Patient Information Leaflet– Australia

Ultimaster Nagomi Sirolimus eluting coronary stent system

You recently received or will receive a sirolimus eluting coronary stent implanted in a coronary artery of your heart. After the procedure your physician will give you an implant card. **Please carry this patient implant card at all times and show it to any medical personnel who may be treating you.**

The following information about your stent is important for you to know:

1. When is Ultimaster Nagomi stent used?

   Ultimaster Nagomi stent is used to improve blood supply to the heart muscle, alleviating your symptoms, such as chest pain and discomfort or shortness of breath.

2. Product description

   The Ultimaster Nagomi stent is a mesh-like tube made of a metal alloy, coated with a drug and a polymer. The stent is placed and expanded against the wall of the coronary artery to increase blood supply to the heart muscle. The polymer allows the drug to be released in a controlled way into the wall of the artery to reduce the chance of a reblockage.

   Table 1: Information on the materials and substances used in the Ultimaster Nagomi stent:

Stent component	Material	Substance	Quantity
Stent platform	Cobalt Chromium alloy	Cobalt*	46.38-56.95 (w/w%)
		Chromium	19.00-21.00 (w/w%)
		Nickel	9.00-11.00 (w/w%)
		Carbon	0.05-0.15(w/w%)
		Manganese	1.00-2.00 (w/w%)
		Silicon	0-0.40 (w/w%)
		Phosphorus	0-0.04 (w/w%)
		Sulphur	0-0.03 (w/w%)
		Tungsten	14.00-16.00 (w/w%)
		Iron	0-3.00 (w/w%)
Drug	Sirolimus		35-197 µg (stents with diameter 2.0; 2.25 or 2.5 mm, depending on stent length) 36-198 µg (stents with diameter 2.75 or 3.0 mm, depending on stent length) 39-197 µg (stents with diameter 3.5; 4.0 or 4.5 mm, depending on stent length)

Polymer	Poly(D,L-lactide-co-caprolactone) copolymer	48-268 µg (stents with diameter 2.0; 2.25 or 2.5 mm, depending on stent length) 49-269 µg (stents with diameter 2.75 or 3.0 mm, depending on stent length) 57-288 µg (stents with diameter 3.5; 4.0 or 4.5 mm, depending on stent length)
* Caution: This device contains Cobalt (CAS N°7440-48-4), classified as CMR 1B, in a concentration above 0.1 % weight per weight. Current scientific evidence supports that medical devices manufactured from alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. (CMR 1B: carcinogenic and toxic to reproduction (CLP regulation EU 1272/2008)		

Caution:

Inform your physician in case of:

- possible allergy to Cobalt-Chromium alloy and nickel
- possible allergy to sirolimus or related compounds, to lactide polymers and caprolactone polymers
- pregnancy/breastfeeding

3. Potential adverse events

Adverse events are listed in alphabetical order. **Please consult your physician for further explanation on the potential adverse events.**

Potential adverse events associated with the procedure of coronary stent placement include but are not limited to:

Abrupt vessel closure	Infection and pain at insertion site
Acute myocardial infarction	Ischemia, myocardial
Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast material, or stent and/or delivery system materials or any other PCI mandatory medication	Myocardial infarction
	Nausea and vomiting
	Prolonged angina
	No reflow
	Pseudoaneurysm
Aneurysm	Renal failure
Arrhythmias, including ventricular fibrillation and ventricular tachycardia	Restenosis of stented segment
	Respiratory failure
Arteriovenous fistula	Rupture of native and bypass graft
Cardiac tamponade	Stent compression
Cardiogenic shock	Stent embolization
Death	Stent migration
Emboli, distal (air, tissue or thrombotic emboli)	Stent thrombosis / occlusion
Emergent Coronary Artery Bypass Surgery	Stroke / cerebrovascular accident
Failure to deliver the stent to the intended site	Thrombosis (acute, subacute, or late)

Fever	Total occlusion of coronary artery
Heart failure	Unstable or stable angina pectoris
Hematoma	Vessel dissection
Hemorrhage, requiring transfusion	Vessel perforation
Hypotension / Hypertension	Vessel spasm

Potential adverse events that may be associated with sirolimus drug are listed below and are consistent for oral intake of sirolimus. In case of stent implantation however, sirolimus is only locally delivered into the vessel wall and amounts of the drug released into the blood are low. Therefore, it is very unlikely that any of the below adverse events (apart from an allergic reaction) associated with oral intake of sirolimus will occur:

Abnormal liver function tests
Anemia
Arthralgias
Changes in lipid metabolism which may include hypertriglyceridemia or hypercholesterolemia
Diarrhea
Hypersensitivity including anaphylactic / anaphylactoid type of reactions
Hypokalemia
Immune suppression, especially in patients with hepatic insufficiency or who are taking medications that inhibit CYP3A4 or P-glycoprotein
Infections
Interstitial lung disease
Leukopenia
Lymphoma and other malignancies
Myalgia
Thrombocytopenia

If you experience any of the above listed adverse events, please report it to your treating physician.

4. Symptoms that could indicate that the device is malfunctioning

If you experience any symptom other than what your physician told you before the procedure, immediately seek medical attention. Symptoms of potential device malfunction after procedure may include sudden shortness of breath and chest pain.

5. Medication and examinations after stent placement

After stent placement it is extremely important that you follow the specific medication regimen your physician prescribed. In case you need to discontinue your medication prematurely, please consult your physician.

Follow the physician's instructions for any further follow-up examinations after stent placement.

6. Lifetime of the implanted stent

This device is a permanent implant and is not intended to be removed.

7. MRI (Magnetic Resonance Imaging) information

The Ultimaster Nagomi stent has been proven to be MRI conditional. This means that you can safely undergo an MRI scan under certain conditions. When you inform your physician on the type of stent you have (e.g. by showing your implant card), your physician will be able to determine these safe scanning conditions.

8. Passing through metal detectors

The Ultimaster Nagomi stent will not set off metal detectors, you can safely pass through metal detectors during security checks (e.g. airport, stores).

9. Incident reporting

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or the Australian sponsor and to the Therapeutic Goods Administration

www.tga.gov.au

Manufacturer:

TERUMO EUROPE N.V.
INTERLEUVENLAAN 40, 3001 LEUVEN, BELGIUM
www.terumo-europe.com

Distributor/Sponsor:

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Product Code	Nominal Expanded Stent Inner Diameter (mm)	Nominal Expanded Stent Length (mm)
DE-RS2009ASM	2.00	9
DE-RS2012ASM	2.00	12
DE-RS2015ASM	2.00	15
DE-RS2018ASM	2.00	18
DE-RS2021ASM	2.00	21
DE-RS2024ASM	2.00	24
DE-RS2028ASM	2.00	28
DE-RS2033ASM	2.00	33
DE-RS2038ASM	2.00	38
DE-RS2044ASM	2.00	44
DE-RS2050ASM	2.00	50
DE-RS2209ASM	2.25	9
DE-RS2212ASM	2.25	12
DE-RS2215ASM	2.25	15
DE-RS2218ASM	2.25	18
DE-RS2221ASM	2.25	21
DE-RS2224ASM	2.25	24
DE-RS2228ASM	2.25	28
DE-RS2233ASM	2.25	33
DE-RS2238ASM	2.25	38
DE-RS2244ASM	2.25	44
DE-RS2250ASM	2.25	50
DE-RS2509ASM	2.50	9
DE-RS2512ASM	2.50	12
DE-RS2515ASM	2.50	15
DE-RS2518ASM	2.50	18
DE-RS2521ASM	2.50	21
DE-RS2524ASM	2.50	24
DE-RS2528ASM	2.50	28
DE-RS2533ASM	2.50	33
DE-RS2538ASM	2.50	38
DE-RS2544ASM	2.50	44
DE-RS2550ASM	2.50	50
DE-RS2709ASM	2.75	9
DE-RS2712ASM	2.75	12
DE-RS2715ASM	2.75	15
DE-RS2718ASM	2.75	18
DE-RS2721ASM	2.75	21
DE-RS2724ASM	2.75	24
DE-RS2728ASM	2.75	28
DE-RS2733ASM	2.75	33
DE-RS2738ASM	2.75	38
DE-RS2744ASM	2.75	44
DE-RS2750ASM	2.75	50
DE-RS3009ASM	3.00	9
DE-RS3012ASM	3.00	12
DE-RS3015ASM	3.00	15
DE-RS3018ASM	3.00	18
DE-RS3021ASM	3.00	21

Product Code	Nominal Expanded Stent Inner Diameter (mm)	Nominal Expanded Stent Length (mm)
DE-RS3024ASM	3.00	24
DE-RS3028ASM	3.00	28
DE-RS3033ASM	3.00	33
DE-RS3038ASM	3.00	38
DE-RS3044ASM	3.00	44
DE-RS3050ASM	3.00	50
DE-RS3509ASM	3.50	9
DE-RS3512ASM	3.50	12
DE-RS3515ASM	3.50	15
DE-RS3518ASM	3.50	18
DE-RS3521ASM	3.50	21
DE-RS3524ASM	3.50	24
DE-RS3528ASM	3.50	28
DE-RS3533ASM	3.50	33
DE-RS3538ASM	3.50	38
DE-RS3544ASM	3.50	44
DE-RS3550ASM	3.50	50
DE-RS4009ASM	4.00	9
DE-RS4012ASM	4.00	12
DE-RS4015ASM	4.00	15
DE-RS4018ASM	4.00	18
DE-RS4021ASM	4.00	21
DE-RS4024ASM	4.00	24
DE-RS4028ASM	4.00	28
DE-RS4033ASM	4.00	33
DE-RS4038ASM	4.00	38
DE-RS4044ASM	4.00	44
DE-RS4050ASM	4.00	50
DE-RS4509ASM	4.50	9
DE-RS4512ASM	4.50	12
DE-RS4515ASM	4.50	15
DE-RS4518ASM	4.50	18
DE-RS4521ASM	4.50	21
DE-RS4524ASM	4.50	24
DE-RS4528ASM	4.50	28
DE-RS4533ASM	4.50	33
DE-RS4538ASM	4.50	38
DE-RS4544ASM	4.50	44
DE-RS4550ASM	4.50	50