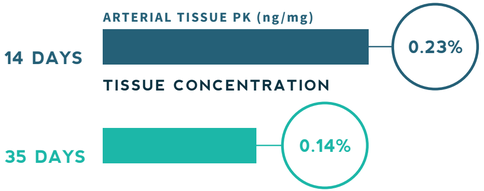
MAXIMISE DRUG TISSUE TRANSFER 03

PK STUDY

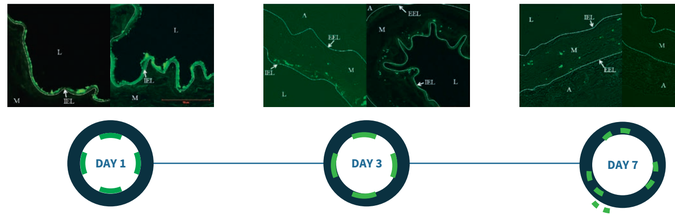


Study showed Sirolimus drug concentrations of good quantity with transient balloon inflations at target site. Concentrations achieved are shown at 14 days and 35 days respectively in an arterial tissue.

MAINTAIN EFFICACY OVER TIME 04

DTF LABELLED STUDY

Medial calcification is a common finding among diabetics with BTK lesions. Hence, proper drug uptake of Sirolimus is required into the layers. The drug distribution and drug retention are important features required to address the peripheral artery disease from a balloon.

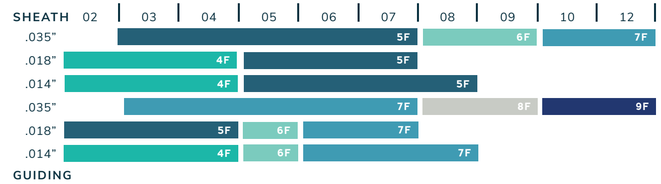


PI: Dr. Renu Virmani, CV Path Institute, USA

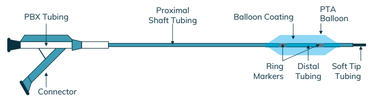
Study with DTF labelled Sirolimus drug was done to study the drug distribution following DCB treatment. The study showed good drug presence at 1, 3 and 7 days. The drug retention and travel was demonstrated with medium to low concentrations observed up to adventitial layer at 7 days indicating in tissue travel of drug.

TECHNICAL SPECIFICATIONS

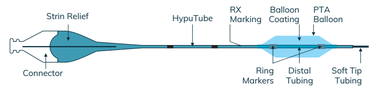
BALLOON MATERIAL	Polyether Block Amide
DRUG	Sirolimus
DRUG DOSE	3 µg/mm²
BALLOON FOLDING	3 and 6 folds*
COATING	Nanolute®
BALLOON COMPLIANCE	Semi Compliant
SHELF LIFE	2 years
BALLOON DIAMETER (MM)	1.50, 2.00, 2.50, 3.00, 3.50, 4.00, 4.50, 5.00, 5.50, 6.00, 7.00, 8.00, 9.00, 10.00 and 12.00*
BALLOON LENGTH (CM)	10, 15, 20, 25, 30, 35, 40, 60, 80, 100, 120, 150 and 200*
GUIDE WIRE COMPATIBILITY	0.014", 0.018", 0.035"
CATHETER SHAFT LENGTH (CM)	**0.035" OTW**: 80, 130, 150; **0.018" OTW**: 120, 150; **0.014" OTW**: 120, 150; **0.014" Rx**: 150
DELIVERY SYSTEMS	0.014" Rx; 0.014" OTW; 0.018" OTW; 0.035" OTW



OTW DELIVERY SYSTEM



Rx DELIVERY SYSTEM



*Specific data inside the leaflet
**RBP (Rated Burst Pressure): The pressure at which Xtreme Touch Neo™ Neo has 95% confidence that 99.9% of the balloons will not burst upon single inflation.
Xtreme Touch Neo™ Sirolimus Coated PTA Balloon Catheter is manufactured by Envision Scientific Pvt. Ltd. and distributed by Concept Medicals All cited trademarks are the property of their respective owners.
CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

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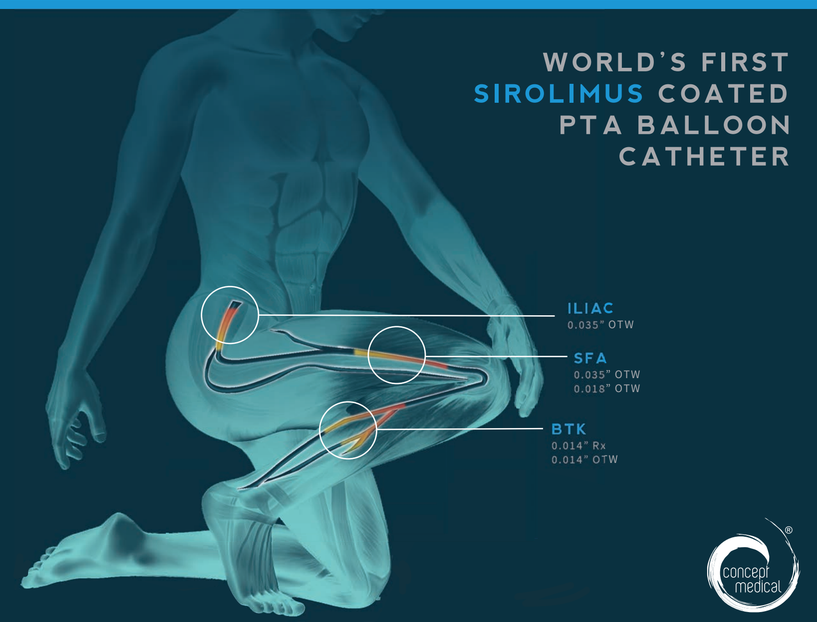
A NOVEL BALLOON IN PERIPHERAL TREATMENT

XTREME TOUCH - NEO™

SIROLIMUS COATED PTA BALLOON CATHETER

WORLD'S FIRST SIROLIMUS COATED PTA BALLOON CATHETER



concept medical®

SCOPE OF DEB

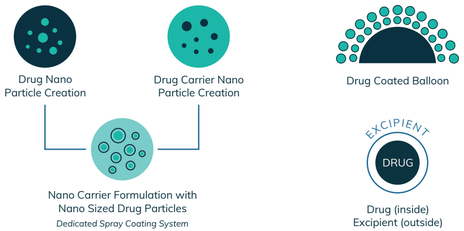
- In-stent Restenosis
- Stent Fracture
- No permanent Implant
- No recurrence via intimal hyperplasia
- Re-intervention in Bifurcation Lesion

ADVANTAGES OF DEB

- Low crossing profile helps in accessing extreme arteries.
- Local drug delivery over very short period of time.
- Better retention of drug in the vessel.
- Absence of polymers avoids chronic inflammation.
- Better re-endothelialization: reduced DAPT.

NANOLUTE™ TECHNOLOGY

Concept Medical has developed the world's first Sirolimus drug coated peripheral balloon catheter, Xtreme Touch Neo™. It utilises the safe and effective Sirolimus drug on the balloon for treatment. Product design involved developing a highly effective coating which could transfer the drug in the shortest time frame.



- Nano carrier based drug elution technology
- Encapsulation technology using biocompatible excipients
- Reduction in particle size creates larger surface area to volume ratio

ADVANTAGES OF NANOLUTE TECHNOLOGY

- Uniform coating surface
- Reduced 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

DESIGN GOALS

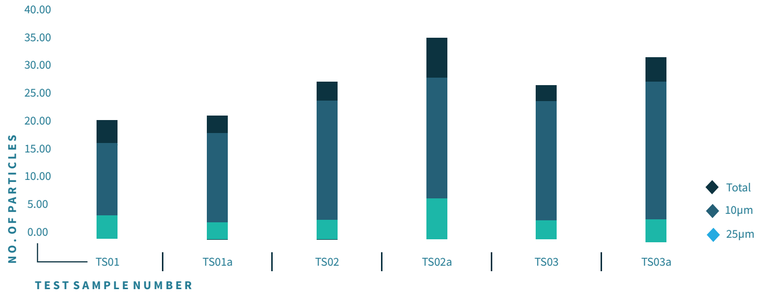
DCB design goals have been refined to match clear targets

LIMIT DRUG DOSE 01

- Nanolute technology is characterized by a low dose of 3µg/mm² of Sirolimus.
- Circumferential coated balloon results in uniform and directional drug release.
- A lower drug dose is highly advantageous as it mitigates the downstream effect caused by Sirolimus, while still delivering a highly efficacious treatment to the target lesion.
- The downstream effect causing embolism is addressed with the decreased size of particulate matter as per mentioned in USP 788 Guidelines

PARTICULATE MATTER

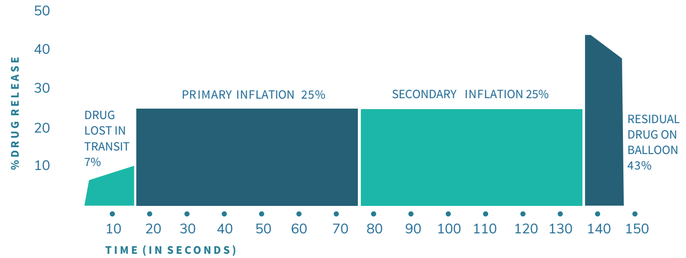
Particulate Matter analysis of samples are done as per USP 788 guidelines
An analysis of number of particles greater than 10 and 25 microns is done.
Mentioned below is the chart : ≤ 10µ and ≥ 25µ and cumalative ≥ 10µ



COATING STABILITY 02

- Minimize drug loss during balloon transit,
- Maximise drug release to vessel wall once the balloon is inflated
- Recommended inflation time is of 60 seconds.

DRUG MECHANISM RELEASE



NANOLUTE TECHNOLOGY PROVIDES

- Lowered in-transit loss
- Acute drug transfer
- Better drug retention
- Targeted drug delivery
- Reduced drug rejection ration
- Controlled drug degradation
- Altered pharmaco-kinetics