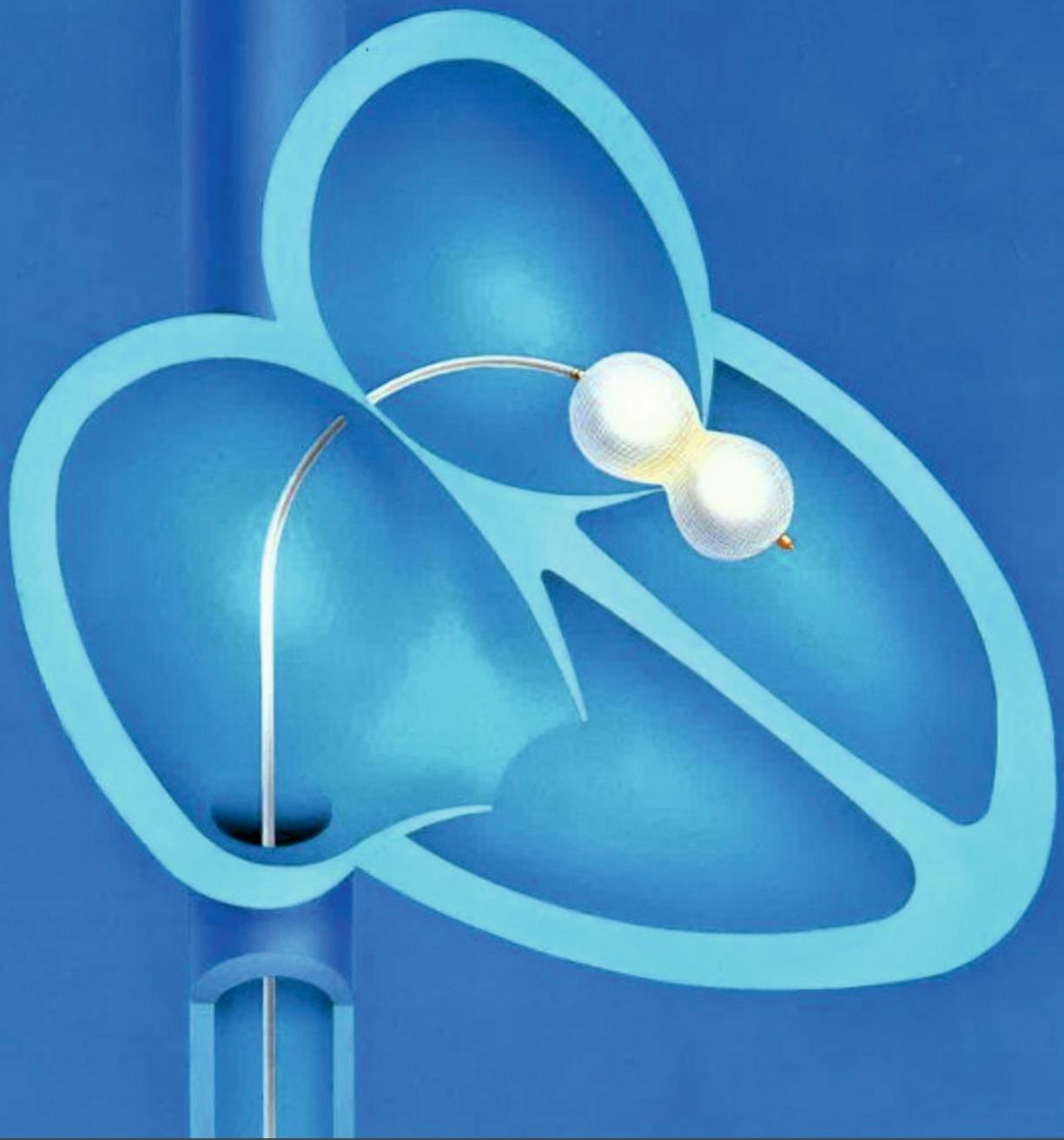


PBMV

Balloon Catheter Set

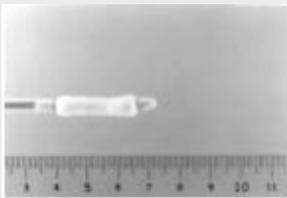
Specially designed for the
treatment of Mitral Valve Stenosis



Major Features

1. Specially designed balloon, perfectly shaped to fit the mitral valve
2. Short inflation/deflation cycle
3. New small & soft tip for safety
4. Longer guidewire to increase safety in taller patients
5. Third vent for extra safety

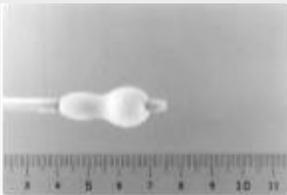
The Balloon Design Exhibits Five Uniquely Different Inflation Stages



Stage 1

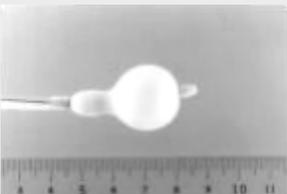
Balloon completely deflated

Allows catheter advancement & passage through the atrial septum



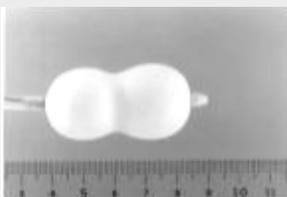
Stage 2

Distal portion partially inflated- When a small volume of dilute contrast medium is injected, the distal portion of the balloon inflates first. The balloon may float across the mitral valve, like a thermodilution catheter



Stage 3

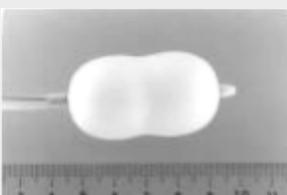
Distal portion completely inflated - When a larger volume of dilute contrast is injected, the distal portion inflates completely. This aids in seating the balloon on the valve.



Stage 4

Hourglass shape

A latex band placed at the center of the balloon constricts inflation. Consequently, when additional dilute contrast medium is injected, the balloon shape resembles an hourglass. This unique shape centers the balloon on the valve and prevents migration.



Stage 5

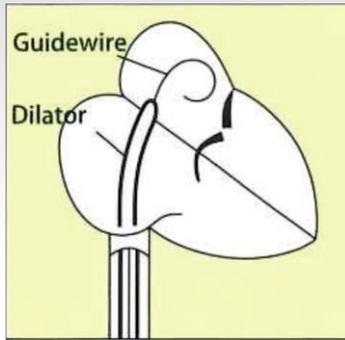
Full Inflation

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

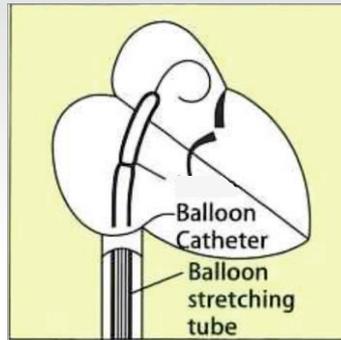
Indication & Direction for Use:

Mitral valve stenosis

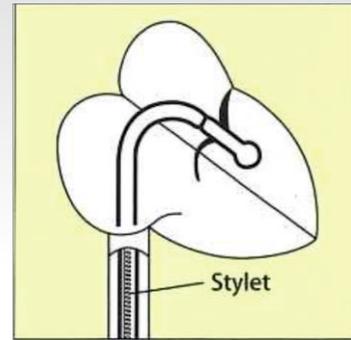
Directions for Use (Summary)



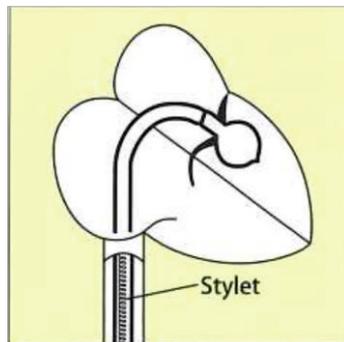
1. After inserting the guidewire into the left atrium, expand atrial septal puncture with the dilator



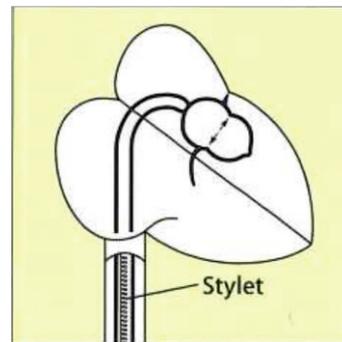
2. Insert the balloon catheter with the balloon stretching tube incorporated



3. Place the balloon at the valvular opening using the stylet

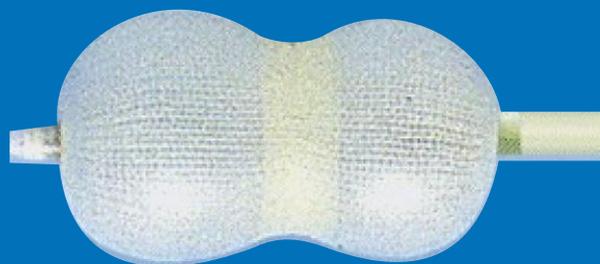


4. Inflate the distal portion of the balloon to place it at the valvular opening.



5. Inflate the entire balloon to expand the opening of the valve.

Balloon Sizes Formula: $\frac{\text{Height in cm}}{10} + 10 = _ \text{ mm}$



Note 1: For details, read package insert (in the kit box)

Note 2: This procedure should be carried out only by physicians trained and qualified in PTMC techniques.

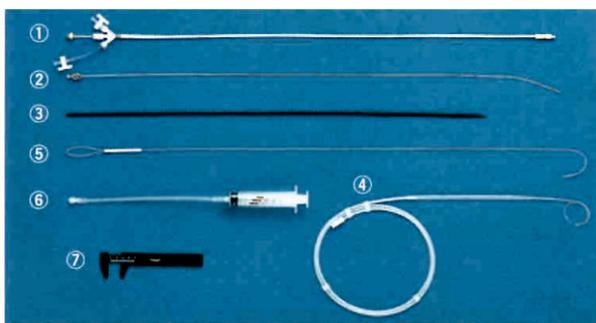
Note 3: Use of this procedure is recommended only in facilities where cardiac surgery can be performed within a reasonable period of time.

Product specification / Ordering information

PBMV balloon catheters are supplied as a complete set containing balloon catheter, guidewire, dilator, stretching tube, stylet, ruler and syringe.

Balloon Code	Inflation Range	PBMV SetCode	Catheter O.D.	12 F
PBMV-20	16-20 mm	PBMV-20S	Catheter Length	800mm
PBMV-22	18-22 mm	PBMV-22S	Maximum working pressure	280 KPa
PBMV-24	20-24 mm	PBMV-24S	Burst Pressure	450 KPa
PBMV-26	22-26 mm	PBMV-26S		
PBMV-28	24-28 mm	PBMV-28S		
PBMV-30	28-30 mm	PBMV-30S		

Item	Purpose	O.D.	Length
Balloon Catheter	Dilating mitral valve	12F	800mm
Stretching tube	Stretching Balloon Catheter	1.2mm	800mm
Dilator	Dilating puncture site	14F	700mm
Guidewire	Guiding balloon catheter	0.025"	1800mm
Stylet	Directing balloon to mitral valve	0.038"	800mm



Use:

1. Dilation of mitral valve
2. Elongation of balloon
3. Dilation of insertion areas
4. Guiding the balloon catheter & dilator
5. Directing balloon to mitral valve
6. Inflation of balloon
7. Measurement of balloon diameter

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