

# Indigenous Stents :- New Technologies & Clinical Data

***Dr. A. Sreenivas Kumar***

M.D., D.M., FACC (USA)

Chief Cardiologist, The Heart Centre  
Continental Institute of CardioVascular Sciences  
Gachibowli, Hyderabad, AP, INDIA

# Disclosure Statement of Financial Interest

**I, Dr.A.Sreenivas Kumar -DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.**

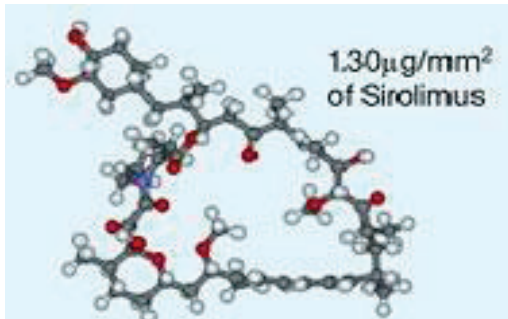
## M' Sure - Cr

### Chromium Cobalt Coronary Stent



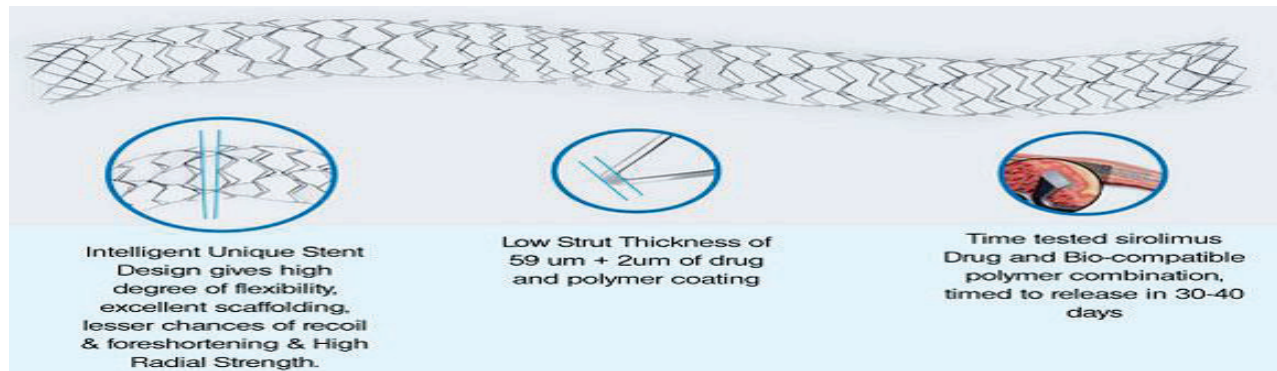
- M'Sure–Cr is made up of Cobalt Chromium L605 which contains no Molybdenum and only 10% of Nickel compared to other brands which uses Cobalt Alloy MP35N, which has 35% Nickel and 10% of Molybdenum.

**M' Sure - S**  
Sirolimus Eluting CoCr stent system



Optimal balance of High radial strength of 1.1 bar and ultra low strut thicknesses of 59 $\mu$ m.

MSure –S uses a validated formulation of low dose Sirolimus (1.30 $\mu$ g/mm<sup>2</sup>) timed to elute in 30days from a biodegradable and biocompatible polymer base, which degrades simultaneously



# PRISM - Basket of Clinical Trials

## PRISM - Basket of Clinical Trials

- **A Prospective Registry to Investigate Safety and Efficacy of M'Sure-S (Sirolimus Eluting Coronary Stent)**
- PRISM trials are series of studies funded by Multimedics in order to investigate and suitably demonstrate the safety and efficacy of M'Sure-S (Sirolimus eluting coronary stent system) in a broad spectrum of clinical indications to build confidence across the globe with operators in different patients with different clinical history that react differently to the same treatment.

## PRISM - PILOT

- **A Prospective Registry to Investigate Safety and Efficacy of M'Sure-S (Sirolimus Eluting Coronary Stent)**
- Results: No MACE was observed, the median in-stent late luminal loss in subjects studied by QCA was 0.05 mm, with 0% binary restenosis at six month angiographic follow-up. No stent thrombosis was observed up to six month follow up.

## PRISM - Indian sub continent

- **A Prospective Registry to Investigate Safety and Efficacy of M'Sure-S (Sirolimus Eluting Coronary Stent)**
- The primary safety and efficacy end-points are major adverse cardiac events (MACE) at 30 days and in-stent late lumen loss at 9 months, measured using QCA. Secondary safety and efficacy end-points included angiographic binary restenosis at 9 month angiographic follow-up. Other end-points included the occurrence of stent thrombosis (acute, subacute, late and very late), percentage of diameter stenosis measured by QCA.

# PRISM - Basket of Clinical Trials

## PRISM - Global

- **A Prospective Registry to Investigate Safety and Efficacy of M'Sure-S (Sirolimus Eluting Coronary Stent)**
- We have selected few centres across the globe, selection process and enrolment is going on.
- The primary safety and efficacy end-points are major adverse cardiac events (MACE) at 30 days and in-stent late lumen loss at 9 months, measured using QCA. Secondary safety and efficacy end-points included angiographic binary restenosis at 9 month angiographic follow-up. Other end-points included the occurrence of stent thrombosis (acute, subacute, late and very late), percentage of diameter stenosis measured by QCA.

## PRISM - M

- **A Prospective Registry to Investigate Safety and Efficacy of My Stent - S (Sirolimus Eluting Coronary Stent)**
- Results: No MACE was observed, the median in-stent late luminal loss in subjects studied by QCA was 0.05 mm, with 0% binary restenosis at six month angiographic follow-up. No stent thrombosis was observed up to six month follow up.