PTCA Balloon Catheter Cardioglide

PTCA balloon catheter with semi-compliant balloon membrane for coronary vascular system in rapid exchange technology

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Location: Moldova

Please read these Instructions for Use carefully before using the product. Also observe the information on the package labelling. Complications may occur if the Instructions for Use and the package labelling are not read and understood. This product may only be used by doctors trained and experienced in the PTCA[1] procedure.

1 Description

The product contains:

- a double-lumen PTCA balloon catheter ("rapid-exchange" technology) with a mounted semi-compliant balloon made of polyamide material and a catheter shaft made of polyamide (distal end) as well as PTFE-coated stainless steel (proximal end).
- two radiopaque markers at the balloon ends, which fluoroscopically mark the working length of the balloon.
- two proximal markings (95 cm and 105 cm from the distal tip) on the shaft of the PTCA balloon catheter which indicate the position of the system relative to the end of a brachial or femoral guide catheter.

At 0.8 MPa (8 bar) of nominal pressure, the balloon reaches its nominal diameter. When dropping below or exceeding the nominal pressure, the balloon changes its diameter (see Compliance Table on product label).

The lumen (27 cm length) starting from the distal tip is intended for use as a guide wire 0.014“ (0.36 mm) and has its exit at the distal end of the catheter (on the balloon side).

The second lumen with Luer connection serves as an inflation and deflation lumen for the balloon.

The working length of the PTCA balloon catheter is 138 cm.

Each PTCA balloon catheter includes a balloon folding attachment to obtain reduced profile and provide protection prior to stent deployment. A mandrel in the catheter tip prevents the tip from being bent during shipping and storage.

2 Description of symbols

Description	Pictogram
This PTCA balloon catheter was sterilized with EO gas.	
Do not use if the package is open or damaged.	
Do not use after the expiration date.	
STERILE - DO NOT RESTERILIZE - INTENDED FOR SINGLE USE ONLY No liability is assumed for resterilization, reprocessing or multiple use.	

[1] **P**ercutaneous **T**ransluminal **C**oronary **A**ngioplasty

Description	Pictogram
Store between 5°C and 40°C.	
Protect against sunlight.	
Keep dry	
Fragile, handle with care.	
Manufacturer	
Date of manufacture	
Batch code	LOT
Catalogue No.	REF
Read operating manual before use	
Balloon diameter	Ø
Balloon length	L
Maximum recommended inflation pressure	RBP
Minimal guiding catheter size	GC
Maximal guide wire diameter	GW

This product is intended for single use only. After reprocessing, the single-use products of Endocor GmbH may have the following defects:

- structural damage
- deterioration of functional and / or material properties
- insufficient sterility
- insufficient absence of pyrogenic substances
- presence of particles and endotoxins
- residue or occurrence of hazardous substances through cleaning, disinfection or resterilization.

If the product is reused, the reprocessed single-use product of Endocor GmbH may not achieve the required performance and/or result in an infection of the patient. This may result in a hazard to the health of patients, users or third parties. Endocor GmbH shall not be liable for possible consequential damage due to the reprocessing. This shall be the liability of the operator and user.

3 Indications

The PTCA balloon catheter is indicated for use in patients with symptomatic ischaemic coronary heart disease due to discrete *de novo* lesions or restenoses of the coronary arteries as well as arterial or venous bypasses with a reference vessel diameter of 1.5 mm to 4.0 mm, and is intended to expand the lumen of the coronary arteries and / or arterial or venous bypasses (see section Individualisation of Treatment).

3.1 Selection of PTCA balloon catheter

The diameter of the selected PTCA balloon catheter should correspond to the reference vessel diameter in a range between 1.5 mm and 4.0 mm. Select the balloon length to ensure sufficient coverage of the lesion; balloon lengths between 10 mm and 50 mm are available. The balloon lengths and diameters of the PTCA balloon catheter are indicated on the labels of the stent packaging.
Additional materials required for use are not part of the PTCA balloon catheter. Additional information may be found in section "10.3 Required material".

4 Contraindications

- Lesions to vessel bifurcations with one or more side branches
- Patients with cardiogenic shock
- Patients for whom therapy with platelet aggregation inhibitors and / or anti-coagulants is contraindicated. This includes patients who have undergone major surgery, or an operation is planned in the first four weeks after dilatation that excludes the administration of platelet aggregation inhibitors, an induced delivery, an organ biopsy, or a puncture of a non-compressible blood vessel within a period of 14 days before this operation. Likewise excluded are patients with gastrointestinal bleeding, acute cerebrovascular events, bleeding due to diabetic retinopathy, or other diseases which prohibit anti-coagulation therapy.
- Target lesions distal to a higher stenosis which cannot be predilated, or target lesions proximal to untreatable areas with significant disease restricting blood flow.
- Resistant (fibrotic or calcified) lesions which cannot be predilated (lesions for which complete balloon inflation is not possible at specified "rated burst pressure" (RBP))
- The estimated reference diameter of the artery is less than 1.5 mm.
- Patients with diffuse vessel diseases in the form of long vessel wall modifications without interim normal vessel sections

- Intracoronary thrombus
- Lesions that do not allow PTCA or another interventional technique
- Patients with significant vessel bending and/or proximal atherosclerosis, in which excellent support by the guide catheter is not possible
- Severe contrast agent allergy
- All patients diagnosed with a lesion that might prevent correct stent positioning, if required at a later stage
- Patients unsuitable for bypass operation
- Coronary artery spasm without evidence of a stenosis

Follow the current medical standard of knowledge.

5 Potential complications

Possible complications which may result from this surgical procedure include:

- acute myocardial infarction
- allergic reaction to anti-coagulants, anti-thrombotic treatment or contrast agent
- aneurysm
- arrhythmia (including ventricular fibrillation and ventricular tachycardia)
- arterial perforation
- arterial rupture
- arteriovenous fistula
- bleeding complications which may necessitate blood transfusion
- bradycardia
- dissection of the coronary artery
- diarrhoea
- embolism
- vessel spasm and trauma
- haematoma
- heart insufficiency
- cardiac tamponade
- hypotension
- infection
- unstable angina pectoris
- ischaemia
- ventricular fibrillation
- cardiogenic shock
- entry site complications
- coronary artery embolism
- coronary artery thrombosis
- emergency coronary bypass operation
- palpitations
- pseudoaneurysm (femoral)
- respiratory insufficiency
- arrhythmias
- stroke / cerebrovascular insult / TIA / cerebral bleeding
- pains
- shock, pulmonary oedema
- side branch occlusions
- death
- total occlusion of the coronary artery
- vascular complications which may necessitate vessel repair
- injury to the coronary artery

The treatment is performed in combination with X-radiation and contrast agents. A precise indication for stent placement is advised upon screening of patients who should follow treatment with PTCA balloon catheter.

Furthermore, complications unknown to date may occur.

Other possible complications include pulmonary infection, urinary tract infection, renal failure, nausea or vomiting, dizziness / drowsiness.

Complications may require surgery, re-dilatation, drug treatment or another intervention.

6 Recommended drug treatment

Dilatation with a PTCA balloon catheter should be performed in connection with a treatment with platelet aggregation inhibitors as required by the physician, and which has already taken effect at the time of dilatation.
A follow-up drug regimen in accordance with the current guidelines of the European Society of Cardiology (ESC; www.escardio.org) is recommended.

7 Warnings

- Should **unusual resistance** be felt **at any time** during lesion access or removal of the PTCA balloon catheter, the guide catheter and the PTCA balloon catheter should be **removed as a single unit**. Applying excessive force to the PTCA balloon catheter can result in the loss of or damage to the balloon and/or the components of the PTCA balloon catheter.

- Because the use of this PTCA balloon catheter is associated with the risk of a subacute thrombosis, vascular complications and/or haemorrhages, meticulous screening of patients and post-interventional monitoring are indispensable.

- The balloon must be removed immediately after its rupture.

- At nominal pressure, the diameter of the balloon may not exceed the diameter of the artery proximally and distally of the stenosis.

- Use only diluted contrast agent for filling the balloon.

- Do not use a guide wire with a diameter greater than 0.014“ (0.36 mm)

- Due to different viscosity, the contrast agent can affect the inflation and deflation time.

- Inject the contrast agent for detecting obstacles while passing the PTCA balloon catheter through the guide catheter.

- Persons allergic to the recommended materials or medications, e.g. radiographic contrast agents or anti-coagulants may experience an allergic reaction.

8 Precautions

(Please also refer to section "Individualisation of Treatment")

- Dilatation using PTCA balloon catheter may be performed only by physicians trained in its application, indication, and possible complications.

- Dilatation may be performed only at medical facilities which are equipped to perform necessary interventional procedures, such as emergency coronary bypass surgery, in case of complications.

- Angioplasty can result in dissection of the vessel and other complications (vasospasm / acute occlusion) which may necessitate additional interventions (e.g. further dilatations, placement of stents).

- During dilatation, pay attention to clinical symptoms and ECG changes which should be considered for specifying the dilatation time.

- When the catheter is deployed in the vascular system, it should only be manipulated under radiographic monitoring.

- Do not try to reposition a partially placed and inflated balloon. This can result in severe vascular damage.

- Should unexpected difficulties occur during inflation, terminate the procedure and remove the catheter. Do not insert the catheter again.

- Should resistance occur while manipulating the catheter, determine the cause of the resistance before continuing the procedure.

- The infusion of other media, such as heparinized physiological saline solution, through the guide wire lumen can negatively impact the performance of the balloon catheter.

- Additional materials are required for dilatation. Refer to the respective usage information for these materials and ensure they are compatible with the PTCA balloon catheter.

- Should it be necessary to use the guide wire for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

- Following dilatation and removal of the catheter from the coronary artery area, the balloon must be emptied completely. Prior to removing the catheter, check for complete balloon deflation under radiographic monitoring.

- In the case of a recoil, redilatation of the artery segment may be required.

8.1 PTCA Balloon Catheter Handling - Precautions

- Prior to opening, check the inner sterile package for damage that could impact on sterility.
- Use only the appropriate balloon inflation medium. Do not use air or any gaseous medium to inflate the balloon, as this may cause embolism and/or uneven expansion.
- During dilatation use a suitable inflation device with manometer only, in order to monitor the pressure and ensure that the maximum working pressure of the balloon (RBP) indicated on the label is not exceeded.
- The Compliance Table values were determined in vitro and may deviate from the values in vivo. For this reason, sufficient dilatation is to be checked using suitable methods, such as repeated angiography, for example.
- Do not allow the PTCA balloon catheter to come in contact with organic solvents, disinfectants, or the like, as this may lead to damage.
- For Luer lock connections, ensure that only suitable components are connected to one another and that the connections are sealed sufficiently. Ensure that none of the connections have been transposed.

The PTCA balloon catheter shaft comprises a tube of conductive medical stainless steel (304L). Due to interactions, the use of magnetic resonance imaging during dilatation represents a danger to the user, patient, and others, and is therefore contraindicated.

8.2 Warning instructions for removal of PTCA Balloon Catheter

Should **unusual resistance** be felt **at any time** during lesion access or removal of the PTCA balloon catheter, the entire system should be **removed as a single unit.**

When removing the PTCA balloon catheter as a single unit:

- Do not retract the PTCA balloon catheter into the guide catheter.
- Position the proximal radiopaque marker of the balloon just distal to the tip of the guide catheter.
- Insert the guide wire distally into the coronary arteries as far as is safely possible.
- Close the rotating haemostatic valve to secure the PTCA balloon catheter on the guide catheter; then remove the guide catheter, the guide wire and the PTCA balloon catheter **as a single unit**.

Non-compliance with these steps and/or application of excess force to the PTCA balloon catheter can result in the loss of or damage to the balloon and/or the components of the PTCA balloon catheter .

Should it be necessary to use the guide wire for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

9 Individualisation of treatment

The risks and benefits for each individual patient must be carefully weighed before using the PTCA balloon catheter. The patient selection criteria should always include an evaluation of the risk of using therapy with platelet aggregation inhibitors. Special consideration should be given to patients with recent reflux oesophagitis, active gastritis or peptic ulcers.

Patients should be examined for previously existing conditions which might increase the risk of intervention or emergency bypass surgery (diabetes mellitus, kidney failure and severe obesity).

The risk of early vessel occlusion for instance, as a result of thrombosis or restenosis, is favoured by a variety of angiographic and therapeutic factors. These include, *inter alia*, small blood vessel diameter, thrombus formation during the surgical intervention, delayed run-off and / or dissection following dilatation. In patients who have undergone dilatation, the persistence of a thrombus or evidence of a dissection should be considered as increased risk for occurrence of an occlusion syndrome. These patients normally require a supplementary drug therapy and should be monitored very carefully at a sufficiently scaled time interval, in particular, during the first month following dilatation. In the medical follow-up treatment and monitoring of patients, the current guidelines of the European Society of Cardiology (ESC; www.escardio.org) are recommended.

10 Preparation and execution

The following describes the work steps and required material for dilatation under radiographic monitoring. The instructions are purely informative in nature and are to be supplemented or adapted by the physician performing the treatment based on his or her clinical experience.

10.1 Aseptic removal

Carefully remove the inner sterile package from the carton and check it for damage that could endanger the sterility of the product. Remove the PTCA balloon catheter under aseptic conditions. Carefully open the sterile package by pulling apart the foil at the corners. Remove the protection device, the dispenser spiral, with the PTCA balloon catheter. Carefully pull the system at the proximal connector from the dispenser spiral. Then remove the distal balloon protective cap by carefully pulling at the distal protective cap end, thereby opening the delivery area. Ensure that the system is not bent and does not come in contact with unsterile materials or is contaminated in any other manner.

10.2 Inspections prior to use

Before using the PTCA balloon catheter, carefully remove the packaging and check the system for bends, kinks, and other damage. Do not use if any defects are noted.

10.3 Material required

The following materials are required for dilatation under radiographic monitoring. These materials are not part of the PTCA balloon catheter scope of delivery.

Material	Requirement
Suitable coronary guiding catheter	The required minimum inner diameter of the guide catheter depends only on the materials used and should be specified according to the diameter of every PTCA balloon catheter or stent system.
Syringe to flush the guide wire lumen of the PTCA dilatation catheter	Syringe with a dull needle, needle diameter maximum 0.4 mm; Sufficient anti-coagulated physiological saline solution Recommended heparin dose 2000 IU / l
If necessary, syringe for balloon preparation	10 - 20 ml; syringe with Luer lock connection; transparent
Guide wire	Maximum diameter 0.014“ (0.36 mm); Minimum length 175 cm
Rotating haemostatic valve	Rotating haemostatic valve with a minimum internal diameter of 0.096" (2.44 mm)
Radiographic contrast agent (for filling the PTCA dilatation catheter)	Recommended: Contrast agent in 1:1 dilution with physiological saline solution. Other concentrations and mixtures could impact visibility during radiographic monitoring and viscosity.
Inflation device	With manometer, burst strength at least RBP of the PTCA balloon catheter used, as specified on the label.
Three-way stop cock	Three-way stop cock; burst strength at least RBP of the PTCA balloon catheter used, as specified on the label.
Torque device	Compatible with the selected guide wire
Guide wire introducer	Compatible with the selected guide wire

Observe the usage information for the required materials. The user has to ensure their suitability for dilatation.

10.4 Preparation of the inflation device

Step	Action
1	Prepare the inflation device according to the manufacturer's instructions.

10.5 Selecting the balloon catheter

Step	Action
1	The balloon inflation diameter may not exceed the diameter of the vessel distally and proximally to the stenosis. If passage through the stenosis with the desired balloon catheter is not possible, select a catheter with a smaller balloon diameter to predilate the passage for the catheter selected for the vessel size.

10.6 Flushing of the guide wire lumen

Step	Action
1	Flush the guide wire lumen from the distal end of the PTCA balloon catheter with anti-coagulated saline solution using the syringe for balloon preparation, until fluid exits at the guide wire lumen exit notch. Please make sure that the catheter is not bent.
2	Examine for curvatures, folds and other damage. Do not use in case of visible damage.

10.7 Balloon preparation

Step	Action
1	Fill an inflation device / syringe with diluted contrast agent.
2	Connect an inflation device / syringe to the inflation port.
3	Hold the PTCA balloon catheter vertically with the tip pointing downwards.
4	Open the stop cock to the PTCA balloon catheter ; apply negative pressure for 30 seconds; return pressure to neutral to fill with contrast agent.
5	Close the stop cock to the PTCA balloon catheter ; purge the inflation device/syringe of all air.
6	Repeat steps 3 through 5 until all air is purged. **NOTE:** If air bubbles are visible in the shaft, repeat balloon preparation steps 3 to 5.
7	If a syringe was used, attach a prepared inflation device to the stop cock.
8	Open the stop cock to the PTCA balloon catheter.
9	Leave at neutral condition.

10.8 Delivery procedure

Step	Action
1	Prepare the vascular access site in accordance with standard practice for coronary angioplasty.
2	Maintain neutral pressure on the inflation device. Open the rotating haemostatic valve as wide as possible.
3	Slide the PTCA balloon catheter onto the proximal section of the guide wire while maintaining the position of the guide wire over the target lesion.
4	Advance the PTCA balloon catheter along the guide wire to the target lesion. Use the radiopaque markers to position the balloon above the lesion; perform angiography to confirm the balloon position. Do not slide the PTCA balloon catheter beyond the distal end of the guide wire.
5	Close the rotating haemostatic valve.

10.9 Dilatation procedure

Step	Action
1	**CAUTION**: Please refer to the product label for the in vitro outer diameter of the balloon, the dilatation pressure, and the guaranteed working pressure (RBP). Dilate the balloon by slowly pressurising the system in 0.2 MPa increments (2 bar) every 5 seconds until the balloon is completely expanded. Maintain the pressure for 30 seconds. If required, the balloon can be pressurized further or once again. **Do not exceed the RBP.**
2	Deflate the balloon by providing sufficient negative pressure for 30 seconds at the inflation device.

NOTE: The specified balloon diameter of the PTCA balloon catheter, depending on pressure (compliance), were determined in-vitro, and could be affected in vivo by various factors, especially vascular anatomy. Using suitable methods, e.g., repeated angiography, ensure that the balloon has expanded sufficiently.

10.10 Removal procedure

Step	Action
1	Ensure that the balloon has been completely deflated, e.g., through repeated angiography.
2	Fully open the rotating haemostatic valve.
3	While maintaining the position of the guide wire and negative pressure on the inflation device, withdraw the PTCA balloon catheter . **NOTE**: Should **unusual resistance** be felt **at any time** during removal of the PTCA balloon catheter after dilatation, the entire system should be **removed as a single unit**. Please observe the warning instructions for removal of the PTCA balloon catheter.
4	Close the rotating haemostatic valve.
5	Repeat angiography to evaluate the dilated area. If necessary, post-dilate the balloon. Balloon inflations should be done with a balloon size which matches that of the blood vessel. **Do not expand the balloon beyond the specified diameter at RBP.**
6	If the result is satisfactory, the guide wire can be removed carefully from the dilated stenosis.
7	Pull the balloon catheter together with the guide wire through the haemostatic valve. Note: If it is necessary to reintroduce the catheter for dilatation, clean the catheter with sterile, heparinized saline solution, and store it in a container with the same solution until it is reintroduced.

11 Disposal

Dispose of all waste in accordance with the applicable waste disposal ordinances. Contaminated waste should be handled as such and disposed of separately if necessary.

12 Complaints

Medical products of Endocor GmbH correspond to state of the art and are treated with highest care in the development, selection of components, manufacture, and final inspection before delivery.

In case of product complaints, the complete PTCA balloon catheter must be returned to Endocor GmbH. Materials used in conjunction with the dilatation should not be discarded until discussed with Endocor GmbH in order, if necessary, to determine the cause of the complaint. A corresponding complaint protocol is to be obtained from Endocor GmbH, filled in and returned.

Improper use, storing or handling, or other manipulation, may damage the PTCA balloon catheter and impair its functionality. Endocor GmbH accepts no liability for malfunctions, failure, and possible medical complications for the patient and hospital staff, or any resulting damage for the patient, user, or third parties due to improper treatment, operation, or storage, force majeure, or other influences beyond Endocor's control.

Due to biological differences from one individual to another, no product can be 100% effective in all circumstances. Endocor GmbH is not liable for harm of any kind caused directly or indirectly through the use and application of the product.

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13 Compliance table

Balloon Ø [mm]	**1.50**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
Pressure [MPa/bar]	**Compliance [mm]**							
0.6 / 6	1.45	1.91	2.15	2.43	2.67	2.93	3.41	3.88
0.7 / 7	1.48	1.95	2.20	2.47	2.71	2.97	3.45	3.94
0.8 / 8	**1.50**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
0.9 / 9	1.52	2.05	2.30	2.53	2.79	3.03	3.55	4.06
1.0 / 10	1.55	2.09	2.35	2.57	2.83	3.07	3.59	4.12
1.1 / 11	1.57	2.14	2.40	2.60	2.87	3.10	3.64	4.18
1.2 / 12	1.59	2.18	2.45	2.63	2.91	3.14	3.68	4.24
1.3 / 13	1.62	2.23	2.50	2.67	2.94	3.17	3.73	4.29
1.4 / 14	1.64	2.27	2.54	2.70	2.98	3.20	3.77	4.35
1.5 / 15	1.66	2.32	2.59	2.73	3.02	3.24	3.82	**4.41**
1.6 / 16	1.68	2.37	2.64	2.77	3.06	3.27	**3.87**	4.47
1.7 / 17	1.71	2.41	2.69	2.80	3.10	**3.31**	3.91	
1.8 / 18	1.73	2.46	2.74	2.83	**3.14**	3.34		
1.9 / 19	**1.75**	**2.50**	**2.79**	**2.87**	3.18			
2.0 / 20	1.78	2.55	2.84	2.90				

Nominal pressure:	**0.8 MPa / 8 bar**
RBP (rated burst pressure) = MRP (maximal recommended pressure)	**x.xx**