公差等级（除非另有说明） Tolerances (Unless otherwise specified)	
.XXXX (4位小数) ± .0005inch或者±0.013mm .XXXX (4 Place Decimals) ± .0005"=[±0.013mm]	.X (1位小数) ± .015inch或者[±0.4mm] .X (1 Place Decimals) ±.015"=[±0.4mm]
.XXX (3位小数) ± .005inch或者±0.0127mm .XXX (3 Place Decimals) ±.005"=[±0.127mm]	其他 ±.01Sinch或者[±0.4mm] Fractional ±1/64=[±0.4mm]
.XX (2位小数) ±.01inch或者±0.25mm .XX (2 Place Decimals) ±.01"=[±0.25mm]	螺纹等级 2 FIT；角度 ±0.5° Threads Class 2 FIT; Angles ±1/2°

BARTYMEDICAL

PTA Scoring Balloon Dilation Catheter CE xxxx

Instruction for Use

I.DEVICE DESCRIPTION

The PTA Scoring Balloon Dilation Catheter is a standard balloon dilatation catheter with a scoring balloon near the distal tip. One lumen is used for inflation of the balloon with contrast medium; the other lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The product is offered on an over-the-wire (OTW) delivery platform.

The distal end of the catheter has a conventional nylonblend balloon and a nitinol scoring element with three or more (depending on balloon size) spiral struts that wrap around the balloon. The struts create focal concentrations of dilating force, which minimize balloon slippage and assists in the luminal expansion of stenotic arteries.

The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specifc pressure.

Product specification information including balloon diameters, balloon lengths, guidewire compatibility, sheath compatibility and catheter lengths can be found in Table 1.

Table 1: Product Specification

Balloon Diameter (mm)	Balloon Length (mm)	Recommended guidewire (inch)	Sheath Compatibility (F)	Catheter Length (mm)
2.00	20	0.014/0.018	5F	130/150
2.00	40		5F	
2.00	100		6F	
2.00	150		6F	
2.50	20		5F	
2.50	40		5F	
2.50	100		6F	
2.50	150		6F	
3.00	20		5F	
3.00	40		5F	
3.00	100		6F	
3.00	150		6F	
3.50	20		5F	
3.50	40		5F	
3.50	100		6F	
3.50	150		6F	
4.00	20	0.018	6F	50/90/130
4.00	40			
4.00	100	0.014/0.018		
4.00	150			
4.00	200			130
5.00	20	0.018		50/90/130
5.00	40			
5.00	100	0.014/0.018		
5.00	150			
5.00	200			130
6.00	20	0.018		50/90/130
6.00	40			
6.00	100	0.014/0.018		
6.00	150			
6.00	200			130
7.00	20	0.018		50/90
7.00	40			50/90/130
7.00	100			50/90
7.00	150			50/90
8.00	20			50/90
8.00	40			50/90/130
8.00	100			50/90
8.00	150			50/90

Ⅱ. INTENDED USE

The PTA Scoring Balloon Dilation Catheter is suitable for percutaneous transluminal angioplasty (PTA) of the peripheral vascular system (including the iliac, femoral, iliac-femoral, popliteal,infra popliteal,and renal arteries),and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Ⅲ. CONTRAINDICATIONS

None known for Percutaneous Trasluminal Angioplasty(PTA) procedures.

Ⅳ.WARNINGS

· This device is intended for single (one) patient use only.Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

· The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage.

· When the catheter is exposed to the vascular system,it should be manipulated while under high quality fluoroscopic observation.

· Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

· Balloon pressure should not exceed the rated burst pressure(RBP). Refer to product label for device specifc information.The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.

· Use only the recommended balloon inflation medium.

· Never use air or any gaseous medium to inflate the balloon.

· Proceed cautiously when using the PTA Scoring Balloon Dilation Catheter in a freshly deployed bare metal or drug eluting stent. The PTA Scoring Balloon Dilation Catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the PTA Scoring Balloon Dilation Catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter).

· Use the catheter prior to the "Use Before" (expiration) date specifed on the package.

Ⅴ. PRECAUTIONS

· A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product.

· Any use for procedures other than those indicated in these instructions is not recommended.

· The device is not recommended for use in lesions which may require inflation pressures higher than those recommended for this catheter.

· Do not use if package is opened or damaged.

· Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specifc procedure for which it is to be used.

· During and after the procedure, appropriate anticoagulants, anti-platelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries.

· Pass the PTA Scoring Balloon Dilation Catheter through the recommended introducer sheath size or minimum size guiding catheter indicated on the product label.

Ⅵ. POTENTIAL ADVERSE EFFECTS

Possible complications associated with the PTA Scoring Balloon Dilation Catheter implantation may include,but are not limited to:

· Total occlusion of the treated artery
· Arterial dissection or perforation
· Arterial spasm
· Pseudo-aneurysm
· Re-stenosis of the dilated artery
· Embolism
· Thrombus
· Retained device components
· Hemorrhage or hematoma
· Arteriovenous fistula

Ⅶ. MATERIALS REQUIRED FOR USE WITH THE PTA Scoring Balloon Dilation Catheter:

WARNING: Use single use items only. Do not resterilize or reuse.

· Femoral introducer sheath and/or guiding catheter (GC):

· 2.0, 2.5, 3.0 or 3.5 mm diameter ×20 and 40mm length balloon catheter: ≥ 5F introducer sheath and/or ≥ 6F GC

· 2.0, 2.5, 3.0, or 3.5 mm diameter × 100 and 150mm length balloon catheter: ≥ 6F introducer sheath and/or ≥ 7F GC

· 4.0, 5.0, 6.0, 7.0 or 8.0 mm diameter balloon catheter: ≥ 6F introducer sheath and/or ≥ 7F GC

· Hemostatic valve
· Radiographic contrast medium diluted ~1:1 with normal saline
· Sterile heparinized normal saline
· 10-cc and 20-cc syringes for flushing and balloon prep
· Inflation device (indeflator)
· Guide wire:

· 2.0, 2.5, 3.0, 3.5 mm diameter and 4.0, 5.0 and 6.0 mm × 100, 150 and 200 mm balloon sizes - 0.014" or 0.018"

· 4.0, 5.0, or 6.0 mm × 20/40/100/150 mm balloon sizes and 7.0 or 8.0 mm diameter balloon catheter - 0.018" only

材 质 Material	80g金东双胶纸 80g Jindong double offset paper	项目名称 Project Name	RD-22
表面处理 Finish	_		
页 数 Sheet	1 of 3	部件名称 Part Name	使用说明书 Instruction for Use
视 角 View		图纸编号 DWG NO.	HB-RD22B017
数 量 QTY	_	杭州巴泰医疗器械有限公司 Hangzhou Barty Medical Equipment Co.,Ltd	
比 例 Scale	_		
版 本 Revision	A0		

A4

公差等级（除非另有说明） Tolerances (Unless otherwise specified)	
.XXXX (4位小数) ± .0005inch或者±0.013mm .XXXX (4 Place Decimals) ± .0005"=[±0.013mm]	.X (1位小数) ± .015inch或者[±0.4mm] .X (1 Place Decimals) ± .015"=[±0.4mm]
.XXX (3位小数) ±.005inch或者±0.0127mm .XXX (3 Place Decimals) ±.005"=[±0.127mm]	其他 ±.015inch或者[±0.4mm] Fractional ± 1/64=[±0.4mm]
.XX (2位小数) ± .01inch或者±0.25mm .XX (2 Place Decimals) ± .01"=[±0.25mm]	螺纹等级 2 FIT；角度 ±0.5° Threads Class 2 FIT; Angles ± 1/2°

· Guide wire introducer
· Guide wire torque device
· Manifold (for pressure monitoring and contrast injection),extension pressure tubing

Ⅶ. INSTRUCTIONS FOR USE

Prior to use of the PTA Scoring Balloon Dilation Catheter, examine carefully for damage and device integrity. Do not use if the catheter has bends, kinks,missing components or other damage. Do not use if inner package is open or damaged.

1.Premedicate patients with anti−coagulants, anti−platelet agents and vasodilators according to institutional protocol for PTA procedures.

2.Perform peripheral angiogram in the view best demonstrating the target lesion prior to device deployment.

3.Utilizing standard fluoroscopic technique, position an appropriately sized guide wire of choice beyond the target lesion (use an exchange length 300 cm guide wire with the 130 cm,150 cm long PTA Scoring Balloon Dilation Catheter).

4.Using sterile technique, remove an appropriately sized PTA Scoring Balloon Dilation Catheter from the sterile package and place on the sterile feld.

· For the 2.0, 2.5, 3.0, or 3.5 mm balloon catheter,size the PTA Scoring Balloon Dilation Catheter ≤ 1.0 × the reference vessel diameter (RVD).

· For the 4.0, 5.0, 6.0, 7.0, or 8.0 mm balloon catheter,size the PTA Scoring Balloon Dilation Catheter a minimum of 0.5 mm LESS than the reference vessel diameter (RVD).

5.Remove the protective tubing from the balloon.

6.Inspect the balloon catheter to ensure that all components are intact.

7.Flush the guide wire lumen by connecting the proximal hub to a 10−cc syringe and injecting heparinized saline into the proximal guide wire lumen until droplets emerge from the distal end.

8.Attach a stopcock to the catheter's balloon inflation port.

9.Attach a 20−cc syringe filled with 2−3 cc of 1:1 mixture of radiographic contrast and normal saline to the stopcock.

10.Open the stopcock to the syringe, aspirate/remove air from the catheter balloon lumen using the 20−cc syringe filled with 2−3 cc of radiographic contrast and leave on vacuum for 30 seconds.

11.Close the stopcock to the catheter balloon inflation port and remove the syringe.

12.Attach inflation device (indeflator), flled with 1:1 mixture of radiographic contrast and normal saline, to the stopcock by creating a meniscus. Avoid introducing air bubbles into the catheter balloon lumen.

13.Open the stopcock to the inflation device and aspirate using the inflation device, locking in vacuum.

NOTE: All air must be removed from the balloon and displaced with contrast medium prior to inserting into the body (repeat steps 8 −12, if necessary).

14.Advance the PTA Scoring Balloon Dilation Catheter over the guide wire(through either a previously placed and appropriately sized hemostatic introducer sheath or guiding catheter) and position at the target lesion utilizing standard fluoroscopic technique.

NOTE: When backloading the catheter onto the guide wire, the catheter should be supported, ensuring that the guide wire does not come in contact with the balloon. Do not advance or retract the PTA Scoring Balloon Dilation Catheter over the floppy portion of the guide wire. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

15.Inflate the PTA scoring balloon per the following recommended protocol:

· Increase the inflation pressure by 2 atmospheres every 10−15 seconds until full balloon inflation is achieved.

· Do not exceed the rated burst pressure (RBP) printed on the package label.

16.Apply negative pressure to the inflation device and confrm that the balloon is fully deflated prior to removing the PTA Scoring Balloon Dilation catheter.

17.Remove the PTA Scoring Balloon Dilation catheter.

NOTE: Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained. Do not rotate the catheter luer hub in excess of fve (5) turns during use. Catheter manipulation, including advancement and retraction, should be performed by grasping the shaft.

18.Perform peripheral angiogram (in the same view(s) as step 2) of the target lesion following completion of PTA Scoring Balloon Dilation Catheter treatment.

19.Inspect all components to ensure that the catheter is intact. Follow institutional procedures for disposal of biohazards. If device malfunction occurs or any defects are noted on inspection, flush the guide wire lumen and clean the outer surface of the catheter with saline, store the catheter in a sealed plastic bag, and contact our company for further instructions.

20.Complete any additional interventions as clinically indicated (e.g. stent placement).

21.Remove the guide wire and perform peripheral angiography (in the same view(s) as step 2) of the target esion following completion of all interventions.

22.Remove all catheters and manage the arterial access site according to institutional protocol.

23.Continue treatment with anti−coagulants, anti−platelet agents and vasodilators according to institutional protocol for PTA procedures.

Ⅸ. REFERENCES

The physician should consult recent literature on current medical practice regarding balloon dilatation and PTA procedures.

Ⅹ. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

There is no express or implied warranty, including any implied warranty of merchant−ability or fitness for a particular purpose, on the BartyMedical© product(s) described in this publication. Under no circumstances shall BartyMedical© be liable for any direct, incidental or consequential damages other than as expressly provided by specifc law. No person has the authority to bind BartyMedical© to any representation or warranty except as specifically set forth herein.

Descriptions or specifications in BartyMedical© printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

BartyMedical© assumes no liability with respect to instruments reused, reprocessed or resterilized.

Ⅺ. STORAGE

Store at controlled room temperature and in a dry place. Keep away from sunlight. Do not expose to organic solvents (e.g. alcohol), corrosive gas, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to the expiration date on package label.

Explanation of symbols on labels and packaging

STERILE EO	EO−sterilized	REF	Specification
LOT	Batch code		Instruction for use
	Keep dry		Do not use if the package is damaged
	Do not resterilize		Consult the Instruction for use
	Single use		Manufacturer
	Exp. Date		Keep away from sunlight
	Production date	RBP	Rated burst pressure
NP	Nominal pressure	OTW	Over the wire
F	Recommended sheath size		

Hangzhou Barty Medical Equipment Co.,Ltd.
South 2F,Building 2−1,No.20 Street,ETDZ,Hangzhou,Zhejiang,China

材 质 Material	80g金东双胶纸 80g Jindong double offset paper	项目名称 Project Name	RD-22
表面处理 Finish	_		
页 数 Sheet	2 of 3	部件名称 Part Name	使用说明书 Instruction for Use
视 角 View		图纸编号 DWG NO.	HB-RD22B017
数 量 QTY	_	杭州巴泰医疗器械有限公司 Hangzhou Barty Medical Equipment Co.,Ltd	
比 例 Scale	_		
版 本 Revision	A0		

A4

公差等级（除非另有说明） Tolerances (Unless otherwise specified)			
.XXXX (4位小数) .XXXX (4 Place Decimals)	± .0005inch或者± 0.013mm ± .0005"=[± 0.013mm]	.X (1位小数) .X (1 Place Decimals)	± .015inch或者[± 0.4mm] ± .015"=[± 0.4mm]
.XXX (3位小数) .XXX (3 Place Decimals)	± .005inch或者± 0.0127mm ± .005"=[± 0.127mm]	其他 Fractional	± .015inch或者[± 0.4mm] ± 1/64=[± 0.4mm]
.XX (2位小数) .XX (2 Place Decimals)	± .01inch或者± 0.25mm ± .01"=[± 0.25mm]	螺纹等级 2 FIT；角度 ± 0.5° Threads Class 2 FIT; Angles ± 1/2°	

修订 Revisions				
修订号 Rev.No	变更 Change	确认 Verify	日期 Date	描述 Description

Annex：Specification of PTA Scoring Balloon Dilation Catheter

Table1

Recommended Guidewire0.014 ″ coaxial catheter						
Catheter length (cm)	Balloon diameter (mm)	Balloon Length(mm)				
		20	40	100	150	200
1300	2.00	K13020002014	K13020004014	K13020010014	K13020015014	x
	2.50	K13025002014	K13025004014	K13025010014	K13025015014	x
	3.00	K13030002014	K13030004014	K13030010014	K13030015014	x
	3.50	K13035002014	K13035004014	K13035010014	K13035015014	x
	4.00	x	x	K13040010014	K13040015014	K13040020014
	5.00	x	x	K13050010014	K13050015014	K13050020014
	6.00	x	x	K13060010014	K13060015014	K13060020014
1500	2.00	K15020002014	K15020004014	K15020010014	K15020015014	x
	2.50	K15025002014	K15025004014	K15025010014	K15025015014	x
	3.00	K15030002014	K15030004014	K15030010014	K15030015014	x
	3.50	K15035002014	K15035004014	K15035010014	K15035015014	x

Annex：Specification of PTA Scoring Balloon Dilation Catheter

Table2

Recommended Guidewire0.018 ″ coaxial catheter						
Catheter length (cm)	Balloon diameter (mm)	Balloon Length(mm)				
		20	40	100	150	200
500	4.00	K05040002018	K05040004018	K05040010018	K05040015018	x
	5.00	K05050002018	K05050004018	K05050010018	K05050015018	x
	6.00	K05060002018	K05060004018	K05060010018	K05060015018	x
	7.00	K05070002018	K05070004018	K05070010018	K05070015018	x
	8.00	K05080002018	K05080004018	K05080010018	K05080015018	x
900	4.00	K09040002018	K09040004018	K09040010018	K09040015018	x
	5.00	K09050002018	K09050004018	K09050010018	K09050015018	x
	6.00	K09060002018	K09060004018	K09060010018	K09060015018	x
	7.00	K09070002018	K09070004018	K09070010018	K09070015018	x
	8.00	K09080002018	K09080004018	K09080010018	K09080015018	x
1300	2.00	K13020002018	K13020004018	K13020010018	K13020015018	x
	2.50	K13025002018	K13025004018	K13025010018	K13025015018	x
	3.00	K13030002018	K13030004018	K13030010018	K13030015018	x
	3.50	K13035002018	K13035004018	K13035010018	K13035015018	x
	4.00	K13040002018	K13040004018	K13040010018	K13040015018	K13040020018
	5.00	K13050002018	K13050004018	K13050010018	K13050015018	K13050020018
	6.00	K13060002018	K13060004018	K13060010018	K13060015018	K13060020018
	7.00	x	K13070004018	x	x	x
	8.00	x	K13080004018	x	x	x

材 质 Material	80g金东双胶纸 80g Jindong double offset paper	项目名称 Project Name	RD-22
表面处理 Finish	_		
页 数 Sheet	3 of 3	部件名称 Part Name	使用说明书 Instruction for Use
视 角 View		图纸编号 DWG NO.	HB-RD22B017

制 图 Drawn By	审 核 Checked By	批 准 Approved By	数 量 QTY	_	杭州巴泰医疗器械有限公司 Hangzhou Barty Medical Equipment Co.,Ltd
			比 例 Scale	_	
			版 本 Revision	A0	

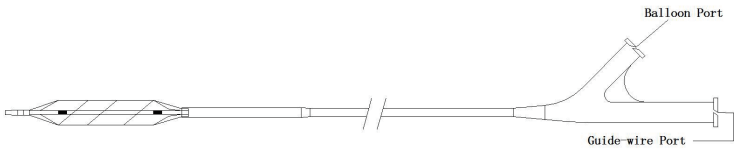
BARTYMEDICAL

PTA Scoring Balloon Dilation Catheter CE xxxx

Instruction for Use

I.DEVICE DESCRIPTION

The PTA Scoring Balloon Dilation Catheter is a standard balloon dilatation catheter with a scoring balloon near the distal tip. One lumen is used for inflation of the balloon with contrast medium; the other lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The product is offered on an over-the-wire (OTW) delivery platform.



The distal end of the catheter has a conventional nylonblend balloon and a nitinol scoring element with three or more (depending on balloon size) spiral struts that wrap around the balloon. The struts create focal concentrations of dilating force, which minimize balloon slippage and assists in the luminal expansion of stenotic arteries.

The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specifc pressure.

Product specification information including balloon diameters, balloon lengths, guidewire compatibility, sheath compatibility and catheter lengths can be found in Table 1.

Table 1: Product Specification

Balloon Diameter (mm)	Balloon Length (mm)	Recommended guidewire (inch)	Sheath Compatibility (F)	Catheter Length (mm)
2.00	20	0.014/0.018	5F	130/150
2.00	40		5F	
2.00	100		6F	
2.00	150		6F	
2.50	20		5F	
2.50	40		5F	
2.50	100		6F	
2.50	150		6F	
3.00	20		5F	
3.00	40		5F	
3.00	100		6F	
3.00	150		6F	
3.50	20		5F	
3.50	40		5F	
3.50	100		6F	
3.50	150		6F	
4.00	20	0.018	6F	50/90/130
4.00	40			
4.00	100	0.014/0.018		
4.00	150			
4.00	200			130
5.00	20	0.018		50/90/130
5.00	40			
5.00	100	0.014/0.018		
5.00	150			
5.00	200			130
6.00	20	0.018		50/90/130
6.00	40			
6.00	100	0.014/0.018		
6.00	150			
6.00	200			130
7.00	20	0.018		50/90
7.00	40			50/90/130
7.00	100			50/90
7.00	150			50/90
8.00	20			50/90
8.00	40			50/90/130
8.00	100			50/90
8.00	150			50/90

Ⅱ. INTENDED USE

The PTA Scoring Balloon Dilation Catheter is suitable for percutaneous transluminal angioplasty (PTA) of the peripheral vascular system (including the iliac, femoral, iliac-femoral, popliteal,infra popliteal,and renal arteries),and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Ⅲ. CONTRAINDICATIONS

None known for Percutaneous Trasluminal Angioplasty(PTA) procedures.

Ⅳ.WARNINGS

· This device is intended for single (one) patient use only.Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

· The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage.

· When the catheter is exposed to the vascular system,it should be manipulated while under high quality fluoroscopic observation.

· Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

· Balloon pressure should not exceed the rated burst pressure(RBP). Refer to product label for device specifc information.The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.

· Use only the recommended balloon inflation medium.

· Never use air or any gaseous medium to inflate the balloon.

· Proceed cautiously when using the PTA Scoring Balloon Dilation Catheter in a freshly deployed bare metal or drug eluting stent. The PTA Scoring Balloon Dilation Catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the PTA Scoring Balloon Dilation Catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter).

· Use the catheter prior to the "Use Before" (expiration) date specifed on the package.

Ⅴ. PRECAUTIONS

· A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product.

· Any use for procedures other than those indicated in these instructions is not recommended.

· The device is not recommended for use in lesions which may require inflation pressures higher than those recommended for this catheter.

· Do not use if package is opened or damaged.

· Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specifc procedure for which it is to be used.

· During and after the procedure, appropriate anticoagulants, anti-platelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries.

· Pass the PTA Scoring Balloon Dilation Catheter through the recommended introducer sheath size or minimum size guiding catheter indicated on the product label.

Ⅵ. POTENTIAL ADVERSE EFFECTS

Possible complications associated with the PTA Scoring Balloon Dilation Catheter implantation may include,but are not limited to:

· Total occlusion of the treated artery
· Arterial dissection or perforation
· Arterial spasm
· Pseudo-aneurysm
· Re-stenosis of the dilated artery
· Embolism
· Thrombus
· Retained device components
· Hemorrhage or hematoma
· Arteriovenous fistula

Ⅶ. MATERIALS REQUIRED FOR USE WITH THE PTA Scoring Balloon Dilation Catheter:

WARNING: Use single use items only. Do not resterilize or reuse.

· Femoral introducer sheath and/or guiding catheter (GC):

· 2.0, 2.5, 3.0 or 3.5 mm diameter ×20 and 40mm length balloon catheter: ⩾ 5F introducer sheath and/or ⩾ 6F GC

· 2.0, 2.5, 3.0, or 3.5 mm diameter × 100 and 150mm length balloon catheter: ⩾ 6F introducer sheath and/or ⩾ 7F GC

· 4.0, 5.0, 6.0, 7.0 or 8.0 mm diameter balloon catheter: ⩾ 6F introducer sheath and/or ⩾ 7F GC

· Hemostatic valve
· Radiographic contrast medium diluted ~1:1 with normal saline
· Sterile heparinized normal saline
· 10-cc and 20-cc syringes for flushing and balloon prep
· Inflation device (indeflator)
· Guide wire:

· 2.0, 2.5, 3.0, 3.5 mm diameter and 4.0, 5.0 and 6.0 mm × 100, 150 and 200 mm balloon sizes – 0.014" or 0.018"

· 4.0, 5.0, or 6.0 mm × 20/40/100/150 mm balloon sizes and 7.0 or 8.0 mm diameter balloon catheter – 0.018" only

· Guide wire introducer

· Guide wire torque device

· Manifold (for pressure monitoring and contrast injection),extension pressure tubing

Ⅶ. INSTRUCTIONS FOR USE

Prior to use of the PTA Scoring Balloon Dilation Catheter, examine carefully for damage and device integrity. Do not use if the catheter has bends, kinks,missing components or other damage. Do not use if inner package is open or damaged.

1.Premedicate patients with anti-coagulants, anti-platelet agents and vasodilators according to institutional protocol for PTA procedures.

2.Perform peripheral angiogram in the view best demonstrating the target lesion prior to device deployment.

3.Utilizing standard fluoroscopic technique, position an appropriately sized guide wire of choice beyond the target lesion (use an exchange length 300 cm guide wire with the 130 cm,150 cm long PTA Scoring Balloon Dilation Catheter).

4.Using sterile technique, remove an appropriately sized PTA Scoring Balloon Dilation Catheter from the sterile package and place on the sterile feld.

· For the 2.0, 2.5, 3.0, or 3.5 mm balloon catheter,size the PTA Scoring Balloon Dilation Catheter ≤ 1.0 × the reference vessel diameter (RVD).

· For the 4.0, 5.0, 6.0, 7.0, or 8.0 mm balloon catheter,size the PTA Scoring Balloon Dilation Catheter a minimum of 0.5 mm LESS than the reference vessel diameter (RVD).

5.Remove the protective tubing from the balloon.

6.Inspect the balloon catheter to ensure that all components are intact.

7.Flush the guide wire lumen by connecting the proximal hub to a 10-cc syringe and injecting heparinized saline into the proximal guide wire lumen until droplets emerge from the distal end.

8.Attach a stopcock to the catheter's balloon inflation port.

9.Attach a 20-cc syringe filled with 2-3 cc of 1:1 mixture of radiographic contrast and normal saline to the stopcock.

10.Open the stopcock to the syringe, aspirate/remove air from the catheter balloon lumen using the 20-cc syringe flled with 2-3 cc of radiographic contrast and leave on vacuum for 30 seconds.

11.Close the stopcock to the catheter balloon inflation port and remove the syringe.

12.Attach inflation device (indeflator), flled with 1:1 mixture of radiographic contrast and normal saline, to the stopcock by creating a meniscus. Avoid introducing air bubbles into the catheter balloon lumen.

13.Open the stopcock to the inflation device and aspirate using the inflation device, locking in vacuum.

NOTE: All air must be removed from the balloon and displaced with contrast medium prior to inserting into the body (repeat steps 8 -12, if necessary).

14.Advance the PTA Scoring Balloon Dilation Catheter over the guide wire(through either a previously placed and appropriately sized hemostatic introducer sheath or guiding catheter) and position at the target lesion utilizing standard fluoroscopic technique.

NOTE: When backloading the catheter onto the guide wire, the catheter should be supported, ensuring that the guide wire does not come in contact with the balloon. Do not advance or retract the PTA Scoring Balloon Dilation Catheter over the floppy portion of the guide wire. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

15.Inflate the PTA scoring balloon per the following recommended protocol:

· Increase the inflation pressure by 2 atmospheres every 10-15 seconds until full balloon inflation is achieved.

· Do not exceed the rated burst pressure (RBP) printed on the package label.

16.Apply negative pressure to the inflation device and confrm that the balloon is fully deflated prior to removing the PTA Scoring Balloon Dilation catheter.

17.Remove the PTA Scoring Balloon Dilation catheter.

NOTE: Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained. Do not rotate the catheter luer hub in excess of fve (5) turns during use. Catheter manipulation, including advancement and retraction, should be performed by grasping the shaft.

18.Perform peripheral angiogram (in the same view(s) as step 2) of the target lesion following completion of PTA Scoring Balloon Dilation Catheter treatment.

19.Inspect all components to ensure that the catheter is intact. Follow institutional procedures for disposal of biohazards. If device malfunction occurs or any defects are noted on inspection, flush the guide wire lumen and clean the outer surface of the catheter with saline, store the catheter in a sealed plastic bag, and contact our company for further instructions.

20.Complete any additional interventions as clinically indicated (e.g. stent placement).

21.Remove the guide wire and perform peripheral angiography (in the same view(s) as step 2) of the target esion following completion of all interventions.

22.Remove all catheters and manage the arterial access site according to institutional protocol.

23.Continue treatment with anti-coagulants, anti-platelet agents and vasodilators according to institutional protocol for PTA procedures.

Ⅸ. REFERENCES

The physician should consult recent literature on current medical practice regarding balloon dilatation and PTA procedures.

Ⅹ. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

There is no express or implied warranty, including any implied warranty of merchant-ability or fitness for a particular purpose, on the BartyMedical© product(s) described in this publication. Under no circumstances shall BartyMedical© be liable for any direct, incidental or consequential damages other than as expressly provided by specifc law. No person has the authority to bind BartyMedical© to any representation or warranty except as specifically set forth herein.

Descriptions or specifications in BartyMedical© printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

BartyMedical© assumes no liability with respect to instruments reused, reprocessed or resterilized.

Ⅺ. STORAGE

Store at controlled room temperature and in a dry place. Keep away from sunlight. Do not expose to organic solvents (e.g. alcohol), corrosive gas, ionizing radiation or ultravio-let light. Rotate inventory so that catheters are used prior to the expiration date on pack-age label.

Explanation of symbols on labels and packaging

STERILE EO	EO-sterilized	REF	Specification
LOT	Batch code		Instruction for use
	Keep dry		Do not use if the package is damaged
	Do not resterilize		Consult the Instruction for use
	Single use		Manufacturer
	Exp. Date		Keep away from sunlight
	Production date	RBP	Rated burst pressure
NP	Nominal pressure	OTW	Over the wire
F	Recommended sheath size		

Hangzhou Barty Medical Equipment Co.,Ltd.
South 2F,Building 2-1,No.20 Street,ETDZ,Hangzhou,Zhejiang,China

Annex：Specification of PTA Scoring Balloon Dilation Catheter

Table1

Recommended Guidewire0.014 ″ coaxial catheter						
Catheter length (cm)	Balloon diameter (mm)	Balloon Length(mm)				
		20	40	100	150	200
1300	2.00	K13020002014	K13020004014	K13020010014	K13020015014	x
	2.50	K13025002014	K13025004014	K13025010014	K13025015014	x
	3.00	K13030002014	K13030004014	K13030010014	K13030015014	x
	3.50	K13035002014	K13035004014	K13035010014	K13035015014	x
	4.00	x	x	K13040010014	K13040015014	K13040020014
	5.00	x	x	K13050010014	K13050015014	K13050020014
	6.00	x	x	K13060010014	K13060015014	K13060020014
1500	2.00	K15020002014	K15020004014	K15020010014	K15020015014	x
	2.50	K15025002014	K15025004014	K15025010014	K15025015014	x
	3.00	K15030002014	K15030004014	K15030010014	K15030015014	x
	3.50	K15035002014	K15035004014	K15035010014	K15035015014	x

Annex：Specification of PTA Scoring Balloon Dilation Catheter

Table2

Recommended Guidewire0.018 ″ coaxial catheter						
Catheter length (cm)	Balloon diameter (mm)	Balloon Length(mm)				
		20	40	100	150	200
500	4.00	K05040002018	K05040004018	K05040010018	K05040015018	x
	5.00	K05050002018	K05050004018	K05050010018	K05050015018	x
	6.00	K05060002018	K05060004018	K05060010018	K05060015018	x
	7.00	K05070002018	K05070004018	K05070010018	K05070015018	x
	8.00	K05080002018	K05080004018	K05080010018	K05080015018	x
900	4.00	K09040002018	K09040004018	K09040010018	K09040015018	x
	5.00	K09050002018	K09050004018	K09050010018	K09050015018	x
	6.00	K09060002018	K09060004018	K09060010018	K09060015018	x
	7.00	K09070002018	K09070004018	K09070010018	K09070015018	x
	8.00	K09080002018	K09080004018	K09080010018	K09080015018	x
1300	2.00	K13020002018	K13020004018	K13020010018	K13020015018	x
	2.50	K13025002018	K13025004018	K13025010018	K13025015018	x
	3.00	K13030002018	K13030004018	K13030010018	K13030015018	x
	3.50	K13035002018	K13035004018	K13035010018	K13035015018	x
	4.00	K13040002018	K13040004018	K13040010018	K13040015018	K13040020018
	5.00	K13050002018	K13050004018	K13050010018	K13050015018	K13050020018
	6.00	K13060002018	K13060004018	K13060010018	K13060015018	K13060020018
	7.00	x	K13070004018	x	x	x
	8.00	x	K13080004018	x	x	x