Instructions for use

Flyer
Coronary Stent System

Balloon-expandable stent system for coronary vessels

Contents of the sterile packaging
1 stent, pre-mounted on an Atrium PTCA catheter

General product description / field of application

The stent is a small metal tube, cut by means of a precision laser, and made of special surgical steel (material for implants), which is expanded by means of a balloon catheter and thus embeds itself in the vascular wall. After expansion in the vessel, the stent forms a metal grid with rounded-off edges and low profile. Its surface is smoothed by means of special surface treatment. A low level of thrombogenicity is thus achieved. The stent is available in various lengths.

The stent is pre-mounted on a balloon catheter with two X-ray markers, which mark the ends of the stent.

The stent is a permanent implant, which presses atherosclerotic plaque against the vascular wall, and is later covered over with neointimal cells and endothelium, until a continuous cell surface is formed.

The Flyer is pre-mounted on a balloon catheter with two X-ray markers, which mark the ends of the stent.

The Flyer is packaged sterile. Sterilization is by means of ethylene oxide. The Flyer is for single use only.

Indications
- De novo (primary use in the case of stenoses or occlusions)
- Residual stenosis after PTCA
- Venous bypass stenosis or occlusion
- High risk of restenosis after PTCA
- Dissection after PTCA
- Recoil after PTCA
- Acute vascular obliteration
- Sub-optimal result after PTCA

Contraindications
- Hemorrhagic diathesis or other disorder such as gastrointestinal ulceration or cerebral circulatory disorders, which restricts the use of platelet aggregation inhibitor therapy and anti-coagulation therapy.
- Operation shortly after myocardial infarction where there are indications of thrombus or poor flow behavior.
- Patients with significant vascular curvature and/or proximal atherosclerosis, where proper support through the guide catheter is not possible.
- Severe allergy to contrast media.
- Lesions which are presumed to be untreatable with PTCA or other interventional techniques.

Possible complications
- Hematoma at the access point
- Pseudoaneurysm
- Acute myocardial infarction
- Pulse arrhythmia
- Acute/subacute stent occlusion
- Angina pectoris
- Arterial perforation
- Spasm
- Death
- Cerebral circulatory disorders
- General bleeding
- Side effects with regard to the accompanying medication (see corresponding product leaflet)
- Distal embolism
- Thrombus formation
- Arterial rupture
- Dissection of the coronary vessel
- Hypotension
- Ventricular fibrillation
- Ischemia
- Artero-venous fistulas
- Palpitations
- Vascular complications which make a surgical operation necessary
- Allergy to contrast medium
- Infection

Warnings / precautionary measures

This product should be used only by physicians with experience in angiography, percutaneous transluminal coronary angioplasty (PTCA) and implanting stents in coronary vessels.

During the procedure, a cardiac surgery team should be on standby.
The Flyer should be considered for implantation only for lesions, which show no signs of a "waist" during balloon dilatation.

When removing the Flyer from the packaging, and when passing the hemostasis valve, great care must be taken that the stent is not damaged or becomes non-sterile. Do not inflate the balloon catheter prematurely. It is possible for the stent to be expanded thus, and to slip off the balloon. The recommended pressure of the balloon catheter must not be exceeded. It is recommended that a pressure gauge is used for monitoring the inflation pressure. If the balloon should become entrapped in the stent struts before the stent has completely expanded, the balloon can then only be removed surgically. If a balloon rupture occurs before complete expansion, the defective balloon should be pulled back and the stent should be completely embedded in the vessel wall by means of a new balloon catheter.

If any resistance becomes apparent at any time during the insertion procedure, the catheter must not be pushed further using force. The resistance can indicate damage to the stent.

If the resistance occurs on the way through the guide catheter, then the feeder system should be pulled back. If a resistance occurs after the stent has left the guide catheter, or if the stent cannot be brought forward to the corresponding target lesion, then the stent can slip off during the attempt to pull the stent back into the guide catheter with the risk of vascular embolization. The balloon catheter with the stent mounted on should then be pulled back as follows:

1. Using fluoroscopy, draw the stent back to the tip of the guide catheter.
2. Pull the guide catheter and the stent back into the ascending aorta, without changing the position of the guide wire.
3. If necessary, fill the balloon slightly, in order to reduce the likelihood of the stent slipping off or being pulled off the balloon.
4. Pull the guide catheter and the Flyer together back through the introducer.

When placing more than one stent, it is recommended that the distal stent is placed first. If nevertheless a further stent has to be placed distally, care must be taken that the guide wire does not find itself between the vascular wall and the stent.

Note: If the stent dislodges from the balloon it will not be possible to safely crimp the stent on the balloon again!

Use of magnetic resonance imaging (MRI)
The stent is not magnetic. However, for reasons of safety NMR should not be used before final endothelialization of the implanted stent (approx. 6-8 weeks), in order to definitely exclude any migration of the stent. Through the distortion of the magnetic field, there is the possibility of formation of artifacts.

Allergic reactions
Stents should not be implanted where the patient has existing allergic reactions to any of the constituents of the stent. The main constituents of the stent (proportions greater than 2 %) are chromium, nickel and molybdenum (special surgical steel).

Assembly, handling and implantation
Before use, the physician must inspect the Flyer in order to ensure that it was not damaged in transport. Remove the Flyer from the sterile packaging. Do not use or re-sterilize if the sterile packaging is damaged.

Check that the stent is placed firmly on the balloon catheter.

After the lesion has been pre-dilated and demonstrates a sufficient lumen for the stent to be placed in, implantation of the stent may be started.

For this, introduce the balloon catheter bearing the stent via the guide wire through the guide catheter into the lesion.

After precise position verification, inflate the balloon using a pressure gauge and under fluoroscopy. Leave the balloon inflated for a few seconds. Then deflate the balloon completely and pull back.

Finally check the result by means of angiography.

In the event of an inadequate result, continue with further dilations, possibly with a balloon of a larger diameter.

Note: For treatment to be successful and provide long-term satisfactory results for the patient, the stent should ideally be embedded in the vascular wall, and where possible cover the whole lesion (plaque). In the case of an unsatisfactory primary result, this can be achieved by the use of high-pressure balloon catheters and subsequent checking of the stent placing by means of intravascular ultrasound.

Introduction of the Flyer
As in conventional balloon angioplasty before the stent implantation, an introducer with a lateral arm adapter is placed in the femoral or brachial artery and rinsed with sterile isotonic sodium chloride solution. Under fluoroscopy, the area of occlusion is carefully explored with a vascular guide wire. As soon as the wire has been guided passed the lesion, a standard balloon angioplasty is carried out. During dilation, care must be taken that the lesion is not over-stretched. In order to lower the potential risk of dilation-induced complications, the lesion can also be deliberately under-dilated. After a (possibly necessary) change of guide wire, the angioplasty catheter is pulled back with the guide wire remaining positioned at the location of the lesion.

Subsequently, the Flyer is moved to the target location, with a balloon diameter adapted to the pre-dilated vascular lesion, and the balloon catheter is inflated. Under no circumstances should the recommended maximum inflation pressure be exceeded.

The correct inflation of the balloon must be monitored visually. During the stent implantation, the optimum diameter of the expanded stent must be judged in comparison to the proximal and distal reference vascular diameters, by means of fluoroscopy. Optimum expansion of the stent has been achieved when the stent is fully pressed against the arterial wall. If it was not possible to expand the stent perfectly using the balloon, there is also the possibility of using a larger dilation balloon, with which the stent can be brought to an optimum diameter.

REMARK: The last inner diameter chosen for the vascular support should correspond to the reference vascular diameter, or be somewhat larger. All measures should be taken to ensure that the stent is not too greatly under-dilated.
NOTE: The stent should be expanded to a width slightly above that of a neighboring non-diseased vessel, or one which corresponds to it.

Ending the operation
After complete and adequate stent expansion has been confirmed by means of fluoroscopy, the balloon catheter, the guide wire and the guide catheter are pulled back through the introducer. The risk of complications at the puncture site can be kept low by careful removal of the introducer. If complications arise in the area of the puncture site, such as small pseudoaneurysms, the need for future treatment may be reduced with the aid of compression guided by ultrasound. After the operation has ended, heparin is stopped. When the ACT value is less than 180 seconds, the introducers should be removed. The punctured artery must be put under pressure, as required, for 15–30 minutes; after that a C-clamp should be applied for 1–2 hours.
Finally, a pressure dressing is applied, and the patient should rest, flat in bed, for at least 24 hours.

Medication schedule
On admission to the hospital, the start and end times for prothrombin time (PT) and partial thromboplastin time (PTT) as well as the thrombocyte count should be documented.
The following medication schedule is intended solely as a guideline, and is not seen as a strict medical stipulation.

Before stent implantation
- ASA 250 to 500 mg 1x daily
- Ticlyd 250 mg 2x daily (if possible, start 2–3 days before implantation)

During stent implantation
- Heparin 70 IU/kg body weight i.v.
- Repeated bolus administration of 2,500 IU heparin, in order to keep the ACT value above 250 seconds.

After the stent implantation
- ASA 250 to 325 mg 1x daily
- Ticlyd 250 mg 2x daily for 4 weeks (check leukocyte count and thrombocyte count after 2 and 4 weeks)
- Introducer removal, normally when ACT value is below 180 seconds and no additional administration of heparin
- In the event of sub-optimal results and/or residual dissections, low-molecular heparin can be given subcutaneously 2x daily for 2 weeks.

Concluding note
The stated dosages, instructions and values must be checked precisely by the user before implantation, and if necessary discussed with experienced colleagues and amended. Due to constant advancements in stent implantation during recent years, other procedures that differ from those described above are certainly conceivable. For this reason, continued training at cardiac centers of excellence is recommended.

Storage
The packed products must be stored at a temperature between 15°C and 25°C and at a relative humidity of between 50% and 60% until usage. Protect the product from direct sunlight.
With proper storage the product may be used until the expiration date given on the packaging.

Subject to technical alterations