Poz. 30. 33184500-8 Kobalto- chromo koronarinis stentas su įvedimo sistema dengtas erdvine/gradientine vaistus išskiriančia danga

DESIGNED BY THE **TRANSRADIAL PIONEER**

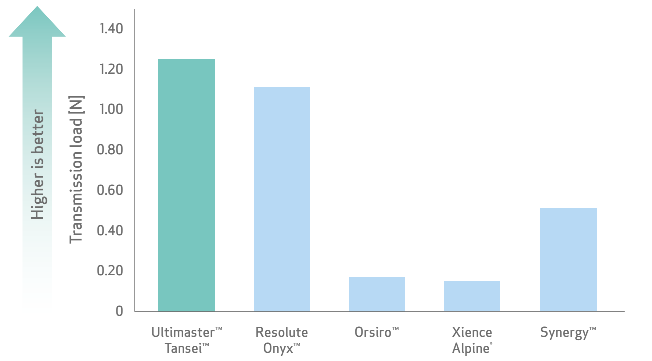
Keep ahead of the curve in complex anatomy

√Enhanced deliverability

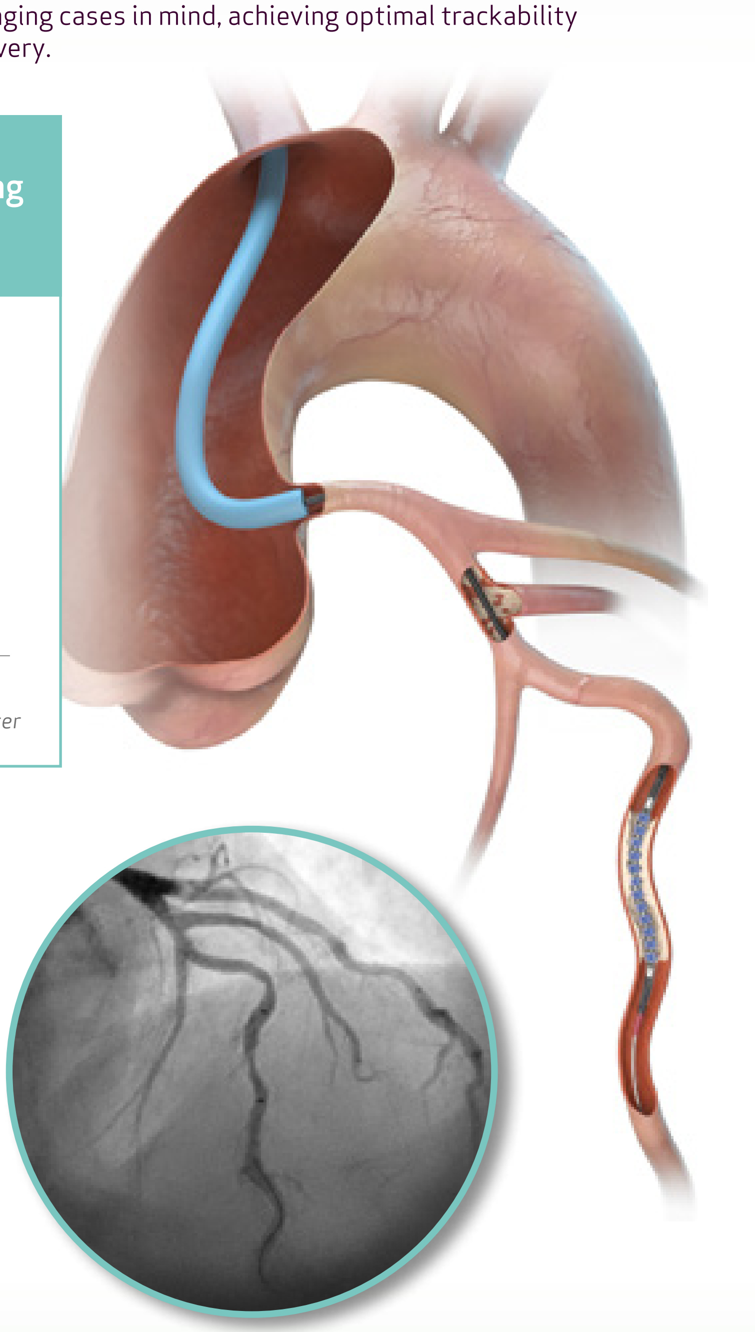
In practice, where **~80% of cases can be expected to be complex**[3], it is more important than ever to have tools you can trust for percutaneous coronary intervention.

Ultimaster™ Tansei™ has been developed with challenging cases in mind, achieving optimal trackability and pushability[5], which are essential for reliable delivery.

Ultimaster™ Tansei™ ensures good transmission force, even when the guiding catheter does not provide sufficient support[5].



Transmission load at the distal end, when the guiding catheter back-up is disengaged by pushing



Let **Terumo** focus on the tools for:

- Transradial PCI
- Calcification
- Bifurcation
- Tortuosity

So you can focus on the most important thing of all: **your patient**

5. Bench test ISCD-523-31-18 performed by, and on file at, Terumo Corporation. Testing performed on Ultimaster™ Tansei™ Stent System (3.0 x 38 mm) n=3, Resolute Onyx™ Stent System (3.0 x 38 mm) n=3, Orsiro™ Stent System (3.0 x 35 mm) n=3, Xience Alpine™ Stent System (3.0 x 38 mm) n=3, Synergy™ Stent System (3.0 x 38 mm) n=3.

Ultimaster™ Tansei™

Sirolimus Eluting Coronary Stent System

PRODUCT SPECIFICATIONS

Stent specifications	
√ Stent design	Open cell
√ Stent material	Cobalt Chromium L605
√ Strut thickness	80 μm
Cell size (for 3 mm stent)	4.57 mm²
√ Drug	Sirolimus
√ Drug dose	3.9 μg/mm stent length
√ Polymer	Poly (DL-lactide-co-caprolactone)
√ Drug coating	Abluminal & gradient
√ Polymer degradation time and drug release	3-4 months

Delivery system specifications	
√ Guidewire compatibility	0.014" (0.36 mm)
Low compliant balloon	Material Nylon 12
√ Nominal pressure	9 atm
√ Rated burst pressure	16 atm - 2.25 to 3.0 mm 14 atm - 3.5 to 4.0 mm
√ Entry profile	0.018" (0.45 mm)
Crossing profile	0.044" (1.12 mm) for 3.0 mm
√ Shaft	Distal - 2.7 Fr (0.89 mm) Proximal - 1.9 Fr (0.64 mm)
√ Coating	Hydrophilic - Distal shaft
Minimum Guide catheter	5 Fr (0.056"/1.42 mm)
√ Usable length	144 cm

Item specifications

√ LENGTH (mm) / DIAMETER (mm) √	2.25	2.50	2.75	3.00	3.50	4.00
9	DE-RQ2209KSM	DE-RQ2509KSM	DE-RQ2709KSM	DE-RQ3009KSM	DE-RQ3509KSM	DE-RQ4009KSM
12	DE-RQ2212KSM	DE-RQ2512KSM	DE-RQ2712KSM	DE-RQ3012KSM	DE-RQ3512KSM	DE-RQ4012KSM
15	DE-RQ2215KSM	DE-RQ2515KSM	DE-RQ2715KSM	DE-RQ3015KSM	DE-RQ3515KSM	DE-RQ4015KSM
18	DE-RQ2218KSM	DE-RQ2518KSM	DE-RQ2718KSM	DE-RQ3018KSM	DE-RQ3518KSM	DE-RQ4018KSM
21	DE-RQ2221KSM	DE-RQ2521KSM	DE-RQ2721KSM	DE-RQ3021KSM	DE-RQ3521KSM	DE-RQ4021KSM
24	DE-RQ2224KSM	DE-RQ2524KSM	DE-RQ2724KSM	DE-RQ3024KSM	DE-RQ3524KSM	DE-RQ4024KSM
28	DE-RQ2228KSM	DE-RQ2528KSM	DE-RQ2728KSM	DE-RQ3028KSM	DE-RQ3528KSM	DE-RQ4028KSM
33	DE-RQ2233KSM	DE-RQ2533KSM	DE-RQ2733KSM	DE-RQ3033KSM	DE-RQ3533KSM	DE-RQ4033KSM
38	DE-RQ2238KSM	DE-RQ2538KSM	DE-RQ2738KSM	DE-RQ3038KSM	DE-RQ3538KSM	DE-RQ4038KSM
Post-dilation limit[12]	4.5 mm	4.5 mm	4.5 mm	4.5 mm	5.5 mm	5.5 mm

Recommended DES in ESC/EACTS 2014 guidelines[10]

1 MONTH DAPT*

CE-mark approved for patients in need to stop DAPT earlier[11]

*Patients should be maintained on clinically adequate post-procedural antiplatelet therapy according to the current guidelines. In case of need, dual antiplatelet therapy can be discontinued earlier, but not before one month.

10. Windecker S et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. 2014 Oct 1;35(37):2541-619.
11. Ultimaster IFU.
12. CE approval was received on August 2nd, 2019. The IFU will be updated to reflect the specified post dilatation limits.

Ultimaster™ Tansei™ is not available for sale in all countries. Please contact your Terumo local sales representative for more information.

TERUMO INTERVENTIONAL SYSTEMS

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Ultimaster™ Tansei™

Sirolimus Eluting Coronary Stent System

MASTERING COMPLEXITY. **SIMPLE.**

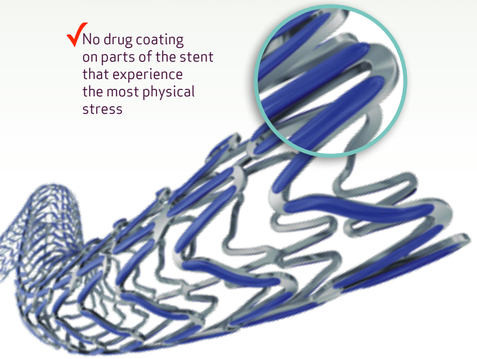
TERUMO INTERVENTIONAL SYSTEMS

Ultimaster™ Tansei™

Sirolimus Eluting Coronary Stent System

Building on the heritage of the Ultimaster™ stent

Ultimaster™ Tansei™ has all the key features of Ultimaster™ for supporting vascular repair [1]



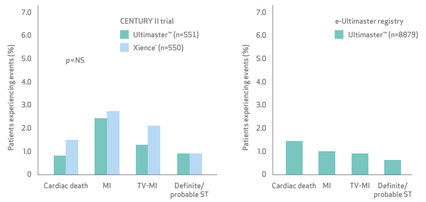
✓ No drug coating on parts of the stent that experience the most physical stress

Innovative **abluminal bioresorbable coating**

- ✓ Drug coating applied in a **gradient** to reduce the risk of polymer cracking and delamination, even when the stent is overexpanded
- ✓ **PCL added to PDLLA,** increasing the elasticity of the bioresorbable polymer coating

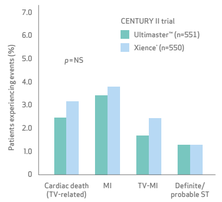
Simultaneous polymer resorption and drug release within 3–4 months, to match the procedure-triggered biological response

Consistent good safety* data at 1 year from controlled clinical trials[2] and routine clinical practice[3]



CENTURY II trial and e-Ultimaster registry - 1year data

Sustained long-term safety from controlled clinical trials[4]



CENTURY II trial - 5year data

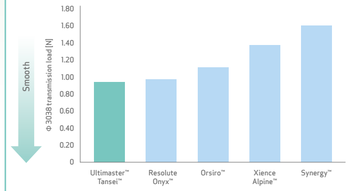
TRACK COMPLEX LESIONS WITH EASE

A tip designed to facilitate treatment of the most challenging cases

Updated design to maximize deliverability, even in the most challenging cases

- ✓ Flexible tip material: supports navigation through tortuous vessels
- ✓ Low passing resistance at the tip: minimizes the force required to cross challenging lesions

Lowered[6] passing resistance



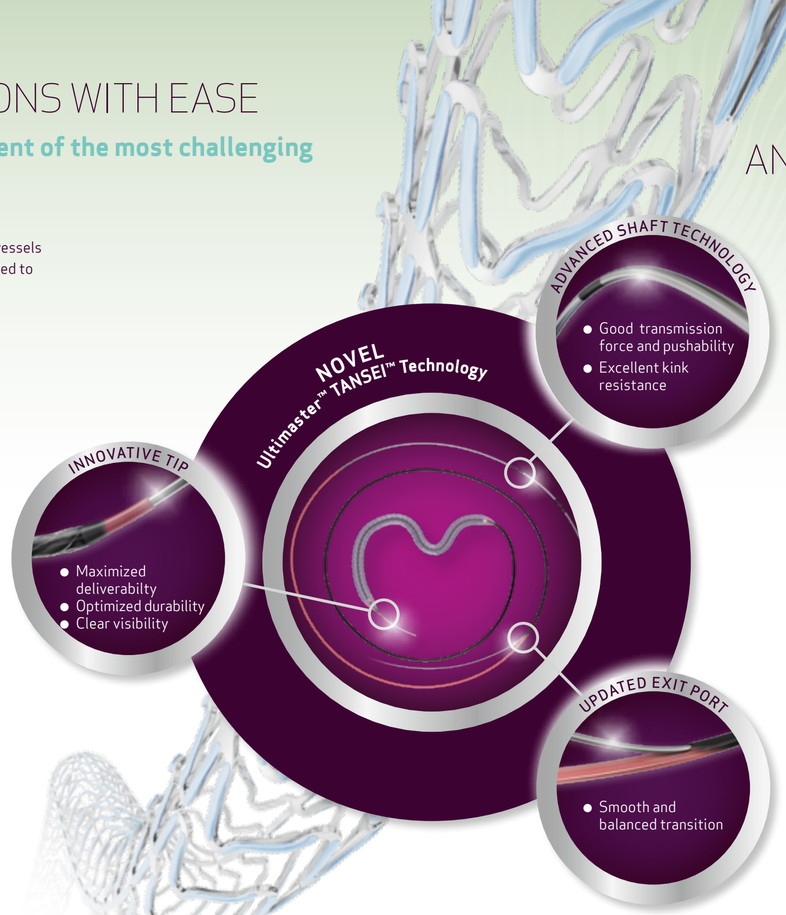
Passing through the 2nd curve of a tortuous vessel model

A tip specifically developed with the composition and shape to support durability

- ✓ Rounded shape: offers durability and crossability, even through areas of calcification
- ✓ Durable material: reduces the risk of tip damage when navigating challenging anatomy

Extended durability[7]

After crossing the calcified lesion model 3 times



Re-colored tip for optimal visibility

- Brightly colored, easily visible red tip: aids guidewire loading

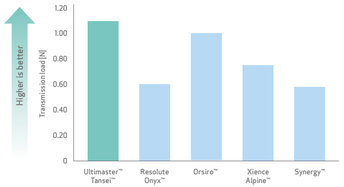
CROSS CHALLENGING ANATOMY WITH CONFIDENCE

Advanced shaft technology for outstanding acute performance

Maximizing transmission force, and kink resistance[8]

- Shaft reinforced with a stainless steel core wire: ensures optimal pushability and transmission force
- Stronger hypotube: maximising kink resistance for effective and reliable deliverability

Enhanced pushability[9]



Transmission load at the distal end, when applying 2 N force at the proximal end

Ensuring a smooth and balanced transition

- A stainless steel tapered core wire at the exit port for optimal pushability across the entire delivery system

PDLLA-PCL : Poly (DL-lactide-co-caprolactone); CENTURY II: n is the number of patients at baseline in the per protocol analysis; e-Ultimaster: n is the number of patients with 1-year follow-up completed (interim analysis); MI, myocardial infarction; NS, not significant; TV, target vessel; ST, stent thrombosis.

1. Discovery 1to3: Chevalier B et al. Circ Cardiovasc Interv 2017;10.
* Based on cardiac death, MI and ST rates in the stated studies.
2. Internal report ISCD-523-37-20 - Report-CEII-1year results
3. Internal report ISCD-523-37-19 - Report-eUM-Interim analysis
4. Saito et al. - Presented at EuroPCR2018

6. Bench test ISCD-523-31-18 performed by, and on file at, Terumo Corporation. Testing performed on Ultimaster™ Tansei™ Stent System (3.0 x 38 mm) n=3, Resolute Onyx™ Stent System (3.0 x 38 mm) n=3, Orsiro™ Stent System (3.0 x 35 mm) n=3, Xience Alpine™ Stent System (3.0 x 38 mm) n=3, Synergy™ Stent System (3.0 x 38 mm) n=3.
7. Bench test ISCD-523-31-18 performed by, and on file at, Terumo Corporation. Testing performed on Ultimaster™ Tansei™ Stent System (3.0 x 38 mm) n=1, Resolute Onyx™ Stent System (3.0 x 38 mm) n=1, Orsiro™ Stent System (3.0 x 35 mm) n=1, Xience Alpine™ Stent System (3.0 x 38 mm) n=1, Synergy™ Stent System (3.0 x 38 mm) n=1.
8. Compared with Ultimaster. Bench test ISCD-523-31-18 performed by, and on file at, Terumo Corporation.
9. Bench test ISCD-523-31-18 performed by, and on file at, Terumo Corporation. Testing performed on Ultimaster™ Tansei™ Stent System (3.0 x 38 mm) n=3, Resolute Onyx™ Stent System (3.0 x 38 mm) n=3, Orsiro™ Stent System (3.0 x 35 mm) n=3, Xience Alpine™ Stent System (3.0 x 38 mm) n=3, Synergy™ Stent System (3.0 x 38 mm) n=3.