

DYNAMX® SIROLIMUS ELUTING CORONARY BIOADAPTOR SYSTEM

PATIENT WEBSITE INFORMATION

Drug Information

Your doctor has treated you with a DynamX bioadaptor. It includes the drug substance Sirolimus. Tell your doctor of any medication you are taking so they may assess potential drug interactions. Eating or drinking grapefruit may interfere with this drug. You should show your doctor the following information regarding Sirolimus:

Drugs which act through the same binding protein (FKBP) may interfere with the efficacy of Sirolimus. Strong inhibitors of CYP3A4 (e.g., ketoconazole) might cause increased Sirolimus exposure. Consideration should be made if the patient is treated concomitantly with system immunosuppressive therapy. Grapefruit may potentially interfere with the metabolism of Sirolimus.

MRI Information

You can safely undergo magnetic resonance imaging (MRI) after receiving a DynamX bioadaptor. You should show your doctor the following information prior to undergoing an MRI scan:

Nominal Value(s) of Static Magnetic Field	1.5 T or 3 T
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 6 mm

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Bioadaptor Materials

The DynamX bioadaptor is made of cobalt chromium alloy. The alloy contains the following metals, listed in order of highest amount to least: cobalt, chromium, tungsten, nickel, iron, manganese. Cobalt chromium alloy is used as a platform for numerous commercially available stents. The largest amount of the alloy on a DynamX bioadaptor is approximately 0.07 grams (g).

The DynamX bioadaptor is coated with a drug called Sirolimus. Sirolimus has been widely used for implants and treatments like yours with established safety and efficacy. The largest amount of Sirolimus on a DynamX bioadaptor is approximately 0.00032 grams.

The DynamX bioadaptor is also coated with two polyactide-based polymers. One polymer is mixed with the Sirolimus drug and allows for release of the drug over a period of time. The second polymer holds the sections of the bioadaptor together. A few months after implantation, the polymer dissolves giving the bioadaptor flexibility inside the vessel. The largest amount of total polymer on a DynamX bioadaptor is approximately 0.0031 grams.

Bioadaptor Lifetime

The DynamX bioadaptor is a permanent implant. It is not designed to be removed. There is no maintenance needed for the DynamX bioadaptor.

Other Helpful Information

After receiving a DynamX bioadaptor, follow the antiplatelet medication recommended by your doctor. Adhere to the follow-up schedule recommend by your doctor.