INSTRUCTIONS FOR USE

Accura Positsoon

PTCA Balloon Catheter (PC)

STERILE: Sterilized with ethylene oxide. Do not use if the sterile package is open or damaged.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions; otherwise, complications may occur.

Use the product before expiration of the „Best-Before-Date" mentioned on the packing.

Description

The PTCA Balloon Catheter is a double lumen coronary dilatation catheter, of transient use (up to 60 minutes), with a balloon located near the distal tip. One lumen is used for the inflation of the balloon with contrast medium. The second lumen in the distal shaft permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated.

The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter at a specific pressure. The goal of the balloon dilatation is the increase of the arterial lumen diameter, enough to reestablish adequate tissue perfusion.

The balloon is designed for coronary vessel dimensions from 1.5 to 5.0 mm diameter and 10 to 40 mm length. The catalogue number of the PTCA Balloon Catheter consists of the balloon diameter and the balloon length (e.g. PC2010: 2.00 mm diameter + 10 mm length). The parameters below are valid for all balloon catheter versions:

- Usable Catheter Length: 142 cm
- Total Catheter Length: 149 cm
- Proximal Shaft Diameter: 0.70 mm
- Distal Shaft Diameter: 0.86 mm

Proximal marker(s) located on the proximal shaft aid in gauging the dilatation catheter position relative to the guiding catheter tip (the marker located closest to the dilatation catheter adapter is for femoral guiding catheters and the other marker is for brachial guiding catheters).

The design of this catheter does not incorporate a lumen for distal dye injections and distal pressure measurements.

Quantity	Material
1	Catheter
1	Instruction for use

Recommended storage

1. Keep in a cool, dark and dry place.
2. Use immediately after the sterile package is opened.
3. Refer to the symbol legend at the end of this document.

Disposal instructions

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Indications

The PTCA Balloon Catheter is indicated for use in coronary vessels with vessel diameters of 1.5 mm to 5.0 mm.

The treated lesion length should be less than the nominal balloon length (10 mm - 40 mm) with reference vessel diameters from 1.5 mm to 5.0 mm.

Contraindications

The PTCA Balloon Catheter is contraindicated for patients with

- Contraindication for anti-platelet and/or anticoagulant therapy. This includes patients after a major surgery, induced labor, organ biopsy, puncture of an incompressible vessel after a period of time of 14 days before this surgery.
- Gastrointestinal bleeding
- Recent cerebrovascular accident (C.V.A)
- Bleedings due to retinopathy diabetic or other diseases connected to long term coagulation inhibition
- Pregnancy
- Severe reactions to contrast agents which cannot be adequately precluded prior to the intervention.
- Unprotected left main coronary artery
- Spasm of coronary arteries with a present significant stenosis

Warnings

Do NOT reprocess, resterilize and/or reuse it.

This device is intended for ONE USE ONLY.

Reuse, reprocessing or resterilization can potentially result in compromised device performance and increase the risk of cross contamination, leading to injuries, illness or death of the patient.

To reduce the potential for vessel damage, the inflated diameter of the filled balloon should correspond approximately to the diameter of the vessel proximal and distal to the stenosis.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of these patients carries special risk.

When the catheter is exposed to the vascular system, it should only 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). The rated burst pressure (RBP) is based on results of in vitro testing. Use of a pressure monitoring device is recommended to prevent over-pressurization.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of an injury or potentially life- threatening complication.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the “Use Before” date specified on the package.

All air must be removed from the balloon and displaced with contrast prior to inserting into the body (repeat preparations if necessary); otherwise, complications may occur.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked as this may result in breakage of the shaft. Instead, prepare a new catheter.

There is an increased risk of possible complications arising in patients with diabetes.

This product shall only be applied by physicians having experience in angiography or in percutaneous transluminal coronary angioplasty (PTCA) in coronary vessels. During the intervention a team of cardiac surgeons should be available.

Possible complications

The following complications may arise, amongst other things:

- Death
- Acute myocardial infarction
- Total occlusion of the coronary artery or bypass
- Dissection, perforation, rupture or damage of the coronary artery
- Restenosis of the dilated artery, in particular in vessels < 3.0 mm
- Unstable angina pectoris
- Arrhythmias, including ventricular fibrillation
- Hypotension/hypertension
- Infections
- Coronary artery spasms

- Coronary embolisms
- Arteriovenous fistulas
- Reactions to drugs, including allergic reactions to contrast media and/or local
- anesthetics
- Bleeding or hematoma in the area around the puncture site

Precautions

Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

The catheter system should only be used by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be administered to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure. Prior to inserting the dilatation catheter into the patient, it should be tested as described in the Instructions for Use section.

Shaft diameter differences should be taken into consideration when opening and closing the haemostatic valve and after the withdrawal of the catheter. It is important that the haemostatic valve is closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

These catheters are not designed to be used for distal pressure monitoring. Should unusual resistance or other problems be felt at any time during lesion access or removal of the PTCA balloon catheter, remove the entire guiding catheter and the balloon catheter system as a single unit.

Clinical and Laboratory Results

The clinical data accumulated so far indicate that the luminal diameter of a coronary artery at the sites of certain types of stenotic lesions can be increased by mechanical dilatation with a balloon dilation catheter. It appears that PTCA is a safe and efficacious procedure for the amelioration of some forms of atherosclerotic coronary artery disease.

Materials required for use with the Coronary Dilatation Catheter

- Min. femoral or brachial guiding catheters 5 F (1.65 mm) in the appropriate size and configuration to select the coronary artery
- Haemostatic valve(s)
- 60% contrast medium diluted 1:1 with normal saline
- Sterile saline
- 20 ml Luer-Lock syringe (optional)
- Inflation device
- Appropriately sized guide wire (max. 0.014 inch / 0.36 mm)
- Guide Wire Introducer, and
- Guide Wire Torque Device

Instructions for use

Prior to use of the Balloon Catheter in PTCA, all equipment to be used for the procedure, including the dilatation catheter, should be carefully examined for defects. Examine the dilatation catheter for bends, kinks or other damage. Do not use any defective equipment.

Prepare the equipment to be used according to the manufacturer's instructions or standard procedure.

Preparation of the Dilatation Catheter

Complete the following steps to prepare the catheter for use:

1. Remove the protective mandrel and cap from the flushing sheath (if necessary).
   a) If the catheter is equipped with a flushing hub, attach a syringe filled with heparinized normal saline to the flushing nozzle, which is attached to the protective balloon sheath, and inject heparinized saline into the lumen, or
   b) Attach a syringe filled with heparinized normal saline to the flushing nozzle, insert the flushing nozzle into the distal end of the catheter and inject heparinized saline into the lumen. Follow the same procedure for subsequent flushing.

2. Flushing solution should be seen coming out of the guide wire exit notch located approximately 30 cm proximal to the balloon.
3. Slide the protective sheath off the balloon.
4. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
5. To evacuate air from the balloon segment, the following procedure should be observed:
   a) Fill a 20 ml syringe or the inflation device with approximately 4 ml of the recommended contrast medium.
   b) After attaching the syringe or inflation device to the balloon inflation lumen, orient the catheter with the distal tip and the balloon pointing in a downward vertical position.
   c) Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.
   d) Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
   e) Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.
   f) Slowly release the device pressure to neutral.
6. Disconnect the 20 ml syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.

Use of the Coronary Dilatation Catheter

1. Insert a guide wire through the haemostatic valve following the manufacturer's instructions or standard practice. Advance the guide wire carefully into and through the guiding catheter. When complete, withdraw the guide wire introducer, if used.
2. Attach a torque device to the wire. Under fluoroscopy, advance the wire to the desired vessel, then across the stenosis.
3. Backload the distal tip of the dilatation catheter onto the guide wire ensuring that the guide wire exits from the notch located approximately 30 cm proximal to the balloon center marker. Advance the dilatation catheter over the guide wire until it approaches the haemostatic valve. Loosen the knurled knob on the valve. Insert the dilatation catheter while maintaining the guide wire position and retighten the knurled knob. To facilitate insertion, the balloon must be fully deflated to negative pressure.

NOTE: The catheter should be supported while back loading it onto the wire. Support the catheter with one hand while advancing it into the guide and grasp the proximal shaft firmly.

4. a) Tighten the knurled knob to create a seal around the dilatation catheter without inhibiting movement of the catheter. This will allow continuous recording of proximal coronary artery pressure.
   b) Advance the dilatation catheter until the appropriate proximal marker aligns with the haemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.
5. Advance the dilatation catheter over the guide wire and into the stenosis. Inflate the balloon to a very low pressure (1 bar/0.1 MPa) to confirm that the balloon is correctly positioned.
6. Inflate the balloon to perform PTCA according to the standard procedure. Maintain negative pressure on the balloon between inflations.
   Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the haemostatic valve. Tighten the knurled knob on the haemostatic valve.

Reuse precaution statement

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

References

The physician should consult recent literature on current medical procedures involving balloon dilatation, such as that published by international cardiologists' associations.

Warranty/Liability

The product and each component have been designed, manufactured, tested and packed with appropriate accuracy. The warning notices being contained in this Instruction of Use have to be considered particularly as an essential part of this clause. Accura grants a warranty on the products up to the mentioned "Best-Before-Date". A warranty exists only under the provision that the use of the product has been carried out in accordance with the Instruction of Use. Accura refuses each warranties or promises of a general usability for a certain purpose of the product. Accura is not

liable for direct, indirect, incidental originated or secondary damages being caused by the product. With exception of a fault or of a considerable fault on the part of Accura a compensation of any damages which occur for the buyer will in no case be higher than the invoiced amount of the faulty product. The warranty contained in this clause considers and replaces the legal warranty for defects and compliance of the directives and excludes each other possibility of liability on the part of Accura howsoever this can be ascribed to the delivered products. This limitation of liability and warranty on the part of Accura does not gear towards to be in contradiction to compulsory regulations of applicable right. Should one of the clauses of the disclaimer of liability be abrogated from a responsible court or should it be declared to be in contradiction to the applicable right the effectiveness of the further clauses of this user contract remain unaffected and valid in the greatest possible extend. In this case the undersigned commit themselves to agree a new arrangement which complies at best with the entitled interests of Accura to restrict their liability or warranty. No one has the authority to oblige Accura for any warranty or liability concerning the product.

Product variants

Lenghts (mm)	10	15	20	25	30	35	40
Diameter (mm)							
1.50	CB1510D	CB1515D	CB1520D				
2.00	CB2010D	CB2015D	CB2020D	CB2025D	CB2030D	CB2035D	CB2040D
2.25	CB2210D	CB2215D	CB2220D	CB2225D	CB2230D	CB2235D	CB2240D
2.50	CB2510D	CB2515D	CB2520D	CB2525D	CB2530D	CB2535D	CB2540D
2.75	CB2710D	CB2715D	CB2720D	CB2725D	CB2730D	CB2735D	CB2740D
3.00	CB3010D	CB3015D	CB3020D	CB3025D	CB3030D	CB3035D	CB3040D
3.25	CB3210D	CB3215D	CB3220D	CB3225D	CB3230D	CB3235D	CB3240D
3.50	CB3510D	CB3515D	CB3520D	CB3525D	CB3530D	CB3535D	CB3540D
4.00	CB4010D	CB4015D	CB4020D	CB4025D	CB4030D	CB4035D	CB4040D
4.50			CB4520D	CB4525D	CB4530D	CB4535D	CB4540D
5.00			CB5020D	CB5025D	CB5030D	CB5035D	CB5040D

Balloon compliance table

	Balloon diameter (mm)										
Pressure [bar]	**1.50 mm**	**2.00 mm**	**2.25 mm**	**2.50 mm**	**2.75 mm**	**3.00 mm**	**3.25 mm**	**3.50 mm**	**4.00 mm**	**4.50 mm**	**4.00 mm**
4	1.40	1.80	2.10	2.30	2.55	2.75	3.00	3.15	3.70	4.25	4.70
5	1.42	1.84	2.13	2.34	2.59	2.80	3.05	3.22	3.76	4.30	4.76
6	1.44	1.88	2.16	2.38	2.63	2.85	3.10	3.29	3.82	4.35	4.82
7	1.46	1.92	2.19	2.42	2.67	2.90	3.15	3.36	3.88	4.40	4.88
8	1.48	1.96	2.22	2.46	2.71	2.95	3.20	3.43	3.94	4.45	4.94
9 (NP)	**1.50**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**4.00**	**4.50**	**5.00**
10	1.52	2.04	2.28	2.54	2.79	3.05	3.30	3.57	4.06	4.55	5.06
11	1.54	2.08	2.31	2.58	2.83	3.10	3.35	3.64	4.12	4.60	5.12
12	1.56	2.12	2.34	2.62	2.87	3.15	3.40	3.71	4.18	4.65	5.18
13	1.58	2.16	2.37	2.66	2.91	3.20	3.45	3.78	4.24	4.70	5.24
14	1.60	2.20	2.40	2.70	2.95	3.25	3.50	3.85	4.30	4.75	**5.30**
15	1.62	2.24	2.43	2.74	2.99	3.30	3.55	3.92	4.36	4.80	-
16 (RBP)	1.64	2.28	2.46	2.78	3.03	3.35	3.60	3.99	**4.42**	**4.85**	-
17	1.66	2.32	2.49	2.82	3.07	3.40	3.65	4.06	-	-	-
18 (RBP)	**1.68**	**2.36**	**2.52**	**2.86**	**3.11**	**3.45**	**3.70**	**4.13**	-	-	-

NP = Nominal Pressure, RBP = Rated Burst Pressure

<table>
<tr><td> 
Sterilized using ethylene oxide</td><td> 
Lot number Batch number</td><td> 
Catalogue number</td><td> 
Manufactur er</td><td> 
Contents</td></tr>
<tr><td rowspan="2">Use-by date</td><td> 
Keep dry</td><td> 
Keep away from sunlight</td><td rowspan="2"> 
Do not resterilize</td><td rowspan="2"> 
Do not re-use</td></tr>
<tr><td colspan="2">Storage Conditions: Keep in a cool, dry and dark place</td></tr>
<tr><td colspan="2"> 
Caution(Read instruction prior to use)</td><td colspan="3"> 
Do not useif package is damaged</td></tr>
</table>

Manufacturer

Accura Medizintechnik GmbH
Max-Planck-Straße 33
611 84 Karben
Germany

Distributor

CZ Pharma, s. r. o.
Náměstí Smiřických 42
281 63 Kostelec nad Černými Lesy
Czech Republic

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