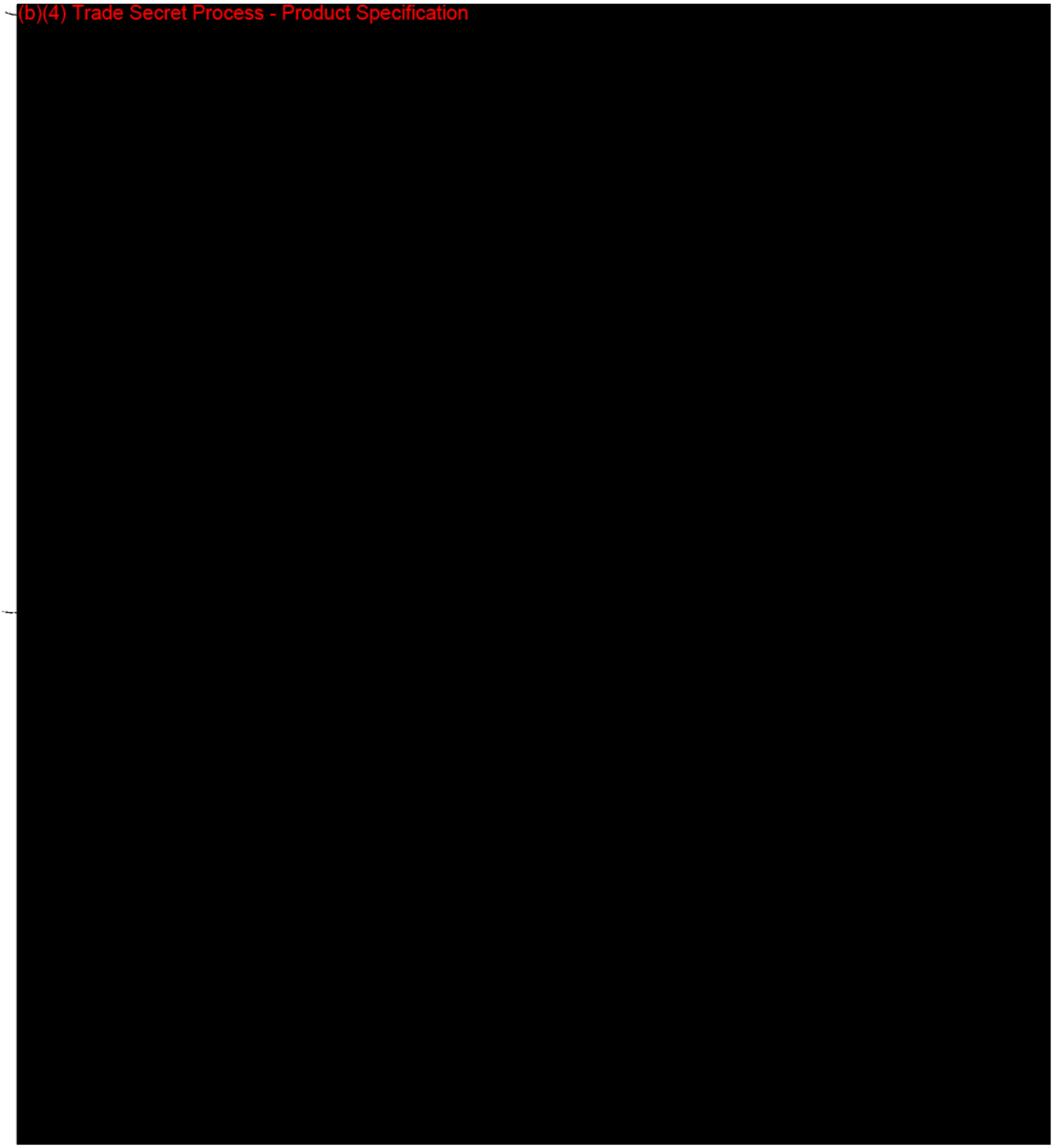
(b)(4) Trade Secret Process - Product Specification

[redacted]

(b)(4) Trade Secret Process - Product Specification



(b)(4) Trade Secret Process - Product Specification



· *Labeling*

The Operator's manual does not contain indications for use, contraindications, or warnings. In addition, the cleaning instructions: "Do not use abrasive cleaning and disinfecting solutions" are inadequate.

x. Please modify your labeling to include specific indications for use, contraindications, warnings, and detailed cleaning instructions.

REVIEWER RECOMMENDATION

Hold for Additional Information

Donna-Bea Tillman 11/15/94
Donna-Bea Tillman Date

Colin M. Pollard 11/16/94
Colin M. Pollard
Chief, Ob/Gyn Devices Branch Date

/✓/ Concur
/ / Do not concur.
Comments:

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DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

Date: October 11, 1994

BETWEEN: Donna-Bea Tillman

AND: Christopher Sanese

TITLE: Regulatory Agent

COMPANY: Sanese Medical

PHONE NUMBER: 614-291-8848

FAX NUMBER:

DOCUMENT NUMBER: K941507

SUMMARY:

(b)(4) Trade Secret Process - Product Specification

[redacted]

Signed: Donna Bea Tillman

Original to: K941507
Copy to: dbtlog

149

K941507/A2

SANESE MEDICAL
CORPORATION
MANUFACTURER OF MEDICAL PRODUCTS

Mr. Collin Pallard/Ms. Donna B. Tillman
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

October 15, 1994

*RE: K941507_*
Thermo-Flo System 3
Laparoscopic/Hysteroscopic
Irrigation System and
Disposable Irrigation/
Aspiration Probe and Tubing
Dated: March 18, 1994

VIA FAX & FEDERAL EXPRESS

Dear Mr. Pallard & Ms. Tillman

(b)(4) Trade Secret Process - Product Specification

[redacted]

Respectfully,

Christopher N. Sanese
REGULATORY AGENT

150

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848/FAX (614) 291-1389

LOT NO. 0300

THERMO-FLO
SYSTEM 3

CONTENTS:

1 - MODEL TFS3 LAPAROSCOPIC IRRIGATION SYSTEM

INDICATED FOR IRRIGATION DURING LAPAROSCOPIC PROCEDURES

Distributed by: SANESE MEDICAL CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

CAUTION: Federal (U.S.A.) Law restricts this device to the sale by, or on the order of a physician.

NON - STERILE: RECOMMENDED FOR LAPAROSCOPIC IRRIGATION IN ADULT AND PEDIATRIC SURGERY

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OPERATIONS MANUAL

THERMO-FLO
SYSTEM 3

LAPAROSCOPIC IRRIGATION SYSTEM

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SANESE MEDICAL
CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

SAFETY PRECAUTIONS

** USE ONLY WITH TFS 3 IRRIGATION TUBE SETS **

* Do not use in volatile atmosphere.

* Use only with 120 volt grounded receptacle.

* Do not immerse unit.

READ BEFORE ADJUSTING AND OPERATING UNIT

It is recommended that all O.R. Unit Managers and others responsible for the operation of this unit become thoroughly familiar with its capabilities and proper operating procedures prior to actual patient use.

PRODUCT DESCRIPTION

The **THERMO-FLO SYSTEM** 3TM* LAPAROSCOPIC IRRIGATION SYSTEM consists of the following components:

1 - **THERMO - FLO SYSTEM** 3TM control device

1 - **THERMO - FLO SYSTEM** 3TM pressure enclosure device

2 - Transportation pouch

153

CONTENTS: **MODEL NO. TFS3 - N 2WP**
1 - Single use, disposable 15' irrigation / aspiration tube set with probe

LOT NO. 0500
FOR SINGLE USE ONLY
CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGES.

INDICATED FOR IRRIGATION DURING LAPAROSCOPIC PROCEDURES

Distributed by: SANESE MEDICAL
CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

RECOMENDED FOR ADULT AND PEDIATRIC LAPAROSCOPIC SURGERY

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

THIS PRODUCT TO ONLY BE USED FOR LAPAROSCOPIC IRRIGATION.
DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

154

CONTENTS: **MODEL NO. TFS3 - 3 WOP**
1 - Single use, disposable 15' irrigation / aspiration tube set.

LOT NO. 0500
FOR SINGLE USE ONLY
CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGES.

INDICATED FOR IRRIGATION DURING LAPAROSCOPIC PROCEDURES

Distributed by: SANESE MEDICAL
CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

RECOMENDED FOR ADULT AND PEDIATRIC LAPAROSCOPIC SURGERY

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

THIS PRODUCT TO ONLY BE USED FOR LAPAROSCOPIC IRRIGATION.
DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

155

CONTENTS: **MODEL NO. TFS3 - 3 WP**

1 - Single use, disposable 15' irrigation / aspiration tube set with probe

LOT NO. 0500

FOR SINGLE USE ONLY

CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGES.

INDICATED FOR IRRIGATION DURING LAPAROSCOPIC PROCEDURES

Distributed by: SANESE MEDICAL CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

RECOMENDED FOR ADULT AND PEDIATRIC LAPAROSCOPIC SURGERY

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

THIS PRODUCT TO ONLY BE USED FOR LAPAROSCOPIC IRRIGATION.
DO NOT USE FOR HYSTEROSCOPIC DISTENTION.

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USAGE RECOMMENDATION

The ***THERMO-FLO SYSTEM*** *3*TM was designed for Laparoscopic surgery and is only to be used by licensed, certified surgical personnel.

RECOMMENDED CARE

Do not leave unit plugged in.
Do not use abrasive cleaning and disinfecting solutions.

LIMITED WARRANTY

Sanese Medical Corporation ("Sanese") warrants the **THERMO-FLO SYSTEM** 3 TM to be free from defects in material and workmanship for a period of one (1) year from date of initial purchase. No warranty shall apply if the goods have been damaged by accident, abuse, misuse, or misapplication, or as a result of service or modification by other than a person authorized by Sanese. Sanese's liability under this warranty, and buyer's exclusive remedy is limited to the cost of materials and labor to repair defective goods, or to their replacement, and in no event shall exceed the purchase price. Repair or replacement of defective goods under warranty will be made only upon their return to Sanese after notice to Sanese and Buyer's receipt of shipping instructions. Upon receipt of goods returned under warranty, Sanese will inspect the goods, will notify buyer of the extent of repair or replacement which Sanese will perform under warranty, which shall be conclusive of Sanese's liability.

Sanese is not responsible for incidental consequential damages resulting from the breach of any expressed or implied warranty, including damage to property and to the extent permitted by law, damages for personal injury. The warranty contained herein is in lieu of all warranties, expressed or implied. No statement of any representative shall extend Sanese's liability as herein established or limited.

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SANESE MEDICAL
CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

FACSIMILE TRANSMISSION

301-594-2359 **9 pages**

ATTENTION:

Mr. Collin Pallard / Ms. Donna B. Tillman
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

October 15, 1994

510(k) Number:K941507
Received: 29-Mar-94
Product:
Thermo-Flo System 3
Laparoscopic /Hysteroscopic

Christopher N. Sanese
Regulatory Correspondent

886 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848/FAX (614) 291-1389

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SANESE MEDICAL
CORPORATION
MANUFACTURER OF MEDICAL PRODUCTS

Mr. Collin Pallard/Ms. Donna B. Tillman
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

October 15, 1994

RE: K941507
Thermo-Flo System 3
Laparoscopic/Hysteroscopic
Irrigation System and
Disposable Irrigation/
Aspiration Probe and Tubing
Dated: March 18, 1994

VIA FAX & FEDERAL EXPRESS

Dear Mr. Pallard & Ms. Tillman

(b)(4) Trade Secret Process - Product Specification

[redacted]

Respectfully,

Christopher N. Sanese
REGULATORY AGENT

005 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-9818/FAX (614) 291-1389

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(b)(4) Trade Secret Process - Draft Label

(b)(4) Trade Secret Process - Draft Label

(b)(4) Trade Secret Process - Draft Label

(b)(4) Trade Secret Process - Draft Label

OPERATIONS MANUAL

THERMO-FLO
SYSTEM 3

LAPAROSCOPIC IRRIGATION SYSTEM

1601

SANESE MEDICAL
CORPORATION

SAFETY PRECAUTIONS

** USE ONLY WITH TFS 3 IRRIGATION TUBE SETS **

* Do not use in volatile atmosphere.

* Use only with 120 volt grounded receptacle.

* Do not immerse unit.

READ BEFORE ADJUSTING AND OPERATING UNIT

It is recommended that all O.R. Unit Managers and others responsible for the operation of this unit become thoroughly familiar with its capabilities and proper operating procedures prior to actual patient use.

PRODUCT DESCRIPTION

The **THERMO-FLO SYSTEM** 3TM* LAPAROSCOPIC IRRIGATION SYSTEM consists of the following components:

1 - **THERMO - FLO SYSTEM** 3TM control device

1 - **THERMO - FLO SYSTEM** 3TM pressure enclosure device

2 - Transportation pouch

*U. S. and International patent pending

SANESE MEDICAL
CORPORATION
685 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

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USAGE RECOMMENDATION

The ***THERMO-FLO SYSTEM*** 3TM was designed for Laparoscopic surgery and is only to be used by licensed, certified surgical personnel.

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Sanese is not responsible for incidental consequential damages resulting from the breach of any expressed or implied warranty, including damage to property and to the extent permitted by law, damages for personal injury. The warranty contained herein is in lieu of all warranties, expressed or implied. No statement of any representative shall extend Sanese's liability as herein established or limited.

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SANESE MEDICAL
CORPORATION
995 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-2848 FAX (614) 291-1289

Hardcopy

SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

K941507/A1

Mr. Collin Pallard
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

August 10, 1994

RE: K941507
Thermo-Flo System 3
Laparoscopic/Hysteroscopic
Irrigation System and
Disposable Irrigation/
Aspiration Probe and Tubing
Dated: March 18, 1994

VIA FAX & REGULAR MAIL

Dear Mr. Pallard,

Here is the additional information you requested regarding the distal tip of the probe.

The material for the distal tip of the probe will be AISI stainless steel type 304 (for disposable) & 316 (for reusable). The Tube set with and with out probe will be sterilized via gamma radiation as determined by AAMI method 1 or 2.5 MRads, which ever is greater, with a Sterility Assurance level of 10^{-6}.

Thank you for your time and efforts, it is greatly appreciated.

Sincerely,

Christopher N. Sanese
Regulatory Correspondent

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885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848/FAX (614) 291-1389

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

July 07, 1994

SANESE MEDICAL CORPORATION
885 NORTHWEST BLVD.
COLUMBUS, OH 43212
ATTN: CHRISTOPHER N. SANESE

510(k) Number: K941507
Product: THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

K941507/S

Mr. Collin Pallard
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

July 5, 1994

RE: K941507
Thermo-Flo System 3
Laparoscopic/Hysteroscopic
Irrigation System and
Disposable Irrigation/
Aspiration Probe and Tubing
Dated: March 18, 1994

Dear Mr. Pallard,

(b)(4) Trade Secret Process - Product Specification

[redacted]

Sincerely,

Christopher N. Sanese
Regulatory Correspondent

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885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848/FAX (614) 291-1389

SANESE MEDICAL CONTROLLED DOCUMENT
Title: Verification/Validation description - System 3 pump
Written: K.A. Kelly
Last Revised on ECN: N/A

No: eo001-03Rev A
Page: 1 of 2
Releasd: 6/28/94

b(4)Trade Secret Process-Product Specs

[redacted]

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b(4)Trade Secret Process-Product Specs

[redacted]

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b(4)Trade Secret Process-Product Specs

[redacted]

172

b(4)Trade Secret Process-Product Specs

[redacted]

b(4)Trade Secret Process-Product Specs

[redacted]

b(4)Trade Secret Process-Product Specs

[redacted]

b(4)Trade Secret Process-Product Specs

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUN - 7 1994

Mr. Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, Ohio 43212

Re: K941507
Thermo-Flo System 3, Laparoscopic/ Hysteroscopic Irrigation System and Disposable Irrigation/Aspiration Probe and Tubing
Dated: March 18, 1994
Received: March 29, 1994

Dear Mr. Sanese:

We have conducted an administrative review of your Section 510(k) notification of intent to market the device referenced above. This administrative review is part of a pilot screening program in the Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices (DRAERD). Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold. We believe that basic information is necessary for us to begin our technical review and to determine whether or not this device is substantially equivalent to a legally marketed device with regard to its safety and effectiveness. In order for us to begin the technical review of your submission, we require the information indicated on the enclosed DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist. An explanation of each of the items on the Checklist is enclosed. Also enclosed for your information is a copy of the Office of Device Evaluation's (ODE) "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)" flow-chart, and a copy of the DRAERD Draft Guidance for the Content of Premarket Notifications. Since your 510(k) premarket notification has not been technically reviewed, additional information may be required during the review process and the file may again be placed on hold.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

You may not market this device until you have provided adequate information as required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, or comments/questions concerning this DRAERD pilot screening program, please contact Robert Gatling at (301) 594-1220. If you need information or assistance concerning the IDE or other regulations or copies of guidance documents, please contact the Division of Small Manufacturers Assistance at their toll free number 1-800-638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

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510(K) ROUTE SLIP

510(k) NUMBER K941507 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC SYSTEM

COMMON NAME LAPAROSCOPIC IRRIGATION PUMP SYSTEM

PRODUCT CODE ___

APPLICANT SANESE MEDICAL CORPORATION
SHORT NAME SANEMEDI
CONTACT CHRISTOPHER N SANESE
DIVISION
ADDRESS 885 NORTHWEST BLVD.
COLUMBUS, OH 43212
PHONE NO. (614) 291-8848 FAX NO. (___) ___-____

MANUFACTURER SANESE MEDICAL CORPORATION REGISTRATION NO.

DATE ON SUBMISSION 16-MAR-94 DATE DUE TO 510(K) STAFF 12-JUN-94

DATE RECEIVED IN ODE 29-MAR-94 DATE DECISION DUE 27-JUN-94

DECISION __ DECISION DATE _____

CORRESPONDENCE	SENT	DUE BACK	
C001	06-JUN-94	06-JUL-94	HOLD LETTER

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Memorandum

Date June 2, 1994

From REVIEWER(S) - NAME(S) Donna-Bea Tillman

K941507

Subject 510(k) NOTIFICATION

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

X (C) Requires more data. Failed Checklist & have called the mfr. about this. cmp

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☒ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

X Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: Colin M. Pollard (BRANCH CHIEF) | HGDB (BRANCH CODE) | 6/6/94 (DATE)

FINAL REVIEW: Roberta for L Yin (DIVISION DIRECTOR) 6/6/94 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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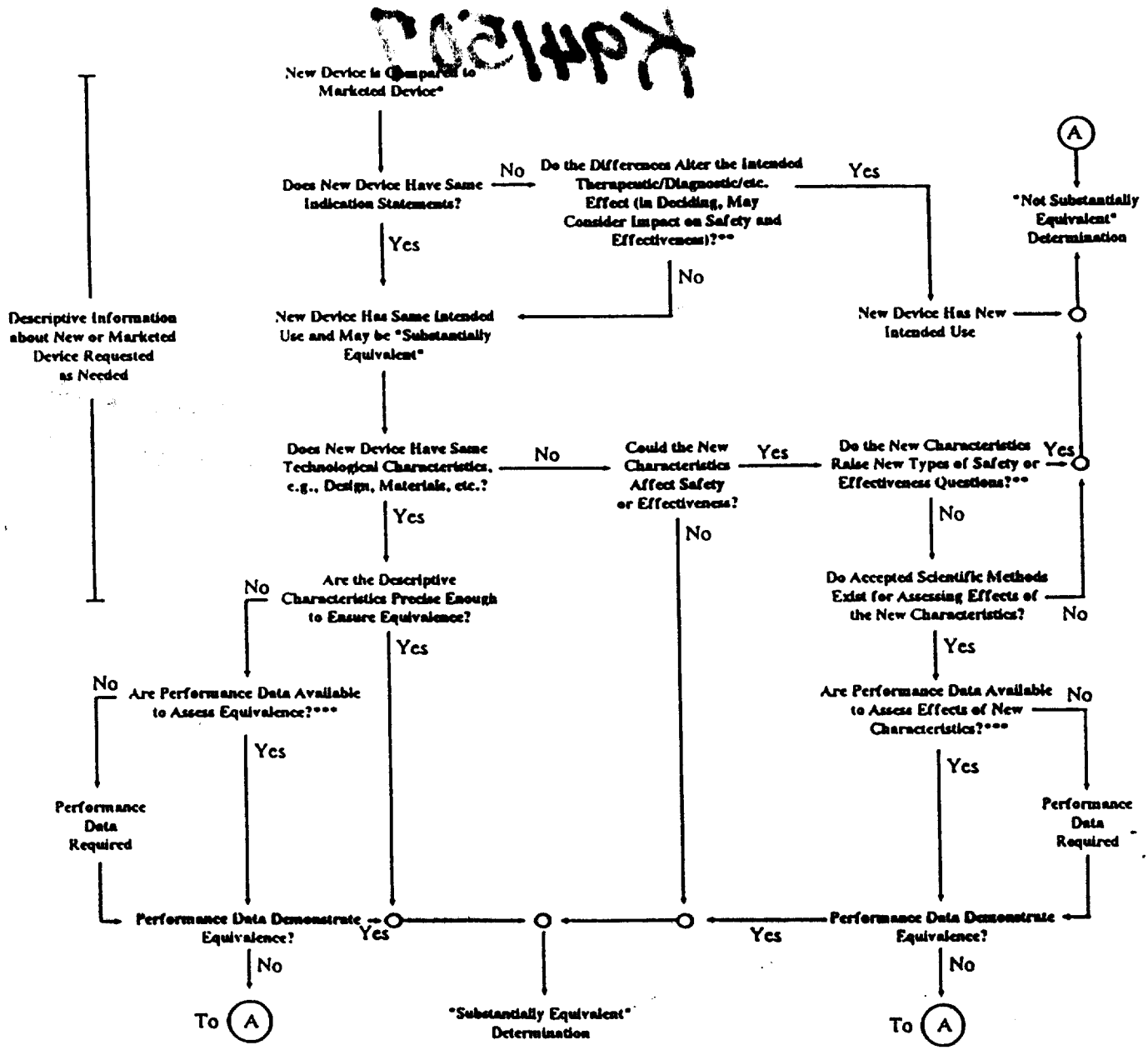
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

RRG/LLD 1/6/93
Rev. 3/30/94

DRAERD Premarket Notification 510(k)
Screening Checklist

510(k) Number &
Device Name K941507 Thermo-Flo System 3 Hysteroscopic/Laparoscopic Irrigation System and Disposable Irrigation/Aspiration Probe and Tubing
Company Sanese Medical Corp.

ITEM	PRESENT Yes	PRESENT No	NEEDED (Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	X	—	—
Reason for 510(k) - new device or modification	X	—	—
Identification of legally marketed equivalent device	X	—	—
2. Proposed Labeling, Labels, Advertisements	X	—	—
Description of new device/modification	X	—	—
Intended use statement	X	—	—
Diagrams, Engineering Drawings, Photographs	X	—	—
3. Comparison of similarities/differences to named legally marketed equivalent device	X	—	—
Equivalent Device Labeling, Labels, Advertising	X	—	—
Intended use of equivalent device	X	—	—
4. List of all patient contacting materials in new device	X	—	—
Comparison of materials to equivalent device	X	—	—
5. Biocompatibility information/data for patient[1] contacting materials, OR,	—	X	Y
Certification - identical material/formulation	—	X	—
6. Performance data: Bench data[2]	—	X	Y
Animal data	—	X	N
Clinical data	—	X	?
7. Sterilization information	X	—	—
8. Software validation & verification*	—	X	Y
*See attached guidance document			
9. 510(k) summary or statement	X	—	—
10. If Class III, Class III Certification & Summary	—	—	NA
11. If kit, kit certification	—	—	NA

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[1] **Biocompatability information**

(b)(4) Trade Secret Process - Product Specification

[redacted]

[2] **Performance data**

(b)(4) Trade Secret Process - Product Specification

[redacted]

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FOR REVIEWER'S USE ONLY

RRG 9/24/93

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL
Reviewer's Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: K941507 TIER (Circle) I / (II) / III

Expedited Review Requested: Y/(N) Granted: Y/(N) OR, FDA Identified Expedited: Y/(N)

ITEM	Yes	No
1. Is the product a device?	X	_
2. Is the device exempt from 510(k) by regulation or policy?	_	X
3. Are you aware that this device has been the subject of a previous NSE decision?	_	X
If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?	_	_
4. Are you aware of the submitter being the subject of an integrity investigation?	_	X
If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?	_	_
5. Is there a specific guidance document for this device or device issue(s)?	X	_

In addition, the following item is new to the 510(k) review process. It will not be counted as a screening deficiency since it is new and "unknown" to the industry. It should be identified as a deficiency and requested as part of the technical review. The Explanation of the DRAERD Screening Checklist has been modified to include this information.

6. Address of manufacturing facility/facilities, and if applicable, sterilization site(s).	X	_

Administrative Reviewer Signature: Dawn Tilbury Date: 6/2/94

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

April 08, 1994

SANESE MEDICAL CORPORATION
885 NORTHWEST BLVD.
COLUMBUS, OH 43212
ATTN: CHRISTOPHER N. SANESE

510(k) Number: K941507
Received: 29-MAR-94
Product: THEMO-FLO SYSTEM 3 LAPAROSCOPIC/HYSTEROSCOPIC

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
  510(k) Status Coordinator
  Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
  Center for Devices and Radiological Health, FDA
  5600 Fishers Lane
  Rockville, Maryland 20857 USA
  Because of staff limitations, we cannot answer telephone status requests.

- 510(k) status requests should include:
  (1) submitter's name and mailing address;
  (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

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(3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
  (1) the branch to which the 510(k) has been assigned;
  (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
  (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.**

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

____ fax
____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____

2. Sponsor's mailing address: _____

_____

_____

B. Requester information:

1. Request name: _____

2. Requester affiliation with sponsor: _____

3. Requester mailing address: _____

_____

_____

4. Request fax number (if applicable): _____

5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____

2. 510(k) number: _____

3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

I certify that the above information is accurate and truthful to the best of my knowledge.

(Rev:2) 1809

_____
Requester signature

SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

K941507

RECEIVED
29 Mar 94 13 06
FDA/CDRH/ODE/DMQ

OB

CLASS II DEVICE
PREMARKET NOTIFICATION

CONFIDENTIAL - 807.95(b, c)
CLAIMS MADE
DO NOT LOG IN PUBLICLY
AVAILABLE LOG

March 18, 1994

Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification of Sanese Medical Corporation's Intention to Market Its Thermo-Flo System 3 Laparoscopic/Hysteroscopic Irrigation System and Sanese Disposable Irrigation/Aspiration Probe and Tubing.

Dear Sir/Madam:

Pursuant to § 510(k)of the Food, Drug & Cosmetic Act, Sanese Medical Corporation (SMC) hereby submits premarket notification of its intention to market a laparoscopic/hysteroscopic irrigation pump system and disposable irrigation/aspiration probe and tubing. Enclosed is an original two copies of SMC's premarket notification for these devices.

Respectfully submitted,

Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
(614) 291-8848

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SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

PREMARKET NOTIFICATION
OF CLASS II
MEDICAL DEVICE

CONFIDENTIAL - 807.95(b, c)
CLAIMS MADE
DO NOT LOG IN PUBLICLY AVAILABLE
LOG

March 16, 1994

Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification of Sanese Medical Corporation 's Intention to Market its Thermo-Flo System 3 Laparoscopic/Hysteroscopic Irrigation System and Sanese Disposable Irrigation/Aspiration Probe and Tubing

Dear Sir/Madam:

I.

Premarket Notification of Intention to Market Laparoscopic/Hysteroscopic Irrigation System and Disposable Irrigation/Aspiration Probe and Tubing

Pursuant to 21 U.S.C. § 360(k) and 21 C.F.R. §§ 807.87 and 807.90, the Sanese Medical Corporation ("SMC") hereby submits premarket notification of its intention to market a Laparoscopic/ Hysteroscopic Irrigation System and Disposable Irrigation/Aspiration Probe and Tubing, which will be marketed under the proprietary names Thermo-Flo System 3™ and Sanese Disposable Irrigation/Aspiration Probe and Tubing.™ These are a Class II medical devices[1/] and are substantially equivalent in terms of safety and effectiveness to other laparoscopic irrigation pumps and aspiration probe and tubing devices currently on the market. (See Exhibits C and D.)

1/ See 21 C.F.R. §§ 884.1690 and 1720. See also 21 C.F.R. § 880.5475 (Jet Lavage) and 21 C.F.R. § 878.4780 (Powered Suction Pump).

II.

The Section 510(k) Summary of Safety and Effectiveness Information for SMC's Thermo-Flo System 3 Laparoscopic/ Hysteroscopic Irrigation System and Sanese Disposable Irrigation/Aspiration Probe and Tubing is attached as Exhibit A.

III.

Supporting Material and Information

A. Names of Devices:

(i) Proprietary Names:

(a) Thermo-Flo System 3 Laparoscopic/ Hysteroscopic Irrigation System®
(b) Sanese Disposable Irrigation/Aspiration Probe and Tubing™

(ii) Common, usual names:

(a) Laparoscopic irrigation pump system
(b) Disposable aspiration/irrigation probe and tubing.

(iii) Classification Names: Hysteroscope and Accessories and Gynecologic Laparoscope and Accessories, 21 C.F.R. §§ 880.1690 and 884.1720.

B. Regulatory Class:

Class II.

C. Actions Required for Compliance With Performance Standards: None. No standards have been promulgated to date.

D. Name and Address of Person Filing 510(k) Submission:

Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
(614) 291-8848

E. Regulatory Correspondent of Person Filing 510(k) Submission:

Christopher N. Sanese
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
(614) 291-8848

F. Registration Number of Device Manufacturer: The Company is not registered presently.

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(b)(4) Trade Secret Process - Product Specification

(b)(4) Trade Secret Process - Product Specification

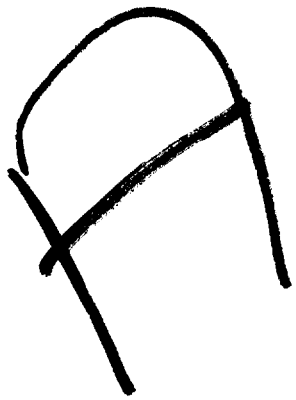
(b)(4) Trade Secret Process - Product Specification

(b)(4) Trade Secret Process - Product Specification

(b)(4) Trade Secret Process - Product Specification

(b)(4) Trade Secret Process - Product Specification

(b)(4) Trade Secret Process - Product Specification



SECTION 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION FOR SMC'S THERMO-FLO SYSTEM 3 LAPAROSCOPIC/ HYSTEROSCOPIC IRRIGATION SYSTEM AND SANESE DISPOSABLE IRRIGATION/ASPIRATION PROBE AND TUBING

Pursuant to Section 12(a) of the Safe Medical Devices Act of 1990, 21 U.S.C. § 360c(i)(3)A and 21 C.F.R. § 807.92, the following summary of information concerning the safety and effectiveness of SMC's Thermo-Flo System 3 Laparoscopic/Hysteroscopic Irrigation System and Sanese Disposable Irrigation/Aspiration Probe and Tubing is hereby submitted.

1. Name and address of device manufacturer submitting 510(k) notification:

   Sanese Medical Corporation
   885 Northwest Boulevard
   Columbus, OH 43212
   (614) 291-8848

2. Regulatory correspondent.

   Christopher N. Sanese
   Sanese Medical Corporation
   885 Northwest Boulevard
   Columbus, OH 43212
   (614) 291-8848

3. Date summary was prepared: March 17, 1994

4. Names of Devices:

   (i) Proprietary Names:

   (a) Thermo-Flo System 3 Laparoscopic/ Hysteroscopic Irrigation System®
   (b) Sanese Disposable Irrigation/Aspiration Probe and Tubing™

   (ii) Common, usual names:

   (a) Laparoscopic irrigation pump system
   (b) Disposable aspiration/irrigation probe and tubing.

   (iii) Classification Names: Hysteroscope and Accessories and Gynecologic Laparoscope and Accessories, 21 C.F.R. §§ 880.1690 and 884.1720.

5. Predicate devices to which SMC is claiming substantial equivalence:

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SMC claims substantial equivalence for purposes of section 510(k) only to:

A. Irrigation Pump System:

The Niagra™ High-Flow Irrigator System, 510(k) Number K924530 by Cabot Medical, 2021 Cabot Boulevard, West Langhorn, PA 19047 (800-523-6078).

B. Disposable Probe and Tubing:

(1) Probe:

Corson™ Disposable Suction Irrigation Probe by Cabot Medical, 2021 Cabot Boulevard, West Langhorn, PA 19047 (800-523-6078).

(2) Tubing:

Core Dynamics Inc. Disposable Irrigation/ Suction Tubing Set (510(k) Number K910246) by Core Dynamics, Inc., 9951 Atlantic Boulevard, Jacksonville, Florida 3225 (904-727-0910).

6. Description of the devices and primary principles of operation:

A. Description of irrigation pump system.

This device consists of a fabric enclosure (pressure envelope) in which a bag of irrigation fluid is placed. The fabric enclosure contains an inflatable bladder that is pneumatically inflated to pressurize the fluid in the irrigation fluid bag. Inflation of the bladder is provided by an air compressor which has a maximum voltage leakage current of 100 microamps. This complies with Underwriters Laboratory Standard 544.

The pressure envelope also contains a heating element to assist in maintaining the temperature of preheated irrigation solution while being used in the pressure envelope. There is also a thermal regulator to control the temperature of the heating element. The heating element and the thermal regulator are powered by an Underwriter Laboratory approved 24 volt electrical power supply.

The air compressor and heating element are controlled by a microcontroller. These components are controlled by the micro-controller through activating solid state switches which control electrical power to the pump, pump solenoids and the heater.

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The pressurized preheated fluid is then introduced into the endoscopic surgery site through a medical grade plastic tube and probe that are discussed below.

B. Description of disposable probe and tubing:

The probe consists of a medical grade plastic, activation valve and metal shaft that will deliver and aspirate fluids to and from an operative site.

The tubing consists of two 15 foot length medical grade surgical tubing that are approximately 10 millimeters in diameter which would be connected to the probe and the irrigation solution bag and the pump when used for irrigation or to the probe and the suction unit when used for aspiration. The probe and tubing are made of medical grade plastic and metal that have been determined by FDA to be safe and effective for this intended usage.

C. Primary Principles of Operation:

(i) Irrigation Pump System:

The primary principles of operation are pressurization through an electrically powered pneumatic compressor for pressurized irrigation fluid flow and thermal transfer through an electrically-powered thermo-conducted heat transfer unit to maintain preheated fluid.

(ii) Probe and Tubing:

With respect to the aspiration/irrigation use of the probe and tubing, the principle operation is vacuum and pressurization.

7. Statement of the purpose for which the device will be recommended:

These devices are intended to be used for irrigation and aspiration during adult and pediatric hysteroscopic or laparoscopic (endoscopic) surgery.

8. Biocompatibility and effectiveness of the device:

(i) Biocompatibility:

The only aspect of the device that comes in contact with the patient is the distal end of the probe. The probe and the probe tubing have been subject to biocompatibility tests and are safe and effective for such usage. The irrigation pump has a maximum voltage

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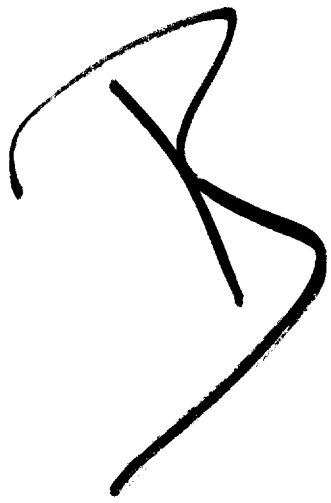
leakage current of 100 microamps in accordance with U.L. Standard 544. Performance tests of the pump demonstrate that it is safe and effective for its intended use. Also, all components of the pump meet U.L. Standards.

Respectfully submitted,

Christopher N. Sanese
Regulatory Correspondent
Sanese Medical Corporation
885 Northwest Boulevard
Columbus, OH 43212
(614) 291-8848

705



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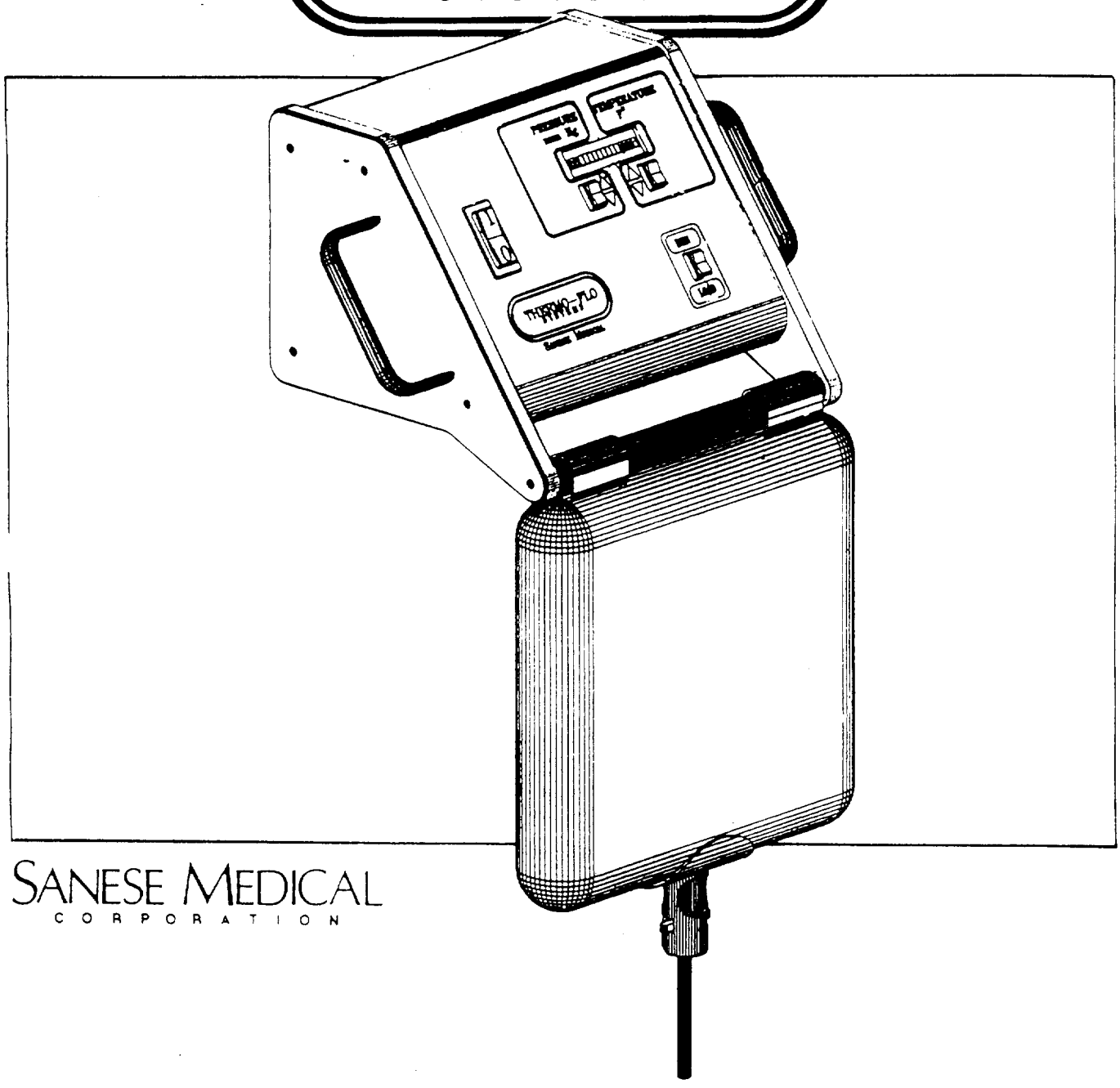
IRRIGATION PUMP SYSTEM

THERMO-FLO
SYSTEM 3



SANESE MEDICAL
CORPORATION

The new **Thermo-Flo System 3** was developed to eliminate the major problems faced everyday by the surgeon and o.r. unit manager.

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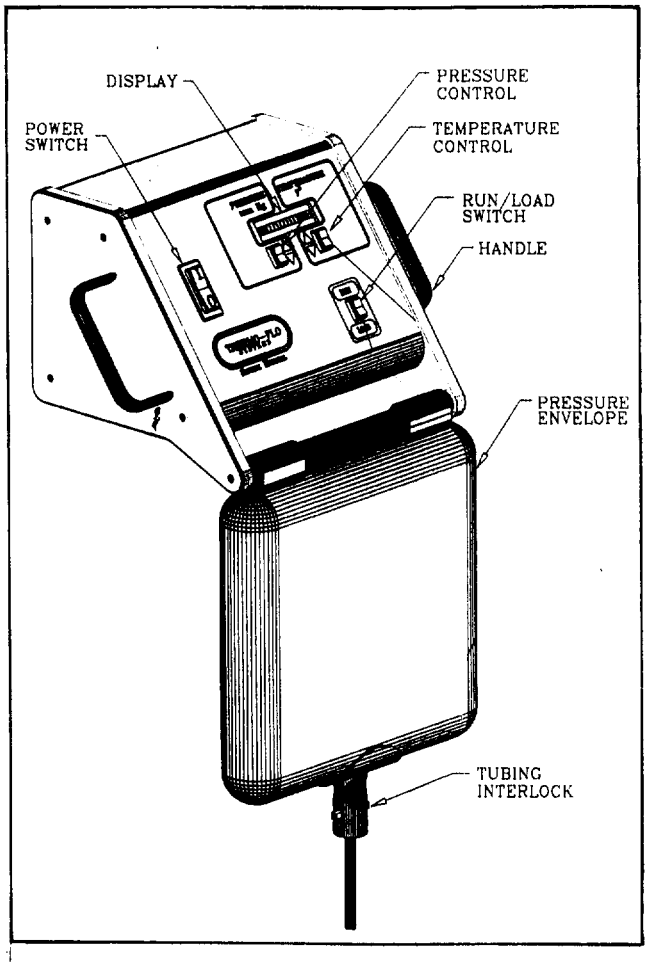
SANESE MEDICAL THERMO-FLO SYSTEM 3 IRRIGATION PUMP SYSTEM

The Thermo-Flow System 3 was developed to eliminate the major problems faced everyday by the surgeons and o.r. unit managers. These are: Cross contamination, inadvertent patient hypothermia, inadequate irrigation solution capacity, ease of set up, tube sets and disposable probes that leak, noise and physical space. Sanese Medical answers these problems with the Thermo-Flow System 3.



1) CROSS CONTAMINATION occures when non sterile fluid enters the patients abdominal cavity through the irrigation line. The Thermo-Flow System 3 eliminates cross contamination.

2) INADVERTENT PATIENT HYPOTHERMIA is the result of the combination of gas and fluids ranging in temperature from 65 to 72 degrees farenhite being introduced into the patient. The Thermo-Flow System 3 maintains the solution temperature at 100 degrees farenhite. Though this system alone cannot prevent hypothermia, it will dramatically effect the reduction of the core temperature due to the existing conditiions of surgery.

3) SOLUTION CAPACITY / EASE OF SET UP
The Thermo-Flow System 3 meets the three liter needs of todays and tomorrows laparoscopic procedures. This amount provides less disruption of the procedure, by not replacing the solution, cap and tube inserts that promotes the inadvertent contamination by the person replacing the solution as often.

THERMO-FLOW SYSTEM 3 PRODUCT SYSTEM

1) The Thermo- Flow System 3 Irrigation Pump.....TFS3 - one per case

2) SMC / TFS-3 Tube set with disposable probe.....TFS3 - 1-WP one per case
(15'tube set: asperation included)

3) SMC / TFS-3 Tube set without disposable probe.....TFS3 - 1WO ten sets per case
(15' tube set: asperation included)

4) SMC-NS Tube set with disposable probe.....TFS3 - N - 1WP ten per case
(15' tube set: aspiration included)

5) SMC-NS Tube set without disposable probe.....TFS3 - N -1W0 ten sets per case
(15' Tube set: aspiration included)

KEY ADVANTAGES OF THE SMC / TFS3
*Delivers strong stream of irrigation fluid
*Choice of disposable or reusable probe
*No capitol equipment necessary
*Simplified O.R. set up / uses I.V.
*Avoids equipment purchase
*Low level sound
* 24 hour, 7 days a week service available

SANESE MEDICAL
CORPORATION

885 Northwest Blvd. / Columbus, Ohio 43212

For further information or to order call (614) 291-8848
Fax (614) 291-1389

LOT NO. 0300

THERMO-FLO
SYSTEM 3

CONTENTS:

1 - MODEL TFS 3 LAPAROSCOPIC / HYSTEROSCOPIC IRRIGATION SYSTEM

INDICATED FOR IRRIGATION DURING LAPAROSCOPIC & HYSTEROSCOPIC SURGERY

Distributed by: SANESE MEDICAL CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

CAUTION: Federal (U.S.A.) Law restricts this device to the sale by, or on the order of a physician.

Non - Sterile - Recommended for irrigation in adult and pediatric laparoscopic / hysteroscopic Surgery

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CONTENTS: **MODEL NO. TFS3 - N 2WP**
1 - Single use, disposable 15' irrigation / aspiration tube set with probe

LOT NO. 0500
FOR SINGLE USE ONLY
CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGES.

INDICATED FOR IRRIGATION / ASPIRATION DURING LAPAROSCOPIC HYSTEROSCOPIC SURGERY.

Distributed by: SANESE MEDICAL CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

RECOMMEND FOR ADULT AND PEDIATRIC
LAPAROSCOPIC / HYSTEROSCOPIC SURGERY

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

710

CONTENTS: **MODEL NO. TFS3 - 3 WOP**
1 - Single use, disposable 15' irrigation / aspiration tube set.

LOT NO. 0500
FOR SINGLE USE ONLY
CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGES.

INDICATED FOR IRRIGATION / ASPIRATION DURING LAPAROSCOPIC HYSTEROSCOPIC SURGERY.

Distributed by: SANESE MEDICAL CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

RECOMMEND FOR ADULT AND PEDIATRIC
LAPAROSCOPIC / HYSTEROSCOPIC SURGERY

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

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CONTENTS: **MODEL NO. TFS3 - 3 WP**

1 - Single use, disposable 15' irrigation / aspiration tube set with probe

LOT NO. 0500

FOR SINGLE USE ONLY

CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGES.

INDICATED FOR IRRIGATION / ASPIRATION DURING LAPAROSCOPIC HYSTEROSCOPIC SURGERY.

Distributed by: SANESE MEDICAL CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

RECOMMEND FOR ADULT AND PEDIATRIC
LAPAROSCOPIC / HYSTEROSCOPIC SURGERY

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

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OPERATIONS MANUAL

THERMO-FLO
SYSTEM 3

LAPAROSCOPIC / HYSTEROSCOPIC IRRIGATION SYSTEM

SANESE MEDICAL
CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

SAFETY PRECAUTIONS

** USE ONLY WITH **TFS 3** IRRIGATION TUBE SETS **

* Do not use in volatile atmosphere.

* Use only with 120 volt grounded receptacle.

* Do not immerse unit.

READ BEFORE ADJUSTING AND OPERATING UNIT

It is recommended that all O.R. Unit Managers and others responsible for the operation of this unit become thoroughly familiar with its capabilities and proper operating procedures prior to actual patient use.

PRODUCT DESCRIPTION

The **THERMO-FLO SYSTEM** 3TM* LAPAROSCOPIC / HYSTEROSCOPIC IRRIGATION SYSTEM consists of the following components:

1 - **THERMO - FLO SYSTEM** 3TM control device

1 - **THERMO - FLO SYSTEM** 3TM pressure enclosure device

2 - Transportation pouch

*U. S. and International patent pending

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CORPORATION
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SPECIFICATIONS

MODEL TFS3*

POWER

120 V AC 1 AMP OR 220 V AC 0.5 AMP 50/60 Hz
(95 to 250 V AC 47 to 63 Hz

WEIGHT

7 LB.. (with out stand)

PRESSURE RANGE

100 mm TO 800 mm HG

HEATER TEMPERATURE RANGE

80 F to 120 F ± 2 F
Safety Shutdown Temperature: 125 F

MAXIMUM LEAKAGE CURRENT

Control unit: 100 micro amps (per UL 544)
Pressure Enclosure: 10 micro amps (per UL544)
Maximum Ground Impedance: 0.1 Ohm (per UL 544)
Fuse. Slow Blow 2.0 Amp. (Located on back of control unit)

ENVIRONMENTAL OPERATING CONDITIONS

40 F TO 150 F, Humidity: non-condensing

* **U. S. and International patent pending**
Specifications subject to change without notice.

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CORPORATION
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SAFETY FEATURES

The **THERMO-FLO SYSTEM 3** IRRIGATION SYSTEM was designed with the following safety features:

OVER PRESSURE	In the event of an over pressure condition a pressure switch cuts power to the air supply.
OVER TEMPERATURE	In the event of an over temperature condition, an independent software circuit cuts the power supply to the heater.
LEAKAGE CURRENT	The leakage current of the pressure cuff is less than 10 micro amps.
WATCHDOG TIMER	If the micro controller is not executing code properly, the watchdog timer resets the unit to its initial conditions.

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CORPORATION
885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

OPERATING THE TFS3TM IRRIGATION SYSTEM

DESCRIPTION OF CONTROLS

Power Switch: The power switch is a double pole single throw 10 Amp switch. (Both the line and neutral are switched per UL544).

Pressure Adjust Switch: Located to the left and below the display is a three position rocker switch which is used to adjust the pressure. The center position is off. The top (Up arrow) and bottom (Down arrow) positions are momentary. Pressing the Up arrow increases the fluid pressure. Pressing the Down arrow decreases the fluid pressure.

Temperature Adjust Switch: Located to the right and below the display is a three position rocker switch which is used to adjust the heater temperature. The center position is off. The top (Up arrow) and bottom (Down arrow) positions are momentary. Pressing the Up arrow increases the heater temperature. Pressing the Down arrow decreases the heater temperature.

Load / Run Switch: This is a two position rocker switch. When in the LOAD position the pump is turned off and the solenoid valve is opened allowing an empty bag of fluid to be unloaded and a full bag loaded. When in the RUN position the pump and solenoid are under control of the microcontroller which turns on the pump and opens the solenoid as needed to keep the pressure at the setpoint.

Display: The display is a 16 character single line LCD Module operated by the microcontroller. In normal operation it displays the pressure and temperature setpoints. It is also used to prompt the user.

Fuse: A 2 amp fuse is located on the back of the unit.

Air Connector: On the back of the unit is located a Colder Connectors into which plugs the mating connector located on the end of the air bladder tube.

Heater Electrical Connector: On the back of the controller is located a connector used to electrically connect the heaters and temperature sensors to the controller.

SANESE MEDICAL
CORPORATION
885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389

DESCRIPTION OF OPERATION

The controller is plugged into a standard wall outlet. The power switch is turned on and the LOAD/RUN switch is placed in the LOAD position. A fresh bag of irrigation fluid is placed in the pressure enclosure. The irrigation bag is connected to the tubing set / probe through the stick fittings which protrude through a hole in the bottom of the pressure enclosure. The LOAD/RUN switch is placed in the RUN position. When power is first turned on the pressure and temperature settings are at minimum. The user adjusts the Pressure and Temperature setpoints to their desired settings. The user then depresses the trumpet valve on the probe to obtain irrigation fluid. After a time the bag becomes empty. The LOAD/RUN switch is then moved to LOAD and the empty bag is replaced with a full one. Then the LOAD/RUN switch is moved to RUN. Because the machine has not been turned off the pressure and temperature settings remain at the value they had before the new bag of fluid was added.

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CORPORATION
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USAGE RECOMMENDATION

The ***THERMO-FLO SYSTEM 3***TM was designed for Laparoscopic / Hysteroscopic surgery and is only to be used by licensed, certified surgical personnel.

RECOMMENDED CARE

Do not leave unit plugged in.
Do not use abrasive cleaning and disinfecting solutions.

LIMITED WARRANTY

Sanese Medical Corporation ("Sanese") warrants the **THERMO-FLO SYSTEM 3** TM to be free from defects in material and workmanship for a period of one (1) year from date of initial purchase. No warranty shall apply if the goods have been damaged by accident, abuse, misuse, or misapplication, or as a result of service or modification by other than a person authorized by Sanese. Sanese's liability under this warranty, and buyer's exclusive remedy is limited to the cost of materials and labor to repair defective goods, or to their replacement, and in no event shall exceed the purchase price. Repair or replacement of defective goods under warranty will be made only upon their return to Sanese after notice to Sanese and Buyer's receipt of shipping instructions. Upon receipt of goods returned under warranty, Sanese will inspect the goods, will notify buyer of the extent of repair or replacement which Sanese will perform under warranty, which shall be conclusive of Sanese's liability.

Sanese is not responsible for incidental consequential damages resulting from the breach of any expressed or implied warranty, including damage to property and to the extent permitted by law, damages for personal injury. The warranty contained herein is in lieu of all warranties, expressed or implied. No statement of any representative shall extend Sanese's liability as herein established or limited.

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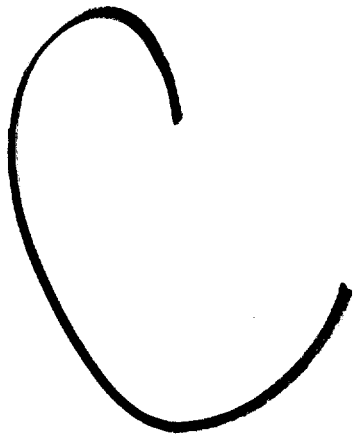
SANESE MEDICAL
CORPORATION

885 NORTHWEST BLVD. COLUMBUS, OHIO 43212 (614) 291-8848 FAX (614) 291-1389



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Niagara™ High-Flow Irrigator Systems

For quiet, convenient, cost-effective irrigation, the Niagara Irrigator sets the standard.

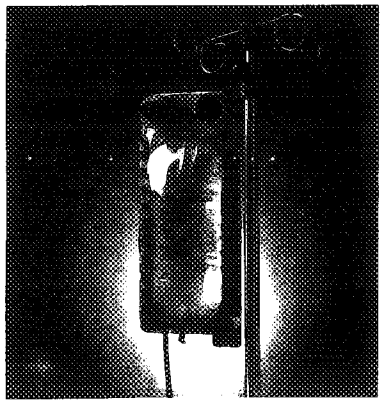
Niagara Irrigator's exclusive pressurized-chamber technology delivers flow rates up to 3L/minute—nearly 50% higher than disposable diaphragm pumps—for confident visualization and precise hydrodissection.

Niagara pumps are easy to use. Just hang from any IV pole...attach to OR air, nitrogen, or O_2, or bottled CO_2,...hang and spike the solution bags...close the chamber...and you're ready.

Niagara Irrigators are built for safety—with double-layer protection to ensure that the pressurizing gas never contacts the irrigant.

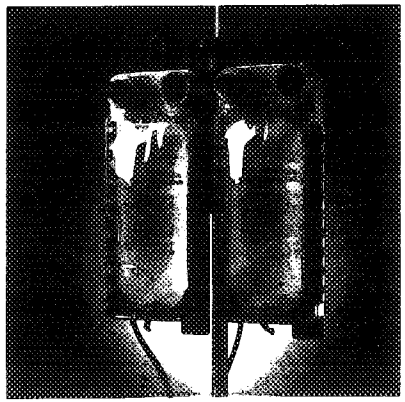
And, because Niagara Irrigators are reusable procedure after procedure, they cut pump/probe costs nearly in half.

Choose from three versatile models designed to fit a wide range of needs.



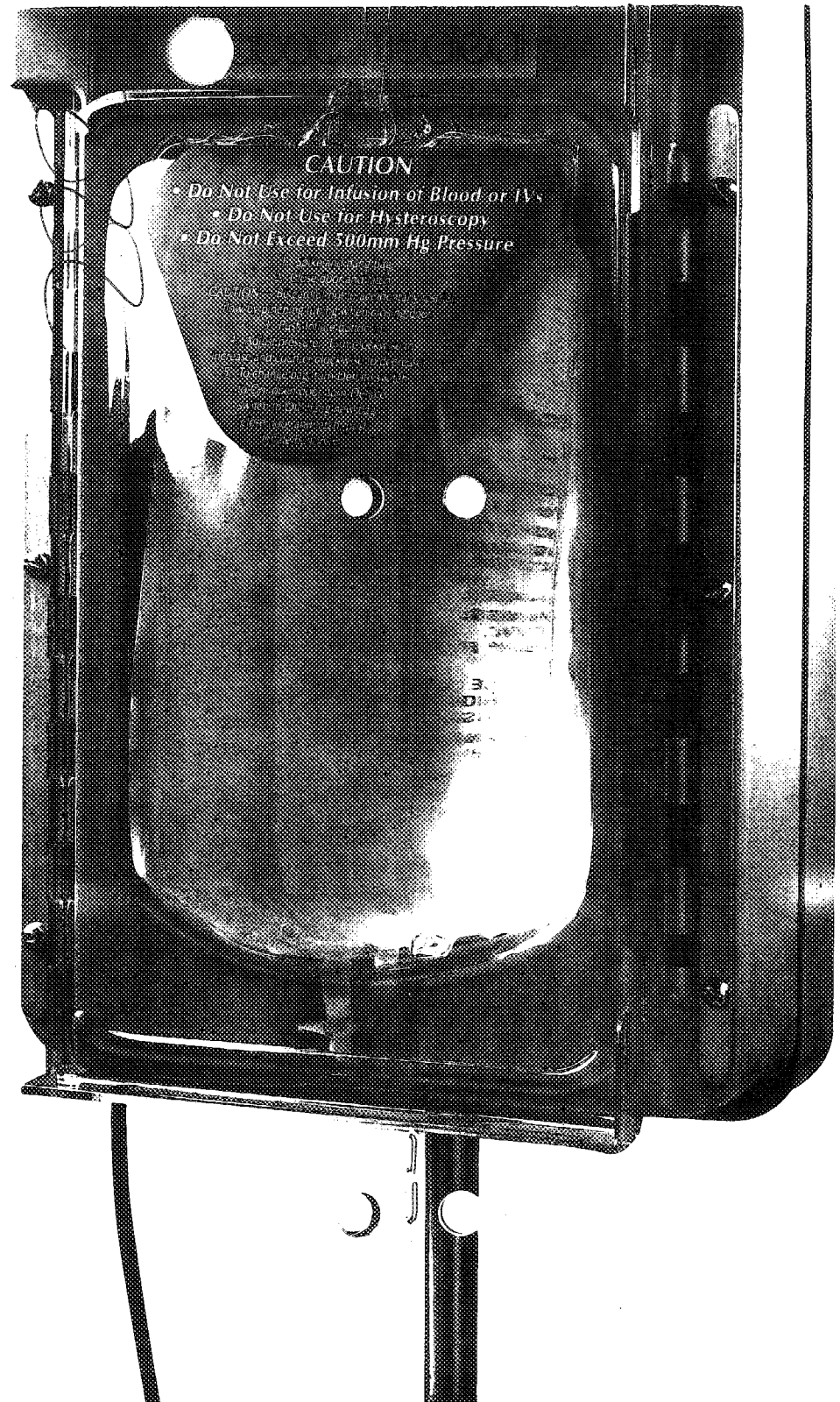
1L Single-Pump Niagara Irrigator

For low-volume applications, the Niagara 1L Single-Pump model provides high-flow performance in a compact, cost-effective package.

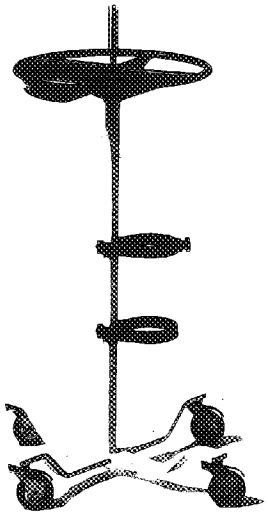


2L Dual-Pump Niagara Irrigator

Equally at home in long and short procedures, the Niagara 2L Dual-Pump accommodates two separately pressurized 1L fluid bags—with instant switchover to assure uninterrupted availability of irrigant.



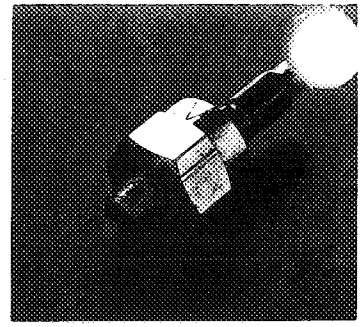
(See last page for complete selection)



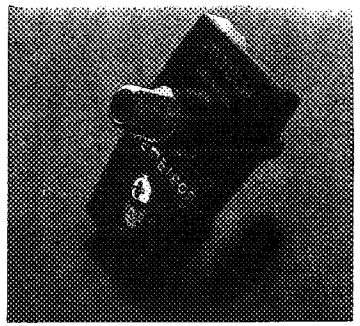
Irrigation Pump Stand

Cabot Irrigation Pump

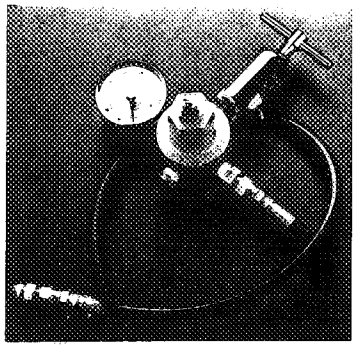
For use with bottled solutions, the CO_2-powered Cabot Irrigation Pump offers continuously adjustable pressure for a range of flow rates—up to 2L/minute at pressures up to 775mm Hg—and continuous availability of irrigant, thanks to its two-bottle design.



Air/Nitrogen Connector



Oxygen Connector

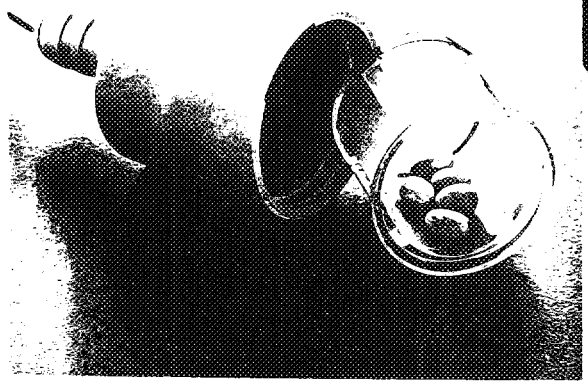


CO_2 Tank Connector

cabot medical

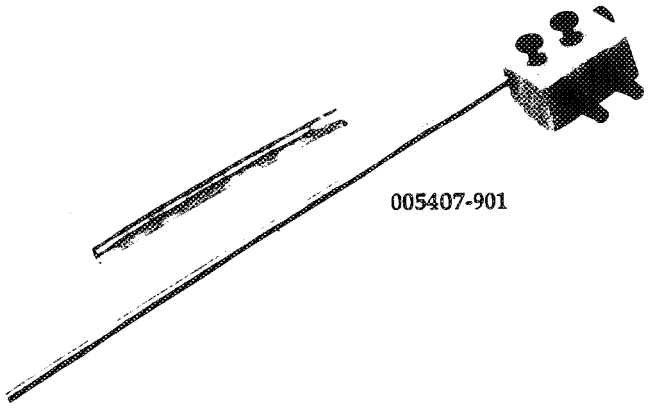
Nobody puts it together like Cabot.

800-523-6078



Tissue Collector

cabot medical



005407-901

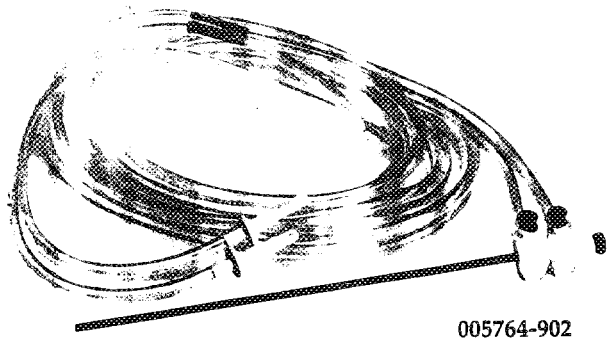
Corson™ Disposable Suction/ Irrigation Probe without Tubing for Use with Disposable Pumps

- Can position suction and irrigation functions according to physician preference.
- Instrument channel provides ability to dissect, lase,cut, cauterize, irrigate or aspirate through a single port.
- High flow design allows for maximum irrigation and suction including aspiration of blood clots and gallstones.
- Innovative trumpet valve virtually eliminates clogging, leaking and sticking.

CORSON™ DISPOSABLE SUCTION/ IRRIGATION PROBE WITHOUT INTEGRATED SUCTION AND IRRIGATION TUBING

(Package of 10)

28 cm	005407-901



005764-902

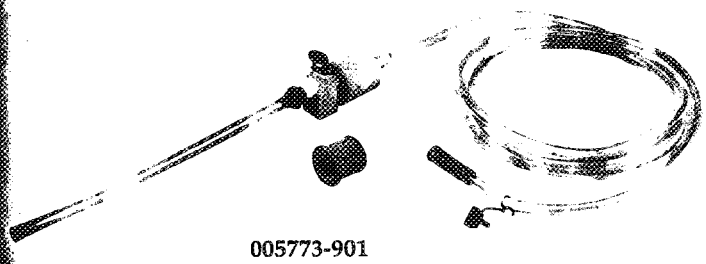
Corson™ Probe Retractors

The Corson™ Probe Retractors are modified versions of the Corson™ Probes and are available in 28 cm working lengths. They are manufactured without holes in the distal ends to enable the probes to be used to suction grasp/retract small organs.

CORSON™ PROBE RETRACTORS

(Package of 8)

Retractor	005765-902
Retractor with Spike	005764-902



005773-901

Big Sucker

10mm Tissue Aspiration and Collection System

Aspirate and collect stones, large clots, biopsies, and ectopic pregnancies.

- Large bore, straight-through design permits aspiration of both rigid and soft specimens.
- Suction-relief collar allows quick release of oversize tissues.
- Tissue collector preserves intact specimens for histopathology.
- Can be used simultaneously with 5mm suction/ irrigation systems.

Big Sucker	005773-901

The Big Sucker 10mm Tissue Aspiration & Collection System

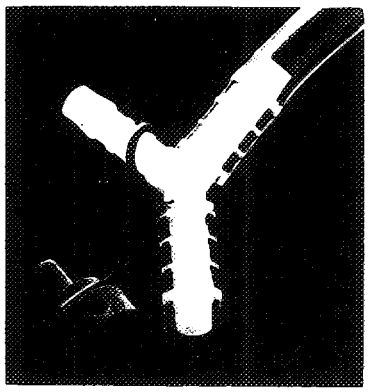
This remarkable new system extends the range of laparoscopic surgery with unprecedented control.

Now you can easily and safely collect "impossible" tissues—including large clots, multiple stones, biopsies, and ectopic pregnancies—without time-consuming, tissue-destroying dissection.

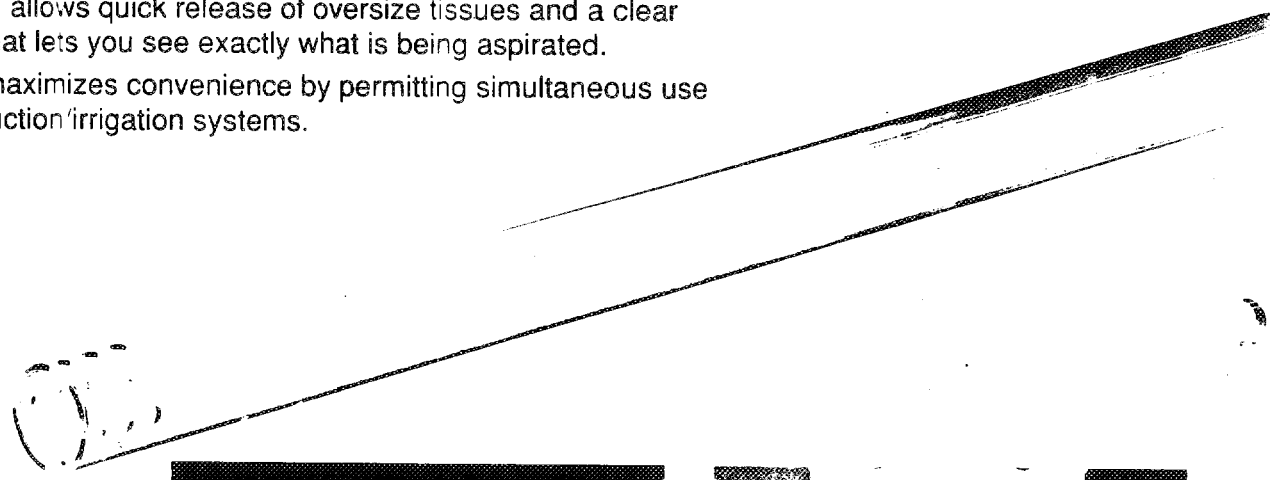
The large-bore cannula and straight-through valve design permit rapid, high-suction aspiration of both rigid and friable specimens while the exclusive tissue collector captures and preserves specimens intact for histopathology.

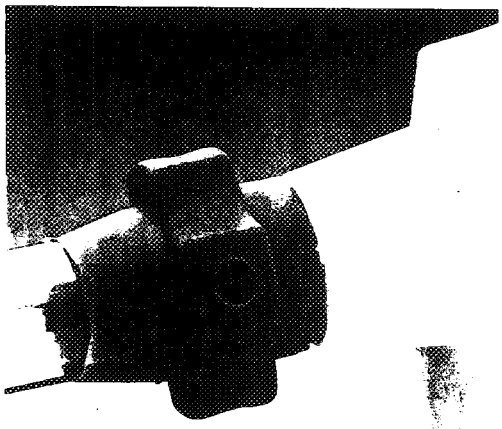
The Big Sucker System maximizes safety and control—with a suction-relief collar that guards against unwanted tissue aspiration, allows quick release of oversize tissues and a clear cannula that lets you see exactly what is being aspirated.

And it maximizes convenience by permitting simultaneous use of 5mm suction/irrigation systems.

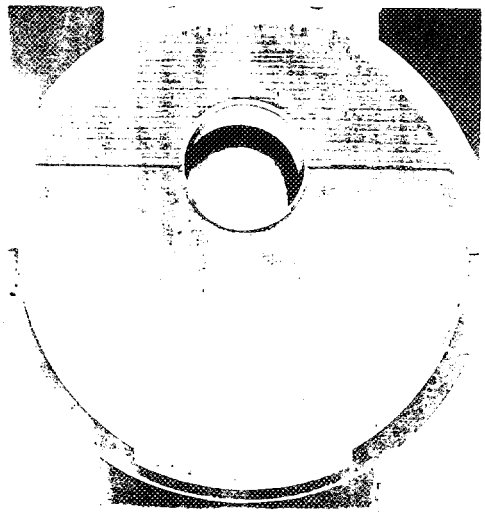


Y-Connector for 5mm Suction/ Irrigation Hook-up

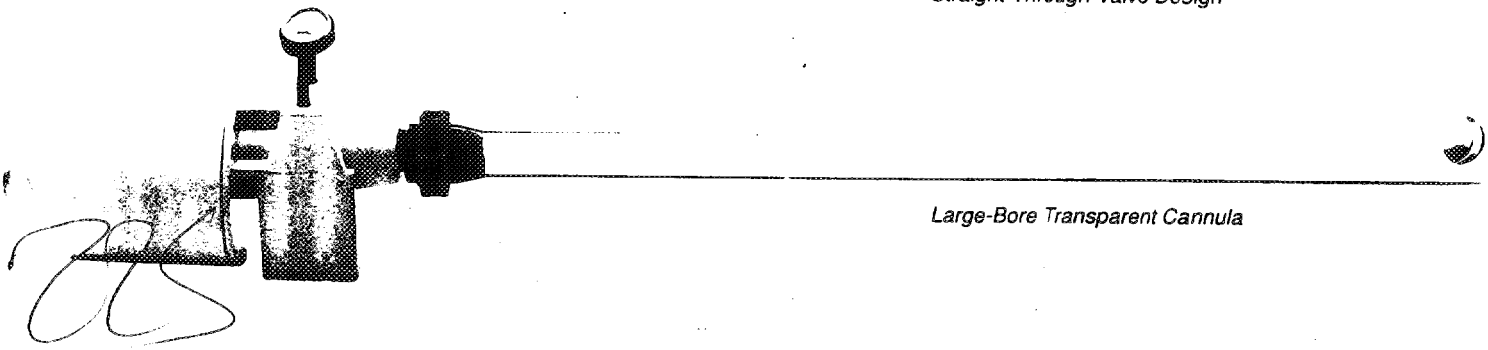




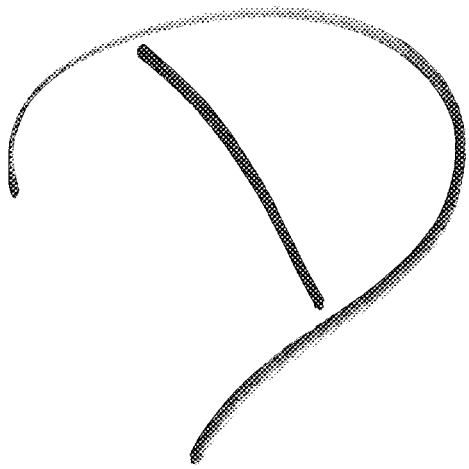
Suction-Relief Collar



Straight-Through Valve Design



Large-Bore Transparent Cannula

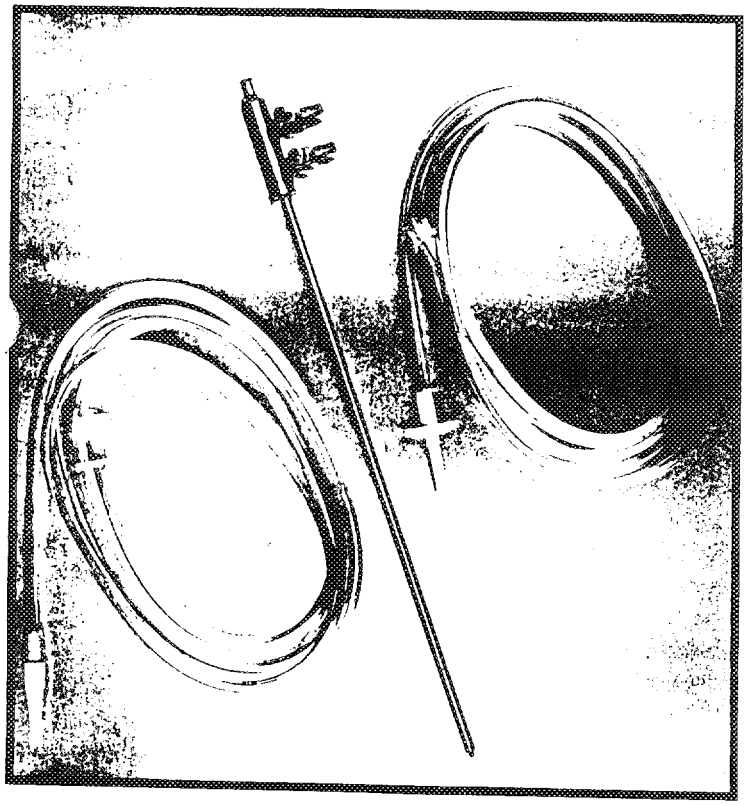


826

CORE DYNAMICS™

DISPOSABLE IRRIGATION/SUCTION TUBING SET

For Laparoscopy, Pelviscopy and Cholecystectomy procedures

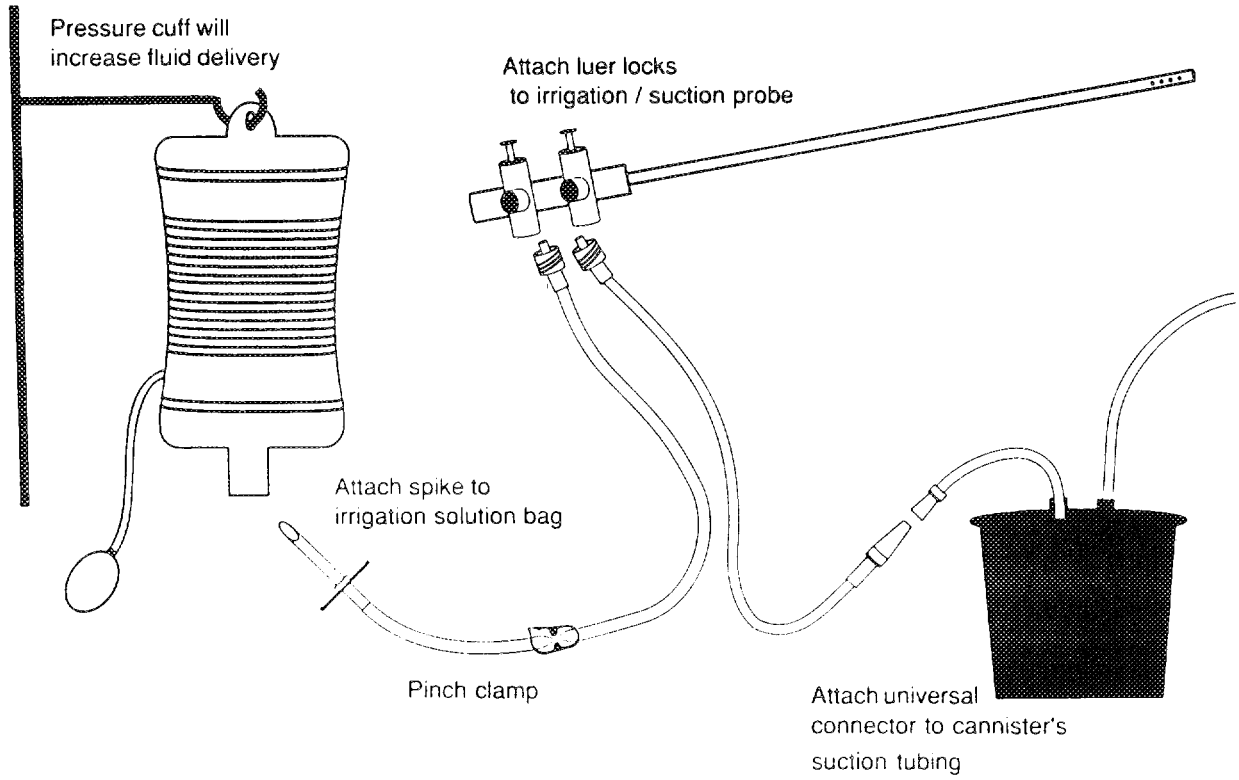


A cost effective disposable irrigation/suction tubing set for all endoscopic procedures. When used directly with a trumpet valve irrigation/suction probe, costly irrigation pumps are eliminated. Easy to set up and minimal equipment monitoring is needed.

Performance Features

- Fits all irrigation/probes with trumpet valves
- Easy to attach luer lock connectors to prevent fluid or vacuum leakage
- Universal spike on irrigation tubing attaches to any solution bag
- Pinch clamp on irrigation tubing allows leak proof disconnection
- Light weight and flexible for better probe control
- Non-kinking
- 8 Foot lengths increases accessibility
- Sterile package
- One time use

Follow diagram below for usage and assembly

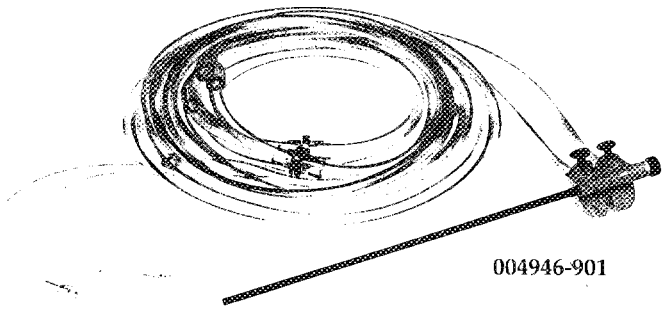


distributor:

Vector Medical Corporation
5859 South Garnett
Tulsa, OK 74146
(918) 252-5400

ORDER INFORMATION		
ORDER #	DESCRIPTION	PACKAGE
CD3400A	*Disposable Irrigation / Suction tubing*	***6 per box***

CORE DYNAMICS,™ INC. 9951 Atlantic Boulevard Jacksonville, Florida 32225 (904)727-0910 fax (904)724-7077



004946-901

Corson™ Disposable Suction/Irrigation Probe for Bottle Fluids

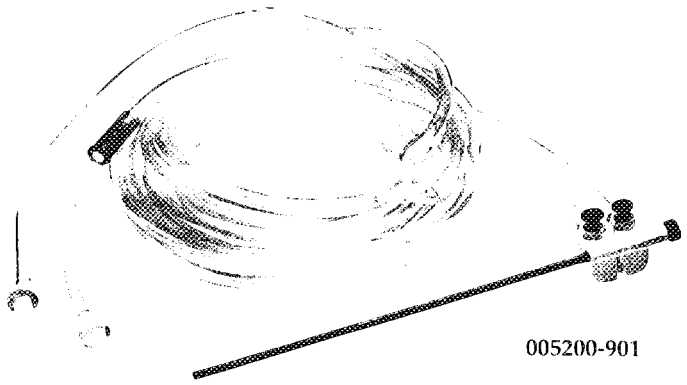
This probe is specifically designed to be compatible with a broad range of Cabot Medical instrument inserts that dissect, lase, cut, cauterize, irrigate or aspirate.

- High-flow design allows for maximum irrigation and suction, including aspiration of blood clots and gallstones.
- Innovative trumpet design virtually eliminates clogging, leaking and sticking.

CORSON™ DISPOSABLE SUCTION/IRRIGATION PROBE WITH INTEGRATED SUCTION AND IRRIGATION TUBING

(Package of 8 for Bottle Fluids)

24 cm	004946-901
28 cm	004946-902
28 cm without holes	005765-902
32 cm	004946-903



005200-901

Corson™ Disposable Suction/Irrigation Probe with Spike for Bag Fluids

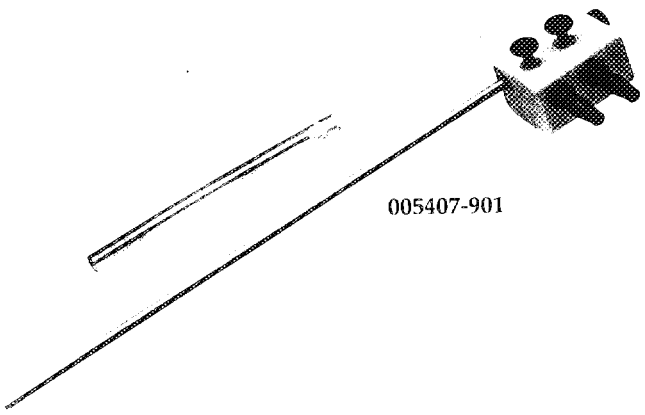
This probe is an adaptation of the Corson™ Probe for procedures using the Niagara™ Irrigator or gravity flow for irrigation.

- Dual spike allows irrigant to be delivered via multi-bag setup.
- Customized check valves prevent fluid from flowing backward into irrigation bags.

CORSON™ DISPOSABLE SUCTION/IRRIGATION PROBE WITH SPIKE WITH INTEGRATED SUCTION AND IRRIGATION TUBING

(Package of 8 for Bag Fluids)

24 cm	005200-901
28 cm	005200-902
28 cm without holes	005764-902
32 cm	005200-903



005407-901

Corson™ Disposable Suction/ Irrigation Probe without Tubing for Use with Disposable Pumps

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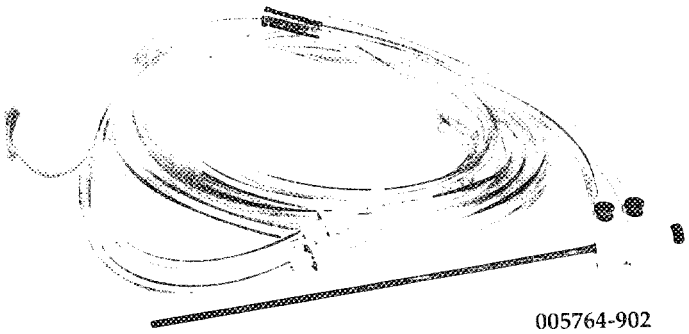
CORSON™ DISPOSABLE SUCTION/ IRRIGATION PROBE WITHOUT INTEGRATED SUCTION AND IRRIGATION TUBING

(Package of 10)

28 cm	005407-901



005764-902

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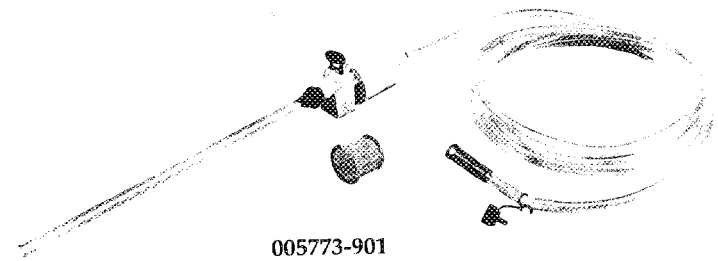
Retractor with Spike	005764-902



005773-901

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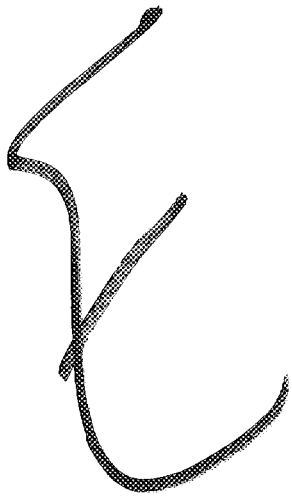
Big Sucker	005773-901



SURGIMEDICS®

TMP® TEXAS MEDICAL PRODUCTS, INC.
A wholly owned subsidiary of SURGIMEDICS, INC.

December 9th., 1993

Mr. Christopher N. Sanese
President
Sanese Medical Corporation
885 Northwest Blvd.
Columbus, Ohio 43212

Dear Chris,

This letter is a follow-up to our conversation on Monday, December 6th. The USP Class VI information that you requested is not readily available from the various vendors that will be providing materials for the tubing set. The normal response to my inquiry was "We do not perform routine Class VI testing to the materials used in the production of our products." As a matter of fact, we at Surgimedics can make the same claim. Class VI testing is time consuming and expensive and is not always a requirement of our customers. I have included a test report that I did obtained from Natvar for tubing that could possibly be used in the tubing set.

Following is a listing of parts, materials and vendors for the components that I have selected for use in the tubing set.

Tubing: Clear PVC (70 durometer Shore "A") Purchased from Natvar Co. Formulation #660.

Male Luer: Natural Acrylic CYRO Industries G-20 Hi-Flo. Purchased from Kippmed #1001-187-004.

Spike Cover: Low Density Polyethylene, Eastman, Tenite 1830 "A"or "E" (Natural)
Purchased From McGaw #X52-018.

Suction Connector: Blue PVC. Purchased from Qosina #57015

Non-Vented Spike: The material that I selected for the custom molded Non-Vented Spike is a White Polycarbonate GE Lexan #144R-112. We currently use this material to produce various medical devices. Attached is a copy of a letter that I received from General Electric concerning regulatory issues.

Chris, I hope that this is enough information to get you started with your 510(k) filing. I will continue to explore the possibility of obtaining Class VI information on the above items but I expect very limited success.

cc: H. Dutra
C. Meehan

Sincerely,

Roger D. Ellis
Manufacturing Engineer

Surgimedics/TMP
9287 Smucker Road
Orrville, Ohio 44667
216-669-2271

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

code of federal regulations

Food and Drugs

21

PARTS 170 TO 199

Revised as of April 1, 1988

212

§ 177.1580 Polycarbonate resins.

Polycarbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Polycarbonate resins are polyesters produced by:

(1) The condensation of 4,4'-iso-propylidenediphenol and carbonyl chloride to which may have been added certain optional adjuvant substances required in the production of the resins; or by

(2) The reaction of molten 4,4'-isopropylidenediphenol with molten diphenyl carbonate in the presence of the disodium salt of 4,4'-isopropylidenediphenol.

(3) The condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, and 0.5 percent weight maximum of *α*2,*α*6-bis (6-hydroxy-*m*-tolyl) mesitol to which may have been added certain optional adjuvant substances required in the production of branched polycarbonate resins.

(b) The optional adjuvant substances required in the production of resins produced by the methods described in paragraph (a)(1) and (3) of this section may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
p-tert-Butylphenol	
Chloroform	
Ethylene dichloride	
Heptane	
Methylene chloride	
Monochlorobenzene	Not to exceed 500 p.p.m. as residual solvent in finished resin.
Phenol (CAS Reg. No. 108-95-2).	
Pyridine	
Toluene: (CAS Reg. No. 108-88-3).	Not to exceed 800 parts per million as residual solvent in finished resin.
Triethylamine	

(c) Polycarbonate resins shall conform to the specification prescribed in paragraph (c)(1) of this section and shall meet the extractives limitations prescribed in paragraph (c)(2) of this section.

(1) *Specification.* Polycarbonate resins can be identified by their characteristic infrared spectrum.

(2) *Extractives limitations.* The polycarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10.

(i) Polycarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(ii) Polycarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(iii) Polycarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 23227, Apr. 24, 1981; 49 FR 4372, Feb. 6, 1984; 50 FR 14096, Apr. 10, 1985]

F

(b)(4)

(b)(4) Trade Secret Process - Testing

Objective:

To determine the pressure at which the pressure enclosure fails in order to establish that the safety factor is sufficient.

Conditions:

(b)(4) Trade Secret Process - Testing

Results:

(b)(4) Trade Secret Process - Testing

Discussion:

(b)(4) Trade Secret Process - Testing

2404

(b)(4) Trade Secret Process - Testing

Objective:

To run the irrigation pump and pressure enclosure at rated pressure for (b) and observe performance.

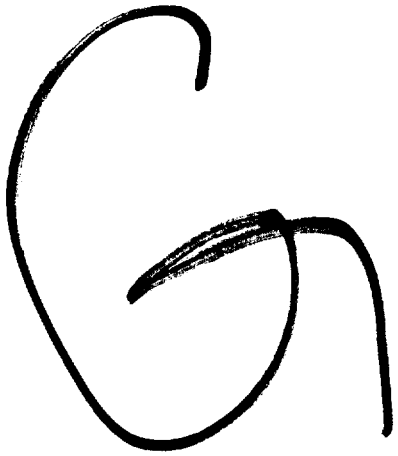
Conditions:

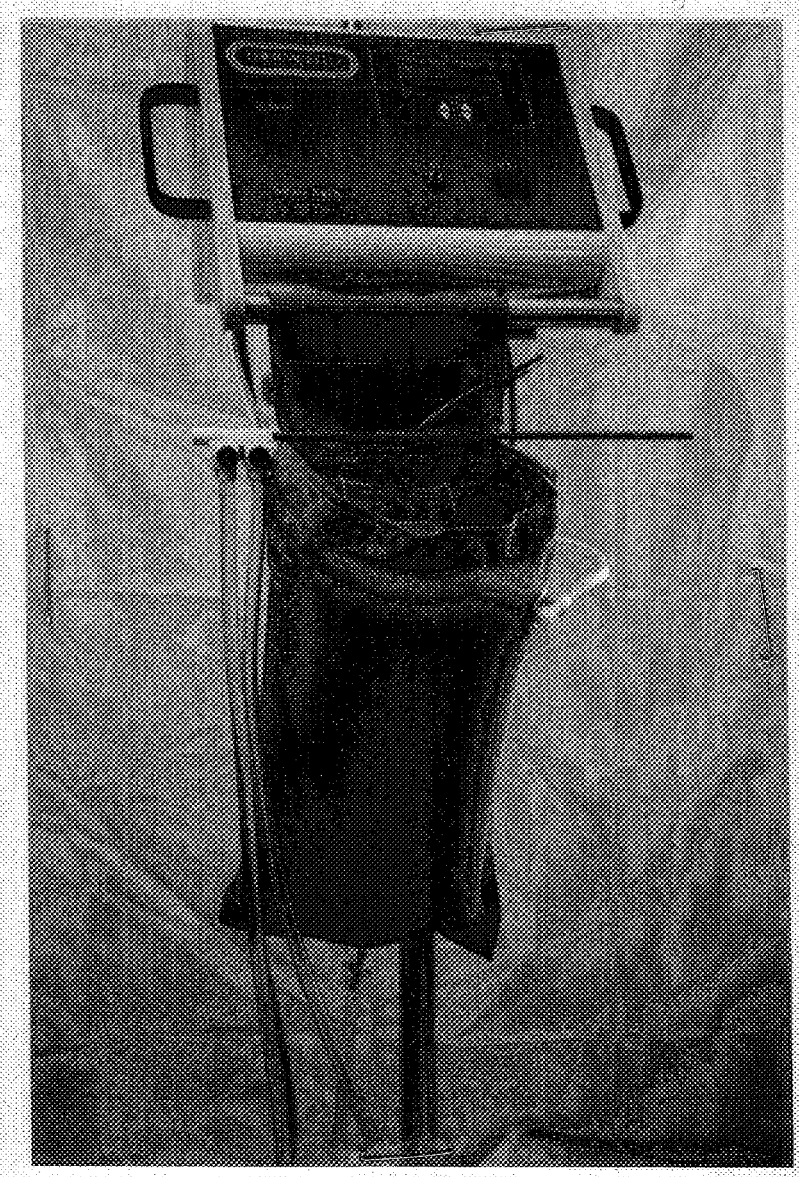
(b)(4) Trade Secret Process - Testing

Results:

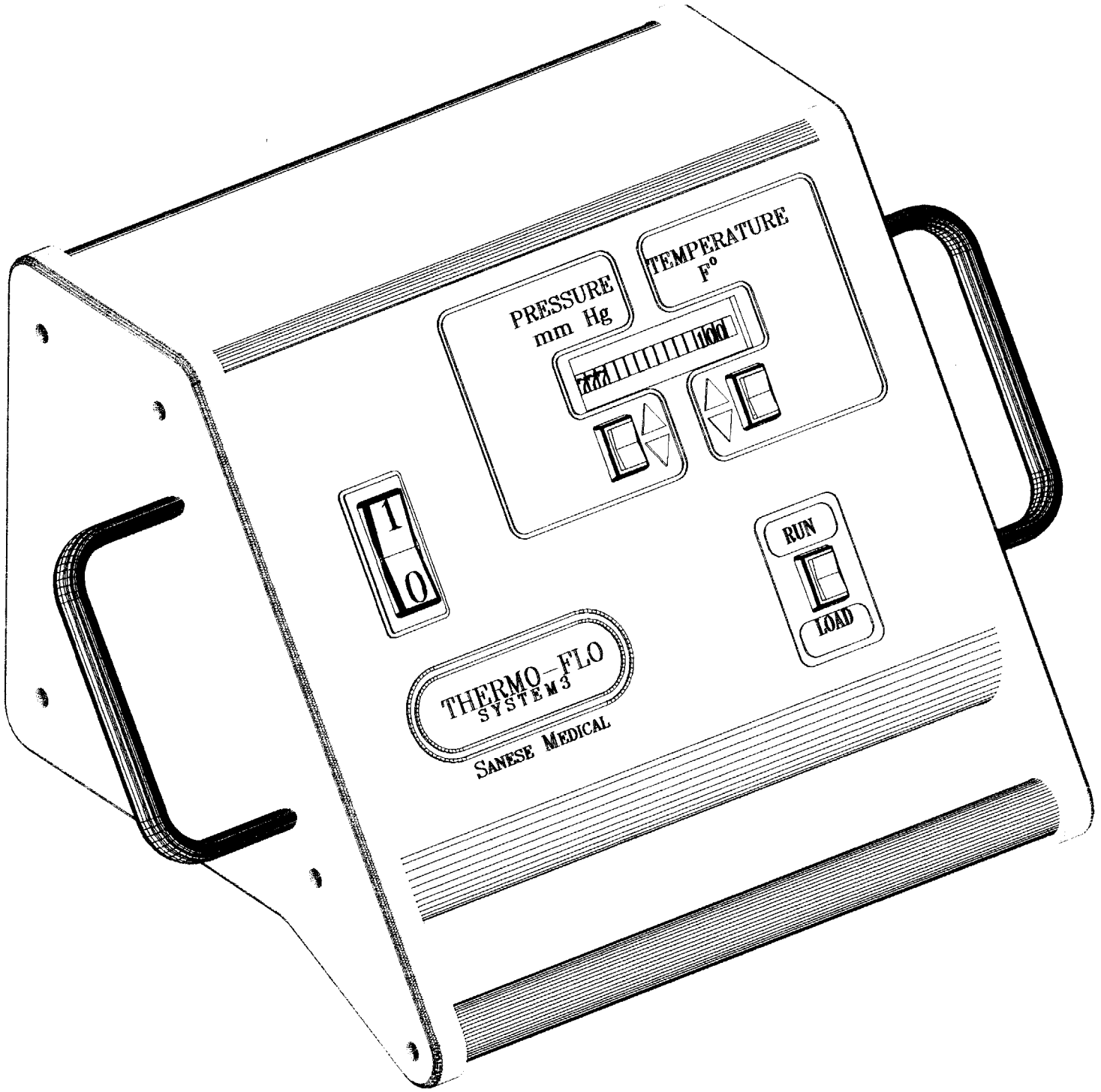
(b)(4) Trade Secret Process - Testing

245



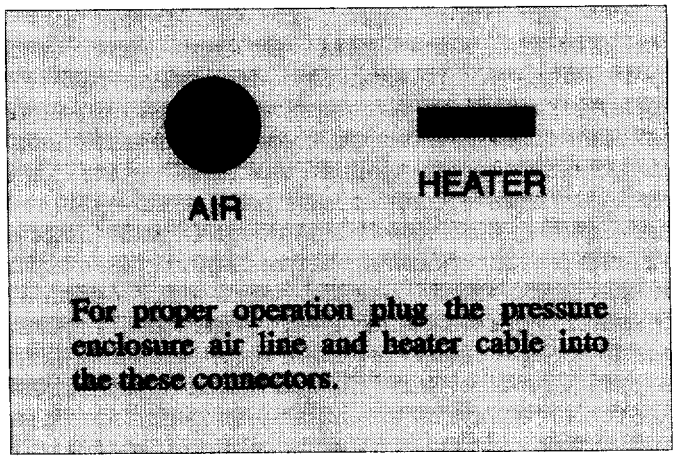


24n


PRESSURE
mm Hg
TEMPERATURE
F°
1
0
RUN
LOAD
THERMO-FLO
SYSTEM 3
SANESE MEDICAL

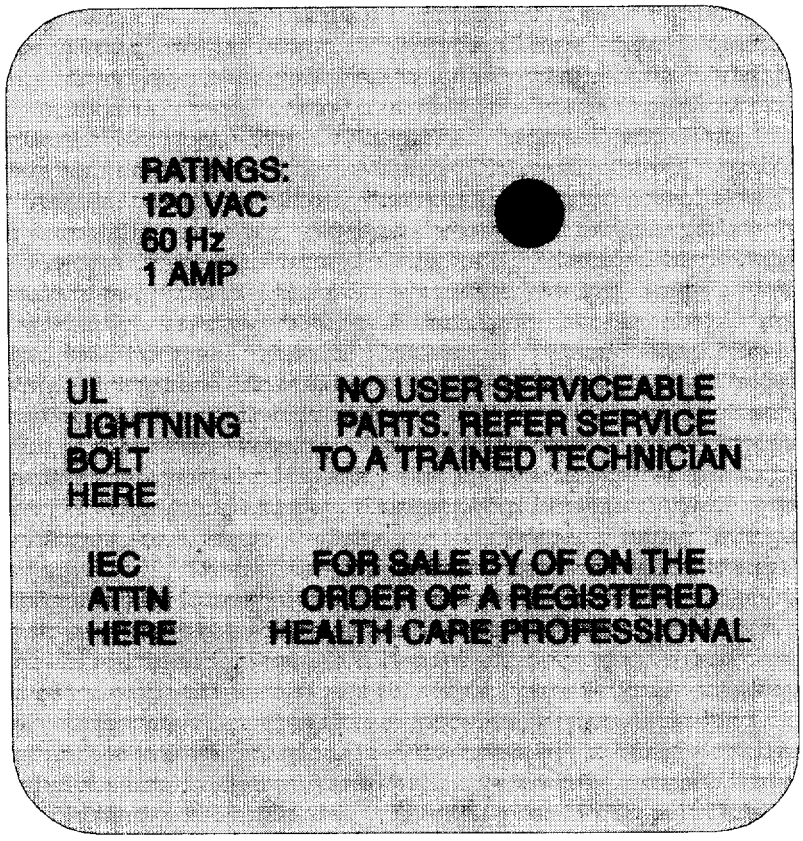
248

CONTROLLER / FABRIC ENCLOSURE CONNECTIONS LABEL (LOCATED ON BACK OF CONTROLLER)

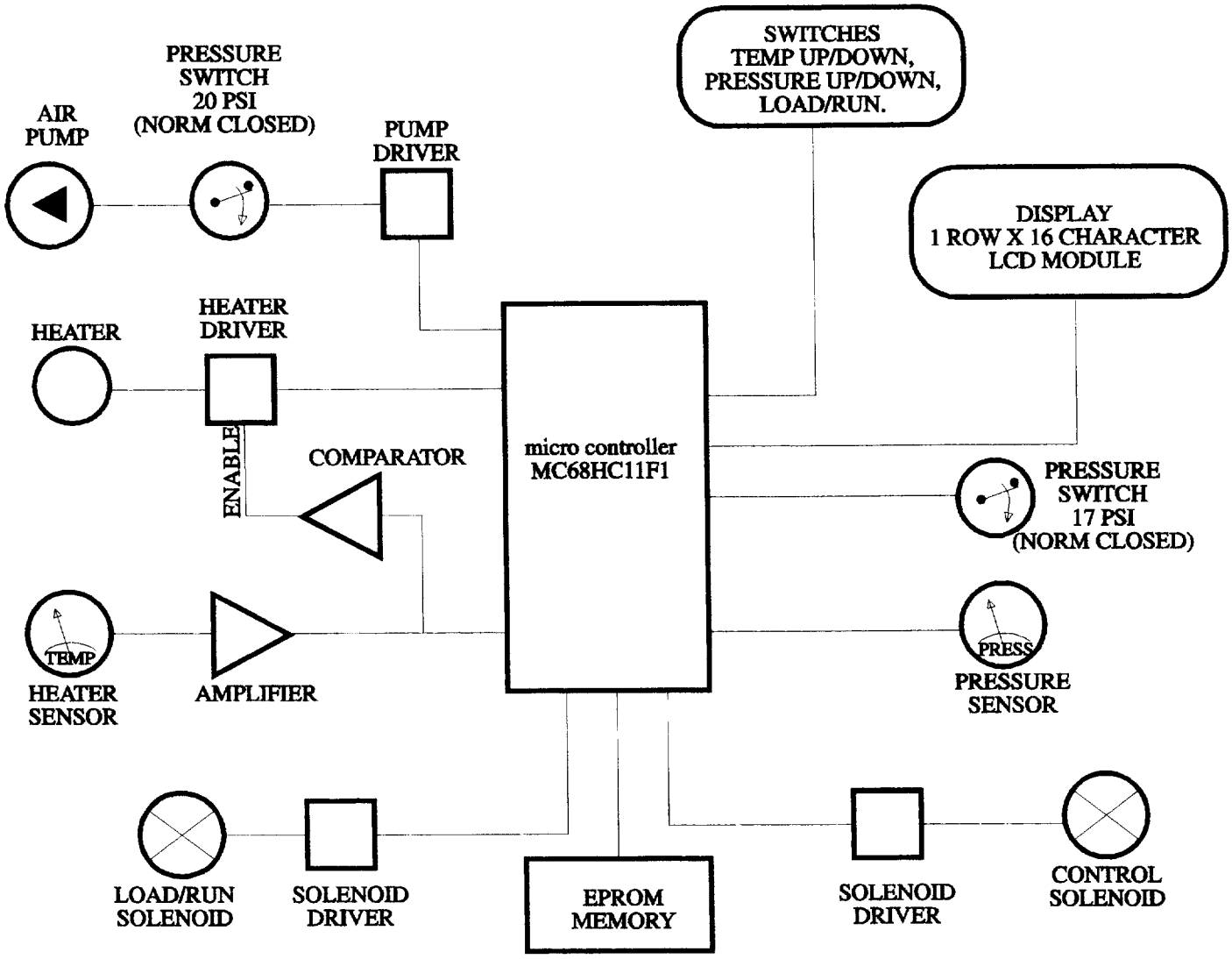


249

CONTROLLER RATINGS / WARNINGS LABEL



250



REV	ECN No.	REVISION	DATE	DWN
A	--------	AS RELEASED	9/12/93	KAK

MATERIAL: --------	NEXT LEVEL: --------	Sanese Medical		
FINISH: --------	MODEL: Thermoflo 3	TITLE: Electrical Block Diagram		
UNLESS OTHERWISE SPECIFIED ALL THE DIMENSIONS ARE IN INCHES.	DWN: KEVIN KELLY	SCALE: NONE	SHT 1 OF 1	DWG/PART NO. Elec_1 / SIZE A
	DATE: 9/12/93			

251

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design Specifications

(b)(4) Trade Secret Process - Engineering Design Specifications

(b)(4) Trade Secret Process - Engineering Design Specifications

(b)(4) Trade Secret Process - Engineering Design Specifications

(b)(4) Trade Secret Process - Software Specifications

(b)(4) Trade Secret Process - Software Specifications

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(b)(4) Trade Secret Process - Software Specifications

(b)(4) Trade Secret Process - Technical Specifications

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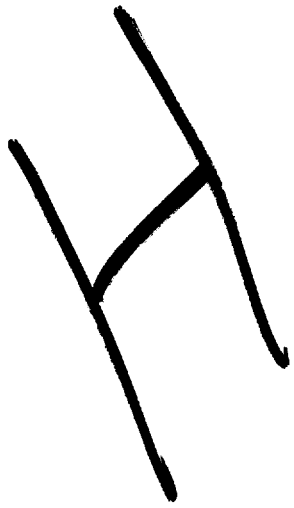
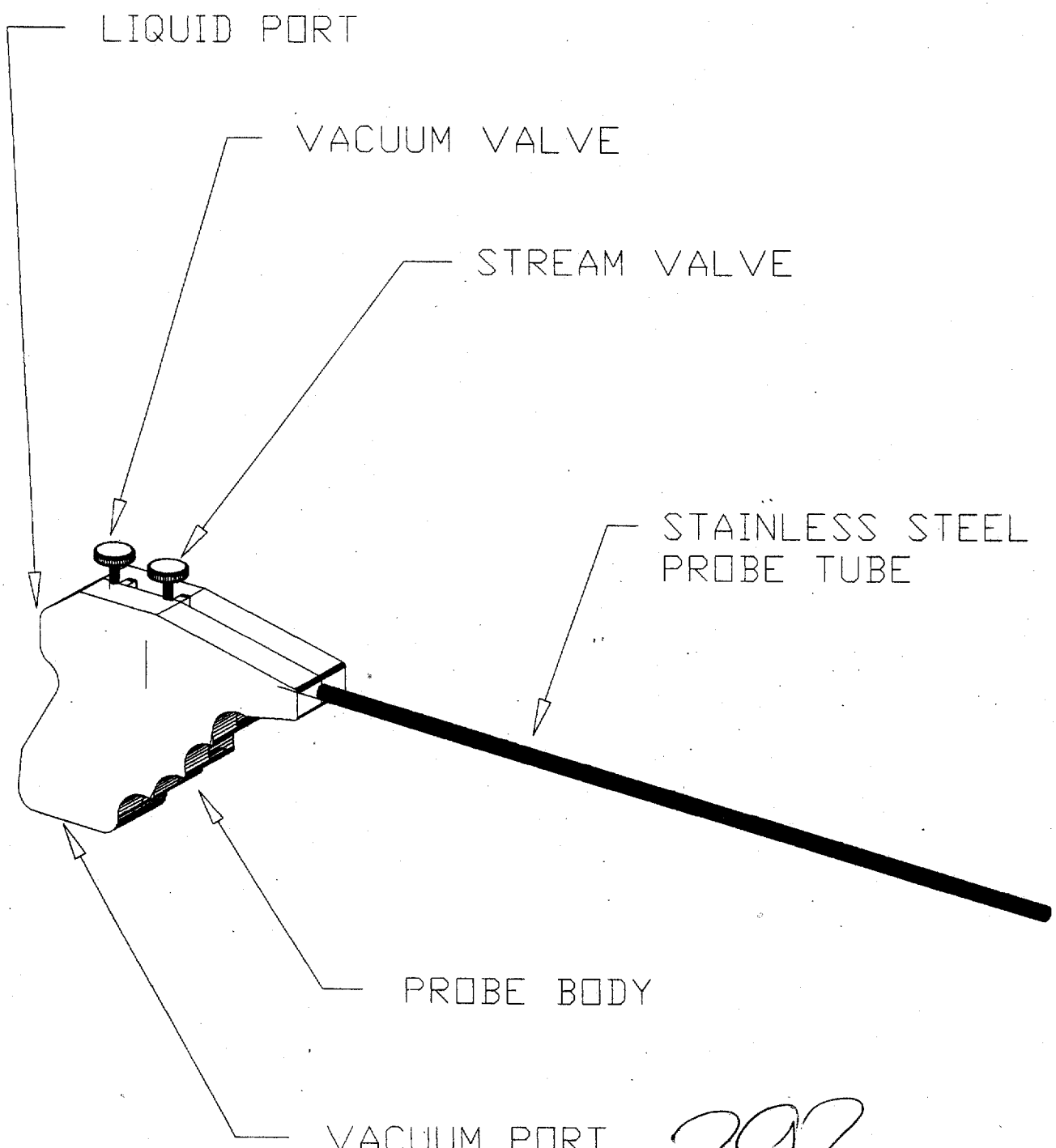


SANESE MEDICAL
CORPORATION

SANESE PROBE



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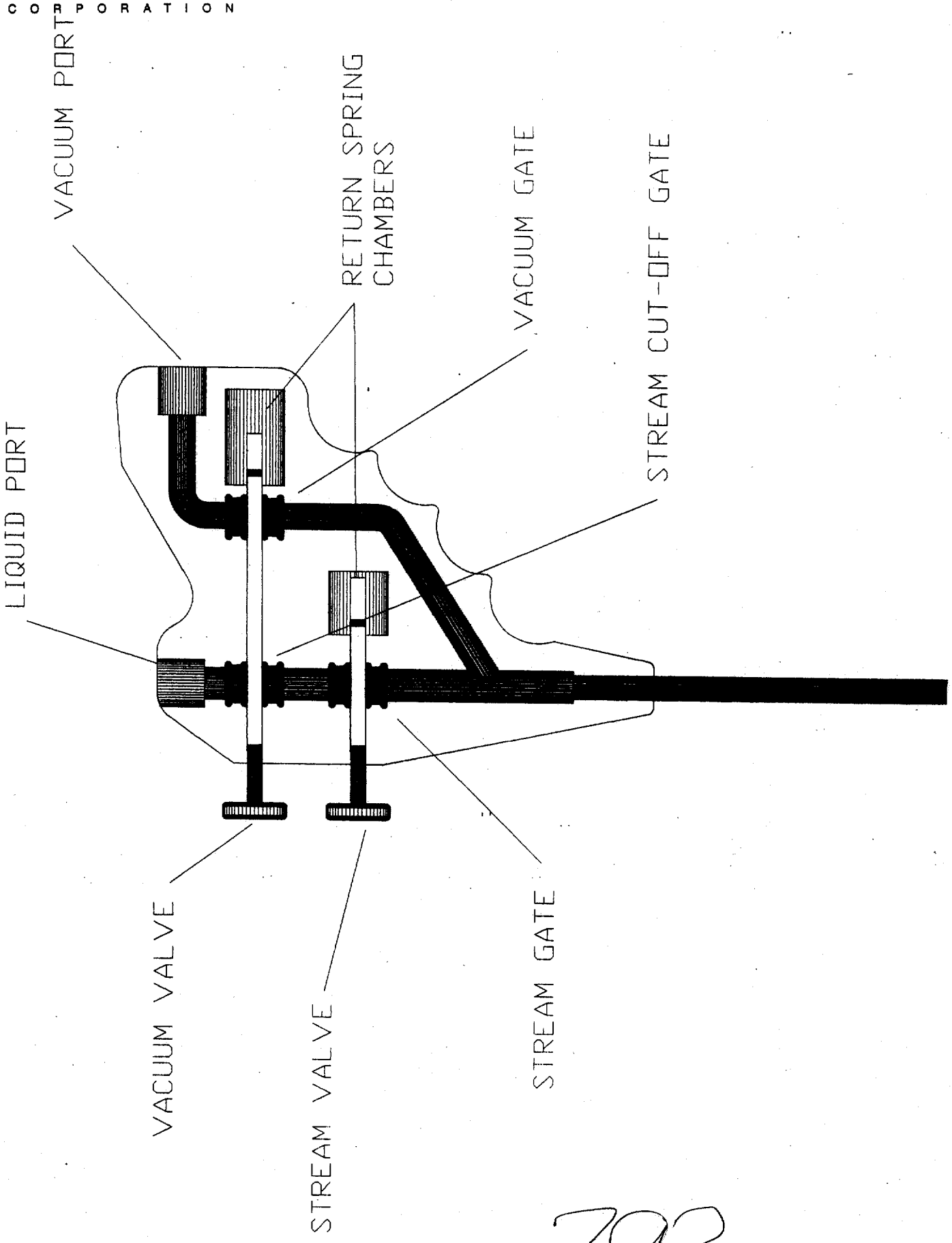

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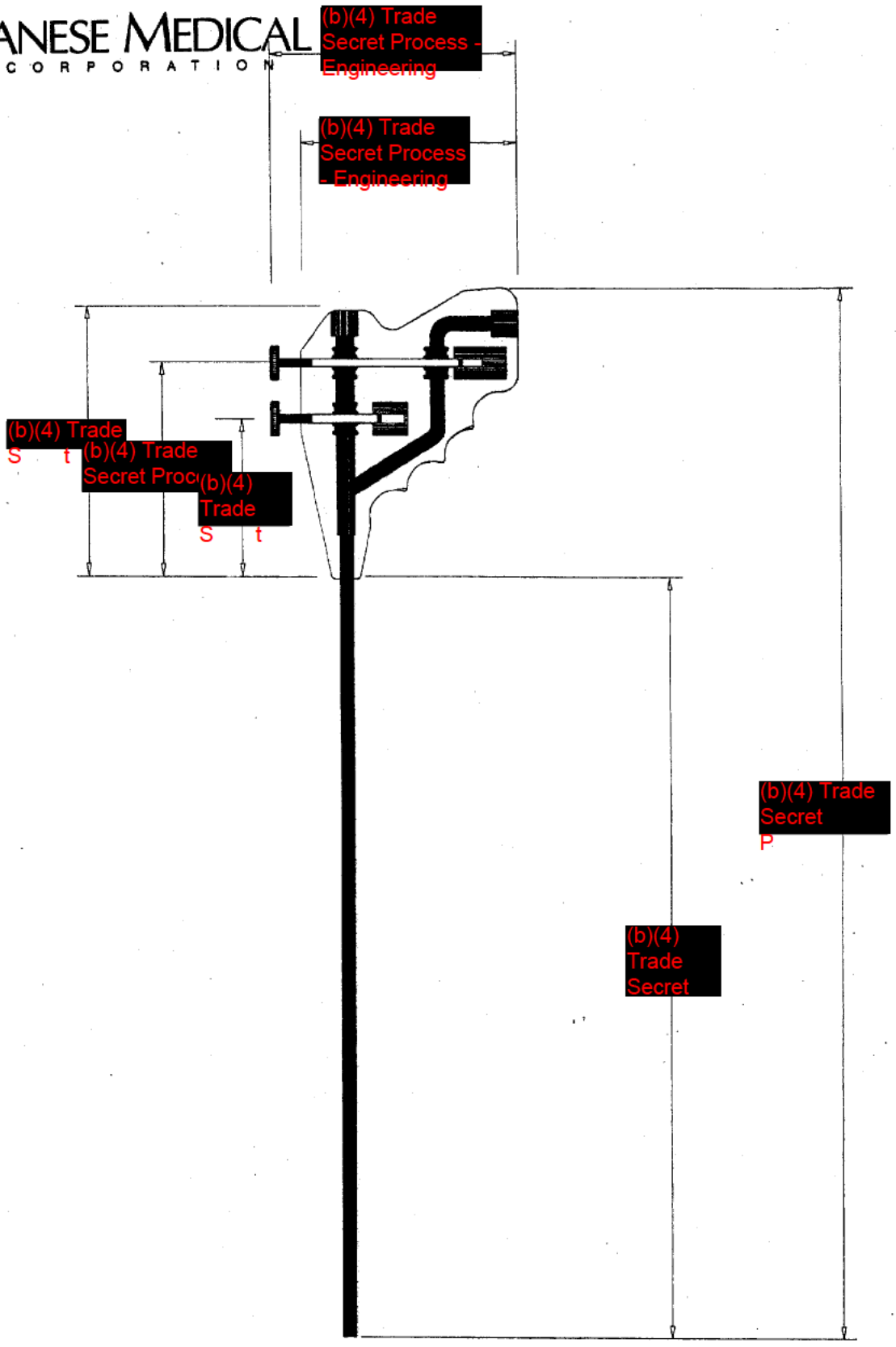

OVERALL DIMENSIONS

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SANESE MEDICAL
CORPORATION

MANUFACTURER OF MEDICAL PRODUCTS

PROBE & TUBE SET STERILIZATION METHOD

* Gamma Radiation: as follows;

STERILITY ASSURANCE LEVEL - S.A.L. = 10^{-6}

Dose to be determined by AAMI Method 1,
Dose to be not less than 2.5 M Rads

Materials

Materials for the Probe

Probe Plastic Valve Housing

GE Lexan -GR or Cycoloc ABS HP or Equivalent

Use Methylene Chloride as the bonding agent

Probe Tube

302 Stainless Steel Seamless Tube

Tubing and Pressure Seals

Norton Tygon S-50-HL PVC Shore A,64

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