Ultimaster Tansei



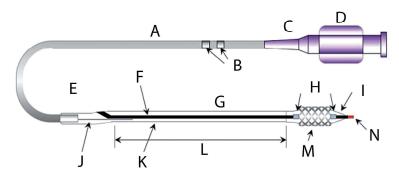
Sirolimus Eluting Coronary Stent System

Ultimaster™ Tansei™ Sirolimus Eluting Coronary Stent System is indicated for improving myocardial blood flow in patients with stenotic lesions in coronary arteries, including but not limited to patients with STEMI, NSTEMI, acute coronary syndrome, diabetes mellitus, multivessel disease, bifurcation lesions, patients older than 65 years, male and female patients, patients with totally occluded lesions, long lesions, lesions residing in small coronary vessels, restenotic lesions including in-stent restenosis, ostial lesions, lesions in left main coronary artery. The Ultimaster™ Tansei™ stent system is suitable for both femoral and radial approach.1

Ultimaster™ Tansei™ provides enhanced pushability² and excellent kink resistance² with a stainless steel tapered core wire at the exit port and advanced shaft technology. With this new DES Terumo introduces a durable yet flexible tip2 specially developed for complex stenting procedures. This innovation will improve the deliverability2 of the whole stent system versus leading stent delivery systems. Building on the heritage of Ultimaster™ with its proven clinical performance^{3,} Ultimaster™ Tansei™ utilises the same abluminal gradient bioresorbable polymer coating to support early vascular repair and potentially shortened DAPT time.

Product Characteristics

- 2-link, bio-inspired stent design
- Enables stent conformability allowing adaptation to natural vessel shape4 Facilitates side-branch access and enables optimal coverage of the bifurcation⁵ thanks to its uniform scaffolding.
- Advanced abluminal bioresorbable coating:
- Polymer coating is only on the abluminal side of the stent for efficient and targeted drug delivery⁶ Drug coating applied in a gradient to reduce the risk of polymer cracking and delamination, even when the stent is overexpanded 7 PCL added to PDLLA, increasing the elasticity of the bioresorbable polymer coating
- Simultaneous polymer resorption and drug release within 3-4 months¹, to match the procedure-triggered biological response
- Ultimaster[™] Tansei[™] facilitates enhanced deliverability² Stronger hypotube and stainless steel tapered core wire for enhanced pushability and excellent kink resistance⁶ A durable yet flexible tip supports navigation through tortuous vessels while reducing the risk of tip damage when navigating challenging anatomy6
- 1 Ultimaster Tansei Instructions for Use, version 01-2018
- 2 Bench test ISCD-523-31-18. Performed by, and data on file at, Terumo Corporation
- 3 Saito S et al. Eur Heart J 2014; 35:2021-2031 and Wijns W et al. Eurointervention 2018;14:343-351
- 4 Bench test ISCD-523-31-35, data on file at Terumo Corporation 5 Bench test ISCD-523-31-34, data on file at Terumo Corporation
- 6 Barbato E et al. EuroIntervention 2015;11:541-8
- 7 Saito N et al. Med Devices 2016;9:33-43



- A Proximal shaft
- B Depth marker C Strain relief
- D Hub
- Middel shaft
- F Inner lumen proximal shaft G Distal shaft H PT markers

- I Balloon J Core wire
- K Outer lumen Distal shaft L Hydrophilic Coating
- M Drug-Eluting Stent

General specifications

Balloon Material	Nylon 12	
Coating	Hydrophilic - Distal Shaft	
Drug	Sirolimus	
Drug Dose Per mm stent length	3.9 µg	
Entry Profile	0.018 in / 0.45 mm	
Guidewire Compatibility - Diameter	0.014 in / 0.36 mm	
Minimum Guide Catheter	0.056 in / 1.42 mm / 5 Fr	
Norminal Pressure	9 atm	
Polymer	Poly (DL-lactide-co-caprolactone)	
Polymer Degradation Time And Drug Release	3 to 4 Months	
Shaft - Maximum Size (distal)	0.89 mm / 2.7 Fr	
Shaft - Minimum Size (proximal)	0.64 mm / 1.9 Fr	
Stent Coating	Abluminal & Gradient	
Stent Design	Open Cell	
Stent Material	Cobalt Chromium L605	
Strut Thickness	80 μm	
Usable Length	144 cm	

Item specifications

Diameter	Length	Rated Burst Pressure	Code
2.25 mm	9 mm	16 atm	DE-RQ2209KSM
2.25 mm	12 mm	16 atm	DE-RQ2212KSM
2.25 mm	15 mm	16 atm	DE-RQ2215KSM
2.25 mm	18 mm	16 atm	DE-RQ2218KSM
2.25 mm	21 mm	16 atm	DE-RQ2221KSM
2.25 mm	24 mm	16 atm	DE-RQ2224KSM
2.25 mm	28 mm	16 atm	DE-RQ2228KSM
2.25 mm	33 mm	16 atm	DE-RQ2233KSM
2.25 mm	38 mm	16 atm	DE-RQ2238KSM
2.5 mm	9 mm	16 atm	DE-RQ2509KSM
2.5 mm	12 mm	16 atm	DE-RQ2512KSM
2.5 mm	15 mm	16 atm	DE-RQ2515KSM
2.5 mm	18 mm	16 atm	DE-RQ2518KSM
2.5 mm	21 mm	16 atm	DE-RQ2521KSM
2.5 mm	24 mm	16 atm	DE-RQ2524KSM
2.5 mm	28 mm	16 atm	DE-RQ2528KSM
2.5 mm	33 mm	16 atm	DE-RQ2533KSM
2.5 mm	38 mm	16 atm	DE-RQ2538KSM
2.75 mm	9 mm	16 atm	DE-RQ2709KSM
2.75 mm	12 mm	16 atm	DE-RQ2712KSM
2.75 mm	15 mm	16 atm	DE-RQ2715KSM
2.75 mm	18 mm	16 atm	DE-RQ2718KSM
2.75 mm	21 mm	16 atm	DE-RQ2721KSM
2.75 mm	24 mm	16 atm	DE-RQ2724KSM
2.75 mm	28 mm	16 atm	DE-RQ2728KSM
2.75 mm	33 mm	16 atm	DE-RQ2733KSM
2.75 mm	38 mm	16 atm	DE-RQ2738KSM
3.0 mm	9 mm	16 atm	
	12 mm	16 atm	DE-RQ3009KSM
3.0 mm			DE-RQ3012KSM
3.0 mm	15 mm	16 atm	DE-RQ3015KSM
3.0 mm	18 mm	16 atm	DE-RQ3018KSM
3.0 mm	21 mm	16 atm	DE-RQ3021KSM
3.0 mm	24 mm	16 atm	DE-RQ3024KSM
3.0 mm	28 mm	16 atm	DE-RQ3028KSM
3.0 mm	33 mm	16 atm	DE-RQ3033KSM
3.0 mm	38 mm	16 atm	DE-RQ3038KSM
3.5 mm	9 mm	14 atm	DE-RQ3509KSM
3.5 mm	12 mm	14 atm	DE-RQ3512KSM
3.5 mm	15 mm	14 atm	DE-RQ3515KSM
3.5 mm	18 mm	14 atm	DE-RQ3518KSM
3.5 mm	21 mm	14 atm	DE-RQ3521KSM
3.5 mm	24 mm	14 atm	DE-RQ3524KSM
3.5 mm	28 mm	14 atm	DE-RQ3528KSM
3.5 mm	33 mm	14 atm	DE-RQ3533KSM
3.5 mm	38 mm	14 atm	DE-RQ3538KSM
4.0 mm	9 mm	14 atm	DE-RQ4009KSM
4.0 mm	12 mm	14 atm	DE-RQ4012KSM
4.0 mm	15 mm	14 atm	DE-RQ4015KSM
4.0 mm	18 mm	14 atm	DE-RQ4018KSM
4.0 mm	21 mm	14 atm	DE-RQ4021KSM
4.0 mm	24 mm	14 atm	DE-RQ4024KSM
4.0 mm	28 mm	14 atm	DE-RQ4028KSM
4.0 mm	33 mm	14 atm	DE-RQ4033KSM
4.0 mm	38 mm	14 atm	DE-RQ4038KSM