DEVICE NAME: ***CRE8™***
MODEL: ***EVO***

What is in this leaflet?

This leaflet answers some common questions about **Cre8™ EVO** coronary drug eluting stent.
It does not contain all the available information. Some of the information it contains may not apply to you.
It does not take the place of talking to your doctor or cardiologist. All treatments have benefits and risks. In deciding to implant you **Cre8™ EVO**, your cardiologist has weighed the risks of you receiving **Cre8™ EVO** against the expected benefits it will have for you.

Always follow the instructions that your doctor and cardiologist give you. If you have any concerns, ask your doctor or cardiologist.
You may wish to keep this leaflet to read again.

Why was I implanted with Cre8™ EVO coronary drug eluting stent?

As a consequence of the *coronary artery disease* or an *heart attack*, you were submitted to a procedure, called *coronary angioplasty*, during which you received a *drug eluting stent* called **Cre8™ EVO**.

What is the coronary arteries disease?

Coronary arteries disease (CAD) is a condition characterized by the deposit of plaque, consisting of fatty material, on the inner wall of an arterial vessel, called *coronary artery*, which is constantly supplying your heart with blood, oxygen, and nutrients. When the plaque forms, the flow of blood to the cardiac muscle is reduced and partially blocked, therefore causing possible chest pain, which is a typical symptom of angina. Reopening of the vessel can be obtained using a technique called *coronary angioplasty*, and the possible consequent implant of a coronary device known as a *stent*.

What is a heart attack or myocardial infarction?

When one of the coronary arteries becomes severely or totally blocked, usually by a blood clot, the result can be a *heart attack*, also known as *myocardial infarction*. The part of the heart muscle that is not receiving the oxygen-rich blood that it needs, it will begin to die and some of the heart muscle may become permanently damaged. If the flow of blood is not restored quickly, the section of heart muscle becomes damaged from lack of oxygen and begins to die.

What is coronary angioplasty?

Coronary angioplasty is a technique used to reopen coronary arteries occluded by the plaque and/or by a blood clot. It is done by threading a catheter (thin tube) through a small puncture in a leg or arm artery to the heart. The catheter has a tiny balloon in it that when inflated compress the plaque and/or the clot against the vessel wall, restoring the blood flow to supply again oxygen to the heart muscle. At the end of the procedure the balloon catheter is removed. After the removal of the balloon is often implanted a device, called *stent*, with the aim of preventing the re-narrowing of the treated coronary lesion.

What is a drug eluting stent?

A *stent* is a small mesh-like metallic tube, which is positioned inside the coronary arteries, at the place where the plaque and/or clot obstructs the blood flow. The stent ensures that the passage for the blood remains open, so as to allow normal oxygenation of the heart. *Drug eluting stents (DES)* are stents loaded with drugs that can prevent the re-narrowing that can occur after the placement of a stent and is the result of too much cell growth inside the stent. *Drug eluting stents* are currently approved and thousands of patients are treated with them each year.

Which are the possible adverse events that may occur after coronary stent implantation?

Coronary stent implantation may give rise to the following complications:

- Collection of blood at the site of puncture (*Access site haematoma*)
- Heart Attack (*Acute myocardial infarction*)
- Allergic reaction to the materials composing the stent
- Sudden tightening of the muscles within the arteries of the heart (*Arterial spasm*)
- Swelling of the vessel wall at the site of puncture (*Artery aneurysm or pseudoaneurysm*)
- Heart rhythm problems (Cardiac arrhythmia)
- Death
- Formation of tears, perforation, rupture of the vessel wall (*Dissection, perforation, rupture of the artery*)
- Particles moving within the blood flow (*Distal embolism*)
- Bleeding (*Haemorrhage*)
- Infection and pain at the site of puncture (*Infection and pain at the access site*)
- Re-narrowing of the vessel (*Restenosis of the vessel*)
- Blockage of the blood flow within the stent length (*Stent occlusion*)
- Formation of a blood clot within the stent within one day, within a month, or later. (Thrombosis (*acute, subacute or late*)
- Chest pain that occurs at rest or with exertion or stress (*Unstable angina*)
- Quiver of the lower heart chambers (*Ventricular fibrillation*)
- Blockage of the vessel flow within the vessel (*Vessel occlusion*)

Other adverse event not listed above may also occur in some patients.

Tell your doctor if you notice any other adverse event. Do not be alarmed by this list of adverse events. Most people do not experience any of them.

What is the care after dismissing from hospital?

You are discharged from hospital to the care of your cardiologist or family doctor. You should be able to return to your normal activities soon. Your doctor will ask you to return for follow-up visits. Be sure to keep all appointments for follow-up care, including blood tests.

Notify your doctor immediately if you experience chest pain (angina), or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.

Should I take any medication?

After you leave the hospital, your cardiologist will instruct you to take a daily dose of aspirin together with another antiplatelet drug containing either ticlopidine, clopidogrel or prasugrel or ticagrelor. Antiplatelets work by making your blood less sticky preventing arteries and stents from being plugged by clots. Your doctor will tell you how long you should continue taking the antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructs you. Follow your medication schedule exactly to avoid possible complications after you receive your stent. Do not miss any doses.
Call your doctor if you cannot keep taking your medications because of side effects such as rash, bleeding, or upset stomach.

Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your stent procedure.
Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your doctor may prescribe antibiotics to avoid the potential of an infection. You should review with your doctor any recommendations from your dentist to stop your prescribed medications.
If surgery or dental work that would require you to stop taking antiplatelet medications is recommended after you have received the stent, you and your doctors should carefully consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications. If you do require discontinuation of antiplatelet medications because of significant bleeding, your cardiologist will carefully monitor you for possible complications. Once your condition has stabilized, your cardiologist may put you back on these medications.

What are the restrictions or cautions after I have received a stent?

Cre8™ EVO will not interfere with diagnostic imaging apparatuses such as magnetic resonance imaging (MRI) equipment even immediately after the procedure. However, the MRI exam has to be performed under specific conditions in order to avoid image artifacts or an increase in the temperature of the device.

If you require MRI, tell your doctor or MRI technician that you have an implanted stent and show the Patient Card, containing information about the conditions to perform the MRI.

Will my stent set off the metal detector at airport security checkpoints?

No, your stent implant will not trigger alarms at security checkpoints.

How long will the stent stay in my body?

Cre8™ EVO is designed to stay in your body permanently and during its lifetime you are not requested to take any specific measure other than carefully follow the advice and prescriptions of your doctor and cardiologist.

How can I help prevent a recurrence of symptoms?

While there is no sure way to prevent a recurrence of symptoms, you can reduce your risk through exercise, not smoking, controlling your blood pressure and cholesterol, taking prescribed medications, and eating a healthy diet. Your doctor can advise you about lifestyle changes.

What substances does Cre8™ EVO contain?

The stent is made of ***cobalt chromium alloy*** coated with a thin layer of pure ***carbon*** (***i***Carbofilm™). It has two markers made of ***platinum*** at the ends to increase its visibility during the implanting procedures. The stent contains a pharmaceutical formulation (Amphilimus™) composed of the drug ***sirolimus*** and a mixture of ***long chain fatty acids***. During the whole production process, particular attention was paid to ensure that no residual substances other than above mentioned remained on the device you received to avoid exposing you to undesirable effects due to the presence of such residuals.

What should I do in the case I supposed to have experienced an incident in relation to Cre8™ EVO?

Refer immediately to your cardiologist.

Notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration (https://www.tga.gov.au/).

Manufactured by: CID S.p.A.
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