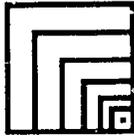


actions of contact of FDA/CDDI/CDC/FDID of CDDI POLITICAL @ fda.gov on 2017-09-11

K791963

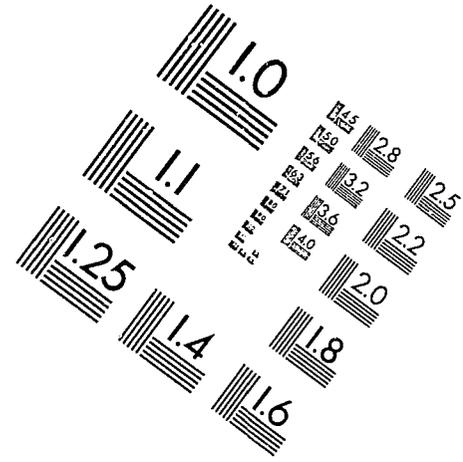
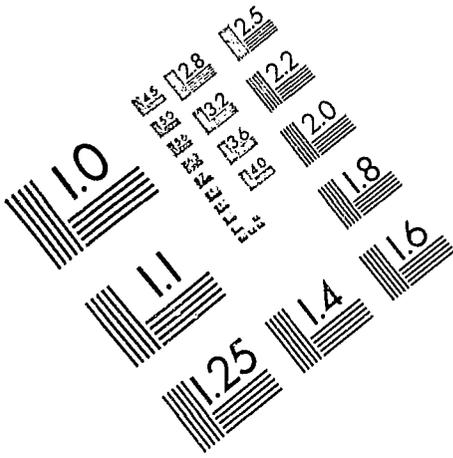
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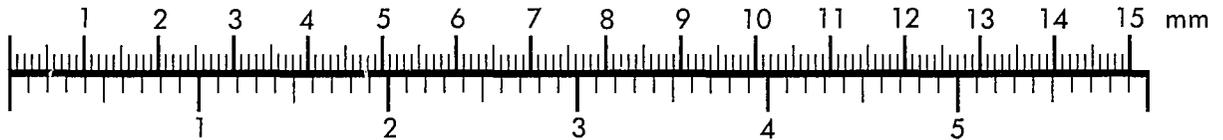


**NATIONAL  
MICROGRAPHICS  
ASSOCIATION**

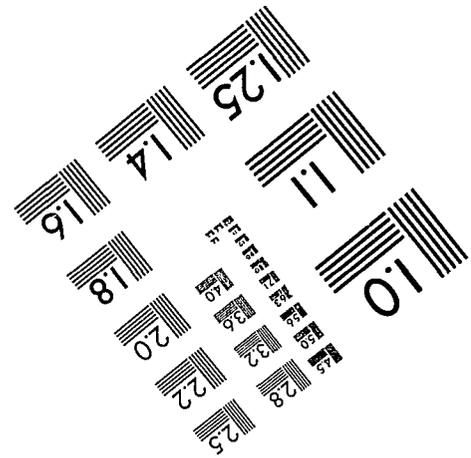
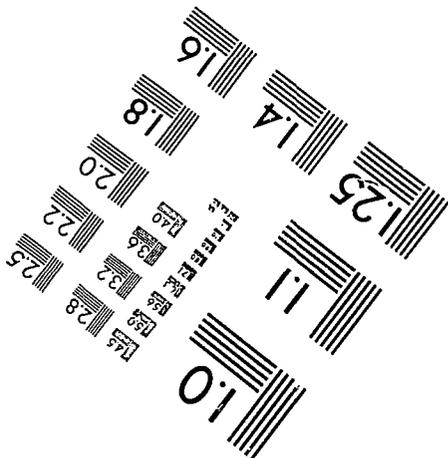
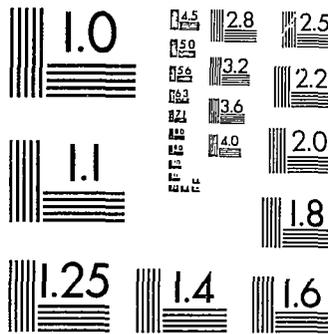
MS303-1980



Centimeter



Inches



K791963

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING, MARYLAND 20910

NOV 13 1979

Mr. Richard A. Flink  
General Counsel  
G.R. Bard, Inc.  
Murray Hill, N.J. 07974

Ref: K791963 - USCI<sup>®</sup> Mullins<sup>™</sup>  
Transseptal Catheter Introducer  
Set

Dear Mr. Flink:

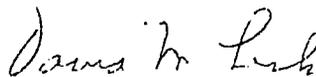
We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Pre-market Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,



David M. Link, Director  
Bureau of Medical Devices



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING, MARYLAND 20910

November 1, 1979

Section : 510(k)  
Number : K791963A  
Received : 10/23/79  
Product : USCIR Mullins<sup>TM</sup>  
Transseptal Catheter

C.R. Bard, Inc.  
ATTN: Richard A. Flink  
Murray Hill, NJ 07974

The supplemental information you have submitted for the referenced device has been received and incorporated with your original submission for processing. Please reference the above document control number in any future correspondence regarding your submission.

We will notify you when processing has been completed or if any further information is required. Questions concerning this submission should be directed to:

Food and Drug Administration  
Bureau of Medical Devices  
Document Control Center (HFK-20)  
8757 Georgia Avenue  
Silver Spring, MD 20910  
(301) 427-7059

Sincerely,

Sharon A. Heil, Chief  
Document Control Center  
Bureau of Medical Devices



Records Processed under FOIA Request # 2015-5319; Released by CDRH on 12-14-2015  
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING, MARYLAND 20910

October 4, 1979

Section : 510(k)  
Number : K791963  
Received : 10/1/79  
Product : USCI<sup>R</sup> Mullins<sup>TM</sup>  
Transseptal Catheter  
Introducer Set

C.R. Bard Inc.  
Murray Hill, N.J. 07974

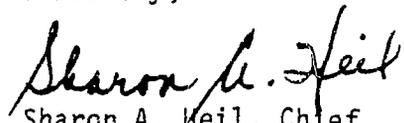
Attn: Granville L. Stevens

The information you have submitted as required by the above Section of the Federal Food, Drug, and Cosmetic Act for the referenced device has been received and assigned a unique document control number. Please cite this number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. Questions concerning this submission should be directed to:

Food and Drug Administration  
Bureau of Medical Devices  
Document Control Center (HFK-20)  
8757 Georgia Avenue  
Silver Spring, MD 20910  
(301) 427-7059

Sincerely,

  
Sharon A. Neil, Chief  
Document Control Center  
Bureau of Medical Devices

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

TO : Robert S. Kennedy, Ph.D.  
HFK-401

DATE:

FROM :

SUBJECT: 510(k) Notification #

K791963 A

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) Is an incomplete submission (see Submission sheet)

*JKE 11/3/79*

Additional Reviewer's Comments

Class Code with Panel # 4D YB (II)

*S W Howard  
10/30/79*

Review:	_____	_____
	Executive Secretary	Date
Final Review:	<u><i>[Signature]</i></u>	<u>11/5/79</u>
	Division Director	Date
Optional Review:	_____	_____
	Assoc. Director for Device Evaluation	Date
Optional Review:	_____	_____
	Bureau Director	Date

510(k) Review

#K 791963 A1

Company Name C R Bard, Inc

Device Name USCI<sup>®</sup> Mullins<sup>TM</sup> Transseptal Catheter

Yes No

- 1. Life-supporting or life-sustaining? Introducer set  Yes  No
- 2. Implant (short-term or long-term)?  Yes  No
- 3. Claims equivalence to USCI<sup>®</sup> Desilets-Hoffman<sup>TM</sup> Percutaneous Catheter Introducer (device name)  Yes  No
- 4. Differs from pre-enactment device how?

The length and size of the transseptal catheter are different from those of the previously marketed catheters.

10/30/79

- 5. If appropriate: provides comparative in vitro data:
- provides a summary of animal testing?
- provides a summary of clinical testing?
- 6. I believe this is equivalent to device # DYB (II)
- I believe this is not equivalent to any pre-enactment device.
- I believe clinical testing is required before a determination can be made.

**C. R. BARD, INC.**



MURRAY HILL, N. J. 07974

HEALTH CARE PRODUCTS

OFFICE OF  
GENERAL COUNSEL



October 18, 1979

Food and Drug Administration  
Bureau of Medical Devices (HFK-20)  
8757 Georgia Avenue  
Silver Spring, MD 20910

RECEIVED  
OCT 22 1979  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE

Re: 510(k) Notification No. K791963  
USCI® Mullins™ Transseptal  
Catheter Introducer Set

Gentlemen and/or Mesdames:

Pursuant to a telephone inquiry from Mr. Shang Hwang on  
October 12, 1979, the following is submitted:

1. Is a spring guide required for the standard percutaneous entry technique?

Response: A spring guide is required for the standard percutaneous entry technique and is identified in Step 3 of the instructions.

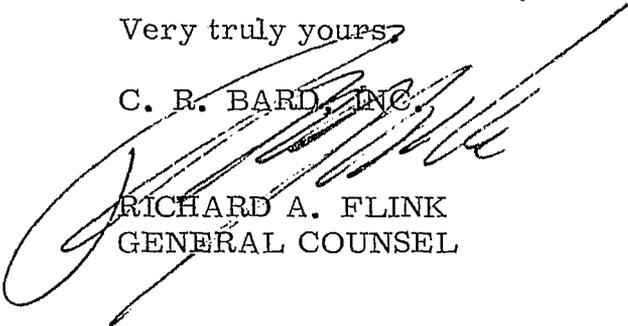
2. If a spring guide is required, what are the sizes, lengths, I.D.'s, etc. for such spring guides?

Response: See attached.

Pursuant to 21 CFR 807.90(c), this letter is being submitted in triplicate and the exhibits hereto in duplicate.

Very truly yours,

C. R. BARD, INC.

  
RICHARD A. FLINK  
GENERAL COUNSEL

RAF:bl  
Enc.

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

USCI® MULLINS™ TRANSSEPTAL CATHETER INTRODUCER SETS

Catalogue Number	French Size	Sheath Length	Dilator Length	Sheath I.D.	Dilator I.D.	Spring Guide O.D.
008530 Pediatric	6 F	17	20	.078	.030	.025
To be assigned Adult	6 F	23	26	.078	.034	.032
008531 Pediatric	7 F	17	20	.091	.030	.025
To be assigned Adult	7 F	23	26	.091	.034	.032
008532 Pediatric	8 F	17	20	.104	.030	.025
To be assigned Adult	8 F	23	26	.104	.034	.032
To be assigned Pediatric	9 F	17	20	.117	.030	.025
To be assigned Adult	9 F	23	26	.117	.034	.032

ALL DIMENSIONS ARE NOMINAL IN INCHES



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING MARYLAND 20910

October 15, 1979

Ref: K791963  
USCI Mullins Transseptal  
Catheter Introducer Set

C. R. Bard, Inc.  
Murray Hill, NJ 07974

ATTN: Granville L. Stevens

We are holding your above-referenced 510(k) submission for 30 days pending receipt of additional information that was requested by this Agency. This information should be submitted in duplicate to:

Food and Drug Administration  
Bureau of Medical Devices  
Document Control Center (HFK-20)  
8757 Georgia Avenue  
Silver Spring, MD 20910

If after 30 days the requested information is not received, your submission will be deleted from our system and returned to you. If you then wish to resubmit this 510(k) notification, a new number will be assigned and acknowledged upon receipt, and the 90-day time period will begin again.

Sincerely,

Sharon A. Heil, Chief  
Document Control Center  
Bureau of Medical Devices

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

TO : Robert S. Kennedy, Ph.D.  
HFK-401

DATE:

FROM :

SUBJECT: 510(k) Notification # K791963

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) Is an incomplete submission (see Submission sheet)

Additional Reviewer's Comments

Class Code  
with Panel # \_\_\_\_\_

Review: \_\_\_\_\_  
Executive Secretary Date

Final Review: \_\_\_\_\_  
Division Director Date

Optional Review: \_\_\_\_\_  
Assoc. Director for Device Evaluation Date

Optional Review: \_\_\_\_\_  
Bureau Director Date

TELEPHONE CONVERSATION

BETWEEN: Richard A. Flink  
General Counsel  
C.R. Bard, Inc.  
Murry Hill, NJ 07974  
201-277-8267

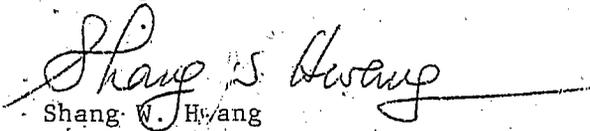
AND: Shang W. Hwang (HFK-450)

DATE: October 12, 1979

SUBJECT: K791963 - USCI Mullins Transeptal Catheter Introducer Set

Mr. Flink returned my earlier call to him.

I asked him to submit more specific information in regarding to the size and the length of both sheath and dilator of this device. I also asked him to submit the information about the size of spring guide to be used with the USCI Transeptal Catheter Introducer set, and how the spring guide should be used in conjunction with this device.

  
Shang W. Hwang

CC: HFK-20  
HFK-450 SWHwang Chron  
HFK-450/SWHwang/tmd/10/12/79

C. R. BARD, INC.



MURRAY HILL, N. J. 07974

HEALTH CARE PRODUCTS

OFFICE OF  
GENERAL COUNSEL

September 26, 1979



RECEIVED  
SEP 27 1979  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE

Food and Drug Administration  
Bureau of Medical Devices (HFK-20)  
8757 Georgia Avenue  
Silver Spring, MD 20910

Re: 510(k) Notification: USCI® Mullins™  
Transseptal Catheter Introducer Set

Gentlemen and/or Mesdames:

K791963

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act and Title 21, Part 807, Subpart E of the regulations promulgated thereunder, C. R. Bard, Inc., is herewith submitting the enclosed Section 510(k) notification for the above-referenced medical device on behalf of its USCI Cardiology & Radiology Products Division.

Pursuant to 21 CFR 807.90(c), the enclosed notification and exhibits are being submitted in duplicate and the covering letter in triplicate. In the event you have any questions or require further information, please contact Richard A. Flink, General Counsel at (201) 277-8267.

Very truly yours,

C. R. BARD, INC.

Granville L. Stevens

GLS:bl  
Attachments  
CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

SECTION 510(k) NOTIFICATION

- (a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device:

USCI® Mullins™ Transseptal Catheter Introducer Set  
(Percutaneous Catheter Introducer Sheath with Dilator)

- (b) The establishment registration number, if available, of the owner or operator submitting the premarket notification submission:

USCI Cardiology & Radiology Products Division  
C. R. Bard, Inc. #1218796

- (c) The class in which the device has been put under Section 513 of the Act and its appropriate panel:

The Cardiovascular Devices Classification Panel and FDA have recommended that percutaneous catheter introducers be placed in Class II. See 44 Federal Register at page 13310, March 9, 1979

- (d) Action taken to comply with the requirements of the Act under Section 514 for performance standards:

USCI will manufacture this device in accordance with the general controls provisions of the Act until an applicable performance standard is adopted by FDA.

- (e) Proposed labels, labeling and advertisements sufficient to describe the device, its intended use and the directions for use:

Attached as Exhibit A is draft labeling including directions for use.

- (f) Statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution:

Please see page two.

The USCI® Mullins™ Transseptal Catheter Introducer Set is indicated for the introduction of certain catheters and temporary pacing catheter electrode probes into the left side of the heart and, as such, is substantially equivalent to at least four percutaneous catheter introducers presently in USCI's line, viz.; the USCI® Desilets-Hoffman™ Percutaneous Catheter Introducer, the "888" Arterial/Venous Catheter Introducer, the Hemaquet™ Introducer, and the "PCI" or Venous Percutaneous Introducer. See Exhibit B for descriptions of these USCI® Introducers. Also, reference is made to FDA 510(k) files K770561, K771982 and K781954 for the USCI® Desilets-Hoffman™, Percutaneous Catheter Introducer, "888" Arterial/Venous Catheter Introducer and USCI® Hemaquet™ Arterial/Venous Catheter Introducer, respectively.

While the USCI® Mullins™ Transseptal Catheter Introducer Set is generally introduced (b) (4)

(b) (4)

(b) (4)

See Brockenbrough, et al., "A New Technic for Left Ventricular Angiocardiology and Transseptal Left Heart Catheterization", The American Journal of Cardiology, December 1960, a copy of which has been attached for your information as Exhibit C.

The USCI® Mullins™ Transseptal Catheter Introducer Set is also substantially equivalent to the USCI® Brockenbrough® and Ross Transseptal Catheters in that they each facilitate transseptal puncture and left heart catheterization. See Exhibit D for information on these two USCI® Catheters.

The USCI® Mullins™ Transseptal Catheter Introducer Set is similar in materials, construction and shape to presently available catheters used in transseptal left heart catheterization as well as those used as percutaneous introducers. ~~The sheath and dilator consist of extruded FEP Teflon material~~ of the same formulation used in other commercially available blood contacting USCI® devices. One primary difference incorporated into the USCI® Mullins™ Transseptal Catheter Introducer Set is that it is longer than the other USCI® Introducers. It differs from the Brockenbrough® and Ross Transseptal Catheters in that the USCI® Mullins™ Transseptal Catheter Introducer Set (b) (4)

(b) (4)

Based upon the foregoing, the USCI® Mullins™ Transseptal Catheter Introducer Set is substantially equivalent to the other USCI® devices described above which were in commercial distribution prior to May 28, 1976.



USCI MULLINS TRANSSEPTAL CATHETER SET  
(Percutaneous Introducer catheter set)

DESCRIPTION:

The set consists of a long teflon sheath and dilator incorporating a curved distal section for positioning against the atrial septum and accommodating the curved USCI Brockenbrough Needle.

INDICATIONS: Intended for introduction of various types of cardiovascular catheters into the left side of the heart.

CONTRAINDICATIONS:

1. Known or suspected left atrial myxoma.
2. Previous systemic embolization from the left side of the heart.
3. Previous intra-atrial septal patch
4. Marked distortion of the thorax configuration, example, kyphosis, scoliosis.
5. Marked right atrial enlargement. *lateral deviation*

TO USE:

1. Perform right side angiography for visualization of the left atrium or recirculation to ascertain size and location of left atrium.
2. Advance the tip of the sheath to the tip of the dilator and measure carefully the distance between the hub of the sheath and the hub of the dilator. This measurement will be necessary later when advancing the Brockenbrough needle.
3. Introduce the USCI Mullins Transseptal Catheter Set using standard percutaneous technique.
4. To minimize potential for air emboli, clear dilator by slowly aspirating blood and then flushing.
5. Advance the dilator and sheath to the superior vena cava using standard Brockenbrough technique (see references).

6. Separate the hubs of the dilator and sheath 1-2cm's by slowly advancing the sheath over the dilator.
7. With the sheath and dilator hubs separated, introduce the USCI® Brockenbrough® Needle into the dilator allowing the needle shaft free mobility as the curved part of the needle passes through the hubs.
8. Withdraw the SHEATH ONLY to reapproximate the sheath and dilator hubs.
9. Slowly advance needle within the dilator to a position where the needle tip is flush or just within the dilator tip in the SVC. (Allow the needle to twist and rotate without resistance as the tip makes its way around bends and deflections in the Inferior Vena Cava).
10. Hook up proximal end of needle to the pressure monitoring system. Make certain that a good pressure is visualized before proceeding.
11. Withdraw the sheath, dilator and needle together into position in the right atrium positioning against the Atrial septum in the region of the fossa ovale using continual pressure monitoring and repeated anterior-posterior and lateral visualization under fluoroscopy.
12. Proceed with Transseptal Puncture. Entry into the left atrium is confirmed by pressure measurement.
13. With a satisfactory Left Atrial pressure continually visualized through the needle, applying firm but not severe pressure, advance the dilator over the needle through the septum. At this point, a sensation of "popping through" will be felt and the dilator is then advanced off of the needle further into the L.A. so that the needle tip is positioned totally within the dilator.
14. With the needle within the dilator and the two positioned freely within the left atrium, the sheath is advanced over the combined needle and dilator into the L.A.
15. When the two hubs are 40+ 5mm's apart (based upon your initial measurements in Step 2), the sheath will be in the L.A.
16. Slowly withdraw the needle out of the dilator.

17. Slowly withdraw the dilator.
18. Attach sheath to the pressure lines and aspirate blood for clearing sheath and a sample.
19. Measure distance of hub of sheath to skin in case future reinsertion of sheath is necessary into L.A.
20. At this point, any type of catheter or electrode may be advanced through the sheath into the L.A. and from there into the L.V., using deflector wires.
21. It is recommended that once the catheter tip is within the L.A. then the sheath may be withdrawn into the R.A. to facilitate further catheter manipulation.
22. If the catheter in the L.A. is to be replaced, the sheath is first readvanced into the L.A. using the skin measurement's previously obtained in Step 17 to be sure of the position.

WARNINGS:

USCI® Mullins Transseptal Catheter Kits are designed for use by physicians engaged in the practice of a specialized branch of medicine. Use of this device should be restricted to those specialists trained to perform transseptal procedures.

PRECAUTIONS:

Careful attention to the directions prior to use will minimize or even eliminate potential dangers associated with the transseptal technique; air embolisms and perforation of the aorta and left atrium. Frequent aspirations and flushing should be performed to minimize potential for air embolisms.

REFERENCES:

1. Brockenbrough, E.C. and Braunwald, E., A New Technique for Left Ventricular Angiocardiography and Transseptal Left Heart Catheterization. American Journal of Cardiology 1062-1064 Dec 1960.

2. Duff, D.F., Mullins, C.E. Transseptal Left Heart Catheterization in Infants and Children. Catheterization and Cardiovascular Diagnosis 4:213-223, 1978.
3. Mullins, C.E., New Catheter, A Technique for Transseptal Left Heart Catheterization in Infants and Children. Abstract. 52nd Scientific Session, A.H.A., Nov. 12-15, 1979\*
4. Neches, W.H., Mullins, C.E., Williams, R.L., Vargo, T.A., McNamara, D.G., Percutaneous Sheath Cardiac Catheterization. American Journal of Cardiology, Volume 30, Sept. 1972.
5. Ross Jr., J. E. Braunwald, and A.G. Morrow. Transseptal Left Atrial Puncture. American Journal of Cardiology P. 663-665 May 1959.
6. Takahashi, M., E. L. Petry, P.R. Lurie, S.E. Kirkpatrick, and R.E. Stanton. Percutaneous Heart Catheterization in Infants and Children: In: Catheter Placement and Manipulation with Guide Wires. Circulation 42: 1037-1048, 1970.

\*Address Reprints requests to C.E. Mullins, M.D., Texas Children's Hospital, 6621 Fannin St., Houston, Texas, 77025

USCI and Brockenbrough are trademarks registered in the U.S. Patent and Trademark Office by C. R. Bard, Inc.

BOX LABEL

USCI<sup>®</sup> MULLINS  
TRANSSEPTAL CATHETER SET

STERILE - NON-PYROGENIC  
UNLESS PACKAGE OPENED  
OR DAMAGED

FOR ONE TIME USE ONLY

Cat. No. 1

SIZE ?  
SHEATH LENGTH  
DILATOR LENGTH  
SHEATH I.D. ?  
DILATOR I.D. ?  
USE O.D. SPRING GUIDE

LOT NO. \_\_\_\_\_

MUST BE STERILE WHEN  
USED. AN ASEPTIC  
TECHNIQUE IS REQUIRED.

CAUTION: FEDERAL (USA)  
LAW RESTRICTS THIS DEVICE  
TO SALE BY OR ON THE  
ORDER OF A PHYSICIAN

CONTENTS 1 SHEATH & DILATOR  
READ DIRECTIONS PRIOR  
TO USE



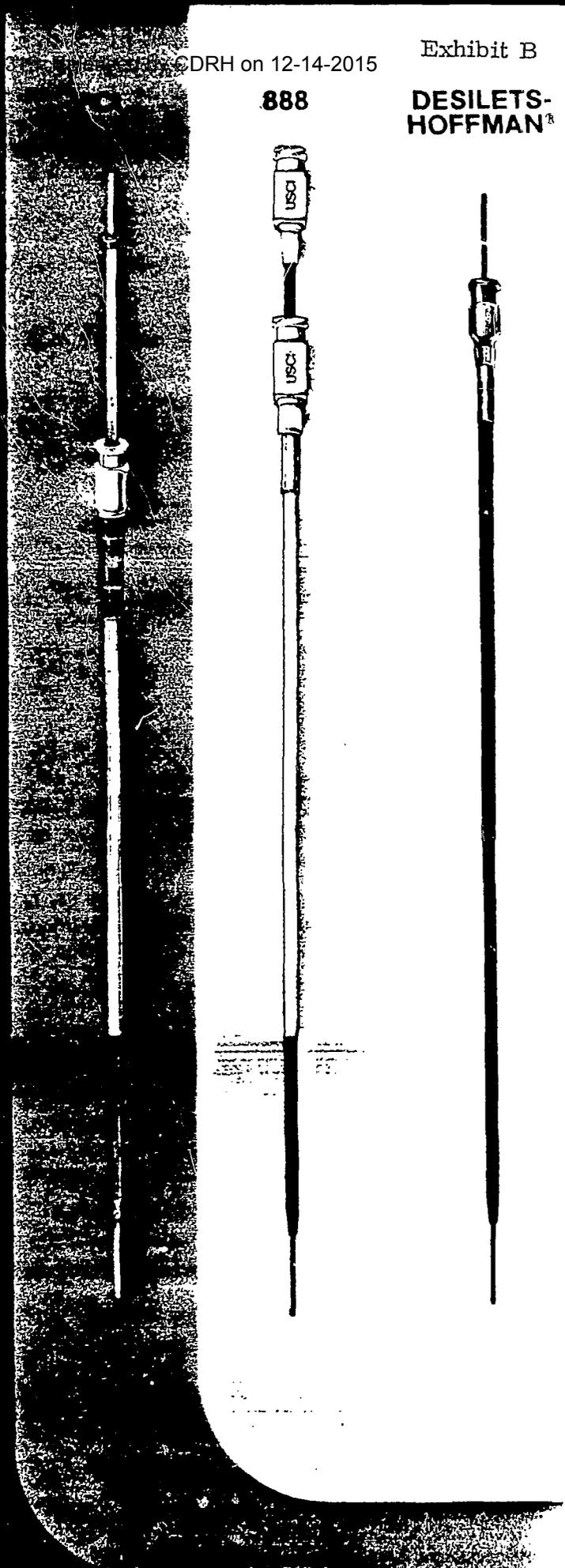
USCI SMITH BLOY & PROLOGIC PRODUCTS  
DIVISION OF B&R BAND INC.  
Billerica, Massachusetts 01821, USA  
800-225-0898



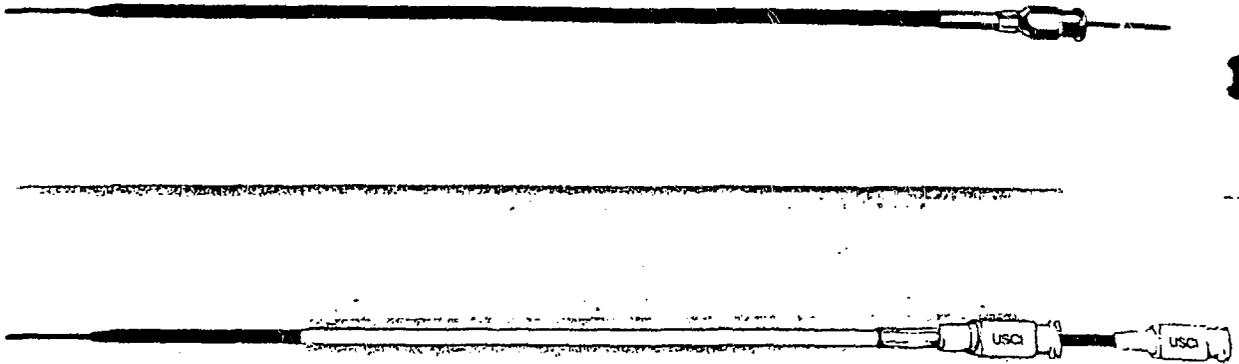
# THE USCI<sup>®</sup> FAMILY OF PERCUTANEOUS CATHETER INTRODUCERS

888

DESILETS-  
HOFFMAN<sup>®</sup>



Questions? Contact FDA/CDRH/OCE/DID at C



• BALLOON CATHETERIZATION • PEDIATRICS • SAMPLING

### **DESILETS—HOFFMAN® PERCUTANEOUS CATHETER INTRODUCER SET**

Filling the need for percutaneous catheter introduction where minimizing puncture size is a prime consideration.

- Multiple French Size Exchange  
Each size fits into the next largest.
- Guaranteed Sterile — Unless package opened or damaged.

### **THE "888" ARTERIAL—VENOUS CATHETER INTRODUCER SET**

The "888" Introducer design combines safety with thin-wall construction. It is well suited for general purpose arterial or venous percutaneous access.

- A Stainless Steel, 45 cm. Spring Guide  
Enhances Safety and Ease of Handling.
- Sheath and Dilator Tip Tapers Spread Tissues Gradually, Reducing Puncture Site Trauma — Increasing Ease of Puncture.
- Guaranteed Sterile — Unless package opened or damaged.

**BEST AVAILABLE COPY**

**DESILETS-HOFFMAN® INTRODUCER**  
 The DESILETS-HOFFMAN® Introducer is used for percutaneous entry of angiography monitoring, balloon, and other cardiovascular catheters into an artery.

- Mylar Sheath — Polyurethane Coating
- TEFLON® Dilator
- Stainless Steel Spring Guide
- Thin Wall Construction Permits Catheter Introduction Without Appreciable Puncture Size Increase in Excess of Catheter Outside Diameter.

**"888" INTRODUCER**

The "888" Introducer is used as an intermediate introducer for arterial or venous entry.

- TEFLON® Sheath
- TEFLON® Dilator
- Stainless Steel Spring Guide
- Intermediate Wall Construction Offers a Broad Range of Applications and Techniques Versatility and Safety in One Instrument.

**PCI INTRODUCER**

The PCI Introducer is a thick-walled introducer designed for venous access.

- TEFLON® Sheath
- TEFLON® Dilator
- Stainless Steel Spring Guide
- Thick Wall Construction — Resists Puncture
- This Catheter Introducer Wall Withstands the Rigors of the Toughest Applications

**• INTERVENTIONAL RADIOLOGY • ARTERIOGRAPHY • MONITORING**

**VENOUS PERCUTANEOUS CATHETER INTRODUCER SET**

The PCI Introducer design permits a high degree of structural strength and does not usually require internal support. The integral wall strength sufficiently resists compressive forces of most applications.

- Guaranteed Sterile — Unless package opened or damaged.

DESILETS-HOFFMAN®  
 PERCUTANEOUS  
 CATHETER  
 INTRODUCER  
 SET

ITEM NUMBER	FRENCH SIZE	SPRING GUIDE O.D.
007162	4F	.025"
007163	5F	.035"
007164	6F	.038"
007165	7F	.038"
007166	8F	.038"
007167	9F	.038"

Spring Guide 35 cm.; Dilator 21 cm.; Sheath 9.5 cm.

"888"  
 ARTERIAL-VENOUS  
 CATHETER  
 INTRODUCER  
 SET

008884	4F	.025"
008885	5F	.035"
008886	6F	.035"
008887	7F	.038"
008888	8F	.038"
008889	9F	.038"

Spring Guide 45 cm.; Dilator 25 cm.; Sheath 12.5 cm.

VENOUS  
 PERCUTANEOUS  
 CATHETER  
 INTRODUCER  
 SET

007865	5F	.035"
007866	6F	.038"
007867	7F	.038"
007868	8F	.038"

Spring Guide 45 cm.; Dilator 30 cm.; Sheath 13 cm.

**INDICATIONS: (DESILETS—HOFFMAN\*)**

The DESILETS—HOFFMAN\* Catheter Introducer set is used for initial percutaneous introduction of a closed end catheter temporary pacing catheter electrode probe or balloon catheter into an artery or vein. The DESILETS—HOFFMAN\* Introducer is radiopaque and packaged sterile. The DESILETS—HOFFMAN\* Introducer may also be used as an instrument for the exchange of catheters during a procedure.

**CAUTION:** FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

**CAUTION:** DO NOT RESTERILIZE BY RADIATION OR FLASH AUTOCLAVE

**CAUTION:** AT NO TIME SHOULD SPRING GUIDE BE ADVANCED OR WITHDRAWN WHEN RESISTANCE IS MET WITHOUT DETERMINING CAUSE BY FLOUROSCOPIC EXAMINATION

**CAUTION:** DO NOT WITHDRAW SPRING GUIDE BACK INTO METAL NEEDLE CANNULA — SHEARING OF THE GUIDE MAY RESULT ALWAYS REMOVE CANNULA FIRST

**CAUTION:** SIMULTANEOUS ADVANCEMENT OF THE SHEATH AND DILATOR WITH A ROTATING MOTION IS ESSENTIAL TO PREVENT SHEATH DAMAGE

**CAUTION:** DESILETS—HOFFMAN\* SHEATHS SHOULD NOT REMAIN INDWELLING WITHOUT INTERNAL SUPPORT OF A CATHETER OR DILATOR

**RECLEANING AND RSTERILIZATION:** Contents of each package are sterile unless opened or damaged. Recommended disposable one time use only. If contents become contaminated before use resterilize sheath and spring guide by steam (250°F 15psi 15 minutes) or gas (ETO). Use procedures recommended by sterilization equipment manufacturer including aeration procedure.

**CAUTION:** STERILIZE TEFLON\* DILATOR IN STEAM AUTOCLAVE (250°F 15psi 15minutes. **DO NOT ETO STERILIZE.**

**REFERENCES**

"A New Method of Percutaneous Catheterization" by Donald T Desilets M.D. and Richard Hoffman M.D. RADIOLOGY Volume 65 July 1965 pages 147-148

"Percutaneous Sheath Cardiac Catheterization" by W.H. Neches M.D. et al. Dept. of Pediatric Cardiology Baylor College of Medicine and Texas Children's Hospital Houston Texas

**INDICATIONS: ("888" ARTERIAL—VENOUS) CATHETER Introducer)**

The radiopaque "888" ARTERIAL—VENOUS CATHETER Introducer is an instrument used for initial introduction of a non-percutaneous catheter temporary pacing catheter, electrode probe, or balloon catheter into an artery or vein. The "888" ARTERIAL—VENOUS CATHETER Introducer may also be used as an instrument for the exchange of catheters during a procedure.

**CAUTION:** FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

**CAUTION:** DO NOT RESTERILIZE SHEATH OR DILATOR BY AUTOCLAVE RADIATION OR ETHYLENE OXIDE GAS

**CAUTION:** AT NO TIME SHOULD GUIDE BE ADVANCED OR WITHDRAWN WHEN RESISTANCE IS MET WITHOUT DETERMINING CAUSE BY FLOUROSCOPIC EXAMINATION

**CAUTION:** DO NOT WITHDRAW THE SPRING GUIDE BACK INTO CANNULA AS THIS MAY RESULT IN SHEARING OF THE GUIDE ALWAYS REMOVE THE CANNULA FIRST

Recommended for one-time use only

Contents of each package is sterile unless opened or damaged

**INDICATIONS: (VENOUS PCI)**

The radiopaque VENOUS PERCUTANEOUS CATHETER Introducer is an instrument used for initial introduction of a non-percutaneous catheter temporary pacing catheter electrode probe or balloon catheter into a vein. The VENOUS PERCUTANEOUS CATHETER Introducer may also be used as an instrument for the exchange of catheters during a procedure.

**CAUTION:** FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

**CAUTION:** DO NOT FLASH AUTOCLAVE OR RESTERILIZE BY RADIATION

**CAUTION:** AT NO TIME SHOULD SPRING GUIDE BE ADVANCED OR WITHDRAWN WHEN RESISTANCE IS MET WITHOUT DETERMINING CAUSE BY FLOUROSCOPIC EXAMINATION

**CAUTION:** DO NOT WITHDRAW THE SPRING GUIDE BACK INTO CANNULA AS THIS MAY RESULT IN SHEARING OF THE GUIDE ALWAYS REMOVE THE CANNULA FIRST

Recommended disposable one time use only. If contents become contaminated before use sterilize by steam (250°F 15psi 15 minutes)

Contents of each package is sterile unless opened or damaged

**CAUTION:** STERILIZE TEFLON\* SHEATH AND DILATOR IN STEAM AUTOCLAVE ONLY (250°F, 15 PSI, 15 MINUTES) DO NOT STERILIZE IN ETHYLENE OXIDE GAS

USCI and DESILETS—HOFFMAN are trademarks registered in the U.S. Patent and Trademark Office by C.R. BARD, Inc.

\* TEFLON is a registered trademark of E.I. DuPont de Nemours & Co., Inc.



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TWX 710-347-1823

Metropolitan Boston 729-6560

TELEX 94-71-20

Massachusetts 667-2511 (call collect)

**DRAFT**

# HEMAQUET™

## ARTERIAL/VENOUS CATHETER INTRODUCER

RADIOPAQUE

STERILE  
Contents sterile unless  
package is opened or  
damaged

Do not resterilize

CATALOG NO.	SIZE	USABLE LENGTH	LOT NO.
88841	MAXIMUM O.D. OF INTRODUCER SHEATH WILL ACCEPT	12.5cm (5")	

USCI, A DIVISION OF C. R. BARD, INC.

BILLERICA, MASS. 01921, U.S.A.

DISPOSABLE  
For one time use only

CONTAINS  
One Introducer  
- Sheath  
- Dilator  
- Spring Guide

FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO  
SALE BY OR ON THE ORDER OF A PHYSICIAN.

IMPORTANT: READ THIS INSERT INCLUDING INSTRUCTIONS ON REVERSE SIDE PRIOR TO USE.

### INDICATIONS FOR USE:

The HEMAQUET™ ARTERIAL/VENOUS CATHETER INTRODUCER (consisting of a sheath, dilator, and spring guide) is recommended for initial percutaneous introduction of a closed end catheter, temporary pacing catheter electrode probe or balloon catheter. The HEMAQUET Introducer may also be used as an instrument to exchange catheters during a procedure. To introduce a balloon catheter via a HEMAQUET Introducer, consult the catheter manufacturer's instructions for recommended introducer size. In general, the HEMAQUET Introducer Set chosen will be one or two french sizes larger than the french size of the balloon catheter. The HEMAQUET Introducer incorporates a gasket seal assembly on the proximal end to prevent blood loss during introduction of a one size smaller catheter shaft.

### CAUTIONS:

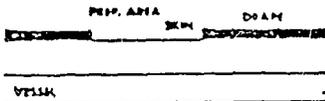
- At no time should Introducer and/or spring guide be advanced or withdrawn when resistance is met without determining cause by fluoroscopic examination.
- When using metal needle cannula, do not withdraw spring guide back into cannula as shearing of the guide may result. Always remove cannula first.
- HEMAQUET Introducer sheaths should not remain indwelling without internal support of a catheter, electrode or dilator.
- Aspiration of all air from the HEMAQUET Introducer is essential prior to infusion through the side port or introduction of a catheter.
- A continuous drip under pressure is required through the side port when the HEMAQUET Introducer is left in the vessel. Aspiration is also recommended on withdrawal of the catheter, probe, or dilator used to remove any fibrin deposition which may have accumulated in or on the tip of the sheath.

USCI is a trademark registered in the U. S. Patent and Trademark Office by C. R. Bard, Inc.

HEMAQUET is a trademark of C. R. Bard, Inc.

**DRAFT**

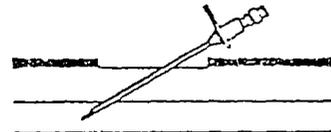
**INSTRUCTIONS**  
Inspect all components prior to use.



1. Prep and drape skin as desired for regular percutaneous puncture.

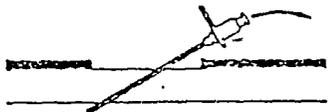


2. Inject local anesthetic as desired.



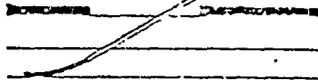
3. Insert 18 gauge (thin wall) puncture needle into vessel.

with cannula



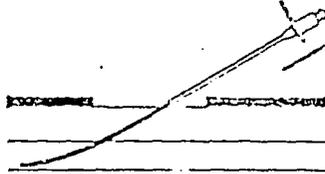
4. Remove inner stylet so that blood flows freely.

Fill assembly with fluid.

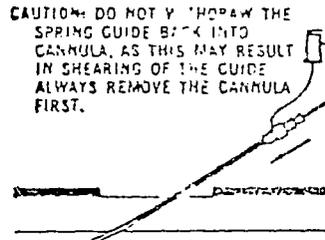


5. Insert short spring guide, flexible end first, through cannula into vessel.

CAUTION: AT NO TIME SHOULD SPRING GUIDE BE ADVANCED OR WITHDRAWN WHEN RESISTANCE IS MET WITHOUT DETERMINING CAUSE BY FLUOROSCOPIC EXAMINATION.



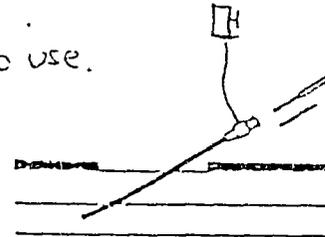
6. Remove cannula or guide. Apply pressure to the puncture site. The puncture site is removed and prior to inserting the catheter.



CAUTION: DO NOT YANK THE SPRING GUIDE BACK INTO CANNULA, AS THIS MAY RESULT IN SHEARING OF THE GUIDE. ALWAYS REMOVE THE CANNULA FIRST.

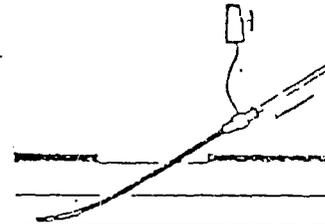
7. Advance spring guide and thin-walled sheath together, over spring guide, and into vessel. CAUTION: SIMULTANEOUS ADVANCEMENT OF SHEATH AND DILATOR WITH A ROTATING MOTION IS RECOMMENDED TO PREVENT SHEATH DAMAGE.

IS RECOMMENDED



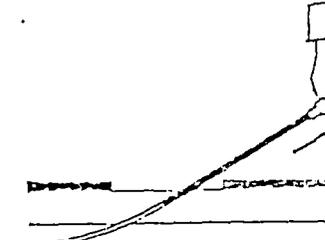
8. Pull sheath back to catheter hub or leave in vessel as desired.

slowly remove dilator and spring guide



9. Insert catheter or electrode through sheath and into vessel.

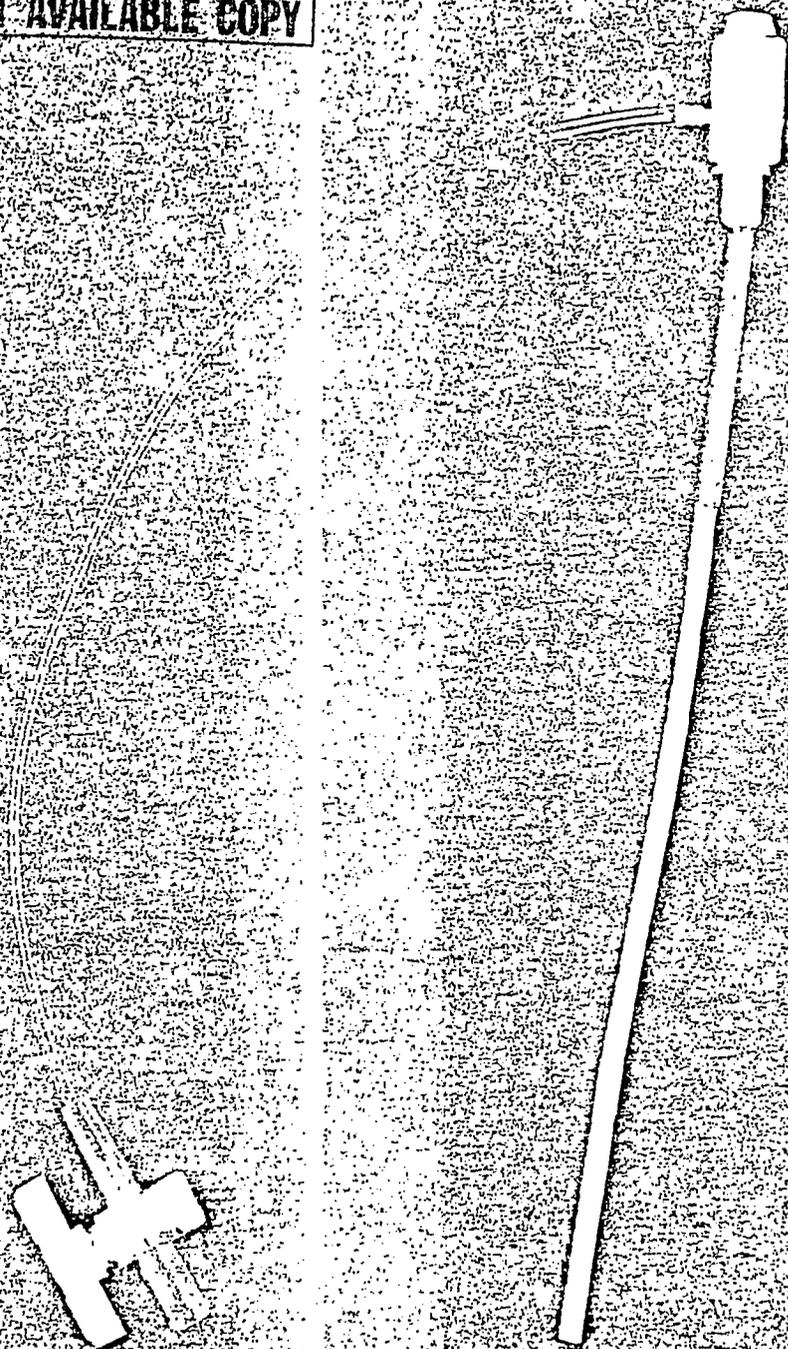
Connect a syringe to the side port assembly. Aspirate all air from the intraluminal and close stopcock. Attach an anticoagulant solution line to the side arm and open stopcock.



10. Pull sheath back to catheter hub or leave in vessel as desired.

insert dilator

**BEST AVAILABLE COPY**





# A New Technic for Left Ventricular Angiocardiography and Transseptal Left Heart Catheterization\*

EDWIN C. BROCKENBROUGH, M.D. and EUGENE BRAUNWALD, M.D.

Bethesda, Maryland

**E**XPERIENCES with transeptal left heart catheterization in 300 patients at the National Heart Institute have demonstrated the advantages of this approach in comparison to other methods of left heart catheterization.<sup>1-4</sup> Although a modified transeptal needle has been employed for left atrial angiocardiography,<sup>5</sup> it had previously not been possible to carry out selective left ventricular angiocardiography, a procedure of considerably greater clinical importance. Accordingly, efforts have been directed toward extending the usefulness of transeptal left heart catheterization by modifying the procedure so as to permit selective left atrial or left ventricular angiocardiography. A technic which would permit the transeptal passage of a flexible radiopaque catheter of sufficient caliber to permit angiocardiography would also provide a better frequency response than the small polyethylene catheter previously employed, as well as means for sampling blood from the left ventricle. Finally, the use of a percutaneous technic for introducing such a catheter would obviate the necessity for exposing and ligating the saphenous vein. The present report constitutes a brief description of this new technic and of our initial clinical experiences with it.

## METHOD

Percutaneous puncture of the right femoral vein is carried out with a #16 gauge needle. A flexible coiled spring guide wire is then passed into the vein through the needle, in the manner described by Seldinger,<sup>6</sup> following which the needle is removed. A radiopaque

polyethylene catheter,† 70 cm. in length, with an internal diameter of 1.15 mm. and an outer diameter of 2.30 mm., and with the curvature of the distal end preset as in Figure 1A, is introduced over the guide wire and advanced well into the femoral vein. The guide wire is then withdrawn. In order to straighten out the loop and to facilitate placing the catheter in the right atrium, a stylet made of 19 gauge hypodermic tubing, 5 mm. shorter than the catheter (Fig. 1B), is inserted into and advanced with the catheter. After the catheter is positioned in the right atrium, the stylet is replaced by a 19 gauge transeptal needle, 71 cm. in length (Fig. 1C).

When the catheter and needle have been correctly positioned against the interatrial septum in the region of the fossa ovale, puncture of the septum is carried out by advancing the needle tip in the manner previously described<sup>5</sup> (Fig. 1E). Entry into the left atrium is confirmed by pressure measurements and the free withdrawal of oxygenated blood. The catheter, its end tapered to facilitate passage across the interatrial septum (Fig. 1D), is then advanced with the needle until both lie within the left atrium (Fig. 1F). With the needle held in place, the catheter is then slipped over the end of the needle and with the aid of the preset curvature of the distal end, is directed into the left ventricle (Fig. 1G). The needle may then be completely withdrawn (Fig. 2) and an adapter attached to the free end of the catheter. Left ventricular pressure is recorded from the catheter. Selective left ventricular angiocardiography may also be carried out, or by withdrawing the catheter the radiopaque dye may be injected into the left atrium. Upon completion of the study the catheter is withdrawn and gentle pressure is applied to the point of

† Odman-Ledin, supplied by Picker X-ray Corp. Cat. No. 17.887-2.

\* From the Clinic of Surgery, National Heart Institute, Bethesda, Maryland.

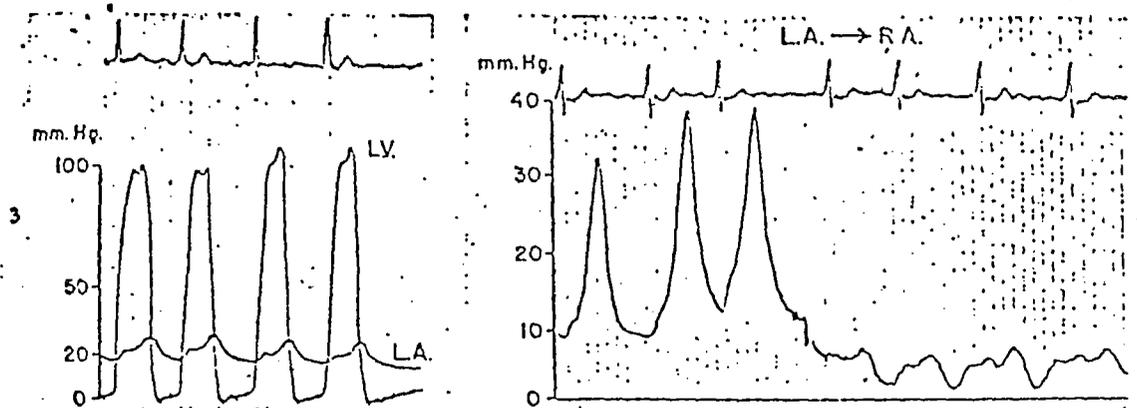


Fig. 3. Simultaneous left atrial and left ventricular pressures obtained in a patient with mitral stenosis and atrial fibrillation. The left atrial pressure was obtained by transeptal puncture and the left ventricular pressure by percutaneous puncture through the anterior chest wall.

Fig. 4. Pressure tracing obtained as the needle was withdrawn from the left atrium (L. A.) across the interatrial septum into the right atrium (R. A.) in a patient with mitral regurgitation.

dissection. The effects of exercise can be determined by pedaling of the ergometer with the opposite leg. The ultimate safety of the technique and the frequency with which the left atrium may be entered must be determined by further clinical studies.

Preliminary experiences with a 17-gauge needle indicate that the left ventricle and aorta may be catheterized by a second smaller catheter passed through it. The experimental studies have also indicated that the larger needle may provide a useful route for selective left atrial angiocardiology.

#### SUMMARY

A new method for the measurement of left atrial pressure in man is described. In 13 patients the interatrial septum was punctured by means of a flexible needle passed through a cardiac catheter which had been introduced

from the saphenous vein and positioned with its tip against the fossa ovalis. No complications were observed after the procedures. The advantages of the technique and its present and projected usefulness are discussed.

#### REFERENCES

1. Ross, J., Jr.: Catheterization of the left heart through the interatrial septum: A new technique and its experimental evaluation. *Surg. Forum* 9: 297, 1959.
2. Ross, J., Jr.: Transeptal left heart catheterization: A new method of left atrial puncture. *Ann. Surg.* 149: 325, 1959.
3. Brock, R., Milstein, E. R., and Ross, D. H.: Percutaneous left ventricular puncture in the assessment of aortic stenosis. *Throm* 11: 163, 1956.
4. Sanders, R. J. and Morrow, A. G.: The diagnosis of circulatory shunts by the nitrous oxide test: Improvements in technic and methods for quantification of the shunt. *Circulation* 18: 856, 1958.

control, the catheter and needle were advanced together until resistance was encountered at the interatrial septum. With the catheter held stationary, the needle was then pushed forward its remaining length of 15 mm through the interatrial septum and into the left atrium (Fig. 2). The position of the needle was verified by visual comparison of blood samples obtained from two atria as well as by the pressure pulse observed on the oscilloscopic screen.

**RESULTS**

In the 13 patients in whom entry into the left atrium was achieved, the initial puncture was successful. Arrhythmias at the time of puncture were not observed. During the entire procedure the patients gave evidence of no more discomfort than that ordinarily experienced during right heart catheterization. In two additional patients, both with grossly enlarged right atria, the left atrium could not be entered, and right heart catheterization alone was performed. No complications were observed in any patient during or following the procedure.

The right ventricular nitrous oxide tests performed immediately before and after septal puncture were all negative.<sup>4</sup>

A typical left atrial pressure pulse contour recorded through the needle in a patient with mitral stenosis is shown in Figure 3. The simultaneous left ventricular pressure was obtained by anterior thoracic puncture. In some patients, the needle was withdrawn from the left atrium, across the septum into the right atrium, as the pressure was recorded continuously. Such a tracing obtained in a patient with mitral insufficiency is reproduced in Figure 4.

**COMMENT**

The transseptal method of left atrial puncture will undoubtedly prove to be a useful alternative to the methods of left heart catheterization presently employed. It permits both right and left heart pressure measurements to be carried out in the course of a single study, and the patient can easily be maintained in a steady basal state. Although the saphenous vein is ligated after the catheter is removed, at least two studies are possible in each patient without extensive

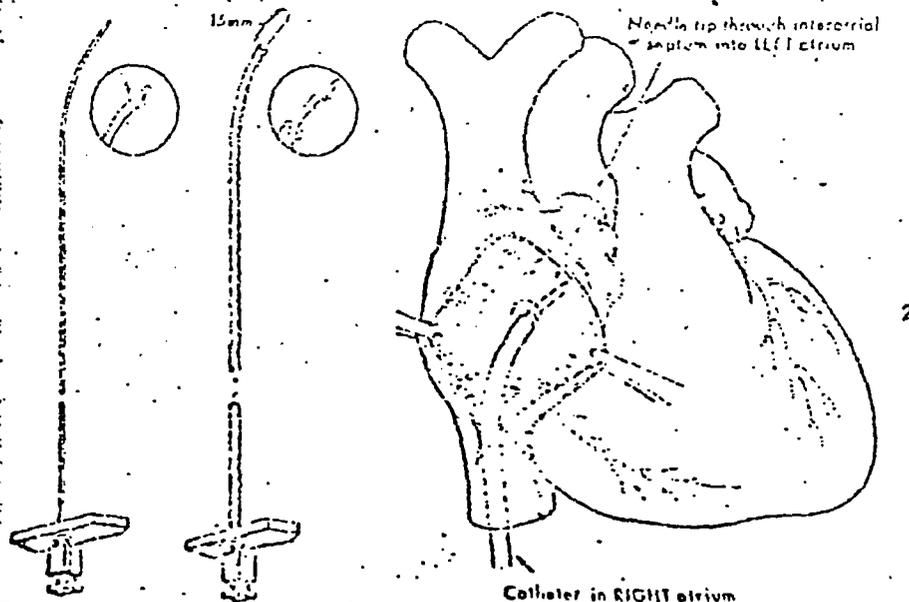


Fig. 1. (Left) Specially constructed 19-gauge needle employed in transseptal left atrial puncture. The metal arrow at the hub indicates the direction of needle curvature. (Right) The needle has been passed through a 25 cardiac catheter the hub of which has been removed.

Fig. 2. Diagrammatic representation of the position of the cardiac catheter and needle following puncture of the atrial septum.

gauge transeptal needle, it is believed that, as with the needle, no persistent opening in the septum will result. Krypton<sup>85</sup> inhalation tests<sup>6</sup> have shown no evidence of a left-to-right shunt in three patients following the procedure described herein. Two dogs in which this procedure was performed were sacrificed two weeks later and their atrial septa were found to be intact. No instances of phlebitis have been encountered.

The technic described is designed to permit left heart angiocardiology to be performed in the course of left heart catheterization without the hazards attendant upon percutaneous left ventricular puncture and without the difficulties involved with retrograde left ventricular catheterization. In addition, when only left heart catheterization is employed, the percutaneous approach described permits the procedure to be accomplished without surgically excising and ligating the saphenous vein. Thus, if necessary, multiple catheterizations may be carried out in any given patient.

The catheter employed is of sufficient size to permit the sampling of blood and its larger lumen certainly improves the quality of the left ventricular pressure pulse tracings. Removal of the needle following positioning of the catheter in the left ventricle enables the patient to be exercised with a standard bicycle ergometer. Since it is also possible to perform both right and left heart catheterizations using the same percutaneous puncture, a complete hemo-

dynamic investigation may be carried out in a relatively short period of time.

#### SUMMARY

A technic is described for introducing a radiopaque catheter into the left heart through the interatrial septum. The chief advantages of the method are that selective left atrial and ventricular angiocardiology may be conveniently performed in conjunction with transeptal left heart catheterization and that surgical exposure of the saphenous vein is not necessary.

#### REFERENCES

1. ROSS, J., JR. Transeptal left heart catheterization. A new method of left atrial puncture. *Ann. Surg.*, 149: 395, 1959.
2. ROSS, J., JR., BRAUNWALD, E. and MORROW, A. G. Transeptal left atrial puncture: new technique for the measurement of left atrial pressure in man. *Am. J. Cardiol.*, 3: 653, 1959.
3. ROSS, J., JR., BRAUNWALD, E. and MORROW, A. G. Left heart catheterization by the transeptal route: a description of the technique and its applications. *Circulation*, in press.
4. COPE, C. Technique for transeptal catheterization of the left atrium: preliminary report. *J. Thoracic Surg.*, 37: 482, 1959.
5. SELDINGER, S. I. Catheter replacement of the needle in percutaneous arteriography. *Acta radiol.*, 39: 368, 1953.
6. SANDERS, R. J. and MORROW, A. G. The identification and quantification of left to right circulatory shunts: a new diagnostic method utilizing the inhalation of a radioactive gas, Kr<sup>85</sup>. *Am. J. Med.*, 26: 508, 1959.

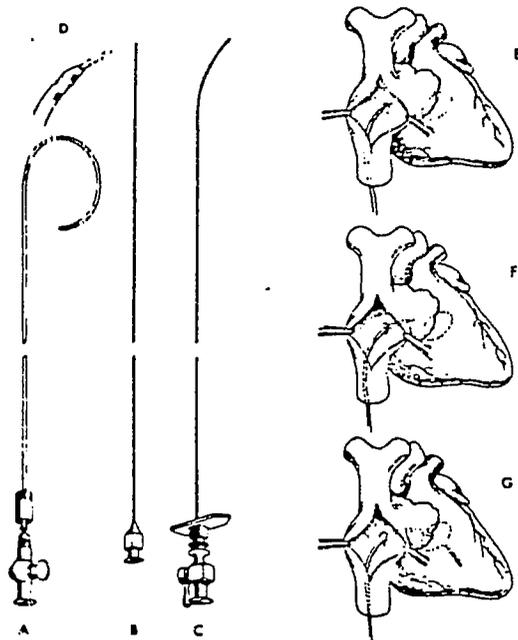


FIG. 1. Drawings of the equipment (A to D) and technic (E to G) employed in the percutaneous method of transseptal left heart catheterization.

entry into the femoral vein in the groin until bleeding ceases.

CLINICAL EXPERIENCES

Left heart catheterization with this technic has been carried out in thirty patients ranging in age from four to forty-seven years. There have been no significant complications. Eight patients have had angiocardiography with either left ventricular or left atrial injections. A representative angiocardiogram is reproduced in Figure 3. It was anticipated that recoil of the catheter into the left atrium during left ventricular injection would present a problem, but so far this has not been serious. The left ventricle was entered in twenty-nine of the patients. Although final comparison must await further experience, it is possible that passage of the catheter into the left ventricle can be performed with greater regularity by this technic than with the polyethylene catheter which cannot be manipulated under fluoroscopic control.

Although the external diameter of the catheter is slightly larger than that of the 17



FIG. 2. Roentgenogram showing the catheter traversing in turn the right atrium, interatrial septum, left atrium and mitral valve. The opening of the catheter is in the left ventricular cavity.

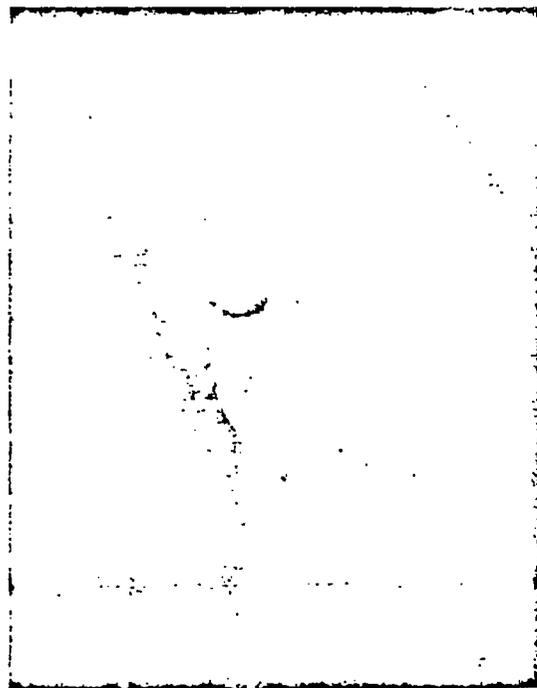


FIG. 3. Left ventricular angiocardiogram performed by the percutaneous transseptal technic in an eight year old boy with congenital valvular aortic stenosis.



CONTENTS  
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 DO NOT STERILIZE IN THIS PACKAGE

CONTENTS: 1 each



Rev. 4/12-77/5011460

**BROCKENBROUGH® TRANSSEPTAL CATHETER**  
 (TEFLON® MATERIAL) CHILD'S TRANSSEPTAL CATHETER

CAT. NO.	FORMERLY	SIZE	LENGTH	LOT NO.
H8015 <b>001880</b>	<b>7620</b>	<b>7F</b>	<b>54cm</b>	

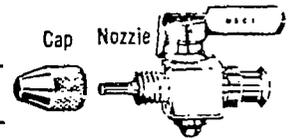
CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

**USCI, A DIVISION OF C. R. BARD, INC. Billerica, Massachusetts 01821, U.S.A.**

USCI® BROCKENBROUGH® Transseptal Catheters are to be used with BROCKENBROUGH® Fittings numbers 002412 and 002414 ONLY.

**BROCKENBROUGH® FITTINGS (NON-STERILE)**

002412	9781	For 7F Catheter	IMPROVED REMOVABLE FITTING, FOR CHILD SIZE, 7F CATHETER (NON-STERILE)
002414	9791	For 8.5F Catheter	IMPROVED REMOVABLE FITTING, FOR ADULT SIZE, 8.5F CATHETER (NON-STERILE)



CAUTION: USE WITH THE FOLLOWING NEEDLES ONLY: CATALOG NUMBERS 003996, 003997, 003998

CAUTION: BROCKENBROUGH CATHETERS MUST BE CAREFULLY INSPECTED PRIOR TO EACH USE. REPEATED CLEANING AND STERILIZATION MAY CAUSE DIMENSIONAL CHANGES IN THE CATHETER THEREBY RENDERING THE CATHETER USELESS. INSPECT THE LENGTH OF THE CATHETER RELATIVE TO THE LENGTH OF THE NEEDLE TO BE USED IN THE PROCEDURE.

**CONNECTION INSTRUCTIONS:**

1. Push proximal end of the BROCKENBROUGH® Catheter onto the male stopcock nozzle to the threaded portion.
2. Slip cap over catheter from the distal tip to the stopcock.
3. Join the cap to the stopcock by threading the cap to the nozzle making sure the catheter is seated all the way on the nozzle.
4. Check assembled system for leaks using distilled water or saline with syringe injection into basin prior to use.
5. CAUTION: Do not attempt to seat the proximal catheter end at the same time the cap is affixed. An incomplete seal may occur.

**SEE INSTRUCTIONS**

# USCI® TEFLON\* AND WOVEN DACRON\* CARDIOVASCULAR CATHETERS

## INDICATIONS:

USCI® TEFLON and Woven DACRON catheters are designed for use in the Cardiovascular System. Various uses include injection of contrast media, recording of intracardiac pressures, blood sampling, intravascular occlusion studies, and transseptal catheterization procedures.

**WARNING:** USCI® TEFLON and WOVEN DACRON CATHETERS SHOULD NOT BE USED BY ANYONE WHO IS NOT FAMILIAR WITH THESE DEVICES OR THE VARIOUS USES DESCRIBED ABOVE.

**WARNING:** DO NOT USE AIR AS AN INFLATION MEDIUM FOR DOTTER-LUKAS® BALLOON CATHETERS SINCE BALLOON RUPTURE MAY ALLOW RELEASE OF AIR INTO THE CARDIOVASCULAR SYSTEM. DILUTE CONTRAST MEDIA IS USUALLY USED TO INFLATE THE BALLOON.

**WARNING:** OVERINFLATION OF THE BALLOON ON DOTTER-LUKAS® BALLOON CATHETERS MAY CAUSE THE BALLOON TO BREAK OR SLIP OUT FROM UNDER THE TIE-DOWNS. DOTTER-LUKAS® BALLOONS SHOULD NOT BE INFLATED WITH MORE THAN 10 CC OF DILUTE CONTRAST MEDIA.

**WARNING:** RADIATION SHOULD NOT BE USED AS A METHOD OF STERILIZATION.

**WARNING:** DO NOT STERILIZE TEFLON CATHETERS WITH ETO GAS. TEFLON CATHETERS SHOULD BE STEAM AUTOCLAVED AT 250°F (120°C) FOR 15 MINUTES.

**CAUTION:** FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

**CAUTION:** CAREFULLY INSPECT EACH CATHETER PRIOR TO USE FOR OVERALL CONDITION OF THE CATHETER AND LATEX BALLOON (IF APPLICABLE).

**CAUTION:** NONSTERILE USCI TEFLON AND WOVEN DACRON CARDIOVASCULAR CATHETERS MUST BE CLEANED AND STERILIZED PRIOR TO INITIAL USE AND ALL SUBSEQUENT REUSES. DO NOT EXCEED 10 TIMES REUSE FOR USCI REUSABLE WOVEN DACRON AND TEFLON CATHETERS. DO NOT REUSE BALLOON CATHETERS.

## CLEANING AND STERILIZATION:

USCI TEFLON and Woven DACRON Cardiovascular Catheters must be cleaned and sterilized prior to use. The Woven DACRON Cardiovascular Catheters may be sterilized by gas (ETO) or steam autoclave (250°, 15 PSI, 15 minutes). TEFLON Catheters should be steam autoclaved at 250°F (120°C) for 15 minutes. Aeration times for gas sterilization should be in accordance with manufacturers' specifications. Prior to sterilizing, clean catheters in a Germicide-Detergent such as DETERGICIDE® solution.

**CAUTION:** DO NOT SUBMIT WOVEN DACRON CATHETERS TO THE FOLLOWING AGENTS:

1. ALCOHOL, ESTERS AND ETHERS.
2. CRESOLS AND PHENOLS, SUCH AS LYSOL, HEXACHLOROPHENE, CARBOLIC ACID, ALL SOAPS AND JELLIES CONTAINING PHENYL OR PHENOL COMPOUNDS.
3. CLEANING AGENTS THAT ARE ALKALINE OR CONTAIN ACETONE OR SOLVENTS OF ANY KIND.
4. HOUSEHOLD SOAPS, TINCTURE OF GREEN SOAP, PEROXIDE, MERCURY COMPOUNDS, OR CHEMICALS CONTAINING ACTIVE CHLORINE OR HYPOCHLORITES.

**CAUTION:** USCI RECOMMENDS BALLOON CATHETERS NOT BE STORED IN DIRECT SUNLIGHT, ULTRAVIOLET, OR INCANDESCENT LIGHT, AS LIGHT MAY CAUSE DETERIORATION OF THE LATEX BALLOON. USCI ALSO RECOMMENDS THESE CATHETERS BE USED ONLY ONCE AS REPEATED CLEANING AND STERILIZATION IS DELETERIOUS TO THE LATEX BALLOON.

**CAUTION:** DO NOT FLASH AUTOCLAVE (275°F) BALLOON CATHETERS.

**WARNING:** TEFLON CATHETERS SHOULD BE STEAM AUTOCLAVED AT 250°F (120°C) FOR 15 MINUTES. DO NOT STERILIZE TEFLON CATHETERS WITH ETO GAS.

**WARNING:** RADIATION SHOULD NOT BE USED AS A METHOD OF STERILIZATION FOR ANY WOVEN DACRON OR TEFLON CATHETERS.

## DIRECTIONS FOR USE:

USCI® TEFLON and Woven DACRON Catheters may be introduced into the Cardiovascular System via cut-down or, when the catheter has a tapered tip to fit a spring guide, the percutaneous technique. (Catheters which can be introduced percutaneously include the GENSINI®, VARIFLEX®, SONES®, and BROCKENBROUGH® catheters.)

The catheter is passed from the introduction site to the desired intracardiac position via fluoroscopy.

Upon completion of catheterization procedure, the catheter is removed from the Cardiovascular System and the entrance site closed in the usual manner. If the catheter is going to be reused, it should be thoroughly cleaned and sterilized. (See cautions above.)

Introduction of closed-end catheters can also be accomplished via Percutaneous Catheter Introducer techniques. The Percutaneous Catheter Introducer Sheath must have an internal diameter slightly larger than the external diameter of the closed-end catheter.

USCI DESILETS-HOFFMAN® Percutaneous Catheter Introducers are recommended for introducing closed-end catheters via percutaneous introduction techniques. Instructions describing the use of the USCI DESILETS-HOFFMAN Percutaneous Catheter Introducer are included with each USCI DESILETS-HOFFMAN product.

On DOTTER-LUKAS® Catheters, the lumens can be identified by the length of the "tails" on the proximal end of the catheter as follows.

### Double Lumen Catheters

Item Number	Former Catalog Number	Shorter Tail	Longer Tail
001205	5261	Distal Lumen	Balloon Inflation Lumen
001207	5262	Balloon Inflation Lumen	Lumen Proximal to Balloon
001209	5263	Balloon Inflation Lumen	Lumen Proximal to Balloon

### Triple Lumen Catheter

Item Number	Former Catalog Number	Shortest Tail	Middle Length Tail	Longest Tail
001213	5265	Distal Lumen	Balloon Inflation Lumen	Lumen Proximal to Balloon

The COURNAND® Double Lumen Catheter lumens can be distinguished as follows:

Item #	Former Catalog #	Shorter Tail	Longer Tail
001556	5910	distal lumen	proximal lumen
001558	5910	distal lumen	proximal lumen
001560	5910	distal lumen	proximal lumen

\*Trademark of E. I. DuPont de Nemours & Co., Inc.  
 BROCKENBROUGH, COURNAND, DETERGICIDE, DOTTER-LUKAS, EPPENDORF, GENSINI, GOODALE-LUBIN, LEHMAN, POSITROL, RODRIGUEZ-ALVAREZ, SHIREY, SONES, USCI and VARIFLEX are Trademarks Registered in the U.S. Patent and Trademark Office by C. R. Bard, Inc.

CARDIOLOGY

**TRANSSEPTAL EQUIPMENT**

**ROSS TRANSSEPTAL EQUIPMENT**

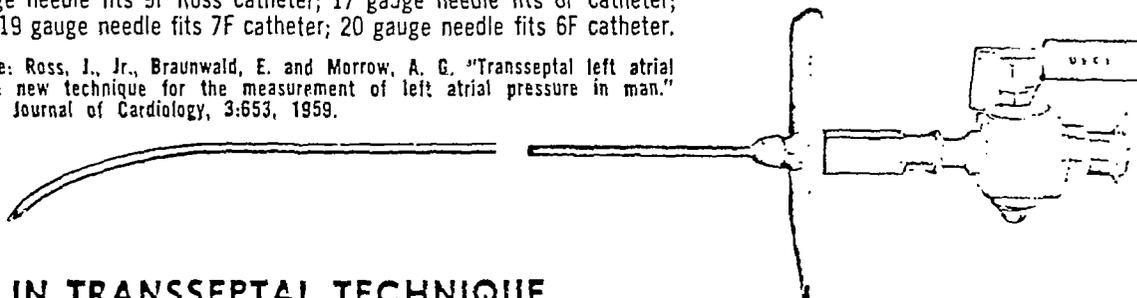
**ROSS TEFLON AND WOVEN DACRON CATHETERS - ROSS TRANSSEPTAL NEEDLES**

The Ross catheter has a thin wall construction utilizing an inner core of smooth bore nylon, reinforced with woven Dacron, in sizes 6F to 8F. Size 9F is constructed of woven Dacron. The 7410 Ross catheter has a thin wall Teflon construction available in sizes 6F to 9F. The 9722 removable Adapter (page 46) and 8457 nylon tubing (page 49) are accessory equipment. The Ross catheter is used for transseptal left heart catheterization.

		LENGTH	SIZES
5410	ROSS CATHETER (WOVEN DACRON, THIN WALL)	59.5 cm	6F to 9F
7410	ROSS CATHETER (TEFLON, THIN WALL)	59.5 cm	6F to 9F
9110	ROSS TRANSSEPTAL NEEDLE	24 inches	16-20 ga.

16 gauge needle fits 9F Ross catheter; 17 gauge needle fits 8F catheter; 18 and 19 gauge needle fits 7F catheter; 20 gauge needle fits 6F catheter.

Reference: Ross, J., Jr., Braunwald, E. and Morrow, A. G. "Transseptal left atrial puncture: new technique for the measurement of left atrial pressure in man." American Journal of Cardiology, 3:653, 1959.

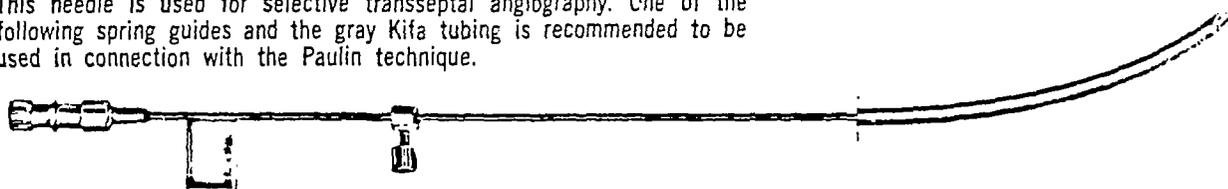


**PAULIN TRANSSEPTAL TECHNIQUE**

**4665 PAULIN TRANSSEPTAL NEEDLE, (COMPLETE WITH BLUNT STYLETTE)**

Needle length 85 cm, diameter 1.5 mm

This needle is used for selective transseptal angiography. One of the following spring guides and the gray Kifa tubing is recommended to be used in connection with the Paulin technique.



**4654 SPRING GUIDE, WITH FLEXIBLE TIP (3cm)**

Size (OD) .054", length 120 cm

**4655 SPRING GUIDE, WITH FLEXIBLE TIP (3cm)**

Size (OD) .054", length 150 cm

**4604 KIFA TUBING, GRAY**

Size 8.4F, 17 ft. coils.

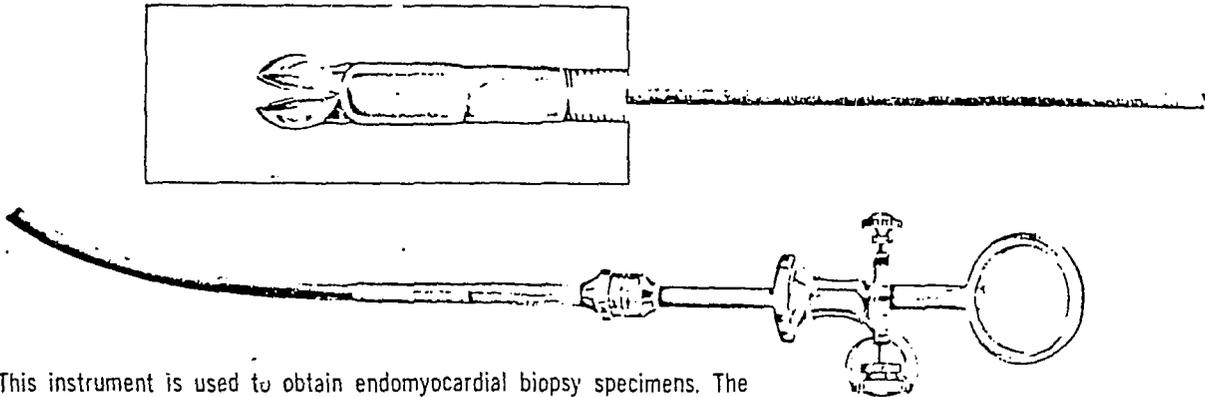
The tubing is cut to desired length (65-75 cm) and curved about 4 cm from the tip to an angle of almost 180 degrees. The inner side of the curve is perforated with 3-5 lateral holes.

**TECHNIQUE:**

The catheter is inserted percutaneously through the right femoral vein and advanced with the aid of a spring guide against the right atrial septum. The spring guide is replaced by the transseptal needle, the sharp tip of which is protected by a blunt stylette. The blunt stylette is withdrawn and the sharp needle advanced 1.5 cm beyond the catheter tip through the atrial septum. The blunt stylette is re-inserted to avoid damage to the catheter when it is advanced over the needle into the left atrium. When all lateral side openings have passed the atrial septum the needle is withdrawn. The catheter may be advanced further to the left ventricle.

*SVC*

**ENDOMYOCARDIAL BIOPTOME**



This instrument is used to obtain endomyocardial biopsy specimens. The method is useful in assisting accurate diagnosis by obtaining a small piece of tissue which is sufficient for histological examination.

The instrument is inserted from the right common carotid or axillary artery to obtain a piece of tissue from the left ventricle. The left cubital or axillary vein is used when obtaining tissue from the right ventricle or right atrium.

The Biopptome can be cleaned and disinfected using Detergicide (Page 53) and sterilized with Ethylene Oxide Gas or boiling water.

When sterilized in boiling water, keep distal tip coiled with a suture.

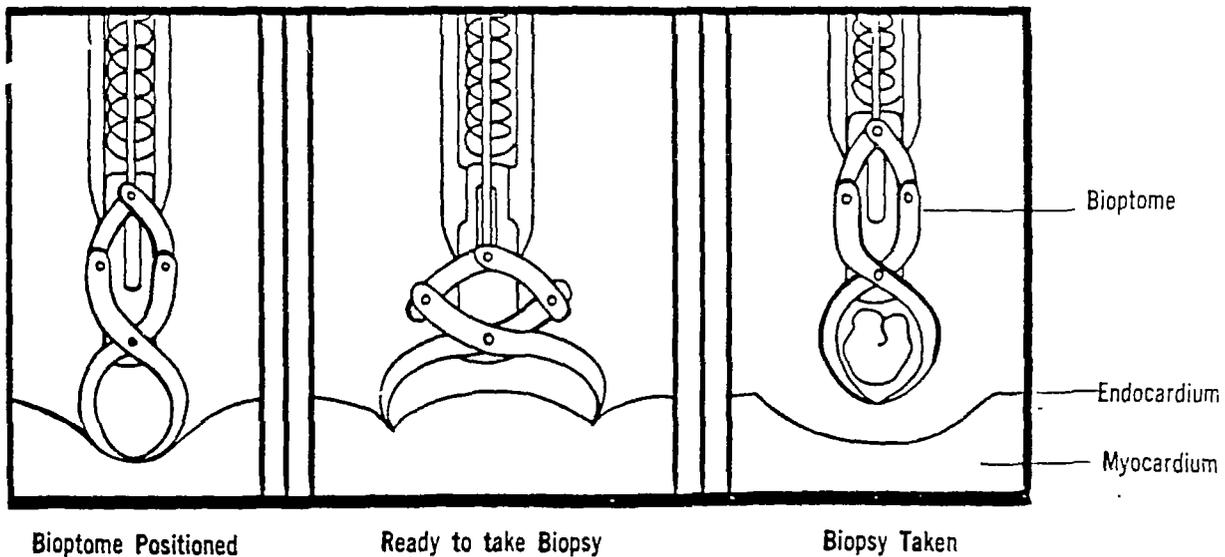
Reference: Souji, Konno, M.D. and Shigeru Sakakibara, M.D., F.C.C.P. "Endo-Myocardial Biopsy." Diseases of the Chest, Vol. 44, No. 4, Oct. 1963.

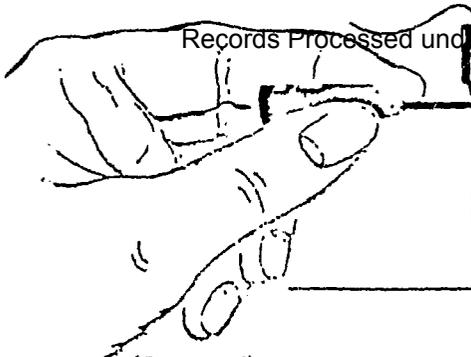
9400

LENGTH ..... SIZE (Small)  
 110 cm tip — 2.5 mm diameter  
 shaft — 2.0 mm diameter

9401

LENGTH ..... SIZE (Large)  
 110 cm tip — 3.5 mm diameter  
 shaft — 3.5 mm diameter





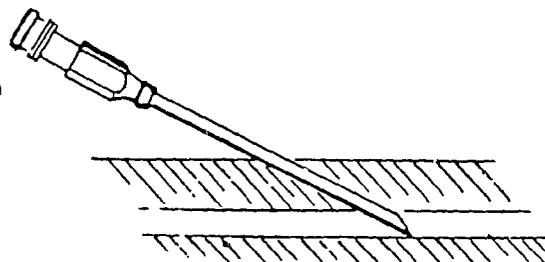
# Technique products ... data

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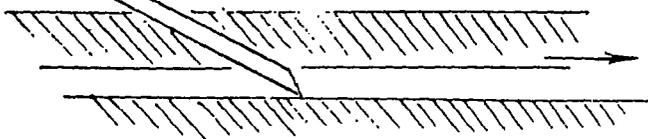
## BROCKENBROUGH NEEDLE SET For Transseptal Left Heart Catheterization and Left Ventricular Angiocardiology

A New Technique for Left Ventricular Angiocardiology and Transseptal Left Heart Catheterization by Edwin C. Brockenbrough, M.D.\* and Eugene Braunwald, M.D.\* The American Journal of Cardiology, December 1960, pages 1061-1064.

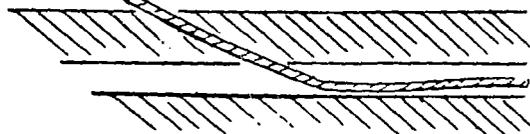
- (1) Percutaneous puncture of right femoral vein by 16G thin-wall needle.



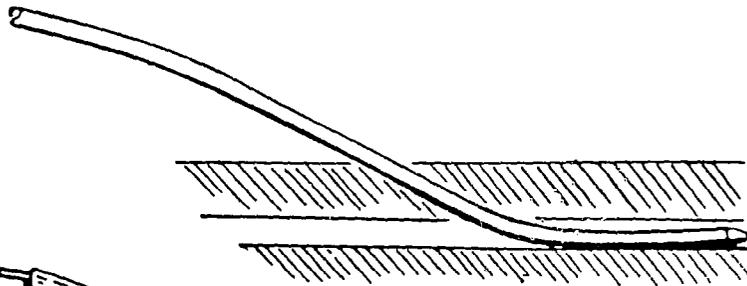
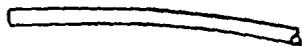
- (2) With stylet removed a flexible guide wire is then passed through the needle and into the vein.



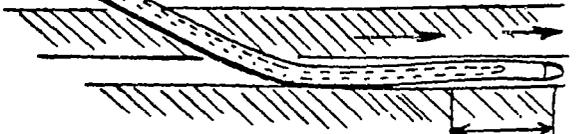
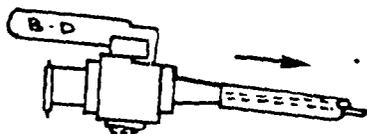
- (3) The needle is removed and a flexible, radiopaque catheter is introduced over the guide wire well into the vein. The catheter is 70 cm long with a pre-set send.



- (4) The wire is removed.



- (5) The 19G straight Ross Needle stylet, 69.5 cm long, is introduced into the catheter. They are advanced together through the femoral vein and inferior vena cava.



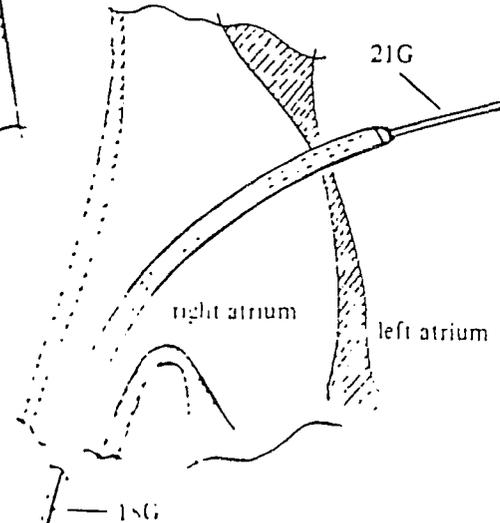
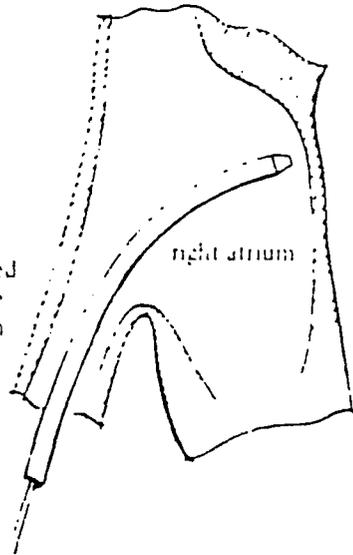
# Technique products ... data

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## BROCKENBROUGH NEEDLE SET For Transseptal Left Heart Catheterization and Left Ventricular Angiography

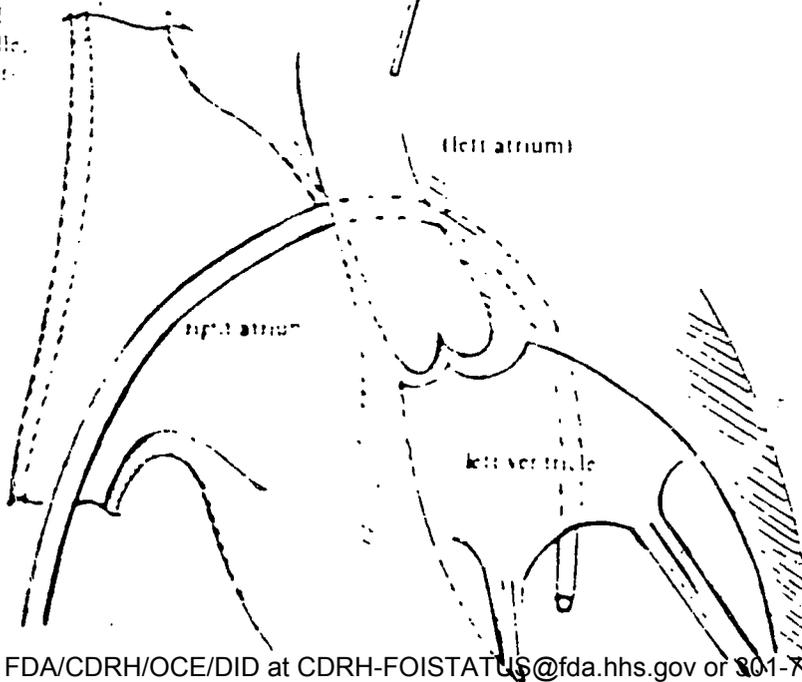
(6) The catheter and stylet are advanced into position in the right atrium.

(7) The stylet is replaced by a pointed 21G transseptal needle 71 cm long, and the catheter and needle positioned against the interarterial septum in the region of the fossa ovale. The septum is then punctured by advancing the needle tip. Entry is confirmed by pressure measurement and the withdrawal of oxygenated blood.

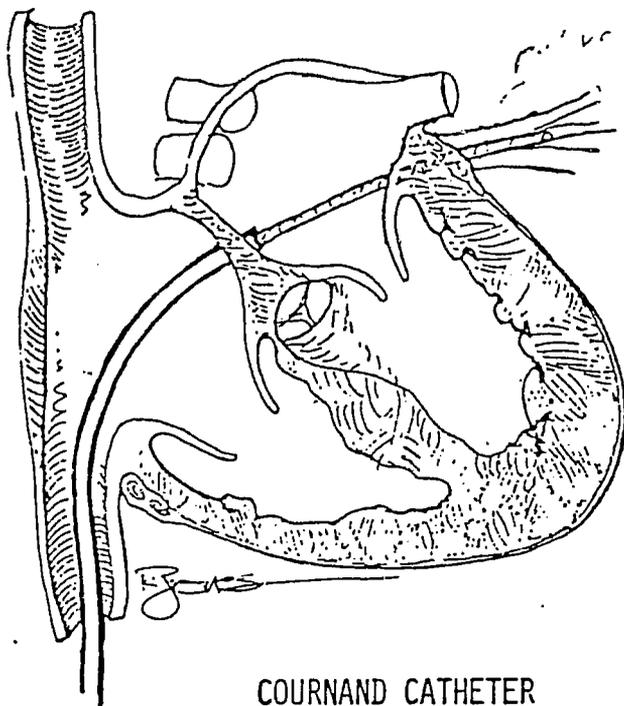


(8) The catheter and needle are then advanced to the point where the needle is within the left atrium.

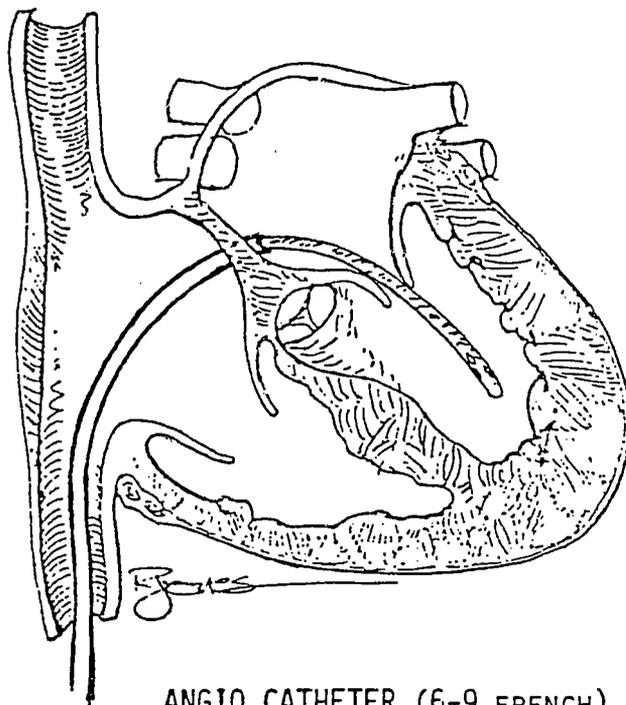
(9) The needle is held in position and the catheter slipped over the needle, and with the aid of the pre-set curvature the catheter is passed into the left ventricle.



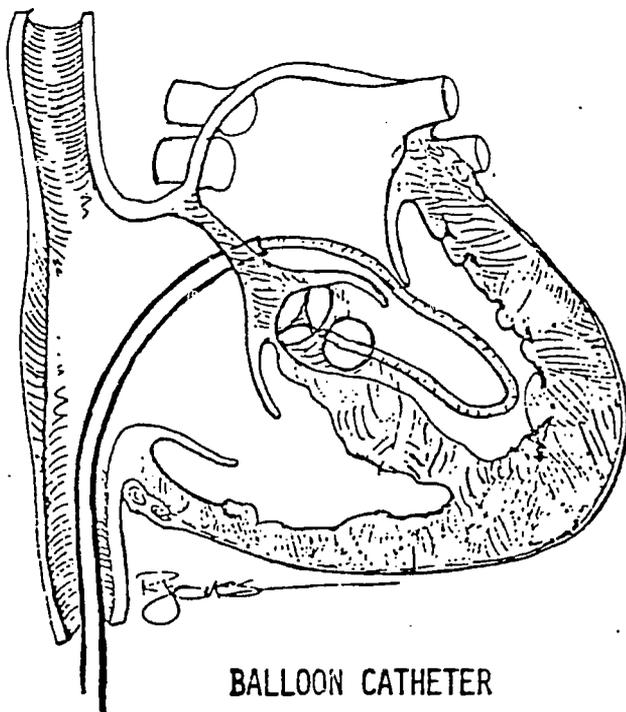
(10) The needle is withdrawn and an adapter attached to the proximal end of the catheter. Pressure is measured and left ventricular angiography is performed selectively in either the atrium or ventricle.



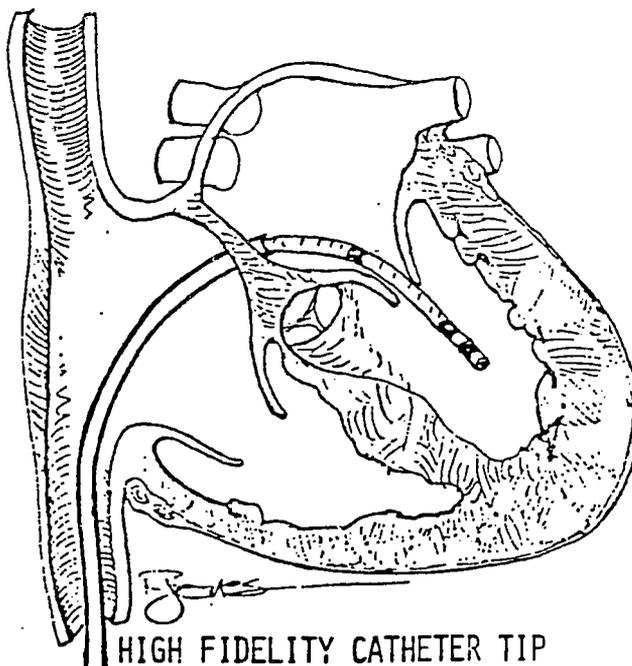
COURNAND CATHETER  
(FOR PUL. VEIN WEDGE ANGIOS)



ANGIO CATHETER (6-9 FRENCH)  
(FOR SELECTIVE LV OR LA ANGIO)



BALLOON CATHETER  
(FOR PROGRADE APPROACH TO Asc. Ao.)



HIGH FIDELITY CATHETER TIP  
TRANSDUCERS AND/OR FLOW METERS,  
ELECTRODE CATHETERS