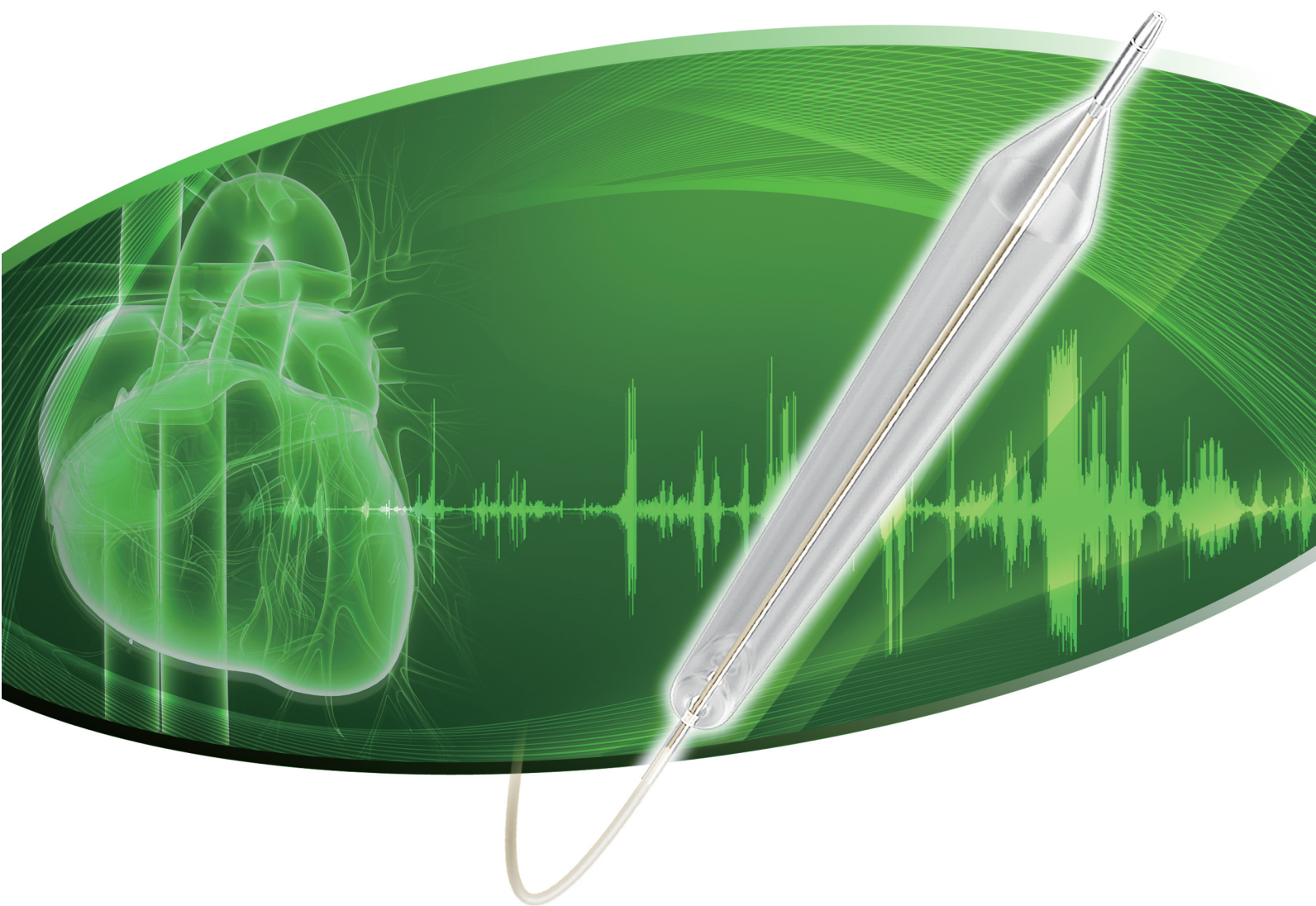




XEMEX IABP Balloon Plus



ZEON MEDICAL INC.

Development of New Concept Balloon

XEMEX IABP Balloon Plus “8F Short Balloon”

Three keys for patient-oriented catheter

XEMEX product development in close cooperation with medical sites

- Prevent renal arterial occlusion
- High augmentation performance
- Reduce balloon leak risk

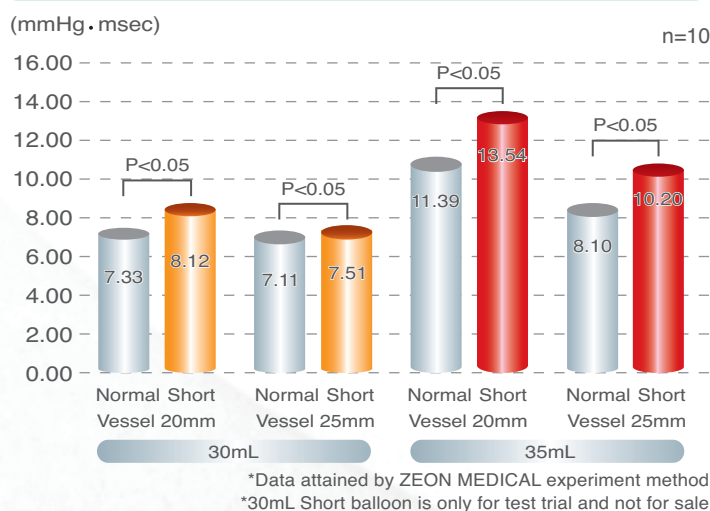


IABP Augmentation Efficacy

-Balloon diameter is increased by 2mm for better augmentation

The experiment proved that 35mL XEMEX Short IABP balloon catheter was remarkable in augmentation effect compared to Normal IABP.

Measurement of augmentation efficacy, short balloon and normal balloon

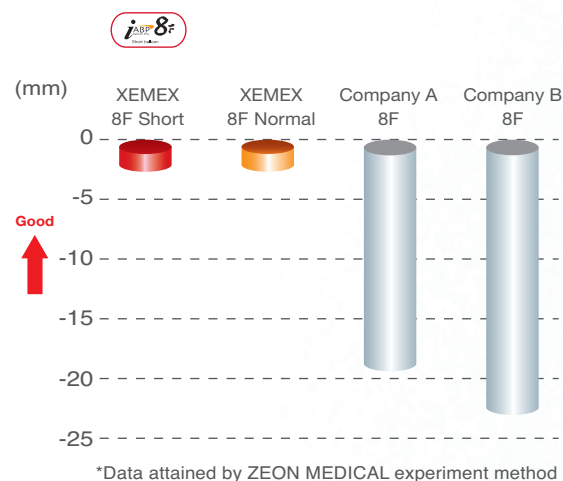


Catheter Migration

-Nylon catheter shaft performs high durability

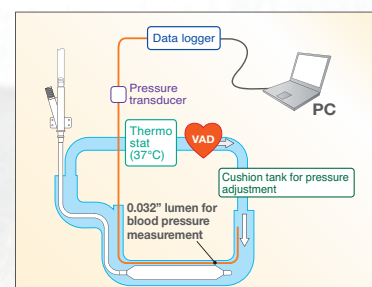
The experiment proved that XEMEX Short IABP is superior to those of competitors as well as XEMEX conventional balloon.

Measured tip positioning after 12-hour driving in the mock circuit



*Comparison of Length (35mL IABP)

- Balloon length is reduced by 25% of conventional balloon catheter
- Better pushability, better trackability and less risk of renal arterial occlusion



Mock circuit for the experiment

Pseudo Blood : 50% glycerin solution, warmed to 37°C (viscosity 4 cps)
Blood Pressure : 100/50 mmHg, heart rate 100bpm
Console : XEMEX IABP Console 908
Assist ratio : 1:4

Measurement of Aorta and analysis of IABP balloon sizes

Each size below was measured via images of CT (Figure 1)

No. of patients: 100 patients on whom contrast-enhanced CT was performed

Reference and citation: "Use of 8F Short Balloons at Our Facility"
by Kazuya Hirata, Department of ME, Hokkaido Social Insurance Hospital, Japan

Measured Items

1. Distance between left subclavian artery and aorta below renal artery
2. Minor diameter of descending aorta
3. Minor diameter of subphrenic aorta
4. Minor diameter of aorta below renal artery

The result shows that the aortic vessel tends to become smaller below the renal artery and appears calcification and intimal hypertrophy in approximately 30% of the patients. Considering IAB balloon length and balloon diameter, when 8F 35mL Normal IABP catheter was used in these patients, the catheter was positioned nearby the area below the renal artery in some cases, which raises the risk of balloon rupture and other complications. To ensure safety in this case, use of 8F 35mL Short IABP catheter seemed to be superior. (Figure 2)

In the analysis of balloon diameter, the diameter of the aortic artery was larger than the balloon diameter of the Short IABP at the site of the positioned IABP catheter. However, since the descending aorta begins to follow a tortuous course nearby the subphrenic region and there is a risk of the balloon contacting the vessel wall at the tortuous points, the augmentation level should be set properly by watching the balloon pressure patterns in order not to expose the vascular wall to excessive stress.

Figure 1 : Sites of measurement

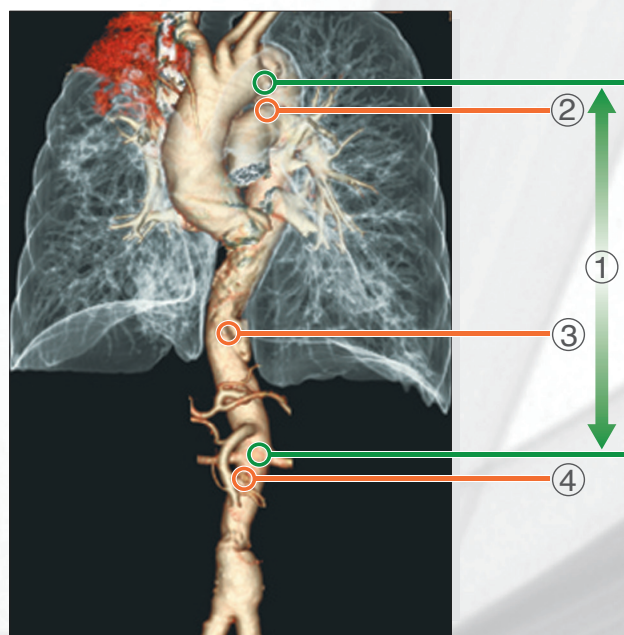
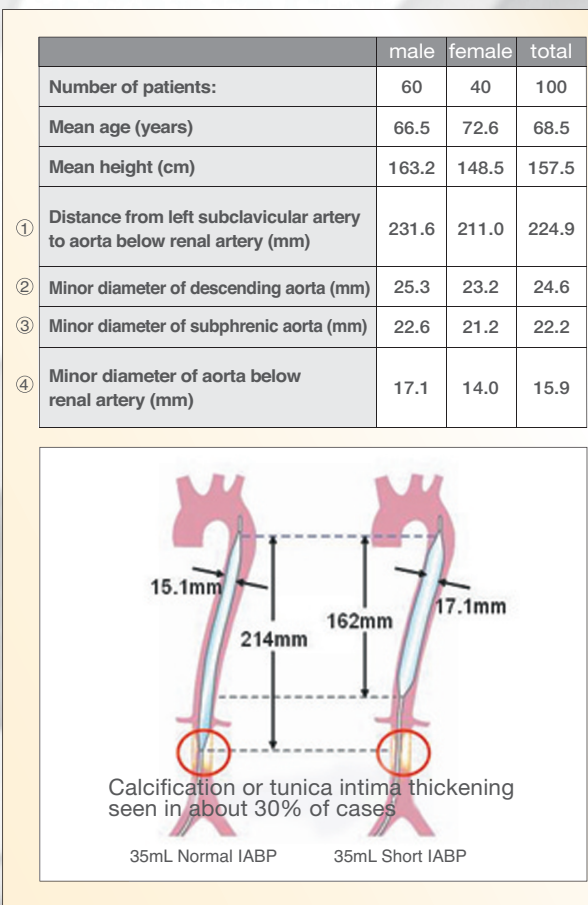


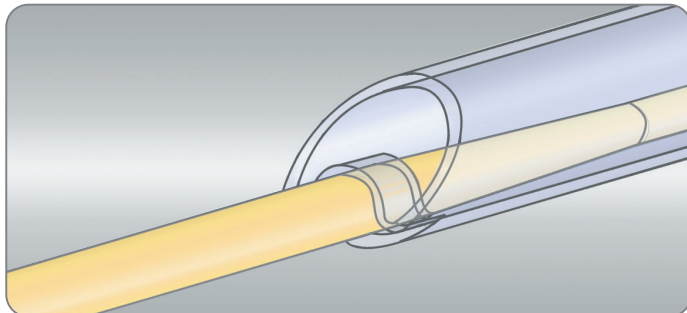
Figure 2 : Results of measurement



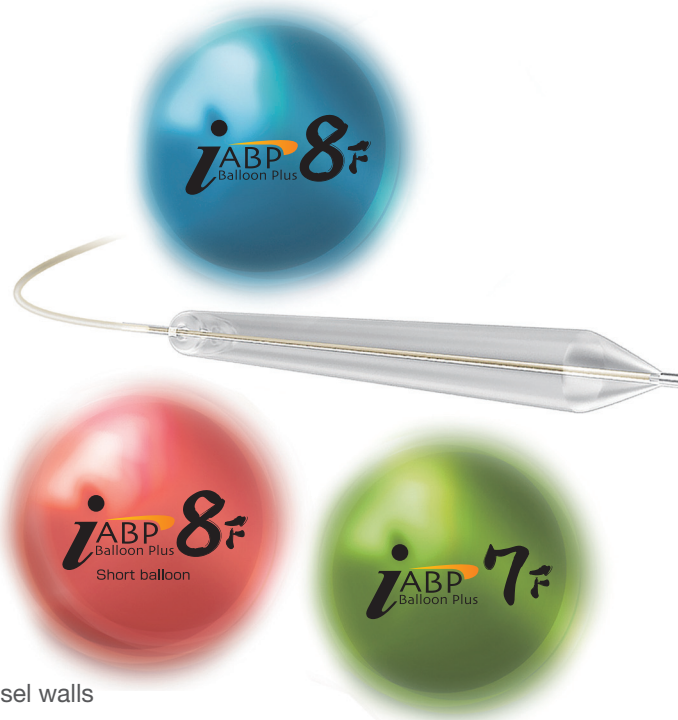
Data collected and analyzed by Hokkaido Social Insurance Hospital, Japan

Technology

1. Inner Stopper



- Strengthened adhesion of inner and outer tubes for stable pumping (patent pending)
- Integrated double lumen structure for superior response performance and durability of the catheter

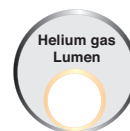


2. High Durability of Catheter Shaft

- Superior stability of Nylon catheter shaft
- Prevents catheter from blood heat softening and damage of vessel walls
- Stiffer shaft provides super trackability to catheter

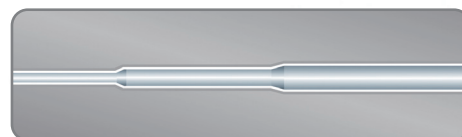
3. Integrated Double Lumen Structure

- Large helium gas lumen provides better response performance with small size catheters
- Kink-resistant performance improved by reliable inner and outer shaft anchoring



4. Three-Level-Diameter

- Tapered structure toward proximal of outer shaft provides catheter shaft durability
- Succeeded in higher response performance by enlargement of helium gas lumen of outer shaft outside of the body

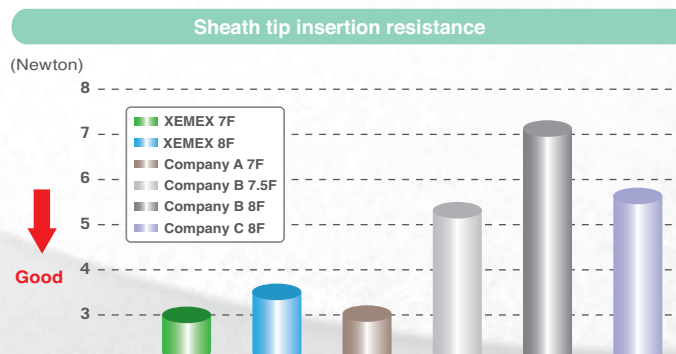


5. Sheath Introducer

Less gap between sheath and dilator



- ZEON MEDICAL's processing technology realized:
 - Smooth transition of diameter gap
 - Less insertion resistance
 - Increased intensity
 - Prevention of distortion or deformation



Excellence trackability of dilator tip to GW

- Downsized dilator tip has increased:
 - Tip flexibility and trackability to the guide wire
 - Prevention of damage to the vessel wall

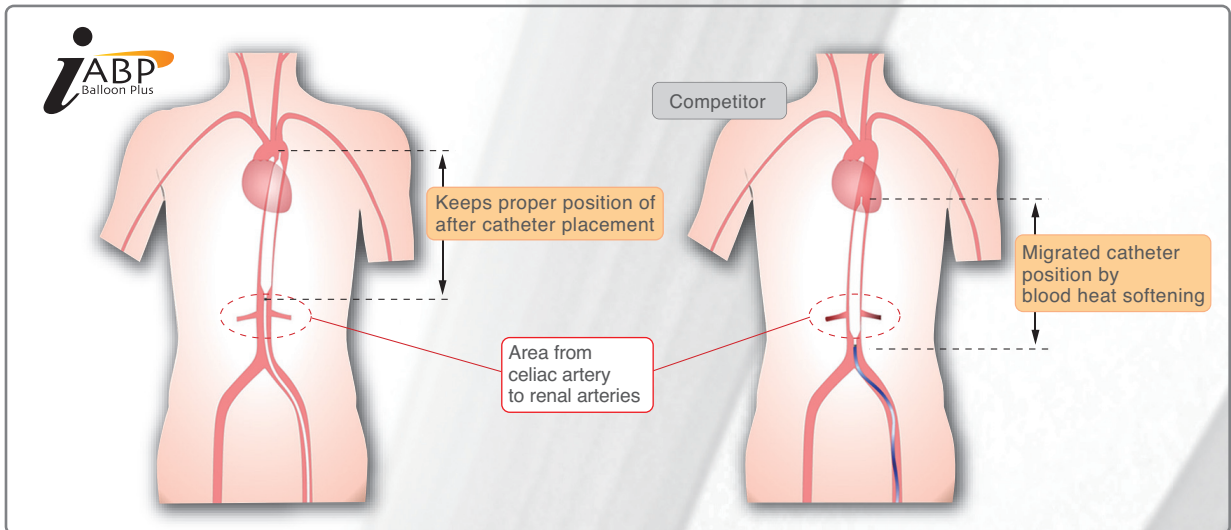
6. Soft tip of catheter prevents unintentional vessel damage

- Sophisticated taper shape and soft material for catheter tip



Advantage

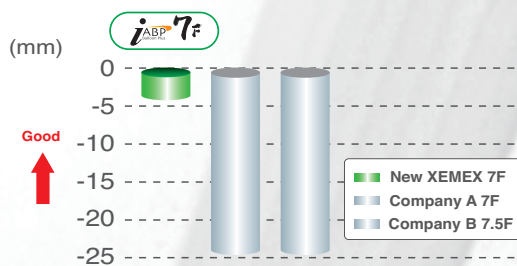
1. High Level Balloon and Catheter Positioning Stability



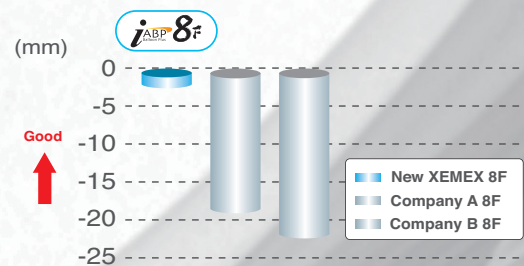
High Balloon position stability:

1. Stiff nylon catheter shaft
2. Three-level-diameter shaft structure

Measurement of balloon position migration after 12-hour driving in the mock vessel



*Data attained by ZEON MEDICAL experiment method



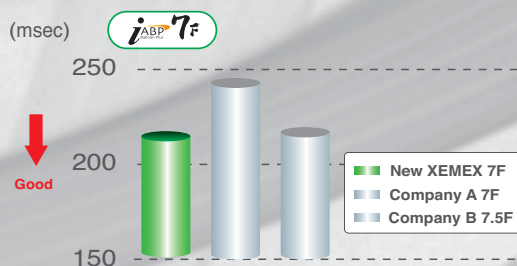
*Data attained by ZEON MEDICAL experiment method

2. Pumping Response Performance

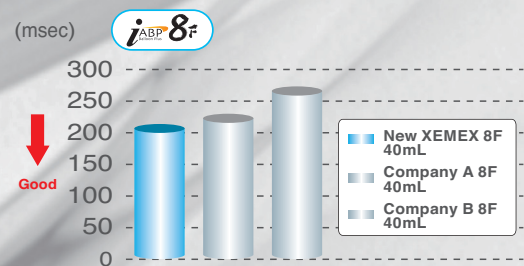
Pumping response performance is ensured by:

1. Double lumen structure with large helium gas lumen
2. Three-level-diameter catheter shaft
3. Inner stopper anchoring

Measurement of total inflation and deflation time



*Data attained by ZEON MEDICAL experiment method



*Data attained by ZEON MEDICAL experiment method

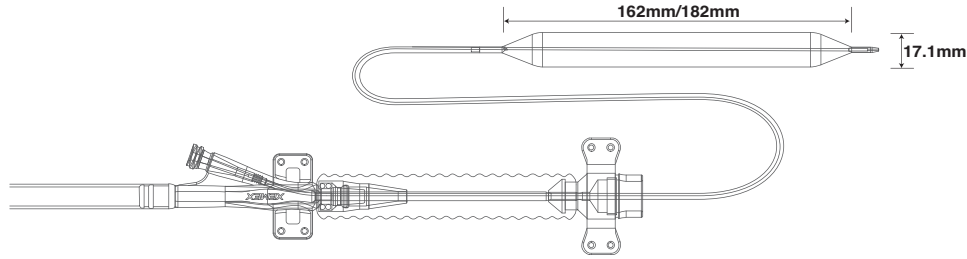
XEMEX IABP Balloon Plus Specification
(insertion with sheath / sheath less)



Catheter Tray			
Code No.	BPGL2570 (E)	BPGL3070 (E)	BPGL3570 (E)
Balloon volume	25mL	30mL	35mL
Catheter outer diameter	2.33mm (7.0F)	2.33mm (7.0F)	2.33mm (7.0F)
Catheter type	Double Lumen Type	Double Lumen Type	Double Lumen Type
Inner diameter	0.71mm (0.028inch)	0.71mm (0.028inch)	0.71mm (0.028inch)
Guide wire	0.50mm (0.020inch)	0.50mm (0.020inch)	0.50mm (0.020inch)
Catheter active length	651mm	681mm	714mm
Balloon length	180mm	210mm	243mm
Balloon diameter	14.1mm	14.1mm	14.1mm
Catheter material	Outer tube: Nylon (antithrombogenic polyurethane coating) Inner tube: Special treated resin		
Balloon material	High-strength antithrombogenic polyurethane coating		
Accessories	50mL syringe, One-way valve for decompression		
Introducer Tray			
Sheath type	Standard type with hemostasis valve		
Sheath active length	17.5cm		
Sheath inner diameter	2.40mm		
Guide wire	J tip guide wire for balloon catheter insertion 0.50mm (0.020 inch) X 150cm J tip guide wire for sheath introducer 0.88mm (0.035 inch) X 80cm		
Accessories	18G Needle, Adapter for other manufacturer's driving consoles, Dilator (6F X 16.5cm), Blood pressure monitoring lines, 3-way stopcock		



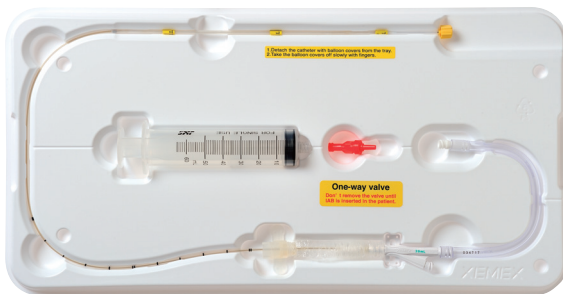
Catheter Tray			
Code No.	BPGL3080 (E)	BPGL3580 (E)	BPGL4080 (E)
Balloon volume	30mL	35mL	40mL
Catheter outer diameter	2.66mm (8.0F)	2.66mm (8.0F)	2.66mm (8.0F)
Catheter type	Double Lumen Type	Double Lumen Type	Double Lumen Type
Inner diameter	0.88mm (0.035inch)	0.88mm (0.035inch)	0.88mm (0.035inch)
Guide wire	0.79mm (0.031inch)	0.79mm (0.031inch)	0.79mm (0.031inch)
Catheter active length	695mm	700mm	725mm
Balloon length	210mm	214mm	243mm
Balloon diameter	14.1mm	15.1mm	15.1mm
Catheter material	Outer tube: Nylon (antithrombogenic polyurethane coating) Inner tube: Special treated resin		
Balloon material	High-strength antithrombogenic polyurethane coating		
Accessories	50mL syringe, One-way valve for decompression		
Introducer Tray			
Sheath type	Standard type with hemostasis valve		
Sheath active length	17.5cm		
Sheath inner diameter	2.73mm		
Guide wire	J tip guide wire for balloon catheter insertion 0.79mm (0.031inch) X 150cm J tip guide wire for sheath introducer 0.88mm (0.035 inch) X 80cm		
Accessories	18G Needle, Adapter for other manufacturer's driving consoles, Dilator (7F X 16.5cm), Blood pressure monitoring lines, 3-way stopcock		



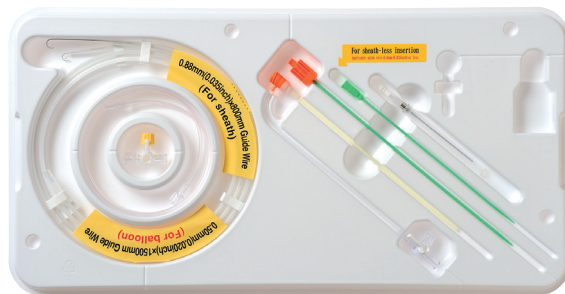
Short balloon

Catheter Tray		
Code No.	BPGL3580-SH (E)	BPGL4080-SH (E)
Balloon volume	35mL	40mL
Catheter outer diameter	2.66mm (8.0F)	2.66mm (8.0F)
Catheter type	Double Lumen Type	Double Lumen Type
Inner diameter	0.88mm (0.035 inch)	0.88mm (0.035 inch)
Guide wire	0.79mm (0.031 inch)	0.79mm (0.031 inch)
Catheter active length	682mm	725mm
Balloon length	162mm	182mm
Balloon diameter	17.1mm	17.1mm
Catheter material	Outer tube: Nylon(antithrombogenic polyurethane coating) Inner tube: Special treated resin	
Balloon material	High-strength antithrombogenic polyurethane coating	
Accessories	50mL syringe, One-way valve for decompression	
Introducer Tray		
Sheath type	Standard type with hemostasis valve	
Sheath active length	17.5cm	
Sheath inner diameter	2.73mm	
Guide wire	J tip guide wire for balloon catheter insertion 0.79mm (0.031inch) X 150cm J tip guide wire for sheath introducer 0.88mm (0.035inch) X 80cm	
Accessories	18G Needle, Adapter for other manufacturer's driving consoles, Dilator (7F X 16.5cm), Blood pressure monitoring lines, 3-way stopcock	

■ Catheter Tray



■ Introducer Tray



■ Driving Tube



For MAQUET Console

For TeleFlex Console

Caution

- Please make sure to use catheter and introducer set packed in the same box.
- Please make sure to read the attached IFU when using the product.



Ordering information

Code No.	Balloon Volume	Catheter O.D.	Balloon Length	Balloon Diameter	Recommended Patient Height ^{**}
BPGL2570 (E)	25mL	7.0F (2.33mm)	180mm	14.1mm	≤150cm ≤4'11"
BPGL3070 (E)	30mL	7.0F (2.33mm)	210mm	14.1mm	150-165cm 4'11"-5'5"
BPGL3570 (E)	35mL	7.0F (2.33mm)	243mm	14.1mm	≥165cm ≥5'5"
BPGL3080 (E)	30mL	8.0F (2.66mm)	210mm	14.1mm	≤155cm ≤5'1"
BPGL3580 (E)	35mL	8.0F (2.66mm)	214mm	15.1mm	155-165cm 5'1"-5'5"
BPGL4080 (E)	40mL	8.0F (2.66mm)	243mm	15.1mm	≥165cm ≥5'5"
BPGL3580-SH (E)*	35mL	8.0F (2.66mm)	162mm	17.1mm	≥145cm ≥4'9"
BPGL4080-SH(E)*	40mL	8.0F (2.66mm)	182mm	17.1mm	≥160cm ≥5'4"

*Short Balloon Type

**Refer to the figure only as a guide.
Please select product by confirming
balloon length and diameter.

Manufactured by:

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Agent: