

TECHNICAL SPECIFICATIONS

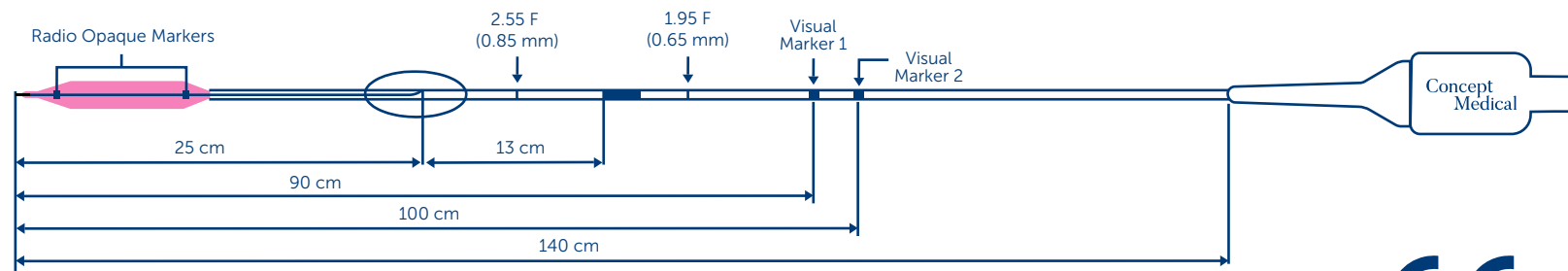
Drug / Excipient	
Drug	Sirolimus
Drug Dose	1.27 µg/mm ²
Drug Carrier	Phospholipid
Balloon	
Balloon Material	Polyamide
Catheter Design	RX/Monorail

Delivery System	
Shaft Diameter - Proximal	1.95 F
Shaft Diameter - Distal	2.67 F
Usable Catheter Length	140 cm
Tip Profile	0.016"
Nominal Pressure	8 Bar
Rated Burst Pressure	14 Bar*
Guiding Catheter Compatibility	6F
Guide Wire Compatibility	0.014" Maximum recommended
Size Available	
Balloon Length (mm)	10, 15, 20, 25, 30, 35, 40
Balloon Diameter (mm)	1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 4.00

* Do not exceed RBP
For Ordering information visit website: www.conceptmedical.com

ORDERING INFORMATION

Dia/length (mm)	Stent Length (mm)						
	10	15	20	25	30	35	40
1.50	CME15010	CME15015	CME15020	CME15025	CME15030	CME15035	CME15040
2.00	CME20010	CME20015	CME20020	CME20025	CME20030	CME20035	CME20040
2.25	CME22510	CME22515	CME22520	CME22525	CME22530	CME22535	CME22540
2.50	CME25010	CME25015	CME25020	CME25025	CME25030	CME25035	CME25040
2.75	CME27510	CME27515	CME27520	CME27525	CME27530	CME27535	CME27540
3.00	CME30010	CME30015	CME30020	CME30025	CME30030	CME30035	CME30040
3.25	CME32510	CME32515	CME32520	CME32525	CME32530	CME32535	CME32540
3.50	CME35010	CME35015	CME35020	CME35025	CME35030	CME35035	CME35040
4.00	CME40010	CME40015	CME40020	CME40025	CME40030	CME40035	CME40040



The above diagram is just an illustration of the product.

Disclaimer: The law restricts these devices to sale by or on the order of a physician. Indications, contradictions, warnings can be found in the product labelling / IFU supplied with each device. For restricted use only in countries where product is registered with applicable health authorities.



Concept Medical

MagicTouch^{ED}

SIROLIMUS COATED BALLOON CATHETER

Concept Medical

Concept Medical B.V.

Hogebrinkerweg 33,
3871 KM Hoevelaken,
The Netherlands.
T: +31 (0) 850 186 886
E: contact@conceptbv.com
W: www.conceptbv.com

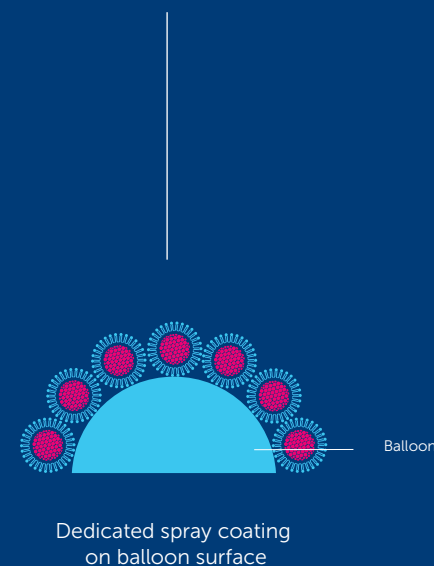
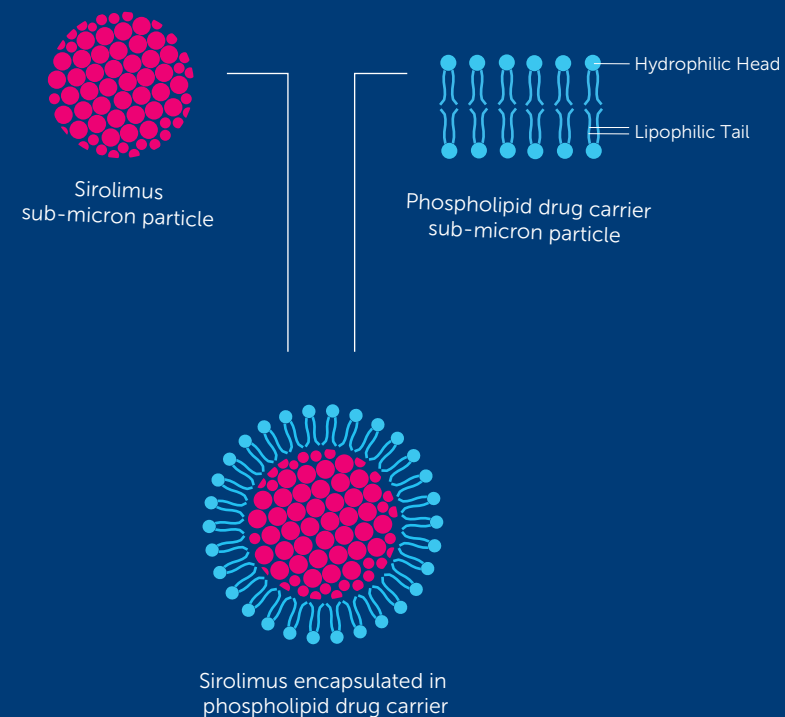
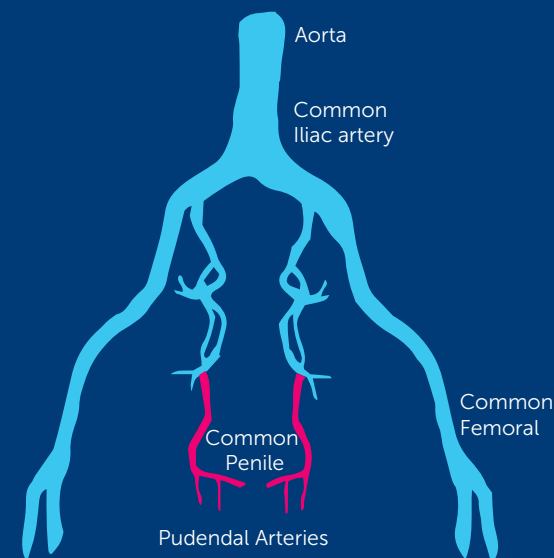
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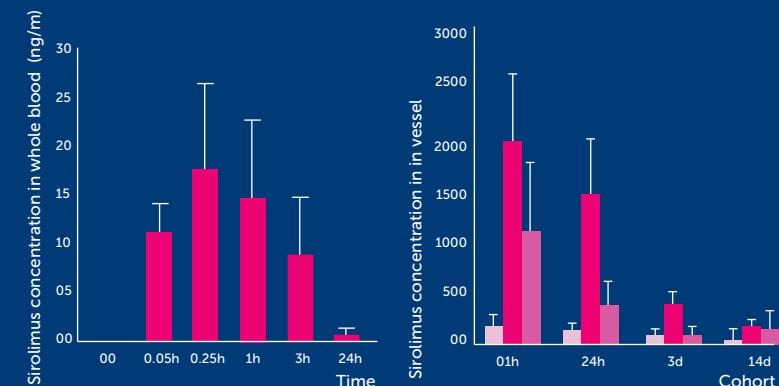
VASCULOGENIC ERECTILE DYSFUNCTION

QUICK FACTS

- Erectile Dysfunction (ED) is defined as the recurrent inability to achieve and maintain an erection satisfactory for sexual intercourse.
- ED is an important and growing health problem. It is estimated that more than 200 million men (between 40 - 70 year) suffer from ED.
- Male sexual arousal is a complex process that involves the brain, hormones, emotions, nerves, muscles and blood vessels. Erectile Dysfunction can result from a problem with any of these. In many cases, Erectile Dysfunction is caused by something physical.
- In many cases, Erectile Dysfunction is caused by blockage in arteries supplying blood to penis (external genitalia), which is commonly called as "vasculogenic ED".
- Common causes include Heart disease, Clogged blood vessels (atherosclerosis - in more than 40% of cases), High cholesterol, High blood pressure, Diabetes (in more than 30% of cases), Obesity, Tobacco use.
- Arterial Inflow atherosclerotic disease (usually pudendal and Dorsal penis arteries stenosis) is a common etiology. Patients who do not respond anymore to PDEI- 5 inhibitors therapy (1° line therapy), may be treated by percutaneous transluminal angioplasty.
- Magic Touch - ED is a Sirolimus Coated Balloon for treatment of ED for male patients with de novo and restenotic lesions in the internal pudendal, dorsal or urethral arteries.



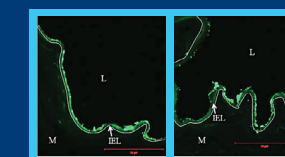
PHARMACOKINETIC STUDY



SIROLIMUS DISTRIBUTION STUDY

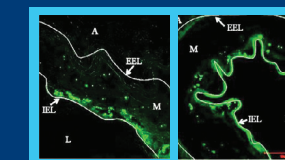
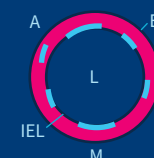
DTF labelled Sirolimus was used to assess the drug distribution following DCB treatment*

1 HR Intima



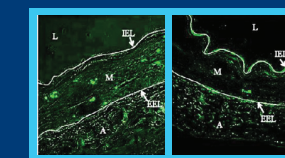
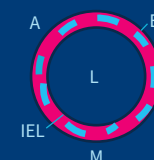
60-70% above IEL

DAY 3 Media



30-40% within Media

DAY 7 Adventitia



30-40% below IEL

A: Adventitia; EEL: External Elastic Lamina; IEL: Internal Elastic Lamina; L: Lumen; M: Media
*EuroIntervention. 2013 May 20;9(1): 148-56

CONFIDENCE WITH EVIDENCE

Treatment Success Reflected by Minimum Clinically Relevant Improvement in the International Index of Erectile Function-5 (IIEF-5) score with Magic Touch - ED SCB.



*Data presented at TCT-2019 by Dr. G Sangiorgi