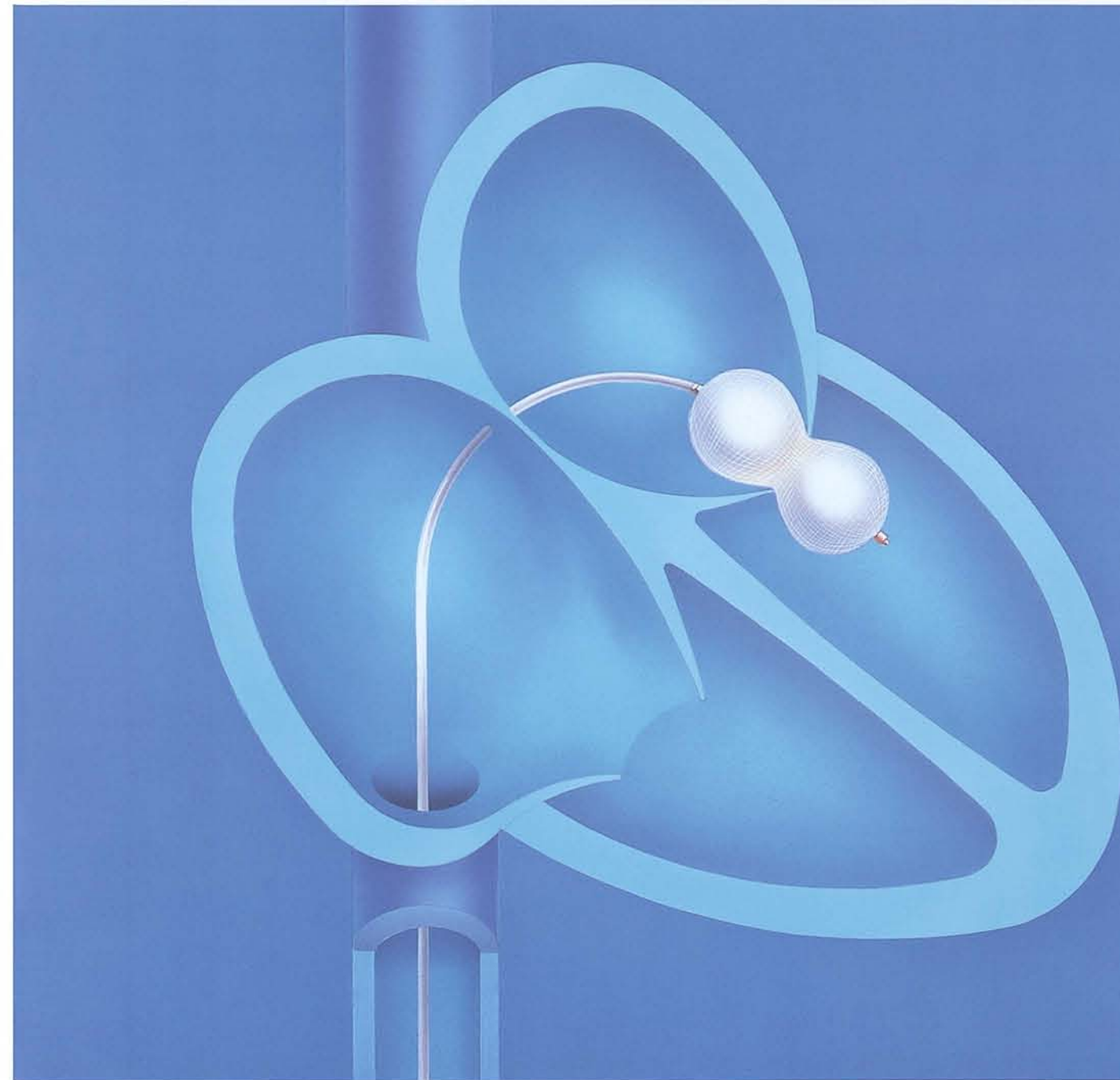


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INOUE-BALLOON



For Percutaneous Transvenous Mitral Commissurotomy (PTMC)

'TORAY'

Exporter:
Toray Medical Co., Ltd.
 ARCA CENTRAL 21F, 2-1, Kinshi 1-chome,
 Sumida-ku, Tokyo 130-0013, JAPAN
 Telephone: +81(3)5610-6536
 Fax: +81(3)5610-6545
 Manufacturer:

Hoshina Co., Ltd.
 Hoshina Bldg., 16-13, Hongo 2-chome,
 Bunkyo-ku, Tokyo 113-0033, JAPAN

Representatives: ☎ 0123
Toray Europe Ltd.
 3rd. Floor, 7 Old Park Lane, London, W1K1AD, England, U.K.
 Telephone: +44(20)7663-7700
Toray Marketing & Sales (America), Inc.
 140 Cypress Station Drive, Suite 210, Houston,
 TX 77090, U.S.A.
 Telephone: +1(281)587-2299, Within USA & Canada (800) 662-1777
Toray Industries (Singapore) Pte. Ltd.
 31C Exeter Road, #03-01 Comcentre II Atrium, Singapore, 239734,
 Republic of Singapore
 Telephone: +65(6734)5271

'TORAY'

Toray Medical Co., Ltd.

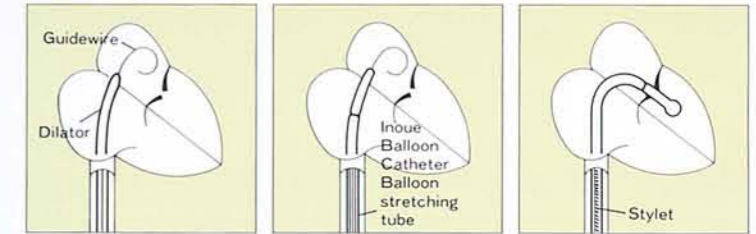
INOUE-BALLOON Permits Safe Percutaneous Transvenous Mitral Commissurotomy (PTMC)



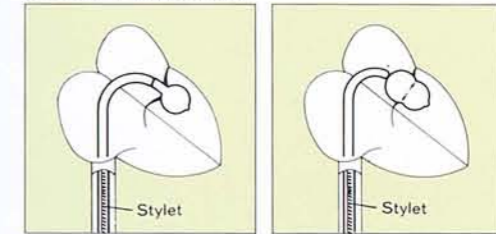
Indication and Directions for Use:

■ 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.

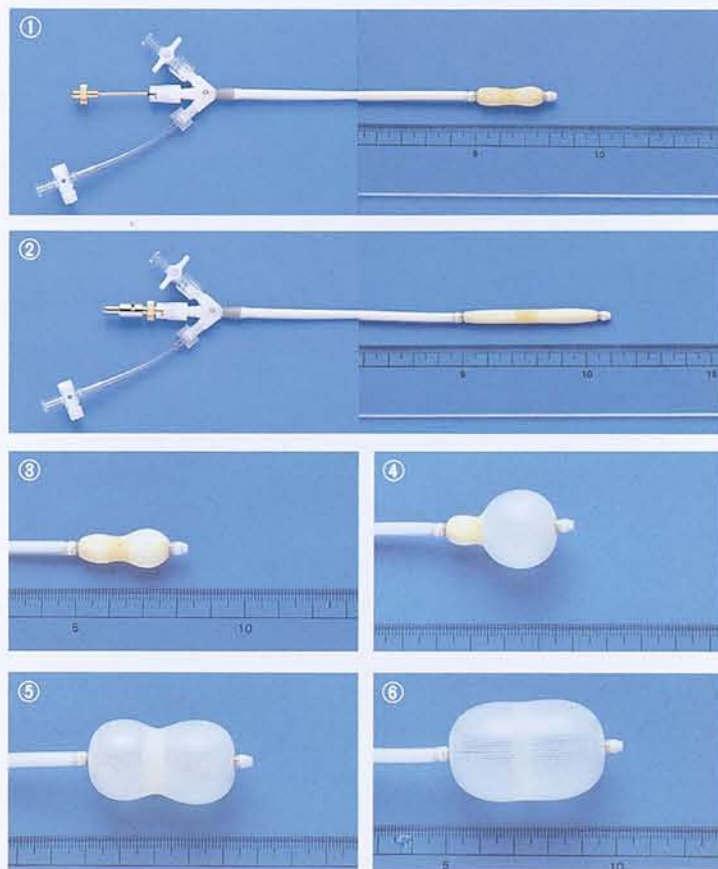
Note 1: For details, read package insert (in the kit box).

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.

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 media.
- ④-⑥ The balloon inflates in three stages.

Advantages:

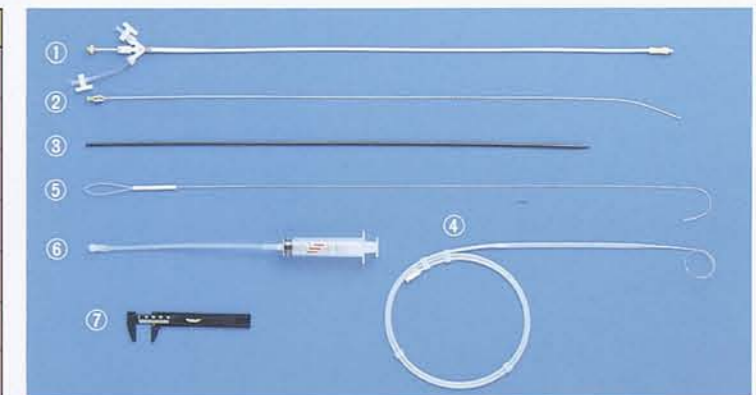
- (1) A single balloon catheter provides a sufficient expansion range to assure a simple as well as safe procedure.
- (2) The low profile of the stretched balloon facilitates percutaneous introduction through the femoral vein. This technique prevents the development of atrial septal defect (ASD). (photo-②)
- (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.

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

1 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	1.4Fr.	70cm
GMS-1	Guidewire	.025"	175cm
SMS-1	Stylet	.038"	80cm
NMS-1	Ruler	—	—

● Package: 2Units/case ● EOG sterile