

## Executive Summary



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1. **Title of the Project:** Accelerating Medical Device Innovation and Entrepreneurship
2. **Date of Start of the Project:** 25 July 2018
3. **Aims and Objectives:** Develop, commercialize and create social impact through at least two innovative medical products. The clinical problems will be identified in consultation with leading doctors, and the devices will be scientifically developed and comprehensively tested as per prevailing quality standards, followed by licensing to Indian companies for mass production and supply. Facilities and resources available in the Institute will be utilized for the above purpose, supported by funding from other sources.
4. **Significant achievements** (< 500 words to include list of patents, publications, prototype, deployment etc):

Three medical device innovation projects were taken up by young innovators in Biomedical Engineering & Technology Innovation Centre, IIT Bombay, followed by incubation of start-up companies for further commercialization.

**Stance-controlled knee ankle foot orthosis** for movement disorder patients (over 5 million in India) was taken up by Aneesh Karma, a Polio victim. He met over 100 patients and doctors to understand their requirements, and evolved a novel orthosis with automatic locking and unlocking of knee joint based on stance, unlike drop-lock calipers which several constrain the movement. He fabricated and tested several prototypes and filed a patent in Feb 2019. He won the Biotechnology Ignition Grant of Rs. 5 million from BIRAC, New Delhi in July 2019, and incubated a start-up called Aumeesh Tech Pvt. Ltd. in Feb 2020. The final prototype was tested in Human Movement Science Lab, MGM Institute of Health Sciences. It was displayed at Medical Device Expo, IIT Bombay; India International Science Festival, Delhi; MSME Expo, Noida and IAAT Conference, Bhubaneswar. It won UPSTART Pioneer award at Tech Kirti, IIT Kanpur; Big Idea Summit, Mumbai; NCPEDP-Mphasis Universal Design Award 2019, and Arohan-Infosys Social Innovation Award in Feb 2020.

**Sterile enclosure for isolation of burns patients** to prevent infections was taken up by Dinoj Joseph after completing Masters in Industrial Design from IIT Bombay. There are over 7 million burn injuries annually in India, with nearly 0.5 million disabilities or deaths, 75% of them due to infection. He visited hospitals in small towns and realized the need for a quickly deployable pre-sterilized isolation unit for mounting on to patient bed, while allowing access

to clinicians to treat the patients. He evolved the concept, fabricated a prototype and filed a patent in Aug 2018. It received good feedback at ARSICON (Association of Rural Surgeons of India Conference), Bagalkot in Nov 2019 and NABICON (National Academy of Burns India Conference), Shimla in Feb 2020. Dinoj obtained Rs. 5 million of funding from BIRAC, New Delhi and incubated a start-up MEDGYOR Pvt Ltd. in Oct 2020 to commercialize the product.

**Diabetic foot screening device** to predict ulcers was developed by Nishant Kathpal after completing M.Tech Electrical Engineering from IIT Bombay in 2018. Among diabetes patients (currently over 60 million in India), about 20% develop foot ulcers, and some of these require amputation (over 200,000 every year, accounting for 80% of all non-traumatic amputations). He developed a compact device for objective screening of such patients, by integrating tiny load-voltage-temperature sensors. He won BIRAC Biotechnology Ignition Grant in early 2019 and incubated a start-up company Ayati Devices Pvt. Ltd. The product was exhibited at MEDEX, IIT Bombay in October 2019. It won IoT India Congress Innovation Challenge, DST NIDHI-PRAYAS and ATTD Start-up Grants. During the pandemic, the team developed a simpler product called VibraSense that has sold over 250 units.

List of publications, patents, supplementary funding, awards, media coverage and scientific social responsibility (invited talks) is appended.



*Left-right: Knee ankle foot orthosis, burn patient isolation unit, diabetic foot screener*

- 5. Concluding remarks:** The Fellowship was utilized to successfully develop three novel medical devices representing *diagnosis* (diabetic foot screener), *rehabilitation* (knee ankle foot orthosis), and *hospital unit* (burns patient isolation) that address unmet clinical needs of financially challenged sections of society. They were developed at BETIC, IIT Bombay in a scientific manner in accordance with ISO 13485 quality management system for medical devices, followed by safety testing in labs and clinical trials in hospitals. The facilities, processes, expertise and network of BETIC enabled rapid progress. Patents were filed and licensed to the innovators, since they came forward to commercialize the technologies by incubating start-up companies. One product has reached the market, one is in clinical trials and the third is in final prototyping stage. Their stories of 'Designed in India and Made in India' medical products will be documented and widely shared to inspire many others for contributing to the healthcare sector. The investigator and team members are grateful to INAE and SERB for supporting the projects through the Fellowship.

## APPENDIX

### PUBLICATIONS

1. B. Ravi, "Technology, Incubation an Start-up Creation: Lessons from BETIC, IIT Bombay" in *Shifting Orbits: Decoding the Trajectory of the Indian Start-up Ecosystem*, Universities Press (India), Hyderabad, 2021, 74-83 (invited paper).
2. B. Ravi, "Medical Device Innovation: Idea to Impact" in *Engineering for the Future*, Centenary Publication, *Institution of Engineers (India)*, 2020, 371-382 (invited paper).

### PATENTS FILED AND LICENSED

1. Aneesh Karma, Rupesh Ghyar, B. Ravi, "Stance controlled knee ankle foot orthosis for weak knee patients," 201921005973, 15 Feb 2019. Licensed to Aumeesh Tech Pvt Ltd.
2. Dinoj Joseph, V.P. Bapat, B. Ravi, Hemanth Bansali, Rupesh Ghyar, "A portable sterile enclosure for surgical procedures," 201821030523, 14 Aug 2018. Licensed to MEDGYOR Pvt Ltd.
3. Chetan Pakhare, Yash Gupte Nishant Kathpal, Rupesh Ghyar, B Ravi, Rajani Mullerpatan, "Device for screening of diabetic foot," 201821005692, 15 Feb 2018. Licensed to Ayati Devices Pvt. Ltd.

### SUPPLEMENTARY FUNDING

Biotechnology Ignition Grant from BIRAC, New Delhi (each approximately Rs. 5 million):

1. Portable diabetic foot screening device, Nishant Kathpal, Ayati Devices Pvt. Ltd., 2019
2. Stance-controlled knee ankle foot orthosis, Aneesh Karma, Aumeesh Tech Pvt. Ltd., 2020
3. Affordable isolation room for burns patients, Dinoj Joseph, Medgyor Pvt. Ltd., 2020.

### OTHER AWARDS

1. Big Idea Summit by Kutchhi Bhanushali Seva Samaj Trust prize to Anish Karma, Dec 2018
2. NCPEDP-Mphasis Universal Design award to Aneesh Karma Aug 2019
3. Aarohan Social Innovation award by Infosys Foundation to Aneesh Karma, Feb 2020
4. IET IOT Challenge: Healthcare Track award to Nishant Kathpal, Aug 2019
5. DST NIDHI-PRAYAS award to Nishant Kathpal, 2020
6. ATTD Start-up Grants to Nishant Kathpal, 2021

### PRODUCT EXHIBITIONS

1. Convocation Exhibition, IIT Bombay, 11 Aug 2018
2. Medical Device Expo (MEDEX), IIT Bombay, 02 Oct 2018
3. India International Science Festival, Lucknow, 08-11 Oct 2018
4. TechConnect, Techfest, IIT Bombay, 14-16 Dec 2018
5. KUTUHAL Product Exhibition, VNIT Nagpur, 09-11 Feb 2019
6. Medical Device Expo (MEDEX), IIT Bombay, 12 Apr 2019
7. Medical Device Expo (MEDEX), IIT Bombay, 02 Oct 2019
8. India International Science Festival, Kolkata, 05-08 Nov 2019
9. Institute Alumni Day, IIT Bombay, 22 Dec 2019
10. TechConnect, Techfest, IIT Bombay, 03-04 Jan 2020
11. Global Bio India, New Delhi, BIRAC, 21-23 Nov 2019
12. KUTUHAL 2020, Pune, S.P. College, Pune, 07-10 Feb 2020

### MEDIA COVERAGE

1. "BETiC-IITB innovator Aneesh Karma wins Aarohan social innovations awards for 2019," *Express Healthcare*, 2 March 2020
2. "Low-cost portable diabetic foot screener makes debut at IIT-Bombay innovation camp," *The Indian Express*, 1 Nov 2019
3. "IIT student's OT can fit in a backpack," *Mumbai Mirror*, 14 April 2019.

## INVITED TALKS

1. "Medical Device Innovation: Idea to Impact," *Med-tech dual degree multi-disciplinary program launch*, AIIMS Jodhpur and IIT Jodhpur, 20 July 2021.
  2. "Med-tech Innovation: Role of Information Technology," *AICTE FDP on Application of Computers in Biology*, Galgotias University, 7 June 2021.
  3. "Medical Device Innovation Powered by 3D Printing" *ATAL Academy Online FDP on 3D Printing and Design for Innovative Medical Devices*, MNIT Jaipur, 28 June 2021.
  4. "RE.INV.ENT: Affordable Healthcare Ecosystem by Leveraging IT," *AICTE FDP on Computers in Biology*, Galgotias University, 7 June 2021.
  5. "RE.INV.ENT Affordable Healthcare," *Maharashtra Health Hackathon*, Maharashtra State Innovation Society, Mumbai, 24 April 2021.
  6. "Smart Medical Devices for Affordable Screening and Diagnosis," *Symposium on 'Towards a New Healthcare regime for the Nation,' 90<sup>th</sup> Annual Session of NASI*, 26 Feb 2021.
  7. "Medical Device Innovation: Stories and Lessons," *Decennial Celebration Mini-symposium*, Institute of Liver and Biliary Sciences, New Delhi, 1 Jan 2021.
  8. "Medical Device Innovation: Opportunities, Challenges & Best Practices," *Emerging Trends in Advanced Medical Systems, Applications & System Design Methodologies*, *AICTE STP*, GHRCE Nagpur, 15 Oct 2020.
  9. "Medical Device Innovation: Opportunities, Challenges and Best Practices," *TechEX*, Venture Centre, Pune, 14 Oct 2020.
  10. "Essence of Medical Device Innovation in India," *Digital Health & Imaging*, IISc Bangalore, 11 Oct 2020.
  11. "Medical Devices: Scope, Challenges and Opportunities," *Biotech Innovation Ignition School*, BIRAC & SRISTI, 1 Oct 2020.
  12. "Medical Device Innovation: Idea to Impact," *ATAL FDP on Design Thinking for Innovative Medical Devices*, MNIT Jaipur, 21 Sep 2020.
  13. "Creating the Eco-system for Traversing Idea > Invention > Innovation > Impact," *CII Young Indians Delhi Tech Summit*, Confederation of Indian Industry, Delhi, 31 July 2020.
  14. "Medical Device Innovation: Stories and Best Practices," *PharmaTalk*, School of Pharmacy & Technology Management, SVKM'S NMIMS, Hyderabad, 25 July 2020.
  15. "Medical Device Innovation: How to create success stories," *Manipal - Karnataka Government Bioincubator*, MAHE, 13 July 2020.
  16. "Creativity, Innovation and Entrepreneurship," *IPR Certification Programme*, i-Hub, Gujarat, 9 July 2020.
  17. "Research to Reality: How to Traverse the 'Valleys of Death'," *Gandhigram Rural Institute*, Dindigul, 12 June 2020.
  18. "Healthcare Innovation & Entrepreneurship Eco-System," *National Academy of Sciences Workshop on Healthcare Innovation in India*, NIRRH Mumbai, 1 March 2020.
  19. "Translating Research Prototypes into Marketable Products," *89<sup>th</sup> Annual Symposium on Science and Technology based Entrepreneurship Development*, National Academy of Sciences, NAARM, Hyderabad, 22 Dec 2019.
  20. "Innovation & Entrepreneurship Eco-System in Academic Institutes," *IIITDM Kanchipuram*, 16 Dec 2019.
  21. "Biomedical Device Innovation Eco-System," *Meeting on Medical Devices*, NITI Aayog, New Delhi, 14 Aug 2019.
  22. "Innovation and Entrepreneurship Eco-System at IIT Bombay," *Regional Interstate Knowledge Sharing Workshop on Startups*, Maharashtra State Innovation Society, IIT Bombay, 5 Aug 2019.
  23. "Assistive Technologies: Idea to Invention to Innovation to Impact," *National Conference on Assistive Technologies for All*, Bangalore, 2 Aug 2019.
  24. "Healthcare Innovation Eco-System," *CII-AMTZ Startup Day*, AMTZ, Visakhapatnam, 25 Mar 2019.
  25. "Bioengineering: Medical Product Design and Manufacturing," *Paediatric Orthopedic Society of India Conference POSICON 2019*, 5 Jan 2019.
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