PHYSICIAN'S MANUAL
INOUE BALLOON CATHETER
FOR
PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY
(PTMC)

Manufacturer: Toray Industries, Inc.
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Chuo-ku, Tokyo 103-8666 JAPAN

CAUTION : Federal (USA) law restricts this device to sale by or on the order of a physician trained or experienced in the use of this device.

CAUTION : This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

Rev. Jul. 1, 2005

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I. INDICATION

The Inoue-Balloon Catheter is indicated for Percutaneous Transvenous Mitral Commissurotomy in patients with hemodynamically significant mitral valvular stenosis resulting primarily from commissural fusion of the mitral valve cusps. An echocardiographic study should suggest that balloon commissurotomy is the appropriate procedure for improving the patient's symptoms and hemodynamic status. The PTMC procedure is one of several methods for treating symptomatic mitral stenosis. Alternative methods which may be considered are medical therapy, surgical commissurotomy, mitral valve repair and mitral valve replacement.

II. DESCRIPTION

The Inoue-Balloon Catheter is manufactured of polyvinyl chloride with a balloon attached to the distal end. The balloon is two latex layers between which is a polyester micromesh. The catheter is supplied in a 12F diameter with a length of 70cm; the length of each balloon is 2.5cm (unstretched). Balloon inflation and catheter venting are accomplished by two proximally positioned stopcocks. A stainless steel tube is used to stretch and slenderize the balloon prior to insertion and a 14F tapered dilator enlarges the interatrial opening. The stainless steel stylet and guidewire are employed to guide the catheter inside the heart and blood vessels. A syringe is used to manually inflate the balloon and balloon diameter is measured with a caliper (ruler). (See Figure 2 on Page 8 for an illustration of catheter components.)

The balloon design exhibits five uniquely different inflation stages [See Figure 1]. Radiopaque dilute contrast medium is injected to achieve inflation. Inflation stage is changed by changing the volume of dilute contrast medium injected. These stages are described below.

Stage 1. <u>Balloon Completely Deflated</u>
Allows catheter advancement and passage through the atrial septum.

Stage 2. <u>Distal Portion Partially Inflated</u>
When a small volume of dilute contrast is injected, the distal portion of the balloon inflates first. The balloon may float across the mitral valve, like a thermodilution catheter.

Stage 3. Distal Portion Completely Inflated
When a larger volume of dilute contrast is injected, the distal portion inflates completely. This aids in seating the balloon on the valve.

Stage 4. Hour-Glass Shape
A latex band placed at the center of the balloon constricts inflation. Consequently, when additional dilute contrast is injected, the balloon shape resembles an hour-glass. This unique shape centers the balloon in the valve and prevents migration.

Stage 5. Fully Inflated
Further injection will inflate the balloon to its full extent. The force of this expansion is used to achieve valvuloplasty.

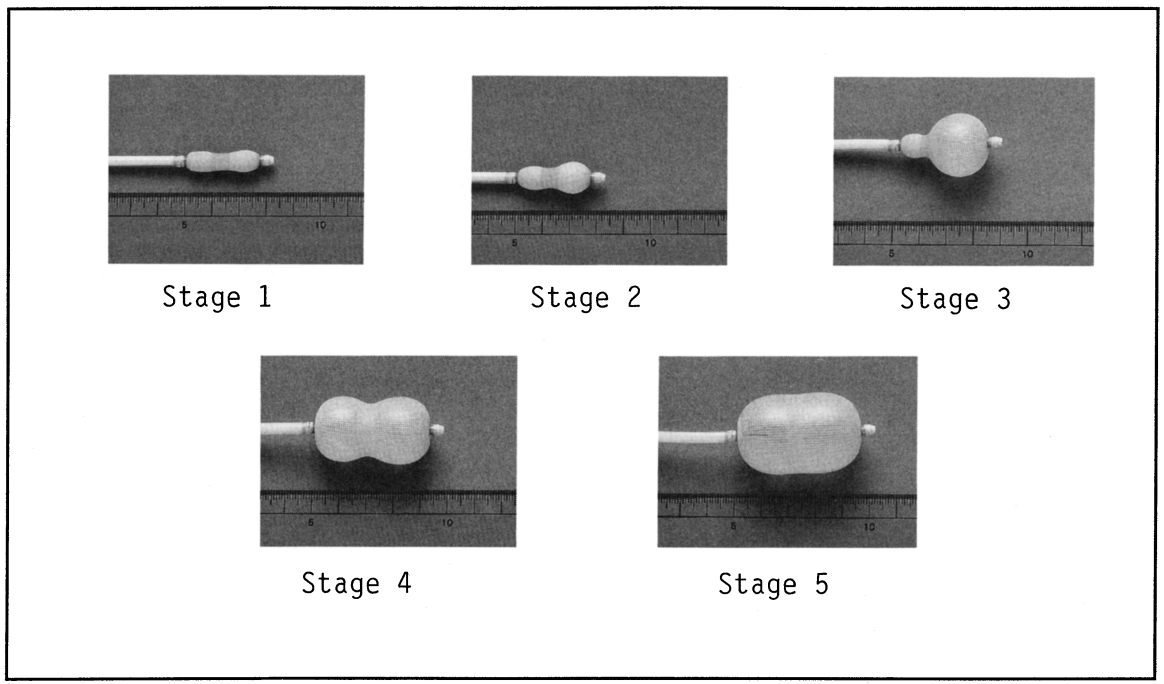

FIGURE 1

III. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

A. Contraindications

Contraindications for use of the Inoue-Balloon Catheter in Percutaneous Transvenous Mitral Commissurotomy (PTMC) include:

1. Mitral valve area $>1.5cm^2$
2. Mitral regurgitation >2+ (on a scale of 0-4)
3. Asymptomatic patients
4. Aortic regurgitation >2+ (on a scale of 0-4)
5. Bacterial endocarditis
6. Suspected formation of fresh (soft) blood thrombus in the left atrium
7. Suspected adhesion of blood thrombus on the interatrial septum or valve
8. Severe subvalvular fibrosis documented by echocardiography in a patient who is an operative candidate or a good surgical risk.
9. Severe mitral valve calcification in a patient who is an operative candidate or a good surgical risk.

B. Warnings

1. If mitral regurgitation occurs or increases significantly, the procedure must not be repeated using a larger inflation volume.
2. Patients who have severe mitral valve calcification and/or severe subvalvular fibrosis should be considered candidates for the procedure only if they are non-operative candidates or poor surgical risks.

C. Precautions

1. This procedure should be carried out only by physicians who have successfully completed device and procedure specific training conducted either by Toray or an experienced user.
2. In facilities where the PTMC procedure is performed, in-house cardiac surgical backup is required, except in

those cases where the patient is clearly too ill to undergo emergency surgery in the event of a serious complication related to the PTMC procedure.

3. For balloon inflation, use only the syringe provided in the package; do not use other syringes with the Inoue Balloon Catheter. Conversely, do not use the Inoue Balloon Catheter syringe with other balloon catheters.
4. After initial catheter introduction, do not disconnect or reconnect the metal hubs from each other or the "W" connector unless the guidewire is in place and fully protrudes from the catheter tip. Should this caution be disregarded, the catheter could bend at an acute angle resulting in damage to the device or difficulty in carrying out the procedure. Never use a kinked balloon.
5. Using too large a balloon inflation volume could damage the valve or result in balloon malfunction, i.e., mesh tear.Once the balloon is inflated, the amount of time the valve opening is blocked must be minimal (5-7 sec).
6. Do not exceed the maximum recommended inflation volume marked on the syringe provided in the package. Over-inflation of the balloon can result in tearing of the inner mesh fabric or other balloon malfunction. Do not use the balloon once it has experienced a mesh tear or any other malfunction.
7. During manipulation of the stylet to direct the balloon, it is very important to hold the W-connector rather than the inner tube (proximal end of the catheter). If the inner tube is held, the lumen of the catheter can become twisted, thus occluding the lumen and blocking subsequent advancement or withdrawal of the guidewire or stylet. Do not twist the catheter lumen in this manner as it may adversely affect balloon performance.
8. In the event that the balloon fails to deflate, do not use normal saline or any other fluid to inflate the balloon. Do not attempt to expand the balloon to the point of rupture as several times the maximum inflation volume is required for rupture to occur.
9. The design of the Inoue-Balloon Catheter does not lend itself to the use of power injection. For this reason, injection should be by hand only.

IV. INSTRUCTIONS FOR USE

A. Patient Evaluation and Product Selection

As previously mentioned, echocardiographic study should suggest that balloon commissurotomy is the appropriate procedure for improving the patient's symptoms and hemodynamic status. A necessary element of pre-procedure evaluation is the transesophageal echocardiogram, which will determine the presence of left atrial thrombus. Additionally, in patients felt to be at high risk for embolic events, such as patients with pre-existing atrial fibrillation, the risks of anticoagulation therapy (such as uncontrolled bleeding) before and during the PTMC procedure should be weighed against the potential benefits. It is recommended that the patient's coagulation status be evaluated carefully prior to the procedure.

The Inoue-Balloon Catheter is a volume-controlled device and each catheter offers a number of inflation volumes, with corresponding balloon diameters. This allows the physician to carry out the PTMC procedure by incrementally increasing the size of the balloon from the minimum to the maximum inflation diameter. This approach is especially important in the elderly patient or in the patient with severe stenosis, but should be employed for all patients. The operator should begin valve dilatation with the smallest inflation volume, increasing the balloon diameter by only 1 or 2 mm on successive inflations as the situation warrants. This will result in the desired gradual opening of the stenosed mitral valve.

The following factors will assist the clinician in determining the number and inflation volume of subsequent dilatations:

(1) The appearance and degree of resultant mitral regurgitation;
(2) The increase in mitral valve area;
(3) The degree of separation of the mitral commissures; and
(4) The reduction of the pressure gradient across the mitral valve.

The balloon diameter size is chosen on the basis of the patient's weight, height, and body surface area, as well as the estimated mitral valve area as determined during cardiac catheterization and/or non-invasive preoperative studies.

The catalog number indicates the maximum expandable balloon diameter size.

Cat. No.	Balloon Dilation Available Range	Diameter Maximum	Patient Weight	Patient Height(cm)	Surface Area(m^2)
PTMC-30	26-30mm	30mm	$\geq$ 70 kg.	$\geq$ 180	$\geq$ 1.9
PTMC-28	24-28mm	28mm	45-70 kg.	160-180	1.6-1.9
PTMC-26	22-26mm	26mm	$\leq$ 45 kg.	$\leq$ 160	$\leq$ 1.6

Other factors to be considered in selecting the balloon diameter size include:

a. Patient age
b. Patient sex
c. Patient occupation and level of activity, as they relate to the workload of the heart
d. Pathological condition of the mitral valve

B. Package Contents [See Figure 2]

ITEM	PURPOSE
1. Inoue-Balloon Catheter Contains Main stopcock (A) Vent stopcock (B) W-Connector Inner tube	Dilatation of the valve
2. Balloon stretching tube, 19G, 80cm	Elongation of balloon
3. Dilator, 14F tapered, 70cm	Dilatation of insertion puncture site and atrial septum
4. Guidewire, 0.025" stainless steel, with spring coil, 175cm	Guide for catheter and dilator
5. Stylet, 0.038" stainless steel, 80cm	Directing balloon to valve
6. Syringe	Inflation of balloon
7. Caliper (ruler)	Measurement of balloon diameter

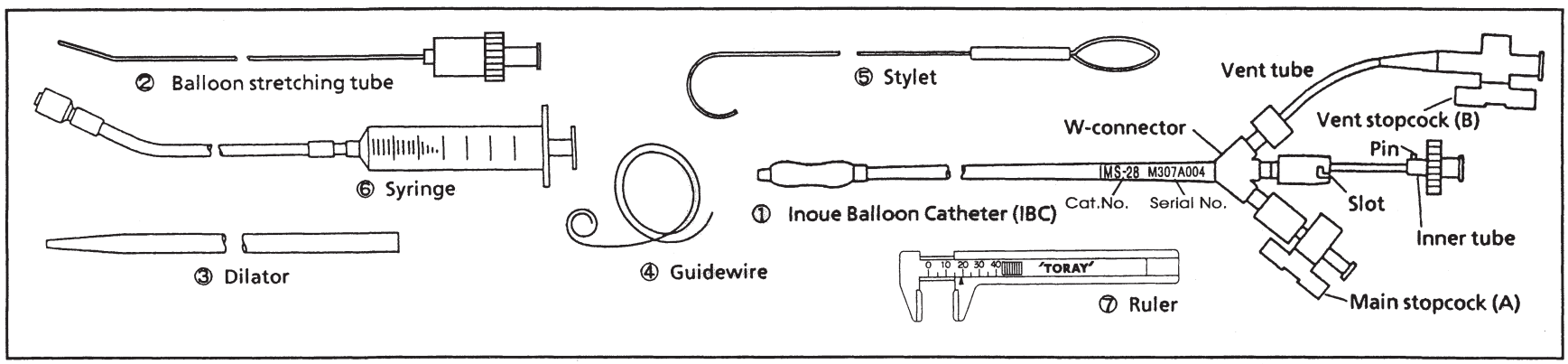

FIGURE 2

The additional items listed below, not included in the package, are needed to perform the commissurotomy procedure. Parentheses ( ) indicate the necessary quantity.

Introducer sets, 7-8F (2), 5F (1)
Transseptal sheath, 8F [optional]

Thermo-dilution catheter, 7F
Spring guidewires, 0.035" (1), J-shape tip 0.032" (1)
Pigtail catheter, 5F
Brockenbrough needle
Brockenbrough catheter
Heparinized saline solution
Dilute contrast medium [For example: Urografin 76% strength, diluted in a 1:2 ratio with saline solution]
Syringes [10-20cc] (3)
Sterile water-soluble medical lubricant [optional]

C. Opening the Sterile Package

The Inoue-Balloon Catheter and its accessories are supplied sterile in poly-peel packages. The package and its contents have been exposed to ethylene oxide gas, and sterility is verified on each lot.

Observing appropriate sterile technique, introduce each component into the sterile field.

D. Preparation of Catheter for Use

The purpose of these steps is to confirm that the balloon is functioning properly. If any abnormality is noted, the catheter should be returned to Toray Industries. Explanation and illustration of catheter preparation follow:

1. Confirmation of Balloon Diameter
   a. Flush balloon catheter inner tube with heparinized saline solution as shown in Figure 3.

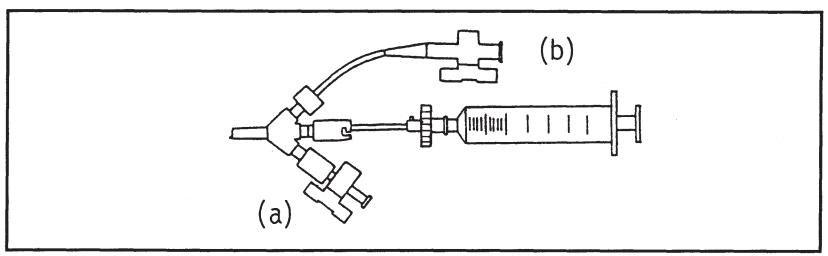

FIGURE 3

b. Inject dilute contrast medium through the vent tube stopcock (B) to fill balloon inflating channel. When full, excess solution will flow from main stopcock (A) [See Figure 4]. Close main and vent stopcocks (A & B).

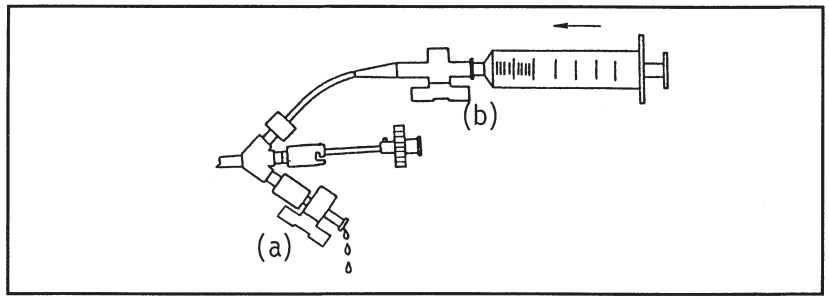

FIGURE 4

c. Ensure that the alphabetical code on the W-connector matches that on the syringe, as shown below in Figure 5. Fill syringe with dilute contrast medium to the proximal end of the red indicator bar representing the MINIMUM volume recommended for balloon inflation.

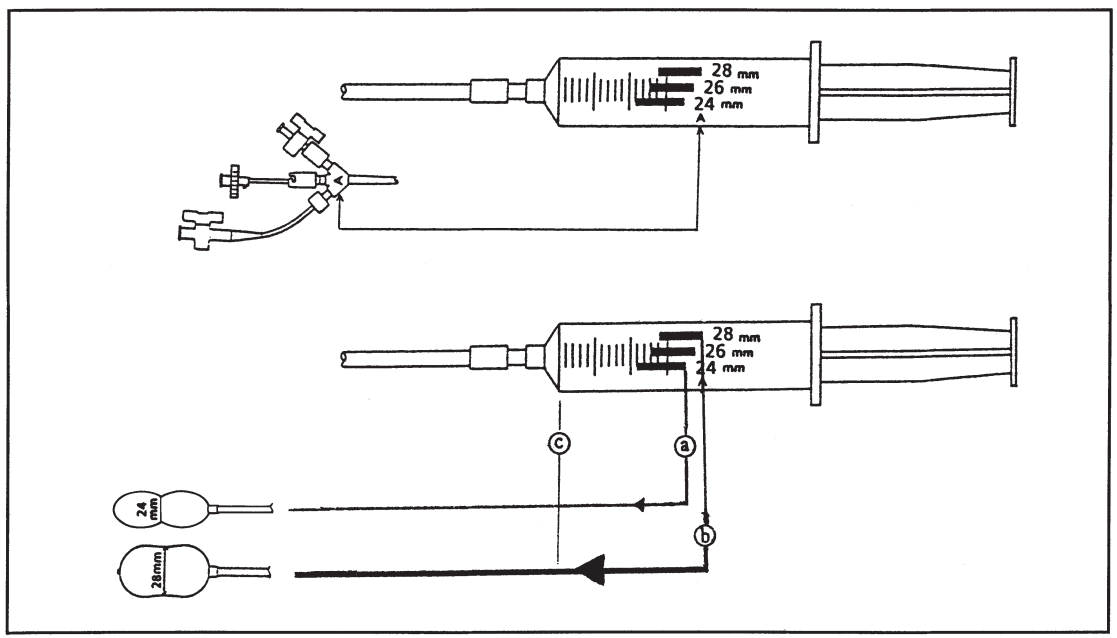

FIGURE 5

d. Connect the syringe to the port of the main stopcock (A) [See Figure 6]. NOTE: Do not use the vent tube (B) to inflate the balloon.

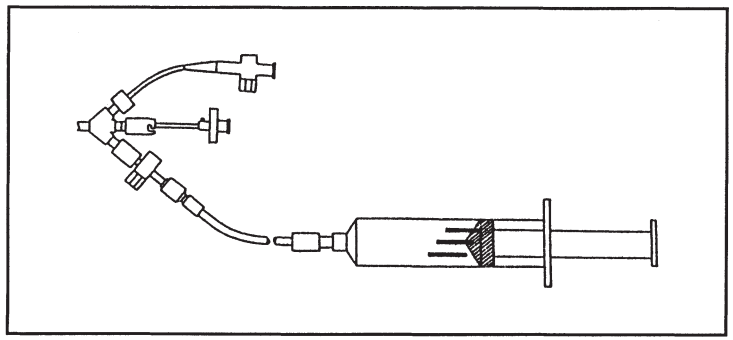

FIGURE 6

e. Open main stopcock (A) and slowly* inject all dilute contrast medium from syringe to inflate balloon fully through the stages of inflation. (See Figure 5c) Using the caliper (ruler), measure balloon diameter; confirm that the volume injected produces the degree of inflation that corresponds with the millimeter reading on the syringe (MINIMUM diameter).(See Figure 5a) Withdraw the dilute contrast medium into the syringe. Repeat steps c, d, and e to confirm the MAXIMUM balloon inflation diameter [See Figure 5b]. Steps c, d, and e may be repeated in order to assure that the memory of the balloon will yield accurate measurements.

* To avoid mesh tear.

2. Assembly of Balloon Catheter

a. Flush the inside of the balloon stretching tube with heparinized saline solution [See Figure 7].

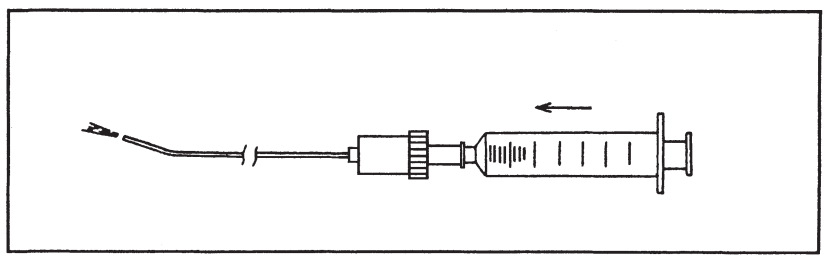

FIGURE 7

b. Insert balloon stretching tube into the catheter inner tube and secure hubs with luer lock [See Figure 8].

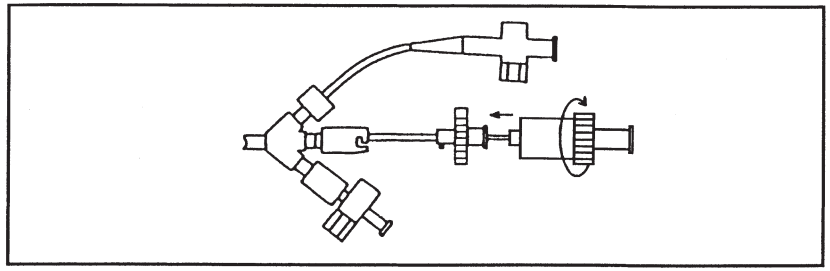

FIGURE 8

c. Advance the catheter inner tube into the W-connector. Place the pin of the inner tube into the slot in the W-connector, then lock [See Figure 9].

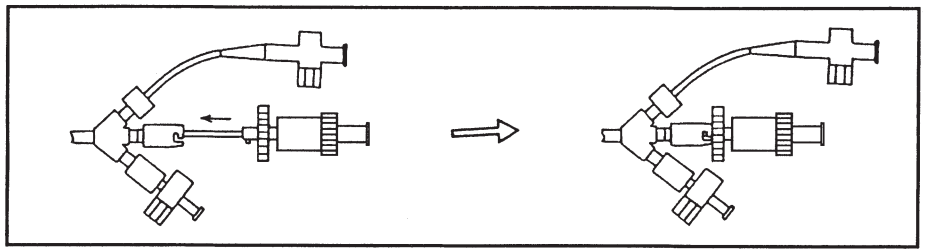

FIGURE 9

The balloon will lengthen and straighten at this point. If desired, apply sterile water-soluble medical lubricant to the balloon to aid in insertion. Rinse guidewire, dilator and stylet with heparinized saline solution.

3. Use of the Stylet

The stylet tip is pre-shaped in a "J" configuration. Prior to use, the stylet may be manually shaped into a curve matching the anatomy of the patient's left atrium. Fully insert the stylet into the balloon catheter to confirm the handling characteristics. During the procedure, the balloon catheter can be maneuvered with the stylet: as the stylet is advanced, the balloon tip moves away from the orifice; conversely, as the stylet is rotated counterclockwise and withdrawn, the balloon tip will move toward the orifice. Withdraw and remove the stylet from the balloon catheter.

E. Percutaneous Transvenous Mitral Commissurotomy

1. Cardiac Catheterization
   a. Using an introducer set, insert a thermo-dilution catheter into the femoral vein or jugular vein, then perform a routine right heart catheterization.
   b. By way of the left femoral artery, insert a 5F pigtail catheter retrograde into the aorta.
   c. By way of the right femoral vein, insert the Brockenbrough catheter and puncture the interatrial septum by means of the Brockenbrough method to insert the Brockenbrough catheter into the left atrium. An 8F transseptal sheath may be used for this purpose.
   d. Administer heparin. The total amount of heparin administered should not be less than 100 units/kg.
   e. Using the above three catheters, measure and record simultaneous pressures inside the left atrium and left ventricle, while measuring the cardiac output.

2. Insertion of Balloon Catheter into Left Atrium
   a. After pressure measurement, insert the guidewire into the left atrium through the Brockenbrough catheter. Remove the Brockenbrough catheter, leaving the guidewire in place. Over the guidewire, introduce the dilator to dilate the femoral vein puncture site and the interatrial septum [See Figure 10]. Remove the dilator.

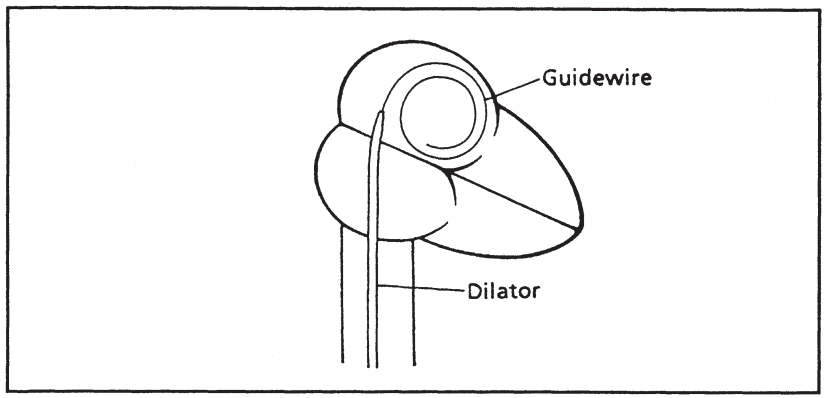

FIGURE 10

   b. Insert the elongated balloon catheter, containing the balloon stretching tube, into the left atrium over the guidewire [See Figure 11a]. NOTE: Echocardiography may be used to assist in passing the catheter through the septum and the valve orifice.

c. When the greatest portion of the balloon has passed the interatrial septum and the tip of the balloon nears the upper wall of the left atrium, withdraw the balloon stretching tube out of the catheter inner tube approximately 2-3cm [See Figure 11b]. This will result in the tip portion of the balloon becoming more elastic. NOTE: In the small patient, do not insert the balloon portion completely through the interatrial septum prior to withdrawal of the balloon stretching tube.
d. Advance both the catheter and balloon stretching tube approximately 5cm and insert the unit archwise into the left atrium along the guidewire, thus passing the entire balloon section through the septum [See Figure 11c]. Unlock the inner tube from the W-connector of the catheter and pull out until resistance is felt, thus returning the extended balloon to its original length [See Figure 11d].
e. Then, advance the balloon catheter further over the guidewire in the shape of the left atrial arch, maintaining the position of the balloon stretching tube [See Figure 11e].
f. Remove both the guidewire and balloon stretching tube simultaneously, leaving only the balloon catheter.

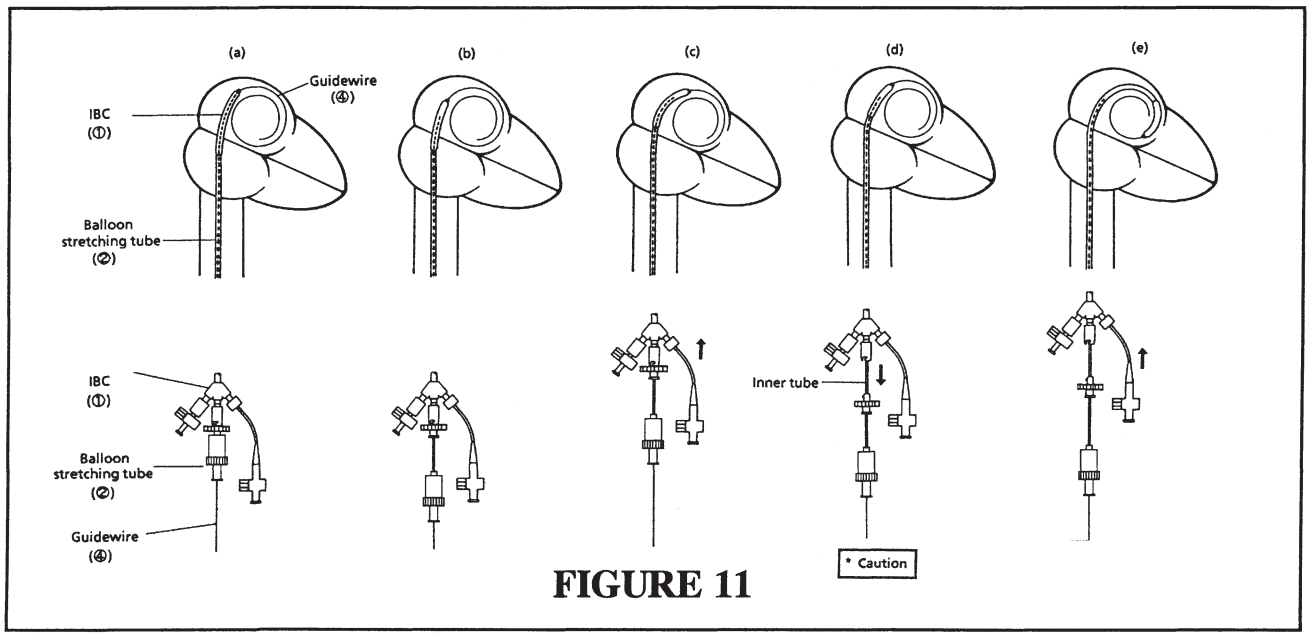

FIGURE 11

CAUTION: After initial catheter introduction, do not disconnect or reconnect the metal hubs from each other or the "W" connector unless the guidewire is in place and fully protrudes from the catheter tip. Should this caution be disregarded, the catheter could bend at an acute angle resulting in damage to the device or difficulty in carrying out the procedure. Never use a kinked balloon.

NOTE: Should kinking occur, observe the following steps:

- DO NOT attempt to reconnect the metal hubs to the "W" connector.
- Inflate and deflate the balloon completely.
- Re-introduce the .025" spring coil guidewire.
- Advance the balloon stretching tube and connect the hubs.
- Connect the hubs to the "W" connector which returns the balloon to the original stretched configuration.
- Withdraw the catheter and discard. Use another balloon.

3. Insertion of Balloon Catheter into Mitral Valve Orifice
   a. Slightly inflate the balloon tip to facilitate passage through the mitral orifice. Inflate balloon tip according to the size of the valve opening seen during cardiac catheterization. If the mitral orifice is very small, do not inflate the balloon tip at this time [See Figure 12]. If the balloon tip becomes lodged in the valve opening, withdraw a small amount of dilute contrast to allow for passage through the valve opening and to prevent a decrease in arterial pressure. (If the tip is too large, it cannot pass through the valve opening, and if too small, there is a possibility of straying among the chordae tendineae.)

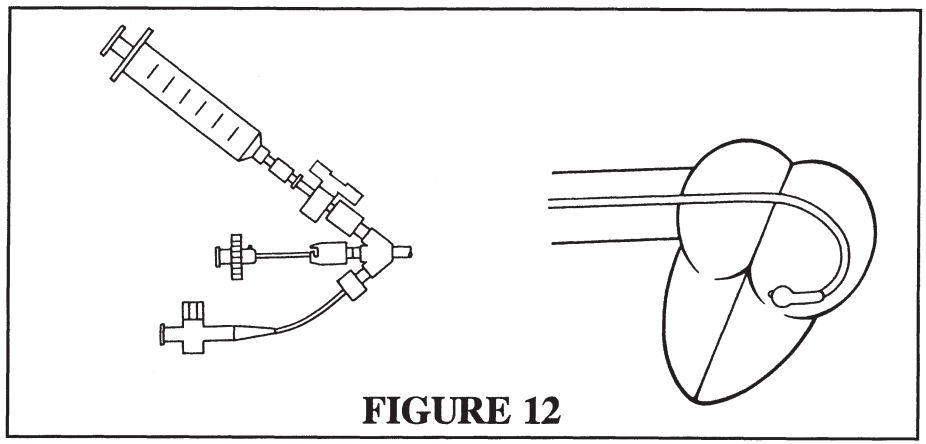

FIGURE 12

   b. Insert the stylet into the balloon catheter and direct the balloon tip into the valve opening. Set the balloon catheter in this position and pull the stylet back 3-5cm. The balloon, with tip inflated, will move forward and flow across the mitral orifice, similar to a thermodilution catheter. Turning the stylet slightly counterclockwise will make insertion easier [See Figure 13]. (The mitral valve opening is usually located on the ventral side.) It is also recommended that the procedure be done positioning the fluoroscope in an anterior oblique position. If the balloon becomes impinged in the septal opening, withdraw the stylet and use the guidewire to advance the catheter.

CAUTION: During manipulation of the stylet to direct the balloon, it is very important to hold the W-connector rather than the inner tube (proximal end of the catheter). If the inner tube is held, the lumen of the catheter can become twisted, thus occluding the lumen and blocking subsequent advancement or withdrawal of the guidewire or stylet. Do not twist the catheter lumen in this manner as it may adversely affect balloon performance.

NOTE: If the above insertion is difficult, the stylet should be removed and the shape modified to correspond with the patient's anatomy.

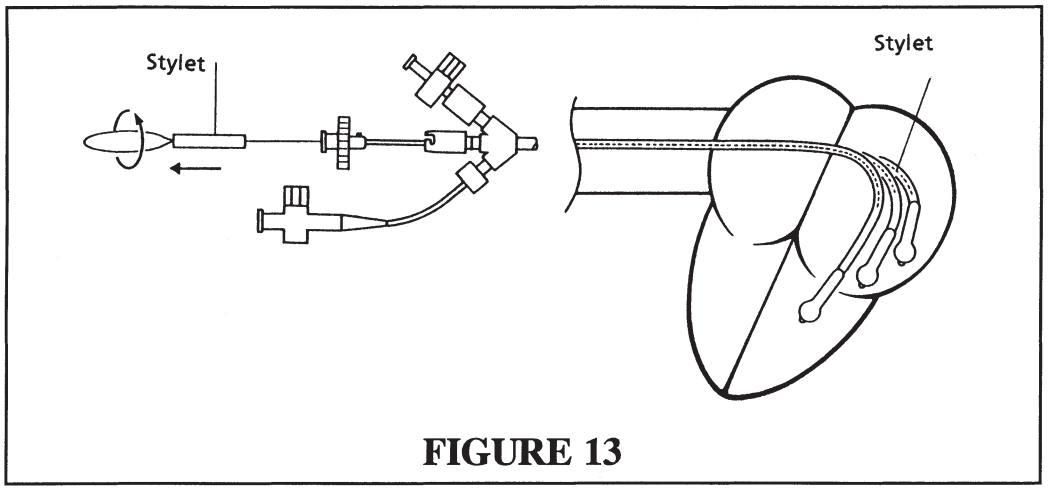

FIGURE 13

4. Enlarging the Mitral Valve Opening
   a. Inflate the distal half of the balloon with dilute contrast medium, injected into the main stopcock (A). (The total amount of dilute contrast medium in the syringe must correspond to the desired balloon diameter as seen on the red indicator bar.) [See Figure 14.]

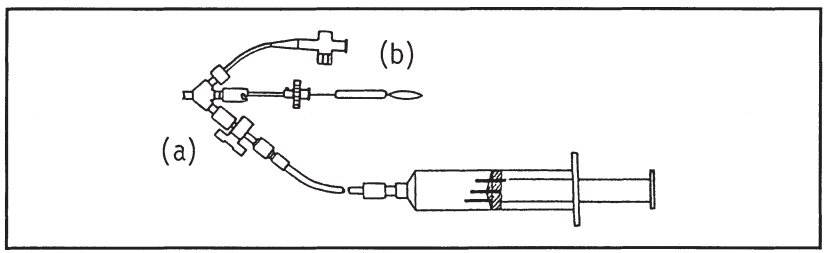

FIGURE 14

b. Move the balloon back and forth 2-3 times inside the left ventricle to confirm that the balloon has not wandered into the chordae tendineae and seat the balloon on the valve opening by pulling gently [See Figure 15]. (If pulled too strongly, the interatrial septum may be damaged. Conversely, if the pull is too light, the balloon will not seat on the valve orifice and may inflate entirely inside the left ventricle.)

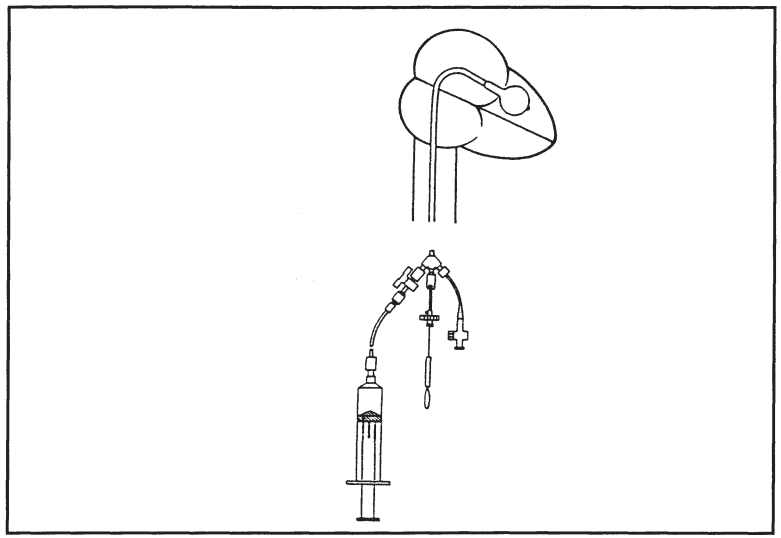

FIGURE 15

c. Inject the remaining dilute contrast medium quickly [See Figure 16a]. Valve dilatation should begin with the smallest inflation volume in order to achieve a gradual opening of the stenosed mitral valve. During inflation, the medial constriction of the balloon will center in the valve opening and prevent migration from this position. Once the balloon is fully expanded, the stenotic valve opening will enlarge due to the balloon volume. Deflate the balloon by withdrawing the dilute contrast medium into the syringe [See Figure 16b].

CAUTION: Using too large a balloon inflation volume could damage the valve or result in balloon malfunction, i.e., mesh tear. Once the balloon is inflated, the amount of time the valve opening is blocked must be minimal (5-7 seconds).

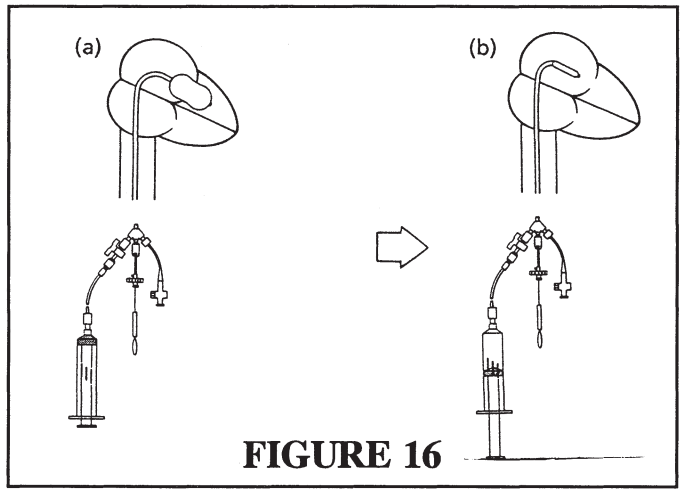

FIGURE 16

d. Following dilatation and deflation, withdraw the balloon catheter into the left atrium and proceed with simultaneous pressure measurements in the left atrium and ventricle via the catheters utilized in the cardiac catheterization. At the same time, measure cardiac output. The degree of valve opening and the existence of mitral regurgitation are determined by hemodynamic evaluation and auscultation as well as examinations by the Doppler method, ultrasound and angiography.
e. If, as a result of the above examinations, the valve is not dilated sufficiently, the procedure may be repeated by further balloon inflations. When the valve opening has reached an appropriate size or mitral regurgitation has occurred or increased significantly, the procedure should be discontinued.

The following factors will assist the clinician in determining the number and inflation volume of subsequent dilatations:

(1) The appearance and degree of resultant mitral regurgitation;
(2) The increase in mitral valve area;
(3) The degree of separation of the mitral commissures; and
(4) The reduction of the pressure gradient across the valve.

CAUTION: If mitral regurgitation occurs or increases significantly, the procedure must not be repeated using a larger balloon inflation volume.

5. Extracting the Balloon Catheter

   The process for balloon catheter extraction is similar to that for catheter insertion. Initially, insert the guidewire and immediately follow with insertion of the balloon stretching tube into the catheter inner tube. To avoid damage to the guidewire, it is recommended that the coiled portions of the guidewire remain outside the distal end of the balloon stretching tube during reinsertion of this assembly. Elongate the balloon section as before, extract the catheter and accessories as a unit. The guidewire must continue to protrude from the catheter tip. When elongating the balloon for removal, care should be taken. If the left atrium is too small for normal withdrawal, it is recommended that the balloon be slenderized by pulling the catheter back toward the metal hubs rather than advancing the inner tube.

6. Alternate Procedure

   An alternate procedure for balloon placement (posterior approach) may be useful in the case of a patient with a very large left atrium or unusual anatomical features, or when the septal puncture is made anteriorly. Insert the device through the septum and into the left atrium as previously described, and maintain a large loop in the catheter. The balloon segment is kept flexible by withdrawing the stylet tip to a point 5 to 6cm from the tip of the catheter [See Figure 17a]. Rotate the stylet clockwise to bring the balloon tip toward the posterior inferior atrial wall [See Figure 17b]. Hold the stylet stationary and advance only the catheter. This will cause the balloon to move forward along the inferior wall of the left atrium and cross the mitral orifice into the left ventricle [See Figure 17c].

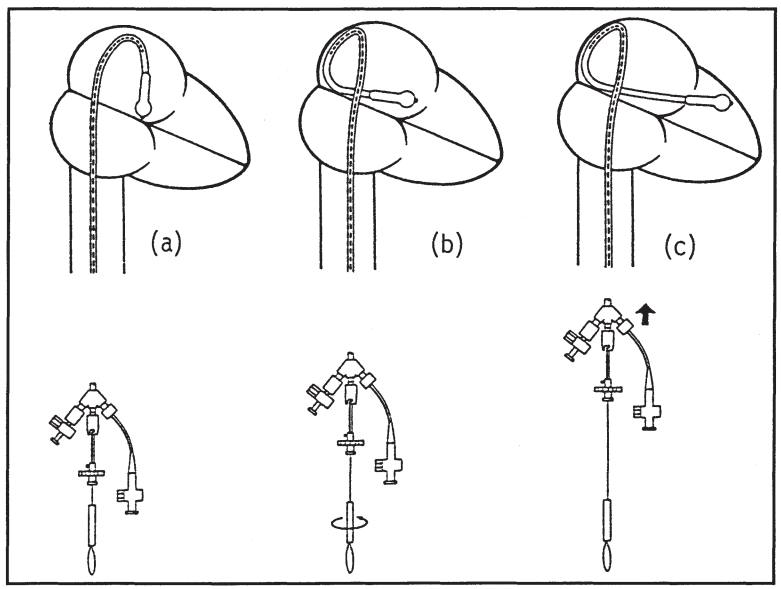

FIGURE 17

F. Possible Complications

1. Possible Complications
   Possible complications associated with use of the Inoue-Balloon Catheter include, but are not limited to:

- Increase in valvular regurgitation.
- Failure of the catheter to traverse the stenotic valve orifice.
- Vasovagal reaction.
- Cardiac dysrhythmias such as atrial fibrillation, heart block, sinus bradycardia, and ventricular tachycardia or fibrillation.
- Vascular injury with or without the need for surgical intervention.
- Congestive heart failure or pulmonary edema.
- Failure or malfunction of the balloon or other components of the catheter kit.
- Injury to or perforation of the myocardial wall with or without cardiac tamponade.
- Damage to the mitral valve or ruptured chordae tendineae.
- Thrombus formation; embolization of thrombus, valve fragments, calcium, or air bubbles.
- Myocardial infarction.
- Transient ischemic attack; transient visual defect.
- Blood loss requiring fluid replacement or transfusion of blood products.
- Atrial septal defect, transient or persistent, with or without hemodynamic compromise.
- Infection.
- Allergy or anaphylactic reaction to dilute contrast medium or device components.
- Failure to traverse the vascular system with the balloon catheter.
- Decreased aortic pressure when blood flow across the valve orifice is temporarily obstructed by the inflated balloon.
- Loss of limb.
- Respiratory arrest.
- Renal failure.
- Death

In addition, it is possible that the procedure will produce insufficient hemodynamic improvement and the patient will have been exposed to the normal risks of cardiac catheterization. Furthermore, restenosis of the dilated valve may occur, with or without return of pre-treatment symptoms.

2. Failure of the balloon to deflate

The clinician should be aware of the measures to take in the rare event that the balloon does not deflate and the dilute contrast medium cannot be withdrawn into the syringe. This occurs only when excessive stress has been placed on the balloon catheter. General measures to prevent undue stress on the catheter include:

- During insertion and advancement of the elongated balloon catheter into the femoral vein, avoid forceful twisting of the catheter.

- When using the stylet to direct the balloon tip into the valve opening, avoid rotating the catheter in the opposite direction to that which the stylet is being rotated. Do not twist the catheter lumen in this manner as it may adversely affect balloon performance.

CAUTION: During manipulation of the stylet to direct the balloon, it is very important to hold the W-connector rather than the inner tube (proximal end of the catheter). If the inner tube is held, the lumen of the catheter can become twisted, thus occluding the lumen and blocking subsequent advancement or withdrawal of the guidewire or stylet. Do not twist the catheter lumen in this manner as it may adversely affect balloon performance.

If the balloon is subjected to twisting forces beyond those which it is designed to withstand, a small opening in the inner balloon layer may develop, thus allowing leakage of the radiopaque dilute contrast medium into the space between the two latex layers of the balloons. At this point, the outer wall of the balloon is the only layer which will expand [See Figure 18].

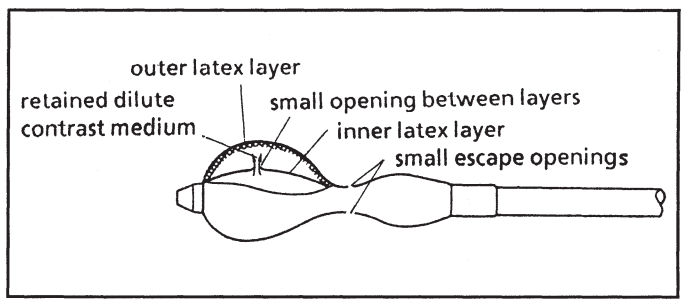

FIGURE 18

Should this occur, the clinician would observe that deflation of the balloon following valvuloplasty becomes impossible. This is due to the continued flow of dilute contrast medium from the center of the balloon into the space between the two layers. The opening between the layers acts as a one-way valve and obstructs the return flow of dilute contrast medium as the inner layer contracts, thus preventing the dilute contrast medium from being withdrawn when negative pressure is exerted on the syringe.

If the balloon cannot be deflated, it must immediately be withdrawn from the valve orifice into the left atrium, then pulled just to the atrial septal wall.

The unique design of the Inoue-Balloon Catheter features two small holes through which the dilute contrast medium will gradually escape. They are located 180° from one another in the outer latex layer of the center (waist) of the balloon. After withdrawing the balloon to the atrial septal wall, the user should then extend the balloon by inserting the guidewire and balloon stretching tube. The guidewire must extend beyond the catheter tip [See Figure 19].

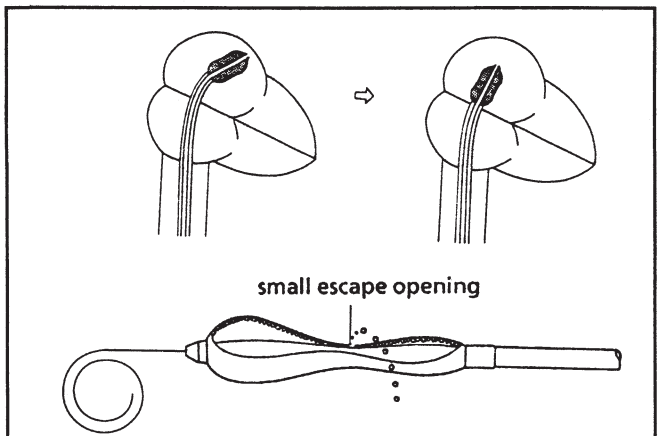

FIGURE 19

This action will facilitate and accelerate the flow of the dilute contrast medium from the balloon, which will take approximately 10 minutes. If deflation is not complete within this time, wait several more minutes until the balloon has deflated spontaneously. At this time, ensure that the heparin has been administered in adequate amounts to prevent thrombus formation; an additional dose may be required. The catheter may be withdrawn across the atrial septum when the balloon diameter is 15mm or less, as the balloon will be soft and pliable due to the fact that only the outer layer has continued to expand.

CAUTION: In this situation, do not use normal saline or any other fluid to inflate the balloon. Do not attempt to expand the balloon to the point of rupture as several times the maximum inflation volume is required for rupture to occur.

G. Recommended Follow-up

Patient follow-up should occur within several weeks and again after several months following the procedure using echocardiography, cardiac catheterization or ultrasound to confirm the hemodynamic effects of the PTMC procedure and to examine for recurrent stenosis. The criteria used to determine the need for repeat balloon dilatation or other intervention should include, in addition to an assessment of the patient's symptom status, an objective assessment of the degree of mitral stenosis and mitral regurgitation. Modalities that may be employed for objective assessment include echo Doppler, catheter pressure recordings and contrast angiography.

V. Sterilization, Handling, Storage

The Inoue-Balloon Catheter and its accessories are sterilized with ethylene oxide gas prior to shipment. Before the package is opened, it should be examined carefully for damage that may have compromised sterility. If such damage is detected, the entire contents should be returned to Toray Industries, Inc. This balloon catheter and its accessories must not be re-sterilized by the user. The device should be stored at room temperature in a dark place; excessive heat or cold may damage the balloon.

VI. Service

Toray Industries, Inc. employs highly trained representatives and clinical engineers to provide training to qualified hospital personnel in the use of this product. In addition, Toray maintains a professional staff of consultants to provide technical and medical consultation to product users. For supplemental information, contact your local representative or call or write Toray.