



PROJECT COMPLETION REPORT

1. **Project Number** : P 8152
2. **Title of the Project** : DEVELOPMENT OF TITANIUM NITRIDE COATED CORONARY STENT SYSTEM
3. **Funding Agency Name** : Technical Research Centre for Biomedical Devices (TRC)
4. **Project Reference Number provided by the Funding Agency:**
P8152
5. **Principal Investigator (Name & Address):**

Sl. No	Name	Role	Address
1	Subhash N. N.	Principal Investigator	Engineer C Division of Artificial Internal Organs, DMDE, BMT Wing, SCTIMST
2	Muraleedharan C. V.	Co-Principal Investigator	Scientist G (Sr. Grade) Division of Artificial Internal Organs, DMDE, BMT Wing, SCTIMST
3	Dr. S Hari Krishnan	Principal Clinical Investigator	Professor, Department of Cardiology, SCTIMST

6. **Co-Investigators (Name & Address):**

- Dr. Sanjay G, Professor, Department of Cardiology
- Dr. Krishna Kumar M, Assistant Professor, Department of Cardiology
- Mr. Sujesh S, Engineer G, Department of Medical Devices Engineering
- Dr. Umashankar PR, Scientist-G, Department of Applied Biology
- Dr. Sachin J Shenoy, Scientist-G, Department of Applied Biology
- Dr. Sabareeswaran A, Scientist-G, Department of Applied Biology
- Mr. Ramesh Babu, Engineer-G, Department of Medical Devices Engineering
- Mr. Rajeev A, Sr. Scientific Assistant, Department of Medical Devices Engineering
- Mr. Subhash Kumar MS, Technical Assistant-A, Department of Medical Devices Engineering

7. **Implementing Institution** : SCTIMST
8. **Collaborating Institutions** : Nil
9. **Date of Commencement** : 15/03/2019

10. Duration : 15/03/2019 to 31/03/2023

11. Date of Completion : 31/03/2023

12. Objectives as approved:

Sl. No	Objective
1	<p>Phase I Objectives:</p> <ul style="list-style-type: none">▪ Design and develop cobalt chromium alloy coronary stent coated with Titanium Nitride.▪ Qualify the device to meet the requirements of relevant national / international standards

13. Deviation made from original objectives if any, while implementing the project and reasons thereof :

Nil

14. Field/Experimental work giving full details of summary of methods adopted, data collected supported by necessary tables, charts, diagrams and photographs:

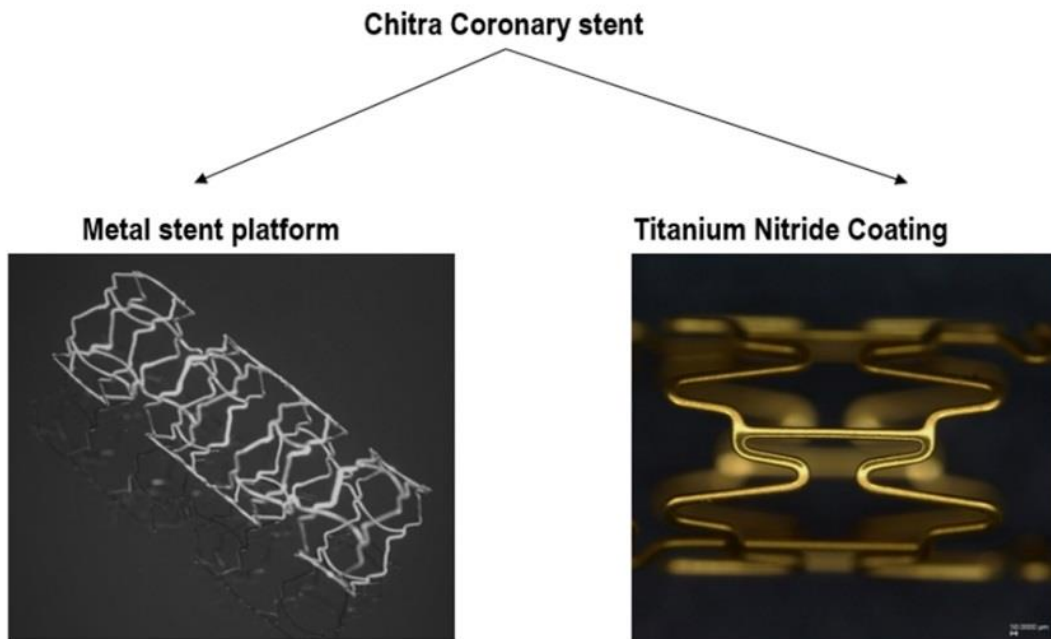


Figure 1. Chitra Coronary Stent System

Phase I Objectives:

- Design and develop cobalt chromium alloy coronary stent coated with Titanium Nitride.
- Qualify the device to meet the requirements of relevant national / international standards

Status of Completion of TRC I Objectives:

- Design verification-in silico (3 nos), in vitro studies (22 Nos) completed
- Proof of concept-animal studies performed (4 Nos)
- Gross and Histopathological evaluation of tissue response to material in end use application study carried out

15. Detailed analysis of results:

Design Verification tests performed were:

The safety and performance of the proof of concept design has been assessed in vitro and in silico by:

- (a) Stent diameter to balloon expansion characterization as per ASTM 2081-06 (2017)
- (b) Dimensional verification as per ASTM F2081-06 (Reapproved 2017)
- (c) Recoil study as per ASTM F2079, ISO 25539-2
- (d) Foreshortening study as per ASTM 2081-06 (2017)
- (e) Percent solid area study as per ASTM 2081-06 (2017)
- (f) Computational structural analysis (ASTM F2514-08 Reapproved 2014)
- (g) Fatigue & durability- computational analysis (ASTM F2514)
- (h) Flexibility of stent as per ASTM F2606-08 (Reapproved 2014)
- (i) Flexibility of stent system as per ASTM F2606-08 (Reapproved 2014)
- (j) Dogboning studies as per ISO/DIS 25539-2:2019(E)
- (k) Deflation time at labeled RBP as per ISO/DIS 25539-2:2019(E)
- (l) Deflation time corresponding to deployed diameter as per ISO/DIS 25539-2:2019(E)
- (m) TiN coating thickness measurement as per ISO/DIS 25539-2:2019(E)
- (n) TiN coating surface roughness as per ISO/DIS 25539-2:2019(E)
- (o) TiN coating integrity as per ISO/DIS 25539-2:2019(E)
- (p) TiN coating trace element analysis as per ISO/DIS 25539-2:2019(E)
- (q) DFSS based robustness (z) assessment: Critical to Quality parameters, vendor evaluation of raw materials and manufacturing process.
- (r) POC Animal studies- Completed animal studies of 3 Chitra stents

The safety and performance indicators showed that the Chitra Stent is safe.

More details may be viewed from Institute website: <https://www.sctimst.ac.in/Technology-Transfer/TiN%20coated%20coronary%20stent%20system/> . Website last accessed on 1 Dec 2023.

**16. Summary sheet of not more than 2 pages under following heads:
(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)**

More details may be viewed from Institute website: <https://www.sctimst.ac.in/Technology-Transfer/TiN%20coated%20coronary%20stent%20system/> . Website last accessed on 1 Dec 2023.

17. Contributions made towards increasing the state of knowledge in the subject :

More details may be viewed from Institute website: <https://www.sctimst.ac.in/Technology-Transfer/TiN%20coated%20coronary%20stent%20system/> . Website last accessed on 1 Dec 2023.

18. Conclusions summarising the achievements and indication of scope for future work :

More details may be viewed from Institute website: <https://www.sctimst.ac.in/Technology-Transfer/TiN%20coated%20coronary%20stent%20system/> . Website last accessed on 1 Dec 2023.

19. Science and Technology benefits accrued :

a. List of research publications with complete details :

- Nil

- b. **Manpower trained on the project :**
- i. **Research Scientists or Research Fellows** : Nil
 - ii. **No. of PhD's produced** : Nil
 - iii. **Other Technical Personnel trained** : 3 (Aneesh, Polson, Binu)
- c. **Patents taken, if any** : Patent granted, 357096 dated 29/01/2021
- d. **Products developed, if any** : Call for technology Transfer-Expression of interest is in progress.
More details may be viewed from Institute website:
<https://www.sctimst.ac.in/Technology-Transfer/TiN%20coated%20coronary%20stent%20system/>
Website last accessed on 1 Dec 2023.

20. **Abstract: (In 300 words for possible publication in Bulletin)**

Through this program we aim to develop a TiN coated coronary stent for coronary artery disease (CAD) management.

Intended end use: The Cobalt-Chromium-Nickel-Tungsten alloy L605 based, Titanium Nitride coated "bare metal" coronary stent system is indicated for improving coronary luminal diameter in patients with native coronary lesion length < 50 mm, and reference vessel diameter (D Ref Vessel) ranging from 2.0 mm < D Ref Vessel < 4.50 mm.

21. **Procurement/Usage of Equipment:**

a. **Details of Equipment:**

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown
1	ALL IN ONE PC	Item No-909/1797 Item codeEQCO MP0314	47,145.00	20/08/2019	Being used for technical documentation, Literature review.	Nil
2	FORCE GAUGE	Item no - 909/1811, Item code - EQDIMS0112	203,175.00	11/03/2020	Being used for measuring force	Nil
3	TORQUE GAUGE	Item No -909/1812 , Item code -			Being used for measuring torque	Nil

		EQDIMS0113				
4	WORKSTATION	Item No -909/1825 , Item code - EQWORKS TA1	600,600.00	24/08/2020	Being used for CAD modeling, Simulation, Analysis driven design	Nil
5	MOBILE WORKSTATION - A	Item No -909/1842 , Item code - EQWRKS01 22/815 2	270,900.00	04/03/2021	Being used for CAD modeling, Simulation, Analysis driven design	Nil
6	MOBILE WORKSTATION - B	Item No - 909/1843, Item code - EQWRKS01 22/8152				Nil
7	MOBILE WORKSTATION - C	Item No - 909/1858, Item code EQWRKS01 22/815 2	142,600.00	12/10/2021	Being used for CAD modeling, Simulation, Analysis driven design	Nil
8	MOBILE WORKSTATION- D	Item No-909/1868, Item codeEQWRKS0122/815 2	142,065.00	03/03/2022	Being used for CAD modeling, Simulation, Analysis driven design	Nil
9	Dell 24 INCH MONITOR	Item No-909/1817, Item CodeXLMO NR0133/815 2	10,350.00	03/02/2022	Being used for screen sharing, technical documentation and meetings	Nil
10	-	-	-	-	-	-

b. Suggestions for disposal of equipment(s):

Not applicable



Subhash N. N.
1 Dec 2023

Routing: Signed copy of "Project completion Report" by PI → root@sctimst.ac.in, rpc@sctimst.ac.in