



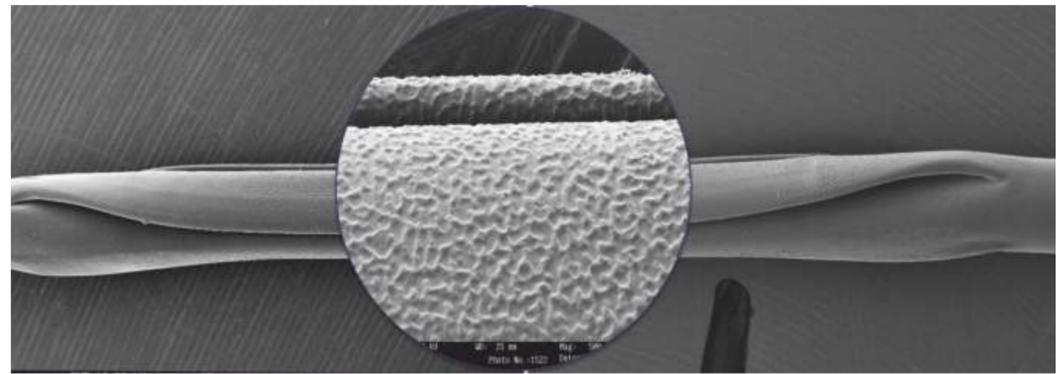
**NANOLUTE™**  
Nanocarrier\*  
based drug delivery technology



NANOLUTE is a nano carrier based drug elution technology for medical devices. It is a creative application of nano technology principles for drug delivery. Our application of nano technology principles in Cardiovascular devices opens up a whole lot of new opportunities. It has capability to deliver variety of drugs irrespective of their nature / attributes.

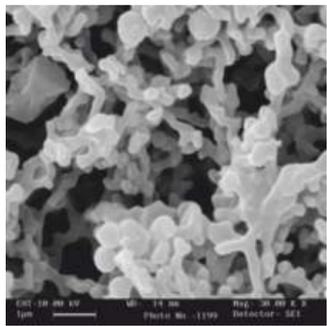
NANOLUTE technology is an encapsulation technology using bio-compatible excipients where in material and structure created decides properties of carrier. The sustained drug release can be designed during nano carrier creation. Our technology of nano carrier encapsulation provides for lowering in-transit loss, better drug retention, acute drug transfer, targeted drug delivery, reduction of drug rejection ratio, controlling drug degradation and alteration of its pharmaco-kinetics.

With a larger surface area to volume ratio of drug particle created on reduction of size, the technology allows for a higher dissolution with better distribution in tissue. The nano carriers are target specific and exhibit a faster / more efficient uptake of drug in tissue.

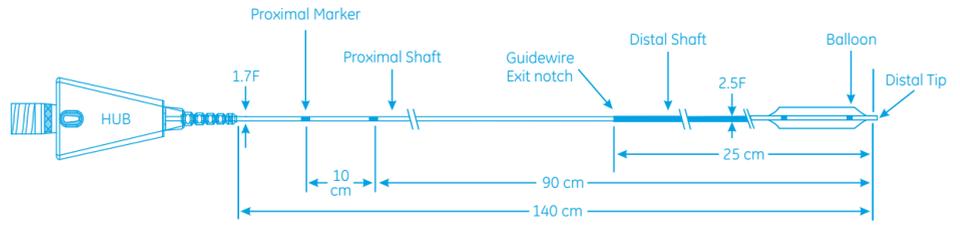


**ADVANTAGES**

- Uniform coating surface
- Reduce in-transit loss of drug
- Increased bio-availability of drug
- Better bio-compatibility of drug
- Encapsulation enhances drug retention
- Faster uptake of drug in tissue on delivery
- Drug released on dissolution of nano carrier
- Programmable Drug release from surface of device



Magic Touch Sirolimus drug coated balloon is a device for treatment of lesions in coronary arteries. The product is available as a rapid exchange balloon catheter for delivery.



**Technical Specifications**

Drug	Sirolimus Drug
Drug Dose	180 micrograms on 3.00 x 15 mm
Drug Carrier	Phospholipid based Excipient
Balloon Material	Polyamide blend
Catheter Design	Rapid Exchange Design
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 (0.056" ID) for all sizes
Guidewire Compatibility	0.014" maximum recommended

**Ordering Information**

Dia / Length	10.00mm	15.00mm	20.00mm	25.00mm	30.00mm	35.00mm	40.00mm
1.50 mm	CMT15010	CMT15015	CMT15020	CMT15025	CMT15030	CMT15035	CMT15040
2.00 mm	CMT20010	CMT20015	CMT20020	CMT20025	CMT20030	CMT20035	CMT20040
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

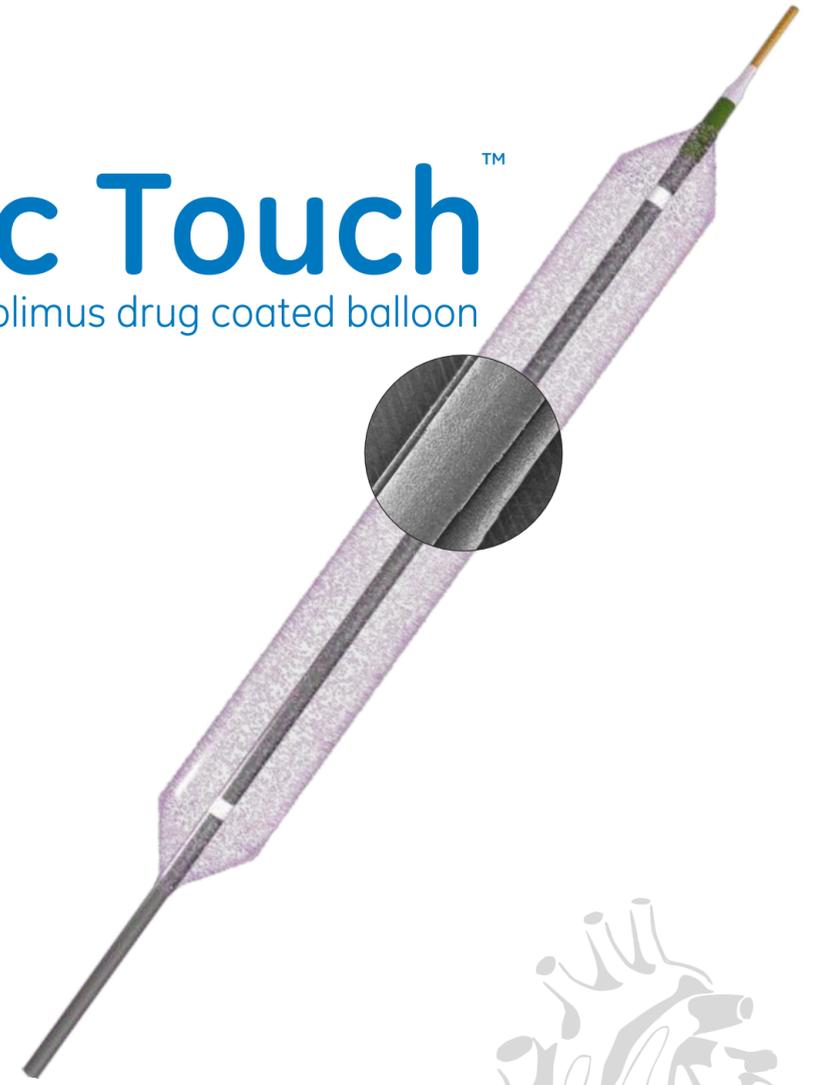
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**Concept Medical Research Pvt. Ltd.**  
Office 1-3, Silver Palm II, Near Sneh Milan Garden, Kadampalli, Nanpura, Surat 395 001. GUJ-INDIA  
T. +91 261 2460003 • F. +91 261 2460006 • www.conceptmedicals.com



**Magic Touch™**  
Sirolimus drug coated balloon



converting concepts into reality...

## Drug Coated Balloon - Why it is needed & challenge in its effective design?

### Unmet Requirements

With the arrival of Drug eluting stents, the scenario of PCI has changed dramatically with more and more adoption. Drug Eluting Stent is a drug coated metal implant which addresses needs of inhibiting neo intimal growth. It has been quite successful in its intended application but has certain areas of improvement in specific treatment indications.

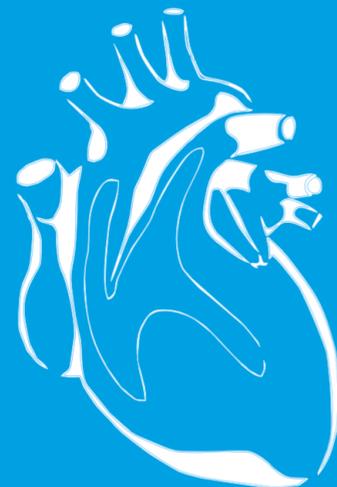
Areas like In-stent restenosis, Bifurcation Lesions, Small vessels require a device with different set of attributes. A Good Drug coated balloon in this kind of indications would show optimal application and better results. This may / may not be possible with DES in this kind of scenario, creating need for a device which specific set of attributes. Hence, DCB surely is a need for specific and intended treatment areas.

### Performance challenges for DCB

Design of a Drug coated balloon has its own specific requirements. It should retain drug from insertion to the lesion site, deliver sufficient quantity of drug in a limited span of time and have retention of drug for addressing therapeutic window.

These requirements are common to the design concept, but with each drug there are specific requirements in terms of its inherent nature. Paclitaxel as a drug is more lipophilic in comparison to Sirolimus. Retention of drug on balloon surface and effective transfer to the tissue is a key success factor for the device.

Most of the Drug coated balloon on market are with Paclitaxel drug which is delivered with either a hydrophilic spacer or a carrier. Limus drugs have become preferred drug in treatment of coronary artery disease because of its safe profile. The challenge is to create a Special device which will deliver Limus drug in short duration, consistently in target lesions with high level of effectiveness.



## Design is innovation made visible.

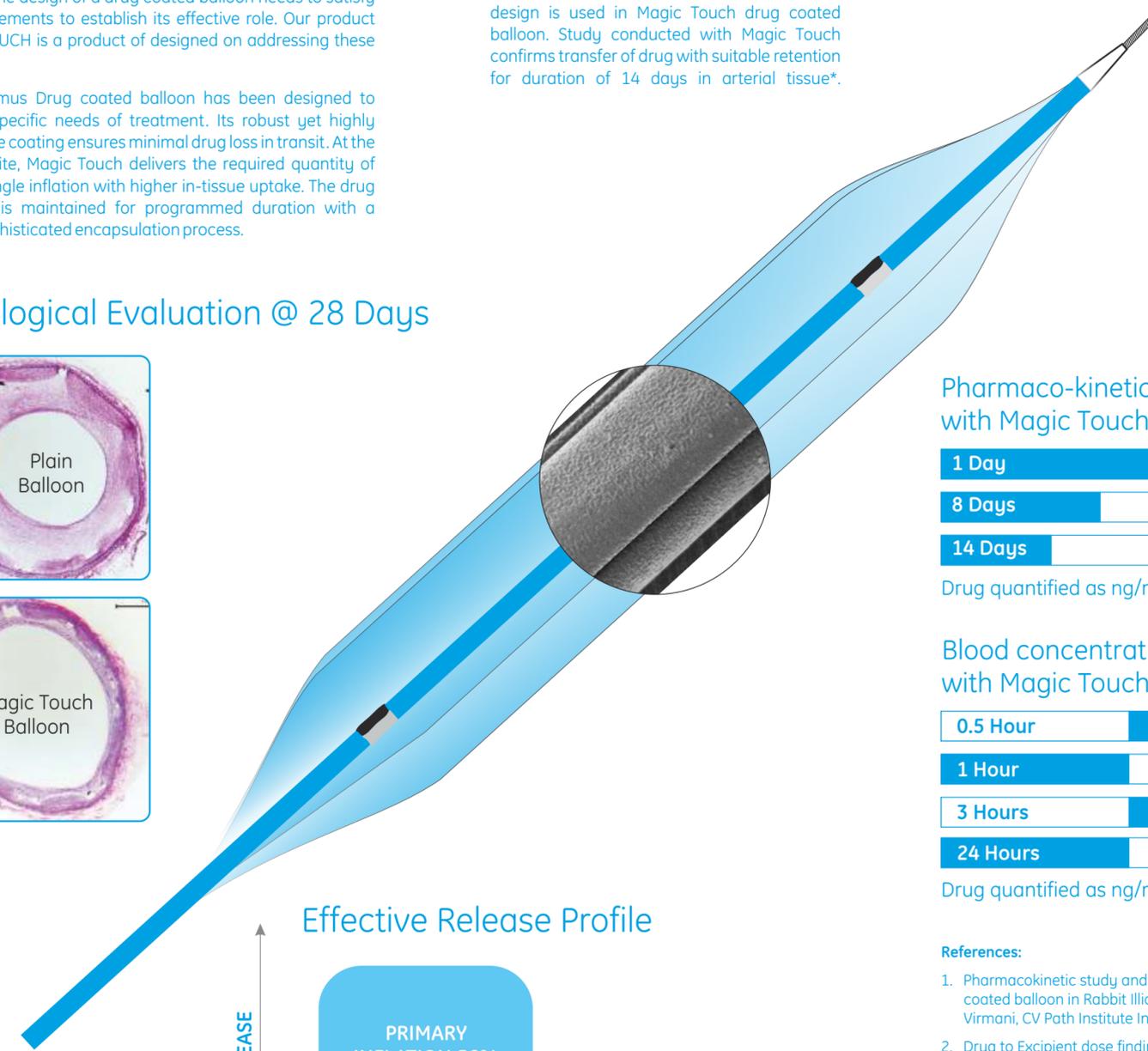
Drug coated balloon as a concept has found acceptance as treatment option for specific applications in cardiovascular disease. The design of a drug coated balloon needs to satisfy the requirements to establish its effective role. Our product MAGIC TOUCH is a product of designed on addressing these needs.

Our Sirolimus Drug coated balloon has been designed to address specific needs of treatment. Its robust yet highly deliverable coating ensures minimal drug loss in transit. At the inflation site, Magic Touch delivers the required quantity of drug in single inflation with higher in-tissue uptake. The drug retention is maintained for programmed duration with a highly sophisticated encapsulation process.

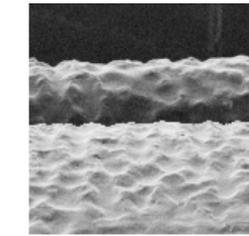
## Sirolimus Drug Coating

Magic Touch utilizes safe and effective **Sirolimus drug** on balloon for treatment. Product Design involved developing a highly effective coating which could transfer the drug in shortest time frame. NANOLUTE Coating design is used in Magic Touch drug coated balloon. Study conducted with Magic Touch confirms transfer of drug with suitable retention for duration of 14 days in arterial tissue\*.

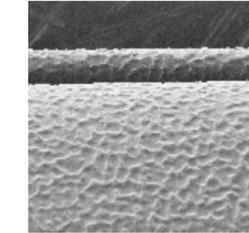
## Histological Evaluation @ 28 Days



High Resolution SEM (1K)



High Resolution SEM (500X)



## Pharmaco-kinetic Study with Magic Touch DCB \*<sup>1</sup>

1 Day	140.6 ng/mg
8 Days	15.5 ng/mg
14 Days	5.5 ng/mg

Drug quantified as ng/mg of arterial tissue

## Blood concentrations with Magic Touch DCB \*<sup>1</sup>

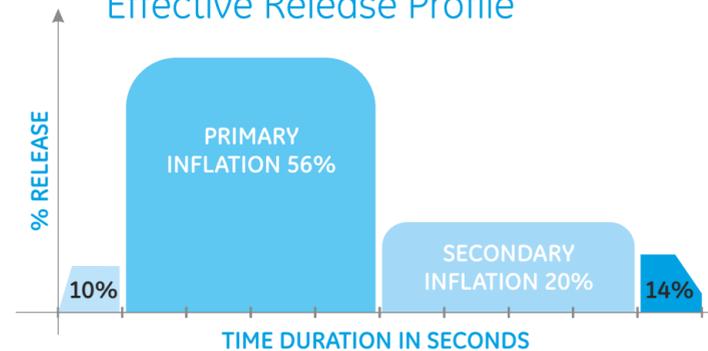
0.5 Hour	9.32 ng/ml
1 Hour	7.08 ng/ml
3 Hours	4.09 ng/ml
24 Hours	0.81 ng/ml

Drug quantified as ng/ml of blood

### References:

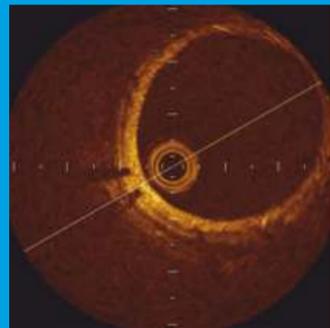
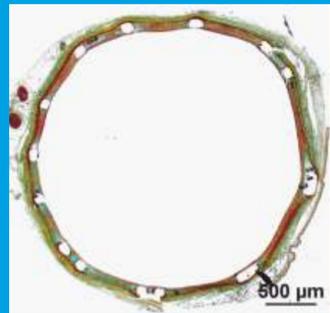
1. Pharmacokinetic study and histologic evaluation of Magic Touch Sirolimus coated balloon in Rabbit iliofemoral artery at 1, 8, 14 and 28 days - Dr Renu Virmani, CV Path Institute Inc. Washington DC USA, MRI 2009 - 012
2. Drug to Excipient dose finding study with Magic Touch Sirolimus coated balloon with OCT (Optical Coherence Tomography) and Histologic evaluation in juvenile domestic swine coronary artery at 28 days - Dr Pedro Lemos, Livetech Solutions, Sao Paulo, Brazil
3. A temporal assessment of drug distribution following local balloon delivery of DTF labeled sirolimus in Rabbit by laser confocal microscopy - Sami Yazdani, Masataka Nakano, Frank D Kolodgie, Renu Virmani CV Path Institute, JACC, TCT2011 Abstracts TCT - 19

## Effective Release Profile



Built for clinical relevance with, exceptional performance

MAGIC TOUCH Sirolimus Drug coated balloon is designed to help you achieve exceptional clinical performance with safety and reliability for your patients.



Histology, OCT and Fluorescent label Images of Magic Touch Study in Rabbit and Porcine coronary artery