U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K926139 - 902 pages
COMPANY:	BARD ACCESS SYSTEMS, INC. (BARDACCESYST)
PRODUCT:	PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAVASCULAR (LJT)
SUMMARY:	Product: CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE CATH
DATE REQUESTED:	Sep 6, 2016
DATE PRINTED:	Sep 6, 2016
Note:	Printed

K926197

JAN - 3 1995

510(k) Summary

The proposed CathLink 20 titanium port is substantially equivalent to the port in the P.A.S. Port™ system currently marketed by Pharmacia Deltec and the Bard Access System Hickman® titanium port (K870260). The modified polyurethane catheter is substantially equivalent to the P.A.S. Port polyurethane catheter. The Pharmacia P.A.S. Port system is currently on the market and has been on the commercial market for an extended time period. It is in widespread use. Bard is not aware of any information suggesting that the device is not legally marketed.

The 510(k) Substantial Equivalence Decision Making Process (Detailed) decision tree (ODE Guidance Memo, December 1989) was used to make a determination of substantial equivalence. The answers to these questions lead to a determination of substantial equivalence.

1. Does the new device have the same indication statements?

Yes, the Cath-Link 20 has the same indication for use as the Hickman Titanium Port and Pharmacia Deltec P.A.S Port. All are totally implanted devices designed for reliable repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

2. Does the new device have the same technological characteristics, e.g. design, materials, etc.?

No, The catheters used with the Hickman Titanium Port (silicone), Pharmacia Deltec P.A.S Port (polyurethane) and the Cath-Link 20 Port (modified polyurethane) are made of different materials. The material used for the portal body (titanium) and the septum (silicone) are the same for all three ports. The CathLink 20 layered silicone septum is different in design from the solid silicone septums in the Hickman Titanium Port and Pharmacia Deltec P.A.S Port.

3. Could the new characteristics affect safety or effectiveness?

Yes, the layered septum of the Cath-Link 20 Port is a unique characteristic of the Cath-Link 20. Its failure could affect the safety or effectiveness of the port. Also, the modified material used for the catheter in the Cath-Link 20 system could have new characteristics that could affect its safety or effectiveness.

4. Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are the same for all central venous port/catheter systems.

5. Do accepted scientific methods exist for assessing effects of the new characteristic?

Yes, the FDA 1989 Port Testing Guideline was used to evaluate the performance of the modified device. The Tripartite Guidance was used to assess that the biocompatibility of the modified catheter is equivalent to currently marketed catheters. The clinical performance of the modified device was evaluated in a clinical study.

6. Are performance data available to assess effects of new characteristics?

Yes, bench testing was conducted on the CathLink 20 system according to the FDA 1989 Port Testing Guideline. A clinical study was done to evaluate the clinical performance of the CathLink 20 port with the layered septum. Biocompatibility testing was evaluated according to the Tripartite Guidance.

7. Does the performance data demonstrate equivalence?

Yes. The data from the performance testing, clinical evaluation and biocompatibility testing demonstrate that the CathLink 20 system is equivalent to the currently marketed Hickman and P.A.S. port systems.

CathLink 20 is a trademark of C.R.Bard, Inc. or an affiliate.
P.A.S. Port is a trademark of Pharmacia Deltec, Inc.
Hickman is a registered trademark of C.R. Bard, Inc. or an affiliate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jane Ann Martin
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

DEC 8 1995

Re: K926139
CathLink® 20 Implanted Port
Dated: November 3, 1995
Received: November 6, 1995

Dear Ms. Martin:

We have reviewed the information dated November 3, regarding the 510(k) notification K926139 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

for Timothy A. Ulatowski
Acting Division Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 8 1995

Ms. Jane Ann Martin
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K926139
CathLink® 20 Implanted Port
Dated: November 3, 1995
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We have reviewed the information dated November 3, regarding the 510(k) notification K926139 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Timothy A. Ulatowski
Acting Division Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-400	BURDICK	12/5						
HFZ-402	Cavanaugh	12/5						
HFZ-410	Stan. mtn	12/6						

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

cc: HFZ-401 DMC
HFZ-403 RChissler
HFZ-420 Pilot Division
D.O.
d/t:
f/t:HFZ-420:WMB:RMD:11/29/95

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 11/6/95

From Document Mail Center (HFZ-401)

Subject Premarket Notification Number(s) K926139/A6

To Division Director, HO (DDIG

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) files(s). Since a final decision has been rendered, the record is officially closed.

Please review the document(s) and return to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

✓ Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP, PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS].

_____ Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE THE NEW 510(K)].

_____ No response necessary (e.g., mailed copy of fax for the trethful and accuracy statement and 510(k) statement).

COMMENTS: _____

This information should be returned to the DMC within 30 days.

Reviewed by: WMB

Date: 11/22/95

K926139/A4

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

3 November 95

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 84104

Re: Additional information for CathLink® 20 Implanted Port
510(k) submission, K926139

Attn: Pat Cricenti

(b)(4)

[redacted]

(b)(4)

[redacted]

Sincerely,

Jane Ann Martin
Regulatory Affairs Adminstrator

Attachment 1 - Lower Arm Placement instructions
Attachment 2 - copy of journal article:
Peripheral Ports Are a New Option for Central Venous Access; Earl Schuman, M.D. and John Ragsdale, M.D.; J. Amer. College of Surgeons; April, 1995; Volume 180, p. 456

cc: Brian Barry
Guy Jordan (w/o attachments)

ATTACHMENT 1

CATHLINK™ 20 Implanted Port

Lower Arm Placement via Antecubital Approach

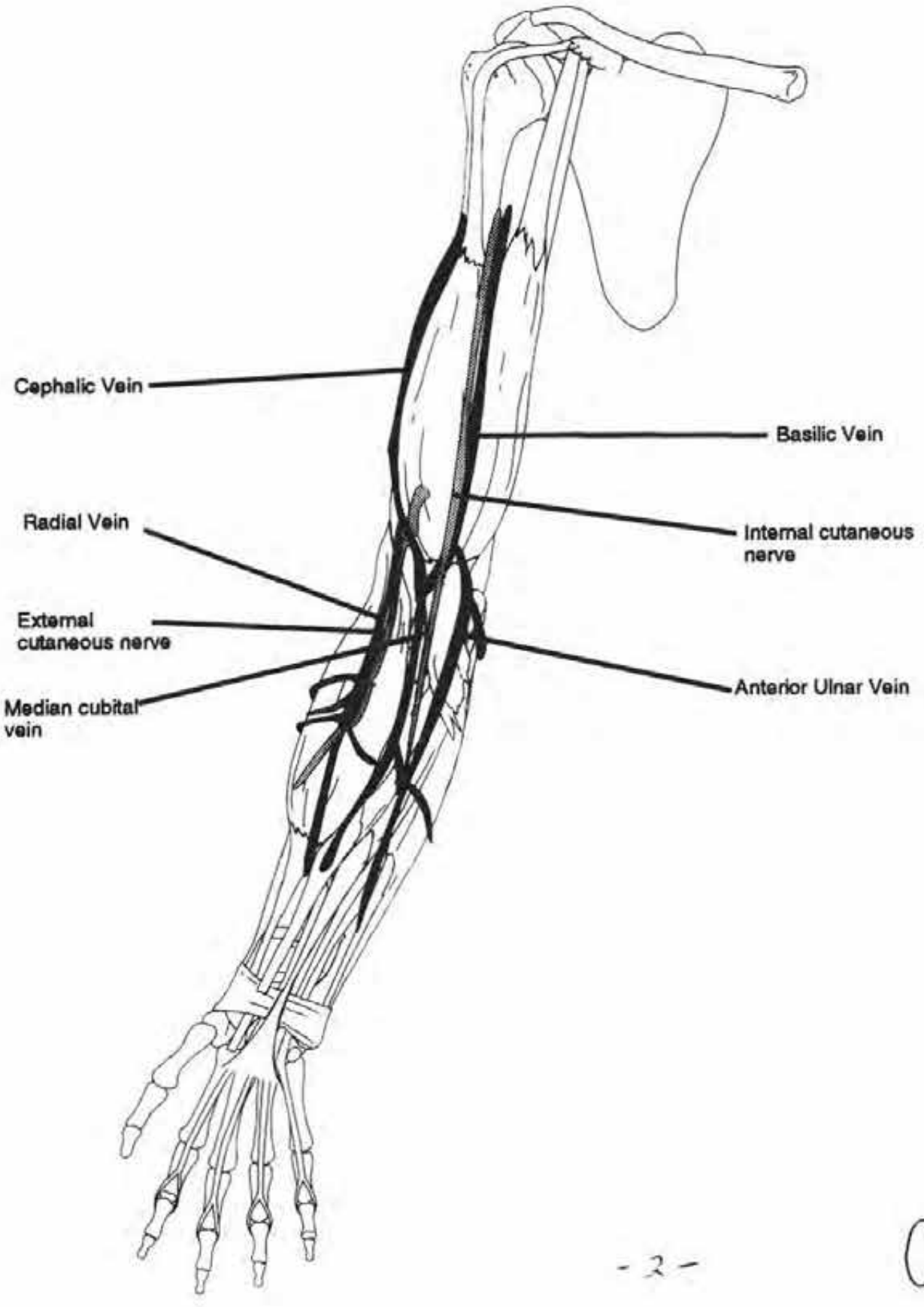
Implantation Instructions

Note: Careful assessment of the patient's anatomy should be made to assure suitable tissue thickness for the port pocket. A minimum tissue thickness of 0.5 cm over the port is generally considered acceptable.

Note: If the CathLink 20 Low Profile Port is implanted in the arm and the patient is accessing his or her own port, a second person may be required to assist.

8

Relevant Anatomy



Implantation Instructions

- Complete patient implant record, including product reorder number and lot number. Using flush connector, flush catheter with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end.
- Place a tourniquet on the upper arm near the mid arm to distend the antecubital veins, and select the appropriate venipuncture site.
- Select a port pocket site distal to desired vein insertion site. Consider a cutaneous tissue thickness appropriate for the port pocket, as excessive tissue will make location and access of the port difficult. Conversely, too thin a tissue layer may lead to tissue erosion. A tissue thickness of 0.5cm is generally considered appropriate.
- After selecting the desired vein and insertion site, release the tourniquet, leaving it under the upper arm.
- Place the patient supine with the arm to be accessed away from the trunk of the body. Place the patient's arm in an abducted, externally rotated position.
- Measure the distance from the insertion site to the location of the desired catheter tip placement.
- Wash hands per hospital protocol and don sterile prep gloves. Establish a sterile field for all supplies and place all supplies in the sterile field.
- Using aseptic technique, prep and drape lower arm.
- Remove prep gloves. Re-apply the tourniquet to distend the selected vein.
- Don sterile gloves. Position drapes around the insertion site and over the tourniquet. You will need to be able to release the tourniquet through the drape after cannulation of the vein without compromising the sterile field.
- Palpate and locate the selected distended antecubital vein.
- Anesthetize the venipuncture site and the port pocket site.
- Puncture the selected vein using an 18 gauge, thin-wall needle attached to a syringe. Aspirate gently as the needle is inserted. When the vein is cannulated, remove the syringe leaving the needle in place.

10

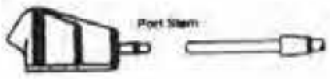
An 18 gauge over-the-needle I.V. catheter can be used in place of the thin-wall needle for vein cannulation. After removal of the I.V. needle, attach a syringe to the hub of the I.V. catheter.

- With the needle (I.V. catheter) well into the vein, release the tourniquet through the sterile drape without compromising the sterile field.
- Advance a long guidewire through the needle (I.V. catheter) into the accessed vein and into the superior vena cava. Recommended guidewire length is 89 centimeters, maximum diameter is .035 inches.
- Remove the needle (I.V. catheter) and make a small incision over the guidewire.
- Place a 7 Fr. dilator over the wire into the vein, maintaining venous access, to pre-dilate the venotomy site.
- Retract the dilator and place the dilator and introducer sheath as a unit over the wire and into the vein. **Refer to Instructions for Use for Bard Access Systems "Peel-Apart" Percutaneous Introducers section to complete the percutaneous introduction of the 6 Fr. catheter.**

  The 6 Fr. catheter may be advanced using a Seldinger technique directly over the guidewire to the desired tip position.
- After the catheter tip is in the selected location, make a transverse incision, approximately 2.0cm in length, over the port pocket site.
- Create a subcutaneous pocket using blunt dissection so that the port does not lie beneath the incision. The CathLink Port should be positioned with the funnel-shaped entrance facing toward the hand.
- With blunt dissection create a subcutaneous tunnel between the pocket and the guidewire incisions.
- Remove the guidewire being careful not to retract the 6 Fr. catheter from its position. Pass the catheter through the tunnel to the port pocket.
- Trim the catheter at a 90° angle to proper final length allowing sufficient slack for body movement and port connection.

- Port to catheter connection:

A. Align port stem with catheter lumen.



B. Advance catheter over port stem <u>to midway point.</u>

Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A light pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

C. Advance catheter lock until flush with port.

Note: Be sure there are no kinks or acute bends in the catheter near the stem. Kinks or acute bends will inhibit access with 20 gauge over-the-needle I.V. catheters.

Note: If disconnection and reconnection are required, re-trim the catheter proximal end to ensure a secure connection. It is important to cut the catheter before disconnection as close to the port stem as possible, as the catheter may be damaged by excessive stretching during the disconnection effort.

- Place the **CathLink** 20 port in the subcutaneous pocket with the funnel-shaped entrance facing toward the hand (distal) and away from the incision line and secure base to the underlying fascia using one non-absorbable, monofilament suture per suture hole. This will reduce the risk of port migration and the possibility of it flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.

- After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.

- Access the **CathLink** 20 port through the skin with an over-the-needle I.V. catheter.

- Conduct flow studies on the catheter using a 10ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned. Aspirate to confirm the ability to draw blood.

- Flush and heparin lock the port system as described under heparin lock procedure.

- Close the incision site so that the port does not lie beneath the incision.

- Apply dressing according to hospital practice.

  Note: Leave over-the-needle I.V. catheter in place if the **CathLink** 20 port is to be used for infusion or aspiration on the same day as implantation. Swelling of the port pocket after implantation may inhibit access. This swelling should diminish over the following 5 days.

B

ATTACHMENT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

JAN - 3 1995

Ms. Jane Ann Martin
Regulatory Affairs Administrator
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K926139
Cathlink™ 20 Titanium Port With
Attachable Polyurethane Catheter
Regulatory Class: Unclassified
Product Code: LJT
Dated: October 1, 1994
Received: October 4, 1994

Dear Ms. Martin:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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 Practices (GMP) for Medical Device: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. 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 on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff, (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) ROUTE SLIP

510(k) NUMBER K926139 PANEL HO DIVISION DGRD BRANCH

TRADE NAME CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE CATH

COMMON NAME

PRODUCT CODE

APPLICANT BARD ACCESS SYSTEMS, INC.
SHORT NAME BARDACCESYST
CONTACT JANE ANN MARTIN
DIVISION
ADDRESS 5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
PHONE NO. (801) 595-0700 FAX NO. (801) 595-4969

MANUFACTURER REGISTRATION NO.

DATE ON SUBMISSION 04-DEC-92 DATE DUE TO 510(K) STAFF 20-FEB-93

DATE RECEIVED IN ODE 07-DEC-92 DATE DECISION DUE 07-MAR-93

DECISION DECISION DATE JAN - 3 1995

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	01-JUN-94	02-JUN-94	16-AUG-94	31-AUG-94	22-SEP-94
S002	01-OCT-94	04-OCT-94	18-DEC-94	02-JAN-95	

CORRESPONDENCE	SENT	DUE BACK	
C001	18-MAR-94	21-JUN-94	HOLD LETTER
C002	22-SEP-94	22-OCT-94	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	02-SEP-93	03-SEP-93			
ADD-TO-FILE	05-NOV-93	05-NOV-93			
ADD-TO-FILE	02-JUN-94	03-JUN-94			

WMB

B

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: December 23, 1994

From: REVIEWER(S) - NAME(S) William M. Burdick

Subject: 510(k) NOTIFICATION K926139/S2

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.

_____ (C) Requires more data.

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

Additional Comments: Please refer to the final 510(K) analysis

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

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

80 LJT - unclassified

Additional Product Code(s) w/Panel (optional): Implanted, subcutaneous, intravascular port + catheter

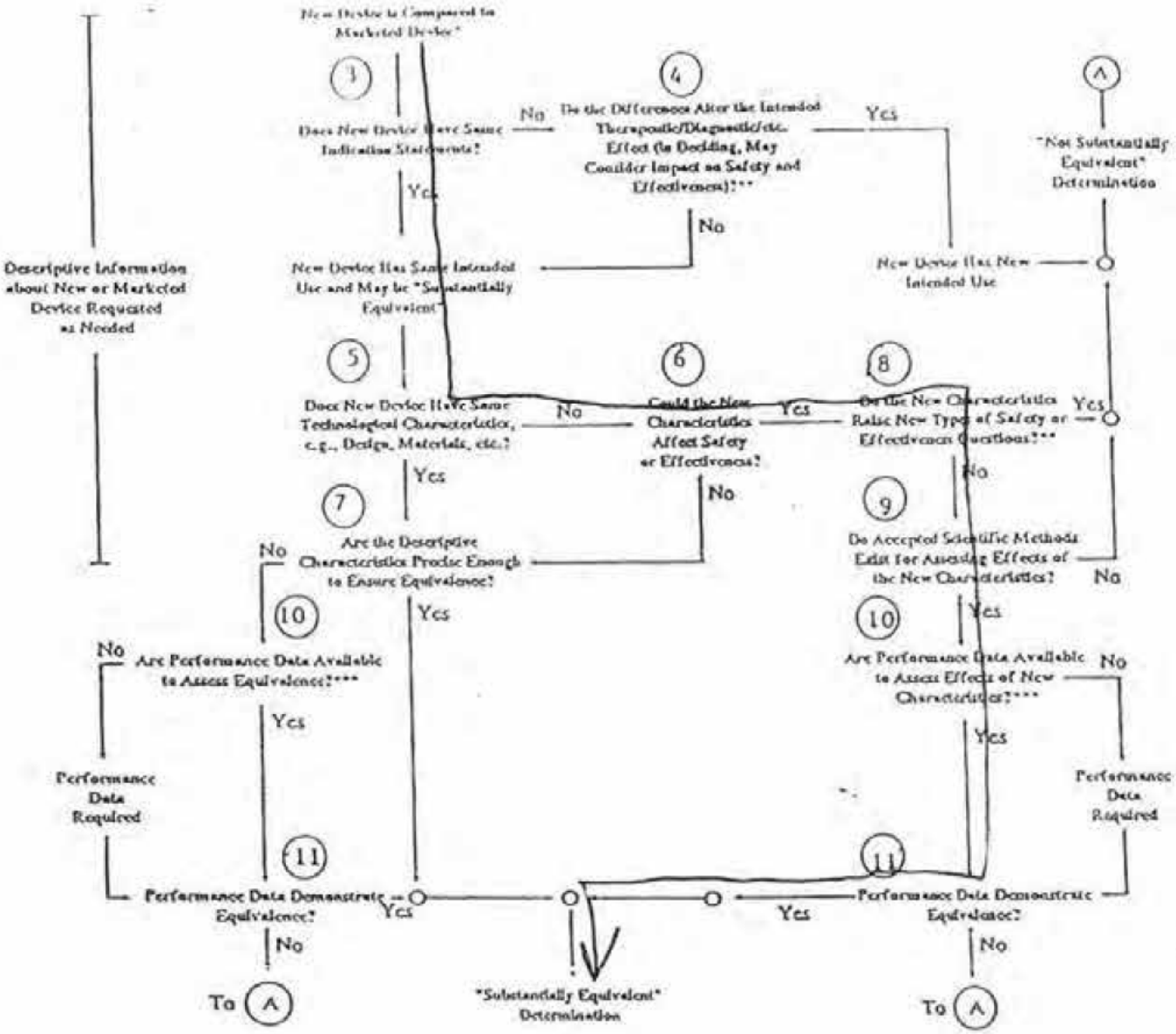
REVIEW: _____ (BRANCH CHIEF) — BRANCH CODE: CHDB — (DATE) 12/27/94

FINAL REVIEW: _____ (DIVISION DIRECTOR) — (DATE) 1/3/95

*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.

K 926139 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: William M. Burdick DIVISION/BRANCH: DGRD / GHDB

TRADE NAME: CathLink™ 20 Titanium Port with attachable polyurethane catheter COMMON NAME: Subcutaneous implantable intravascular port with attachable catheter

PRODUCT TO WHICH COMPARED: Hickman® Titanium Port (K870260)
(510(k) NUMBER IF KNOWN)

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

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: Please refer to #2 of the attached "MEMO TO THE RECORD, 510(K) REVIEW".

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: Please refer to the attached "MEMO TO THE RECORD, 510(K) REVIEW".

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: N/A

2. EXPLAIN WHY NOT SUBJECT TO 510(k):
N/A

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:
N/A

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:
N/A

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS (b) (4) [redacted]

(b) (4) [redacted]

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR

(b) (4) [redacted]

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: (b) (4)

(b) (4)

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

N/A

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

N/A

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

(b) (4)

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

(b) (4)

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "MEMO TO THE RECORD, 510(K) REVIEW".

MEMO TO THE RECORD
510(K) REVIEW

K926139

DATE: December 20, 1994
FROM: William M. Burdick DIVISION:DGRD/GHDB

COMPANY NAME: Bard Access Systems, Inc.
DEVICE NAME: CathLink™20 Titanium Port with attachable polyurethane catheter

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

This device is a single-use totally implantable port and catheter device along with a kit which contains materiel required to successfully implant the device. (b) (4) [redacted]

The device is intended for the long-term infusion of medications, parenteral nutrition solutions, blood products and imaging contrast agents, and the withdrawal of blood samples. It differs dramatically from presently available ports with respect to the method of access, the device components for access, and the placement of the device within the patient, as described below.

The CathLink™20 Titanium Port is composed (b) (4) [redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

2. INTENDED USE:

This device is a single-use, totally implantable port and catheter device for the long-term infusion of medications, parenteral nutrition solutions, blood products, and imaging contrast agents, and the withdrawal of blood samples.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: NO
B. Implant (short-term or long-term): YES
C. Is the device sterile? YES
If yes, is sterility information provided? YES

D. Is the device for single use? YES

E. Is the device for prescription use? YES
If yes, is prescription labeling included? YES

F. Is the device for home use or portable? YES

G. Does the device contain drug or biological product as a component? NO

H. Is this device a kit? YES
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? YES

I. Software-driven: NO

J. Electrically Operated: NO

K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): YES, AAMI method for EtO sterilization.

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Hickman® Titanium Port (K870260) by Bard Access System, Inc.

M. Submission provides comparative specifications? YES[a]
comparative in vitro data? YES[b]
performance data? YES[c]
animal testing? NO[d]
clinical testing? YES[e]
biocompatibility testing? YES[f]

a. A comparison of similarities and differences (features, specifications, intended use, materials, design, theory of operation, accessories,etc.) in tabular form should be included. Differences should be explained with supporting rationale and/or data. If differences include new intended use or new technological characteristics, clinical data would be needed to demonstrate that no new issues of safety and effectiveness are raised. If reference literature is accepted by the FDA to support any differences, copies of the articles must be provided as opposed to listing the author and titles, the significant areas of the articles must be highlighted, and a summary must be provided relating the information to the issue at hand, including a discussion of the study protocol, data, statistical analyses, and a summary of the results.

b. If applicable, comparative bench testing including protocol, data, and a summary of the results should be provided.

c. Performance data including protocol, data, and summary explaining how testing and data demonstrate that the device performs as intended should be provided.

d. If applicable, animal testing including protocol, data, and a summary of the results should be provided.

e. If applicable, clinical testing, including the investigational plan, data, statistical analyses and a summary of results should be provided. If the study was performed under an investigational device exemption (IDE), the IDE number should be provided. If the device is nonsignificant risk, the study should be conducted under the auspices of the institutional review board (IRB) even though an IDE would not need to be filed with the FDA.

f. If applicable, biocompatibility testing, including the protocol for each test required as outlined in the Tripartite Biocompatibility Guidance, the pass/fail criteria, data, and a summary of results should be provided.

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

This device is similar to the predicate Hickman® device, also by C. R. Bard, in that both ports are constructed of titanium, and the septums are comprised, mostly, of silicone. They differ in that the catheter for the CathLink™ is primarily fabricated from polyurethane, while the catheter for the Hickman® is primarily fabricated from silicone.

The CathLink™ device differs dramatically from all other implantable port and catheter devices in terms of the means of percutaneous access to the implanted port and the region of the body in which it is implanted. Access to all other legally marketed ports is accomplished by jabbing a Huber noncoring needle into an elastomeric septum, which seals the port entrance upon removal of the needle. Access to the port for the CathLink™20 is accomplished by advancing an over-the-needle introducer catheter through the three-layered septum and into the port body. The CathLink™ is implanted in the non-axilla area of the upper arm, while the majority of other port and catheter devices are implanted somewhere besides the extremities.

A comparison between mechanical and performance properties of the CathLink™20 Titanium Port with attachable polyurethane catheter and the predicate Hickman® Titanium Port (K870260) is given below:

(Continued on Next Page.)

13

Test	CathLink	Hickman
Flow Rate (ml./hr.)	1392–1645	340–434
Blood Clearance Flushing Vol.	4.5 ml.	–
Septum Puncture Life (1000 punctures)	10 of 10 passed	All passed.
Port Failure Pressure Test	No failure to 150 psi.	No failure to 200 psi.
Catheter Tensile Pull Test (Assembled Dry)		
Axial Pull (lbs.)	Mean: 4.3 Std. Dev.: 0.7	Mean: 4.6 Std. Dev.: 0.8
Pull @ 45° to port (lbs.)	Mean: 5.9 Std. Dev.: 0.6	Mean: 5.2 Std. Dev.: 0.4
Catheter Tensile Test (psi.)	Mean: 8244 Std. Dev.: 529	Mean: 986 Std. Dev.: 27
Catheter Elongation (%)	Mean: 459 Std. Dev.: 24	Mean: 640 Std. Dev.: 22
Catheter Burst Pressure (psi.)	Mean: 181 Std. Dev.: 4.5	Mean: 97 Std. Dev.: 6.0

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? YES

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 LJT

Implanted, subcutaneous, intravascular port and catheter devices are presently unclassified.

William M. Burdick
Biomedical Engineer

FOR JZO

14

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

October 05, 1994

BARD ACCESS SYSTEMS, INC.
5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
ATTN: JANE ANN MARTIN

510(k) Number: K926139
Product: CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE

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

K926139/S2

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

1 October 94

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: K926139 Amendment
CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter

Attn: Bill Burdick

Bard Access Systems, C.R. Bard, Inc., is submitting two copies of this amendment to K926139, the CathLink 20 Titanium Port to provide responses to the request for additional information, as requested in our telephone conversation on 20 September 94.

C. R. Bard, Inc., has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C.R. Bard, Inc., requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification (including amendments) in accordance with 21 CFR 807.95(b). C.R. Bard, Inc., also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any additional questions, please contact the undersigned at 801-595-4982.

Thank you.

Sincerely,

J Martin

Jane Ann Martin
Regulatory Affairs Administrator

TABLE OF CONTENTS

K926139, CathLink 20 Titanium Port
Responses to 20 Sept 94 request for additional information

Question 1.

Response: (b)(4) [redacted]

Question 2.

(b)(4)

[redacted]

Response:

Question 3.

sub-axill

Response:

Is this the same as sub-axilla?

19

Exh. 1

Exhibit 1

CathLink 20 Port Access Assessment

Objective: (b)(4) [redacted]

Method: [redacted]

(b)(4) [redacted]

(b)(4)

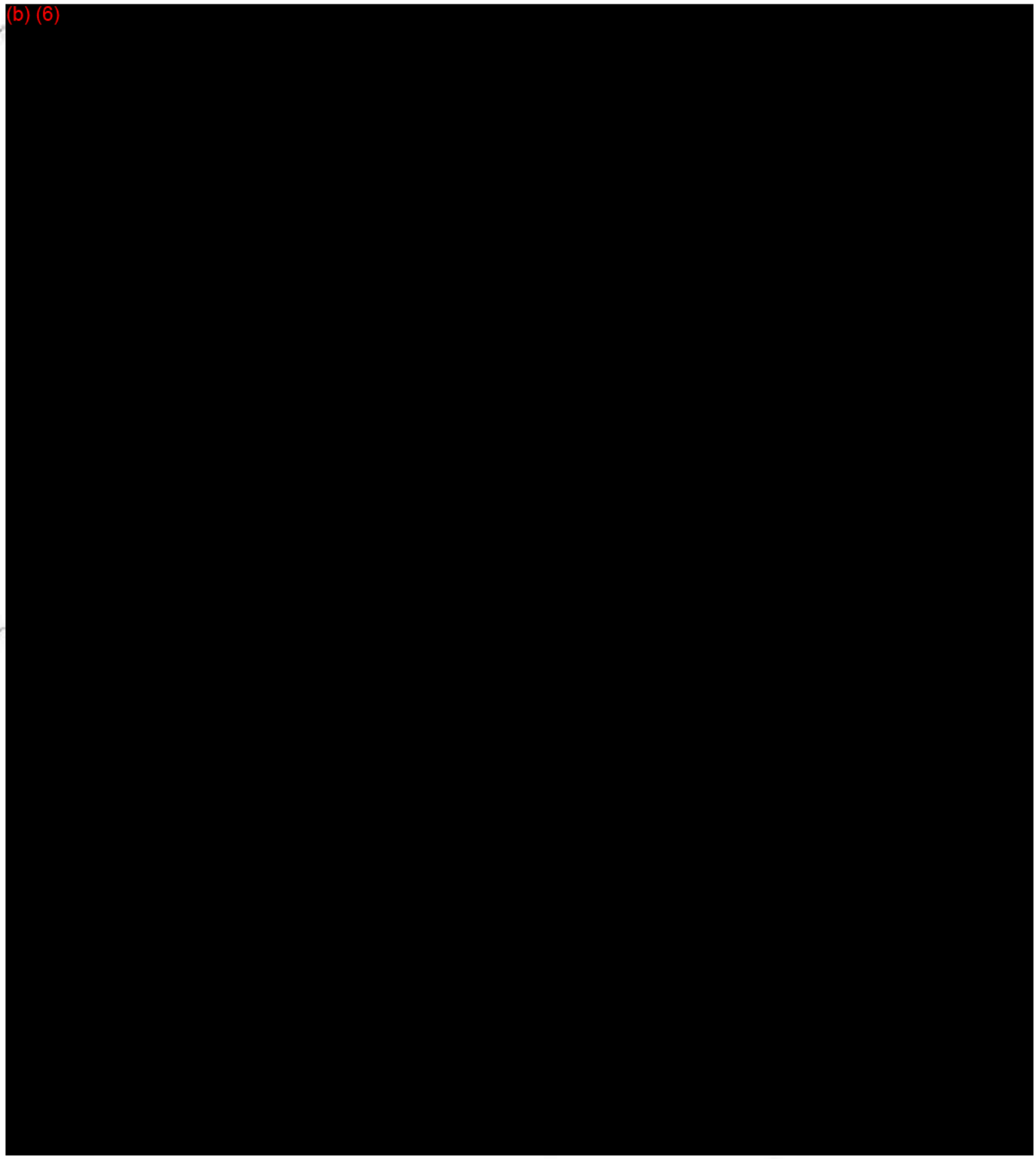
NURSES ADVISORY PANEL

BACKGROUND INFORMATION

(b) (6)

[redacted]

(b) (6)



(b) (6)

[redacted]

Exh.

2

6. Using the thumb and forefinger of dominant hand, advance the over-the-needle I.V. catheter completely into the CathLink 20 port by grasping and advancing the catheter hub only, while simultaneously withdrawing the needle. This can also be accomplished by advancing the over-the-needle I.V. catheter with one hand and withdrawing the needle with the other.

7. Dispose of the needle according to hospital guidelines.
8. Immediately, attach syringe or extension set to over-the-needle I.V. catheter.
9. Verify correct over-the-needle I.V. catheter placement by blood aspiration. If blood aspiration is not achieved, a longer over-the needle I.V. catheter may be appropriate. Failure to confirm placement may result in extravasation.
10. Proceed with infusion protocol.
11. The port must be flushed following injection.
11. Perform heparin lock procedure.

Caution: The over-the-needle I.V. catheter hub should not be left open to air while it is in the CathLink 20 port.

Note: It is recommended that the dressing and infusion components be changed every 24-48 hours during infusion therapy.

Deaccessing the CathLink™ 20 Port

To reduce potential for blood backflow into the catheter tip and possible catheter clotting, always remove the over-the-needle I.V. catheter slowly, while injecting the last 0.5ml of solution. Stabilize the CathLink 20 port with two fingers during over-the-needle I.V. catheter withdrawal.

Exhibit 2

Eln.

3

Exhibit 3

NOTE: INFORMATION IN THIS EXHIBIT WAS ALSO PROVIDED TO THE FDA IN EXHIBIT 2.2 OF THE RESPONSE SUBMITTED 6/1/94. **BASED ON THE REVIEWER'S QUESTIONS ON 9/20/94, ADDITIONAL INFORMATION HAS BEEN PROVIDED AND IS PRESENTED IN A DISCUSSION SECTION AND UNDERLINED.**

PUNCTURE LIFE at DESIGN LIMITS TESTS

OBJECTIVE: The primary objective was to evaluate the performance of the CathLink 20 port septum using a (b) (4) [redacted]

METHOD: (b) (4) [redacted]

(b) (4) [redacted]

RESULTS:

1.0

CATHLINK 20 PORT, INITIAL LEAK TESTING (N=37)

Test Conditions	Percent Passed	Percent Failed
(b) (4) [redacted]	100%	0%
	100%	0%
	100%	0%

2.0

CATHLINK 20 PORT AFTER 500, 1000, 2000, 2500 AND 3000 PUNCTURES (N=37)

Test Conditions	Percent Passed	Percent Failed
(b) (4) [redacted]	100%	0%
	100%	0%

3.0

CATHLINK 20 PORT, MAXIMUM PRESSURE AFTER 3000 PUNCTURES

Test Conditions	Percent Passed	Percent Failed
(b) (4) [redacted]	100%	0%
	100%	0%

4.0

VALVE ANGLE AND VALVE BOND

Summary of Valve Slit Angle Measurement Results (Before & After 3000 Punctures) N=30				
Statistic	**Valve Angle Degree (Before)**	**Valve Angle Degree (After)**	**Difference (Degrees)**	**Valve Adhesion**
Average	(b)(4)Proprietary Information			n = 30 valve bonds intact
Maximum				
Minimum				

DISCUSSION: The purpose of the valve adhesive is to hold the valves together during port assembly. After assembly, the septum is compressed axially and the interface between the septum layers does not undergo further shear or tensile stress. Thus, while the bond is not functionally necessary for the septum once assembled, the adhesive bond was maintained after repeated punctures. The small difference in angle represents measurement variability so we can conclude that the angle formed by the slits in the valves did not change after repeated punctures. Note: The minimum angle actually tested ([redacted] in results table 4.0) exceeds our acceptance criteria range ([redacted]° as listed in the methods section table). Therefore, holding a precise 90° angle is not necessary and the acceptable range is within manufacturing capability.

SPECIFICATION: [redacted]

Determination of specification limits: The tests with an IV catheter in place simulate conditions during infusion. [redacted]

CONCLUSION: The CathLink 20 port exceeds puncture life requirements at design tolerance extremes. Further, the CathLink 20 port is leak tight after 3000 punctures (three times the specification) at a pressure [redacted]

[redacted]

Exh.

4

Caution: Read directions prior to use. Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Caution: When utilizing the Arm Placement via Brachial/Basilic approach, the port should be implanted in the [redacted]

Precautions

- Only physicians qualified in the implantation of subcutaneous vascular access devices should implant these devices.
- Care must be exercised when implanting the port system to avoid mechanical damage to the catheter. Catheters should only be clamped with smooth-edged atraumatic clamps or forceps. The catheter should not be used if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolization which may require surgical removal.
- The port system should be implanted carefully to avoid any sharp or acute angles which could compromise the patency of the catheter lumen.
- Caution should be observed when using insertion techniques which require guide wires, since mechanical damage can be inflicted upon the catheter lumen during insertion or removal of the wire, resulting in possible perforation, tear, or fracture of the catheter.
- Caution should be exercised when using percutaneous introducers to avoid inadvertent injury to vital structures. Instructions for use are provided with **all Bard Access Systems** percutaneous introducer kits and should be carefully followed.
- To avoid air embolism, all air must be purged from the device by filling the port system with sterile heparinized saline solution prior to attaching an open-ended catheter.
- To ensure proper catheter connection, the connection technique outlined in these instructions should be carefully followed.
- The instructions for catheter handling and care provided in this instruction booklet should be followed to avoid circumstances that could jeopardize catheter patency or function.
- Only 20 gauge over-the-needle I.V. catheters 1 ¼" or longer should be used with **CathLink** 20 port. Non-coring needles should not be used. The exact I.V. catheter length will be determined by the clinical situation. Longer over-the-needle I.V. catheters may be used for added security in [redacted]
- Do not reuse over-the-needle I.V. catheters. Reuse may cause tip deformities which may tear or damage the **CathLink** 20 multi-layered septum.
- If sutures are used to secure the **ChronoFlex** catheter, care should be taken to avoid occluding or injuring the catheter.
- Infusion pressures in excess of 25 psi may damage blood vessels and are not recommended.

Please note that smaller syringes generate more pressure than larger syringes. A three pound force on the barrel of a 3cc syringe generates pressure in excess of 25 psi whereas the same three pound force on the barrel of 10cc syringe generates less than 10 psi of pressure. It is recommended to use no syringe smaller than a 10 cc size with Bard Access Systems implanted ports.

- Correct positioning of the over-the-needle I.V. catheter within the **CathLink** 20 port should always be determined before infusion of any substance to ensure that the I.V. catheter is positioned properly through the silicone septum layers. The preferred method to confirm placement is by the aspiration of blood. If blood aspiration is not achieved, a longer over-the-needle I.V. catheter may be appropiate. Failure to confirm placement may result in extravasation. If there is doubt regarding proper over-the-needle I.V. catheter placement, a radiographic dye study should be performed to confirm placement.
- Injections should be discontinued and appropriate medical intervention begun immediately if signs of extravasation exist.
- Prior to infusion of any substance via the port, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
- **Bard Access Systems** ports are intended for single patient use and should never be reused.

---

[1] Aitken DR, Minton JP. "The Pinch-off Sign: and A Warning of Impending Problems with Permanent Subclavian Catheters", Am J. Surg 148: 633-636, 1984.

Exhibit 4
pg. 1

220

CATHLINK™ 20 Implanted Port

Brachial/Basilic Approach

Implantation Instructions

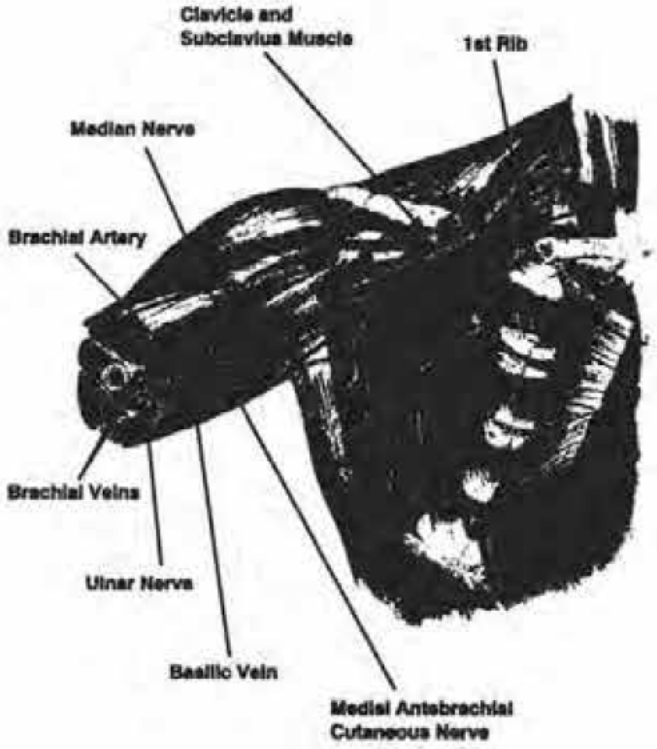


Exhibit 4
pg. 2

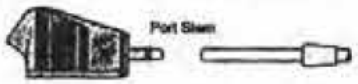
Implantation Instructions

[redacted] via Brachial/Basilic

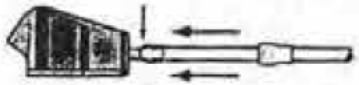
- Complete patient implant record, including product reorder number and lot number.
- Insert an over-the-needle I.V. catheter in a peripheral vein in the same upper extremity distal to the proposed CathLink 20 port venous access site.
- Position the arm in an abducted, externally rotated position.
- Select desired port site. (refer to page 13)
- Sterilely prep and drape the upper arm and axilla.
- Using flush connector, flush open-ended catheter with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end. **Note:** Catheter should be clamped on segment that will be cut off prior to attachment to port to avoid catheter damage.
- Inject contrast dye into the distal peripheral over-the-needle I.V. catheter to allow for visualization of the selected vein to be accessed under fluoroscopy.
- Under local anesthesia, puncture the selected brachial or basilic vein at the midpoint of the arm with an 18 gauge thin-wall needle.
- Under fluoroscopic guidance, advance the extra-long guidewire through the needle into the accessed vein and into the superior vena cava.
- Remove the needle and make a small incision over the guidewire.
- Place a 7 Fr. dilator over wire into the vein to maintain venous access.
- Make a transverse incision, approximately 2.5cm in length, over the port pocket site.
- Create a subcutaneous pocket using blunt dissection so that the port does not lie beneath the incision.
  Note: The CathLink 20 port should be positioned with the funnel-shaped entrance facing toward the elbow (distal).
- Remove the dilator and advance the catheter over the guidewire.
- With blunt dissection create a subcutaneous tunnel between the pocket and the guidewire incisions.
- Position the catheter tip at the desired infusion site.
  Note: A common location for catheter tip placement is the junction of the Superior Vena Cava and right atrium.

- Confirm catheter position via fluoroscopy.
- Remove guidewire and pass the catheter through the tunnel to the port pocket, making certain fluoroscopically that the desired catheter tip position is maintained.
  Note: An injection of radiographic contrast may be used for additional visualization.
- Trim catheter at a 90° angle to proper final length allowing sufficient slack for body movement and port connection.
- Port to catheter connection

A. Align port stem with catheter lumen.



B. Advance catheter over port stem to midway point.



Warning: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

C. Advance catheter lock until flush with port.

Caution: If the catheter and lock are connected and then disconnected, the catheter end must be re-trimmed prior to re-connection to ensure a secure connection. It is important to cut the catheter before each re-connection, as the catheter may be damaged by excessive stretching during disconnection.

Exhibit 4
pg. 3

Site Preparation

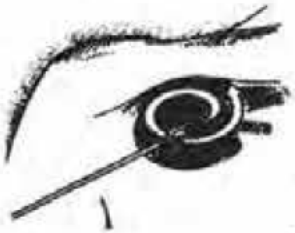
Inspection and aseptic preparation of the injection site should always be performed prior to accessing the port.

Equipment:

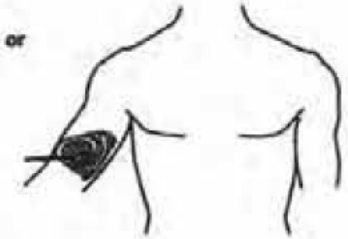
- Sterile gloves
- Alcohol wipe
- Antiseptic swabs (3)

Procedure:

1. Explain procedure to patient. Warn of needle prick sensation.
2. Wash hands thoroughly.
3. Don sterile gloves.
4. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 4-5 inches in diameter.
5. Repeat Step #4 with antiseptic swabs three times.



or



Accessing the CathLink™ 20 Port

Equipment:

- 20 gauge over-the-needle I.V. catheter in a 1¼" minimum length*
- 10ml or larger syringes
- Extension Set with Clamp

Procedure:

Note: If the CathLink 20 Port is implanted in the arm and the patient is accessing his or her own port, a second person may be required to assist.

1. Perform aseptic site preparation.
2. Utilizing a sterile gloved hand:
   - Locate the **CathLink** 20 port and identify the funnel-shaped entrance by palpation.
3. Stabilize the **CathLink** 20 port by "holding" between thumb and forefinger of non-dominant hand.

4. Aim for the funnel shaped entrance which is between these two fingers.
5. Insert a 20 gauge over-the-needle I.V. catheter into the **CathLink** 20 port funnel shaped entrance until resistance is felt.

Precaution: Only 20 gauge over-the-needle I.V. catheters 1¼" or longer should be used with **CathLink** 20 port. Non-coring needles should not be used. The exact I.V. catheter length will be determined by the clinical situation. Longer over-the-needle I.V. catheters may be used for added security **as above pictured.**

Exhibit 4
pg. 4

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

September 22, 1994

BARD ACCESS SYSTEMS, INC.
5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
ATTN: JANE ANN MARTIN

510(k) Number: K926139
Product: CATHLINK 20
TITANIUM PORT
W/ATT.
POLYURETHANE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate 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 telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

510(K) ROUTE SLIP

510(k) NUMBER K926139 PANEL HO DIVISION DGRD BRANCH

TRADE NAME CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE CATH

COMMON NAME

PRODUCT CODE

APPLICANT BARD ACCESS SYSTEMS, INC.
SHORT NAME BARDACCESYST
CONTACT JANE ANN MARTIN
DIVISION
ADDRESS 5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
PHONE NO. (801) 595-0700 FAX NO. (801) 595-4969

MANUFACTURER REGISTRATION NO.

DATE ON SUBMISSION 04-DEC-92 DATE DUE TO 510(K) STAFF 20-FEB-93

DATE RECEIVED IN ODE 07-DEC-92 DATE DECISION DUE 07-MAR-93

DECISION DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	01-JUN-94	02-JUN-94	16-AUG-94	31-AUG-94	22-SEP-94

CORRESPONDENCE	SENT	DUE BACK	
C001	18-MAR-94	21-JUN-94	HOLD LETTER
C002	22-SEP-94	22-OCT-94	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	02-SEP-93	03-SEP-93			
ADD-TO-FILE	05-NOV-93	05-NOV-93			
ADD-TO-FILE	02-JUN-94	03-JUN-94			

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: Sept. 21, 1994

From: REVIEWER(S) - NAME(S) William M. Burdick

Subject: 510(k) NOTIFICATION K926139/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.

✓ (C) Requires more data. Hold - send DMC Hold letter

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

Additional Comments: Refer to memoranda dated 9/9/94, 9/16/94, and 9/20/94.

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

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

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

_____

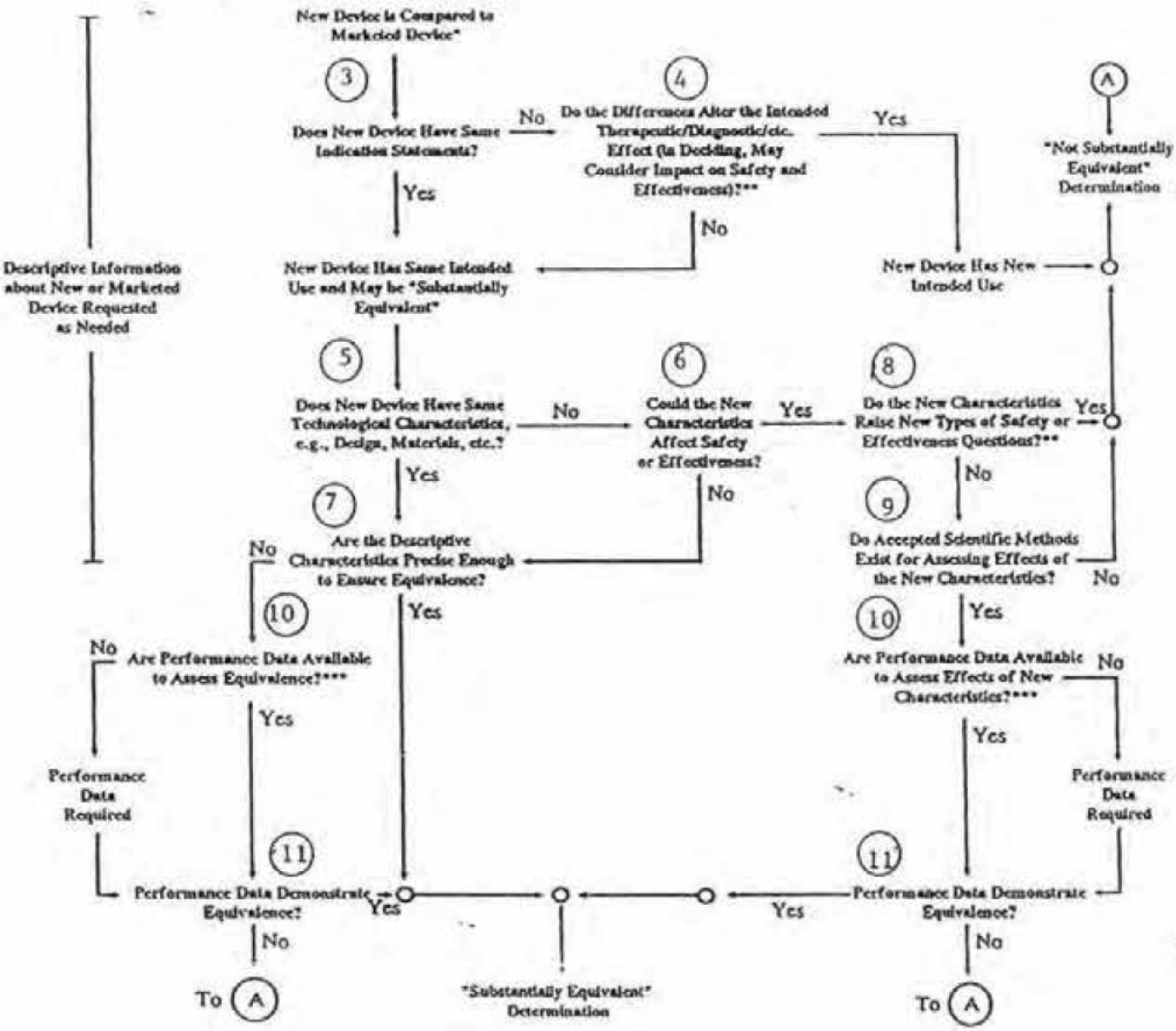
REVIEW: [signature] (BRANCH CHIEF) — GHDB (BRANCH CODE) — 9/21/94 (DATE)

FINAL REVIEW: [signature] for T.V. 9/21/94 (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.

MEMORANDUM OF TELEPHONE CONVERSATION

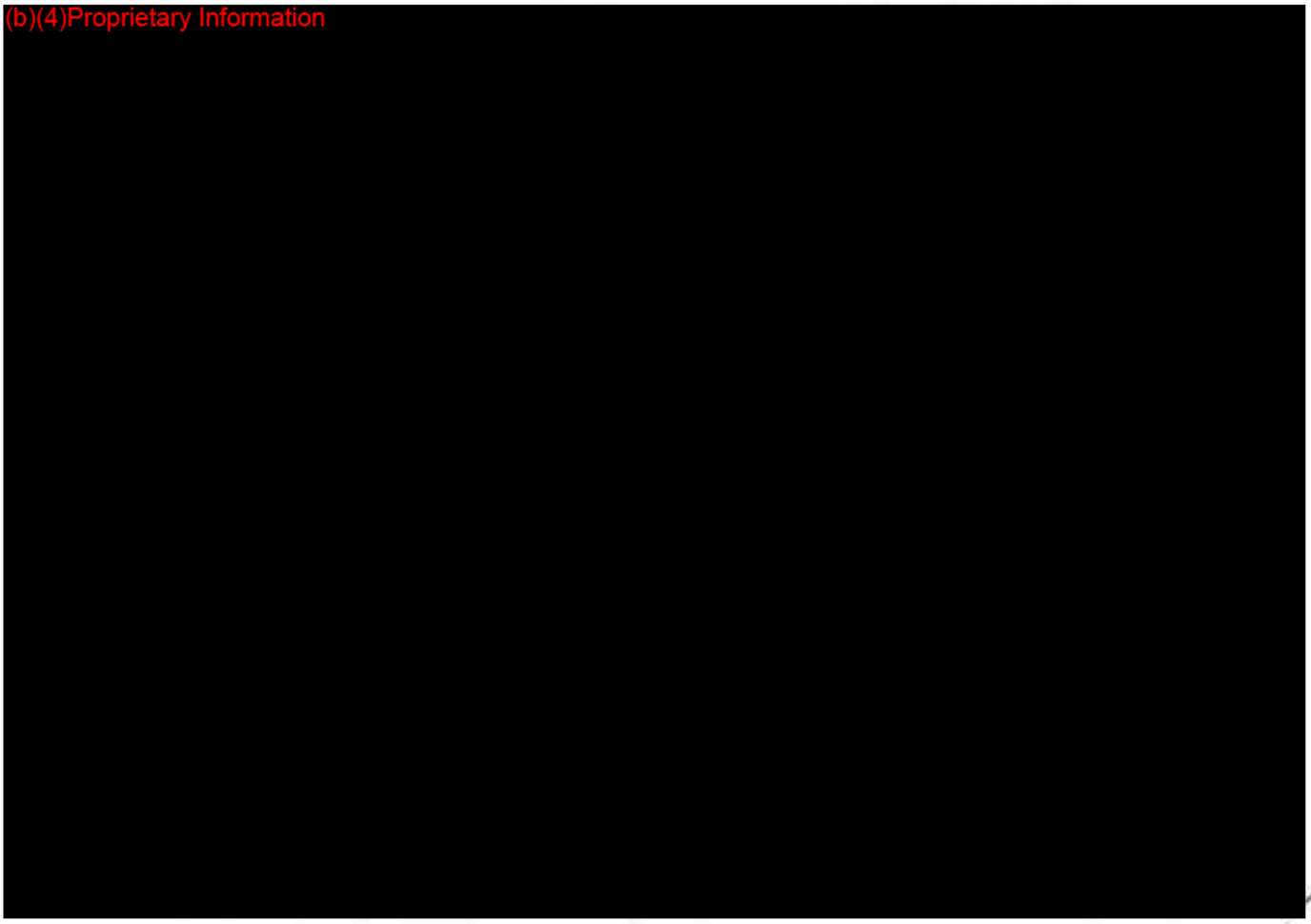
DATE: September 20, 1994

TO: Jane Ann Martin
Regulatory Affairs Administrator
Bard Access Systems, Inc.
5245 West Amelia Earhart Drive
Salt Lake City, UT 841116

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DGRD/GHDB
HFZ-410
1390 Piccard Drive
Rockville, MD 20850

SUBJECT: 510K Number K926139 - CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter

(b)(4)Proprietary Information



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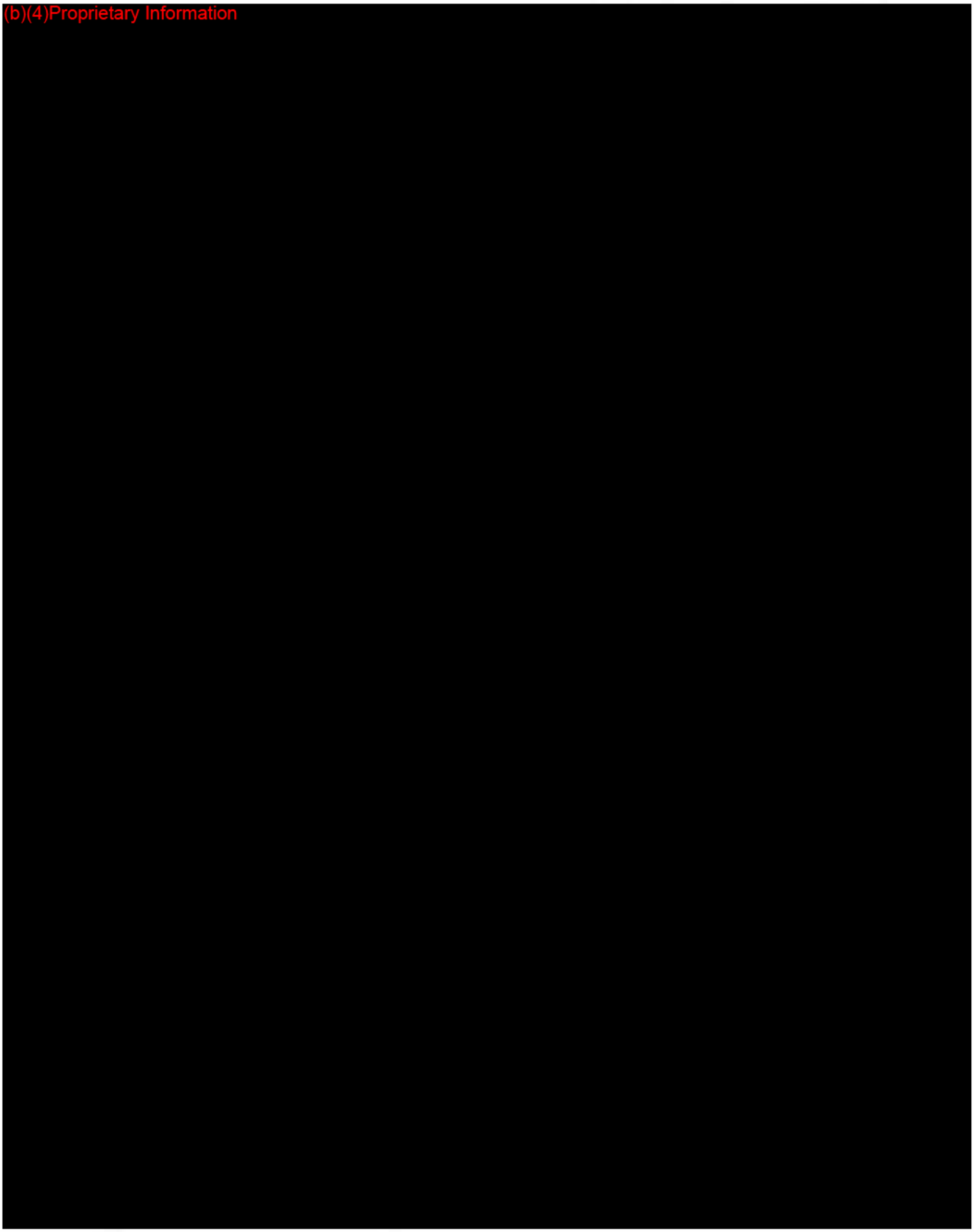


(b)(4)Proprietary Information

[redacted]

I concluded our conversation by telling Ms. Martin, et. al., that the submission would be placed on "Hold" until the information was received by our Document Mail Center. She stated that they would send the information ASAP.

Sincerely,

William M. Burdick

William M. Burdick
Biomedical Engineer

2/1/94

cc. K926139
CHRON file

MEMORANDUM TO THE RECORD

DATE: September 16, 1994

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DGRD/GHDB
HFZ-410
1390 Piccard Drive
Rockville, MD 20850

SUBJECT: 510K Number K926139B - CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter

(b)(4)Proprietary Information

[redacted]

Sincerely,

William M. Burdick

William M. Burdick
Biomedical Engineer

cc. K926139B
CHRON file

MEMORANDUM TO THE RECORD

DATE: September 9, 1994

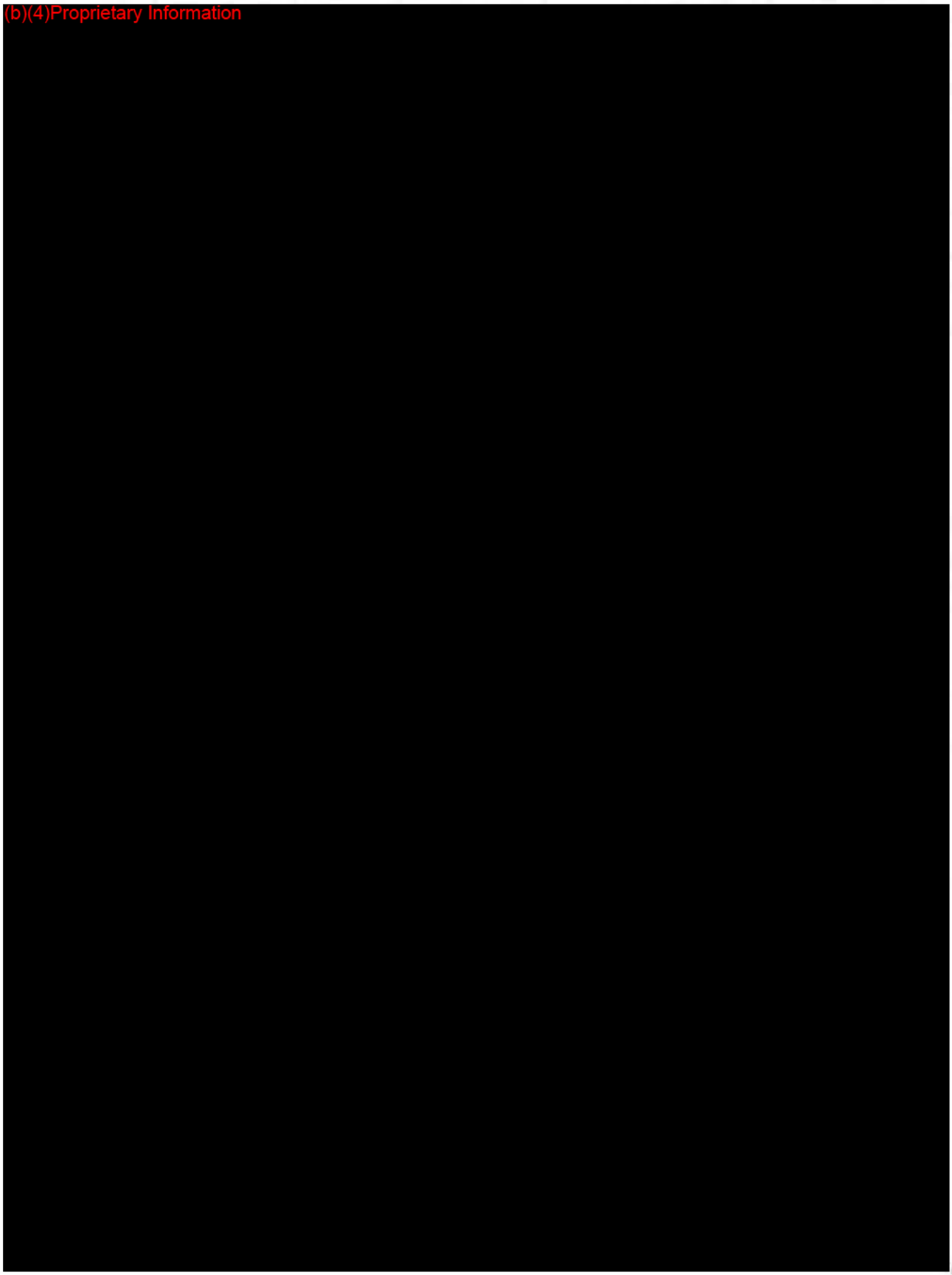
FROM: William M. Burdick
HHS/PHS/FDA/ODE/DGRD/GHDB
HF2-410
1390 Piccard Drive
Rockville, MD 20850

SUBJECT: Meeting to Address Remaining Deficiencies Regarding 510K Number K926139 (CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter)

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

Sincerely,

William M. Burdick

William M. Burdick
Biomedical Engineer

cc. K926139
CHRON file

11

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

June 07, 1994

BARD ACCESS SYSTEMS, INC.
5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
ATTN: JANE ANN MARTIN

510(k) Number: K926139
Product: CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE

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

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

K926139/S1

BARD

1 June 94

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: K926139 Amendment
CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter

Attn: Brenda Bolden

Bard Access Systems, C.R. Bard, Inc., is submitting two copies of this amendment to K926139, the CathLink 20 Titanium Port to provide responses to the request for additional information, as outlined in your letter of 21 March 94.

C. R. Bard, Inc., has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C.R. Bard, Inc., requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification (including amendments) in accordance with 21 CFR 807.95(b). C.R. Bard, Inc., also requests that the FDA keep and maintain confidential the contents of this letter.

The information in this amendment supports our position that the CathLink 20 port is substantially equivalent in both design and intended use to the predicate

B

devices, the Hickman port and P.A.S. port. If you still have questions after examining the sample port and port components we have shipped under separate cover to Brenda Bolden and reading the responses, we would be happy to meet with you to further explain any remaining questions. A meeting might be very helpful in facilitating your review.

If you have any additional questions, please contact the undersigned at 801-595-4982.

Thank you.

Sincerely,

Jane Ann Martin
Regulatory Affairs Administrator

TABLE OF CONTENTS

EXHIBIT LISTING

Exhibit #	Re: Question #	Description
1	1.1, 6.1	CathLink 20 Port Drawing
2	1.2.2, 4.3 &	Septum Puncture Test Data
2.1	2.2.3.3	Septum Puncture Life Test Data (to 1000 punctures)
2.2	1.5.4, 2.2.3.3, 6.1	Septum Puncture Life Test Data (to 3000 punctures)
3	1.2.3	Elongation Test Data
4	1.2.4, 2.1.2.1	Flow Rate Test Data
5	1.5.2, 3.3	Peripheral IV Catheter Compatibility with CathLink 20 port
6	1.5.4 &	Extravasation Data
6.1	9.2	Comparative IV Catheter Retention Test Data
6.2		Pressure Test Data
7	1.3.1, 2.1.2.2	Blood Clearance Test Data
8	1.5.5	Septum Chamber Diagrams
9	1.5.6	P.A.S. Port Brochure
10	1.5.6 &	Dr. Ensminger's Information Packet
10.1	3.5, 4.1, 9.2	Additional Information from Dr. Ensminger

	10.2	9.2	Reprint: Experience with Subcutaneous Infusion Ports in Three Hundred Patients, T.E. Brothers, W.D. Ensminger, et al, Surgery Gynecology & Obstetrics, April, 1988, Vol. 166, No. 4, p. 295.
	10.3	4.1, 9.2	Reprint: Initial Clinical Evaluation of a New Implanted Port Accessed by Catheter Over-the-needle Systems, W.D. Ensminger, et al, J. Infusional Chemotherapy, Vol. 3, No.4, 1993, p. 200. [Published paper from the draft included in the original CathLink 20 Port 510(k) submission.]
11		1.5.7	Needle stop and IV Catheter Insertion Damage Information
	11.1		Needle stop Function Drawing
	11.2		IV Catheter Damage After Insertion Into the CathLink Port test data and photographs
12		1.3.2, 1.5.3, 1.5.7, 1.5.8, 2.2.4.4, 3.1, 3.2, 3.6, 3.7, 3.8, 3.9, 3.11, 3.12, 4.1, 4.5.2, 8.	Revised Instructions For Use (IFU)
13		3.12	CathLink 20 Diagrams Illustrating the Preformed Tip of the (b) (4) Polyurethane Catheter and Catheter-Port Assembly
14			FDA letter requesting additional information
15		2.2.4.4	Port Failure Pressure Test Data
16		2.3	Additional FDA Port Guidance Test Data
	16.1		Port/Catheter Connection - Static Load Test Data
	16.2		Port/Catheter Connection - Cyclic Load
	16.3		Catheter Pull Test after (b) (4) Exposure to Fluid
17		3.5, 4.1	Reprint, Initial Experience with Percutaneous Placement of the PAS Port Implantable Venous Access Device, Marc L. Kahn, et al, Radiology JVIR, Vol.3, No.3, August 1992, p459.
18		3.5, 4.1, 9.2	Reprint: Placement and Management of Long-Term Central Venous Access Catheters and Ports, D.F. Denny, Jr., AJR 1993, 161:385.

19		3.10, 5.1	ETO Sterilization of Nylon Sutures Test Data
20		3.10, 5.2	Glove Sterilization Test Data
21		4.1	Copy of PAS Port IFU cover and pg. 1
22		5.3	Separate Drug IFU Packaged in the Kits
	22.1		Sterile Saline IFU
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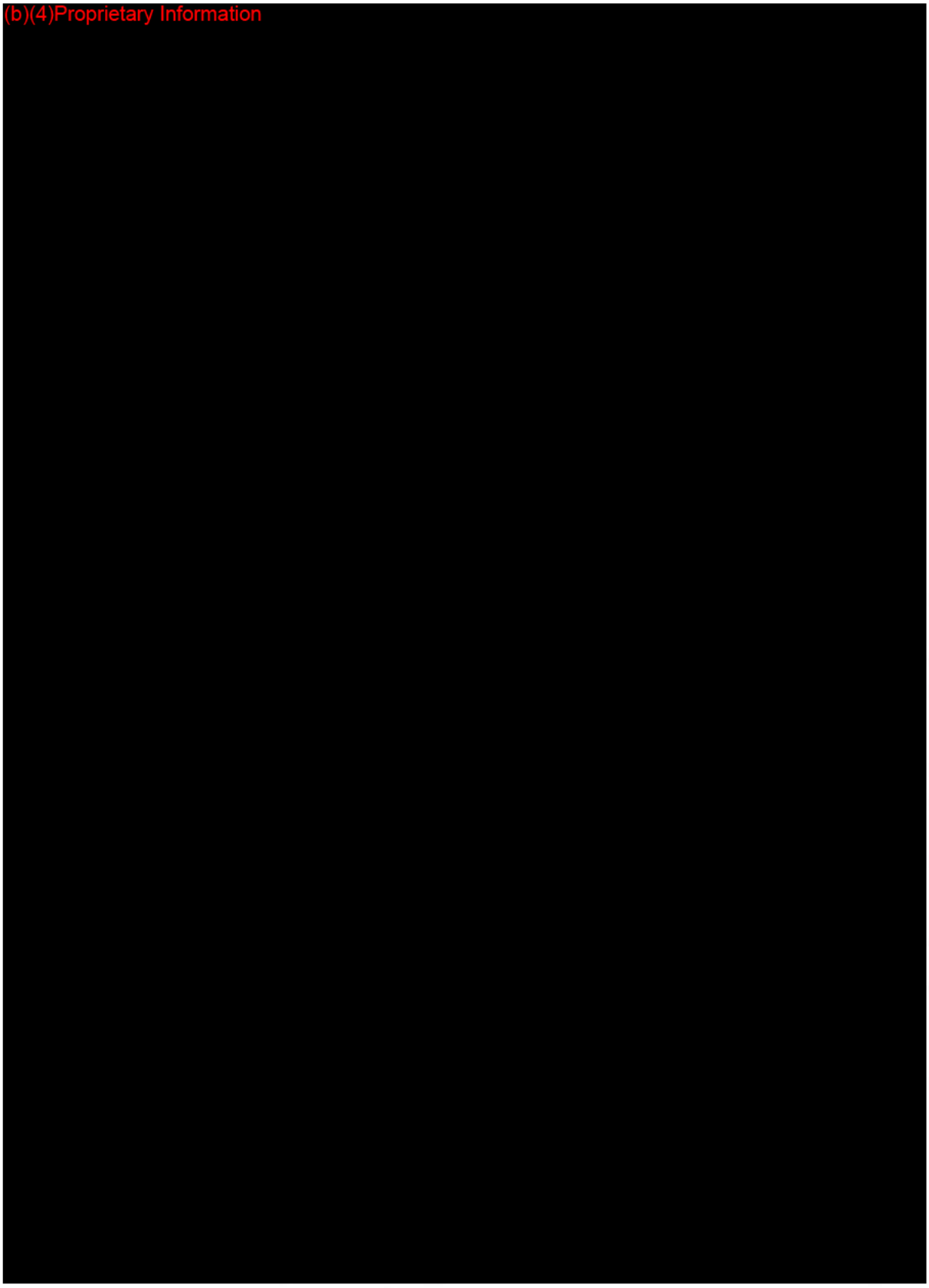
23		1.4	(b) (4) Catheter Master Device File Information
24		7.1	Septum Function Diagram
25		4.5.2	Effects of IV Catheter Insertion Over Time
	25.1		Continuous Use Data from Original 510(k) submission
	25.2		Slit Layer Reseal Test Data
26		1.5.8, 3.1.8	Analysis of IV Catheter Engagement for Various Port Placement Depths and IV Catheter Lengths

K926139, CathLink 20 Titanium Port
Responses to 21 Mar 94 request for additional information

(b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information



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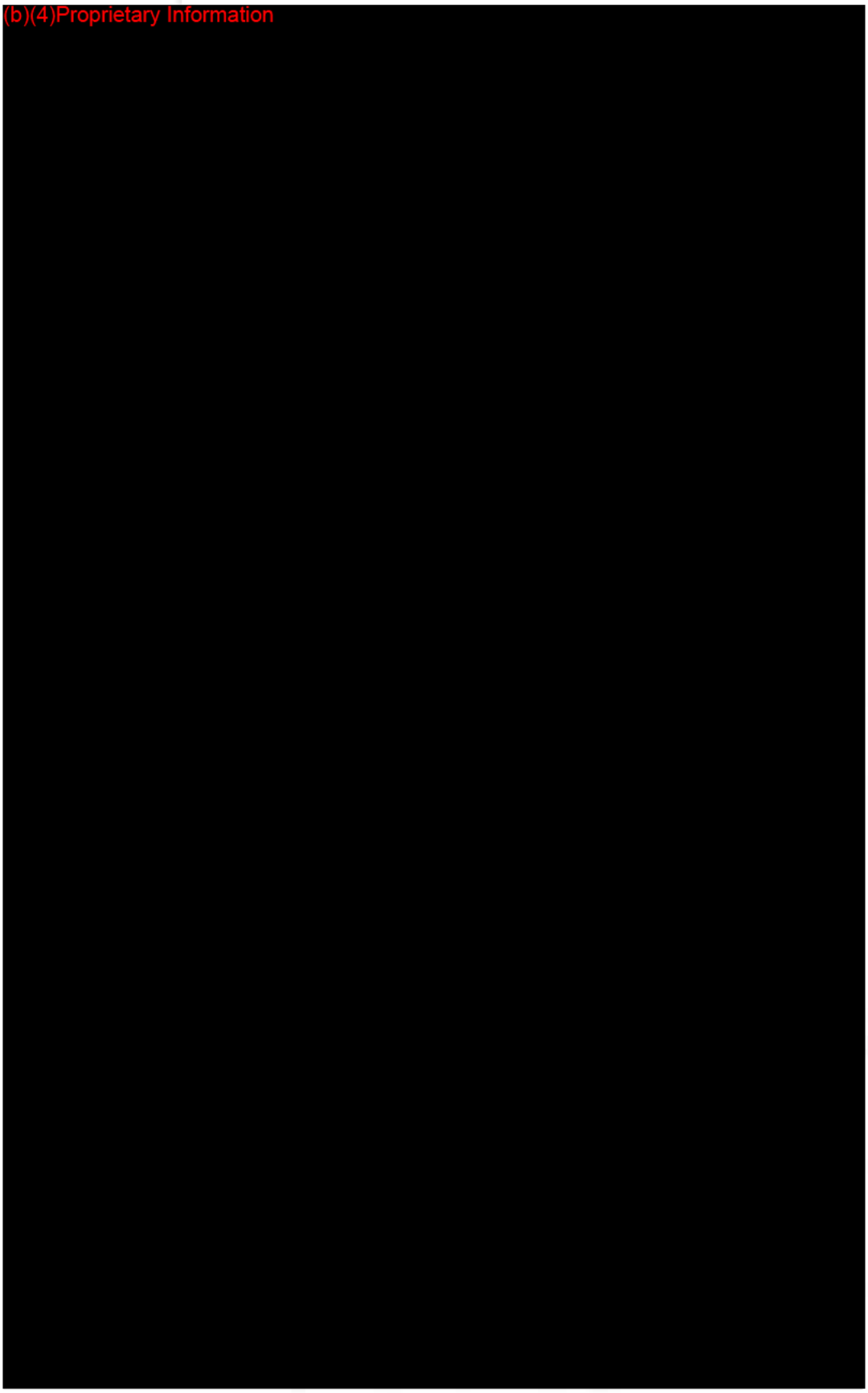

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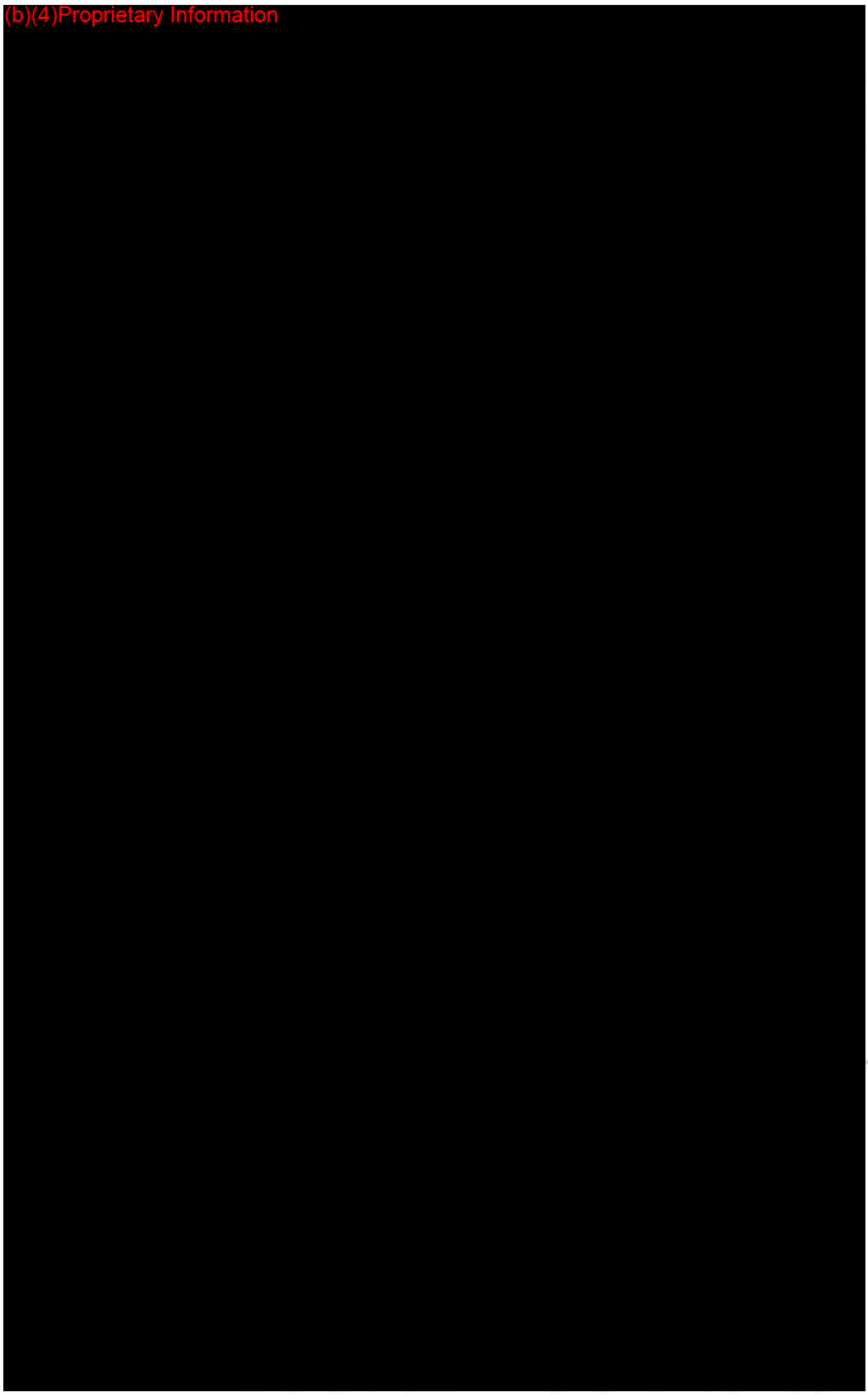

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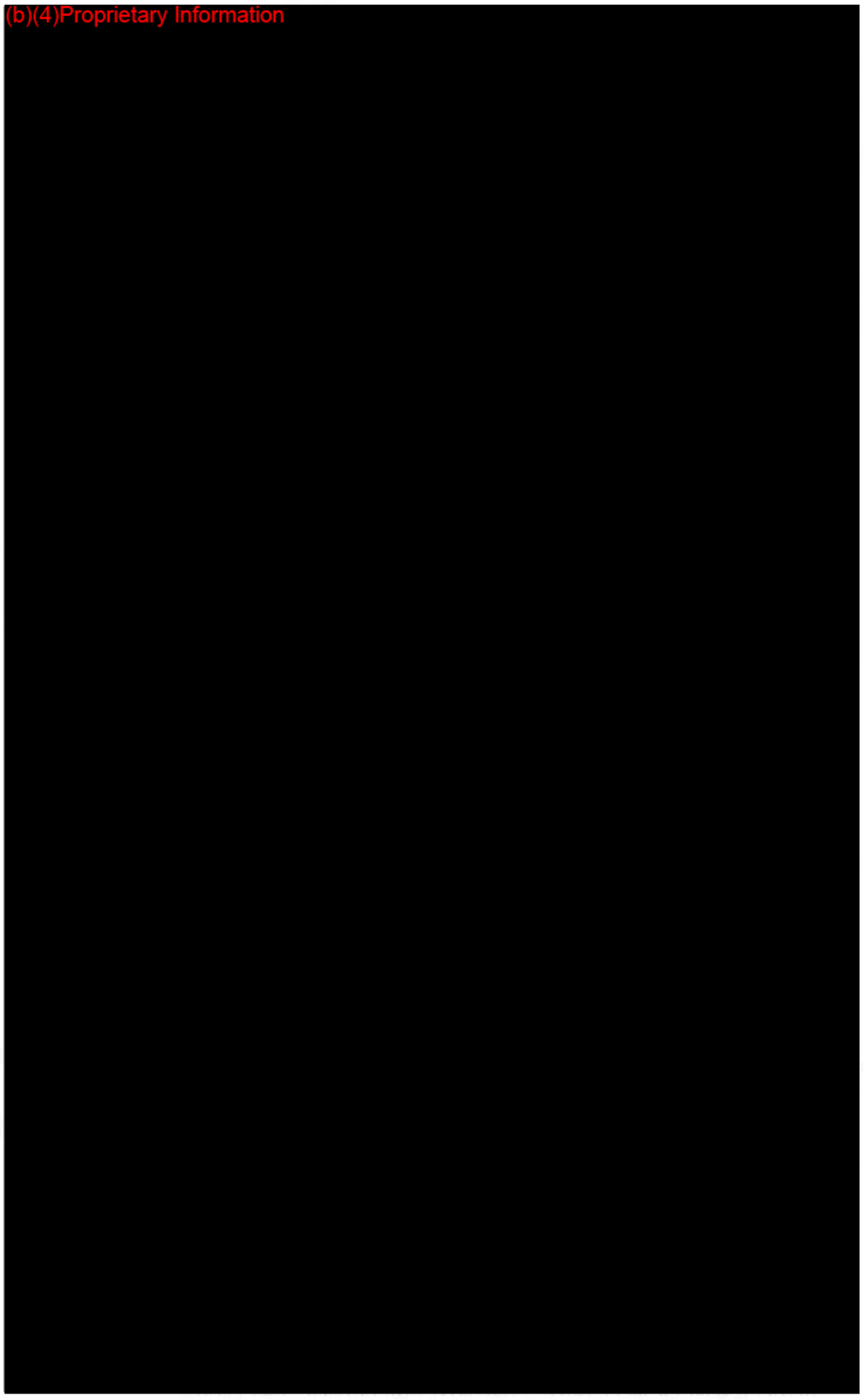

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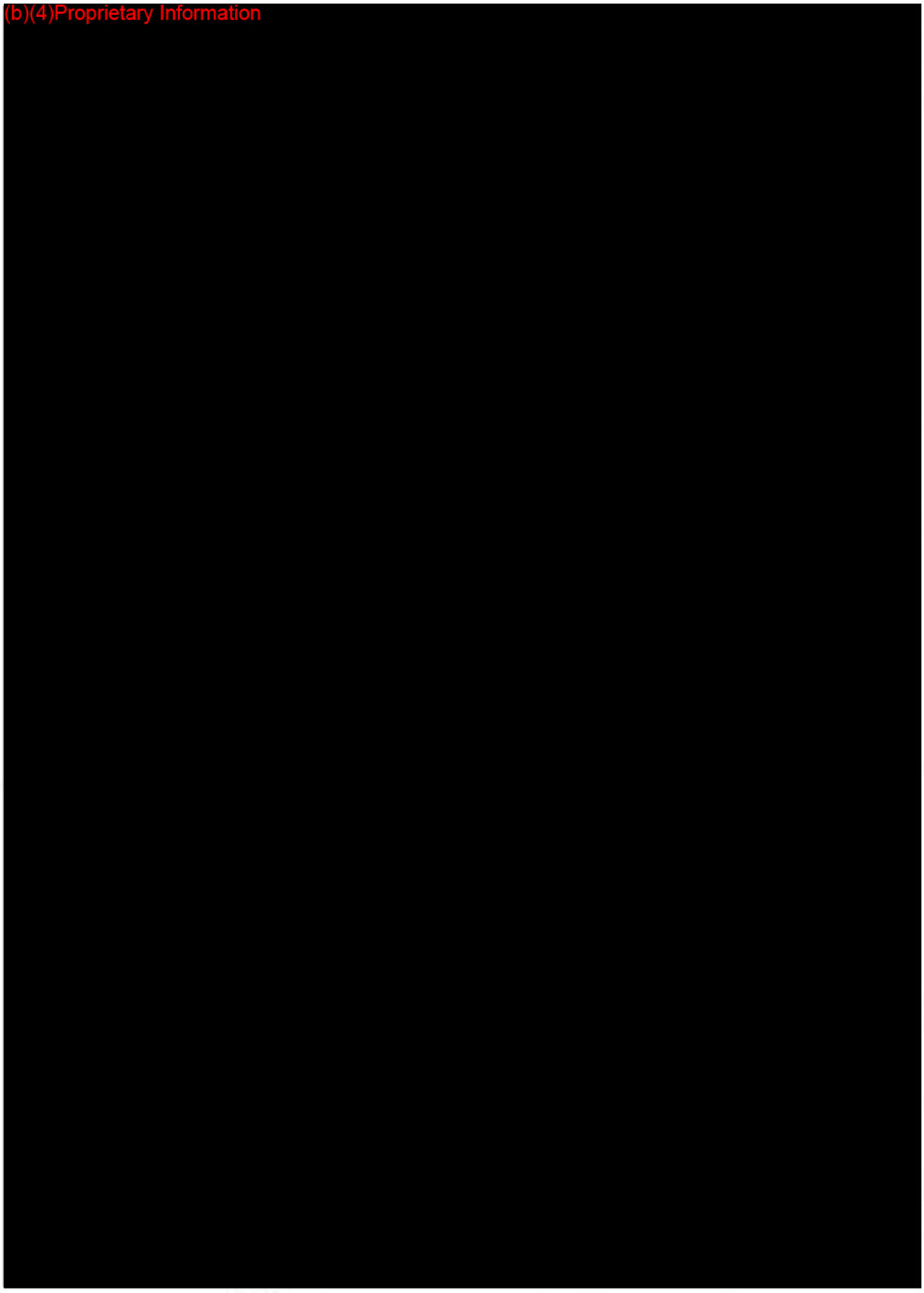

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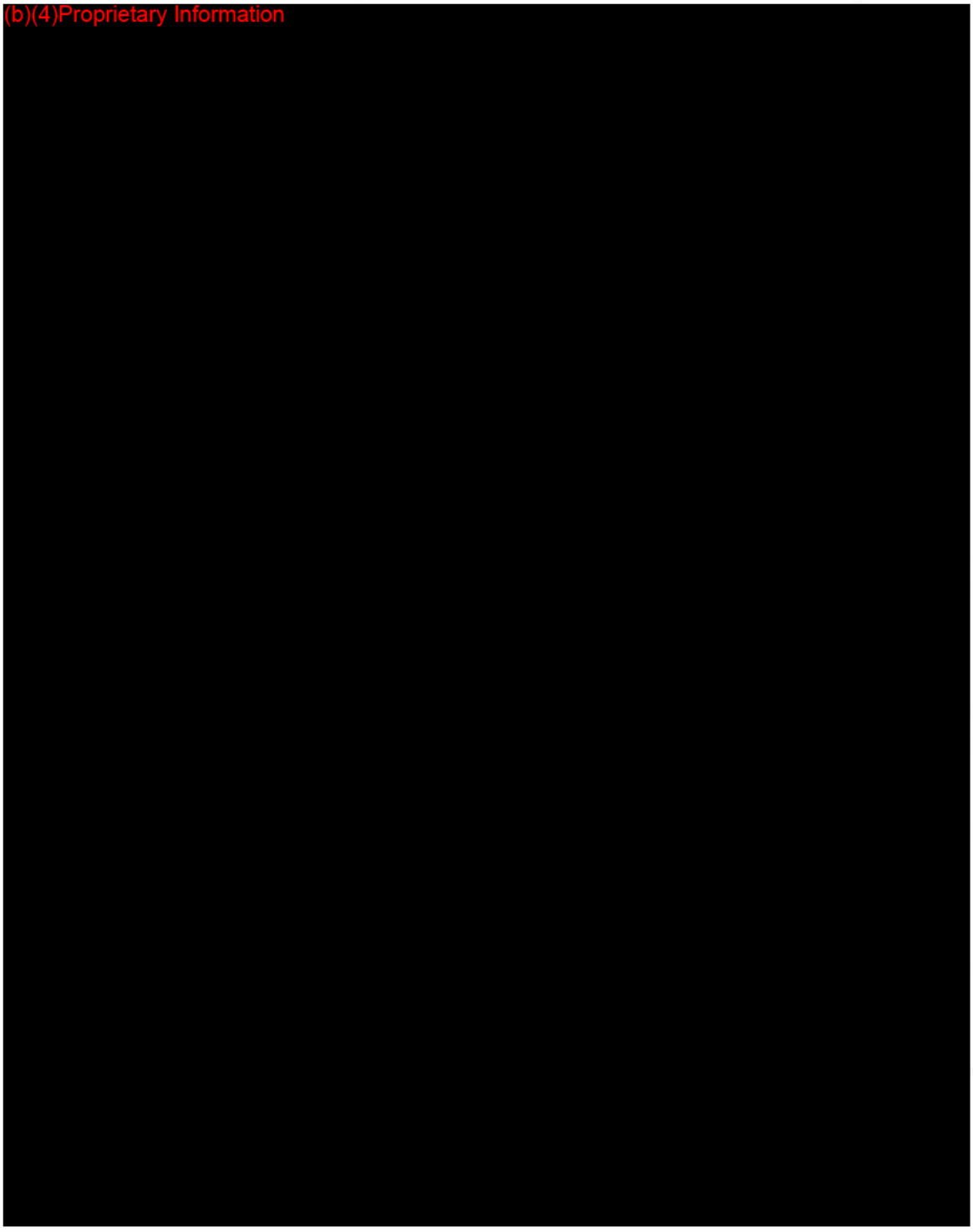

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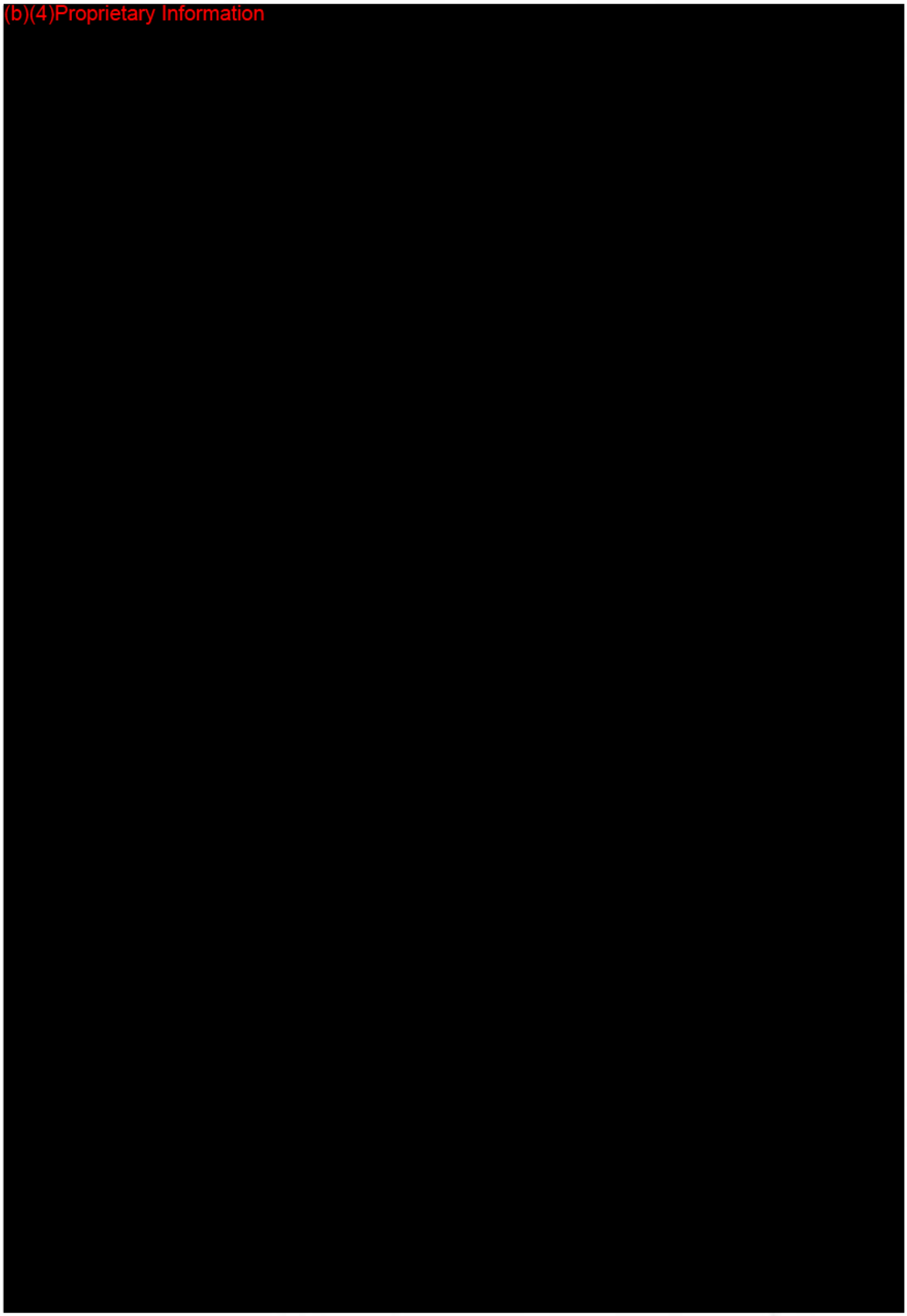

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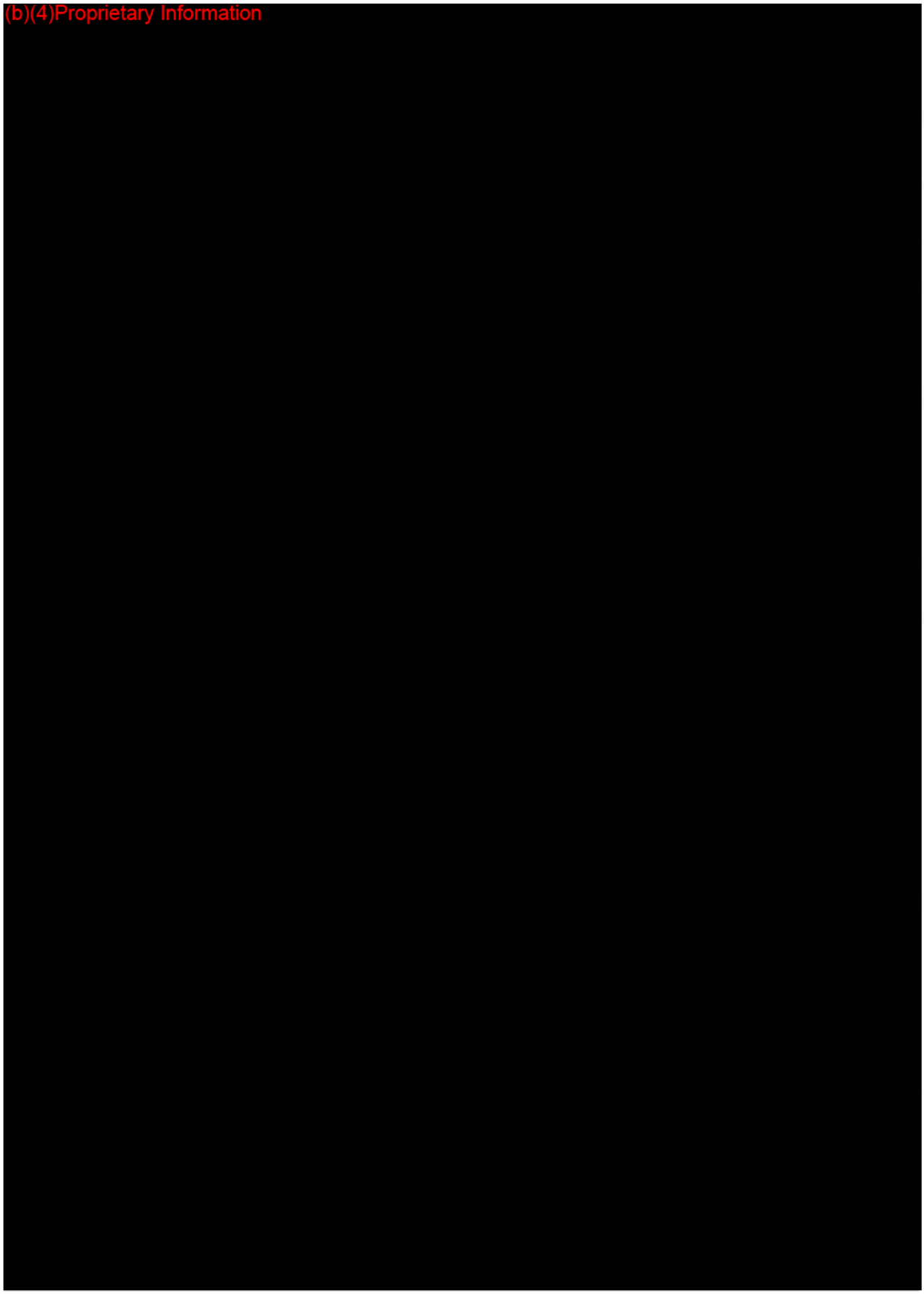

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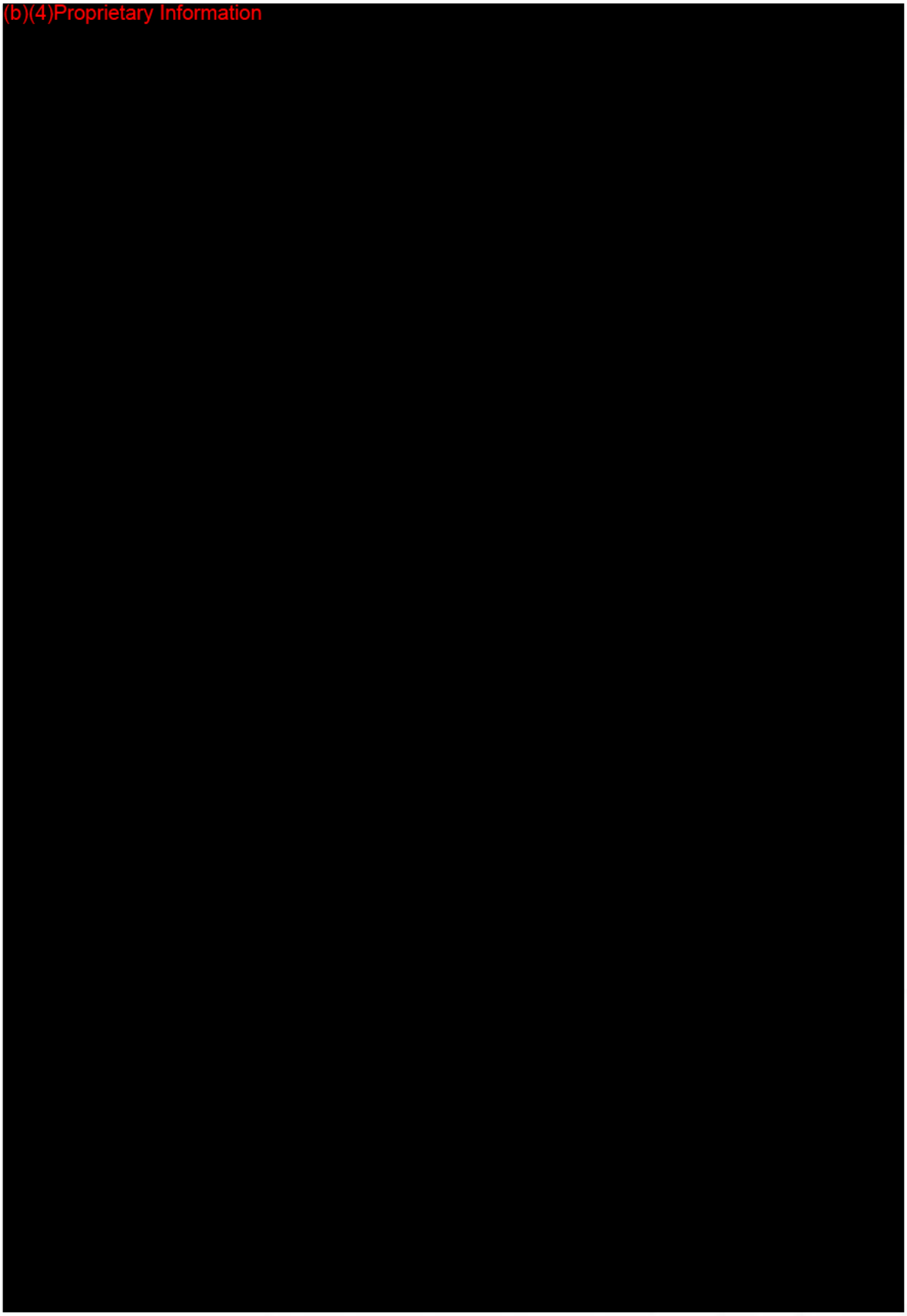

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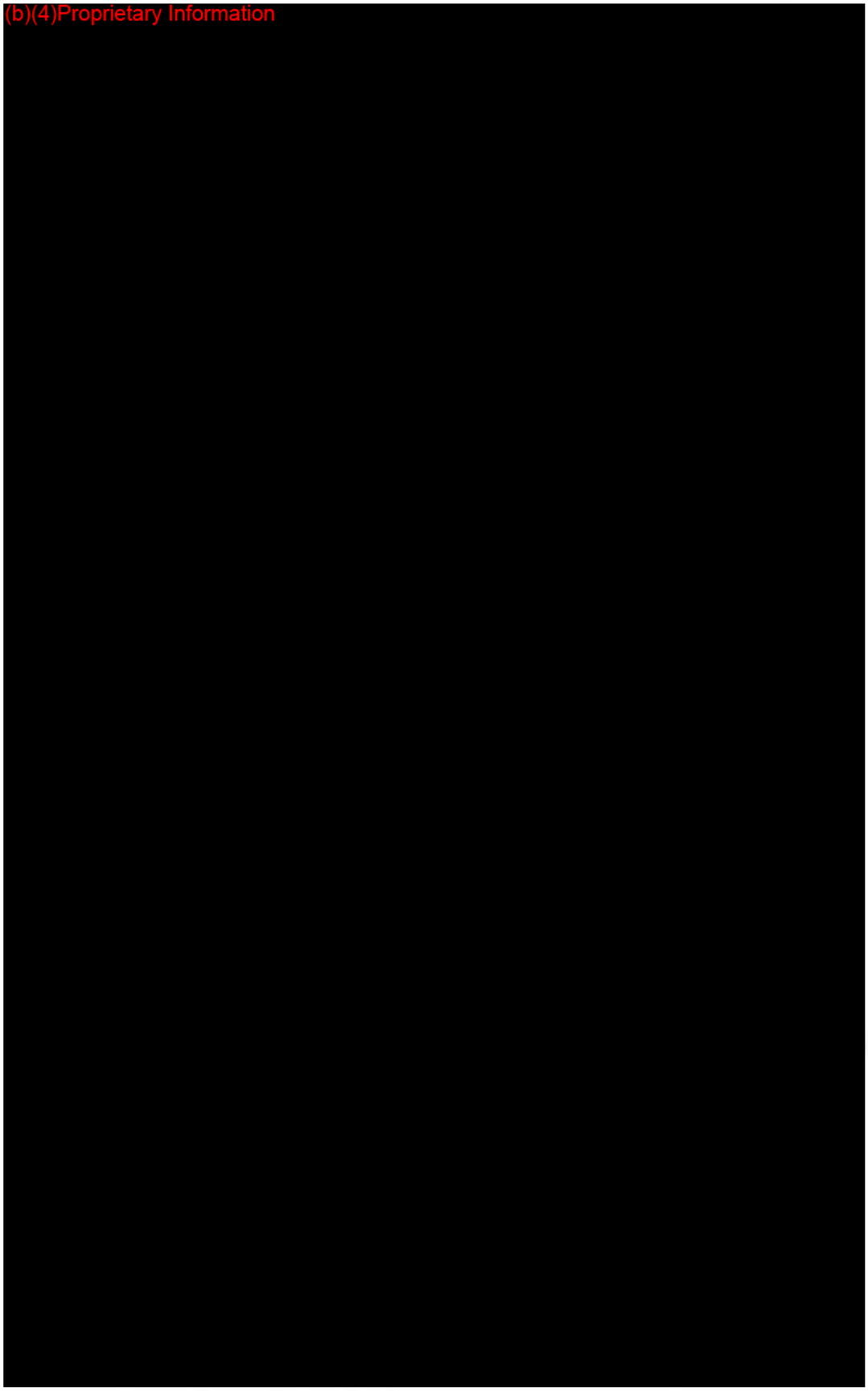

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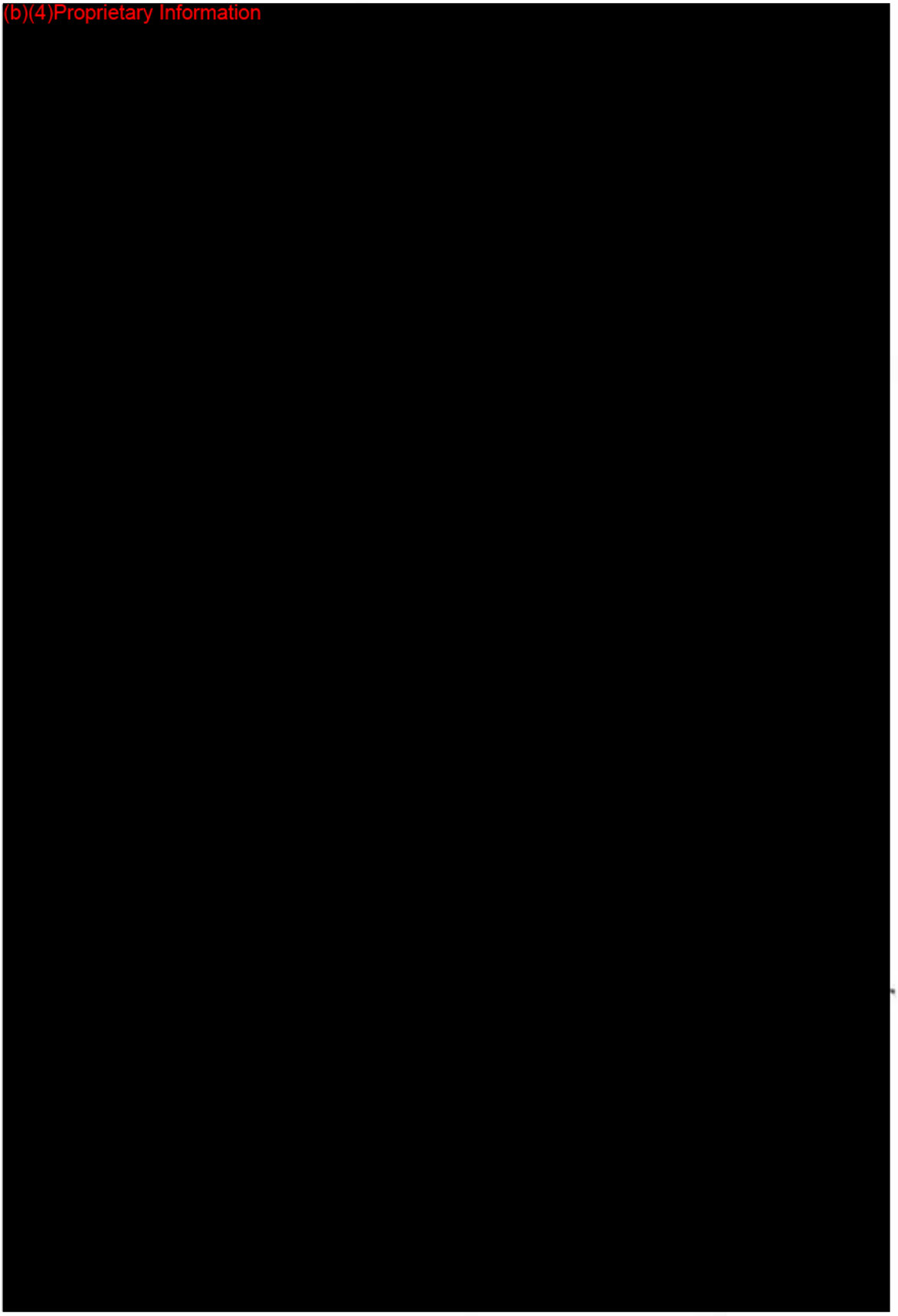

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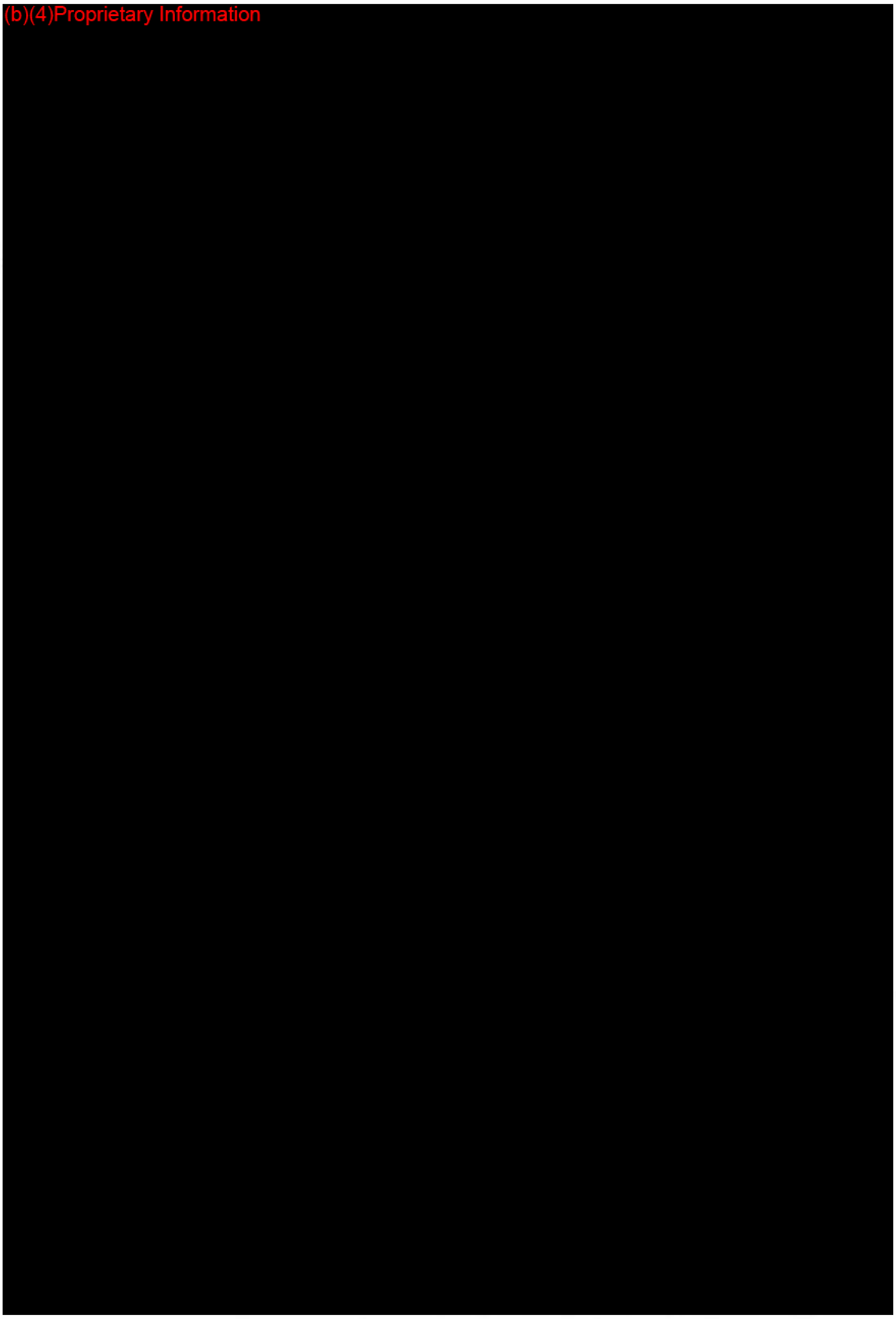

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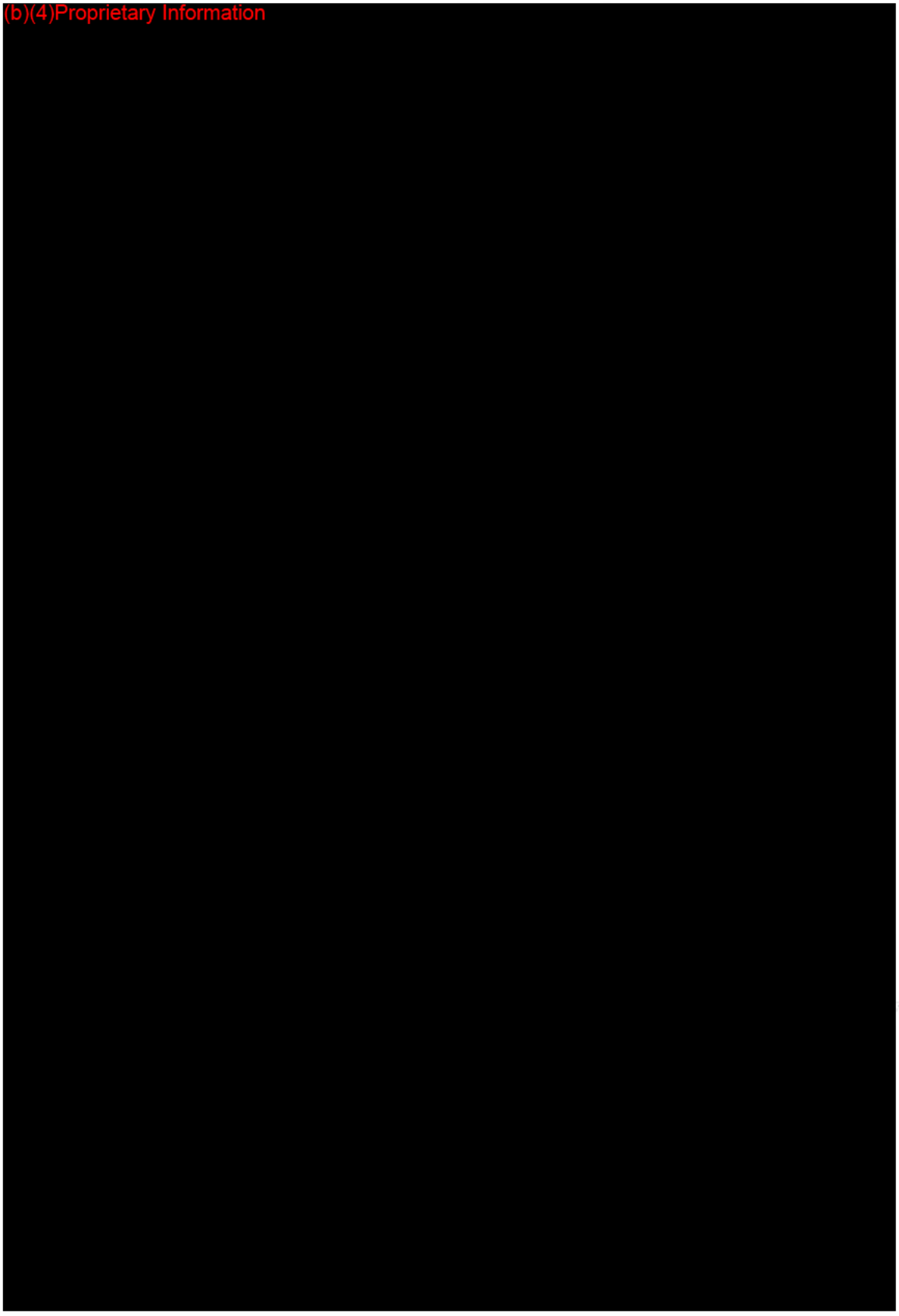

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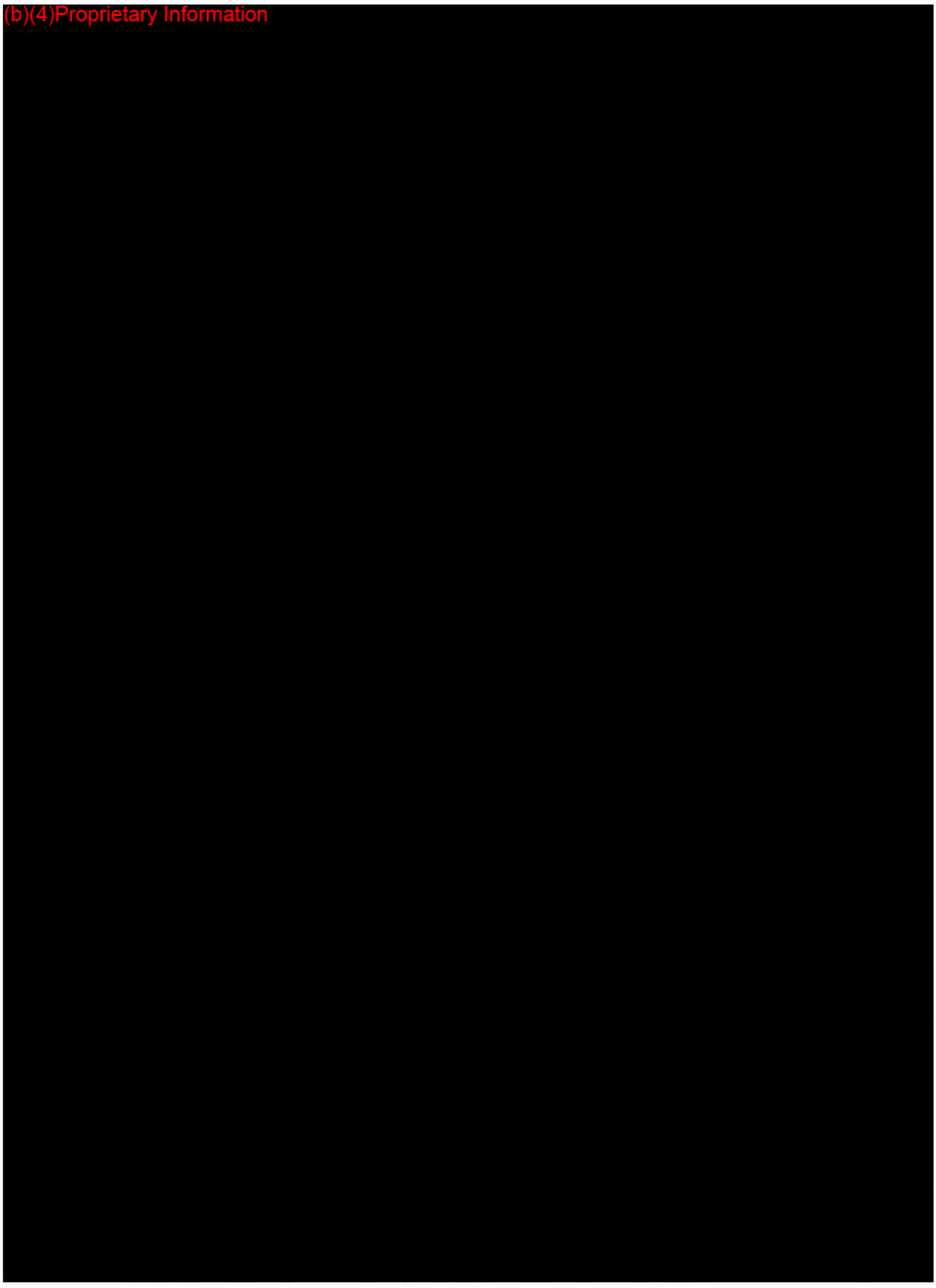

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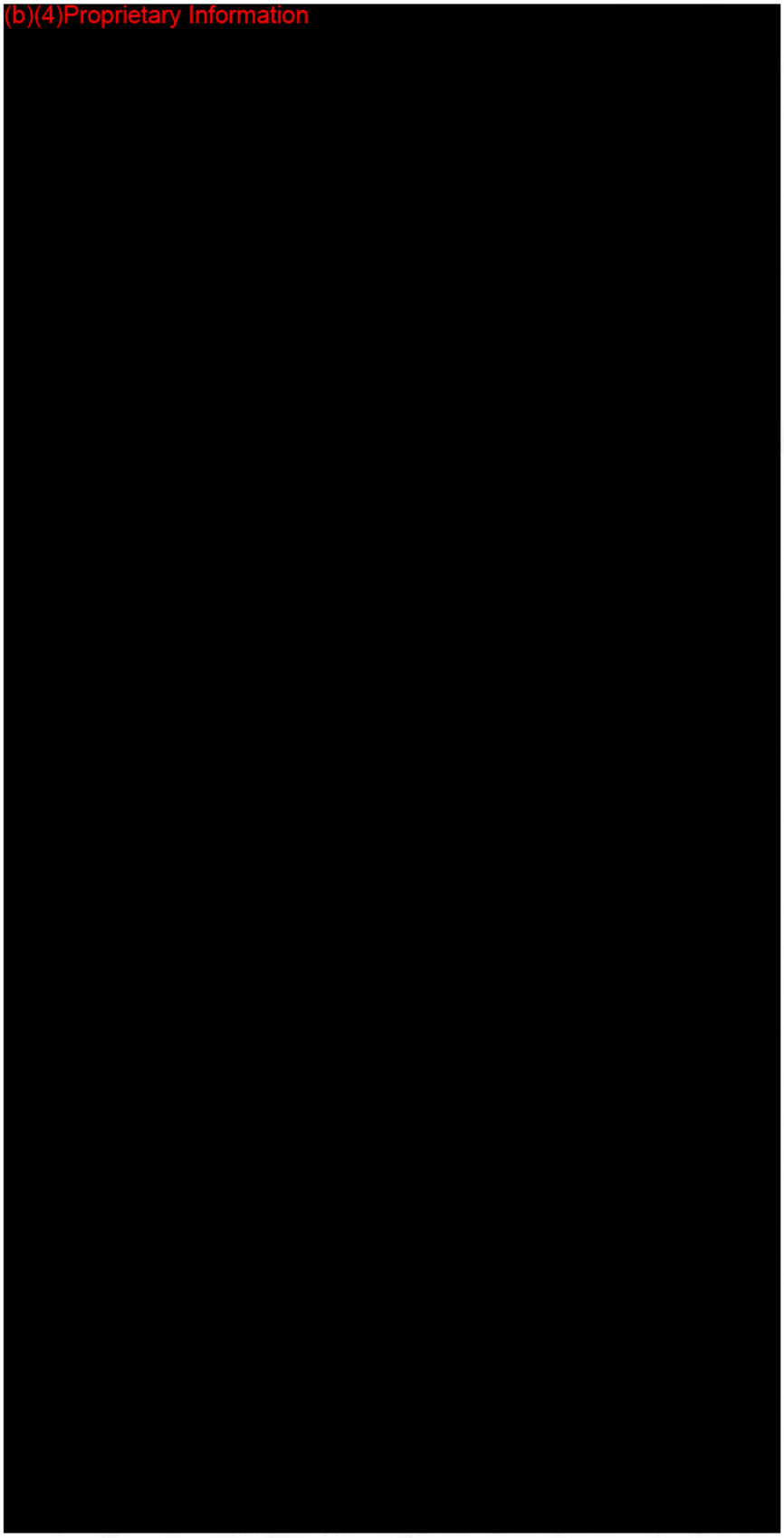

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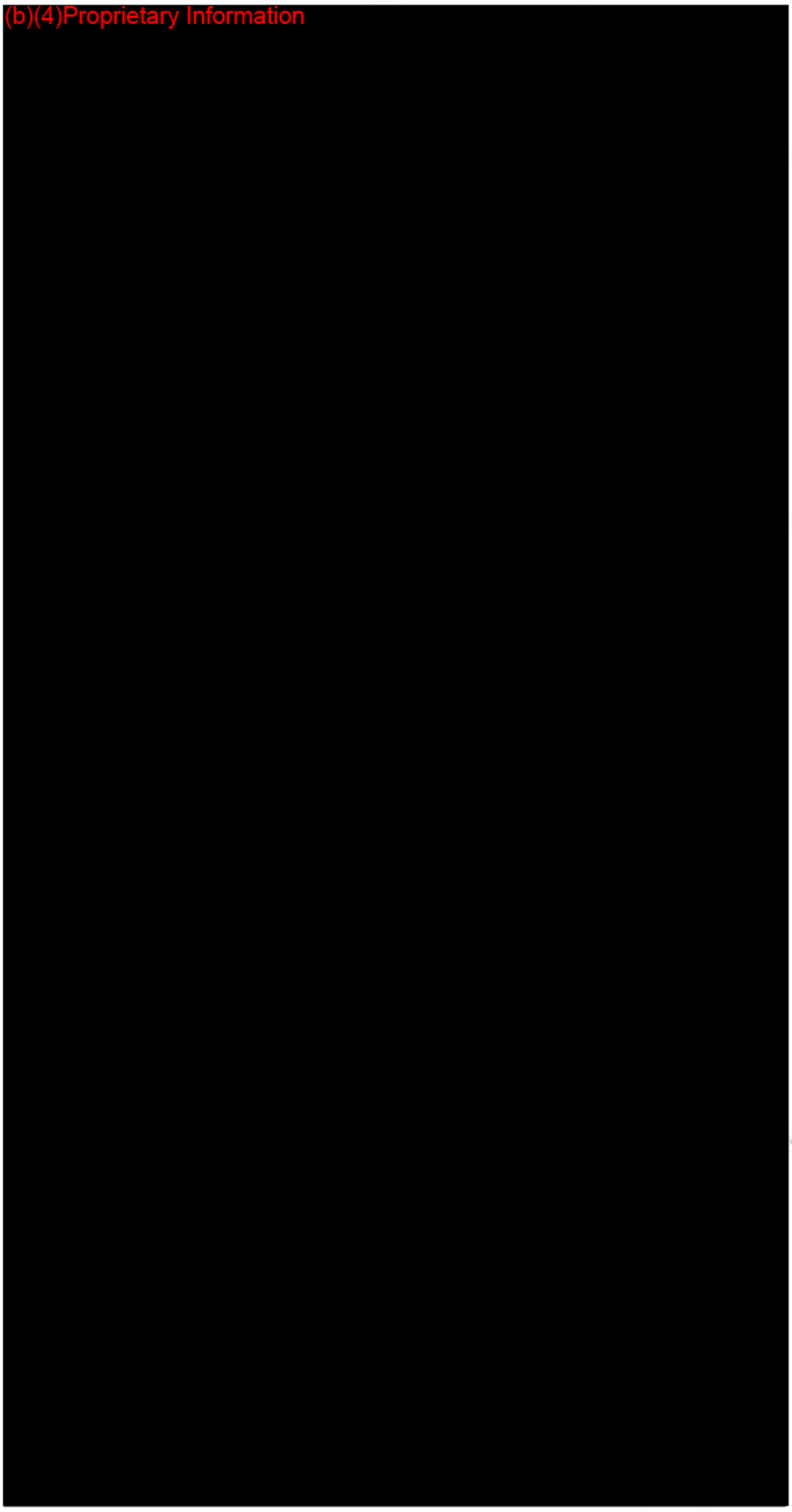

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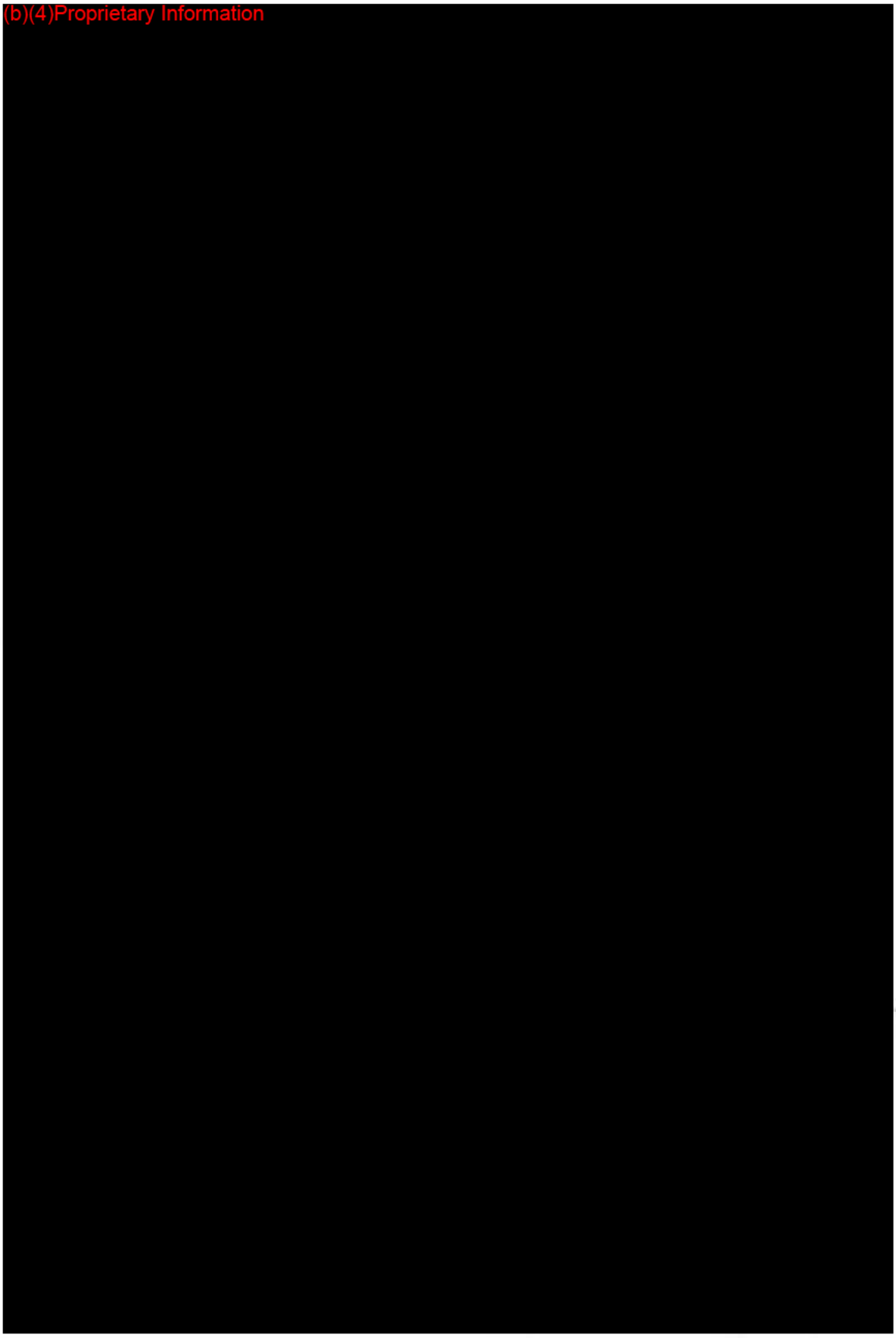

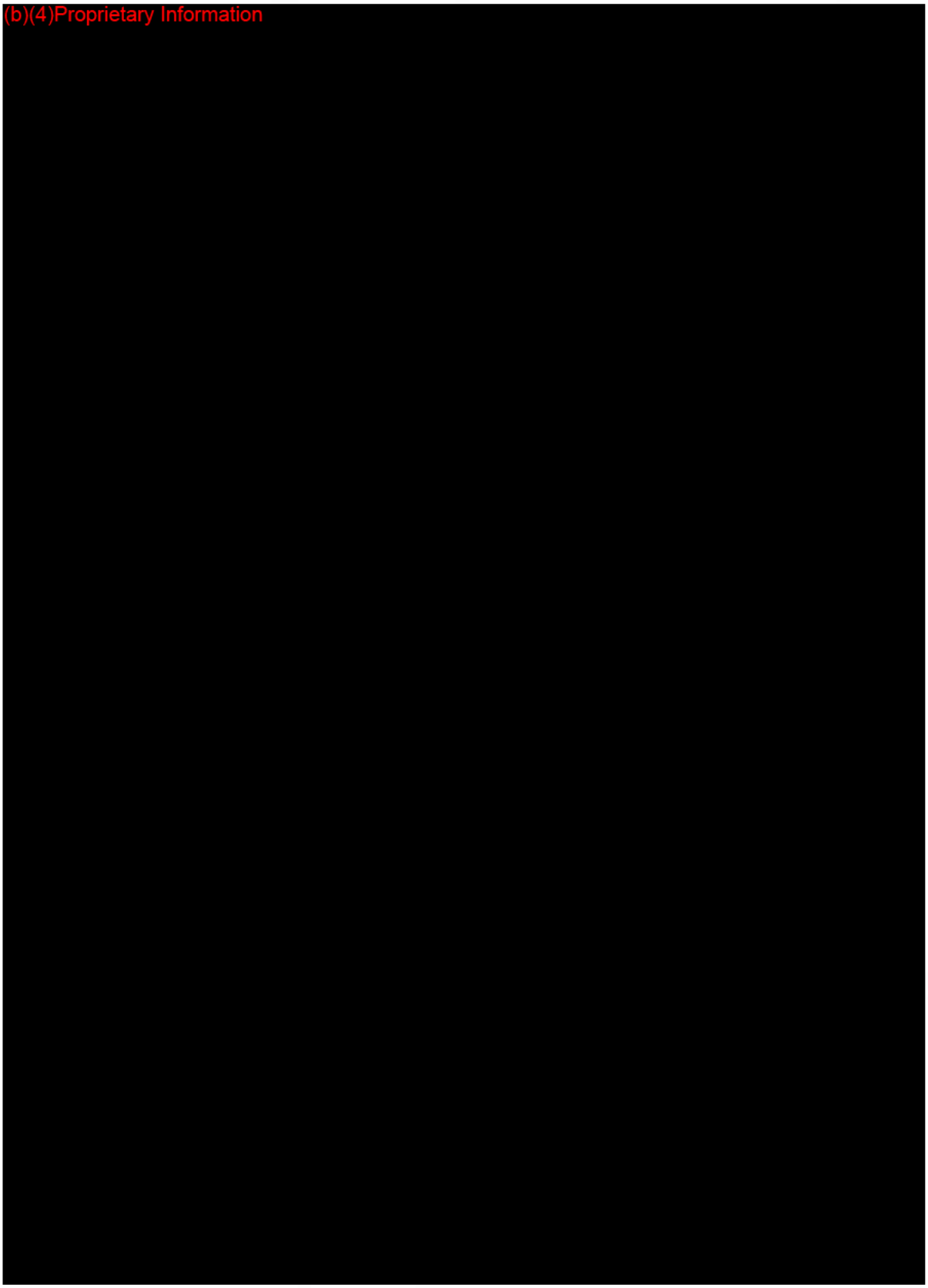
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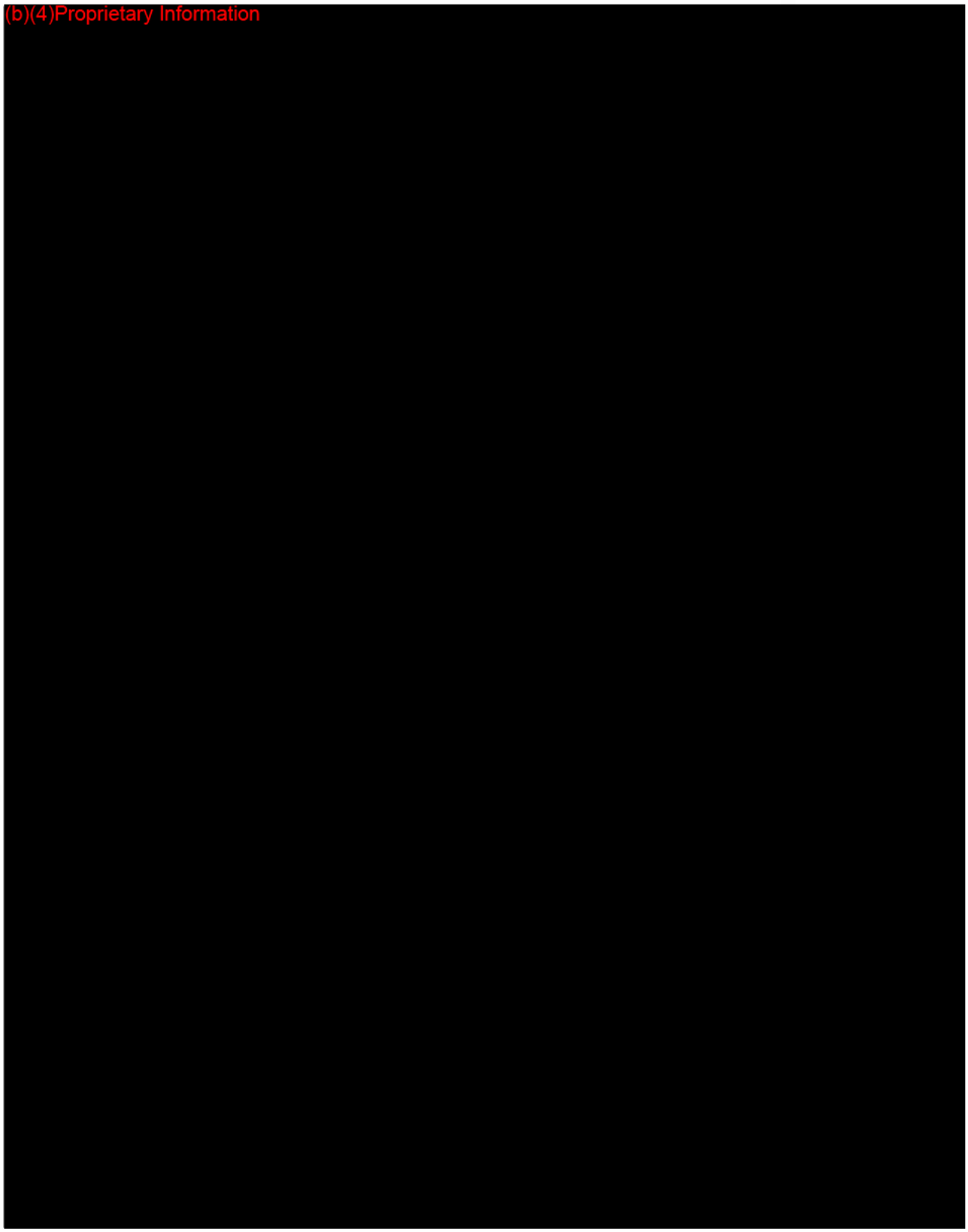

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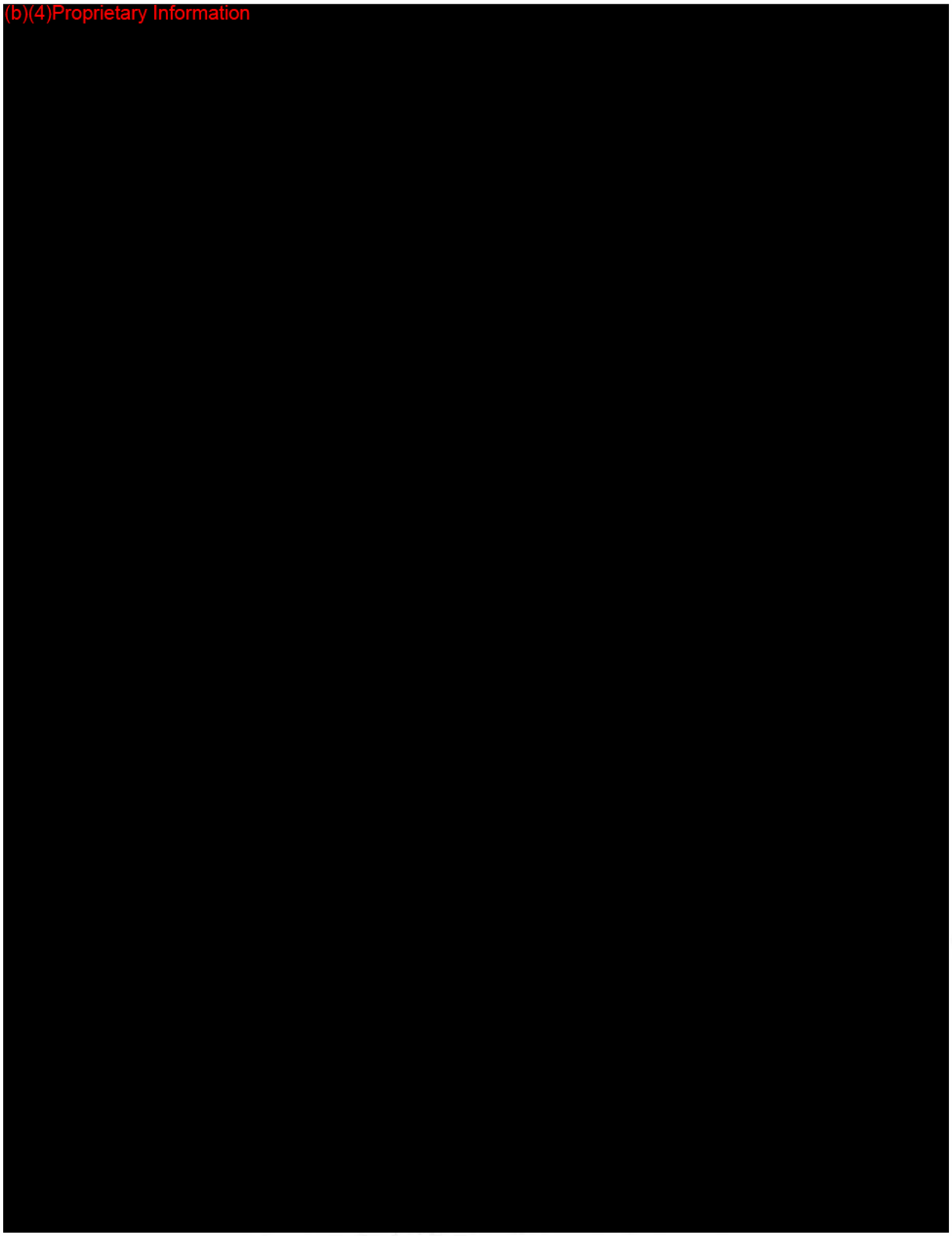

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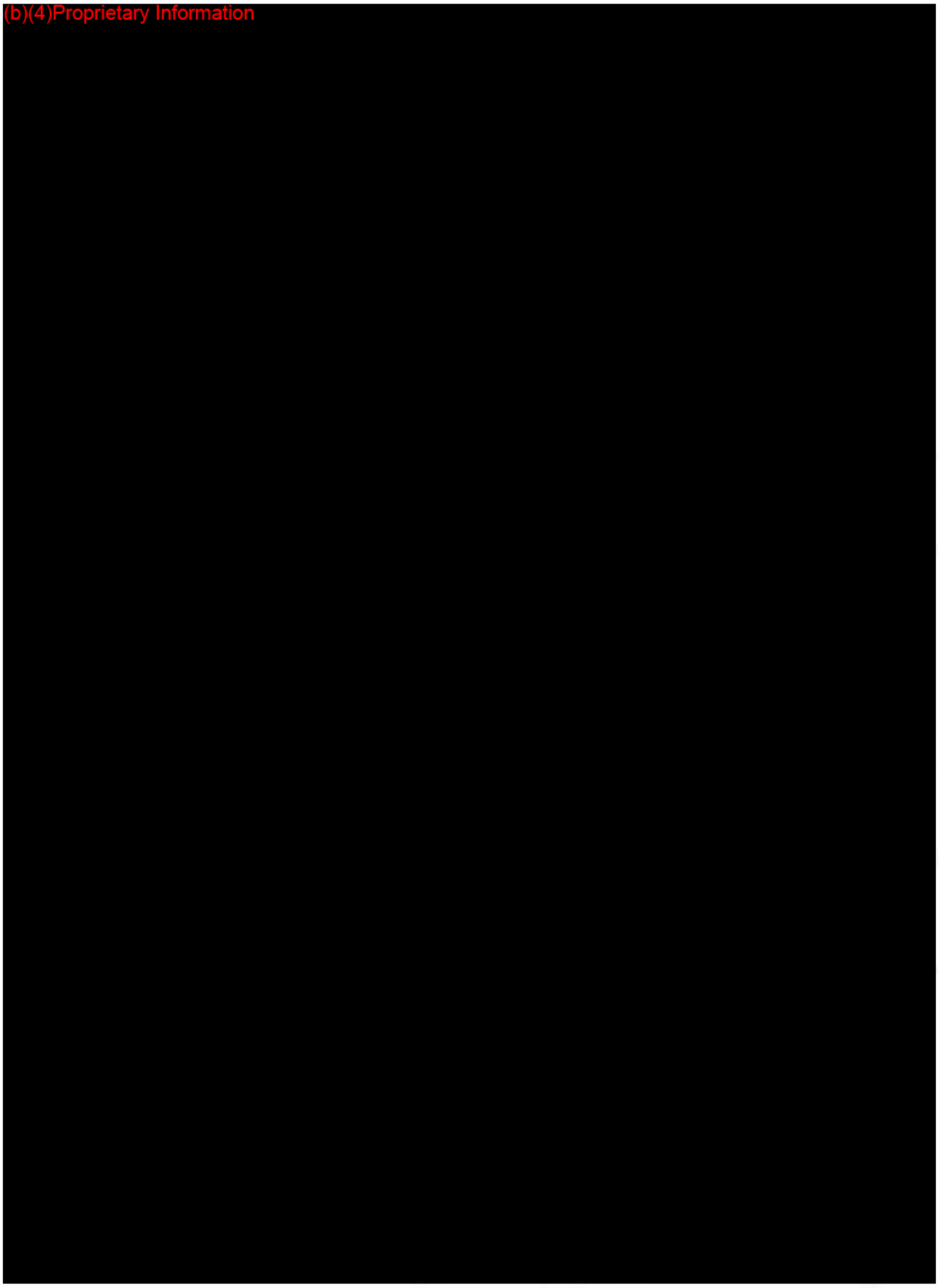

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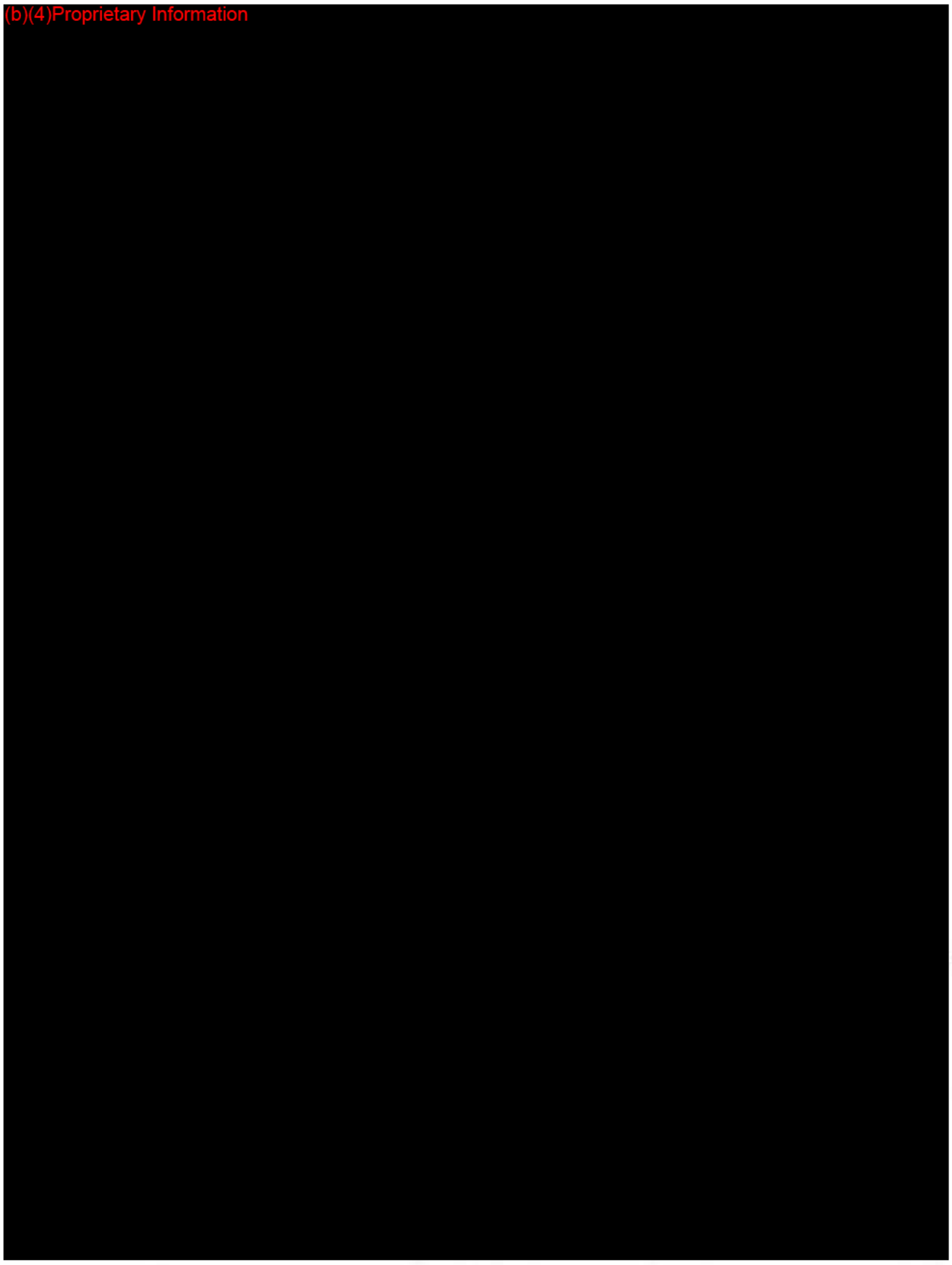

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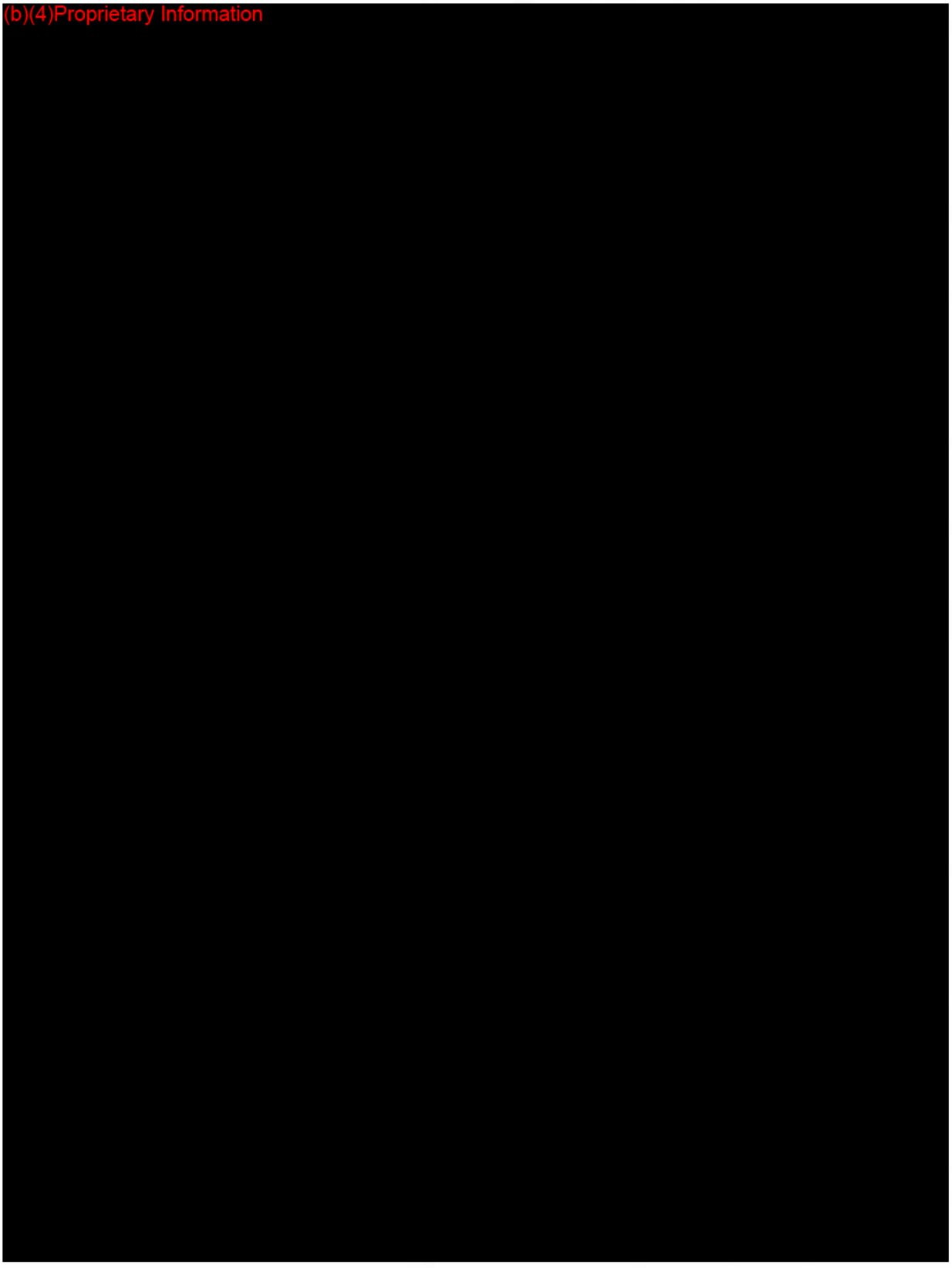

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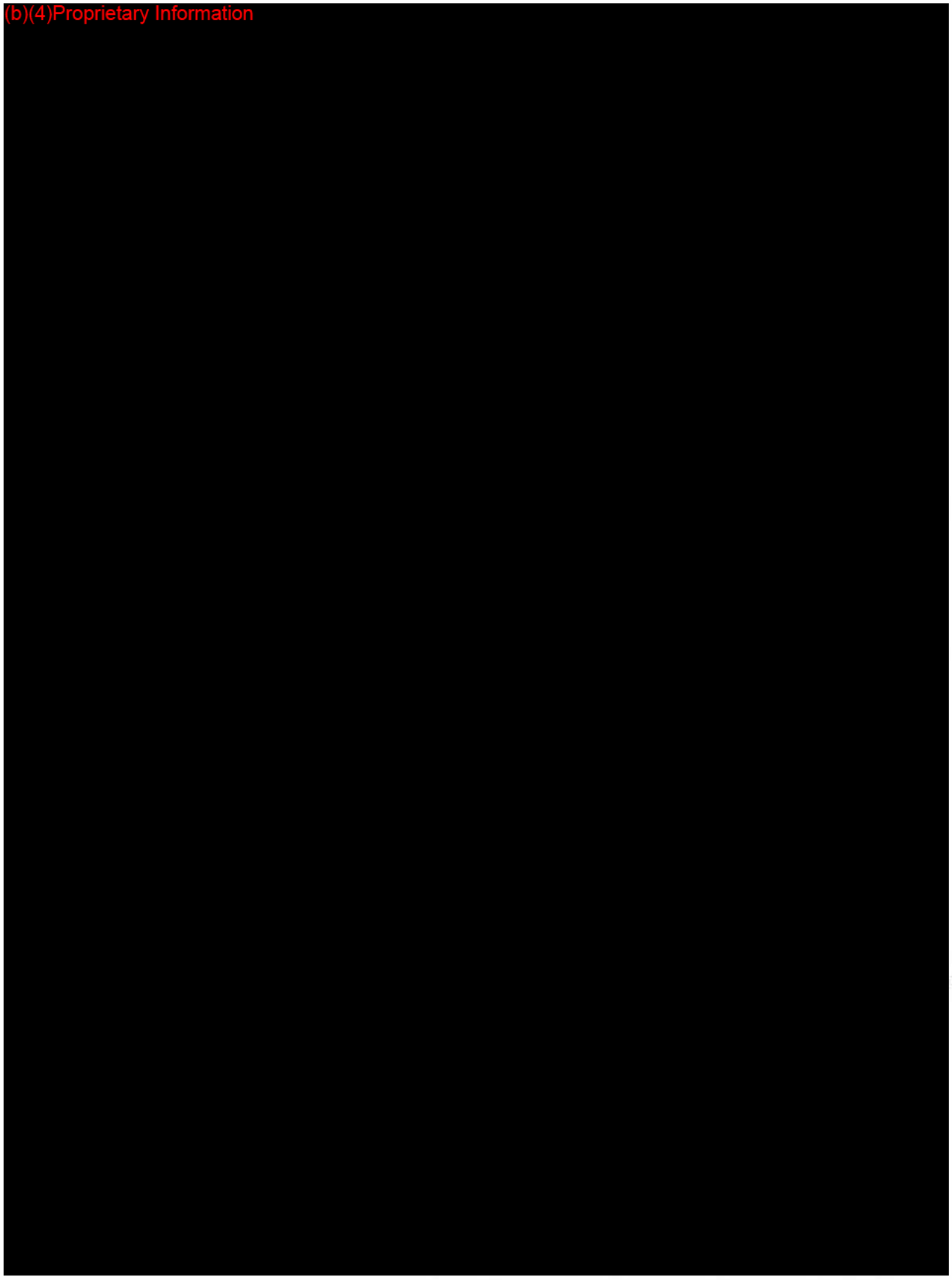

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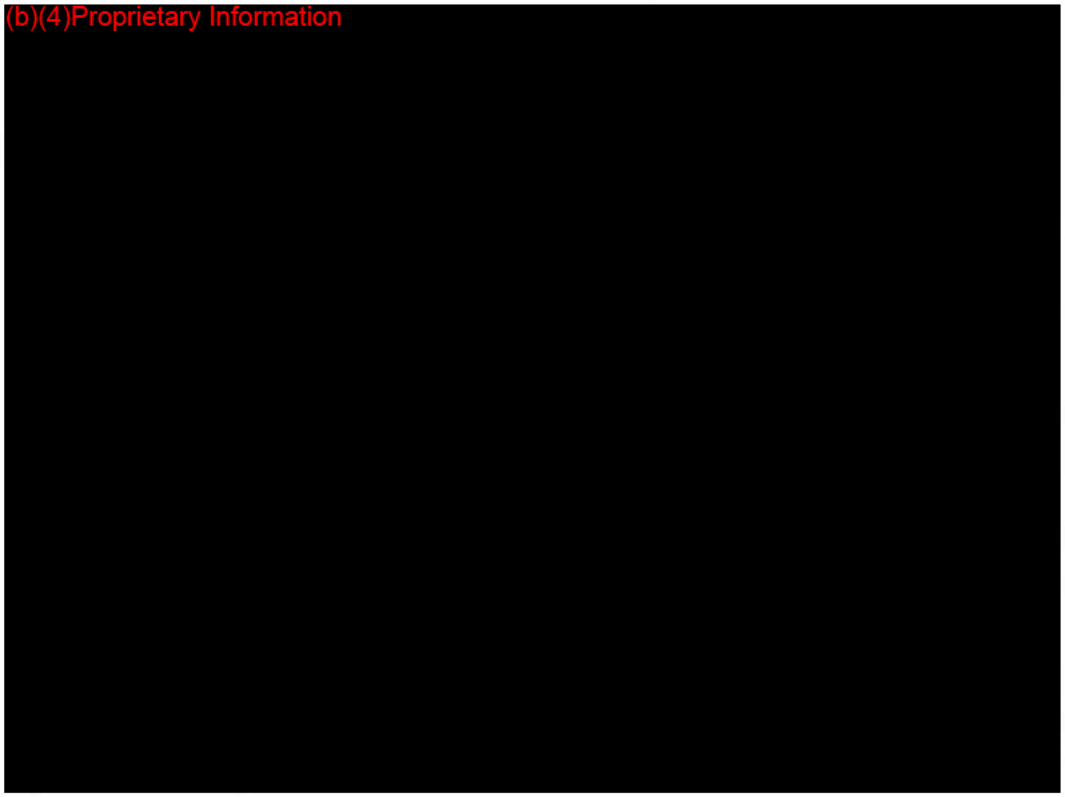

Exh. 1

CATH-LINK PORT
GENERAL DIMENSIONAL CHARACTERISTICS

(ALL DIMENSIONS ARE IN INCHES)

(b)(4)Proprietary Information

(b)(4)Proprietary Information

CONFIDENTIAL

(b)(4)Proprietary Information

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Exhibit 1

Exh. 2

Exhibit 2.1

NOTE: INFORMATION IN THIS EXHIBIT WAS ALSO PROVIDED IN THE ORIGINAL 510(K) SUBMISSION. BASED ON THE REVIEWER'S QUESTIONS, ADDITIONAL INFORMATION HAS BEEN PROVIDED AND IS UNDERLINED.

SEPTUM PUNCTURE LIFE

Objective: The septum life test simulates repeated port usage and verifies that the septum does not leak after multiple insertions.

Method: (b)(4)Proprietary Information [redacted]

Results: (b)(4)Proprietary Information [redacted]

Conclusion: [redacted]

(b) (6) [redacted]

Exhibit 2.2

PUNCTURE LIFE at DESIGN LIMITS TESTS

OBJECTIVE: The primary objective was to evaluate the performance of the CathLink 20 port septum using a (b)(4)Proprietary Information [redacted]

METHOD: [redacted]

(b)(4)Proprietary Information [redacted]

RESULTS:

CATHLINK 20 PORT, INITIAL LEAK TESTING (N=37)

Test Conditions	Percent Passed	Percent Failed
(b)(4)Proprietary Information	100%	0%
	100%	0%
	100%	0%

CATHLINK 20 PORT AFTER 500, 1000, 2000, 2500 AND 3000 PUNCTURES (N=37)

Test Conditions	Percent Passed	Percent Failed
(b)(4)Proprietary Information	100%	0%
	100%	0%

CATHLINK 20 PORT, MAXIMUM PRESSURE AFTER 3000 PUNCTURES

Test Conditions	Percent Passed	Percent Failed
(b)(4)Proprietary Information	100%	0%
	100%	0%

Specification: (b)(4)Proprietary Information (b) (6)
(b)(4)Proprietary Information

Determination of specification limits: (b)(4)Proprietary Information

CONCLUSION: The CathLink 20 port exceeds puncture life requirements at design tolerance extremes. Further, the CathLink 20 port is leak tight after (b)(4)Proprietary Information

Exh.

3

Exhibit 3

NOTE: INFORMATION IN THIS EXHIBIT WAS ALSO PROVIDED IN THE ORIGINAL 510(K) SUBMISSION. BASED ON THE REVIEWER'S QUESTIONS, ADDITIONAL INFORMATION HAS BEEN PROVIDED AND IS UNDERLINED.

CATHETER PHYSICAL PROPERTIES

Objective: Tensile and burst tests were done to assure adequate physical properties of the catheter.

Method: (b)(4)Proprietary Information [redacted]

Results: The catheter physical properties are listed below.

(b)(4)Proprietary Information [redacted]

Exh. 3
pg. 2

(b)(4)Proprietary Information

[redacted]

Conclusion: (b)(4)Proprietary Information [redacted]

(b) (6) [redacted]

Exh.

4

Exhibit 4

NOTE: INFORMATION IN THIS EXHIBIT WAS ALSO PROVIDED IN THE ORIGINAL 510(K) SUBMISSION. STATEMENTS THAT DIRECTLY RELATE TO THE QUESTIONS HAVE BEEN BOLD-FACED.

PORT FLOW RATE

Objective: (b)(4)Proprietary Information [redacted]

Method: [redacted]

Results: The flow rates are listed below.

(b)(4)Proprietary Information [redacted]

Conclusion: [redacted] (b)(4)Proprietary [redacted]

(b) (6) [redacted]

Exh.

5

Exhibit 5

PERIPHERAL IV CATHETER COMPATIBILITY WITH CATHLINK PORT

OBJECTIVE:

(b)(4)Proprietary Information [redacted]

METHOD:

(b)(4)Proprietary Information [redacted]

Exh. 5
pg. 2

RESULTS:

A. Dimensions

Lot Data	Outside Diameter (inches) for IV Catheters (b)(4)Proprietary Information [redacted]
Average	
Std Deviation	
Minimum	
Maximum	
+ 3 Std Dev	
- 3 Std Dev	

COMPARISON OF IV CATHETER AND PORT PATHWAY DIMENSIONS

IV catheter size range O.D. (in.)	Entry Path I.D. (in.)	Septum Center Hole I.D. (in.)	Exit Path I.D. (in.)	Indwelling ChronoFlex catheter I.D. (in.)
(b)(4)Proprietar [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

(b) (6) [redacted]

00060

B. IV Catheter Columnar Load Capacity

	Columnar Load Capacity of IV Catheters (grams force) n = 10 each					
	Jelco	Viggo	B-D Angiocath	Insyte	Terumo	Cooke 3.0 Fr
Average	(b)(4)Proprietary Information					
Std Deviation						
+ 3 Std Dev						
- 3 Std Dev						
Maximum						
Minimum						

	Insertion Force of IV Catheters (grams force) n = 10 each					
	Jelco	Viggo	B-D Angiocath	Insyte	Terumo	Cooke 3.0 Fr
Average	(b)(4)Proprietary Information					
Std Deviation						
Minimum						
Maximum						
- 3 Std Dev						
+ 3 Std Dev						

(b) (6)

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Ratio	Ratio of Average Columnar Load Capacity to Average Insertion Force					
	Jelco	Viggo	B-D Angiocath	Insyte	Terumo	Cooke 3.0 Fr

(b)(4)Proprietary Information

(b) (6)

CONCLUSIONS

(b)(4)Proprietary Information

Exh. 6

Exhibit 6.1 COMPARATIVE CANNULA RETENTION

OBJECTIVE:

Compare instantaneous cannula pullout resistance and cannula retention as a function of load and cycles [where the cannula is an IV catheter for the CathLink 20 port and a non-coring needle for the conventional ports: Hickman port (Bard) and P.A.S. Port (Pharmacia Deltec)].

METHODS:

1. **Dynamic Cannula Pull Tests**

(b)(4)Proprietary Information

[redacted]

2. **Instantaneous Cannula Pull Resistance for Ports**

This test characterizes the static load required to withdraw the cannula from the septum of the CathLink20, Hickman and P.A.S. Ports. (b)(4)Proprietary Information

[redacted]

RESULTS

1. CathLink20 Port Cannula Retention Under Cyclic Conditions

Applied Static Load (grams)	Cycles of Motion to Cause Cannula Removal (Number of cycles)			
	Average	Std Deviation	Minimum	Maximum
(b)(4)Proprietary Information	[redacted]			

Notes:

(b)(4)Proprietary Information

[redacted]

Exh. 6/1
pg. 3

HICKMAN Port Cannula Retention Under Cyclic Conditions

Applied Static Load (grams)	Cycles to Cause Cannula Removal			
	Average	Std Deviation	Minimum	Maximum
(b)(4)Proprietary Information	[redacted]			

Note

a.

Exh. 6.1
pg. 4

P.A.S. Port Cannula Retention Under Cyclic Conditions

Applied Static Load (grams)	Cycles to Cause Cannula Removal			
	Average	Std Deviation	Minimum	Maximum
(b)(4)Proprietary Information	[redacted]			

Note: [redacted]

*NOTE: DATA FROM ABOVE CHARTS IS PRESENTED GRAPHICALLY IN FIGURE 3. FIGURE 4 IS A GRAPHIC ILLUSTRATION OF THE STANDARD DEVIATION NORMALIZED BY THE AVERAGE NUMBER OF PULL-OUT CYCLES.

2. Instantaneous Cannula Pull Resistance (Perpendicular Pull)

Statistic	Cannula Retention (Maximum Pull Load, Pounds)		
	CathLink20, n = 10	P.A.S.Port, n = 10	Hickman, n = 10
(b)(4)Proprietary Information	[redacted]		

CONCLUSIONS:

(b)(4)Proprietary Information

[redacted]

TESTING OF IV CATHETER INSERTION AND WITHDRAWAL FORCES: DYNAMIC TEST UNDER STATIC LOAD.

TEST METHOD: (b)(4)Proprietary Information

CONFIDENTIAL

KEN ELIASEN 4-1-94

Exh. 1.1 Figure 1

0069

TESTING OF IV CATHETER INSERTION AND WITHDRAWAL FORCES: STATIC LOAD

(b)(4)Proprietary Information

Exh. 1.1, Figure 2

Exhibit 6.1
Figures 3, 4

Figure 3 Average Cannula Retention Under Static Loads and Cyclic Conditions

(b)(4)Proprietary Information

Figure 4 Variability of Cannula Retention Under Static Loads and Cyclic Conditions

(b)(4)Proprietary Information

Exhibit 6.2

Pressure Testing of various IV catheter brands

Objective: The purpose of the test is to demonstrate that the inserted IV catheters will not leak under pressure (conditions of use).

Method: (b)(4)Proprietary Information [redacted]

(b)(4)Proprietary Information [redacted]

(b) (6) [redacted]

Exh. 7

Exhibit 7

NOTE: INFORMATION IN THIS EXHIBIT WAS ALSO PROVIDED IN THE ORIGINAL 510(K) SUBMISSION. BASED ON THE REVIEWER'S QUESTIONS, ADDITIONAL INFORMATION HAS BEEN PROVIDED AND IS UNDERLINED. STATEMENTS THAT DIRECTLY RELATE TO THE QUESTIONS HAVE BEEN BOLD-FACED.

PORT/CATHETER BLOOD CLEARANCE

Objective: (b)(4)Proprietary Information [redacted]

Method: [redacted]

Results: The average flushing volume required to clear blood from the proposed port is listed below.

BLOOD CLEARANCE FLUSHING VOLUME

(b)(4)Proprietary Information [redacted]

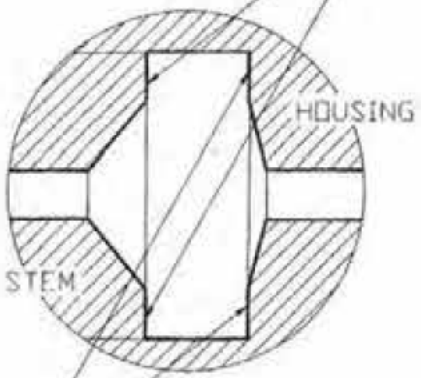
Specification: (b)(4)Proprietary Information [redacted]

Conclusion: (b)(4)Proprietary Information [redacted]

(b) (6) [redacted]

Exh. 9

SEPTUM CHAMBER DESIGN



(b)(4)Proprietary Information

(b)(4)Proprietary Information

SEAL CRITERIA

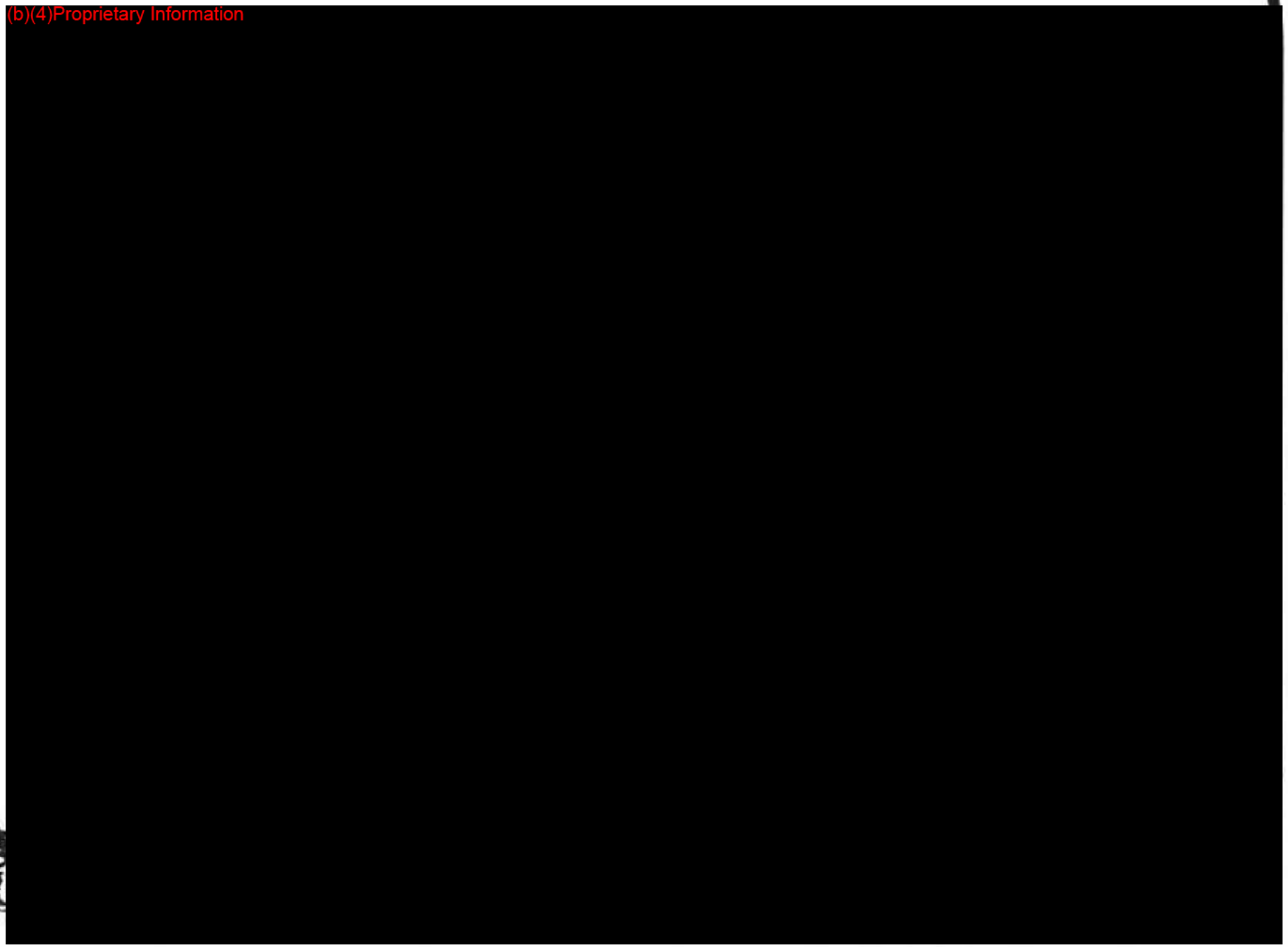
(b)(4)Proprietary Information

CONFIDENTIAL

(b)(4)P

SEPTUM COMPRESSION DESIGN

(b)(4)Proprietary Information



Exh.
9

The P.A.S. PORT®
Implantable Peripheral Access System

It's More

The P.A.S. PORT® system can offer more of your patients the option of an implantable venous access system. Specifically constructed for arm placement, it provides an attractive alternative to conventional access systems for patients with cancer, infectious disease, respiratory disease, immunodeficiency, or other conditions that require intravenous therapy.

It's Less

The P.A.S. PORT system is designed to provide a less traumatic placement procedure. The small, ultra-low profile portal is designed for comfortable arm placement and cosmetic appeal.

It's the Same

The P.A.S. PORT system offers the same therapy applications as chest-placed systems for chemotherapy, antibiotic therapy, delivery of pain medications, and administration of blood products and blood withdrawal.

It also offers the same access techniques, maintenance protocols, and patient mobility.

(actual size)

0079

Exh.

10

(b)(4)Clinical Study

(b)(4)Clinical Study

(b)(4)Clinical Study

Exh.

11

"NEEDLE STOP" FUNCTION

(b) (4)

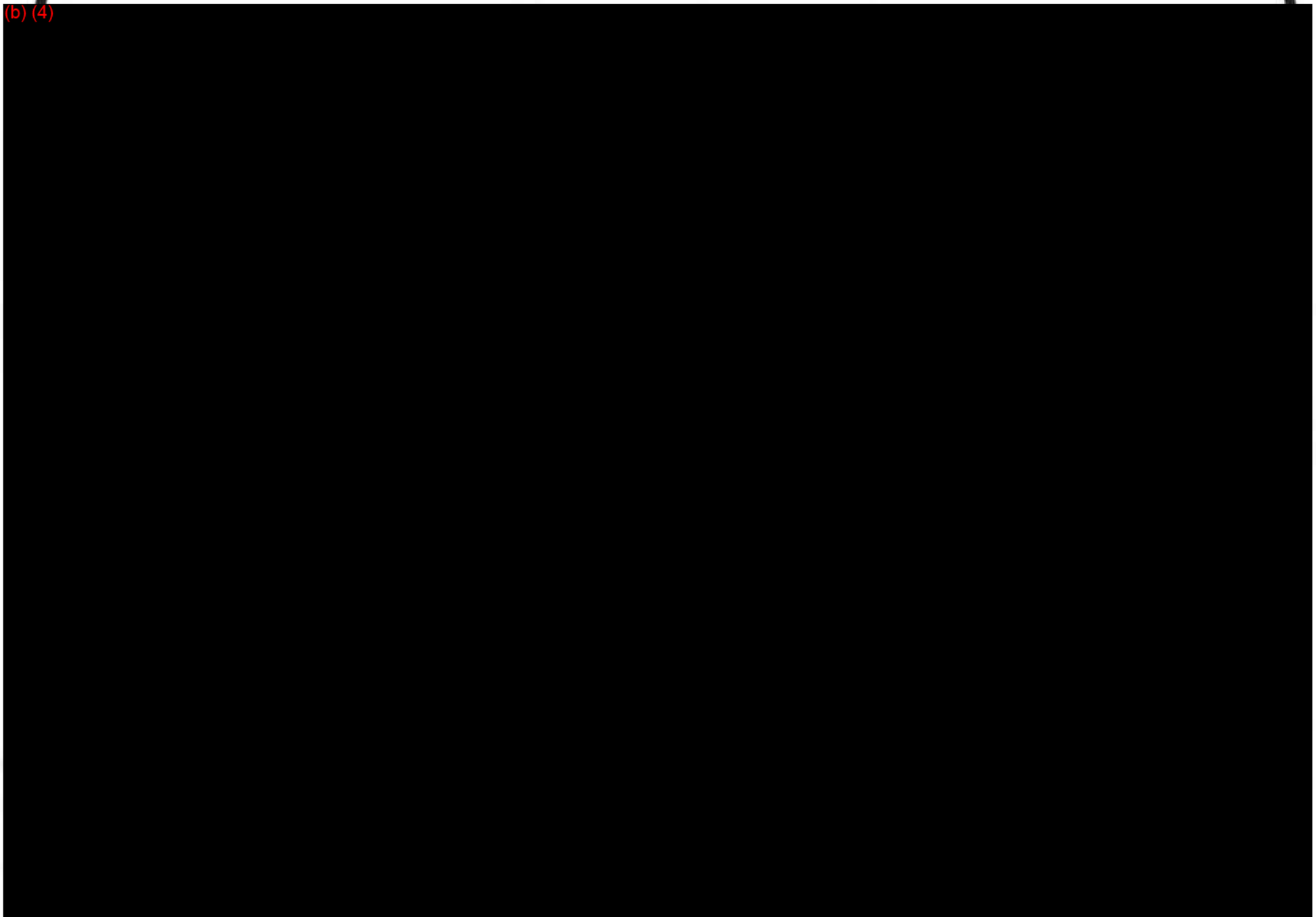


Exhibit 11

Exhibit 11.2

IV CATHETER DAMAGE AFTER INSERTION INTO THE CATHLINK PORT

OBJECTIVE: (b)(4)Proprietary Information

METHOD:

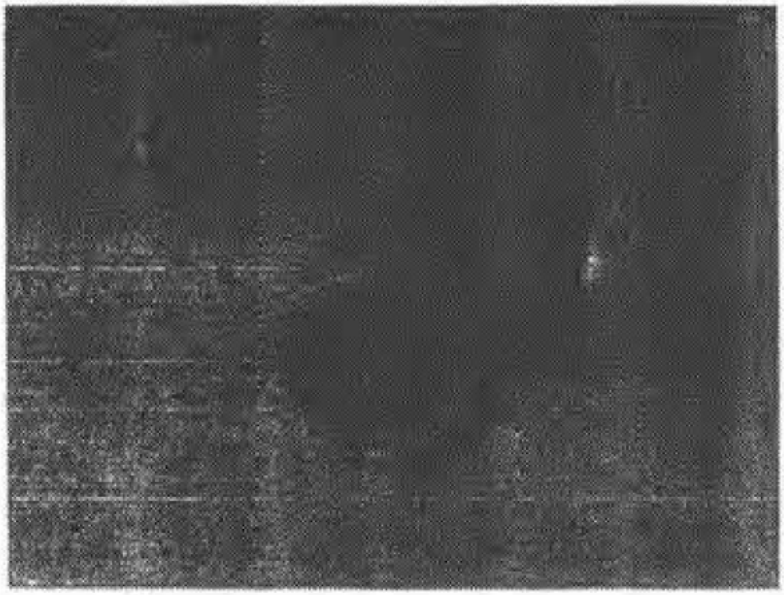
RESULTS:

CONCLUSIONS:

(b) (6)

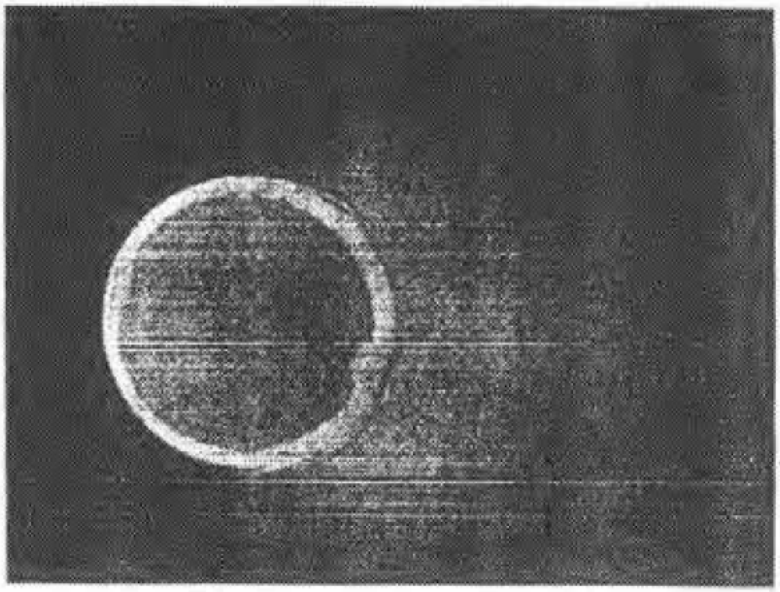
Exh. 11.2
pg. 2

Representative IV Catheter Samples Demonstrating Tip Effect After One Insertion



COOK #4
3.0 Fr X 15cm
4/19/94

TEFLON VESSEL DILATOR
LOT 9290.136632.333



INSYTE #5
20g X 2"
4/19/94

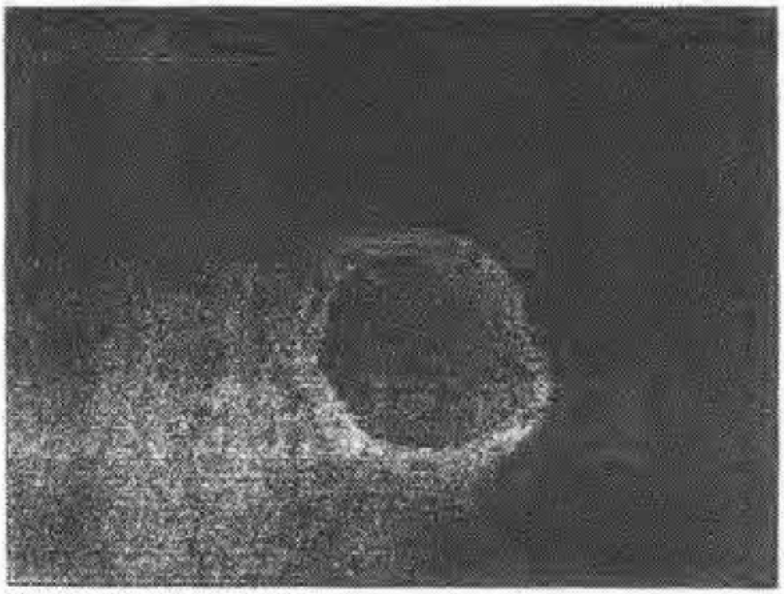
PIN 387201
LOT H3BA1330

(b) (6)

[redacted]

Exh. 11.2
pg. 3

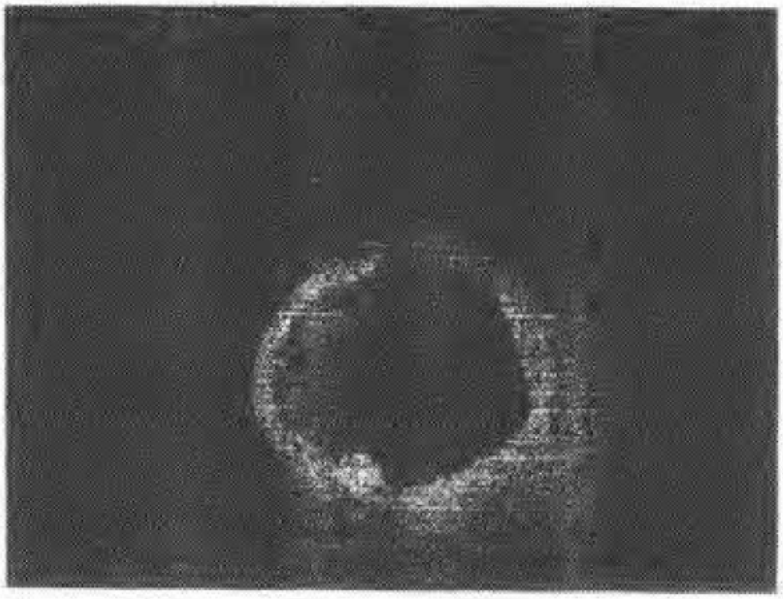
Representative IV Catheter Tip Damage After a Single Insertion Through the CathLink Port



ANGIOCATH #5
20 ga X 1¼"
4/19/94

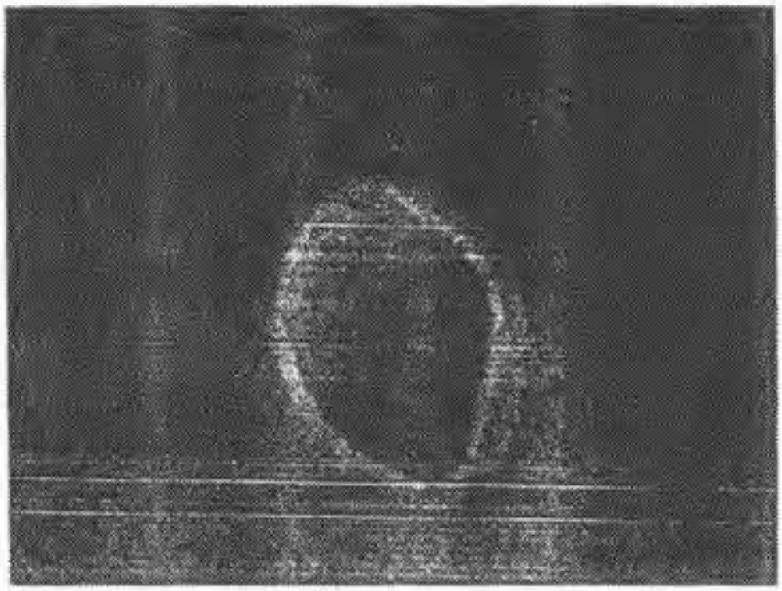
P/N 3829781
LOT H2PA550

(b) (6)



JELCO #1
20g x 1¾"
4/19/94

PIN 15-4059
LOT 0973E4129



TERUMO SURFLO #2
20ga x 1¼"
4/19/94

PIN SROX2032CA
LOT PP2026

(b) (6)

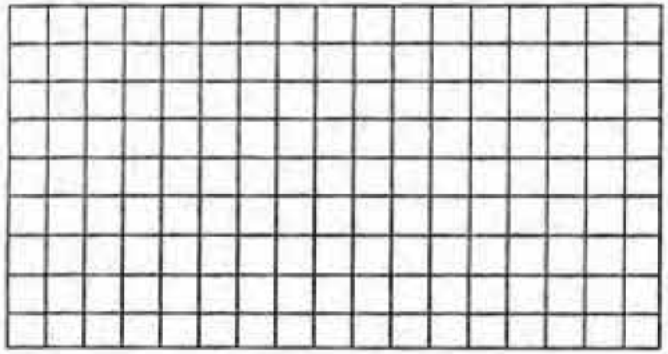
Exh.

12

Bard Access Systems

CATHLINK™ 20 Implanted Port

Instructions for Implantation and Use



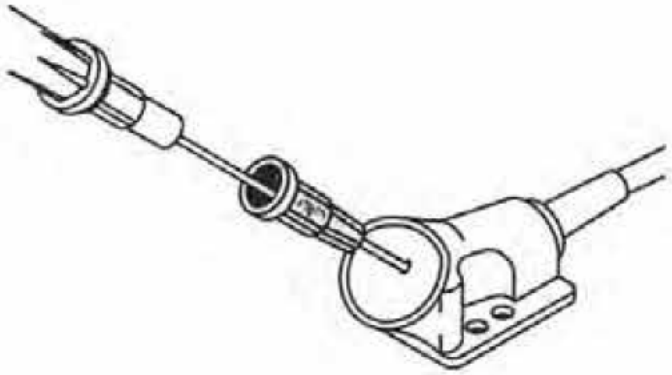
BARD

Exhibit 12

Table of Contents

Introduction

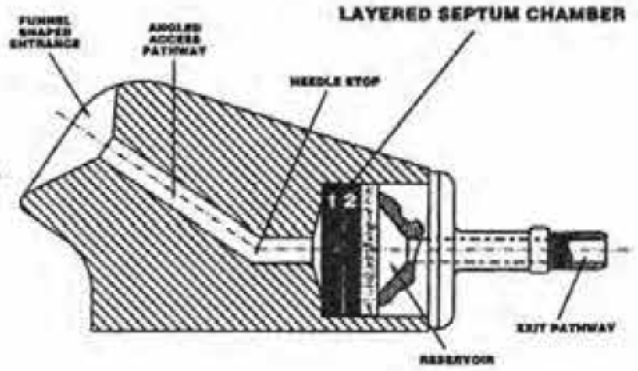
The **CathLink** 20 implanted port is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions and blood products. It is also useful for the withdrawal of blood samples. **CathLink** 20 port access is performed by percutaneous insertion of a 20 gauge over-the-needle I.V. catheter in a 1¼" minimum length. Non-coring needles should not be used.



0103

Product Description

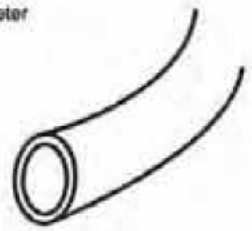
The **CathLink** 20 port system consists of two primary components: a titanium injection port featuring a multi-layered silicone septum with a predetermined route of entry, and a radiopaque ChronoFlex™ polyurethane catheter. All materials are biocompatible and can be used with virtually all injectable solutions.



The funnel shaped entrance to the **CathLink** 20 port guides the over-the-needle I.V. catheter assembly into the angled access pathway to the needle stop. The **CathLink** 20 port is designed so that the needle cannot pass beyond the needle stop area; however, the flexible catheter tip passes further through the access pathway. The layered septum seals around the flexible catheter tip once it has been advanced and the needle has been removed.

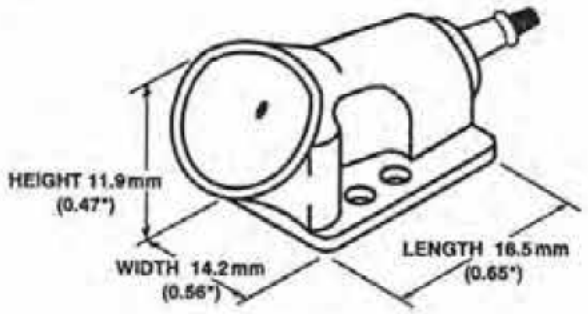
CathLink 20 implanted ports are available with an attachable Open-Ended single lumen catheter.

Open-Ended Catheter



Device Specifications

CathLink 20 Implanted Port



0104

A typical **CathLink** 20 system complete procedure tray contains:

QTY	DESCRIPTION
• 1 Each	- **CathLink** 20 Port
• 1 Each	- Catheter, 8 French **ChronoFlex** polyurethane, Single Lumen, Open-Ended, 2.0mm O.D., 1.3mm I.D., 61cm Length
• 2 Each	- Catheter Locks
• 1 Each	- CSR Wrap
• 2 Pair	- Surgical Gloves (Powderless) Size 7
• 1 Each	- Fenestrated Drape 38" x 48" (Fenestration: 4" x 8")
• 4 Each	- Utility Drapes w/Tape 16" x 13"
• 1 Each	- Disposable Absorbent Towel
• 2 Each	- PVP Scrub Swabsticks, 3/pk.
• 2 Each	- PVP Paint Swabsticks, 3/pk.
• 3 Each	- Alcohol Swabsticks
• 10 Each	- 4" x 4" Gauze Sponges
• 1 Each	- 22 ga. x 1 ½" Needle for Skin Wheals
• 2 Each	- 18 ga. x 1 ½" Filter Needles for Anesthetic & Saline
• 2 Each	- 20 cc Syringes (Luer Slip) for Anesthetic & Flushing
• 1 Each	- 30 cc Ampule of Lidocaine 1%
• 1 Each	- 18 ga. (TW) x 2 ½" Needle for Guidewire Introduction
• 1 Each	- 21 ga. x 2 ½" Needle for Vessel Location
• 1 Each	- 5 cc Syringe (Luer Slip) for Vessel Location
• 1 Each	- 10 cc Syringe (Luer Slip) for Guidewire Introduction
• 3 Each	- 10 cc Ampules of Sodium Chloride 0.9% for Flushing
• 1 Each	- Vein Pick
• 1 Each	- Addison Tooth Forcep
• 1 Each	- Half Curved Forcep
• 1 Each	- Spring Guidewire .035" x 17 ¾"
• 1 Each	- Spring Guidewire .035" x 35"
• 1 Each	- Mini Scalpel
• 1 Each	- Trocar
• 1 Each	- Scissors
• 1 Each	- Percutaneous Introducer System

QTY	DESCRIPTION
• 1 Each	- Needle Holder
• 2 Each	- 3.0 Nylon Suture w/Cutting Needle
• 1 Each	- Betadine Ointment
• 2 Each	- Transparent Dressing
• 1 Each	- Wound Closure Strips (¼" x 1 ½")
• 2 Each	- 20 ga. x 2" I.V. Catheters
• 1 Each	- 8" Extension Set without "Y"-Site
• 1 Each	- Catheter Flushing Connector
• 1 Each	- Face Mask with Shield
• 1 Each	- Face Mask without Shield
• 1 Each	- Surgical Tape
• 1 Each	- **CathLink** 20 Implanted Port Instructions for Use
• 1 Each	- Lidocaine Instructions for Use
• 1 Each	- Sodium Chloride Instructions for Use
• 1 Each	- Implant Record
• 1 Each	- Patient Identification Card

Caution: Read directions prior to use. Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Precautions

- Only physicians qualified in the implantation of subcutaneous vascular access devices should implant these devices.
- Care must be exercised when implanting the port system to avoid mechanical damage to the catheter. Catheters should only be clamped with smooth-edged atraumatic clamps or forceps. The catheter should not be used if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolization which may require surgical removal.
- The port system should be implanted carefully to avoid any sharp or acute angles which could compromise the patency of the catheter lumen.
- Caution should be observed when using insertion techniques which require guide wires, since mechanical damage can be inflicted upon the catheter lumen during insertion or removal of the wire, resulting in possible perforation, tear, or fracture of the catheter.
- Caution should be exercised when using percutaneous introducers to avoid inadvertent injury to vital structures. Instructions for use are provided with all **Bard Access Systems** percutaneous introducer kits and should be carefully followed.
- To avoid air embolism, all air must be purged from the device by filling the port system with sterile heparinized saline solution prior to attaching an open-ended catheter.
- To ensure proper catheter connection, the connection technique outlined in these instructions should be carefully followed.
- The instructions for catheter handling and care provided in this instruction booklet should be followed to avoid circumstances that could jeopardize catheter patency or function.
- Only 20 gauge over-the-needle IV catheters 1 ¼" or longer should be used with **CathLink** 20 port. Other access devices cannot be used. The exact I.V. catheter length will be determined by the clinical situation. A longer I.V. catheter (such as a 2") may be desired for larger patients, continuous infusion therapies, or for **CathLink** 20 ports placed in the chest.

- Do not reuse or reinsert the needle into the over-the-needle IV catheter. Reinsertion of the needle may cause damage to the IV catheter which may lead to extravazation.
- If sutures are used to secure the **ChronoFlex** catheter, care should be taken to avoid occluding or injuring the catheter.
- Infusion pressures in excess of 25 psi may damage blood vessels and are not recommended.

Please note that smaller syringes generate more pressure than larger syringes. A three pound force on the barrel of a 3cc syringe generates pressure in excess of 25 psi whereas the same three pound force on the barrel of 10cc syringe generates less than 10 psi of pressure. It is recommended to use no syringe smaller than a 10 cc size with Bard Access Systems implanted ports.

- Correct positioning of the over-the-needle IV catheter within the **CathLink** 20 port should always be determined before infusion of any substance. The preferred method to confirm placement is by the aspiration of blood. If there is doubt regarding proper over-the-needle IV catheter placement, a radiographic dye study should be performed to confirm placement.
- Injections should be discontinued and appropriate medical intervention begun immediately if signs of extravasation exist.
- Prior to infusion of any substance via the port, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
- **Bard Access Systems** ports are intended for single patient use and should never be reused.

---

[1] Aitken DR, Minion JP. "The Pinch-off Sign: and A Warning of Impending Problems with Permanent Subclavian Catheters", Am J Surg 148: 633-636, 1984.

Caution: Read directions prior to use. Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Precautions

- Only physicians qualified in the implantation of subcutaneous vascular access devices should implant these devices.
- Care must be exercised when implanting the port system to avoid mechanical damage to the catheter. Catheters should only be clamped with smooth-edged atraumatic clamps or forceps. The catheter should not be used if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolization which may require surgical removal.
- The port system should be implanted carefully to avoid any sharp or acute angles which could compromise the patency of the catheter lumen.
- Caution should be observed when using insertion techniques which require guide wires, since mechanical damage can be inflicted upon the catheter lumen during insertion or removal of the wire, resulting in possible perforation, tear, or fracture of the catheter.
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- To avoid air embolism, all air must be purged from the device by filling the port system with sterile heparinized saline solution prior to attaching an open-ended catheter.
- To ensure proper catheter connection, the connection technique outlined in these instructions should be carefully followed.
- The instructions for catheter handling and care provided in this instruction booklet should be followed to avoid circumstances that could jeopardize catheter patency or function.
- Only 20 gauge over-the-needle IV catheters 1 ¼" or longer should be used with **CathLink** 20 port. Other access devices cannot be used. The exact I.V. catheter length will be determined by the clinical situation. A longer I.V. catheter (such as a 2") may be desired for larger patients, continuous infusion therapies, or for **CathLink** 20 ports placed in the chest.

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- Correct positioning of the over-the-needle IV catheter within the **CathLink** 20 port should always be determined before infusion of any substance. The preferred method to confirm placement is by the aspiration of blood. If there is doubt regarding proper over-the-needle IV catheter placement, a radiographic dye study should be performed to confirm placement.
- Injections should be discontinued and appropriate medical intervention begun immediately if signs of extravasation exist.
- Prior to infusion of any substance via the port, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
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---

[1] Aitken DR, Minton JP. "The Pinch-off Sign: and A Warning of Impending Problems with Permanent Subclavian Catheters", Am J. Surg 148: 633-636, 1984.

Possible Complications

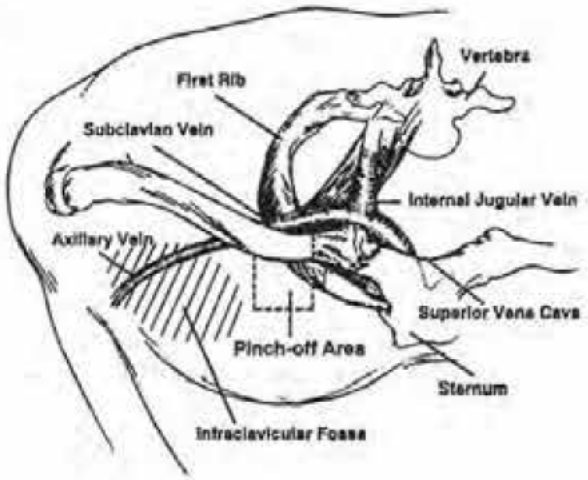
- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Peripheral Nerve Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter or Port Occlusion
- Catheter Occlusion, Damage, or Fracture with Embolism due to Compression Between the Clavicle and First Rib
- Catheter or Port-related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

CATHLINK™ 20 Implanted Port

Axillary-Subclavian Approach

Implantation Instructions

Relevant Anatomy



Warning: Catheters placed percutaneously into the subclavian vein, should be inserted at the point of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter *should not* be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and the clavicle, which can cause damage and even severance of the catheter. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

Implantation Instructions

Complete patient implant record including product reorder number and lot number. Using flush connector, flush catheter with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end.

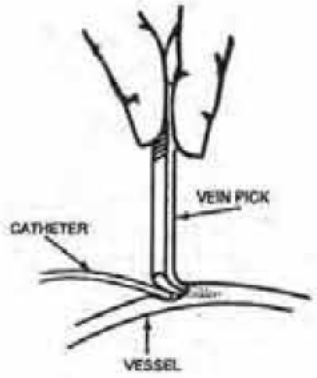
Note: Catheter should be clamped on the segment that will be cut off and discarded prior to attachment to port to avoid catheter damage.

- Select the site for device placement. The infraclavicular fossa is a satisfactory site, but the actual site will vary based on individual patient factors. Site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility, create pressure points, or interfere with clothing. Placement should consider the amount of cutaneous tissue over the port as excessive tissue will make location of the **CathLink** 20 port and over-the-needle I.V. catheter insertion difficult. Conversely, too thin a tissue layer may lead to tissue erosion. A tissue thickness of 0.5cm to 1.5cm is generally considered appropriate.
- Surgically prep and drape the operative site.
- Establish satisfactory anesthesia for the intended procedure.
- The catheter may be inserted into the vein either directly through the pocket incision or via a subcutaneous tunnel from the device pocket to the venous entry site.
- Catheter insertion may be accomplished by either cutdown technique through a small venotomy or by percutaneous technique.

Caution: Catheters placed percutaneously into the axillary-subclavian vein should only be inserted at the point that identifies the outer and middle thirds of the clavicle. If the catheter is inserted into the subclavian vein medially near the articulation of the clavicle with the sternum and the cartilage of the first rib, the catheter could be compressed or pinched leading to damage or severance of the catheter.

Cut-Down Procedure

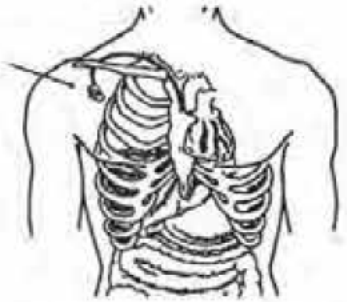
- After an appropriate vessel is isolated and stabilized, perform the vessel incision.
- Grasp the ribbed handle of the vein pick.
- Insert the tapered end of the vein pick through the incision and advance it into the vessel.
- With the vein pick in position, slide the catheter tip into the pick's grooved underside and advance the catheter into the vessel.
- Withdraw the vein pick from the vessel.
- Advance the catheter into the vessel to the desired position.



- Position the catheter tip at the desired infusion site. Correct positioning of the catheter tip in the superior vena cava should be verified and documented by x-ray.

Warning: If sutures are placed around the intravenous catheter, exercise care not to occlude or cut the catheter.

- Create a subcutaneous pocket using blunt dissection. Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision. The **CathLink** 20 port should be positioned with the funnel-shaped entrance facing downward (caudad) toward the umbilicus..



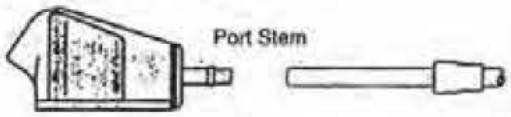
- For remote placement, a subcutaneous tunnel is used. Tunnel the catheter from the venous entry site retrograde to the pocket site, - **remove the catheter lock from the catheter prior to tunneling.**

  The **Bard Access Systems** Tunneler is used to create the tunnel between the port pocket and the venous entry site. After removing the catheter lock and pulling the catheter through the tunnel, the catheter lock must be replaced for proper port-catheter assembly with the catheter fashioned to a 90° angle. It is easier to replace the catheter lock on the catheter if you first cut the port end of the catheter at an acute (45°) angle. Slide the catheter lock over the catheter, then cut the catheter to proper length at a 90° angle.

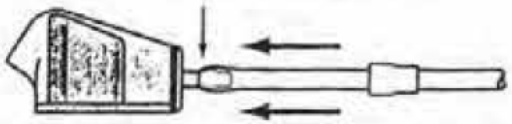
- Cleanse all system components with irrigation solution.
- Trim catheter to proper length allowing sufficient slack for body movement and port connection.

Port to Catheter Connection

- Align port stem with catheter lumen.



- Advance catheter over port stem to midway point.



Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter

- Advance catheter lock until flush with port.

Note: Once the catheter and lock are connected, should disconnection and re-connection be required, the catheter end must be re-trimmed to ensure a secure connection. It is important to cut the catheter before disconnection and as close the the port stem as possible, as the catheter may be damaged by excessive stretching during the disconnection effort.

- Place the **CathLink** 20 port in the subcutaneous pocket with the funnel-shaped entrance facing caudad toward the umbilicus, and away from the incision line and secure flat base to the underlying fascia using one non-absorbable, monofilament suture per suture hole. This will reduce the risk of port migration and the possibility of it flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.
- After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
- Access the **CathLink** 20 port through the skin with an over-the-needle I.V. catheter.
- Conduct flow studies on the catheter using a 10ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned. Aspirate to confirm the ability to draw blood.
- Flush and heparin lock the port system as described under heparin lock procedure.
- Close the incision site, so that the port does not lie beneath the incision.
- Apply dressing according to hospital practice.

Note: Leave over-the-needle I.V. catheter in place if the **CathLink** 20 port is to be used for infusion or aspiration on the same day as implant.

Indications for use for Bard Access Systems Percutaneous Introducer Systems

The **Bard Access Systems** percutaneous introducer kits are designed for insertion of the indicated catheter of the **Bard Access Systems** implanted port into the vascular system.

Warning: Care should be exercised during catheter placement to avoid injury of vital structures. Catheters placed percutaneously should be inserted into the axillary-subclavian vein at the point of the outer and middle third of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle which can result in fracture of the catheter. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

Precautions

- Read instructions prior to use.
- Before beginning the procedure, verify that the catheter fits easily through the introducer sheath.
- The **Bard Access Systems** percutaneous introducer system should be used by a physician trained in the technique of percutaneous catheter placement. The percutaneous introducer sheath should not remain indwelling without the internal support of a catheter or dilator.
- Simultaneous advancement of sheath and dilator with rotational motion is essential to help prevent sheath damage.
- To assist in locating the axillary-subclavian vein, use the Trendelenburg-position or elevate the lower extremities.
- Use only forceps with non-serrated jaws or forceps with padding to introduce or insert catheter (to avoid catheter damage).

Possible Complications

- Air embolus
- Pneumothorax, hemothorax, or hydrothorax
- Hematoma formation
- Brachial Plexus injury
- Catheter occlusion, damage, or breakage due to crimping of the catheter between the clavicle and the first rib
- Perforation or laceration of vessels or viscus
- Vascular thrombosis

Relative Contraindications

- Severe chronic obstructive lung disease.
- Past irradiation of the tentative insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

Instructions for Use with Intro-Eze™ Percutaneous Introducer System

1. The axillary-subclavian vein is entered percutaneously at the point that identifies the outer and middle thirds of the clavicle using the needle and syringe. **Caution: If the catheter is inserted into the subclavian vein medially near the articulation of the clavicle with the sternum and the cartilage of the first rib, the catheter could be compressed or pinched, leading to damage or fracture of the catheter.**

2. Aspirate gently as the insertion is made. **If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.**

3. When the axillary-subclavian vein has been entered, remove the syringe leaving the needle in place. **Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.**

4. Straighten "J" tip of guidewire with tip straightener and insert tapered end of tip straightener into the needle. Tip straightener should not be advanced over the guidewire beyond the guidewire tip. Advance the guidewire as far as appropriate for the procedure. **Verify correct positioning, using fluoroscopy.**

5. Gently withdraw and remove needle and tip straightener. **Caution: If the guidewire must be withdrawn while the needle is still inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.**

6. Make a small incision parallel to the clavicle with the guidewire at the center of the incision to permit introduction of vessel dilator and sheath introducer.

7. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance into the axillary subclavian vein as a unit, leaving approximately 2 centimeters of sheath exposed.

8. Withdraw the vessel dilator and "J" wire, leaving the sheath in place. **Hold thumb over exposed orifice of sheath to prevent air aspiration.**

The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

9. Insert catheter into the sheath. Advance the catheter through the sheath and into the vein. Confirm appropriate catheter tip position with fluoroscopy.

10. Pull the storage tube from the slitter. Place the tubular portion of the slitter onto the catheter near the proximal end of the introducer sheath.

11. Grasp the proximal end of the slitter between the thumb and index finger of one hand. With the tips of the fingers, reach around the slitter and secure the catheter into the tubular portion.

12. Withdraw the sheath over the catheter, sliding the proximal opening of the sheath over the nose of the slitter and into the blade. While holding the slitter stationary continue to withdraw the sheath, pulling it away from the catheter, until it is completely slit. Remove and discard the slit sheath.

13. Follow Instruction pages 14 through 17 for completion of placement.

Instructions for Use for Bard Access Systems "Peel-Apart" Percutaneous Introducers

1. The axillary-subclavian vein is entered percutaneously at the point that identifies the outer and middle thirds of the clavicle using the needle and syringe. **Caution: If the catheter is inserted into the subclavian vein medially near the articulation of the clavicle with the sternum and the cartilage of the first rib, the catheter could be compressed or pinched leading to damage or fracture of the catheter.**

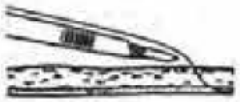
2. Aspirate gently as the insertion is made. **If the artery is entered, withdraw the needle and apply manual pressure for several minutes.** If the pleural space is entered, withdraw needle and evaluate patient for possible pneumothorax.

3. When the axillary-subclavian vein has been entered, remove the syringe leaving the needle in place. **Place a finger over the hub of the needle to minimize blood loss and risk of air aspiration.** The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

4. Straighten "J" tip of guidewire with tip straightener and insert tapered end of tip straightener into the needle. Tip straightener should not be advanced over the guidewire beyond the guidewire tip. Advance the guidewire as far as appropriate for the procedure. **Verify correct positioning, using fluoroscopy.**

5. Gently withdraw and remove needle and tip straightener. **Caution: If the guidewire must be withdrawn while the needle is still inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.**

6. Make a small incision parallel to the clavicle with the guidewire at the center of the incision to permit introduction of vessel dilator and sheath introducer.



7. Advance the vessel dilator and sheath introducer as a unit, over the exposed wire using a rotational motion. Advance into the axillary-subclavian vein as a unit, leaving approximately 2 centimeters of sheath exposed.

8. Withdraw the vessel dilator and "J" wire, leaving the sheath in place. **Hold thumb over exposed orifice of sheath or gently squeeze sheath body to prevent air aspiration.** The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

9. Insert catheter into the sheath. Advance the catheter tip through the sheath and into the vein. Confirm appropriate catheter position with fluoroscopy.

10. Looking at the introducer sheath from above, initiate the handle "break" by rotating the ends toward each other. The handle may also be separated by grasping both ends and pulling them apart.

11. With catheter well advanced, remove sheath by rolling handle ends away from each other in a downward direction. This will cause the sheath to tear longitudinally. Continue to peel apart the sheath while withdrawing from the vessel. **(Note: Care must be taken not to withdraw the catheter as the sheath is being removed.)**

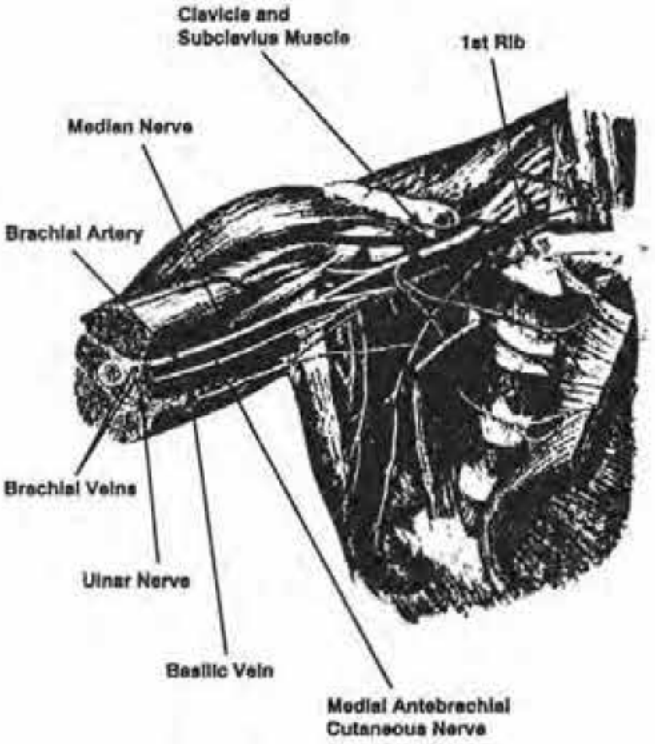
12. Follow instructions pages 14 through 17 for completion of placement.

CATHLINK™20 Implanted Port

Brachial/Basilic Approach

Implantation Instructions

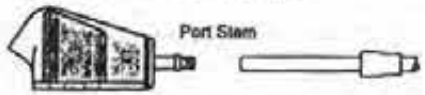
Relevant Anatomy



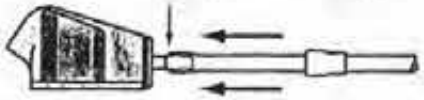
Implantation Instructions

- Complete patient implant record, including product reorder number and lot number.
- Insert an over-the-needle I.V. catheter in a peripheral vein in the same upper extremity distal to the proposed **CathLink** 20 port venous access site.
- Position the arm in an abducted, externally rotated position.
- Select desired port site. (refer to page 13)
- Sterilely prep and drape the upper arm and axilla.
- Using flush connector, flush open-ended catheter with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end. **Note:** Catheter should be clamped on segment that will be cut off prior to attachment to port to avoid catheter damage.
- Inject contrast dye into the distal peripheral over-the-needle I.V. catheter to allow for visualization of the selected vein to be accessed under fluoroscopy.
- Under local anesthesia, puncture the selected brachial or basilic vein at the midpoint of the arm with an 18 gauge thin-wall needle.
- Under fluoroscopic guidance, advance the extra-long guidewire through the needle into the accessed vein and into the superior vena cava.
- Remove the needle and make a small incision over the guidewire.
- Place a 7 Fr. dilator over wire into the vein to maintain venous access.
- Make a transverse incision, approximately 2.5cm in length, over the port pocket site.
- Create a subcutaneous pocket using blunt dissection so that the port does not lie beneath the incision.
  Note: The **CathLink** 20 port should be positioned with the funnel-shaped entrance facing toward the elbow (distal).
- Remove the dilator and advance the catheter over the guidewire.
- With blunt dissection create a subcutaneous tunnel between the pocket and the guidewire incisions.
- Position the catheter tip at the desired infusion site.
  Note: A common location for catheter tip placement is the junction of the Superior Vena Cava and right atrium.
- Confirm catheter position via fluoroscopy.
- Remove guidewire and pass the catheter through the tunnel to the port pocket, making certain fluoroscopically that the desired catheter tip position is maintained.
  Note: An injection of radiographic contrast may be used for additional visualization.
- Trim catheter at a 90° angle to proper final length allowing sufficient slack for body movement and port connection.
- Port to catheter connection

A. Align port stem with catheter lumen.

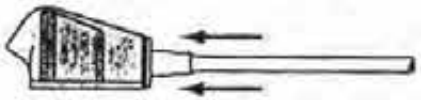


B. Advance catheter over port stem to midway point.



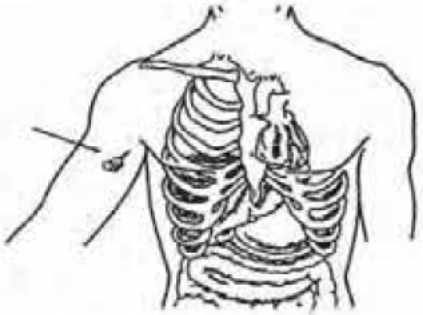
Warning: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

C. Advance catheter lock until flush with port.



Caution: If the catheter and lock are connected and then disconnected, the catheter end must be re-trimmed prior to re-connection to ensure a secure connection. It is important to cut the catheter before each re-connection, as the catheter may be damaged by excessive stretching during disconnection.

- Place the **CathLink** 20 port in the subcutaneous pocket with the funnel-shaped entrance facing toward the elbow (distal), and away from the incision line and secure flat base to the underlying fascia using one non-absorbable, monofilament suture per suture hole. This will reduce the risk of port migration and the possibility of it flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.



- After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
- Access the **CathLink** 20 port through the skin with an over-the-needle I.V. catheter.
- Conduct flow studies on the catheter using a 10ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned. Aspirate to confirm the ability to draw blood.
- Flush and heparin lock the port system as described under heparin lock procedure.
- Close the incision sites.
- Apply dressing according to hospital practice.

Note: Leave over-the-needle I.V. catheter in place if the **CathLink** 20 port is to be used for infusion or aspiration on the same day as implant.

CATHLINK™ 20 Implanted Port

Use and Maintenance Instructions

Site Preparation

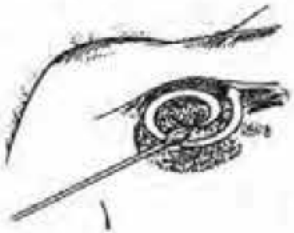
Inspection and aseptic preparation of the injection site should always be performed prior to accessing the port.

Equipment:

- Sterile gloves
- Alcohol wipe
- Antiseptic swabs (3)

Procedure:

1. Explain procedure to patient. Warn of needle prick sensation.
2. Wash hands thoroughly.
3. Don sterile gloves.
4. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 4-5 inches in diameter.
5. Repeat Step #4 with antiseptic swabs three times.



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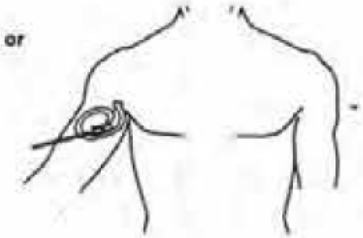


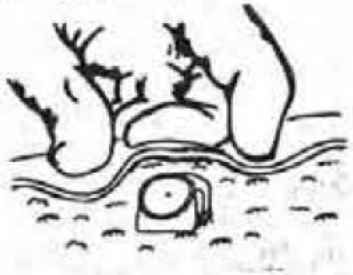
Accessing the CathLink™ 20 Port

Equipment:

- 20 gauge over-the-needle I.V. catheter in a 1 ¼" minimum length*
- 10ml or larger syringes
- Extension Set with Clamp

Procedure:

1. Perform aseptic site preparation.
2. Utilizing a sterile gloved hand:
   - Locate the **CathLink** 20 port and identify the funnel-shaped entrance by palpation.
3. Stabilize the **CathLink** 20 port by "holding" between thumb and forefinger of non-dominant hand.



4. Aim for the funnel shaped entrance which is between these two fingers.
5. Insert a 20 gauge over-the-needle I.V. catheter into the **CathLink** 20 port funnel shaped entrance until resistance is felt.

*** Caution:** Only 20 gauge over-the-needle I.V. catheters 1 ¼" or longer should be used with **CathLink** 20 port. Non-coring needles should not be used. The exact I.V. catheter length will be determined by the clinical situation. Longer over-the-needle I.V. catheters may be used for added security.

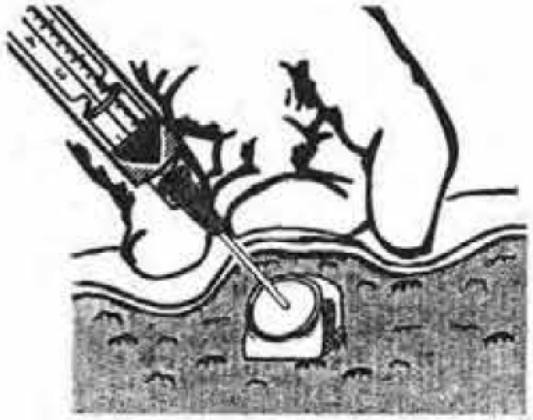
6. Using the thumb and forefinger of dominant hand, advance the over-the-needle IV catheter completely into the **CathLink** 20 port by grasping and advancing the catheter hub only, while simultaneously withdrawing the needle. Do not reuse or reinsert the needle into the over-the-needle IV catheter. Reinsertion of the needle may cause damage to the IV catheter which may lead to extravazation.

7. Dispose of the needle according to hospital guidelines.
8. Immediately, attach syringe or extension set to over-the-needle IV catheter.
9. Verify correct over-the-needle IV catheter placement by blood aspiration.
10. Proceed with infusion protocol.
11. The port must be flushed following injection.
11. Perform heparin lock procedure.

Caution: The over-the-needle IV catheter hub should not be left open to air while it is in the CathLink 20 port.

***Note:* It is recommended that the dressing and infusion components be changed every 24-48 hours during infusion therapy.**

Deaccessing the CathLink™ 20 Port



To reduce potential for blood backflow into the catheter tip and possible catheter clotting, always remove the over-the-needle IV catheter slowly, while injecting the last 0.5ml of solution. Stabilize the **CathLink** 20 port with two fingers during over-the-needle IV catheter withdrawal.

Bolus Injection

Procedure for **CathLink** 20 port

Equipment:

- 20 gauge over-the-needle I.V. catheter in a 1 ¾" minimum length
- 10ml syringe filled with sterile normal saline
- Extension set with clamp

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach 10ml syringe filled with sterile normal saline to extension set. Expel all air and clamp extension.
3. Locate and stabilize the **CathLink** 20 port. (see page 33)
4. Aseptically access the port and verify correct over-the-needle I.V. catheter placement by blood aspiration. (see page 34) Failure to confirm placement may result in extravasation.
5. Attach extension set and flush port with 10ml sterile normal saline. Clamp the extension set and remove the syringe.
6. Connect syringe containing the drug to extension set. Release clamp and administer injection.
7. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
8. When the injection is completed, clamp the extension set.
9. Flush after each injection with 10ml of sterile normal saline to help prevent interaction between incompatible drugs.
10. Perform heparin lock procedure.

Continuous Infusion

Procedure for **CathLink** 20 port

Equipment:

- Prescribed I.V. solution
- Extension set with clamp
- 10 ml syringe filled with sterile normal saline
- 20 Ga. over-the needle I.V. catheter in a 1 ¾" minimum length
- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- Antibacterial ointment
- 2" x 2" gauze pads

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach 10 ml syringe filled with sterile normal saline to extension set. Expel all air and clamp the extension set.
3. Locate and stabilize the **CathLink** 20 port. (see page 33)
4. Aseptically access the port and verify correct over-the-needle I.V. catheter placement by blood aspiration. (see page 34) Failure to confirm placement may result in extravasation. Attach extension set.
5. Apply antibacterial ointment to injection site. Secure over-the-needle I.V. catheter with sterile tape strips and transparent dressing to help prevent inadvertent dislodgement.
6. Open clamp and flush the **CathLink** 20 port with sterile normal saline. Clamp extension set and remove syringe.
7. Connect fluid delivery system (I.V. set or infusion pump as indicated). **Note:** To provide additional security during pump infusion, tape all tubing connections. Pumps must incorporate a functional automatic pressure limiting switch which will shut pump off before pressure exceeds 25 psi.
8. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.

9. When infusion is completed, clamp extension set and then remove the fluid delivery system.
10. Flush after each infusion with 10 ml sterile normal saline to help prevent interaction between incompatible drugs.
11. Perform heparin lock procedure.

Note: For long-term infusions, longer length over-the-needle I.V. catheters may be used for added security.

Blood Sampling

Procedure for **CathLink** 20 port

Equipment:

- 2-way stopcock or extension set with clamp
- 20 Ga. over-the needle I.V. catheter in a 1 ¾" minimum length
- 10ml syringe filled with 5cc sterile normal saline
- 20ml syringe (2)
- Sterile normal saline

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Locate and stabilize the **CathLink** 20 port. (see page 33)
3. Aseptically access the port and verify correct over-the-needle I.V. catheter placement by blood aspiration. (see page 34) Failure to confirm placement may result in extravasation.
4. Flush the **CathLink** 20 port with sterile normal saline in 10ml syringe.
5. Withdraw at least 5ml of blood and discard syringe.
6. Aspirate desired blood volume into 20ml syringe and transfer it into appropriate blood sample tube.
7. Once sample is obtained, immediately flush the system with 20ml of sterile normal saline.
8. Perform heparin lock procedure.

Heparin Lock

Procedure for the **CathLink** 20 port.

To help prevent clot formation and catheter blockage, the **CathLink** 20 port should be filled with sterile heparinized saline after each use. If the **CathLink** 20 port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

Recommended flushing volumes:

FLUSHING VOLUMES	
PROCEDURE	VOLUME
CathLink 20 port not in use	5ml heparinized saline
After each infusion of medication or TPN	10ml sterile normal saline then 5ml heparinized saline
After blood withdrawal	20ml sterile normal saline then 5ml heparinized saline
PRIMING VOLUMES	
CathLink 20 LP Port	0.04 ml
Catheter	1.20 ml

Equipment:

- 20 gauge over-the-needle I.V. catheter in a 1 ¼" minimum length
- 10ml syringe filled with sterile heparinized saline (100 U/ml)*

***Note:** Other flushing schedules as well as concentrations of heparinized saline (10 to 1000 U/ml) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Locate and stabilize the **CathLink** 20 port. (see page 33)
3. Aseptically access the port and verify correct over-the-needle I.V. catheter placement by blood aspiration. (see page 34) Failure to confirm placement may result in extravasation.
4. Attach a 10ml syringe filled with sterile heparinized saline to over-the-needle I.V. catheter.
5. Flush the system. To reduce potential for blood back flow into the catheter tip and possible catheter clotting, always remove the over-the-needle I.V. catheter slowly. Maintain positive pressure in the system by withdrawing the syringe and over-the-needle I.V. catheter while injecting the last 0.5ml. Stabilize the port with two fingers during over-the-needle I.V. catheter withdrawal.

Use of Urokinase for Catheter Blockage

Use of a fibrinolytic agent such as urokinase has successfully cleared clotted catheters when change of body position and gentle irrigation and aspiration have failed. **The following procedure may be employed on the order of a physician. Additional instructions provided by the drug manufacturer should be followed.**

Equipment:

- 20 gauge over-the-needle I.V. catheter in a 1¼" minimum length
- 10ml syringe containing 2ml of 5,000 u/ml urokinase
- 20ml syringe filled with sterile normal saline.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access the **CathLink** 20 port. Attach 10ml syringe, void of air and filled with 2ml of 5,000 u/ml urokinase.
3. Gently instill urokinase solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter.

Warning: Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force entire amount into catheter.

4. Leave solution in place for 15 minutes.
5. Attempt to aspirate urokinase and the clot(s).
6. If the clot(s) cannot be aspirated, repeat procedure.
7. Once the blockage has been cleared, flush catheter with at least 20ml of sterile normal saline.
8. Perform heparin lock procedure.

Re-Use of a Bard Access Systems Medical Device

Bard Access Systems products are single use devices and should never be reimplanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. **Any device that has been contaminated by blood should not be reused or resterilized.**

All **Bard Access Systems** ports are supplied in double sterile packages. The package should be examined carefully prior to opening. Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility. **Do not resterilize any damaged or opened packages.**

Warning: An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact **Bard Access Systems** to see if additional product information is available.

Issued date: October 1993

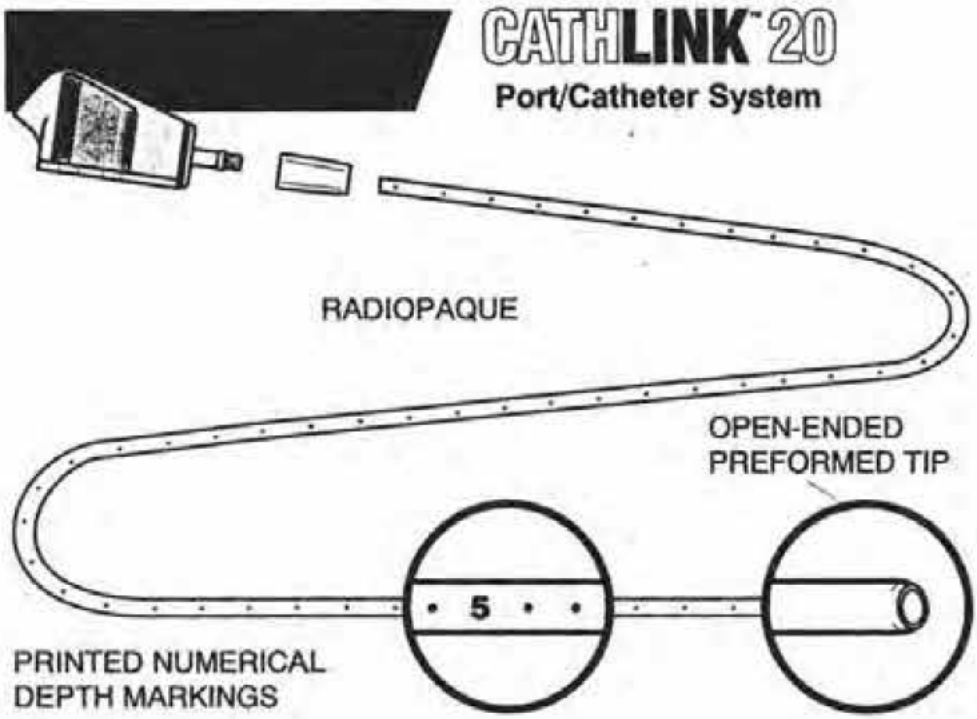
0396744
9310R

BARD

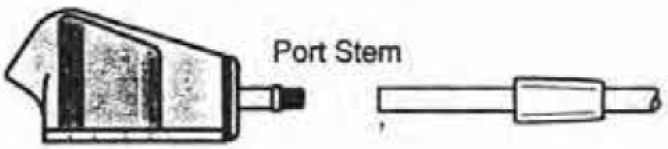
Bard Access Systems
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116
For ordering information call Customer Service: 800/545-0890
For clinical information call: 800/443-3385

0127

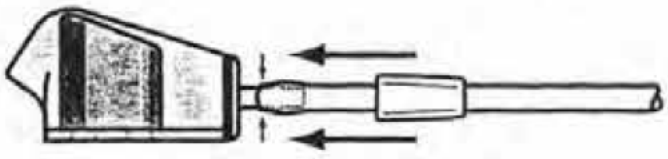
Exh. 13



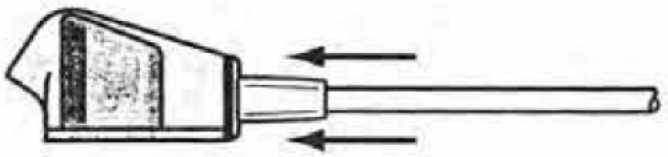
ALIGN PORT STEM WITH CATHETER LUMEN



ADVANCE CATHETER OVER PORT STEM TO MIDWAY POINT



ADVANCE CATHETER LOCK UNTIL FLUSH WITH PORT



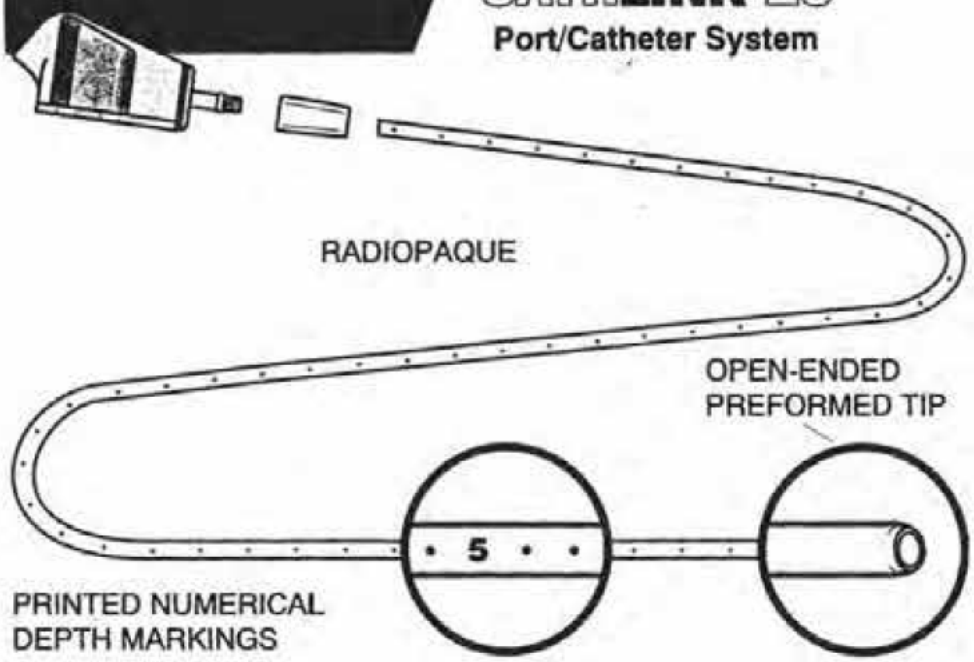
Exh.

13

Exh. 13

CATHLINK™ 20

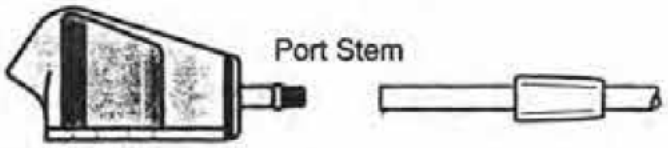
Port/Catheter System



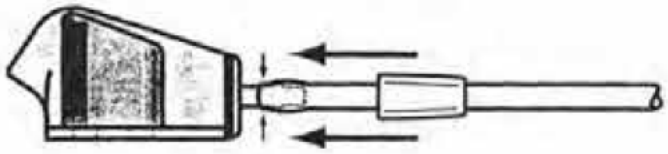
CATHLINK™ 20

Port/Catheter Locking System

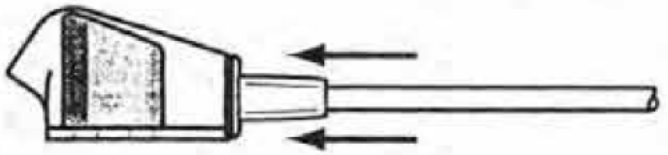
ALIGN PORT STEM WITH CATHETER LUMEN



ADVANCE CATHETER OVER PORT STEM TO MIDWAY POINT



ADVANCE CATHETER LOCK UNTIL FLUSH WITH PORT



Exh. 14

Exhibit 14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 21 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

REGULATORY AFFAIRS
MAR 24 1994

Ms. Jane Ann Martin
Regulatory Affairs Administrator
Bard Access Systems, Inc.
5425 W. Arnelia Earhart Drive
Salt Lake City, Utah 84116

Re: K926139
CathLink 20™ Titanium Port
Dated: December 4, 1992
Received: December 7, 1992

Dear Ms. Martin:

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. In order for us to complete the review of your submission, we require the following additional information:

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[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)
1390 Piccard Drive
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 Ms. Brenda Bolden at (301) 594-1307. 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,

for Philip J. Phillips
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Exh. 15

Exhibit 15

NOTE: INFORMATION IN THIS EXHIBIT WAS ALSO PROVIDED IN THE ORIGINAL 510(K) SUBMISSION. BASED ON THE REVIEWER'S QUESTIONS, ADDITIONAL INFORMATION HAS BEEN PROVIDED AND IS UNDERLINED.

PORT FAILURE PRESSURE TEST

Objective: (b)(4)Proprietary Information [redacted]

Method: [redacted]

Results: The maximum internal pressure for each port is listed below.

(b)(4)Proprietary Information [redacted]

Conclusion: (b)(4)Proprietary Information [redacted]

(b) (6) [redacted]

Exh.

16

Exhibit 16.1

Port/Catheter Connection - Static Load

Objective: (b)(4)Proprietary Information

Method:

STATIC LOAD TEST

(b)(4)Proprietary Information

(b) (6)

Exhibit 16.2

Port/Catheter Connection - Cyclic Load

Objective: (b)(4)Proprietary Information [redacted]

Method:

(b)(4)Proprietary Information [redacted]

(b) (6) [redacted]

Exhibit 16.3

CATHETER PULL TEST (b)(4)Proprietary Information

Objective: (b)(4)Proprietary Information

Method:

Results: (b)(4)Proprietary Information

(b)(4)Proprietary Information

(b) (6)

Exh.

17

Exh.

18

Exh.

19

Exhibit 19

ETO STERILIZATION OF NYLON SUTURES

Objective:

(b)(4)Proprietary Information

[redacted]

Method:

(b)(4)Proprietary Information

[redacted]

Results:

(b)(4)Proprietary Information

[redacted]

Conclusion:

(b)(4)Proprietary Information

[redacted]

Exh.

20

Exhibit 20

ETO STERILIZATION OF EXAMINATION GLOVES

OBJECTIVE:

(b)(4)Proprietary Information

[redacted]

METHOD:

(b)(4)Proprietary Information

[redacted]

RESULTS:

(b)(4)Proprietary Information

[redacted]

Exh. 20
Pg. 2

TEST SAMPLE	TENSILE (MPa)	ELONGATION (%)
Ansell Initial Qual	(b)(4)Proprietary Information	
1 year, no ETO		
1 year, 3x ETO		
1 year, 3x ETO, heated		

Specification: (b)(4)Proprietary Information

CONCLUSION:
(b)(4)Proprietary Information

Melinda R. Flood
Sterilization Quality Engineer

19 May 94
Date

Exh. 421

PORT-A-CATH®, P.A.S. PORT®, ULTRA-LOCK®, CATH-FINDER®, and *a better way to care®* are registered trademarks of Pharmacia Deltec Inc.

FLUORO-FREE™ is a trademark of Pharmacia Deltec Inc.

Printed in U.S.A.

Pharmacia Deltec Inc.
St. Paul, Minnesota 55112

January 1992
40-2527-01B

0164

PORT-A-CATH®

P.A.S. PORT® FLUORO-FREE™

Implantable Access System

Instructions for Use

Pharmacia Deltec
a better way to care

Exh. 21

I. INTRODUCTION

The PORT-A-CATH® P.A.S. PORT® FLUORO-FREE™ Implantable Access System is designed to permit repeated access to the venous system. It consists of a portal with a self-sealing septum, accessible by percutaneous needle puncture, and a catheter for the parenteral delivery of medications, fluids, and nutritional solutions to selected sites within the venous system, and for the sampling of venous blood.

It is important that the *Instructions for Use* be brought to the attention of all healthcare personnel involved in the care and management of the patient.

1. Indications

The system is indicated for peripheral placement in the arm when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

2. Contraindications

Do not use the system with chemicals that are incompatible with any of its components.

Exh. 21
Pg. 2

Exh.

22

Exhibit 22.1

J-1500b

ESI ELKINS-SINN, INC.

SODIUM CHLORIDE INJECTION, USP, 0.9%

DESCRIPTION

Sodium Chloride Injection, USP is a sterile, non-pyrogenic, isotonic solution of sodium chloride 0.9% (9 mg/mL) in Water for Injection containing no antimicrobial agent or other added substance. The pH is between 4.5 and 7.0. Its chloride and sodium ion concentrations are approximately 0.154 mEq of each per milliliter and its calculated osmolality is 0.308 milliosmols per mL.

Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol.

The empirical formula for sodium chloride is NaCl, and the molecular weight is 58.44.

CLINICAL PHARMACOLOGY

Sodium chloride comprises over 90% of the inorganic constituents of the blood serum. Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance. The small volume of fluid and amount of sodium chloride provided by Sodium Chloride Injection, USP, 0.9%, when used only as a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.

INDICATIONS AND USAGE

Sodium Chloride Injection is used to flush intravascular catheters or as a sterile, isotonic single dose vehicle, solvent, or diluent for substances to be administered intravenously, intramuscularly or subcutaneously and for other extemporaneously prepared single dose sterile solutions according to instructions of the manufacturer of the drug to be administered.

WARNINGS

Sodium chloride must be used with caution in the presence of congestive heart failure, circulatory insufficiency, kidney dysfunction or hypoproteinemia.

Excessive amounts of sodium chloride by any route may cause hypokalemia and acidosis. Excessive amounts by parenteral routes may precipitate congestive heart failure and acute pulmonary edema, especially seen in patients with preexisting cardiovascular disease and those receiving corticosteroids, corticotropin or other drugs that may give rise to sodium retention.

For use in newborns, when a Sodium Chloride solution is required for preparation or diluting medications, or in flushing intravenous catheters, only preservative-free Sodium Chloride Injection, USP, 0.9% should be used.

PRECAUTIONS

GENERAL

Since Sodium Chloride Injection does not contain antimicrobial agents and is intended for single use, any unused amount must be discarded immediately following withdrawal of any portion of the contents of the vial or ampul. Do not open ampul until it is to be used.

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.

PREGNANCY

Pregnancy Category C—Animal reproduction studies have not been conducted with Sodium Chloride Injection. It is also not known whether Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

When used as a diluent, solvent or intravascular flushing solution, this parenteral preparation is unlikely to pose a threat of sodium chloride or fluid overload except possibly in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures.

DOSAGE AND ADMINISTRATION

Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, specific references should be checked for any possible incompatibility with sodium chloride.

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing intravenous catheters. Prior to and after administration of the medication, the intravenous catheter should be flushed in its entirety with Sodium Chloride Injection, USP, 0.9%. Use in accord with any warnings or precautions appropriate to the medicaton being administered.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

2 mL DOSETTE® vials packaged in 25s (*NDC 0641-0495-25*)
5 mL DOSETTE® ampuls packaged in 25s (*NDC 0641-1500-35*) and 100s (*NDC 0641-1500-36*)
10 mL DOSETTE® ampuls packaged in 25s (*NDC 0641-1510-35*) and 100s (*NDC 0641-1510-36*)

STORAGE
Avoid freezing.

* * * * * *

Additional package inserts may be obtained by contacting the Professional Services Department.

Revised April 1989

Manufactured by
ELKINS-SINN, INC. Cherry Hill, NJ 08003-4099
A subsidiary of A.H. Robins Company

Exhibit 22.2 pg. 1

Xylocaine®(lidocaine hydrochloride) Injections
Xylocaine®(lidocaine HCl) with Epinephrine Injections

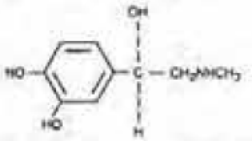
For Infiltration and Nerve Block

DESCRIPTION

Xylocaine (lidocaine HCl) Injections are sterile, non pyrogenic, aqueous solutions that contain a local anesthetic agent with or without epinephrine and are administered parenterally by injection. See INDICATIONS for specific uses.

Xylocaine solutions contain lidocaine HCl, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride and has the molecular wt. 270.8. Lidocaine HCl ($C_{14}H_{22}N_2O \cdot HCl$) has the following structural formula:

Epinephrine is (-) -3, 4-Dihydroxy-α-[(methylamino) methyl] benzyl alcohol and has the molecular wt. 183.21. Epinephrine ($C_9H_{13}NO_3$) has the following structural formula:



Dosage forms listed as Xylocaine-MPF indicate single dose solutions that are Methyl Paraben Free (MPF).

Xylocaine MPF is a sterile, non pyrogenic, isotonic solution containing sodium chloride. Xylocaine in multiple dose vials, each mL also contains 1 mg methylparaben as antiseptic preservative. The pH of these solutions is adjusted to approximately 6.5 (5.0-7.0) with sodium hydroxide and/or hydrochloric acid.

Xylocaine MPF with Epinephrine is a sterile, non pyrogenic, isotonic solution containing sodium chloride. Each mL contains lidocaine hydrochloride and epinephrine, with 0.5 mg sodium metabisulfite as an antioxidant and 0.2 mg citric acid as a stabilizer. Xylocaine with Epinephrine in multiple dose vials, each mL also contains 1 mg methylparaben as antiseptic preservative. The pH of these solutions is adjusted to approximately 4.5 (3.3-5.5) with sodium hydroxide and/or hydrochloric acid. Filled under nitrogen.

CLINICAL PHARMACOLOGY

Mechanism of Action: Lidocaine stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses thereby effecting local anesthetic action.

Hemodynamics: Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. With central neural blockade these changes may be attributable to block of autonomic fibers, a direct depressant effect of the local anesthetic agent on various components of the cardiovascular system, and/or the beta-adrenergic receptor stimulating action of epinephrine when present. The net effect is normally a modest hypotension when the recommended dosages are not exceeded.

Pharmacokinetics and Metabolism: Information derived from diverse formulations, concentrations and usages reveals that lidocaine is completely absorbed following parenteral administration, its rate of absorption depending, for example, upon various factors such as the site of administration and the presence or absence of a vasoconstrictor agent. Except for intravascular administration, the highest blood levels are obtained following intercostal nerve block and the lowest after subcutaneous administration.

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 µg of free base per mL 60 to 80 percent of lidocaine is protein bound. Binding is also dependent on the plasma concentration of the alpha-1-acid glycoprotein.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative *N*-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. *N*-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various metabolites, and less than

During the administration of epidural anesthesia, it is recommended that a test dose be administered initially and that the patient be monitored for central nervous system toxicity and cardiovascular toxicity, as well as for signs of unintended intrathecal administration, before proceeding. When clinical conditions permit, consideration should be given to employing local anesthetic solutions that contain epinephrine for the test dose because circulatory changes compatible with epinephrine may also serve as a warning sign of unintended intravascular injection. An intravascular injection is still possible even if aspirations for blood are negative. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical condition. Lidocaine should also be used with caution in patients with severe shock or heart block.

Lumbar and caudal epidural anesthesia should be used with extreme caution in persons with the following conditions: existing neurological disease, spinal deformities, septicemia, and severe hypertension.

Local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully circumscribed quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Preparations containing a vasoconstrictor should be used with caution in patients during or following the administration of potent general anesthetic agents, since cardiac arrhythmias may occur under such conditions.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be accomplished after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of central nervous system toxicity.

Since amide-type local anesthetics are metabolized by the liver, Xylocaine Injection should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations. Xylocaine Injection should also be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.

Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for the management of malignant hyperthermia should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenous package insert before using).

Proper tourniquet technique, as described in publications and standard textbooks, is essential in the performance of intravenous regional anesthesia. Solutions containing epinephrine or other vasoconstrictors should not be used for this technique.

Lidocaine should be used with caution in persons with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine.

Use in the Head and Neck Area: Small doses of local anesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should have their circulation and respiration monitored and be constantly observed. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded. (See DOSAGE and ADMINISTRATION.)

Information for Patients: When appropriate, patients should be informed in advance that they may experience temporary loss of sensation and motor activity, usually in the lower half of the body, following proper administration of epidural anesthesia.

Clinically Significant Drug Interactions: The administration of local anesthetic solutions containing epinephrine or norepinephrine to patients receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe, prolonged hypertension.

Phenothiazines and butyrophenones may reduce or reverse the pressor effect of epinephrine.

Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential.

Exh. 22-
pg. 2

10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2,6-dimethylaniline.

The elimination half-life of lidocaine following an intravenous bolus injection is typically 1.5 to 2.0 hours. Because of the rapid rate at which lidocaine is metabolized, any condition that affects liver function may alter lidocaine kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6.0 µg free base per mL. In the rhesus monkey arterial blood levels of 18-21 µg/mL have been shown to be threshold for convulsive activity.

INDICATIONS AND USAGE

Xylocaine (lidocaine HCl) Injections are indicated for production of local or regional anesthesia by infiltration techniques such as percutaneous injection and intravenous regional anesthesia by peripheral nerve block techniques such as brachial plexus and intercostal and by central neural techniques such as lumbar and caudal epidural blocks, when the accepted procedures for these techniques as described in standard textbooks are observed.

CONTRAINDICATIONS

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

WARNINGS

XYLOCAINE INJECTIONS FOR INFILTRATION AND NERVE BLOCK SHOULD BE EMPLOYED ONLY BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIES THAT MIGHT ARISE FROM THE BLOCK TO BE EMPLOYED AND THEN ONLY AFTER ENSURING THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY EQUIPMENT AND THE PERSONNEL NEEDED FOR PROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES. (See also ADVERSE REACTIONS and PRECAUTIONS.) DELAY IN PROPER MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE AND/OR ALTERED SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

To avoid intravascular injection, aspiration should be performed before the local anesthetic solution is injected. The needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.

Local anesthetic solutions containing antimicrobial preservatives, (e.g., methylparaben) should not be used for epidural or spinal anesthesia because the safety of these agents has not been established with regard to intrathecal injection, either intentional or accidental.

Xylocaine with epinephrine solutions contain sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

PRECAUTIONS

General: The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. Standard textbooks should be consulted for specific techniques and precautions for various regional anesthetic procedures.

Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. (See WARNINGS and ADVERSE REACTIONS.) The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Syringe aspirations should also be performed before and during each supplemental injection when using indwelling catheter techniques.

Concurrent administration of vasopressor drugs (for the treatment of hypotension related to obstetric blocks) and ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents.

Drug/Laboratory Test Interactions: The intramuscular injection of lidocaine may result in an increase in creatine phosphokinase levels. Thus, the use of this enzyme determination, without isoenzyme separation, as a diagnostic test for the presence of acute myocardial infarction may be compromised by the intramuscular injection of lidocaine.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted.

Pregnancy: Teratogenic Effects — Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

Labor and Delivery: Local anesthetics rapidly cross the placenta and when used for epidural, paracervical, pudendal or caudal block anesthesia, can cause varying degrees of maternal, fetal and neonatal toxicity. (See CLINICAL PHARMACOLOGY, Pharmacokinetics.) The potential for toxicity depends upon the procedure performed, the type and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus and neonate involve alterations of the central nervous system, peripheral vascular tone and cardiac function.

Maternal hypotension has resulted from regional anesthesia. Local anesthetics produce vasodilation by blocking sympathetic nerves. Elevating the patient's legs and positioning her on her left side will help prevent decreases in blood pressure. The fetal heart rate also should be monitored continuously, and electronic fetal monitoring is highly advisable.

Epidural, spinal, paracervical, or pudendal anesthesia may alter the forces of parturition through changes in uterine contractility or maternal expulsive efforts. In one study, paracervical block anesthesia was associated with a decrease in the mean duration of first stage labor and facilitation of cervical dilation. However, spinal and epidural anesthesia have also been reported to prolong the second stage of labor by removing the parturient's reflex urge to bear down or by interfering with motor function. The use of obstetrical anesthesia may increase the need for forceps assistance.

The use of some local anesthetic drug products during labor and delivery may be followed by diminished muscle strength and tone for the first day or two of life. The long-term significance of these observations is unknown. Fetal bradycardia may occur in 20 to 30 percent of patients receiving paracervical nerve block anesthesia with the amide-type local anesthetics and may be associated with fetal acidosis. Fetal heart rate should always be monitored during paracervical anesthesia. The physician should weigh the possible advantages against risks when considering a paracervical block in prematurity, toxemia of pregnancy, and fetal distress. Careful adherence to recommended dosage is of the utmost importance in obstetrical paracervical block. Failure to achieve adequate analgesia with recommended doses should arouse suspicion of intravascular or fetal intracranial injection. Cases compatible with unintended fetal intracranial injection of local anesthetic solution have been reported following intended paracervical or pudendal block or both. Babies so affected present with unexplained neonatal depression at birth, which correlates with high local anesthetic serum levels, and often manifest seizures within six hours. Prompt use of supportive measures combined with forced urinary excretion of the local anesthetic has been used successfully to manage this complication.

Case reports of maternal convulsions and cardiovascular collapse following use of some local anesthetics for paracervical block in early pregnancy (as anesthesia for elective abortion) suggest that systemic absorption under these circumstances may

be rapid. The recommended maximum dose of each drug should not be exceeded. Injection should be made slowly and with frequent aspiration. Allow a 5-minute interval between sides.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lidocaine is administered to a nursing woman.

Pediatric Use: Dosages in children should be reduced, commensurate with age, body weight and physical condition. See DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS

Systemic: Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption or inadvertent intravascular injection, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

Central Nervous System: CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular System: Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic: Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to local anesthetic agents or to the methylparaben used as a preservative in the multiple dose vials. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

Neurologic: The incidences of adverse reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered and are also dependent upon the particular drug used, the route of administration and the physical status of the patient. In a prospective review of 10,440 patients who received lidocaine for spinal anesthesia, the incidences of adverse reactions were reported to be about 3 percent each for positional headaches, hypotension and backache; 2 percent for shivering; and less than 1 percent each for peripheral nerve symptoms, nausea, respiratory inadequacy and double vision. Many of these observations may be related to local anesthetic techniques, with or without a contribution from the local anesthetic.

In the practice of caudal or lumbar epidural block, occasional unintentional penetration of the subarachnoid space by the catheter may occur. Subsequent adverse effects may depend partially on the amount of drug administered subdurally. These may include spinal block of varying magnitude (including total spinal block), hypotension secondary to spinal block, loss of bladder and bowel control, and loss of perineal sensation and sexual function. Persistent motor, sensory and/or autonomic (sphincter control) deficit of some lower spinal segments with slow recovery (several months) or incomplete recovery have been reported in rare instances when caudal or lumbar epidural block has been attempted. Backache and headache have also been noted following use of these anesthetic procedures.

OVERDOSAGE

Acute emergencies from local anesthetics are generally related to high plasma levels

Caudal and Lumbar Epidural Block: As a precaution against the adverse experience sometimes observed following unintentional penetration of the subarachnoid space, a test dose such as 2-3 mL of 1.5% lidocaine should be administered at least 5 minutes prior to injecting the total volume required for a lumbar or caudal epidural block. The test dose should be repeated if the patient is moved in a manner that may have displaced the catheter. Epinephrine, if contained in the test dose, (10-15 µg have been suggested), may serve as a warning of unintentional intravascular injection. If injected into a blood vessel, this amount of epinephrine is likely to produce a transient "epinephrine response" within 45 seconds, consisting of an increase in heart rate and systolic blood pressure, circumoral pallor, palpitations and nervousness in the unsedated patient. The sedated patient may exhibit only a pulse rate increase of 20 or more beats per minute for 15 or more seconds. Patients on beta blockers may not manifest changes in heart rate, but blood pressure monitoring can detect an evanescent rise in systolic blood pressure. Adequate time should be allowed for onset of anesthesia after administration of each test dose. The rapid injection of a large volume of Xylocaine Injection through the catheter should be avoided, and, when feasible, fractional doses should be administered.

In the event of the known injection of a large volume of local anesthetic solution into the subarachnoid space, after suitable resuscitation and if the catheter is in place, consider attempting the recovery of drug by draining a moderate amount of cerebrospinal fluid (such as 10 mL) through the epidural catheter.

MAXIMUM RECOMMENDED DOSAGES

Adults

For normal healthy adults, the individual maximum recommended dose of lidocaine HCl with epinephrine should not exceed 7 mg/kg (3.5 mg/lb) of body weight, and in general it is recommended that the maximum total dose not exceed 500 mg. When used without epinephrine the maximum individual dose should not exceed 4.5 mg/kg (2 mg/lb) of body weight, and in general it is recommended that the maximum total dose does not exceed 300 mg. For continuous epidural or caudal anesthesia, the maximum recommended dosage should not be administered at intervals of less than 90 minutes. When continuous lumbar or caudal epidural anesthesia is used for non-obstetrical procedures, more drug may be administered if required to produce adequate anesthesia.

The maximum recommended dose per 90 minute period of lidocaine hydrochloride for paracervical block in obstetrical patients and non-obstetrical patients is 200 mg total. One half of the total dose is usually administered to each side. Inject slowly, five minutes between sides. (See also discussion of paracervical block in PRECAUTIONS.)

For intravenous regional anesthesia, the dose administered should not exceed 4 mg/kg in adults.

Children

It is difficult to recommend a maximum dose of any drug for children, since this varies as a function of age and weight. For children over 3 years of age who have a normal lean body mass and normal body development, the maximum dose is determined by the child's age and weight. For example, in a child of 5 years weighing 50 lbs the dose of lidocaine HCl should not exceed 75-100 mg (1.5-2 mg/lb). The use of even more dilute solutions (i.e., 0.25-0.5%) and total dosages not to exceed 3 mg/kg (1.4 mg/lb) are recommended for induction of intravenous regional anesthesia in children.

In order to guard against systemic toxicity, the lowest effective concentration and lowest effective dose should be used at all times. In some cases it will be necessary to dilute available concentrations with 0.9% sodium chloride injection in order to obtain the required final concentration.

NOTE: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and container permit. The injection is not to be used if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

Exh. 22.2
Pg. 4

encountered during therapeutic use of local anesthetics or to unintended subarachnoid injection of local anesthetic solution (see ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS).

Management of Local Anesthetic Emergencies: The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic injection. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions, as well as underventilation or apnea due to unintended subarachnoid injection of drug solution, consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to the use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. Underventilation or apnea due to unintentional subarachnoid injection of local anesthetic solution may produce these same signs and also lead to cardiac arrest if ventilatory support is not instituted. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

The oral LD_{50} of lidocaine HCl in non-fasted female rats is 459 (346-773) mg/kg (as the salt) and 214 (159-324) mg/kg (as the salt) in fasted female rats.

DOSAGE AND ADMINISTRATION

Table 1 (Recommended Dosages) summarizes the recommended volumes and concentrations of Xylocaine Injection for various types of anesthetic procedures. The dosages suggested in this table are for normal healthy adults and refer to the use of epinephrine-free solutions. When larger volumes are required, only solutions containing epinephrine should be used except in those cases where vasopressor drugs may be contraindicated.

These recommended doses serve only as a guide to the amount of anesthetic required for most routine procedures. The actual volumes and concentrations to be used depend on a number of factors such as type and extent of surgical procedure, depth of anesthesia and degree of muscular relaxation required, duration of anesthesia required, and the physical condition of the patient. In all cases the lowest concentration and smallest dose that will produce the desired result should be given. Dosages should be reduced for children and for the elderly and debilitated patients and patients with cardiac and/or liver disease.

The onset of anesthesia, the duration of anesthesia and the degree of muscular relaxation are proportional to the volume and concentration (i.e., total dose) of local anesthetic used. Thus, an increase in volume and concentration of Xylocaine Injection will decrease the onset of anesthesia, prolong the duration of anesthesia, provide a greater degree of muscular relaxation and increase the segmental spread of anesthesia. However, increasing the volume and concentration of Xylocaine Injection may result in a more profound fall in blood pressure when used in epidural anesthesia. Although the incidence of side effects with lidocaine is quite low, caution should be exercised when employing large volumes and concentrations, since the incidence of side effects is directly proportional to the total dose of local anesthetic agent injected.

For intravenous regional anesthesia, only the 50 mL single dose vial containing Xylocaine (lidocaine HCl) 0.5% Injection should be used.

Epidural Anesthesia

For epidural anesthesia, only the following dosage forms of Xylocaine Injection are recommended:

1% without epinephrine	30 mL ampules, 30 mL single dose vials
1% with epinephrine 1:200,000	30 mL ampules, 30 mL single dose vials
1.5% without epinephrine	20 mL ampules, 20 mL single dose vials
1.5% with epinephrine 1:200,000	30 mL ampules, 30 mL single dose vials
2% without epinephrine	10 mL ampules, 10 mL single dose vials
2% with epinephrine 1:200,000	20 mL ampules, 20 mL single dose vials

Although these solutions are intended specifically for epidural anesthesia, they may also be used for infiltration and peripheral nerve block, provided they are employed as single dose units. These solutions contain no bacteriostatic agent.

In epidural anesthesia, the dosage varies with the number of dermatomes to be anesthetized (generally 2-3 mL of the indicated concentration per dermatome).

Table 1. Recommended Dosages

Procedure	Xylocaine (lidocaine hydrochloride) Injection (without epinephrine) Conc (%)	Vol (mL)	Total Dose (mg)
Infiltration			
Percutaneous	0.5 or 1	1-60	5-300
Intravenous regional	0.5	10-60	50-300
Peripheral Nerve Blocks, e.g.			
Brachial	1.5	15-20	225-300
Dental	2	1-5	20-100
Intercostal	1	3	30
Paravertebral	1	3-5	30-50
Pudendal (each side)	1	10	100
Paracervical			
Obstetrical analgesia (each side)	1	10	100
Sympathetic Nerve Blocks, e.g.			
Cervical (stellate ganglion)	1	5	50
Lumbar	1	5-10	50-100
Central Neural Blocks			
Epidural*			
Thoracic	1	20-30	200-300
Lumbar			
Analgesia	1	25-30	250-300
Anesthesia	1.5	15-20	225-300
	2	10-15	200-300
Caudal			
Obstetrical analgesia	1	20-30	200-300
Surgical anesthesia	1.5	15-20	225-300

*Dose determined by number of dermatomes to be anesthetized (2-3 mL/dermatome).

THE ABOVE SUGGESTED CONCENTRATIONS AND VOLUMES SERVE ONLY AS A GUIDE. OTHER VOLUMES AND CONCENTRATIONS MAY BE USED PROVIDED THE TOTAL MAXIMUM RECOMMENDED DOSE IS NOT EXCEEDED.

STERILIZATION, STORAGE AND TECHNICAL PROCEDURES

Disinfecting agents containing heavy metals, which cause release of respective ions (mercury, zinc, copper, etc.) should not be used for skin or mucous membrane disinfection as they have been related to incidents of swelling and edema. When chemical disinfection of multi-dose vials is desired, either isopropyl alcohol (91%) or ethyl alcohol (70%) is recommended. Many commercially available brands of rubbing alcohol, as well as solutions of ethyl alcohol not of U.S.P. grade, contain denaturants which are injurious to rubber and therefore are not to be used.

Dosage forms listed as Xylocaine-MPF indicate single dose solutions that are Methyl Paraben Free (MPF).

HOW SUPPLIED

		Xylocaine-MPF											Xylocaine		
		Ampules (mL)					Single Dose Vials (mL)						Multiple Dose Vials (mL)		
Xylocaine (lidocaine HCl) Concentration	Epinephrine Dilution (if present)	2	5	10	20	30	2	5	10	20	30	50	10	20	50
0.5%												X			X
0.5%	1:200,000														X
1%		X	X			X	X	X	X		X		X	X	X
1%	1:100,000												X	X	X
1%	1:200,000					X		X	X		X				
1.5%					X				X	X					
1.5%	1:200,000		X			X		X	X		X				
2%		X		X			X	X	X				X	X	X
2%	1:100,000												X	X	X
2%	1:200,000				X			X	X	X					

All solutions should be stored at room temperature, approximately 25°C (77°F). Protect from light.

ASTRA® | Astra Pharmaceutical Products, Inc.
Westborough, MA 01581

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Exh.

23

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

(b)(4)Proprietary Information

R 19 1993

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Dear (b)(4)P

This acknowledges receipt of your submission dated March 30, 1993 pertaining to your ChronoFlex Biostable Medical-Grade Elastomer.

This material is retained as a Master File for a device, and it has been assigned the number (b)(4)P. You may amend this master file to include additional information at any time. All amendments shall be submitted in duplicate, identified with the above MAF number, and addressed to:

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

Information in your MAF may be incorporated by your client in their premarket approval applications (PMAs), investigational device exemptions (IDEs), premarket notification submissions, reclassification petitions, color additive petitions or other submissions to FDA.

Reference to your MAF can only be authorized by you. In order that your client's submission, if you are submitting this MAF on behalf of a client, will not be found deficient for lack of an authorizing letter and to expedite processing, please provide it directly to your client with the instruction that the original of your letter be included in the original copy of the client's submission along with a copy in each additional copy. Under this approach your MAF need not be amended to include the letter of authorization.

If you require assistance regarding device master files procedures, you may contact the Premarket Approval (PMA) Section at (301) 427-1186.

Sincerely yours,

Mary Jo Robinson
Assistant to the Director
Premarket Approval Section
Center for Devices and
Radiological Health

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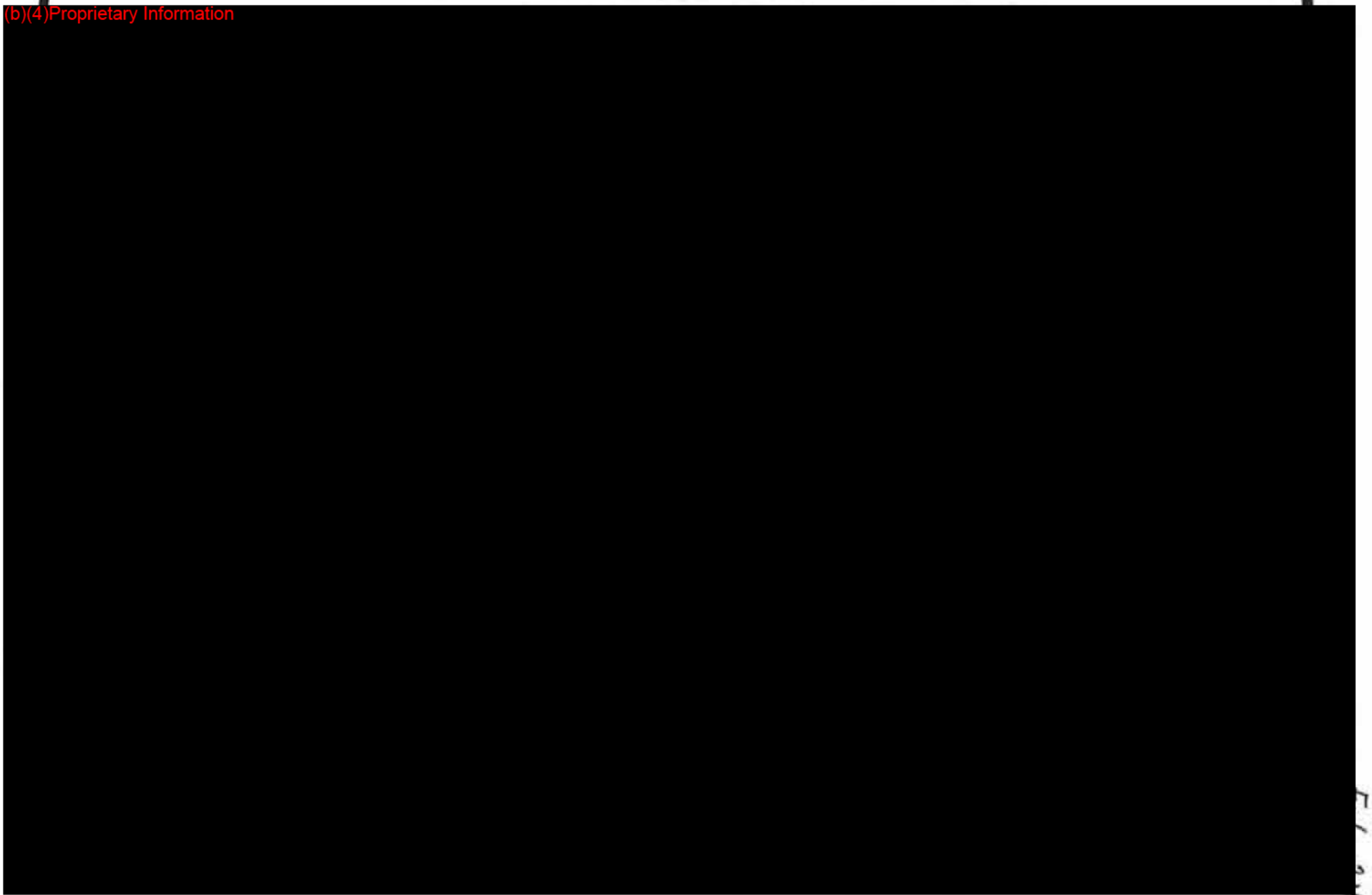
Exh.

24

EXPLANATION OF CATH-LINK SEPTUM FUNCTION IN ACTIVE AND PASSIVE MODES.

(b)(4)Proprietary Information



Exh.
25

Exhibit 25.1

NOTE: INFORMATION IN THE EXHIBIT WAS ALSO PROVIDED IN THE ORIGINAL 510(K) SUBMISSSION. BASED ON THE REVIEWER'S QUESTIONS, ADDITIONAL INFORMATION HAS BEEN PROVIDED AND IS UNDERLINED.

CONTINUOUS USE

Objective: (b)(4)Proprietary Information

Method:

Results:

(b)(4)Proprietary Information

Conclusion: (b)(4)Proprietary Information

(b) (6)

Exhibit 25.2

SLIT LAYER RESEAL

OBJECTIVE:

(b)(4)Proprietary Information

[redacted]

METHOD:

(b)(4)Proprietary Information

[redacted]

RESULTS:

(b)(4)Proprietary Information

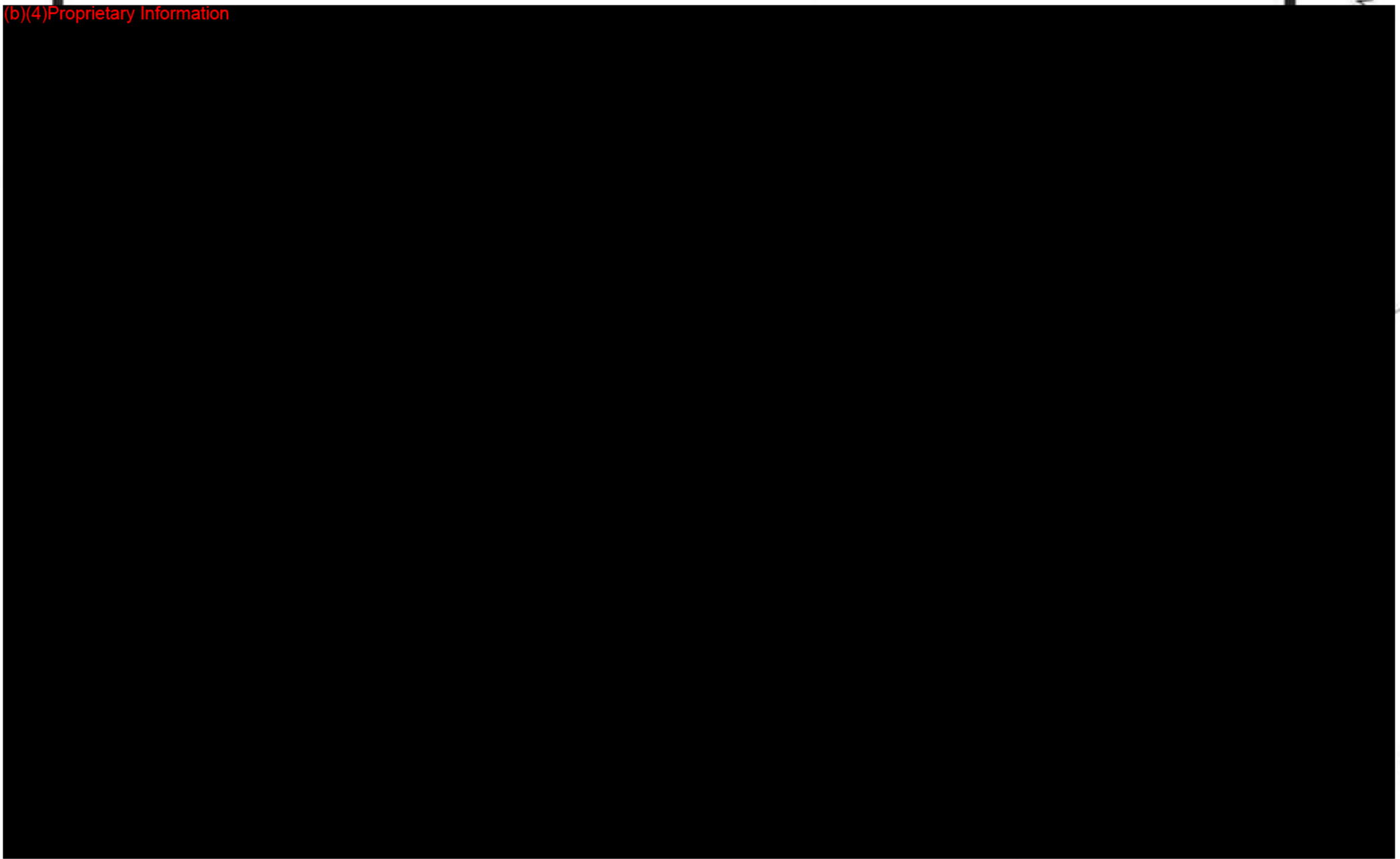
[redacted]

Exh.

26

ANALYSIS OF IV CATHETER ENGAGEMENT FOR VARIOUS PLACEMENT DEPTHS AND IV CATHETER LENGTHS.

(b)(4)Proprietary Information



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

May 19, 1994

BARD ACCESS SYSTEMS, INC.
5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
ATTN: JANE ANN MARTIN

510(k) Number: K926139
Product: CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE

Extended Until: 21-JUN-94

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

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-0901

BARD

17 May 94

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: K926139
CathLink 20 Titanium Port with Attachable Polyurethane Catheter

This letter is to request an additional 30 day extension to 17 June 94 for submission of the additional information requested in your 21 March 94 letter.

If you have any questions, please call me at 1-800-443-5505. Thank you.

Sincerely,

Jane Ann Martin
Regulatory Affairs Administrator

cc: Brian Barry
Eric Ankerud
Catherine Beath

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 26, 1994

BARD ACCESS SYSTEMS, INC.
5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116
ATTN: JANE ANN MARTIN

510(k) Number: K926139
Product: CATHLINK 20 TITANIUM PORT W/ATT. POLYURETHANE

Extended Until: 21-MAY-94

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

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4960

BARD

21 April 94

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: K926139
CathLink™ 20 Titanium Port

Via Federal Express

This letter is to request a 30 day extension to 21 May 94 for submission of the additional information requested in your 21 March 94 letter.

If you have any questions, please call me at 1-800-443-5505. Thank you.

Sincerely,

J Martin

Jane Ann Martin
Regulatory Affairs Administrator

cc: Brian Barry
Eric Ankerud
Catherine Beath

0185

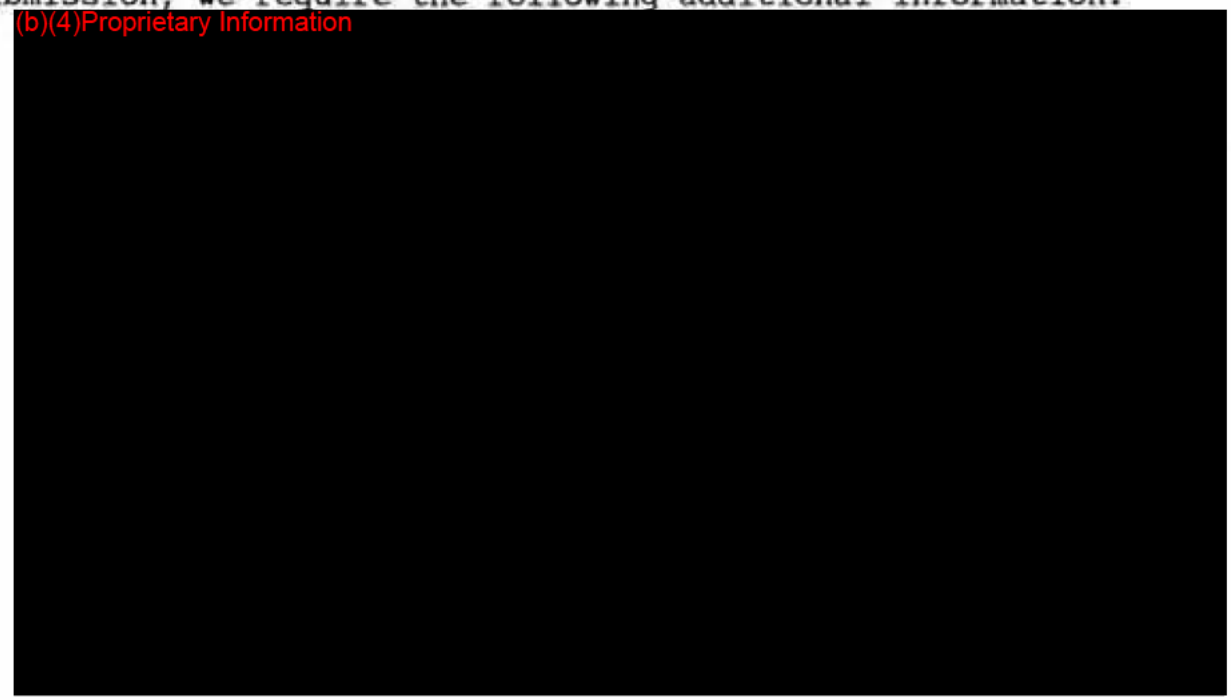
Ms. Jane Ann Martin
Regulatory Affairs Administrator
Bard Access Systems, Inc.
5425 W. Arnelia Earhart Drive
Salt Lake City, Utah 84116

Re: K926139
CathLink 20™ Titanium Port
Dated: December 4, 1992
Received: December 7, 1992

Dear Ms. Martin:

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. In order for us to complete the review of your submission, we require the following additional information:

(b)(4)Proprietary Information



(b)(4)Proprietary Information

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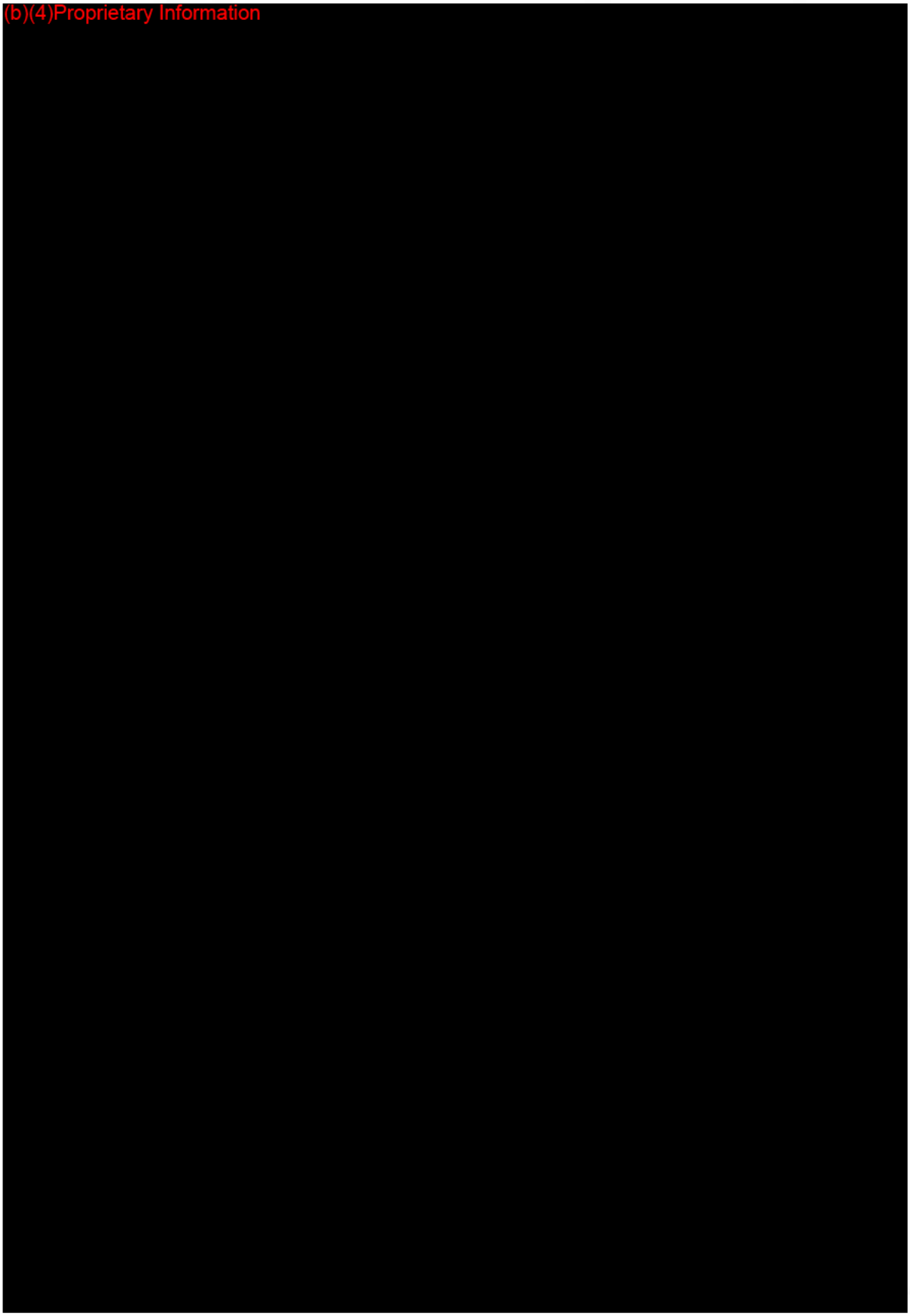
(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[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)
1390 Piccard Drive
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 Ms. Brenda Bolden at (301) 594-1307. 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,

Philip J. Phillips
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

0191

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-410	DBolden	3/18/94			
HFZ-410	DBell	3/18/94			

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-518-771

bcc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRD
D.O.
d/t:
f/t:HFZ-410:BYB:RMD:3/18/94

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 3/18/94

From REVIEWER(S) - NAME(S) Roger Budd / Bolden

Subject 510(k) NOTIFICATION K926139

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.

✓ (C) Requires more data. Hold - see attached Memo

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

Additional Comments: CathLink 20 Titanium Port with attachable polyurethane catheter (Port and Catheter, infusion, implanted, s.c.p.) See memo

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

___ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

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

REVIEW: _____ (BRANCH CHIEF) GHDB (BRANCH CODE) 3/18/94 (DATE)

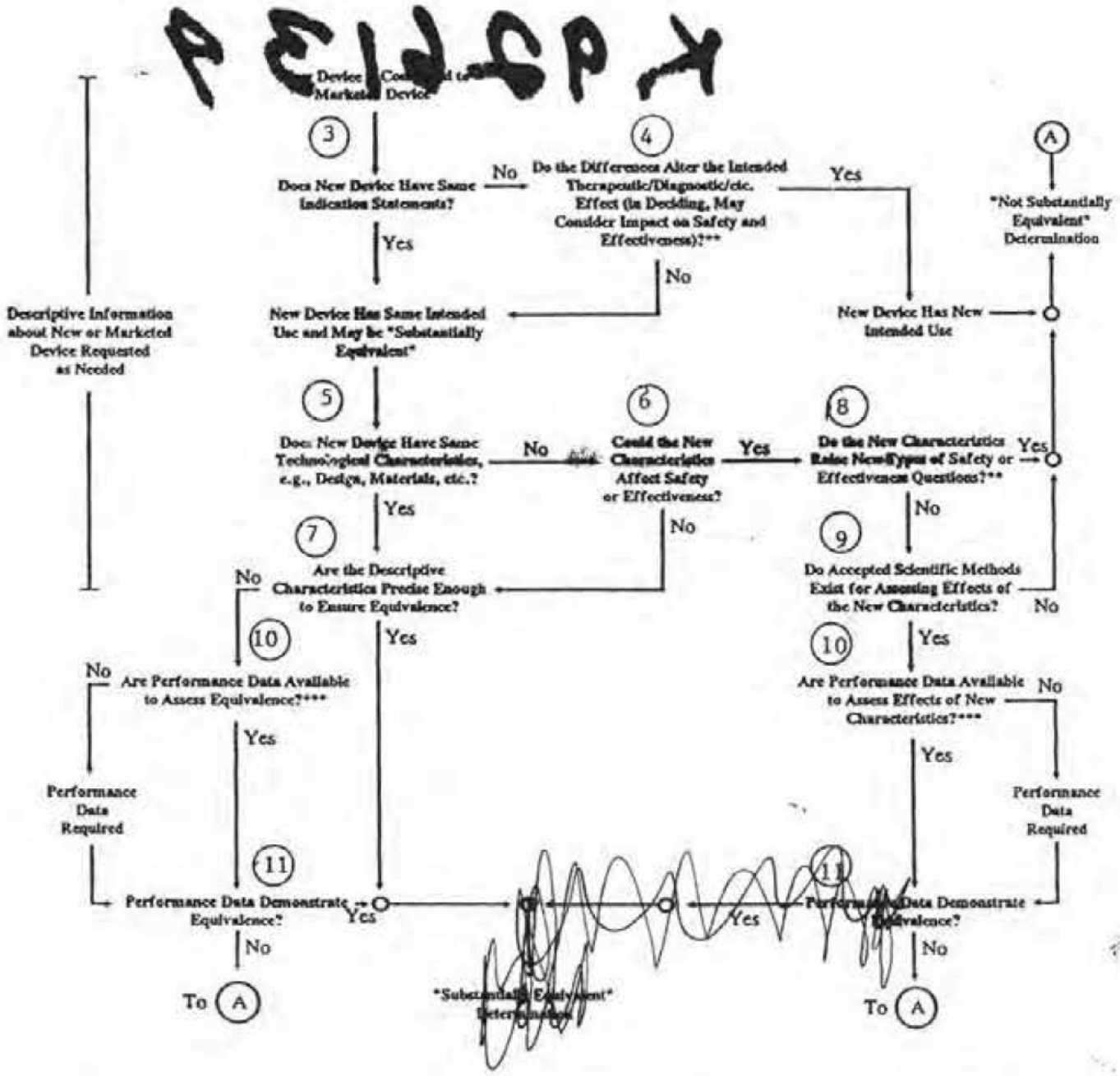
FINAL REVIEW: _____ for T.U. 3/18/94 (DIVISION DIRECTOR) (DATE)

0193

*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.

MEMO RECORD

DATE: 3/7/94

FROM: Brenda Bolden, Biologist

DIVISION: DGRD/GH

TO: The Record

OFFICE: ODE

SUBJECT: Bard CathLink 20 Port w/Attachable PU Catheter, K926139

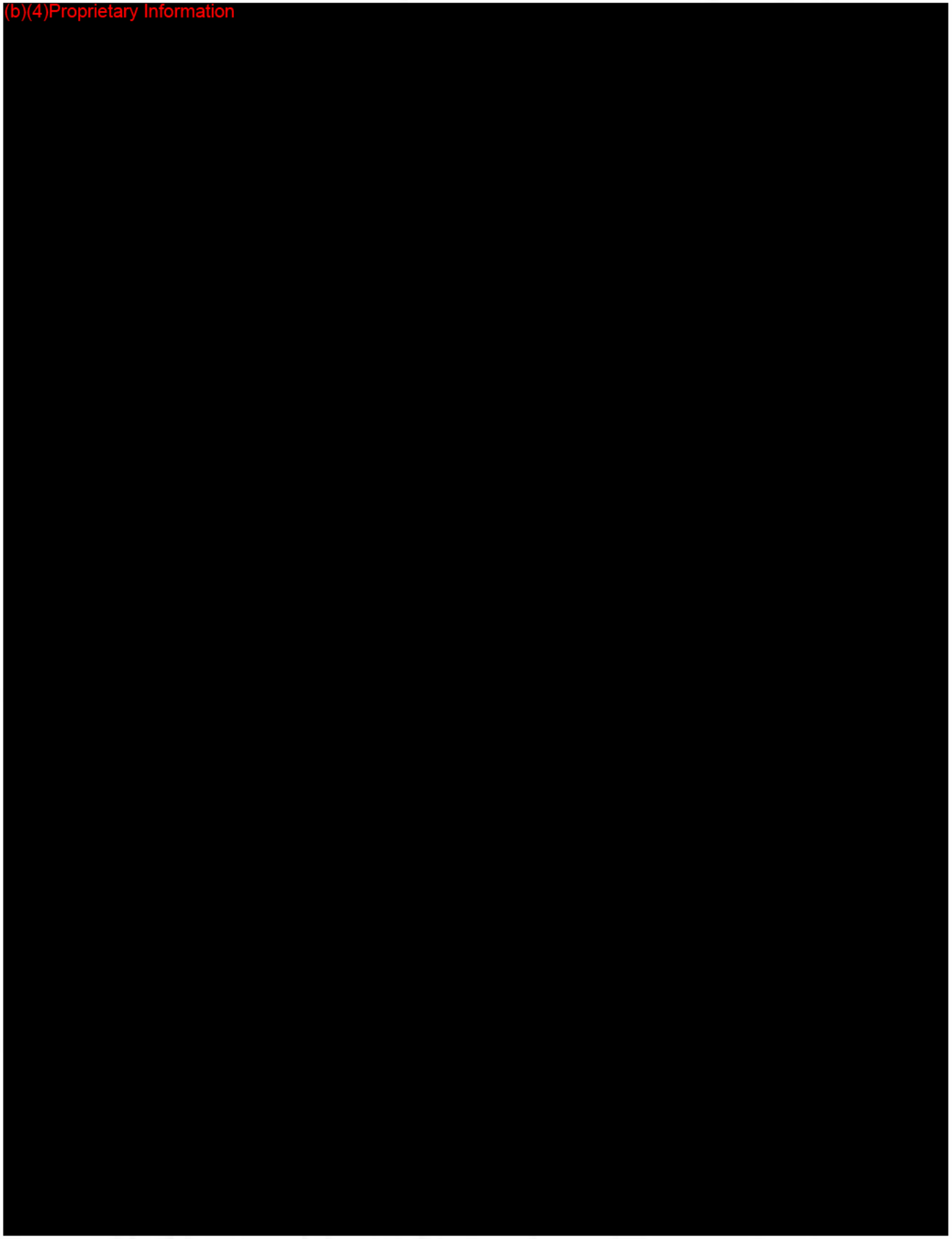
SUMMARY

This is a totally implantable device designed for reliable repeated long term access to the vascular system for infusion of medications, parenteral nutrition solution, blood products or imaging solutions, and withdrawal of blood samples.

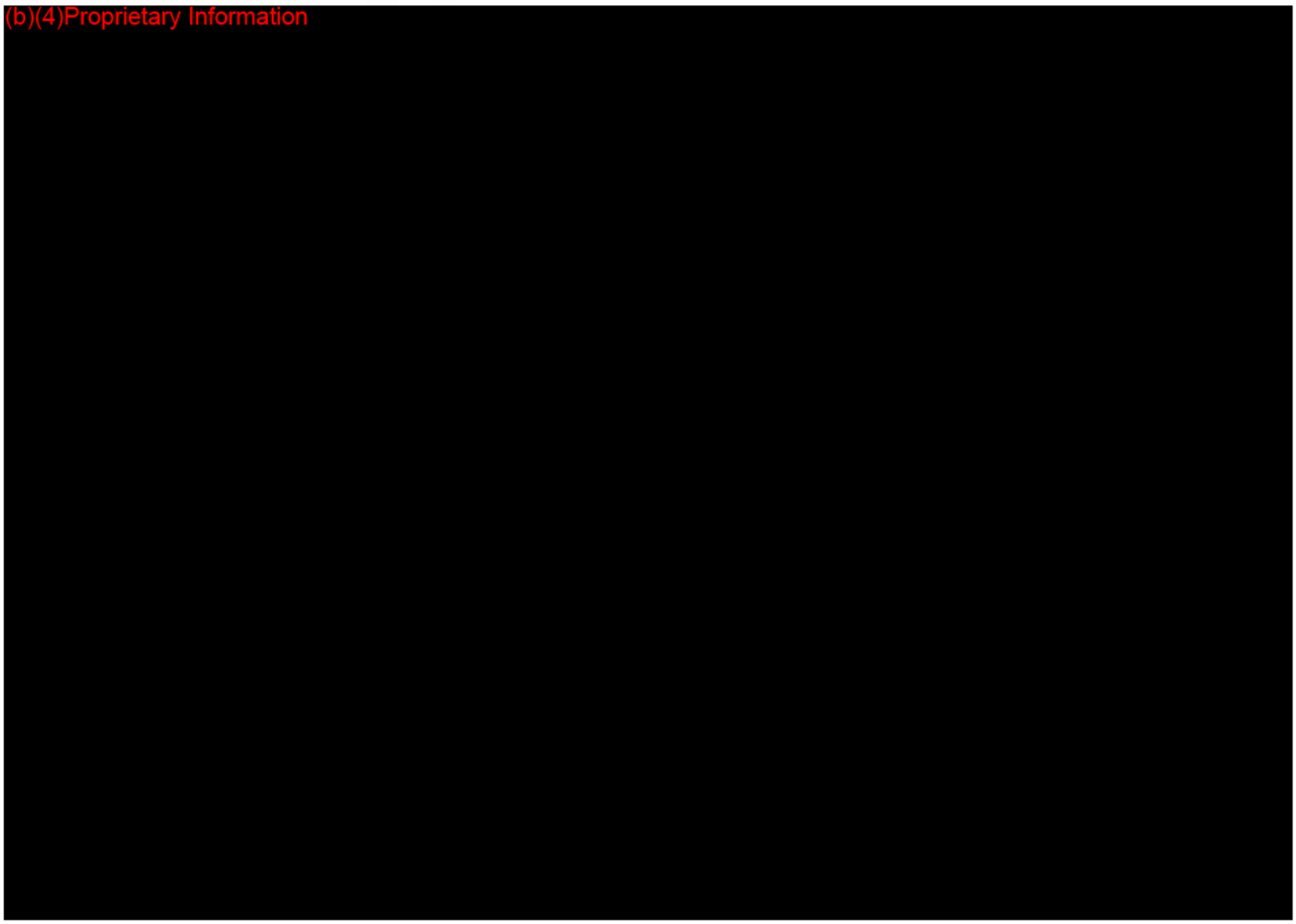
This submission was reviewed by Roger Budd. (b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information



(b)(4)Proprietary Information



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

510(k) Number: K926139

Reviewer: Roger Budd Division/Branch: DGRD/GHDB

Manufacturer Name: Bard Access Systems Inc.

Trade Name: CathLink 20 Titanium Port with attachable polyurethane catheter

Common Name: Port and catheter, infusion, implanted, subcutaneous, intraperitoneal

Products To Which Compared: 1. C.R. Bard, Inc.-Bard Access System Hickman titanium port (K870260) 2. Pharmacia Deltec-P.A.S. Port system

		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 GO TO 5
4.	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	___*	___	IF YES STOP > NE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	___	X	IF YES GO TO 7
6.	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	X*	___	IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	___	___	IF YES STOP > SE IF NO GO TO 10
8.	NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	___*	X	IF YES STOP > NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?	X	___	IF NO STOP > NSE
10.	PERFORMANCE DATA AVAILABLE?	X	___	IF NO REQUEST DATA
11.	DATA DEMONSTRATE EQUIVALENCE?	X*	___	>

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation (see last page).

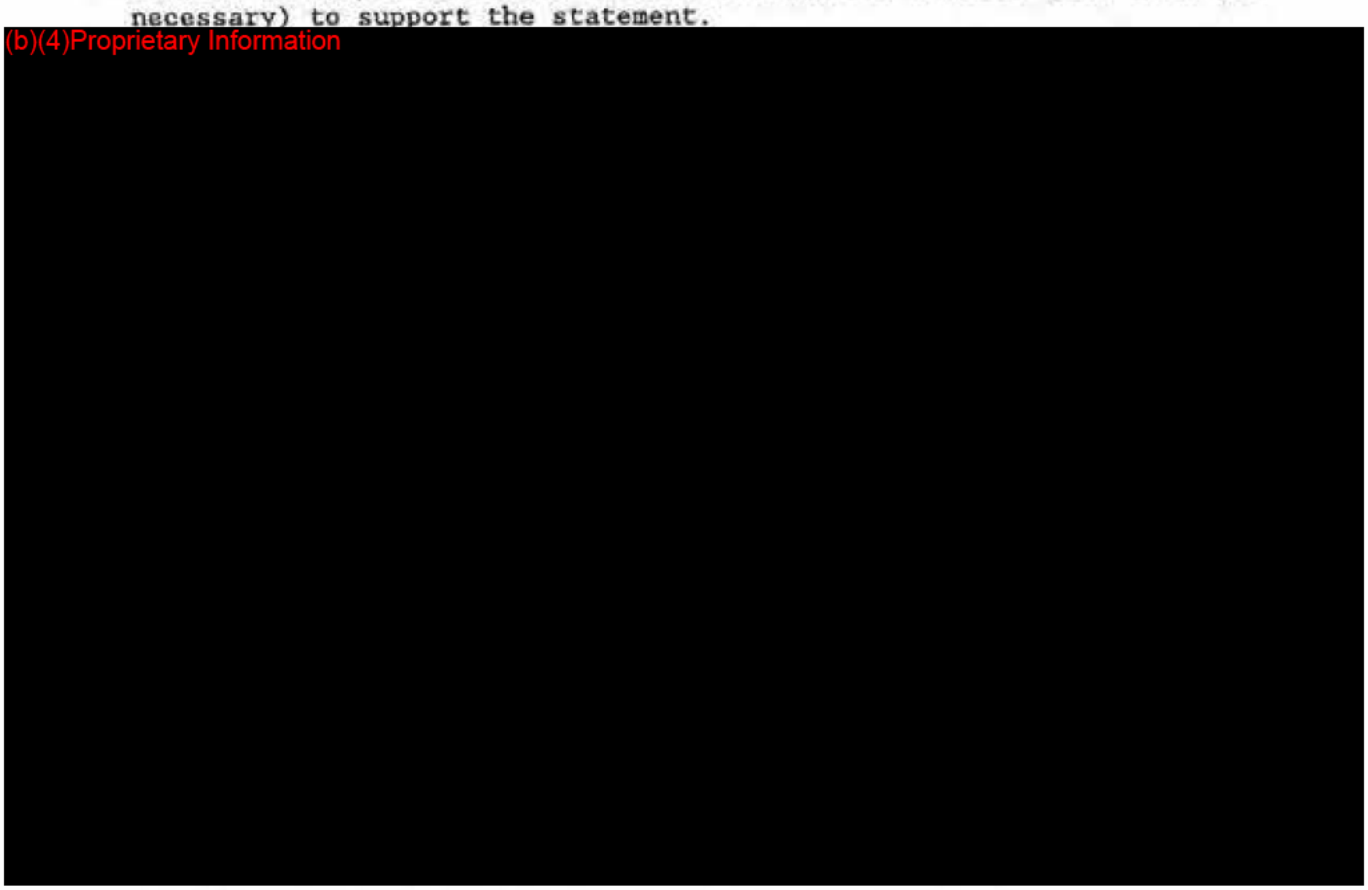
NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

This port system is an implanted device for use in patients requiring repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products, or imaging solutions, and for the withdrawal of blood samples.

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

(b)(4)Proprietary Information



	YES	NO
Is the device life-supporting or life sustaining?	___	_X_
Is the device implanted (short-term or long term)?	_X_	___
Does the device use software?	___	_X_
Is the device sterile?	_X__	___
Is the device for single (patient) use?	_X_	___
Is the device for home use?	___	_X_
Is the device for prescription use?	_X_	___
Does the device contain a drug or biological product as a component?	___	_X_
Is this device a kit?	_X_	___
If a kit, were appropriate certification statements supplied?	___	_X_

Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

1. Performance testing was done in accordance with the port guidance document.

2. All the sterilization procedures were addressed in the application.

(b)(4)Proprietary Information

EXPLANATIONS TO "YES" AND "NO" ANSWER TO QUESTIONS ON PAGE 1 AS NEEDED
(Delete questions which are not applicable)

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

The CathLink 20 layered septum is different in design from the solid silicon septums in the referenced predicate devices. The catheter uses different materials then the predicate devices.

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

(b)(4)Proprietary Information

[redacted]

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

The safety and effectiveness questions are the same for all central venous port/catheter systems.

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

The performance testing data,clinical evaluation and biocompatibility testing demonstrate that the CathLink 20 system is equivalent to the two referenced predicate devices.

ATTACH ADDITIONAL SUPPORTING INFORMATION

I spoke to Ms Jane Ann Marten at Bard access systems, Inc. on 8/16/93. I requested the following missing information: 1. summary of safety and effectiveness information and 2. kit certification.

I have reviewed the subject 510(k) documentation and recommend it for SE.

Roger Budd
8/16/93

add to file

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

5 November 93

FDA/CDRH/OSB
93 NOV 12 AM 7:52

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: Premarket Notification, K926139
CathLink 20™ Titanium Port with attachable polyurethane catheter

Please change the official correspondent for the above named 510(k) submission from Jack Speer to Jane Ann Martin. Mr. Speer is no longer with this company.

If you have any questions regarding this change, please call me. Thank you.

JMartin

Jane Ann Martin
Regulatory Affairs Administrator

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

5 November 93

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: Premarket Notification, K926139
CathLink 20™ Titanium Port with attachable polyurethane catheter

Please change the official correspondent for the above named 510(k) submission from Jack Speer to Jane Ann Martin. Mr. Speer is no longer with this company.

If you have any questions regarding this change, please call me. Thank you.

JMartin

Jane Ann Martin
Regulatory Affairs Administrator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date October 21, 1993

From Mathematical Statistician (G. Kamer) HFZ-162
Statistics Branch, Division of Biometric Sciences, OSB

Subject Statistical Review for 510(k) K926139: CathLink 20 Titanium Port with Attachable Polyurethane Catheter, Davol, Inc.

To Brenda Bolden - HFZ-410
Division of General and Restorative Devices, ODE
Through: Director, Division of Biometric Sciences, OSB
Through: Chief, Statistical Branch, DBS, OSB

Reviewer's Comments

A review of this submission, claiming substantial equivalence, resulted in the following statistical concerns:

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

Gary L. Kamer

cc: Paul R. Beninger, M.D. (HFZ-410)
Timothy A. Ulatowski (HFZ-410)
Medical Device File
Board File

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date October 21, 1993

From Mathematical Statistician (G. Kamer) HFZ-162
Statistics Branch, Division of Biometric Sciences, OSB

Subject Statistical Review for 510(k) K926139; CathLink 20 Titanium Port with Attachable Polyurethane Catheter, Davol, Inc.

To Brenda Bolden - HFZ-410
Division of General and Restorative Devices, ODE
Through: Director, Division of Biometric Sciences, OSB
Through: Chief, Statistical Branch, DBS, OSB

Reviewer's Comments

A review of this submission, claiming substantial equivalence, resulted in the following statistical concerns:

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

Gary L. Kamer

cc: Paul R. Beninger, M.D. (HFZ-410)
Timothy A. Ulatowski (HFZ-410)
Medical Device File
Board File

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date October 21, 1993

From Mathematical Statistician (G. Kamer) HFZ-162
Statistics Branch, Division of Biometric Sciences, OSB

Subject Statistical Review for 510(k) K926139; CathLink 20 Titanium Port with Attachable Polyurethane Catheter, Davol, Inc.

To Brenda Bolden - HFZ-410
Division of General and Restorative Devices, ODE
Through: Director, Division of Biometric Sciences, OSB
Through: Chief, Statistical Branch, DBS, OSB

Reviewer's Comments

A review of this submission, claiming substantial equivalence, resulted in the following statistical concerns:

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

Gary L. Kamer

cc: Paul R. Beninger, M.D. (HFZ-410)
Timothy A. Ulatowski (HFZ-410)
Medical Device File
Board File

Date: September 13, 1993

From: Biologist, General Hospital Devices Branch, Division of General and Restorative Devices (HFZ-412)

Through: Associate Director for General Devices, Division of General and Restorative Devices (HFZ-410)____

To: Harry Bushar, Chief Statistics Branch, Division of Biometrics and Statistics (DBS), (HFZ-162)

Subject: Consult Review of a CathLink 20 Titanium Port with Attachable Polyurethane Catheter, K926139

Davol Inc., a C.R. Bard, Inc. subsidiary, is planning to market a single lumen titanium port with a modified silicone septum and an attachable polyurethane (PU) catheter. The proposed port is a low profile totally implantable, side-entry titanium port having a 3-layered septum, each having an opening to allow access to the catheter with a 20 gauge peripheral IV catheter. The side-entry port is a relatively new design with the 3 layers requiring clinical and in-vitro data. We have seen two side entry devices called the OmegaPort reviewed under K905646 and the Norport-SP under K872838. (b)(4)Proprietary Information [redacted]

It is intended for use in patients requiring repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products, or imaging solutions, and for the withdrawal of blood samples.

(b)(4)Proprietary Information [redacted]

Please review the clinical data provided in exhibits 5 and 6 along with publications for adequacy of the statistical analysis and results.

Brenda Bolden

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

2 September 93

Office of Device Evaluation
Document Mail Center (HFZ-401)
CDRH, Food and Drug Administration
1390 Piccard Dr.
Rockville, MD 20850

Attn: Roger Budd or Brenda Bolden

Re: K926139 - CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter

Bard Access Systems Division, C.R. Bard, Inc., is submitting two copies of this amendment to 510(k) #K926139 for the above referenced device to provide responses to the questions asked by Roger Budd during a telephone conversation on August 16, 1993.

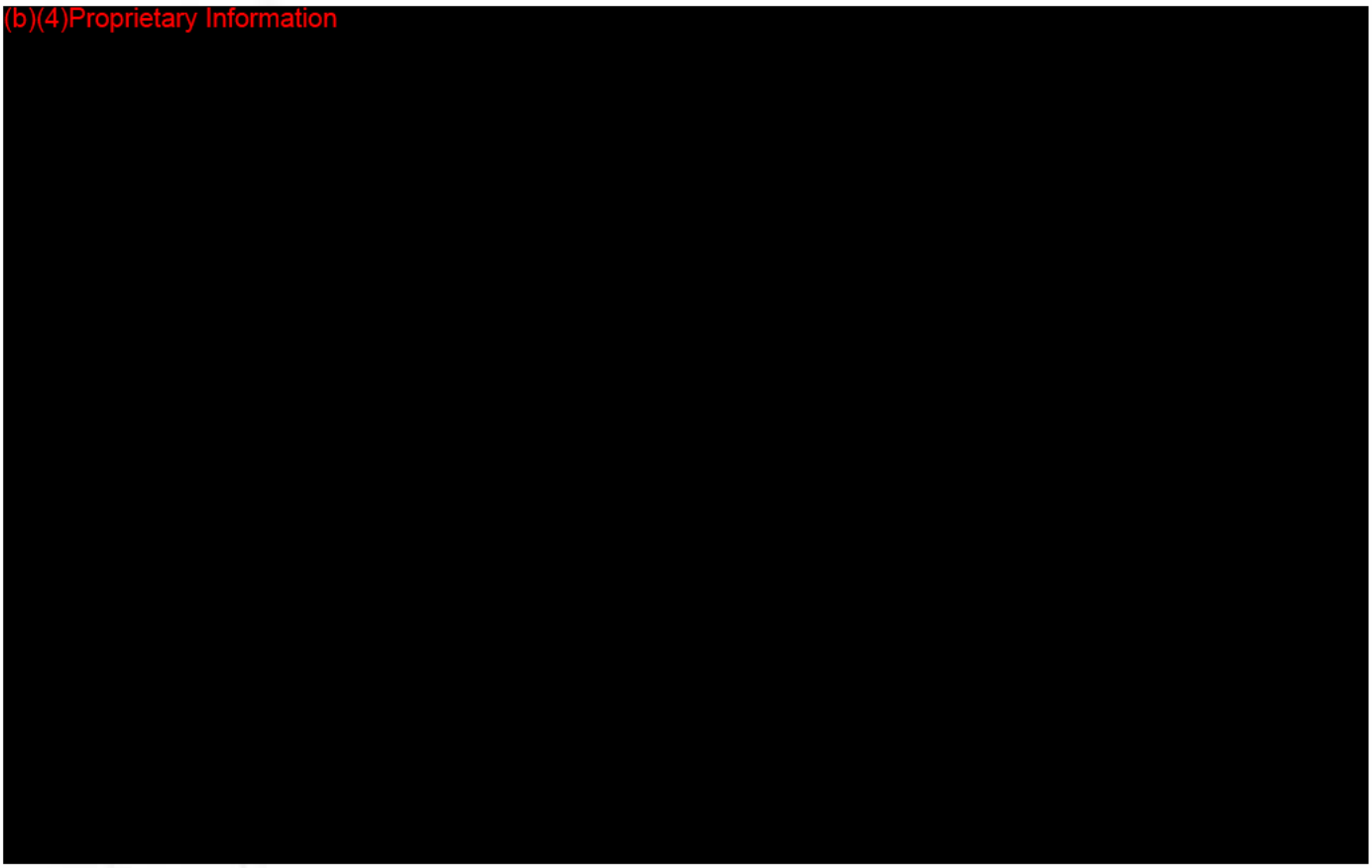
C.R. Bard, Inc., has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C.R. Bard, Inc., requests that the FDA keep and maintain confidential both the existence and the contents of this 510(k) submission in accordance with 21 CFR 807.95(b). C. R. Bard, Inc., also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any additional questions, please contact me at 1-800-443-3385.

Sincerely,

Jane Ann Martin
Regulatory Affairs Administrator

(b)(4)Proprietary Information



Exh.

1

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

510(k) Summary of Safety and Effectiveness Information

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The proposed CathLink 20 titanium port is substantially equivalent to the port in the P.A.S. Port™ system currently marketed by Pharmacia Deltec and the Bard Access System Hickman® titanium port (K870260). The modified polyurethane catheter is substantially equivalent to the P.A.S. Port polyurethane catheter. The Pharmacia P.A.S. Port system is currently on the market and has been on the commercial market for an extended time period. It is in widespread use. Bard is not aware of any information suggesting that the device is not legally marketed.

The 510(k) Substantial Equivalence Decision Making Process (Detailed) decision tree (ODE Guidance Memo, December 1989) was used to make a determination of substantial equivalence. The answers to these questions lead to a determination of substantial equivalence.

1. **Does the new device have the same indication statements?**

Yes, the Cath-Link 20 has the same indication for use as the Hickman Titanium Port and Pharmacia Deltec P.A.S Port. All are totally implanted devices designed for reliable repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

2. **Does the new device have the same technological characteristics, e.g, design, materials, etc.?**

No, The catheters used with the Hickman Titanium Port (silicone), Pharmacia Deltec P.A.S Port (polyurethane) and the Cath-Link 20 Port (modified polyurethane) are made of different materials. The material used for the portal body (titanium) and the septum (silicone) are the same for all three ports. The CathLink 20 layered silicone septum is different in design from the solid silicone septums in the Hickman Titanium Port and Pharmacia Deltec P.A.S Port.

3. **Could the new characteristics affect safety or effectiveness?**

Yes, the layered septum of the Cath-Link 20 Port is a unique

characteristic of the Cath-Link 20. Its failure could affect the safety or effectiveness of the port. Also, the modified material used for the catheter in the Cath-Link 20 system could have new characteristics that could affect its safety or effectiveness.

4. **Do the new characteristics raise new types of safety or effectiveness questions?**

   No. The safety and effectiveness questions are the same for all central venous port/catheter systems.

5. **Do accepted scientific methods exist for assessing effects of the new characteristic?**

   Yes, the FDA 1989 Port Testing Guideline was used to evaluate the performance of the modified device. The Tripartite Guidance was used to assess that the biocompatibility of the modified catheter is equivalent to currently marketed catheters. The clinical performance of the modified device was evaluated in a clinical study.

6. **Are performance data available to assess effects of new characteristics?**

   Yes, bench testing was conducted on the CathLink 20 system according to the FDA 1989 Port Testing Guideline. A clinical study was done to evaluate the clinical performance of the CathLink 20 port with the layered septum. Biocompatibility testing was evaluated according to the Tripartite Guidance.

7. **Does the performance data demonstrate equivalence?**

   Yes. The data from the performance testing, clinical evaluation and biocompatibility testing demonstrate that the CathLink 20 system is equivalent to the currently marketed Hickman and P.A.S. port systems.

J.A. Martin
Regulatory Affairs Administrator

ODE/DGRD REQUEST FOR CONSULTATION

FROM Brenda Bolden TO DRAERD / Bob Phillips

THROUGH _____ PMA/IDE/510(K) NO. K926139

FIRM NAME Daval Inc. DEVICE NAME Cath-Link 20

DESIRED COMPLETION DATE _____

REASON FOR REQUEST

NEW SUBMISSION	RESPONSE TO DEFICIENCY LETTER
MODIFIED PROTOCOL	MODIFIED DESIGN
NEW MATERIALS	✓LABELING
MODIFIED MANUFACTURING	✓OTHER Indications statements on labeling

---

TYPE OF REVIEW REQUESTED

O ENGINEERING	O MATERIALS
O STERILITY	O TOXICOLOGY
O CLINICAL	O STATISTICAL
O LABELING	OOTHER _____

COMMENTS/SPECIAL INSTRUCTIONS

The Cath-Link 20 Implanted Port is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medications, IV fluids, TPN, blood products, and imaging solutions. Please review for this intended use.

Brenda Bolden 9/13/93

SIGNATURE OF REQUESTOR DATE

Exh.
2

CathLink™ 20 Implanted Port Kit Components

Notes:

1. The kit components listed below are arranged sequentially in one or more inner molded plastic trays that are then placed in a CSR wrap. The wrapped trays are put into an outer tray and sealed with a Tyvek® lid. The kits will be sterilized using a validated ethylene oxide (EtO) cycle [redacted] (b)(4) Proprie [redacted] Validation is performed in accordance with the AAMI, March 31, 1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The maximum levels of ethylene oxide, ethylene chlorhydrin and ethylene glycol residues remaining on the items will be determined and evaluated for conformance with the applicable limits as proposed by FDA in the June 12, 1978, Federal Register.

2. Kit components for the CathLink 20 port in a complete procedural tray are listed in the following table. Subsets of the complete procedural tray will also be made available.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
CathLink Port	Subject of this 510(k)	N/A	N/A
Catheter, 6 Fr (b)(4)Proprietary 2.0 mm X 1.3 mm 61 cm long, Tipped and Marked	Subject of this 510(k)	N/A	N/A
Catheter Lock	Subject of this 510(k)	N/A	N/A
CSR Wrap	Vendor of this component (sterilization wrap) states that it is a preamendment device. 21 CFR 880.6850, Class II	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

0219

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Surgical Gloves, Powderless (size 7)	K850635, 21 CFR 878.4460, Class I	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Fenestrated Drape, 38" X 48", with 4" x 8" fenestration	Vendor of this component (surgical drape) states that it is a preamendment device. 21 CFR 878.4370, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Utility Drape with Tape 16" X 13"	K842115, 21 CFR 878.4370, Class II.	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Towel, disposable absorbant	K781682, 21 CFR 880.5300, Class I, 510(k) exempt	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
PVP (povidone iodine USP) Scrub swabsticks	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer container (sterile contents), labeled by vendor
PVP (povidone iodine USP) Swabsticks	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer container (sterile contents), labeled by vendor
Alcohol Swab Sticks	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile, labeled by vendor

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

0222

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
4" X 4" Gauze Sponge	Vendor of this component states that it is a preamendment device. 21 CFR 878.4450, Class II, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
22 Ga X 1.5" Needle for skin wheals	Vendor of this component states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
18 Ga X 1 1/2" Filter needle	Vendor of this component (anesthesia conduction filter) states that it is a preamendment device. 21 CFR 868.5130, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
20 cc Syringe (luer slip)	Vendor of this component states that it is a preamendment device. 21 CFR 880.5860, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
30cc Ampule of Lidocaine, 1% (with Manufacturer's Instructions for Use)	Prescription drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer container, labeled by vendor.
18 Ga (TW) X 2.5" Needle	Vendor of this component states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
21 Ga X 2.5" Needle for Vessel Location	Vendor of this component states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
5 cc Syringe (luer slip)	Vendor of this component states that it is a preamendment device. 21 CFR 880.5860, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
10cc Syringe (luer slip)	Vendor of this component states that it is a preamendment device. 21 CFR 880.5860, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
10 cc Ampule, Sterile Saline for Flushing (with Manufacturer's Instructions for Use)	Prescription drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer vial, labeled by vendor.
Vein Pick	Vendor of this component (vessel stabilizer) states that it is a preamendment device. 21 CFR 880.6980, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Addison Tooth Forcep	Vendor of this component states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Half-Curved Forcep	Vendor of this component states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Spring Guide Wire .035" X 17 3/4"	K920884, 21 CFR 870.1330, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Spring Guidewire .035" X 35"	K920884, 21 CFR 870.1330, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Mini Scalpel	Vendor of this component (one piece scapel) states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Trocar	Vendor of this component states that it is a preamendment device. 21 CFR 870.1390, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Scissors, disposable	Vendor of this component states that it is a preamendment device. 21 CFR 880.6820, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
7 Fr IntroEze Sheath Dilator Introducer System with 5 Fr Slitter	K903530, 21 CFR 870.1310 (dilator), 870.1340 (introducer), Class II.	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Needle Holder	Vendor of this component states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
3.0 Nylon Suture with cutting needle	NDA #85142, 21 CFR 878.5020, Class II.	We certify that this component is a legally marketed device (previously approved as a drug).*	Bulk, non-sterile outer packs with sterile contents, labeled by vendor.
Betadine Ointment (drug)	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer packs, labeled by vendor.
Transparent Dressing	Vendor of this component states that it is a preamendment device. 21 CFR 880.5240, Class I.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Wound Closure Strips (1/4" X 1 1/2")	Vendor of this component states that it is a preamendment device. 21 CFR 880.5240, Class I.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
20 Ga X 2 " I.V. Catheter	Vendor of this component states that it is a preamendment device. 21 CFR 880.5200, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
8" Extension Set W/O "Y site	K863606.. 21 CFR 880.5440, Class II.	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Catheter - Flushing connector	Vendor of this component (blunt single lumen hypodermic cannula) states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Face Mask with Shield	K924291, 21 CFR 878.4040, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Face Mask without Shield	K924291, 21 CFR 878.4040, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

These certifications are based solely on information provided by our vendors in response to Bard Access Systems requests and is assumed to be accurate and true. C.R. Bard, Inc. is not aware of any information suggesting that these devices are not legally marketed.

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Surgical Tape	Vendor of this component states that it is a preamendment device. 21 CFR 880.5240, Class I.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
7.0 Fr peel-apart Sheath Dilator	K860432, 21 CFR 870.1310 (dilator), 870.1340 (introducer), Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

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Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

2 September 93

Office of Device Evaluation
Document Mail Center (HFZ-401)
CDRH, Food and Drug Administration
1390 Piccard Dr.
Rockville, MD 20850

Attn: Roger Budd or Brenda Bolden

Re: K926139 - CathLink™ 20 Titanium Port with Attachable Polyurethane Catheter

Bard Access Systems Division, C.R. Bard, Inc., is submitting two copies of this amendment to 510(k) #K926139 for the above referenced device to provide responses to the questions asked by Roger Budd during a telephone conversation on August 16, 1993.

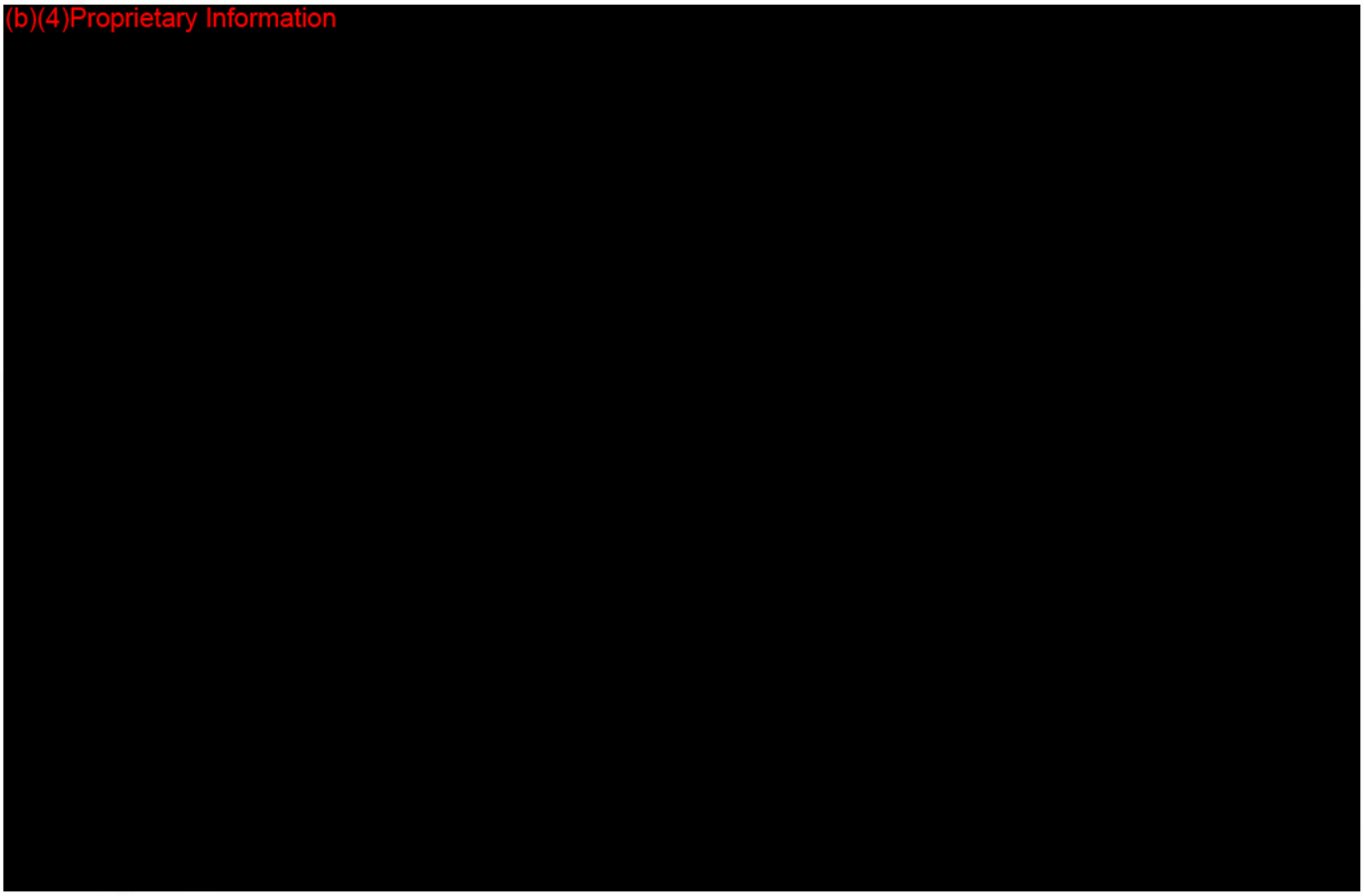
C.R. Bard, Inc., has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C.R. Bard, Inc., requests that the FDA keep and maintain confidential both the existence and the contents of this 510(k) submission in accordance with 21 CFR 807.95(b). C. R. Bard, Inc., also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any additional questions, please contact me at 1-800-443-3385.

Sincerely,

Jane Ann Martin
Regulatory Affairs Administrator

(b)(4)Proprietary Information



Exh. 1

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

510(k) Summary of Safety and Effectiveness Information

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The proposed CathLink 20 titanium port is substantially equivalent to the port in the P.A.S. Port™ system currently marketed by Pharmacia Deltec and the Bard Access System Hickman® titanium port (K870260). The modified polyurethane catheter is substantially equivalent to the P.A.S. Port polyurethane catheter. The Pharmacia P.A.S. Port system is currently on the market and has been on the commercial market for an extended time period. It is in widespread use. Bard is not aware of any information suggesting that the device is not legally marketed.

The 510(k) Substantial Equivalence Decision Making Process (Detailed) decision tree (ODE Guidance Memo, December 1989) was used to make a determination of substantial equivalence. The answers to these questions lead to a determination of substantial equivalence.

1. **Does the new device have the same indication statements?**

Yes, the Cath-Link 20 has the same indication for use as the Hickman Titanium Port and Pharmacia Deltec P.A.S Port. All are totally implanted devices designed for reliable repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

2. **Does the new device have the same technological characteristics, e.g, design, materials, etc.?**

No, The catheters used with the Hickman Titanium Port (silicone), Pharmacia Deltec P.A.S Port (polyurethane) and the Cath-Link 20 Port (modified polyurethane) are made of different materials. The material used for the portal body (titanium) and the septum (silicone) are the same for all three ports. The CathLink 20 layered silicone septum is different in design from the solid silicone septums in the Hickman Titanium Port and Pharmacia Deltec P.A.S Port.

3. **Could the new characteristics affect safety or effectiveness?**

Yes, the layered septum of the Cath-Link 20 Port is a unique

characteristic of the Cath-Link 20. Its failure could affect the safety or effectiveness of the port. Also, the modified material used for the catheter in the Cath-Link 20 system could have new characteristics that could affect its safety or effectiveness.

4. **Do the new characteristics raise new types of safety or effectiveness questions?**

   No. The safety and effectiveness questions are the same for all central venous port/catheter systems.

5. **Do accepted scientific methods exist for assessing effects of the new characteristic?**

   Yes, the FDA 1989 Port Testing Guideline was used to evaluate the performance of the modified device. The Tripartite Guidance was used to assess that the biocompatibility of the modified catheter is equivalent to currently marketed catheters. The clinical performance of the modified device was evaluated in a clinical study.

6. **Are performance data available to assess effects of new characteristics?**

   Yes, bench testing was conducted on the CathLink 20 system according to the FDA 1989 Port Testing Guideline. A clinical study was done to evaluate the clinical performance of the CathLink 20 port with the layered septum. Biocompatibility testing was evaluated according to the Tripartite Guidance.

7. **Does the performance data demonstrate equivalence?**

   Yes. The data from the performance testing, clinical evaluation and biocompatibility testing demonstrate that the CathLink 20 system is equivalent to the currently marketed Hickman and P.A.S. port systems.

CathLink 20 is a trademark of C.R.Bard, Inc. or an affiliate.
P.A.S. Port is a trademark of Pharmacia Deltec, Inc.
Hickman is a registered trademark of C.R. Bard, Inc. or an affiliate.

J.A. Martin
Regulatory Affairs Administrator

CathLink™ 20 Implanted Port Kit Components

Notes:

1. The kit components listed below are arranged sequentially in one or more inner molded plastic trays that are then placed in a CSR wrap. The wrapped trays are put into an outer tray and sealed with a Tyvek® lid. The kits will be sterilized using a validated ethylene oxide (EtO) cycle with [redacted](b)(4)P. Validation is performed in accordance with the AAMI, March 31, 1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The maximum levels of ethylene oxide, ethylene chlorhydrin and ethylene glycol residues remaining on the items will be determined and evaluated for conformance with the applicable limits as proposed by FDA in the June 12, 1978, Federal Register.

2. Kit components for the CathLink 20 port in a complete procedural tray are listed in the following table. Subsets of the complete procedural tray will also be made available.

0239

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
CathLink Port	Subject of this 510(k)	N/A	N/A
Catheter, 6 Fr (b)(4)Proprietary 2.0 mm X 1.3 mm 61 cm long, Tipped and Marked	Subject of this 510(k)	N/A	N/A
Catheter Lock	Subject of this 510(k)	N/A	N/A
CSR Wrap	Vendor of this component (sterilization wrap) states that it is a preamendment device. 21 CFR 880.6850, Class II	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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0240

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Surgical Gloves, Powderless (size 7)	K850635, 21 CFR 878.4460, Class I	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Fenestrated Drape, 38" X 48", with 4" x 8" fenestration	Vendor of this component (surgical drape) states that it is a preamendment device. 21 CFR 878.4370, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Utility Drape with Tape 16" X 13"	K842115, 21 CFR 878.4370, Class II.	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Towel, disposable absorbant	K781682, 21 CFR 880.5300, Class I, 510(k) exempt	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
PVP (povidone iodine USP) Scrub swabsticks	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer container (sterile contents), labeled by vendor
PVP (povidone iodine USP) Swabsticks	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer container (sterile contents), labeled by vendor
Alcohol Swab Sticks	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile, labeled by vendor

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
4" X 4" Gauze Sponge	Vendor of this component states that it is a preamendment device. 21 CFR 878.4450, Class II, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
22 Ga X 1.5" Needle for skin wheals	Vendor of this component states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
18 Ga X 1 1/2" Filter needle	Vendor of this component (anesthesia conduction filter) states that it is a preamendment device. 21 CFR 868.5130, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
20 cc Syringe (luer slip)	Vendor of this component states that it is a preamendment device. 21 CFR 880.5860, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
30cc Ampule of Lidocaine, 1% (with Manufacturer's Instructions for Use)	Prescription drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer container, labeled by vendor.
18 Ga (TW) X 2.5" Needle	Vendor of this component states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
21 Ga X 2.5" Needle for Vessel Location	Vendor of this component states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
5 cc Syringe (luer slip)	Vendor of this component states that it is a preamendment device. 21 CFR 880.5860, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
10cc Syringe (luer slip)	Vendor of this component states that it is a preamendment device. 21 CFR 880.5860, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
10 cc Ampule, Sterile Saline for Flushing (with Manufacturer's Instructions for Use)	Prescription drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer vial, labeled by vendor.
Vein Pick	Vendor of this component (vessel stabilizer) states that it is a preamendment device. 21 CFR 880.6980, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Addison Tooth Forcep	Vendor of this component states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Half-Curved Forcep	Vendor of this component states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Spring Guide Wire .035" X 17 3/4"	K920884, 21 CFR 870.1330, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

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0247

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Spring Guidewire .035" X 35"	K920884, 21 CFR 870.1330, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Mini Scalpel	Vendor of this component (one piece scapel) states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Trocar	Vendor of this component states that it is a preamendment device. 21 CFR 870.1390, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Scissors, disposable	Vendor of this component states that it is a preamendment device. 21 CFR 880.6820, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
7 Fr IntroEze Sheath Dilator Introducer System with 5 Fr Slitter	K903530, 21 CFR 870.1310 (dilator), 870.1340 (introducer), Class II.	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Needle Holder	Vendor of this component states that it is a preamendment device. 21 CFR 878.4800, Class I, 510(k) exempt.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
3.0 Nylon Suture with cutting needle	NDA #85142, 21 CFR 878.5020, Class II.	We certify that this component is a legally marketed device (previously approved as a drug).*	Bulk, non-sterile outer packs with sterile contents, labeled by vendor.
Betadine Ointment (drug)	OTC drug	We certify that this drug component is packaged and labeled consistent with its approval.*	Bulk, non-sterile outer packs, labeled by vendor.
Transparent Dressing	Vendor of this component states that it is a preamendment device. 21 CFR 880.5240, Class I.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
Wound Closure Strips (1/4" X 1 1/2")	Vendor of this component states that it is a preamendment device. 21 CFR 880.5240, Class I.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
20 Ga X 2 " I.V. Catheter	Vendor of this component states that it is a preamendment device. 21 CFR 880.5200, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
8" Extension Set W/O "Y site	K863606. 21 CFR 880.5440, Class II.	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Catheter - Flushing connector	Vendor of this component (blunt single lumen hypodermic cannula) states that it is a preamendment device. 21 CFR 880.5570, Class II.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile

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0251

DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Face Mask with Shield	K924291, 21 CFR 878.4040, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile
Face Mask without Shield	K924291, 21 CFR 878.4040, Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

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DESCRIPTION	*REGULATORY STATUS*	*CERTIFICATION*	*HOW PURCHASED*
Surgical Tape	Vendor of this component states that it is a preamendment device. 21 CFR 880.5240, Class I.	We certify that this component is a legally marketed preamendment device.*	Bulk, non-sterile
7.0 Fr peel-apart Sheath Dilator	K860432, 21 CFR 870.1310 (dilator), 870.1340 (introducer), Class II	We certify that this component is a legally marketed device, having been found substantially equivalent through the premarket notification process for the use(s) for which the kit is intended.*	Bulk, non-sterile

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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

DECEMBER 16, 1992

BARD ACCESS SYSTEMS, INC. DIV. OF C.R
ATTN: JACK SPEER
5425 W. AMELIA EARHART DRIVE
SALT LAKE CITY, UT 84116

510(k) Number: K926139
Received: 12-07-92
Product: CATHLINK 20
TITANIUM PORT
W/ATT. POLYURETHANE

We have 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 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.

In addition, the SMDA 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 manufacturers 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 a 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.

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) 227-8639.

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) 427-1190.

Sincerely yours,

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

K926139

Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

4 December 1992

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20856

Re: Premarket Notification
Cath.ink 20™ Titanium Port with attachable polyurethane catheter

Pursuant to 21 CFR 870.90 enclosed are two copies of the 510(k) Notification for the above named device and two copies of this letter.

The terms "substantially equivalent", "similar", and related terms and descriptions in this notification are defined terms or words of art used to meet the requirements of the Federal Food, Drug, and Cosmetic Act as amended and regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

It is the understanding of C.R. Bard, Inc., that written notification will be received from FDA if this device is subject to §522 of the Federal Food, Drug, and Cosmetic Act, i.e. Postmarket Surveillance.

A 510(k) Summary is included in this premarket notification (Exhibit 1).

If you have any questions, please contact Jane Ann Martin at (800) 443-3385 x4982.

Sincerely,

Jack Speer
Quality Assurance/Regulatory Affairs Director

C. R. BARD
510(K) NOTIFICATION

Date: 12/4/92

Device Proprietary Name:
CathLink 20™ Single Lumen Port with Attachable Polyurethane Central Venous Catheter

Device Common, Usual or classification Name:
Vascular Access Port

Code: LJT

Division/Subsidiary Name:
Bard Access Systems, Inc.

Est. Registered Number:
1720496

Notification for:

☐ New Device ☒ Significant Change/Modification ☐ Change In Intended Use

Classification Panel Name:
General Hospital

Pursuant to Section 513 of the Act and 21 CFR Part 860, this device is:

☐ Class I ☐ Class II ☐ Class III
☒ Not classified - the following provides the basis for this determination:

Pursuant to Section 514 of the Act and 21 CFR Part 861, the following action has or will be taken to assure conformance to appropriate performance standard(s):

☒ Not applicable ☐ No Standard(s) presently exist for this device
☐ The following performance Standard(s) apply and are being complied with:

The following is attached, where appropriate, in support of this 510(K) Notification:

☒ Labels, labeling, advertisements and/or directions
☒ Finished product photographs and/or engineering drawings
☒ Statement and data supportive of similarity/difference of comparable product types in commercial distribution
☒ Supportive data in consideration of consequences and effects of a change or modification as relate to safety and effectiveness including a detailed description of the significant change/modification
☐ Supportive data in consideration of consequences and effects as related a new use of the device including a detailed description of the new intended use

Confidentiality of intent to market:
☒ Applicable
☐ Not applicable

C. R. Bard, Inc. certifies pursuant to 21 CFR 807.95(b) that it has not divulged the fact of its intention to market this product to any individuals outside the employ of the Company, other than paid consultants in advertising or law firms, pursuant to commercial agreements, with appropriate safeguards for secrecy.

Submitted by: Jack Speer **Title:** QA/RA Director
Signed: _____ **Telephone:** (801) 595-0700
Bard Access Systems, Inc. (Subsidiary of C. R. Bard Inc.)
725 West Amelia Earhart Drive
Salt Lake City UT 84116

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PREMARKET NOTIFICATION FOR A TITANIUM PORT WITH ATTACHABLE CATHETER

I. INTRODUCTION

Davol Inc., a C.R. Bard, Inc. subsidiary, began market distribution of its Hickman® titanium subcutaneous port in 1987. Implanted ports were developed to help provide reliable vascular access for patients requiring long-term drug or fluid therapy. Totally implanted vascular access devices permit the infusion of medications, parenteral solutions, blood products and other fluids and also permit blood sampling without the need for repeated venipunctures or daily care of an external catheter.

In 1989, C.R. Bard, Inc. purchased Catheter Technology in Salt Lake City, the manufacturer of the Groshong® catheter and Dome Titanium Port, and named it Davol Specialty Access Systems. In 1992, C.R. Bard, Inc. changed the name from Davol Specialty Access Systems to Bard Access Systems.

Davol Inc. received 510(k) concurrence (K870260) for its totally implantable Hickman titanium subcutaneous port on April 15, 1987. It has a titanium port body (single lumen) with a silicone septum and either a preattached or attachable silicone catheter.

This premarket notification is for a single lumen titanium (CathLink 20™) port with a modified silicone septum and an attachable polyurethane catheter.

II. DEVICE DESCRIPTION

A. Port description

The proposed port is a low profile totally implantable, side-entry titanium port having a layered silicone septum with an attachable polyurethane catheter. The port system is shown in Exhibit 2, pg.1). The port is accessed through a side opening that is funnel shaped to help guide the access device [peripheral intravenous (I.V.) catheter] into the port. Three silicone layers, each having an appropriate opening, form a complete septum system that will allow access to the catheter with a 20 gauge peripheral I.V. catheter instead of a non-coring needle. The port housing has been designed so that the introducer needle of the peripheral I.V. catheter cannot come in contact with the septum system. The port access procedure is illustrated in Exhibit 2, pages 2 and 3.

Each of the three septum layers has a unique opening - two have slits and one has a center hole. The slitted layers are placed with the slits at a 90 degree angle to each other and secured together with silicone medical adhesive (glue). The septum layers are placed as illustrated in Exhibit 2, pg.4. The stem is press-fitted into the housing after placing the septum assembly unit in the septum chamber. A central venous catheter is attached to the port stem by the physician during implantation.

The septum system allows the peripheral I.V. catheter to be passed through it into the central venous catheter. All fluid exchange takes place through the peripheral I.V. catheter. The port functions as follows:

1. The port is accessed with a 20 gauge peripheral I.V. catheter. The I.V. catheter needle is prevented from contact with the septum by the needle stop in the angled access pathway.
2. The center hole of the septum layer adjacent to the access pathway seals around the I.V. catheter.
3. The slitted layers provide a seal for the port system when the I.V. catheter is not in place.
4. The septum chamber is designed so that pressure is exerted on the outer edges of the septum layer to form a leak-proof seal.

B. Attachable catheter description

The port system with attachable single lumen, open-ended catheter is shown in Exhibit 2, pg.1. The catheter is made of (b) (4)P ™ polyurethane - an aliphatic ester-free, ether-free polyurethane.

The (b) (4)P polyurethane catheter will be secured to the port stem by the physician using a catheter locking system similar to the locking system used on other Bard Access Systems ports (K873213). The locking mechanism (cath-lock) is made of polycarbonate and is the same material used with the MRI Dual Plastic Port (K912702). The cath-lock is shown in Exhibit 2, pg.1. The distal end of the stem is barbed to provide an interference fit between the stem, catheter and cath-lock. Once the catheter is placed on the stem, the cath-lock is pushed over the stem to form the stem/catheter assembly. The inside diameter of

the cath-lock essentially crimps the catheter onto the port stem. The catheter wall is compressed around the stem, forming a seal and increasing the strength of the connection. This type of catheter lock system has been used successfully with the Hickman Plastic Ports in the clinical setting since 1987.

C. Performance Testing

The performance testing for the CathLink 20 system was done in accordance with the FDA 1989 Port Testing Guideline (see Exhibit 8). The testing data is presented in Exhibit 3. The CathLink 20 system was found to be acceptable as a totally implanted venous access port system.

D. Clinical Evaluation

(b) (6)

[redacted]

(b)(4)Proprietary Information [redacted]

E. Kit components

The proposed port with attachable catheter will be marketed in several procedure tray configurations. We have been in communication with the suppliers of our kit/tray components. As a result of this communication, we believe that all kit/tray components are legally on the market via the 510(k) process or are pre-amendment products or are exempt from the 510(k) filing process. We, of course, are aware that under the Federal Food, Drug, and Cosmetic Act we are legally responsible for any product we introduce into interstate commerce bearing Bard labeling. If, in the future, any substitution of kit/tray components are to be made, we will obtain assurances from the manufacturer that they are being legally marketed.

The port and catheter will be available in a cut-down tray, two percutaneous trays (one with a peel-away sheath introducer and one with a slittable sheath introducer) and a full procedural tray. The tray contents are listed on the labels in Exhibit 11.

F. Sterilization/Packaging

The proposed port system will be sterilized using a validated ethylene oxide (EtO) cycle with an SAL of

(b)(4)Proprietary Information [redacted]

is performed in accordance with the AAMI, March 31, 1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The proposed port system will be packaged in an inner molded plastic tray of sequentially arranged components in a C.S.R. wrap. This inner tray is placed in an outer tray with a sealed Tyvek® lid. The maximum levels of ethylene oxide, ethylene chlorhydrin and ethylene glycol residues remaining on the product will be within the limits for a blood contacting device as proposed by FDA in the June 12, 1978, Federal Register.

The port system is identified as non-pyrogenic as determined by Limulus Amebocyte Lysate (LAL) testing performed in accordance with the USP

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monograph for bacterial endotoxins testing. Validation of the LAL test is performed in accordance with the FDA "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices", December, 1987.

G. Components and Materials

The major tissue/blood contacting components of the proposed port/catheter and their construction materials are given in the following chart. Additionally, other products reviewed by FDA using a similar material are identified.

COMPONENT	MATERIAL	CURRENT PRODUCT USE
Port	Titanium (President Titanium, (b)(4)Proprietary Information)	Dome titanium port (K880571)
Septum	Medical grade silicone (b))	Hickman titanium port (K870260)
Adhesive (glue)	(b) (4)P i t	various B.A.S. products including the Groshong CV Catheter Repair Kit (K871998)
Catheter Lock	(b) ® (b) (4)P polycarbonate	Dual Port (K912702)
Catheter	(b)(4)Proprietary Information polyurethane with 13% barium sulfate	none

All tissue/blood contacting materials are biocompatible and meet Class VI requirements. These materials (except for (b) (4)P i t polyurethane) are widely used in medical devices for many applications.

The (b) (4)P i t material underwent an extensive evaluation program that included Tripartite biocompatibility testing for chronic use blood contacting devices and additional testing to evaluate biodurability. The biocompatability evaluation report for the (b) (4)P i t material is presented in Exhibit 7. Testing done in accordance with the Good Laboratory Practices (GLP) regulation

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is so designated in the report. We conclude that the (b)(4)Proprietary material is biocompatible and equivalent to the polyurethane central venous catheter marketed in the Pharmacia Deltec P.A.S. Port™ system (Exhibit 9) and is suitable for use as a central venous catheter.

III. INTENDED USE

This port system is a totally implantable device designed for reliable repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

IV. SUBSTANTIAL EQUIVALENCE

The proposed titanium port is substantially equivalent to the port in the P.A.S. Port system currently marketed by Pharmacia Deltec (see Exhibit 9) and the Bard Access System Hickman titanium port (K870260). The modified polyurethane catheter is substantially equivalent to the P.A.S. Port polyurethane catheter as evidenced by the test data in this submission. The Pharmacia P.A.S. Port system is currently on the market and has been on the commercial market for an extended time period. It is in widespread use. Bard is not aware of any information suggesting that the device is not legally marketed. The physical characteristics of these three devices are compared in Exhibit 10.

The 510(k) Substantial Equivalence Decision Making Process (Detailed) decision tree from the ODE Guidance Memo, December, 1989 (Exhibit 12) was used to make a determination of substantial equivalence. The answers to these questions lead to a determination of substantial equivalence.

1. Does the new device have the same indication statements?

Yes, the CathLink 20 has the same indication for use as the Hickman Titanium Port and Pharmacia Deltec P.A.S Port. All are totally implanted devices designed for reliable repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

2. Does the new device have the same technological characteristics, e.g. design, materials, etc.?

No, the catheters used with the Hickman Titanium Port (silicone), Pharmacia Deltec P.A.S Port (polyurethane) and the CathLink 20 Port (modified polyurethane) are made of different materials. The material used for the portal body (titanium) and the septum (silicone) are the same for all three ports. The CathLink 20 layered silicone septum is different in design from the solid silicone septums in the Hickman Titanium Port and Pharmacia Deltec P.A.S Port.

3. Could the new characteristics affect safety or effectiveness?

Yes, the layered septum of the CathLink 20 Port is a unique characteristic of the CathLink 20. Its failure could affect the safety or effectiveness of the port. Also, the modified material used for the catheter in the CathLink 20 system could have new characteristics that could affect its safety or effectiveness.

4. Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are the same for all central venous port/catheter systems.

5. Do accepted scientific methods exist for assessing effects of the new characteristic?

Yes, the FDA 1989 Port Testing Guideline was used to evaluate the performance of the modified device. The Tripartite Guidance was used to assess that the biocompatibility of the modified catheter is equivalent to currently marketed catheters. The clinical performance of the modified device was evaluated in a clinical study.

6. Are performance data available to assess effects of new characteristics?

Yes, bench testing was conducted on the CathLink 20 system according to the FDA 1989 Port Testing Guideline. A clinical study was done to evaluate the clinical performance of the CathLink 20 port with the layered septum. Biocompatibility testing was evaluated according to the Tripartite Guidance.

7. Does the performance data demonstrate equivalence?

Yes. The data from the performance testing, clinical evaluation and biocompatibility testing demonstrate that the CathLink 20 system is equivalent to the currently marketed Hickman and P.A.S. Port systems.

V. Labeling

The draft labeling is presented in Exhibit 11.

CathLink 20 is a trademark of C.R. Bard Inc. or an affilite. Hickman is a registered trademark of C.R. Bard, Inc. or an affiliate.
(b) [redacted] is a trademark of Polymedica Industries, Inc.
(4)P i t

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510(k) Summary

The proposed CathLink 20 titanium port is substantially equivalent to the port in the P.A.S. Port™ system currently marketed by Pharmacia Deltec and the Bard Access System Hickman® titanium port (K870260). The modified polyurethane catheter is substantially equivalent to the P.A.S. Port polyurethane catheter. The Pharmacia P.A.S. Port system is currently on the market and has been on the commercial market for an extended time period. It is in widespread use. Bard is not aware of any information suggesting that the device is not legally marketed.

The 510(k) Substantial Equivalence Decision Making Process (Detailed) decision tree (ODE Guidance Memo, December 1989) was used to make a determination of substantial equivalence. The answers to these questions lead to a determination of substantial equivalence.

1. Does the new device have the same indication statements?

Yes, the Cath-Link 20 has the same indication for use as the Hickman Titanium Port and Pharmacia Deltec P.A.S Port. All are totally implanted devices designed for reliable repeated long term access to the vascular system for the infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

2. Does the new device have the same technological characteristics, e.g. design, materials, etc.?

No, The catheters used with the Hickman Titanium Port (silicone), Pharmacia Deltec P.A.S Port (polyurethane) and the Cath-Link 20 Port (modified polyurethane) are made of different materials. The material used for the portal body (titanium) and the septum (silicone) are the same for all three ports. The CathLink 20 layered silicone septum is different in design from the solid silicone septums in the Hickman Titanium Port and Pharmacia Deltec P.A.S Port.

3. Could the new characteristics affect safety or effectiveness?

Yes, the layered septum of the Cath-Link 20 Port is a unique characteristic of the Cath-Link 20. Its failure could affect the safety or effectiveness of the port. Also, the modified material used for the catheter in the Cath-Link 20 system could have new characteristics that could affect its safety or effectiveness.

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4. Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are the same for all central venous port/catheter systems.

5. Do accepted scientific methods exist for assessing effects of the new characteristic?

Yes, the FDA 1989 Port Testing Guideline was used to evaluate the performance of the modified device. The Tripartite Guidance was used to assess that the biocompatibility of the modified catheter is equivalent to currently marketed catheters. The clinical performance of the modified device was evaluated in a clinical study.

6. Are performance data available to assess effects of new characteristics?

Yes, bench testing was conducted on the CathLink 20 system according to the FDA 1989 Port Testing Guideline. A clinical study was done to evaluate the clinical performance of the CathLink 20 port with the layered septum. Biocompatibility testing was evaluated according to the Tripartite Guidance.

7. Does the performance data demonstrate equivalence?

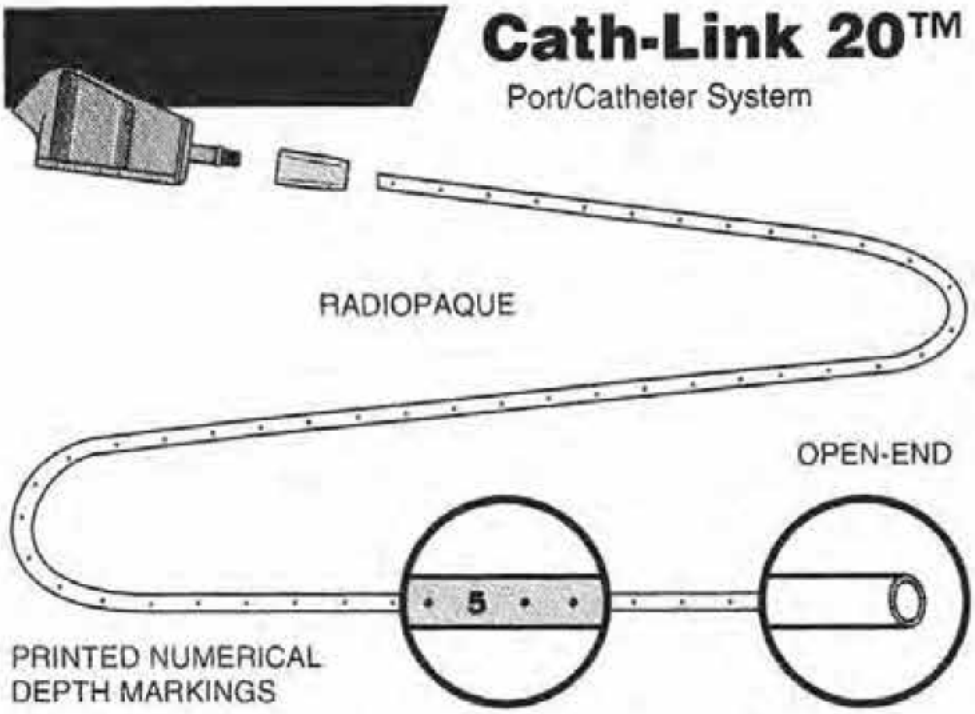
Yes. The data from the performance testing, clinical evaluation and biocompatibility testing demonstrate that the CathLink 20 system is equivalent to the currently marketed Hickman and P.A.S. port systems.

Exh. 2

Exhibit 2 pg. 1

Cath-Link 20™

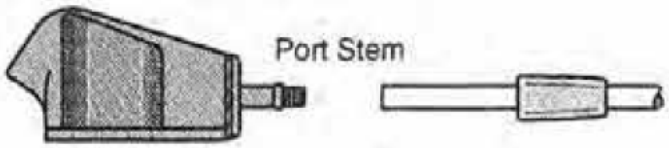
Port/Catheter System



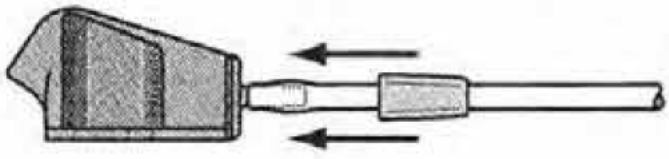
Cath-Link 20™

Port/Catheter Locking System

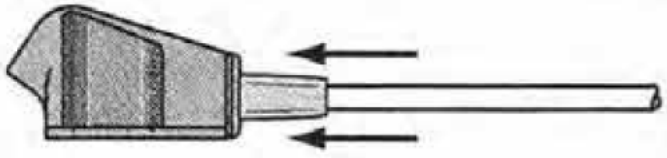
ALIGN PORT STEM WITH CATHETER LUMEN



ADVANCE CATHETER OVER PORT STEM TO MIDWAY POINT



ADVANCE CATHETER LOCK UNTIL FLUSH WITH PORT



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Cath-Link 20™

Port Access

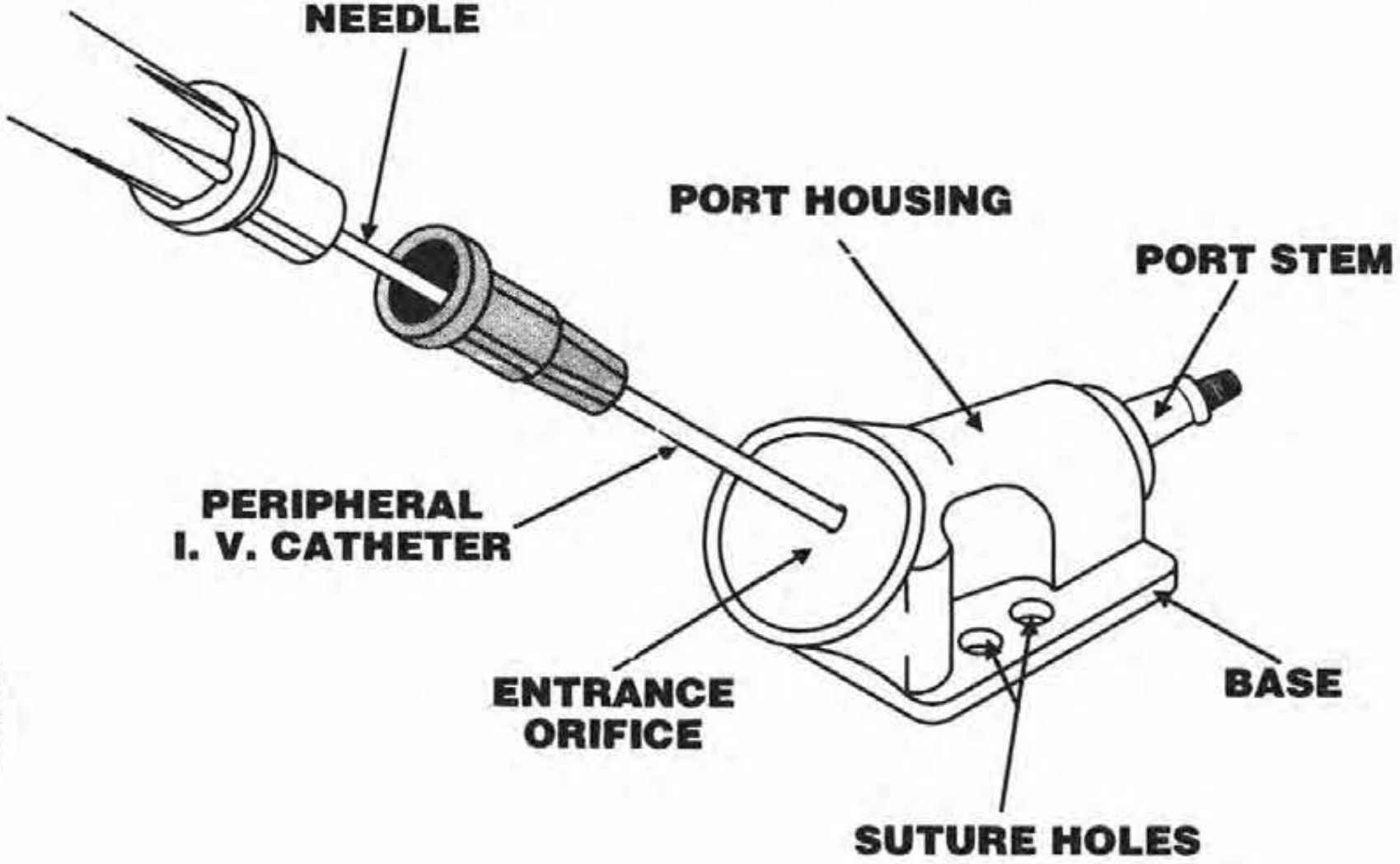
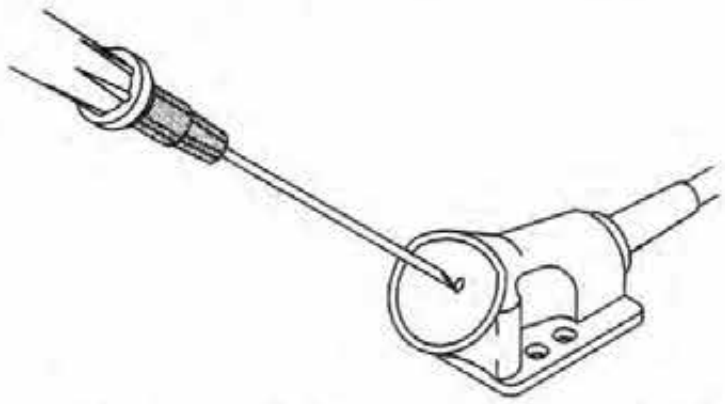


Exhibit 2 pg. 3

Cath-Link 20™
Port Access



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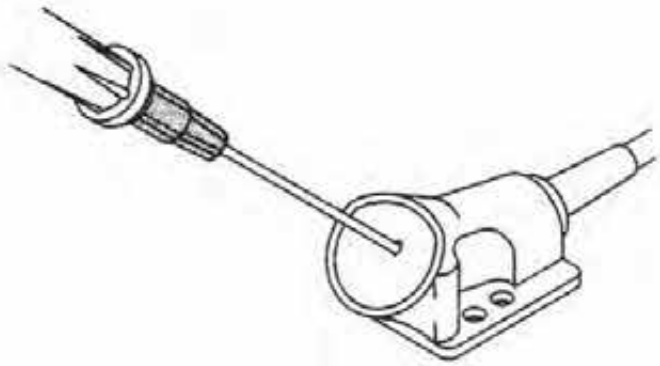
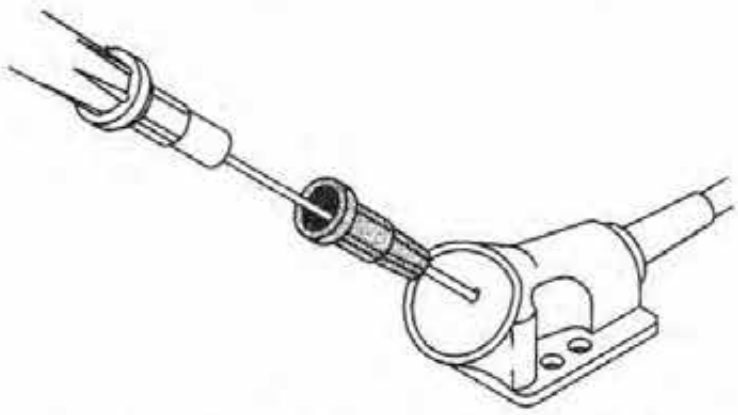


UNTIL NEEDLE MEETS STOP



ADVANCE CATHETER OVER NEEDLE

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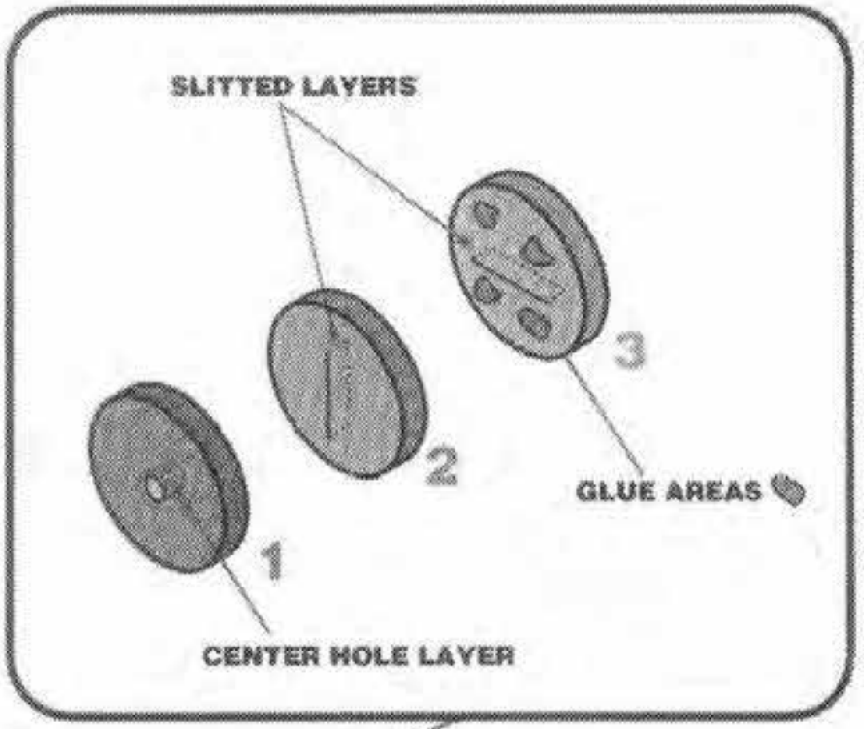
Cath-Link 20™ Port



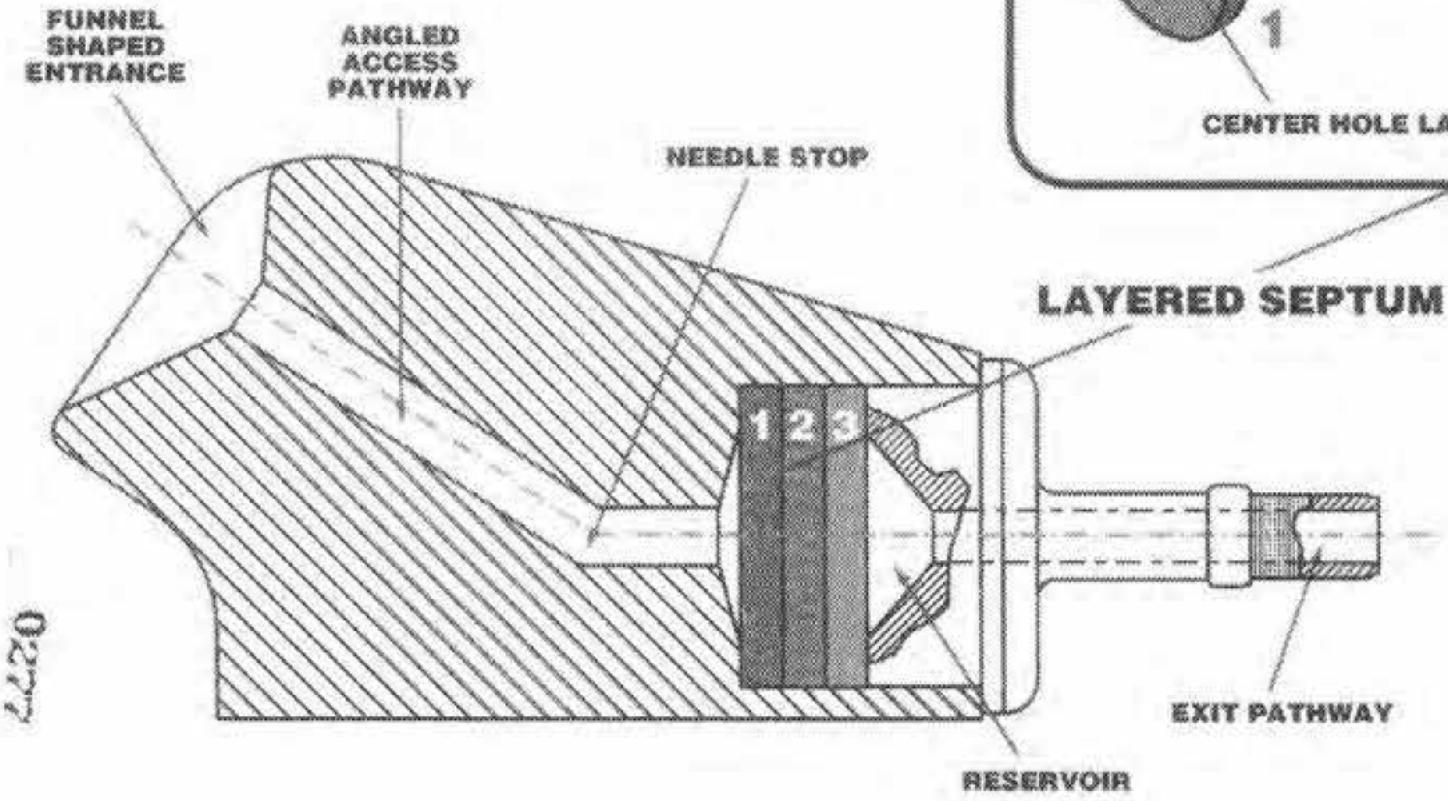


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Exhibit 12 pg. 4 of 7

Exh.

3

Exhibit 3 pg. 1

PORT FLOW RATE

Objective: The flow rate test measures the flow characteristics of the proposed port and catheter.

Method: (b)(4)Proprietary Information

Results:

(b)(4)Proprietary Information

Conclusion: (b)(4)Proprietary Information

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PORT/CATHETER BLOOD CLEARANCE

Objective: To verify that the flush characteristics of the proposed port/catheter system are sufficient for adequate clearance of blood from the system with the flushing volume stated in the instructions for use.

Method: (b)(4)Proprietary Information [redacted]

Results: The average flushing volume required to clear blood from the proposed port is listed below.

BLOOD CLEARANCE FLUSHING VOLUME

	MEAN (mls)	RANGE	N
Cath-Link 20/ 6 Fr	(b)(4)Proprietary Information [redacted]		

Conclusion: (b)(4)Proprietary Information [redacted]

Exhibit 3 pg. 3

SEPTUM PUNCTURE LIFE

Objective: The septum life test simulates repeated port usage and verifies that the septum does not leak after multiple insertions.

Method: (b)(4)Proprietary Information [redacted]

Results:

SEPTUM PUNCTURE LIFE (1000 Punctures)

	# Pass	# Fail	N
(b)(4)Proprietary Information [redacted]			

Conclusion: The CathLink 20 with multilayer septum provides a reliable, leak free system after repeated use.

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Exhibit 3 pg. 4

PORT FAILURE PRESSURE TEST

Objective: The purpose of the test is to determine the internal pressure that the port can withstand before failure. The anticipated mode of failure with the CathLink 20 port is leakage. The anticipated mode of failure with standard ports is expulsion of the septum from the port.

Method: (b)(4)Proprietary Information [redacted]

Results: The maximum internal pressure for each port is listed below.

PORT FAILURE PRESSURE

	(b)(4)Proprietary Information
CathLink 20 Port	[redacted]
Hickman Port	
P.A.S. Port	

CathLink 20 specification: (b)(4)P[redacted]

Conclusion: (b)(4)Proprietary Information [redacted]

0282

CONTINUOUS USE

Objective: To demonstrate the performance of the proposed port after multiple insertions, with continuous application of pressure.

Method: (b)(4)Proprietary Information [redacted]

Results: Continuous use results are listed below.

CONTINUOUS USE

	# PASS	# FAIL	N
CathLink 20 Hickman Port P.A.S. Port	(b)(4)Proprietary Information [redacted]		

Conclusion: The CathLink 20 with multilayer septum provides a reliable, leak free system for continuous therapy.

Exhibit 3 pg 6

CATHETER PULL TEST

Objective: The purpose of the catheter pull test is to measure strength of the catheter/port connection.

Method: (b)(4)Proprietary Information [redacted]

Results: The results of the catheter/port connection testing are given below.

CATHETER PULL TEST

Port/Catheter	(b)(4)Proprietary Information [redacted]
CathLink 20/ 6 Fr (b)(4)P i t Mean Std.Dev.	
P.A.S. Port/ 5.8 Fr PU Mean Std.Dev.	
Hickman Port/ 6.6 SILASTIC Mean Std.Dev.	

Conclusion: (b)(4)Proprietary Information [redacted]

0284

Exhibit 3 Pg. 7

CATHETER PHYSICAL PROPERTIES

Objective: Tensile and burst tests were done to assure adequate physical properties of the catheter.

Method: (b)(4)Proprietary Information [redacted]

Results:

CathLink 6 Fr. (b)(4)Proprietary PU	(b)(4)Proprietary Information [redacted]
Hickman 6.6 Fr. SILASTIC	
P.A.S. Port 5.8 Fr. PU Catheter	

CathLink 6 Fr. (b)(4)Proprietary	(b)(4)Proprietary Information [redacted]
Hickman 6.6 Fr. SILASTIC	
P.A.S. Port 5.8 Fr. PU Catheter	

Conclusion: (b)(4)Proprietary Information [redacted]

0285

Exh.

4

Exhibit 4

JUNE 1991

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Exh.

5

(b)(4)Clinical Study

A CLINICAL STUDY OF THE CATH-LINK 20™ SYSTEM, AN IMPLANTABLE VASCULAR ACCESS PORT

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Exh. 6

(b)(4)Clinical Study

Exh. 7

CONFIDENTIAL

Exhibit 7

(b) (4) [redacted] POLYURETHANE

BIOCOMPATIBILITY EVALUATION

0688

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Exh.

8

Exhibit 8

January 31, 1990

RE: PORT GUIDELINE

TO: INTERESTED PARTIES

FROM: Chief, General Hospital and Personal Use Devices Branch

Please provide FDA with any comments you have on the guideline. Adjustments will be made to the content of the document as necessary. The guideline does not establish regulatory requirements, but rather our current considerations for evaluation criteria. Alternatives to the methods outlined in the document can be presented with justification.

Although the guideline eliminates the need for in vivo data for "me-too" devices, this of course does not supercede your decision to pursue such testing as you deem necessary. A summary of any in vivo data collected should be submitted with the application.

If you have any questions call Tim Ulatowski at (301) 427-1225.

Guidance on Implanted Ports

December 1989

General Submission Requirements

A person proposing to begin the introduction of a new implanted drug infusion/blood sampling port into interstate commerce must submit a premarket notification (510(k)) submission to FDA at least 90 days prior to its introduction.

The general requirements for 510(k) submissions are provided under 21 CFR 807, Subpart E. The 510(k) submissions for implanted ports are evaluated by the General Hospital and Personal Use Devices Branch, Division of Gastroenterology-Urology and General Use Devices.

Overview

A score of implanted ports have been found substantially equivalent through the 510(k) process. The great majority of these ports have been indicated for intravascular (intravenous and intraarterial) use. These determinations have been based upon comparisons of design specifications with other marketed ports and analysis of performance data derived from in vitro and in vivo testing.

Tens of thousands of ports are now implanted yearly. The design features and clinical experience with ports have matured to a point where FDA believes that the clinical performance of a new intravascular port is predictable provided it has the same technological characteristics as other marketed ports, satisfactory in vitro testing, and adequate instructions for use.

As a result, in general, in vivo (animal or clinical) data are unnecessary to evaluate equivalence in a 510(k) application of a port for intravascular use that meets the above factors. As detailed below, in specified instances FDA may request in vivo data to establish equivalency.

Specific Data Requirements for Implanted Ports for Intravascular Use

1. Description of Device

   a. specifications of port and catheter (include catheter physical tests, e.g., tensile, burst)

   b. engineering drawings (or equivalent)

   c. materials, i.e., exact identification, not simply 'stainless steel'

2. Labelling/Instructions for Use

a. Description and specifications

b. Indications/route of administration, e.g., IV, IA, blood sampling, drug administration, bolus, continuous administration, etc.

Note: If specific drugs are indicated in the labelling for infusion by the port, the drugs must be approved for the indicated route of administration.

c. Contraindications for those with known or suspected infections, bacteremia, etc.; allergies; intolerance to implants.

d. Complications

e. Warnings and Precautions

f. Site Selection

g. Implantation

preparing the patient
preparing the port
implant procedure
post-operative care

h. Using the port for bolus infusion (and continuous if indicated), or blood sampling, noting needles to use, use of heparin, and clearing blockages

3. Table of Comparisons

a. Devices vs. Specifications Grid

Provide a grid comparing the subject device and other ports with comparable characteristics to which equivalence is claimed.

Specifications include dimensions, reservoir volume, catheter ID/OD, materials of port housing, septum, catheter, and catheter lock system.

b. Provide a detailed analysis of comparability based upon the grid.

4. Provide a sample, if possible.

5. Bench Test Data

NOTE: All bench testing should be statistically evaluated.

The number of units to be evaluated are dependant upon the statistical test parameters. It is the responsibility of the sponsor to justify the actual specific protocol used. As FDA evaluates data based upon these criteria, more specific information on test methodology will be provided.

a. Catheter Pull Test

Purpose: To test strength of catheter to port connection.

Applied load in dry and 150 ohm-cm saline/glyverine environment to approximate viscosity of blood on a series of ports/catheters. Two segments to testing, one with linear traction and another with flexion are desirable. It is noted that some sponsors have used a soapy water environment but variabilites and approximation to blood are questionable.

Preparation of saline/glycerine solution: distilled, deionized water mixed with 45% glycerine by weight. Titrate NaCl to 150 ohm-cm at 37° C.

Load must approximate potential in vivo applied force plus safety factor, and be justified.

b. Septum Puncture

Purpose: To test durability of septum.

Use needles listed in labelling on series of ports. Typically, noncoring needles are used. The number of punctures are dependent upon life of port, punctures per day, plus safety factor of x 1/3. Conduct leak test after punctures with applied internal pressure above that encountered in vivo, and in a 37° water bath to check for bubbles.

c. Port Leak Testing

Purpose: To test durability of port.

Intermittent and continuous applied pressures on a series of ports to simulate bolus use and continuous administration. The pressures applied must be justified in view of those encountered with syringe/pump use and backpressure conditions. Test in 37° C water bath. Check for port seams and septum leaks.

Submit burst (failure) pressure on the port.

d. Fluid Dynamics Tests

(1.) Clearance Test

Purpose: To test clearance kinetics of reservoir.

Fill port with 150 ohm-cm glycerine/saline mix. Put impedance transducer on catheter. Insert non-coring needle in septum. Attach a specified syringe, e.g, 10 ml, with specified volume of flushing solution. Submerge in 37° C bath and let equilibrate. Flush with solution at a determined rate. Record impedance over time until impedance of flushing solution is achieved.

The data set on this can be used to establish flushing parameters. Comparison to other port data may provide comparative fluid dynamic capabilities of ports.

Results from alternative test methods may be submitted along with the test protocol.

(2.) Blood Flow Dynamics

Blood is a unique liquid which exhibits flow characteristics and other properties that cannot be fully duplicated by substitute liquids more amenable to laboratory procedures. While the clearance test [5.d.(1.) above] approximates the clearance of a liquid with the viscosity of blood, the test is not an ideal substitute for evaluating actual blood sampling and flushing. Sponsors should consider bench test methodology which further demonstrates flow patency under repeated blood sampling/flushing procedures.

Situations Which Require Additional Data

1. New designs

Port designs which are not similar to those currently on the market may require additional in vitro and in vivo testing and data. The need for additional data will be made on a case by case basis. Such design characteristics could include, for example, a new profile or angle of septum access, a unique catheter lock, or a new type of catheter.

2. New material

There are several commonly used materials for port construction. A material not previously used for ports may require biocompatibility, material specifications, or drug interaction data.

3. New route of administration

a. Until there is further experience with intraperitoneal (IP) use, an IP indication must be supported by clinical

data.

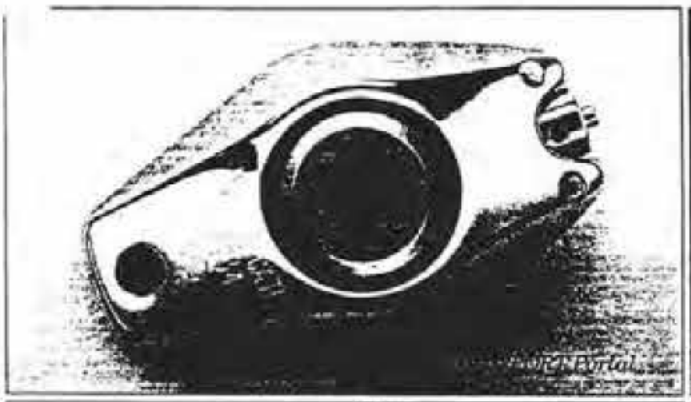
b. Intraspinal administration is Class III and requires premarket approval through a PMA application.

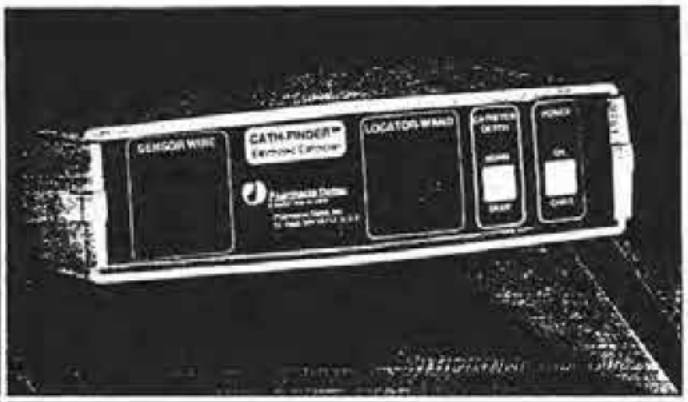
4. Comparative or expanded labelling claims, e.g., reduction of infection or occlusion, may require supportive clinical or other data.

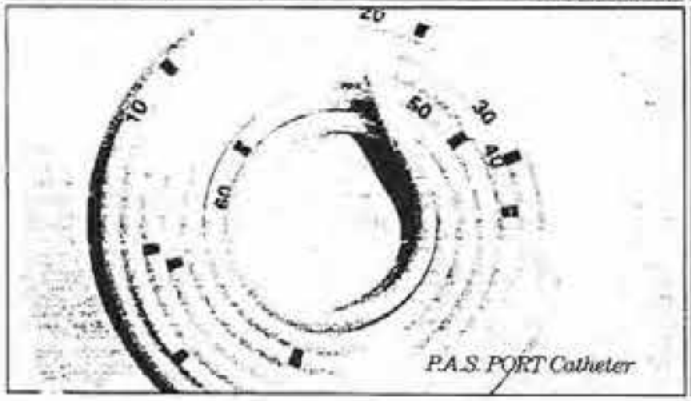
Exh. 9

Exhibit 9

The P.A.S. PORT™ Implantable Access System And CATH-FINDER™ Catheter Tracking System Specifications* And Re-Order Information







P.A.S. PORT System

- Provides central venous access from a peripheral arm location.
- Specifically addresses the special needs of arm placement.

	Reorder Numbers
P.A.S. PORT System	21-4501
P.A.S. PORT System with introducer tray (when available)	21-4502

PORTAL

- Small, low profile designed to fit the contour of the arm.

Material:	Titanium
Weight:	5.6 g
Height:	7.4 mm
Length:	26.7 mm
Septum Diameter:	6.6 mm

CATHETER

Material:	Radiopaque polyurethane
Length:	76 cm
O.D.:	1.9 mm
Introducer Size:	6 French
I.D.:	1.0 mm

DISPOSABLE SENSOR WIRE

- Preassembled within the catheter

*Nominal

Supplies/Accessories

	Reorder Number
6F INTRODUCER SET	38C

- 10 per case.
- Supplies for percutaneous introduction of catheter in the forearm.
- Introducer needle, syringes.

	Reorder Numbers
NON-CORING NEEDLES	
Metal hub	
22g 1½"	21-2314
20g 1½"	21-2315
Plastic hub	
22g 1½"	21-2316
20g 1½"	21-2317

- Shorter length with 90° bend for low profile placement in the port.
- Supplied individually packaged, 12 per case.

CATH-FINDER Catheter Tracking System

- Portable technology for convenience during catheter placement.
- Battery powered.
- Provided in durable storage case.

	Reorder Number
CATH-FINDER CATHETER TRACKING SYSTEM	21-6000

ELECTRONIC CONTROLLER

- Lightweight for portability and storage.

LOCATOR-WAND

- Fits in the hand for maneuverability.

BATTERY CHARGER

- Maintains battery power for controller.

EXTENSION CABLES

- Adds length for flexibility and maneuverability.
- Supplied for both:
  Sensor wire Locator-wand

To Order Call 1-800-426-2448

Pharmacia Deltec
a better way to care

-490-

0760

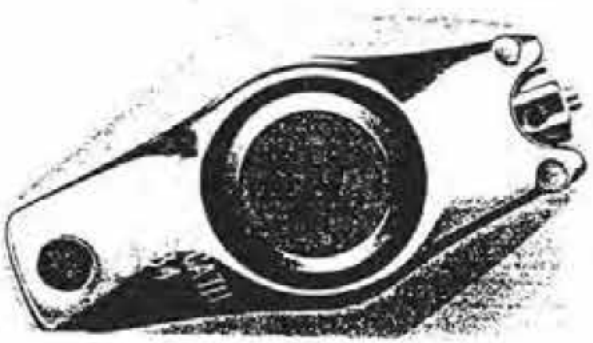
Introducing The P.A.S. PORT™ System And The CATH-FINDER™ Catheter Tracking System.

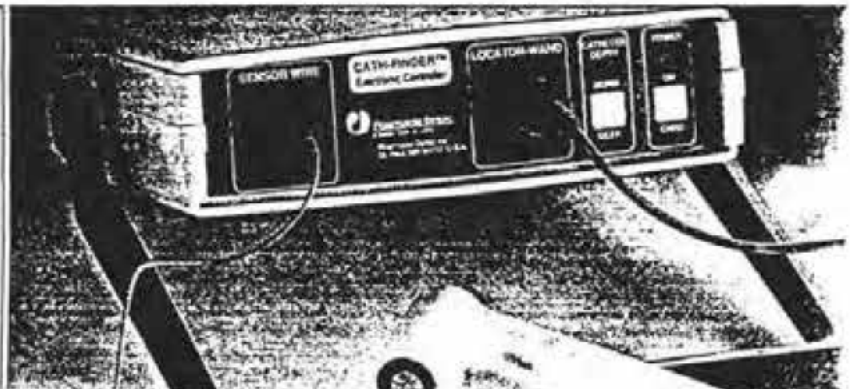
The First Implantable Access System Designed Exclusively For Arm Placement.

- A revolutionary system designed with the leadership and experience of PORT-A-CATH® Implantable Access Systems.
- The P.A.S. PORT System allows clinicians to prescribe an implantable venous access device (I.V.A.D.) to more patients than ever before.
- The P.A.S. PORT System can be used in situations when chest placement is limited by:
  - extensive prior surgery and scarring
  - radiation requirements
  - disease complications
  - patient's fear of additional surgery
- Oncology nurses have found the P.A.S. PORT System to be:
  - Similar to other fully implantable devices
    - no daily dressings to change
    - low maintenance
  - Accessible
    - can palpate in the arm
    - can locate and access septum
  - Useful For A Variety of Therapy Needs
    - chemotherapy
    - antibiotics
    - blood sampling
    - TPN
  - Well accepted by patients
- The P.A.S. PORT System is designed to:
  - simplify the placement procedure
  - minimize patient trauma
  - eliminate the need for x-rays during the placement procedure
- The P.A.S. PORT System provides oncologists the option of prescribing an I.V.A.D. for more I.V. therapies.
- Patients have found the P.A.S. PORT System to be cosmetically appealing
  - no bulky dressing required
  - small and low-profile contour to the arm
  - minimal interference of day-to-day activities
- The portable CATH-FINDER Tracking System allows surgeons to implant the P.A.S. PORT System with simplicity and convenience.
- The CATH-FINDER System helps surgeons track and locate the tip of the catheter during the catheter placement procedure without the use of x-rays or exposure to fluoroscopy (a final confirmatory x-ray is still required).

Pharmacia Deltec
a better way to care

0761





Exh.

10

PHYSICAL CHARACTERISTICS COMPARISON TABLE			
	CL20	P.A.S. PORT	HICKMAN PORT
Housing Material	Titanium	Titanium	Titanium
Septum Material	Medical Grade Silicone	Medical Grade Silicone	Medical Grade Silicone
Catheter Material	(b) (4) [redacted] Polyurethane with 13% $BaSO_4$	Radiopaque Polyurethane	SILASTIC with 13% $BaSO_4$
Lock Material	Polycarbonate	Titanium	Polycarbonate+SILASTIC
Port Dimensions: Septum, O.D.	.250"	.260"	.500"
Weight	6.3 gm	5.6 gm	24 gm
Base Dimensions	.56" Wide x .65" Long	.65" Wide x 1.05" Long	1.20" Diameter
Height	.47"	.39"	.55"
Reservoir	.02 mls	.02 mls	0.6 mls
Catheter Dimensions: Catheter Size	6 Fr.	5.8 Fr.	6.6 Fr.
Catheter I.D.	.050"	.039"	.039"
Catheter Length	24"	30"	30"
Catheter Priming Volume	0.8 mls	0.6 mls	0.6 mls

Exhibit 10

Exh.

11

BARD ACCESS SYSTEMS

Cath-Link 20™
Implanted Port

INSTRUCTIONS
FOR
IMPLANTATION AND USE

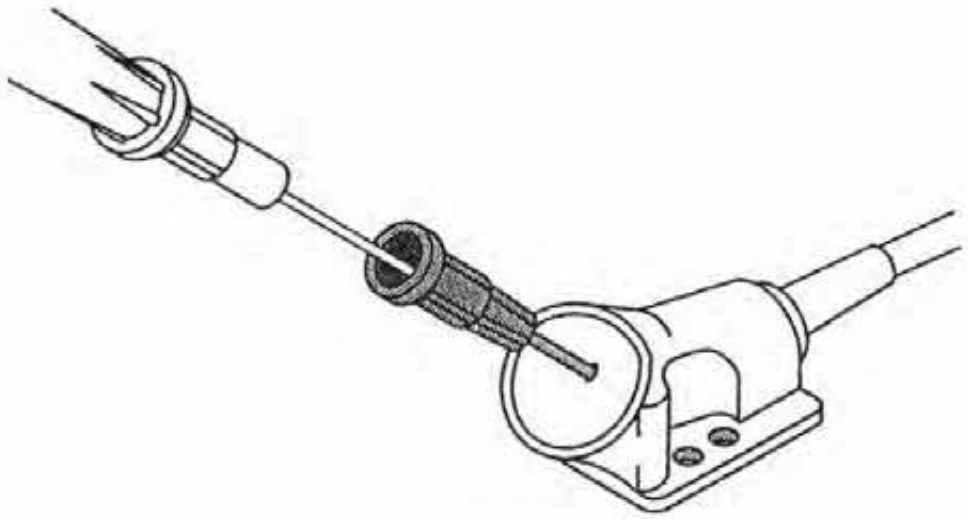
BARD

December 4, 1992

Table of Contents

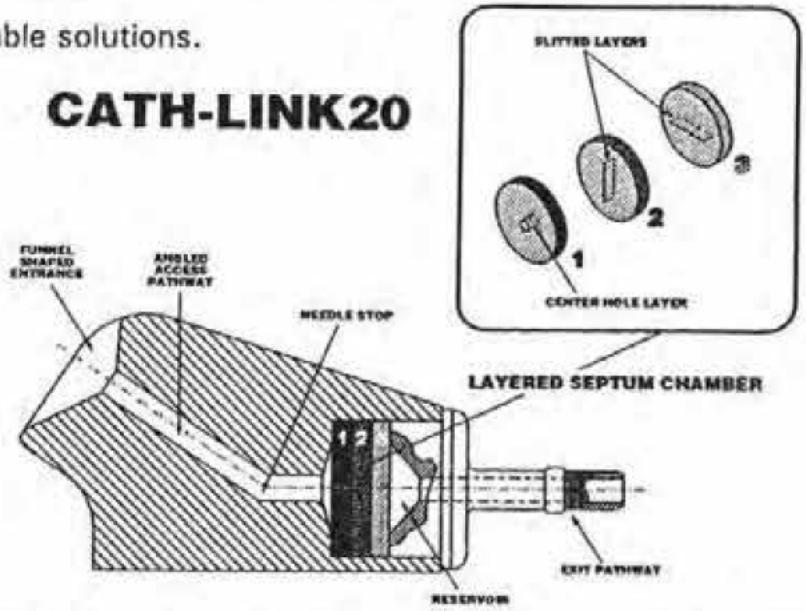
Introduction

The **Cath-Link 20** Implanted Port is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, blood products and imaging solutions. It is also useful for the withdrawal of blood samples. **Cath-Link 20** access is performed by percutaneous insertion of a 20 gauge over-the-needle IV catheter in a 1 1/4" minimum length. **Non-coring needles should not be used.**



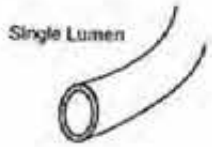
Product Description

The Cath-Link 20 system consists of two primary components: an injection port featuring a multi-layered silicone septum with a predetermined route of entry, and a radiopaque catheter. All materials are biocompatible and can be used with virtually all injectable solutions.



The funnel shaped entrance to Cath-Link 20 guides the over-the-needle IV catheter assembly into the angled access pathway to the needle stop. Cath-Link 20 is designed so that the needle cannot pass beyond the needle stop area, however, the flexible catheter tip passes further through the access pathway. The layered septum seals around the flexible catheter tip once it has been advanced and the needle has been removed.

Cath-Link 20 Implanted Ports are available with an attachable open-ended single lumen catheter.



Open-ended Catheter

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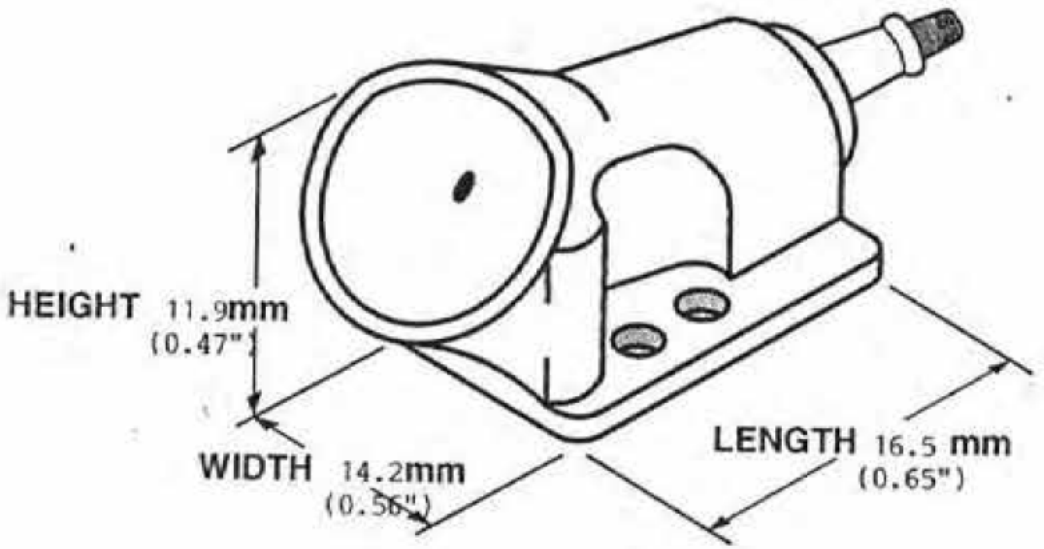
Device Specifications

Cath-Link 20 Implanted Port



Cath-Link 20 Implanted Ports are packaged in a complete procedural tray which includes the following:

QTY	DESCRIPTION
1	Cath-Link 20 Port
1	Catheter
2	Catheter Locks
1	CSR Wrap (30" x 30")
2	Pair Surgical Gloves (Powderless)
1	Fenestrated Drape 38" x 48" (Fenestration: 4" x 8")
4	Towels w/Tape 16" x 13"
2	Self Contained Povidone Prep Sponges
3	Alcohol Swabsticks
10	4" x 4" Gauze Sponges
1	25 Ga x 2" Needle for Skin Wheals
2	18 Ga x 1" Filter Needle for Anesthetic & Saline
2	20 cc Syringes (Luer Slip) for Anesthetic & Flushing
1	Sharp Cushion

1	30 cc Ampule of Lidocaine 1%
1	18 Ga (TW) x 2.5" Needle for Guidewire Introduction
1	21 Ga x 2.5" Needle for Vessel Location
1	3 cc Syringe For Vessel Location
1	10 cc Syringe (Luer Slip) for Guidewire Introduction
3	10 cc Ampules of Sterile Saline for Flushing
1	Spring Guidewire .035" x 17 3/4"
1	Spring Guidewire .035" x 35" Coated w/J-tip
1	Mini Scalpel
1	Trocar
1	Scissors
1	Intro-Eze System w/Slitter
1	Needle Holder
2	3.0 Nylon Suture w/Cutting Needle
1	Betadine Ointment
2	Transparent Dressing (4" x 4 3/4")

1	Instructions for Use
1	Implant Identification Label
1	Patient Identification Label
1	Packet Steri-Strips (1/4" x 1 1/2")
2	20 Ga 1 1/4" over-the-needle IV Catheters
1	8" Extension Set with Clamp
1	5 Fr Dilator
1	14 Fr Dilator

A percutaneous placement tray is also available that includes the following:

- Sheath introducer with vessel dilator
- Sheath slitter (With Intro-Eze™ Introducer)
- Disposable syringe
- Flexible "J" Guidewire
- Stainless Steel Tunneler
- Introducer Needle
- Extra-long Guidewire
- Cath-Link 20 Port
- Catheter with Catheter Lock
- Over-the-needle IV Catheters
- Catheter Flushing Connector
- Instructions For Use
- Implant Identification Labels
- Patient Identification Cards
- Extension Set
- Vein Pick

A basic sterile tray is also available which includes:

- **Cath-Link 20** Port
- Catheter with Catheter Lock
- Over-the-needle IV Catheters
- Extension Set
- Catheter Flushing Connector
- Instructions For Use
- Implant Identification Labels
- Patient Identification Card
- Vein Pick

Indications for Use

The **Cath-Link 20** Implanted Port is indicated for patient therapy requiring repeated access to the vascular system. The port system can be used for infusion of medications, parenteral nutrition solutions, blood products or imaging solutions and for the withdrawal of blood samples.

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Contraindications

The **Cath-Link 20** Implanted Port is contraindicated for patient therapy whenever:

- The presence of infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted port or catheter.
- The patient is known or is suspected to be, allergic to materials contained in the device or has exhibited a prior intolerance to implanted devices.
- Local tissue factors will prevent proper device stabilization and/or access.

Cautions: Read directions prior to use. Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Precautions

- Only physicians qualified in the implantation of subcutaneous vascular access devices should implant these devices.
- All **Bard Access Systems** Ports are supplied in double sterile packages. The package should be examined carefully prior to opening and the contents resterilized if there is any evidence of damage to the package or package seal that could compromise the sterility of the contents (Contact **Bard Access Systems** Customer Service for resterilization information or see page 69.)
- Care must be exercised when implanting the port system to avoid mechanical damage to the delicate material of the catheter. Catheters should only be clamped with smooth-edged atraumatic clamps or forceps. The catheter should not be used if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolization which may require surgical removal.
- The port system should be implanted carefully to avoid any sharp or acute angles which could compromise the patency of the catheter lumen.
- Caution should be observed when using insertion techniques which require guide wires, since mechanical damage can be inflicted upon the delicate catheter lumen during insertion or removal of the wire, resulting in possible perforation, tear, or fracture of the catheter.

- Caution should be exercised when using percutaneous introducers to avoid inadvertent injury to vital structures. Instructions for use are provided with all **Bard Access Systems** percutaneous introducer kits and should be carefully followed.
- To avoid air embolism, all air must be purged from the device by filling the port system with sterile heparinized saline solution prior to attaching an open-ended catheter.
- To ensure proper catheter connection, the connection technique outlined in these instructions should be carefully followed.
- The instructions for catheter handling and care provided in this instruction booklet should be followed to avoid circumstances that could jeopardize catheter patency or function.
- Only 20 gauge over-the-needle IV catheters 1 1/4 inches or longer should be used with **Cath-Link 20**. Other access devices cannot be used.
- Do not reuse over-the-needle IV catheters. Reuse may cause tip deformities which may tear or damage the **Cath-Link 20** multi-layered septum.
- If sutures are used to secure the **Cath-Link 20** catheter, care should be taken to avoid occluding or injuring the catheter.
- Infusion pressures in excess of 25 psi may damage blood vessels and are not recommended, even though the port and catheter are designed to withstand higher pressurization.

Please note that smaller syringes generate more pressure than larger syringes. A three pound force on the barrel of a 3cc syringe generates pressure in excess of 25 psi whereas the same three pound force on the barrel of 10cc syringe generates less than 10 psi of pressure. It is recommended to use no syringe smaller than a 10 cc size with Bard Access Systems implanted ports.

- Correct positioning of the over-the-needle IV catheter within the **Cath-Link 20** port should always be determined before infusion of any substance. The preferred method to confirm placement is by the aspiration of blood. If there is doubt regarding proper over-the-needle IV catheter placement, a radiographic dye study should be performed to confirm placement.
- Injections should be discontinued and appropriate medical intervention begun immediately if signs of extravasation exist.
- Prior to infusion of any substance via the port, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
- **Bard Access Systems** ports are intended for single patient use and should never be reused.

Warning: Catheters placed percutaneously into the subclavian vein should be inserted at the junction of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle, which can cause obstruction or damage to the catheter resulting in rupture or fragmentation. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle[1].

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[1]Aitken DR. Minton JP. "The Pinch-off Sign: A Warning of Impending Problems with Permanent Subclavian Catheters", Am J. Surg 148: 633-636, 1984.

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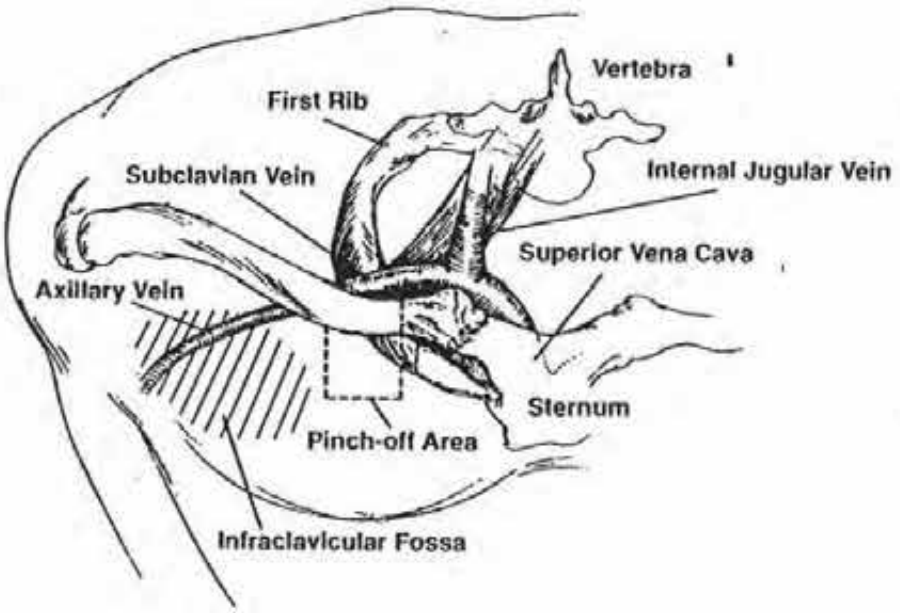
Possible Complications

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Peripheral Nerve Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter or Port Occlusion
- Catheter Occlusion, Damage, or Fracture with Embolism due to Compression Between the Clavicle and First Rib
- Catheter or Port-related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

Implantation Instructions
For
Cath-Link 20™ Implanted Port
Axillary-Subclavian Approach

RELEVANT ANATOMY



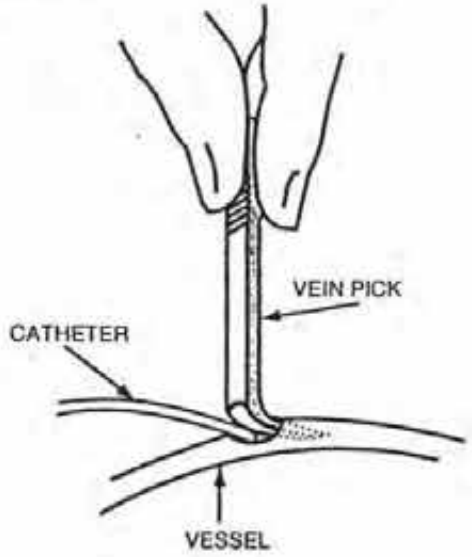
Warning: Catheters placed percutaneously into the subclavian vein, should be inserted at the point of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter ***should not*** be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and the clavicle, which can cause damage and even severance of the catheter. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

- Catheter insertion may be accomplished by either cutdown technique through a small venotomy or by percutaneous technique.

Caution: Catheters placed percutaneously into the axillary-subclavian vein should only be inserted at the point that identifies the outer and middle thirds of the clavicle. If the catheter is inserted into the subclavian vein medially near the articulation of the clavicle with the sternum and the cartilage of the first rib, the catheter could be compressed or pinched leading to damage or severance of the catheter.

Cut-Down Procedure

- After an appropriate vessel is isolated and stabilized, perform the vessel incision.
- Grasp the ribbed handle of the vein pick.
- Insert the tapered end of the vein pick through the incision and advance it into the vessel.
- With the vein pick in position, slide the catheter tip into the pick's grooved underside and advance the catheter into the vessel.
- Withdraw the vein pick from the vessel.
- Advance the catheter into the vessel to the desired position.



Implantation Instructions

Complete patient implant record including product reorder number and lot number.

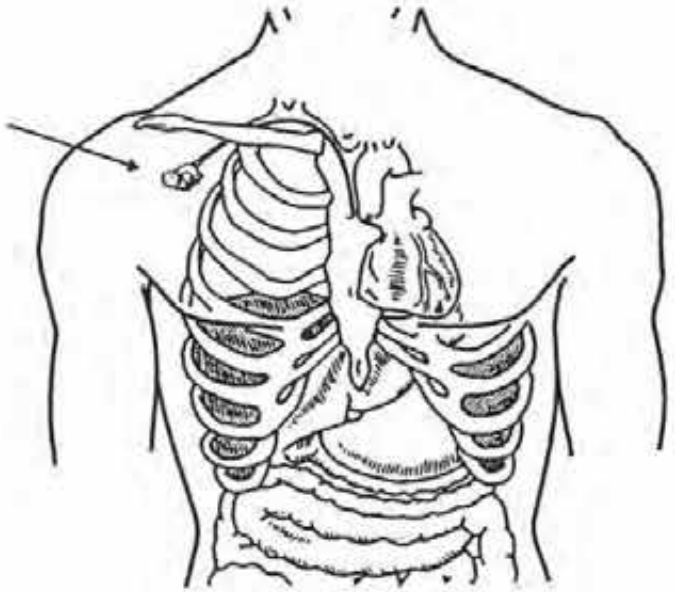
Using flush connector, flush catheter with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end. **Note:** Catheter should be clamped on the segment that will be cut off and discarded prior to attachment to port to avoid catheter damage.

- Select the site for device placement. The infraclavicular fossa is a satisfactory site, but the actual site will vary based on individual patient factors. Site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility, create pressure points, or interfere with clothing. Placement should consider the amount of cutaneous tissue over the port as excessive tissue will make location of **Cath-Link 20** and over-the-needle IV catheter insertion difficult. Conversely, too thin a tissue layer may lead to port erosion. A tissue thickness of 0.5cm to 1.5cm is generally considered appropriate.
- Surgically prep and drape the operative site.
- The catheter may be inserted into the vein either directly through the pocket incision or via a subcutaneous tunnel from the device pocket to the venous entry site.

- Position the catheter tip at the desired infusion site. Correct positioning of the catheter tip in the superior vena cava should be verified and documented by x-ray.

Warning: If sutures are placed around the intravenous catheter, exercise care not to occlude or cut the catheter.

- Create a subcutaneous pocket using blunt dissection. Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision. **Cath-Link 20** should be positioned with the funnel-shaped entrance facing downward (caudad).



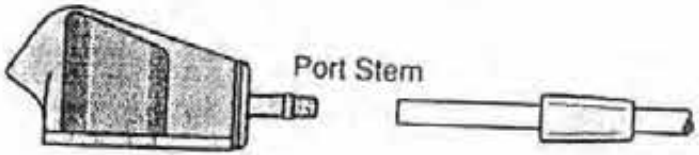
- For remote placement, a subcutaneous tunnel is used. The open-ended catheter may be advanced from the port pocket site to the venous entry site. If the catheter is tunneled in the opposite direction (from the venous entry site retrograde to the pocket site), **remove the catheter lock from the catheter prior to tunneling.**

  The **Bard Access Systems** Tunneler is used to create the tunnel between the port pocket and the venous entry site. After removing the catheter lock and pulling the catheter through the tunnel, the catheter lock must be replaced for proper port-catheter assembly with the catheter fashioned to a 90° angle. It is easier to replace the catheter lock on the catheter if you first cut the port end of the catheter at an acute (45°) angle. Slide the catheter lock over the catheter, then cut the catheter to proper length at a 90° angle.

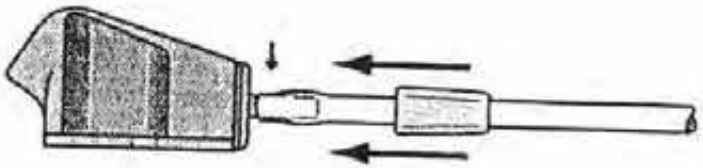
- Cleanse all system components with irrigation solution.
- Trim catheter to proper length allowing sufficient slack for body movement and port connection.

Port to Catheter Connection

- Align port stem with catheter lumen.



- Advance catheter over port stem to midway point.



Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter

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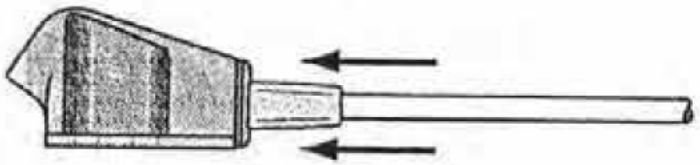
- Advance catheter lock until flush with port.



Note: Once the catheter and lock are connected, should disconnection and reconnection be required, the catheter end must be re-trimmed to ensure a secure connection. It is important to cut the catheter before disconnection and as close the the port stem as possible, as the catheter may be damaged by excessive stretching during the disconnection effort.

- Place **Cath-Link 20** in the subcutaneous pocket with the funnel-shaped entrance facing caudad, and away from the incision line and secure flat base to the underlying fascia using one non-absorbable, monofilament suture per suture hole. This will reduce the risk of port migration and the possibility of it flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.
- After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
- Access **Cath-Link 20** through the skin with an over-the-needle IV catheter.

- Conduct flow studies on the catheter using a 10ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned. Aspirate to confirm the ability to draw blood.
- Flush and heparin lock the port system as described under heparin lock procedure.
- Close the incision site, so that the port does not lie beneath the incision.
- Apply dressing according to hospital practice.

Note: Leave over-the-needle IV catheter in place if Cath-Link 20 is to be used for infusion or aspiration on the same day as implant.

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Indications for use for Bard Access Systems Percutaneous Introducer Systems

The **Bard Access Systems** percutaneous introducer kits are designed for insertion of the indicated catheter of the **B ard Access Systems** Implanted Port, into the vascular system via the axillary-subclavian vein.

Precautions

- Read instructions prior to use.
- Prior to use, inspect kit for inclusion of all components.
- Before beginning the procedure, verify the catheter fits easily through the introducer sheath.
- The **Bard Access Systems** percutaneous introducer system should be used by a physician trained in the technique of percutaneous catheter placement.
- The percutaneous introducer sheath should not remain indwelling without the internal support of a catheter or dilator.
- Simultaneous advancement of sheath and dilator with rotational motion is essential to help prevent sheath damage.

- To assist in locating the subclavian vein, use the Trendelenburg position or elevate the lower extremities.
- Use only forceps with non-serrated jaws or forceps with padding to introduce or insert catheter (to avoid catheter damage).

Warning: Care should be exercised during catheter placement to avoid injury of vital structures. Catheters placed percutaneously should be inserted into the subclavian vein at the point of the outer and middle third of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle which can result in fracture of the catheter. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

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Possible Complications

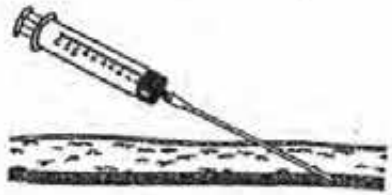
- Air embolus
- Pneumothorax, hemothorax, or hydrothorax
- Hematoma formation
- Brachial Plexus injury
- Catheter occlusion, damage, or breakage due to crimping of the catheter between the clavicle and the first rib
- Perforation or laceration of vessels or viscus
- Vascular thrombosis

Relative Contraindications

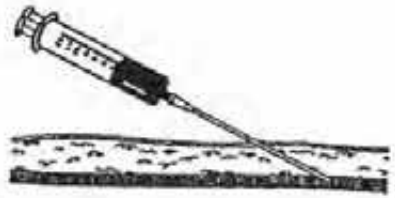
- Severe chronic obstructive lung disease.
- Past irradiation of the tentative insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

Instructions for Use with Intro-Eze™ Percutaneous Introducer System

1. The subclavian vein is entered percutaneously at the point that identifies the outer and middle thirds of the clavicle using the needle and syringe. **CAUTION: If the catheter is inserted into the subclavian vein medially near the articulation of the clavicle with the sternum and the cartilage of the first rib, the catheter could be compressed or pinched, leading to damage or fracture of the catheter.**



2. Aspirate gently as the insertion is made. **If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.**

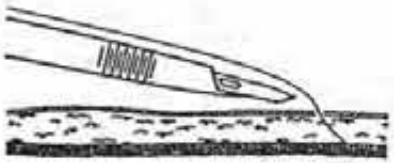


3. When the subclavian vein has been entered, remove the syringe leaving the needle in place. **Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.**

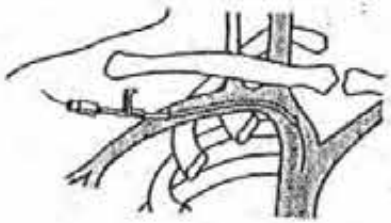
4. Straighten J tip of guidewire with tip straightener and insert tapered end of tip straightener into the needle. Tip straightener should not be advanced over the guidewire beyond the guidewire tip. Advance the guidewire as far as appropriate for the procedure. **Verify correct positioning, using fluoroscopy.**

5. Gently withdraw and remove needle and tip straightener. **Caution: If the guidewire must be withdrawn while the needle is still inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.**

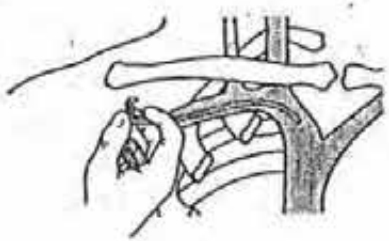
6. Make a small incision parallel to the clavicle with the guidewire at the center of the incision to permit introduction of vessel dilator and sheath introducer.



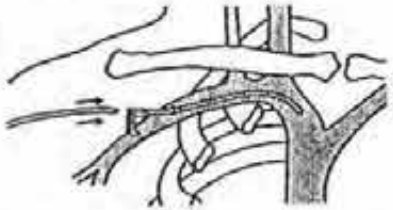
7. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance into the axillary subclavian vein as a unit, leaving approximately 2 centimeters of sheath exposed.



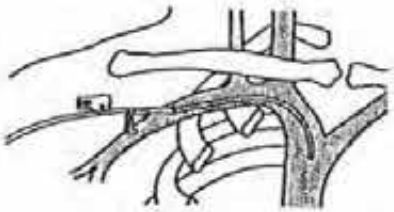
8. Withdraw the vessel dilator and "J" wire, leaving the sheath in place. **Hold thumb over exposed orifice of sheath to prevent air aspiration.** The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.



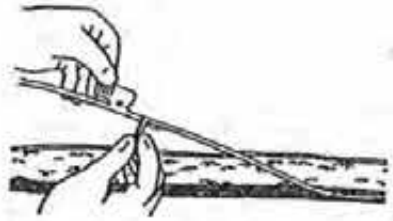
9. Insert catheter into the sheath. Advance the catheter through the sheath and into the vein.



10. Pull the storage tube from the slitter. Place the tubular portion of the slitter onto the catheter near the proximal end of the introducer sheath.



11. Grasp the proximal end of the slitter between the thumb and index finger of one hand. With the tips of the fingers, reach around the slitter and secure the catheter into the tubular portion.

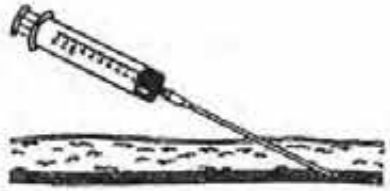


12. Withdraw the sheath over the catheter, sliding the proximal opening of the sheath over the nose of the slitter and into the blade. Continue to withdraw the sheath, pulling it away from the catheter, until it is completely slit. Remove and discard the slit sheath.

13. Follow instruction pages 24 through 28 for completion of placement.

Instructions for Use for Bard Access Systems "Peel-Apart" Percutaneous Introducers

1. The subclavian vein is entered percutaneously at the point that identifies the outer and middle thirds of the clavicle using the needle and syringe. **CAUTION: If the catheter is inserted into the subclavian vein medially near the articulation of the clavicle with the sternum and the cartilage of the first rib, the catheter could be compressed or pinched leading to damage or fracture of the catheter.**



2. Aspirate gently as the insertion is made. **If the artery is entered, withdraw the needle and apply manual pressure** for several minutes. If the pleural space is entered, withdraw needle and evaluate patient for possible pneumothorax.

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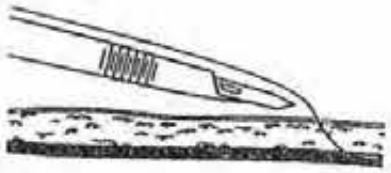
3. When the subclavian vein has been entered, remove the syringe leaving the needle in place. **Place a finger over the hub of the needle to minimize blood loss and risk of air aspiration.** The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

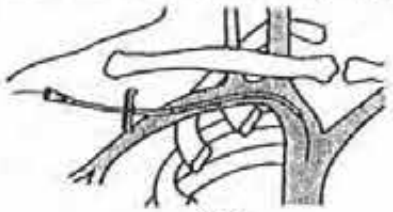
4. Straighten J tip of guidewire with tip straightener and insert tapered end of tip straightener into the needle. Tip straightener should not be advanced over the guidewire beyond the guidewire tip. Advance the guidewire as far as appropriate for the procedure. **Verify correct positioning, using fluoroscopy.**

5. Gently withdraw and remove needle and tip straightener. **Caution: If the guidewire must be withdrawn while the needle is still inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.**

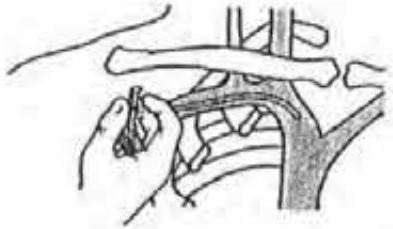
6. Make a small incision parallel to the clavicle with the guidewire at the center of the incision to permit introduction of vessel dilator and sheath introducer.



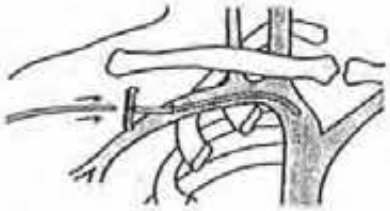
7. Advance the vessel dilator and sheath introducer as a unit, over the exposed wire using a rotational motion. Advance into the axillary-subclavian vein as a unit, leaving approximately 2 centimeters of sheath exposed.



8. Withdraw the vessel dilator and "J" wire, leaving the sheath in place. **Hold thumb over exposed orifice of sheath or gently squeeze sheath body to prevent air aspiration.** The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

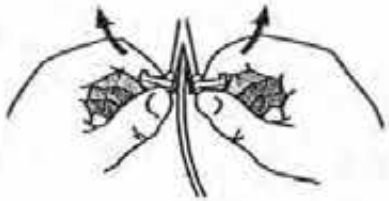


9. Insert catheter into the sheath. Advance the catheter through the sheath and into the vein.



10. Looking at the introducer sheath from above, initiate the handle "break" by rotating the ends toward each other. The handle may also be separated by grasping both ends and pulling them apart.

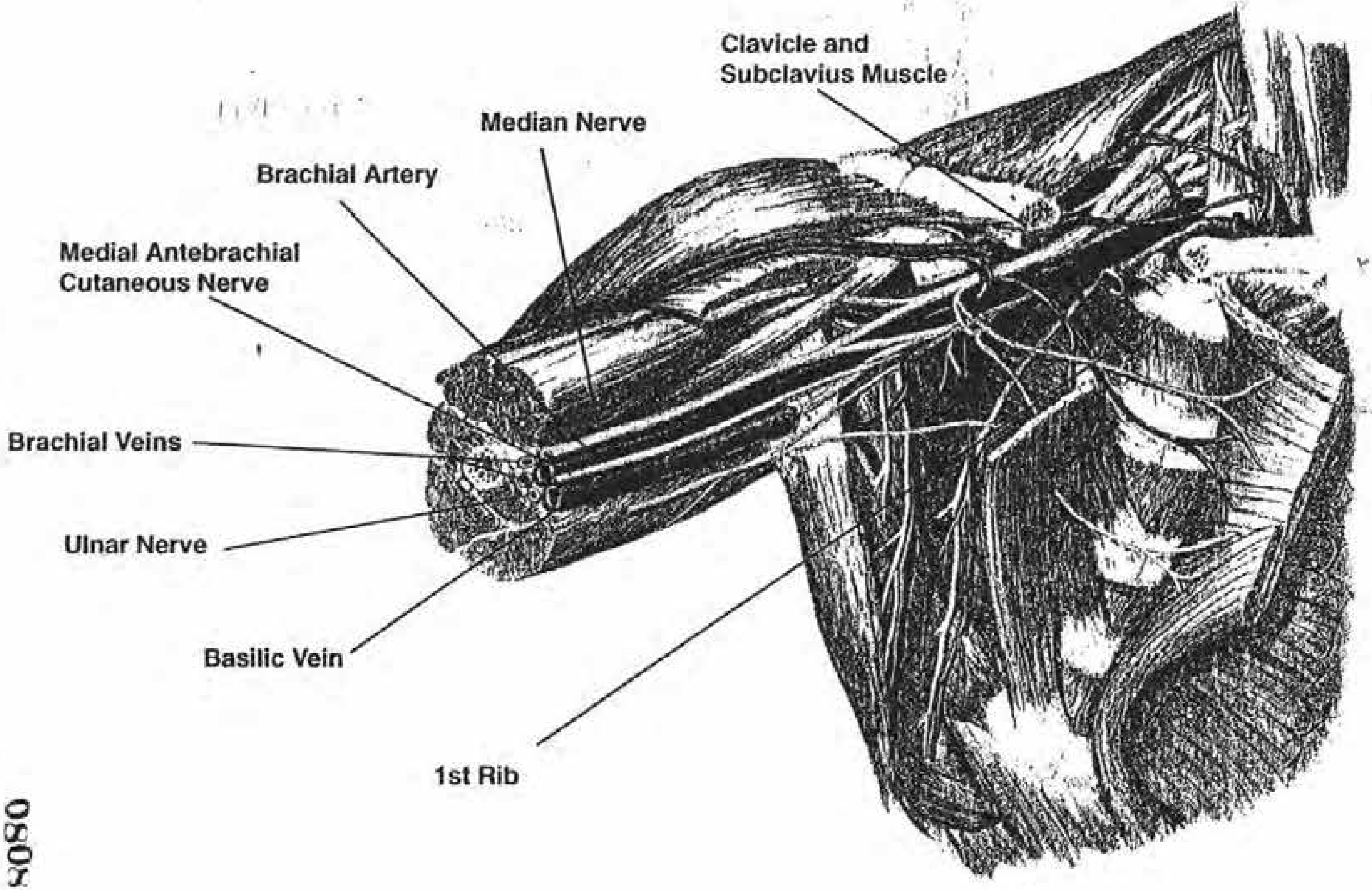
11. With catheter well advanced, remove sheath by rolling handle ends away from each other in a downward direction. This will cause the sheath to tear longitudinally. Continue to peel apart the sheath while withdrawing from the vessel. **(Care must be taken not to withdraw the catheter as the sheath is being removed.)**



12. Follow instructions pages 24 through 28 for completion of placement.

Implantation Instructions
For
Cath-Link 20™
Brachial/Basilic Approach

RELEVANT ANATOMY



IMPLANTATION INSTRUCTIONS

- Complete patient implant record, including product reorder number and lot number.
- Insert an over-the-needle IV catheter in the same upper extremity distal to the proposed Cath-Link 20 venous access site.
- Position the arm in an abducted, externally rotated position.
- Sterilely prep and drape the upper arm and axilla.
- Using flush connector, flush open-ended catheter with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end. **Note:** Catheter should be clamped on segment that will be cut off prior to attachment to port to avoid catheter damage.
- Inject contrast dye into the distal peripheral over-the-needle IV angiocath to allow for visualization of the selected vein under fluoroscopy.
- Using local anesthesia, puncture the brachial or basilic vein at the midpoint of the arm with an 18 gauge thin-wall needle.
- Under fluoroscopic guidance, advance the extra-long guidewire through the needle and into the superior vena cava.
- Make a small incision over the guidewire and remove the needle.

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- Place a 5 Fr dilator over wire into the vein to maintain venous access.
- Make a transverse incision, approximately 2.5cm in length over the port pocket site.
- Create a subcutaneous pocket using blunt dissection.

  Note: Cath-Link 20 should be positioned with the funnel-shaped entrance facing toward the elbow (distal).
- Remove the dilator and advance the catheter over the guidewire.
- Position the catheter tip at the desired infusion site.

  Note: A common location for the catheter tip is the junction of the Superior Vena Cava and right atrium.
- Confirm catheter position via fluoroscopy.
- Remove guidewire, making certain fluoroscopically that the desired catheter tip position is maintained.

  Note: An injection of radiographic contrast may be used for additional visualization.
- Trim catheter at a 90° angle to proper final length allowing sufficient slack for body movement and port connection.

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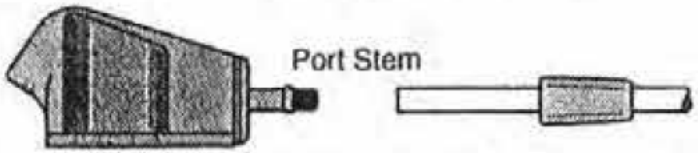
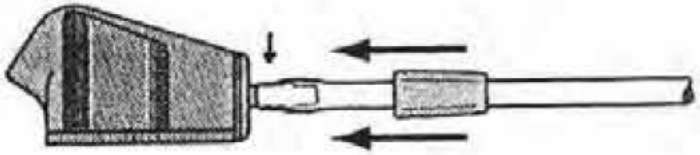
0810

- Port to catheter connection

A. Align port stem with catheter lumen.

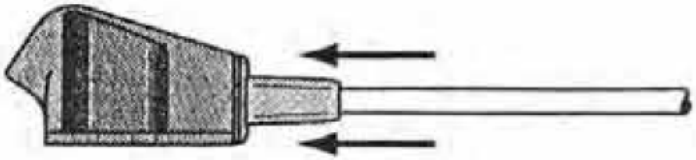


B. Advance catheter over port stem to midway point.



Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

C. Advance catheter lock until flush with port.



Note: If the catheter and lock are connected and then disconnected, the catheter end must be retrimmed prior to reconnection to ensure a secure connection. <u>It is important to cut the catheter before each reconnection</u>, as the catheter may be damaged by excessive stretching during disconnection.

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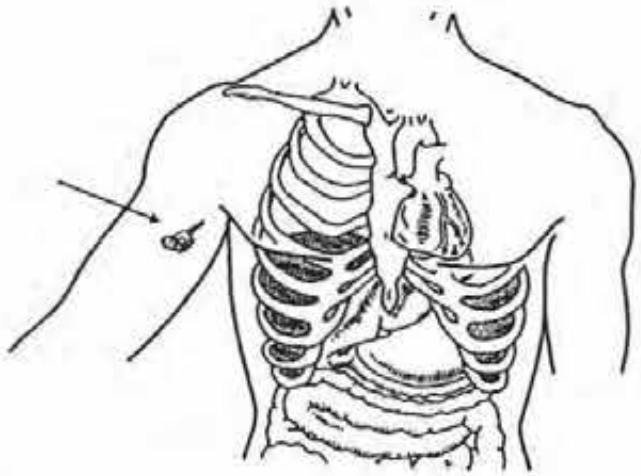
- Place **Cath-Link 20** in the subcutaneous pocket with the funnel-shaped entrance facing toward the elbow (distal), and away from the incision line and secure flat base to the underlying fascia using one non-absorbable, monofilament suture per suture hole. This will reduce the risk of port migration and the possibility of it flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.



- After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
- Access Cath-Link 20 through the skin with an over-the-needle IV catheter.
- Conduct flow studies on the catheter using a 10ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned. Aspirate to confirm the ability to draw blood.
- Flush and heparin lock the port system as described under heparin lock procedure.

- Close the incision site, so that the port does not lie beneath the incision.
- Apply dressing according to hospital practice.

Note: Leave over-the-needle IV catheter in place if Cath-Link 20 is to be used for infusion or aspiration on the same day as implant.

Cath-Link 20™
Implanted Port

Use and Maintenance Instructions

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Site Preparation

Inspection and aseptic preparation of the injection site should always be performed prior to accessing the port.

Equipment:

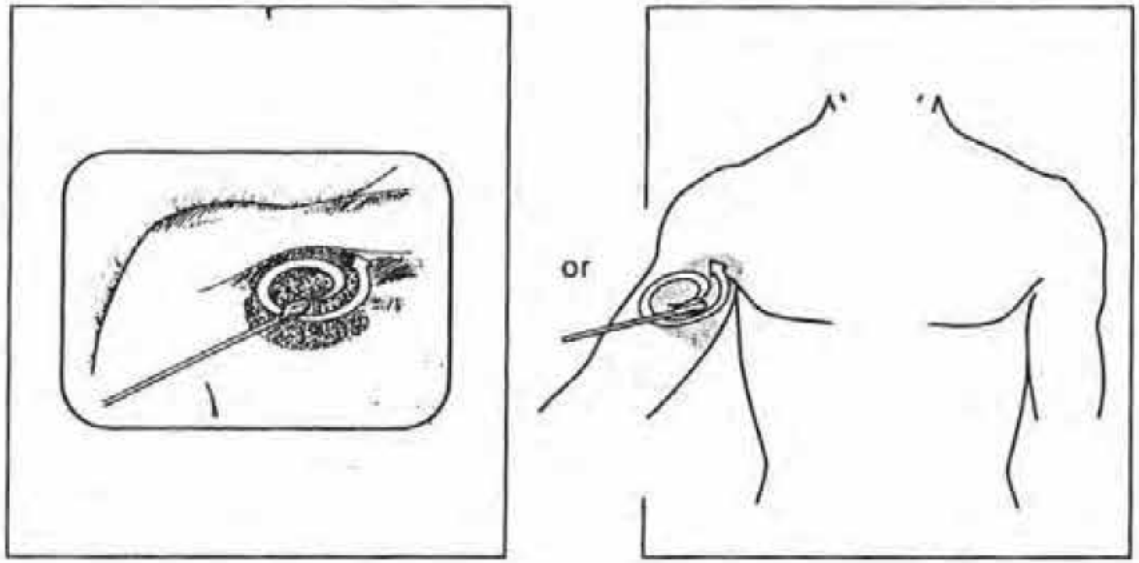
- Sterile gloves
- Alcohol wipe
- Antiseptic swabs (3)

Procedure:

1. Explain procedure to patient. Warn of needle prick sensation.
2. Wash hands thoroughly.
3. Don sterile gloves.
4. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 4-5 inches

4. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 4-5 inches in diameter.

5. Repeat Step #4 with antiseptic swabs three times.



Accessing Cath-Link 20

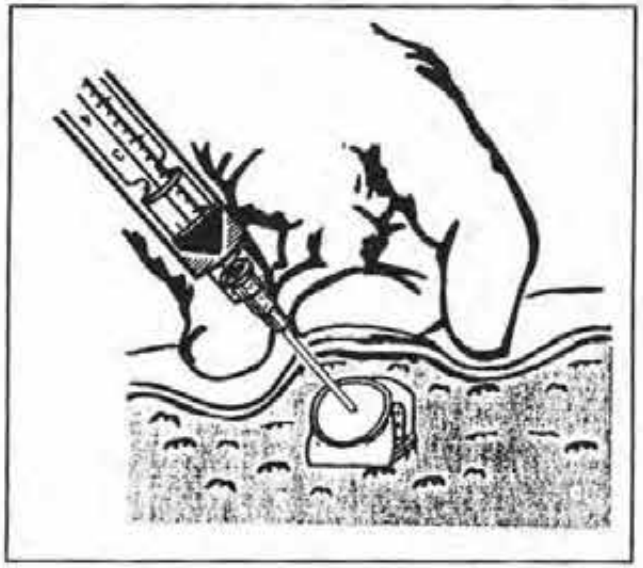
Equipment:

- 20 gauge over-the-needle IV catheter in 1 1/4" minimum length
- 10ml or larger syringes
- Extension Set with Clamp

Procedure:

1. Perform aseptic site preparation.
2. Utilizing a sterile gloved hand:
   - Locate **Cath-Link 20** and identify the funnel-shaped entrance by palpation.

3. Stabilize **Cath-Link 20** by "pinching" between thumb and forefinger of non-dominant hand.



4. Aim for the funnel shaped entrance which is between these two fingers.

5. Insert a 20 gauge over-the-needle IV catheter into the Cath-Link 20 funnel shaped entrance until resistance is felt.

6. Using the thumb and forefinger of dominant hand, advance the over-the-needle IV catheter completely into **Cath-Link 20** by grasping and advancing the catheter hub only, while simultaneously withdrawing the needle.

7. Dispose of the needle according to hospital guidelines.
8. Immediately, attach syringe or extension set to over-the-needle IV catheter.
9. Verify correct over-the-needle IV catheter placement by blood aspiration.
10. Proceed with infusion protocol.
11. The port must be flushed following injection.

11. Perform lock procedure.

Note: It is recommended that the dressing and infusion components be changed every 24-48 hours during infusion therapy.

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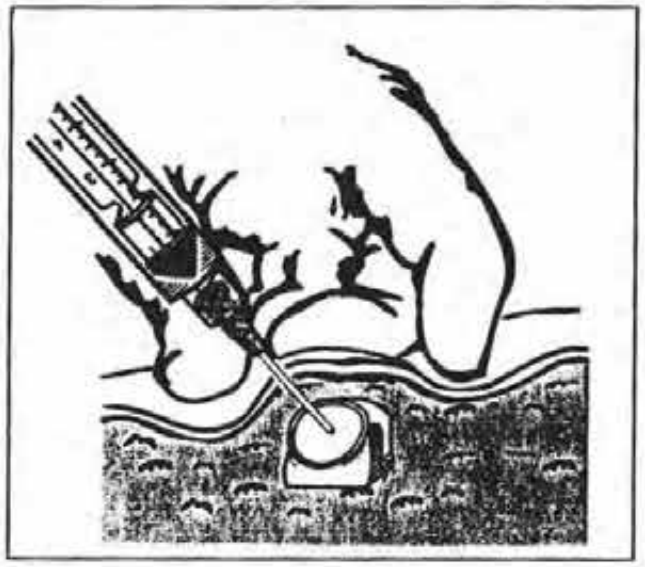
0820

Deaccessing Cath-Link 20

Implanted Ports



To reduce potential for blood backflow into the catheter tip and possible catheter clotting, always remove the over-the-needle IV catheter slowly, while injecting the last .5ml of solution. Stabilize **Cath-Link 20** with two fingers during over-the-needle IV catheter withdrawal.

Bolus Injection

Procedure for Cath-Link 20

Equipment:

- 20 gauge over-the-needle IV catheter in a 1 1/4" minimum length
- 10ml syringe filled with sterile normal saline
- Extension set with clamp

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach 10ml syringe filled with sterile normal saline to extension set. Expel all air and clamp extension.

3. Aseptically locate and access **Cath-Link 20.**
4. Attach extension set and flush port with 10ml sterile normal saline. Clamp the extension set and remove the syringe.
5. Connect syringe containing the drug to extension set. Release clamp and administer injection.
6. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
7. When the injection is completed, clamp the extension set.
8. Flush after each injection with 10ml of sterile normal saline to help prevent interaction between incompatible drugs.
9. Perform heparin lock procedure.

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Note: The over-the-needle IV catheter hub should not be left open to air while it is in the **Cath-Link 20.**

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Continuous Infusion

Procedure for Cath-Link 20

Equipment:

- Prescribed I.V. solution
- Extension set with clamp
- 10 ml syringe filled with sterile normal saline
- 20 gauge over-the-needle IV catheter in 1 1/4" minimum length
- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- Antibacterial ointment
- 2 x 2 gauze pads

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach 10 ml syringe filled with sterile normal saline to extension set. Expel all air and clamp the extension set.
3. Aseptically locate and access **Cath-Link 20**. Attach extension set.
4. Apply antibacterial ointment to injection site. Secure over-the-needle IV catheter with sterile tape strips and transparent dressing to help prevent inadvertent dislodgement.
5. Open clamp and flush **Cath-Link 20** with sterile normal saline. Clamp extension set and remove syringe.
6. Connect fluid delivery system (I.V. set or infusion pump as indicated).

   Note: To provide additional security during pump infusion, tape all tubing connections. Pumps must incorporate a functional automatic pressure limiting switch which will shut pump off before pressure exceeds 25 p.s.i.
7. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.
8. When infusion is completed, clamp extension set and then remove the fluid delivery system.
9. Flush after each infusion with 10 ml sterile normal saline to help prevent interaction between incompatible drugs.

10. Perform heparin lock procedure.

Note: For long-term infusions, longer length over-the-needle IV catheters may be used for added security.

Blood Sampling

Procedure for Cath-Link 20

Equipment:

- 2-way stopcock or extension set with clamp
- 20 gauge over-the-needle IV catheter
- 10ml syringe filled with 5cc sterile normal saline
- 20ml syringe (2)
- Sterile normal saline

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access **Cath-Link 20.**
3. Flush **Cath-Link 20** with sterile normal saline in 10ml syringe.
4. Withdraw at least 5ml of blood and discard syringe.

5. Aspirate desired blood volume into 20ml syringe and transfer it into appropriate blood sample tube.

6. Once sample is obtained, immediately flush the system with 20ml of sterile normal saline.

7. Perform heparin lock procedure.

Procedure for Cath-Link 20

To help prevent clot formation and catheter blockage, **Cath-Link 20** should be filled with sterile heparinized saline after each use. If **Cath-Link 20** remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

Recommended flushing volumes:

FLUSHING VOLUMES	
PROCEDURE	**VOLUME**
Cath-Link 20 not in use	5cc heparinized saline
After each infusion of medication or TPN	10cc sterile normal saline then 5cc heparinized saline
After blood withdrawal	20cc sterile normal saline then 5cc heparinized saline

Equipment:

- 20 gauge over-the-needle IV catheter in 1 1/4" minimum length
- 10ml syringe filled with sterile heparinized saline (100 U/ml)*

*Note: Other concentrations of heparinized saline (10 to 1000 U/ml) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access **Cath-Link 20**.
3. Attach a 10ml syringe filled with sterile heparinized saline to over-the-needle IV catheter.
4. Flush the system. To reduce potential for blood back flow into the catheter tip and possible catheter clotting, always remove the over-the-needle IV catheter slowly. Maintain positive pressure in the system by withdrawing the syringe and over-the-needle IV catheter while injecting the last 0.5ml. Stabilize the port with two fingers during over-the-needle IV catheter withdrawal.

Use of Urokinase for

Catheter Blockage

Use of a fibrinolytic agent such as urokinase has successfully cleared clotted catheters when change of body position and gentle irrigation and aspiration have failed. **The following procedure may be employed on the order of a physician. Additional instructions provided by the drug manufacturer should be followed.**

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Equipment:

- 20 gauge over-the-needle IV catheter in 1 1/4" minimum length
- 10ml syringe containing 2ml of 5,000 u/ml urokinase
- 20ml syringe filled with sterile normal saline.

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Procedure:

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access **Cath-Link 20**. Attach 10ml syringe, void of air and filled with 2ml of 5,000 u/ml urokinase.
3. Gently instill urokinase solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter.

Warning: Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force entire amount into catheter.

4. Leave solution in place for 15 minutes.
5. Attempt to aspirate urokinase and the clot(s).
6. If the clot(s) cannot be aspirated, repeat procedure.
7. Once the blockage has been cleared, flush catheter with at least 20ml of sterile normal saline.
8. Perform heparin lock procedure.

RE-USE OF A BARD ACCESS SYSTEMS MEDICAL DEVICE

Bard Access Systems specialty access products are single use devices and should never be reimplanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. **Any device that has been contaminated by blood should not be reused or resterilized.**

Sterilization Guidelines for Unused Devices:

Ethylene Oxide Sterilization

Only opened, unused trays containing **Bard Access Systems** catheters, ports, tray components and accessories, that do not have **VitaCuff® Antimicrobial Cuffs** may be sterilized once with ethylene oxide.

EtO Concentration	500 milligrams/liter
Relative Humidity	30 - 70%

Temperature	120 - 130° F
Exposure Time	Will vary depending on the type of equipment used. Equipment manufacturer's recommendations should be carefully reviewed and followed along with the proper use of monitors.
Aeration Cycles	Removal of ethylene oxide residuals should be carried out according to the equipment manufacturer's instructions.
Cycle Validation	Cycles and procedures should be validated per hospital procedure.

-1.9.5-

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Warning: An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact **Bard Access Systems** to see if additional product information is available.

Issued date: June 1992

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BARD

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Groshong is a trademark of C.R. Bard, Inc. or an affiliate

Cath-Link 20 is a trademark of C.R. Bard, Inc. or an affiliate

VitaCuff is a registered trademark of Vitaphore Corporation

Patent Nos.: 4,753,640, 4,995,863, other U.S. and Foreign patents pending.

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Rev 917R

Bard Access Systems

Subsidiary of C.R. Bard, Inc.

5425 West Amelia Earhart Drive

Salt Lake City, Utah 84116

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For ordering information call Customer Service: 800/545-0890

For clinical information call: 800/443-3385

8915M

Cath-Link 20™
Implanted Port
With Open-ended Catheter

Implant Record
O.R. File Copy
Titanium Port

Patient Name_____
Product Code_____ Lot Number_____
Implant Site_____ Implant Date_____
Implanting Surgeon_____
***Caution:** Access Only with 20 Ga Over-the-Needle IV Catheter*

Cath-Link 20™
Implanted Port
With Open-ended Catheter

Implant Record
Patient File Copy
Titanium Port

Patient Name_____
Product Code_____ Lot Number_____
Implant Site_____ Implant Date_____
Implanting Surgeon_____
***Caution:** Access Only with 20 Ga Over-the-Needle IV Catheter*

Cath-Link 20™
Implanted Port
With Open-ended Catheter

Implant Record
Titanium Port

Patient Name_____
Product Code_____ Lot Number_____
Implant Site_____ Implant Date_____
Implanting Surgeon_____
***Caution:** Access Only with 20 Ga Over-the-Needle IV Catheter*

Bard Access Systems
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Medical Alert
Identification Card

This patient has
an implanted

Cath-Link 20™
Implanted Port

With Open-end Catheter

Caution: Access only with a 20 Ga
Over-the-Needle IV catheter

Bard Access Systems
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Product
Code
8800000

Cath-Link 20™
Implanted Port

with Intro-Eze™ Percutaneous Introducer System
and Complete Procedural Tray

Kit Contents:

1 Each - Cath-Link 20 Port
1 Each - Catheter, 6 French Chronoflex Single Lumen Open-End, 2.0mm O.D., 1.3mm I.D., 61cm Length
2 Each - Catheter Lock
1 Each - CSR Wrap (30" x 30")
2 Each - Pair Surgical Gloves (Powderless)
1 Each - Fenestrated Drape 38" x 48" (Fenestration: 4" x 8")
4 Each - Towels w/Tape 16" x 13"
2 Each - Self Contained Povidone Prep Sponges
3 Each - Alcohol Swabsticks
10 Each - 4" x 4" Gauze Sponges
1 Each - 25 Ga x 2" Needle for Skin Wheals
2 Each - 18 Ga x 1" Filter Needle for Anesthetic & Saline
2 Each - 20 cc Syringes (Luer Slip) for Anesthetic & Flushing
1 Each - Sharp Cushion
Each - 30 cc Ampule of Lidocaine 1%
1 Each - 18 Ga (TW) x 2.5" Needle for Guidewire Introduction
1 Each - 21 Ga x 2.5" Needle for Vessel Location
1 Each - 3 cc Syringe For Vessel Location
1 Each - 10 cc Syringe (Luer Slip) for Guidewire Introduction
3 Each - 10 cc Ampules of Sterile Saline for Flushing
1 Each - Vein Pick
1 Each - Spring Guidewire .035" x 17 3/4"
1 Each - Spring Guidewire .035" x 35" Coated w/J-tip
1 Each - Mini Scalpel
1 Each - Trocar
1 Each - Scissors
1 Each - Intro-Eze System w/Slitter
1 Each - Needle Holder
2 Each - 3.0 Nylon Suture w/Cutting Needle
1 Each - Betadine Ointment
2 Each - Transparent Dressing (4" x 4 3/4")
1 Each - Instructions for Use
1 Each - Implant Identification Label
1 Each - Patient Identification Label
1 Each - Packet Steri-Strips (1/4" x 1 1/2")
2 Each - 20 Ga 1 1/4" IV Catheters
1 Each - 8" Extension Set with Clamp
1 Each - 5 Fr Dilator
1 Each - 14 Fr Dilator
1 Each - Catheter Flushing Connector

Single Use - Do Not Resterilize
See Inside For Instructions

BARD ACCESS SYSTEMS
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
PHONE: 801-595-0700

Sterile:
Sterile, non-pyrogenic unless package is damaged or open. Sterillized by ethylene oxide.

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

Product
Code
8800010

Cath-Link 20™
Implanted Port

with Percutaneous Introducer
and Complete Procedural Tray

Kit Contents:

1 Each - Cath-Link 20 Port
1 Each - Catheter, 6 French Chronoflex Single Lumen Open-Ended, 2.0mm O.D.,1.3mm I.D., 61cm Length
2 Each - Catheter Lock
1 Each - CSR Wrap (30" x 30")
2 Each - Pair Surgical Gloves (Powderless)
1 Each - Fenestrated Drape 38" x 48" (Fenestration: 4" x 8")
4 Each - Towels w/Tape 16" x 13"
2 Each - Self Contained Povidone Prep Sponges
3 Each - Alcohol Swabsticks
10 Each - 4" x 4" Gauze Sponges
1 Each - 25 Ga x 2" Needle for Skin Wheals
2 Each - 18 Ga x 1" Filter Needle for Anesthetic & Saline
2 Each - 20 cc Syringes (Luer Slip) for Anesthetic & Flushing
1 Each - Sharp Cushion
1 Each - 30 cc Ampule of Lidocaine 1%
1 Each - 18 Ga (TW) x 2.5" Needle for Guidewire Introduction
1 Each - 21 Ga x 2.5" Needle for Vessel Location
1 Each - 3 cc Syringe For Vessel Location
1 Each - 10 cc Syringe (Luer Slip) for Guidewire Introduction
1 Each - Vein Pick
3 Each - 10 cc Ampules of Sterile Saline for Flushing
1 Each - Spring Guidewire .035" x 17 3/4"
1 Each - Spring Guidewire .035" x 35" Coated w/J-tip
1 Each - Mini Scalpel
1 Each - Trocar
1 Each - Scissors
1 Each - Needle Holder
2 Each - 3.0 Nylon Suture w/Cutting Needle
1 Each - Betadine Ointment
2 Each - Transparent Dressing (4" x 4 3/4")
1 Each - Instructions for Use
1 Each - Implant Identification Label
1 Each - Patient Identification Label
1 Each - Packet Steri-Strips (1/4" x 1 1/2")
2 Each - 20 Ga 1 1/4" IV Catheters
1 Each - 8" Extension Set with Clamp
1 Each - 5 Fr Dilator
1 Each - 14 Fr Dilator
1 Each - Catheter Flushing Connector

Single Use - Do Not Resterilize
See Inside For Instructions

BARD ACCESS SYSTEMS
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
PHONE: 801-595-0700

Sterile:
Steril, non-pyrogenic unless package is damaged or open. Sterillized by ethylene oxide.

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

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-567

Product
Code
8800020

Cath-Link 20™
Implanted Port

with Intro-Eze™ Percutaneous Introducer System

Kit Contents:

1 Each - Cath-Link 20 Port
1 Each - Catheter, 6 French Chronoflex Single Lumen Open-Ended, 2.0mm O.D., 1.3mm I.D., 61cm Length
2 Each - Catheter Lock
1 Each - Sheath Introducer with Vessel Dilator
2 Each - Disposable Syringe 18 Gauge x 1"
2 Each - Flexible "J" Guidewire .035" x 17 3/4"
2 Each - Stainless Steel Tunneler
2 Each - Sheath Slitter
2 Each - Introducer Needle 18 Gauge (TW) x 2.5"
2 Each - Extra-Long Guidewire .035" x 35" Coated w/J-tip
2 Each - IV Catheters, 20 Gauge 1 1/4"
2 Each - Catheter Flushing Connector
2 Each - 8" Extension Set with Clamp
1 Each - Vein Pick
1 Each - Instructions for Use
Each - Implant Identification Labels
1 Each - Patient Identification Labels

Single Use - Do Not Resterilize

See Inside For Instructions

BARD ACCESS SYSTEMS
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
PHONE: 801-595-0700

Sterile:
Sterile, non pyrogenic unless package is damaged or open. Sterillized by ethylene oxide.

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

0841

Product
Code
8800030

Cath-Link 20™
Implanted Port

with Percutaneous Introducer

Kit Contents:

1 Each - Cath-Link 20 Port
1 Each - Catheter, 6 French Chronoflex Single Lumen Open-Ended, 2.0mm O.D., 1.3mm I.D., 61cm Length
2 Each - Catheter Lock
1 Each - Sheath Introducer with Vessel Dilator
2 Each - Disposable Syringe 18 Gauge x 1"
1 Each - Flexible "J" Guidewire .035" x 17 3/4"
1 Each - Stainless Steel Tunneler
1 Each - Introducer Needle 18 Gauge (TW) x 2.5
1 Each - Extra-Long Guidewire .035" x 35" Coated w/J-tip
2 Each - IV Catheters, 20 Gauge 1 1/4"
1 Each - Catheter Flushing Connector
1 Each - 8" Extension Set with Clamp
Each - Vein Pick
. Each - Instructions for Use
1 Each - Implant Identification Labels
1 Each - Patient Identification Labels

Single Use - Do Not Resterilize
See Inside For Instructions

BARD ACCESS SYSTEMS
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
PHONE: 801-595-0700

Sterile:
Sterile, non-pyrogenic unless package is damaged or open. Sterillized by ethylene oxide.

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

0842

Product
Code
8800040

Cath-Link 20™
Implanted Port

Kit Contents:

1 Each - Cath-Link 20 Port
1 Each - Catheter, 6 French Chronoflex Single Lumen Open-Ended, 2.0mm O.D., 1.3mm I.D., 61cm length
2 Each - Catheter Lock
2 Each - IV Catheters, 20 Gauge 1 1/4"
1 Each - 8" Extension Set with Clamp
1 Each - Catheter Flushing Connector
1 Each - Vein Pick
1 Each - Instructions for Use
1 Each - Implant Identification Labels
1 Each - Patient Identification Card

Single Use - Do Not Resterilize
See Inside For Instructions

BARD ACCESS SYSTEMS
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
PHONE: 801-595-0700

Sterile:
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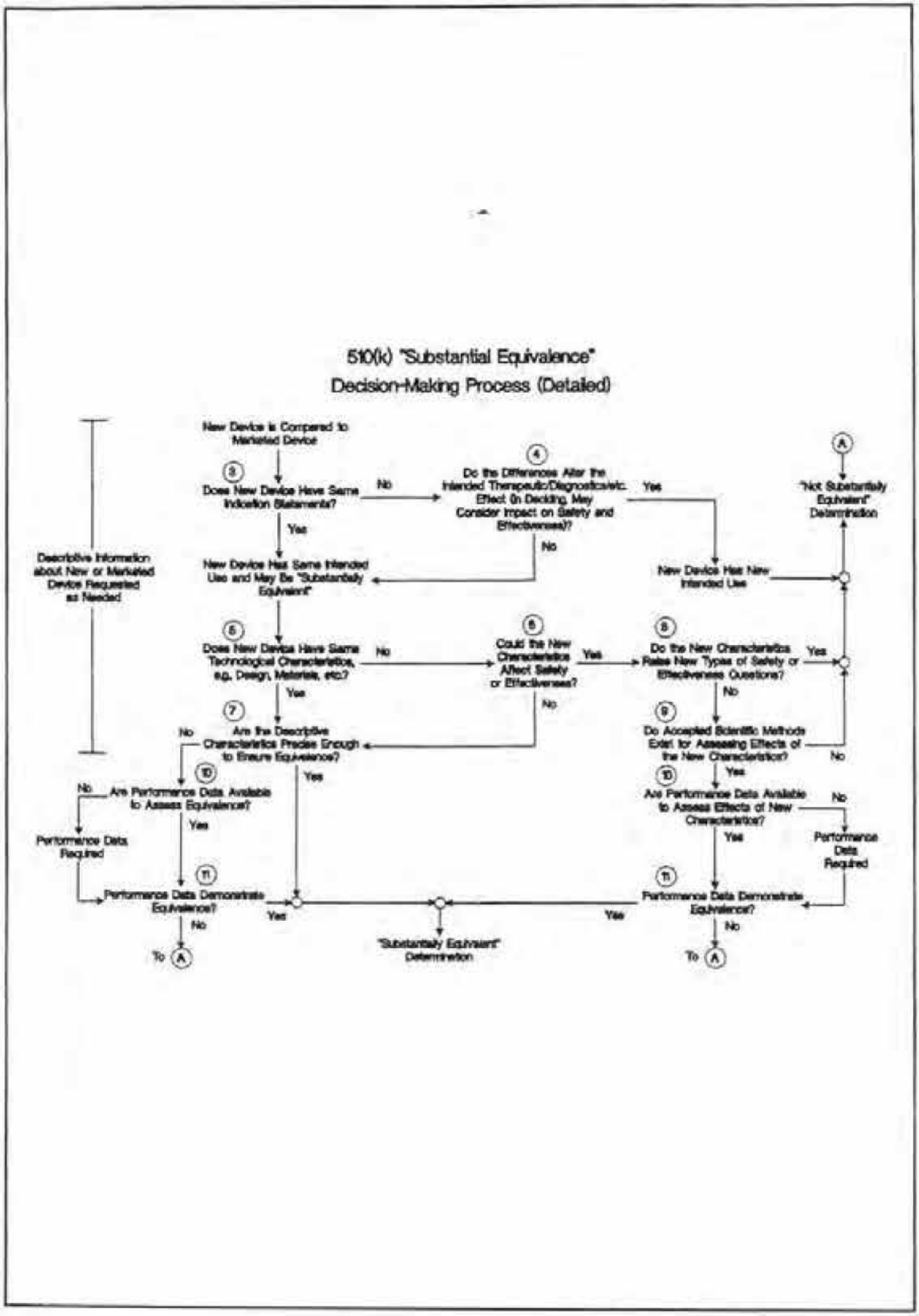
Exh.

12

Exhibit 12



0845