IMPLANTATION OF MAGICTOUCH TECHNOLOGY

1. LESION

2. PRE-DILATATION

PRE-DILATATION RECOMMENDED IN ALL CASES

For pre-dilatation in all cases use a standard balloon (approx 0.5mm smaller than RVD).
Choose a MagicTouch SCB with normal size equal to reference diameter.

3. MAGICTOUCH SCB

Duration time 30-60 sec

DRUG RELEASE WITHIN 60 SECONDS

Longer inflation times are possible at discretion of the operator to pursue optimal mechanical dilatation - but this has no effect on additional drug release.

SINGLE MAGICTOUCH SCB

Each lesion should be addressed with separate balloon

OVERLAPPING OF MAGICTOUCH SCB

In longer lesions MagicTouch SCB overlapping is indicated

LESION 1, MAGICTOUCH SCB 1

LESION 2, MAGICTOUCH SCB 2

IN CASE OF ISR

If stent is present, size of balloon should be greater than the stent by 2 mm on each ends.

TECHNICAL SPECIFICATIONS

DRUG / EXCIPIENT

DRUG	Sirolimus
DRUG DOSE	1.27 µg/mm^2
DRUG CARRIER	Phospholipid Based Excipient

BALLOON

BALLOON MATERIAL	Polyamide
CATHETER DESIGN	Rapid Exchange (RX) Design

DELIVERY SYSTEM

Shaft Diameter - Proximal	1.7 F
Shaft Diameter - Distal	2.5 F
Usable Catheter Length	140 cm
Tip Profile	0.016"
Nominal Pressure	6 bar

Rated Burst Pressure	16 bar (14 bar for 4.00 / 25 to 40 mm)
Guiding Catheter Compatibility	5F
Guidewire Compatibility	0.014" maximum recommended

ORDERING INFORMATION

Diameter/Length	10 mm	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm
1.50 mm	CMT15010	CMT15015	CMT15020	CMT15025	CMT15030	CMT15035	CMT15040
2.00 mm	CMT20010	CMT20015	CMT20020	CMT20025	CMT20030	CMT20035	CMT20040
2.25 mm	CMT22510	CMT22515	CMT22520	CMT22525	CMT22530	CMT22535	CMT22540
2.50 mm	CMT25010	CMT25015	CMT25020	CMT25025	CMT25030	CMT25035	CMT25040
2.75 mm	CMT27510	CMT27515	CMT27520	CMT27525	CMT27530	CMT27535	CMT27540
3.00 mm	CMT30010	CMT30015	CMT30020	CMT30025	CMT30030	CMT30035	CMT30040
3.50 mm	CMT35010	CMT35015	CMT35020	CMT35025	CMT35030	CMT35035	CMT35040
4.00 mm	CMT40010	CMT40015	CMT40020	CMT40025	CMT40030	CMT40035	CMT40040

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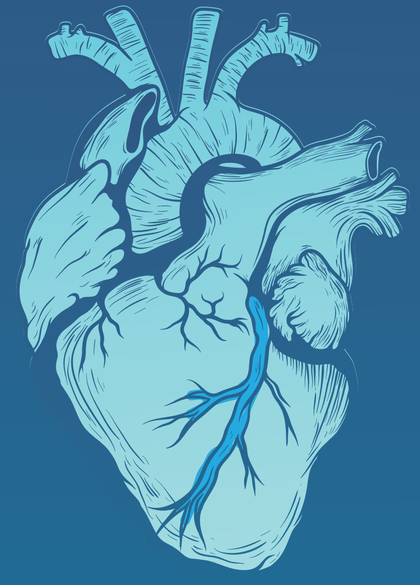
MagicTouch

Sirolimus Coated Balloon

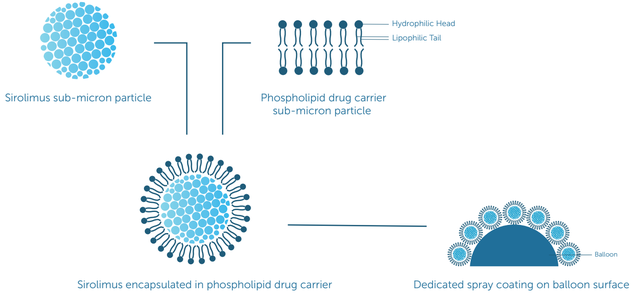


MagicTouch

MagicTouch is a Sirolimus Drug Coated Balloon Catheter for the treatment of coronary artery disease; intended for In-Stent Restenosis, Small Vessels, Bifurcation lesions and De-Novo lesions.

NANOLUTE TECHNOLOGY

- Conversion of Sirolimus drug into submicron sized particles.
- Encapsulation of submicron sized Sirolimus drug into highly biocompatible drug carrier – Phospholipid.
- Phospholipid comprises of one hydrophilic head and two lipophilic tails, which improves adhesion property of encapsulated Sirolimus.
- Upon inflation of MagicTouch SCB at target site, drug carrier with Sirolimus drug inside gets transferred to the vessel wall following the principle of co-efficient diffusion.
- Upon body PH variation, drug carrier mimics the body lipids and liberates Sirolimus.
- The submicron sized Sirolimus drug particles penetrate the deepest layer of the vessel over a period.

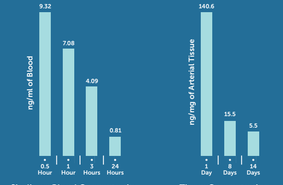


ADVANTAGES OF NANOLUTE TECHNOLOGY

- Facilitates better adhesion of Sirolimus on the balloon surface
- Effective drug transfer to the deepest layer of the vessel
- Circumferential coating
- Better in-tissue bioavailability of Sirolimus

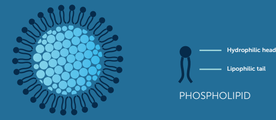
DRUG

Drug	Sirolimus
Dose	1.27µg/mm²
Nature	Less Lipophilic
Action	Cytostatic
Therapeutic Range	Wide



PHARMACOKINETIC STUDY

CARRIER



Carrier	Phospholipid
Nature	Biocompatible
Action	Excipient + Stabilizer

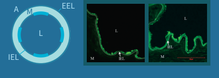
BALLOON

Balloon	Semi-compliant
Pre-Dilatation	Recommended
Crossing Profile (Vary with size)	0.029"
Entry Profile	0.016"

SIROLIMUS DISTRIBUTION STUDY

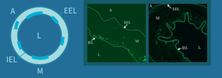
DTF labelled Sirolimus was used to study the drug distribution following DCB treatment*

1 HR



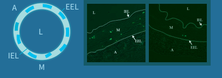
Presence of drug in tissue layer
Intima

DAY 3



Presence of drug in tissue layer
Media

DAY 7

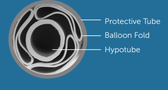


Presence of drug in tissue layer
Adventitia

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

UNIQUE COATING TECHNOLOGY

COATING
Low pressure inflation and coating



REFOLDING

INFLATION
Circumferential (100%) surface coating