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I. Percutaneous Transvenous Mitral Commissurotomy: PTMC (Mitral Valvuloplasty)

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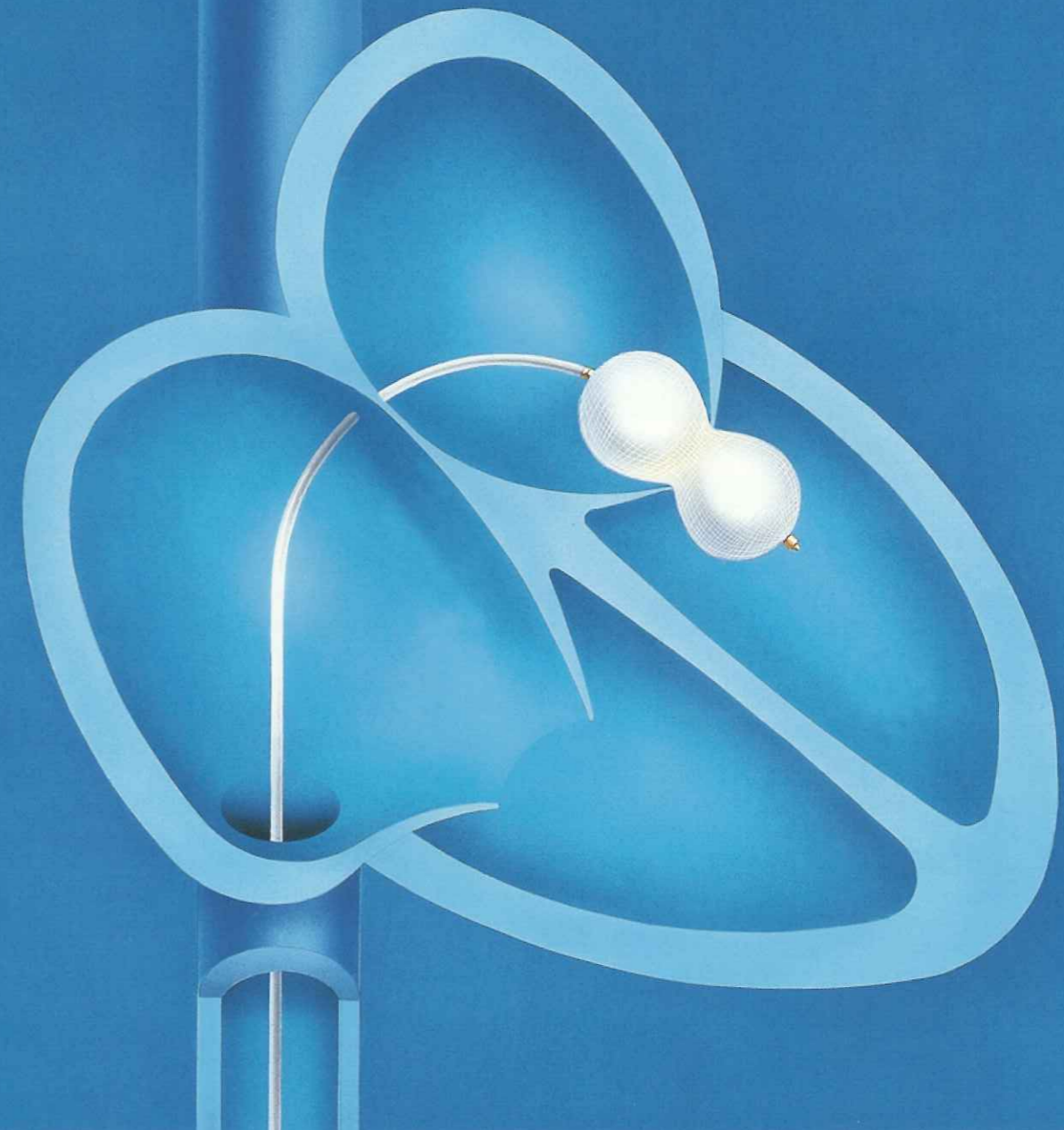
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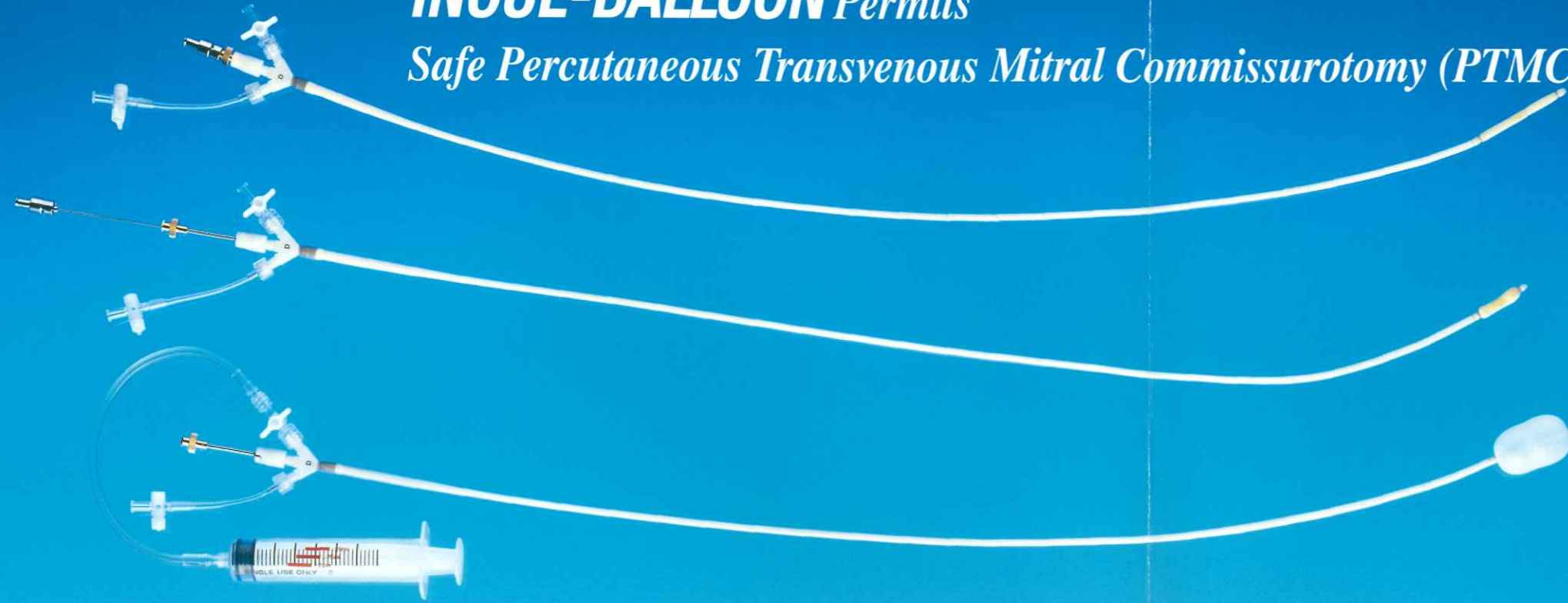


For Percutaneous Transvenous Mitral Commissurotomy (PTMC)

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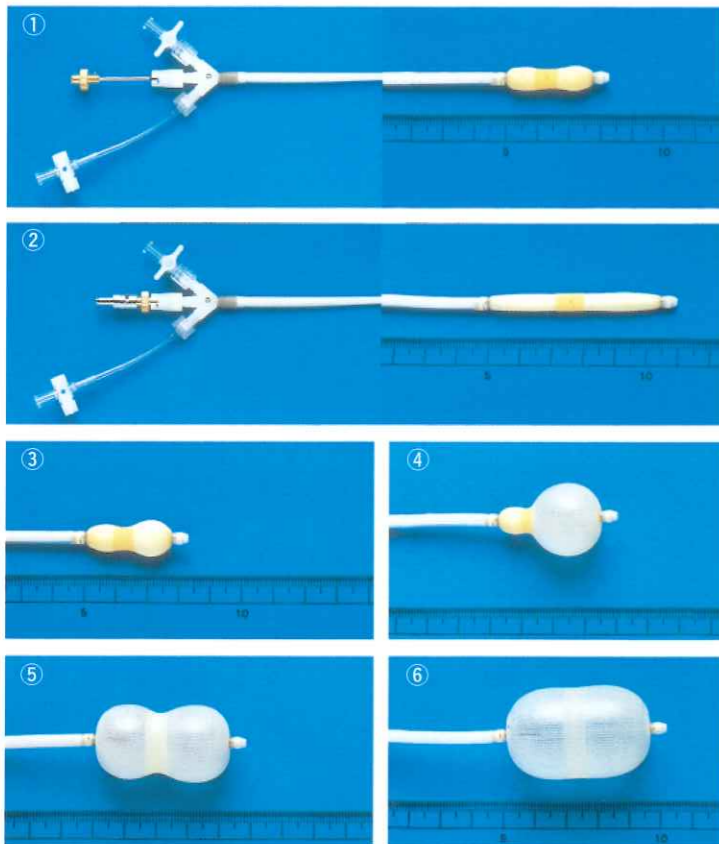
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INOUE-BALLOON Permits Safe Percutaneous Transvenous Mitral Commissurotomy (PTMC)



The first balloon catheter for the treatment of mitral stenosis has the following simple operative procedures :

Simple Operative Procedure:



- ① Original shape.
- ② Introduce the balloon stretching tube to slenderize and elongate the balloon.
- ③ Inflate the distal portion of the balloon slightly (10-15mm) with dilute contrast medium.
- ④~⑥ The balloon inflates in three stages.

Advantages:

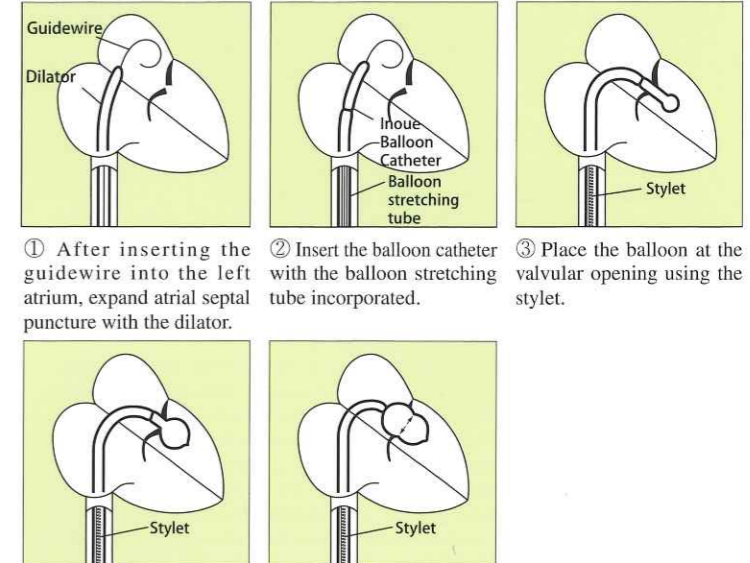
- (1) A single balloon catheter provides a sufficient expansion range to assure a simple as well as safe procedure.
- (2) The low profile of the stretched balloon facilitates percutaneous introduction through the femoral vein. This technique prevents the development of atrial septal defect (ASD). (photo-②)
- (3) Changing the shape of the balloon with the filling volume simplifies placing the catheter at the site of stenosis (photo-③). The volume controlled hour-glass shape of the balloon assures proper positioning at the stenosis, prevents migration of the catheter and provides optimal dilation (photo-④,⑤,⑥)
- (4) The range of each balloon size is controlled by the volume of dilute contrast medium. (See table).

Cat. No.	Balloon diameter range
PTMC-30, IMS-30	26mm ~ 30mm
PTMC-28, IMS-28	24mm ~ 28mm
PTMC-26, IMS-26	22mm ~ 26mm
PTMC-24, IMS-24	20mm ~ 24mm
PTMC-22, IMS-22	20mm ~ 22mm
PTMC-20, IMS-20	18mm ~ 20mm

- (5) The unique balloon construction exhibits dynamic inflation properties sufficient for valvular expansion. Rapid inflation/deflation cycle (5sec.) quickly returns valve to normal function.
- (6) This treatment (PTMC) is performed without thoracotomy with the following special features:
-Short procedure time -Short hospital stay -Can be indicated for the debilitated elderly, patients with renal insufficiency; pregnant women; patients with poor surgical risk.

Indication and Directions for Use:

- Mitral valve stenosis
- Directions for Use (Summary)



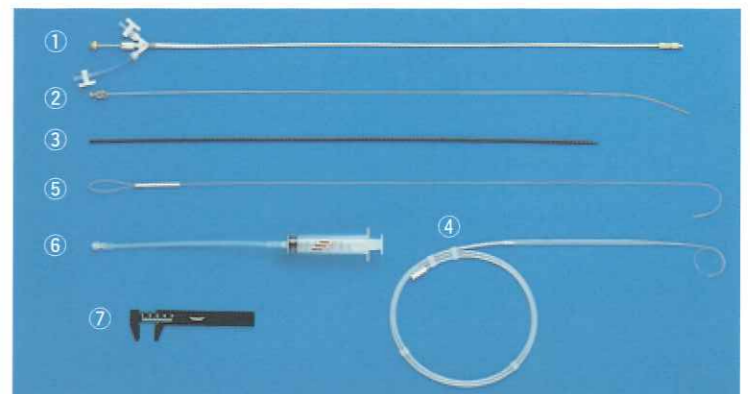
- ① After inserting the guidewire into the left atrium, expand atrial septal puncture with the dilator.
- ② Insert the balloon catheter with the balloon stretching tube incorporated.
- ③ Place the balloon at the valvular opening using the stylet.

- 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.

- 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.

Set Contents

Description	Use
① Inoue Balloon Catheter	Dilation of mitral valve
② Balloon stretching tube	Elongation of balloon
③ Dilator	Dilation of insertion areas
④ Guidewire	Guiding the balloon catheter and dilator
⑤ Stylet (spring)	Directing balloon to mitral valve
⑥ Syringe	Inflation of balloon
⑦ Ruler	Measurement of balloon diameter



SPECIFICATION

INOUE-BALLOON

Cat. No.	Balloon Diameter (Max)	Catheter Size		Patient Height
		Outer Diameter	Length	
PTMC-30, IMS-30	30mm	12Fr.	70cm	> 180cm
PTMC-28, IMS-28	28mm	12Fr.	70cm	> 160cm
PTMC-26, IMS-26	26mm	12Fr.	70cm	> 147cm
PTMC-24, IMS-24	24mm	12Fr.	70cm	≤ 147cm
PTMC-22, IMS-22	22mm	12Fr.	70cm	≤ 147cm
PTMC-20, IMS-20	20mm	12Fr.	70cm	≤ 147cm

※ IMS-30, IMS-28, IMS-26, IMS-24, IMS-22, IMS-20, contains balloon catheter and syringe only.

- Package: 1 set/case
- EOG sterile

Individually supplied as follows

Cat. No.	Description	Size	
		Outer Diameter	Length
KMS-1	Balloon stretching tube	1.2mm	80cm
DMS-1	Dilator	14Fr.	70cm
GMS-1	Guidewire	.025"	175cm
SMS-1	Stylet	.038"	80cm

Cat. No.	Description	Measurement range	Degree of accuracy
NMS-1	Ruler	0mm ~ 40mm	±0.5mm

- Package: 2 Units/case
- EOG sterile