



GO REALISM PRIVATE LIMITED

Stage: PROTOTYPE – PILOT LOT VALIDATION -

Eureka! ID **EU2513051**

EU2627520

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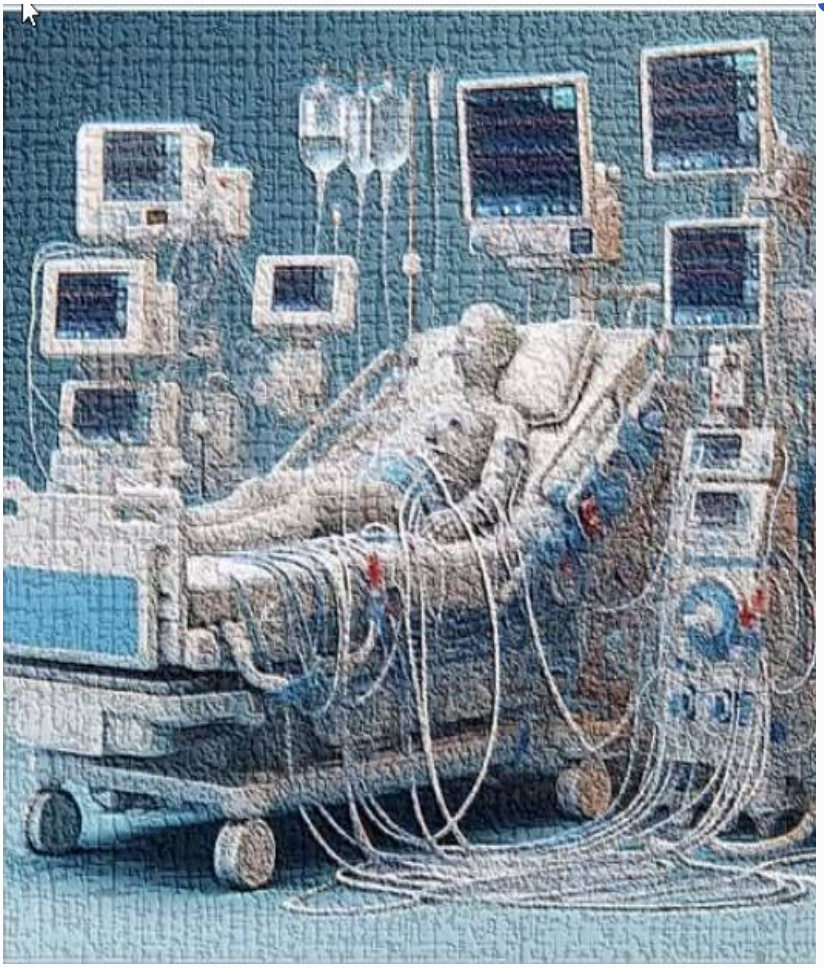
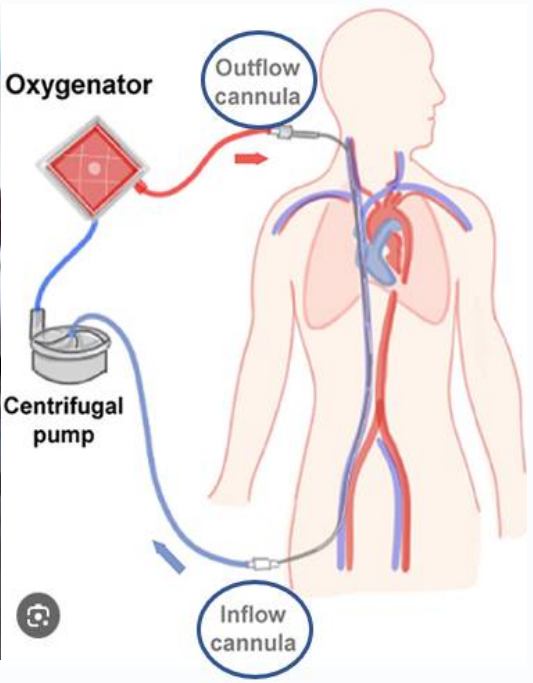
Stage: PROTOTYPE – PILOT LOT VALIDATION -

Revolutionizing ECMO Cannula Manufacturing in India











ECMO CANNULA Project

ECMO (Extracorporeal membrane oxygenation)
A mechanical device therapy to support a CRITICAL HEART & / or LUNG FAILURE
Used as a life saving device to bail out many life threatening emergencies

Similar to Dialysis machine for Kidney failure and
A miniature form of Heart Lung machine in ICU (Similar to Bypass machine for heart surgeries)

GO REALISM PRIVATE LIMITED – PROJECT TEAM AND DIRECTORS



Dr Pranay Oza
ECMO Co Director, Riddhi Vinayak Multispecialty Hospital
ELSO ADULT ECMO CERTIFICATION (E-AEC)
Past President – ECMO Society of India
Secretary – SWAACELSO
Director ECMO India Foundation
Director ECLS Bharat Pvt Ltd
Member of Research Cell, ELSO



Dr VENKAT GOYAL
MD, DM (CARDIOLOGY)
•Special focus on Heart Failure and MCS
(Fellowship in 2006 – Berlin Heart Institute)
•More than 400 ECMO experience in last 17 years
•Heart transplant & artificial heart devices
@ Riddhivinayak Group of Hospitals
•ECMO society of India – 2010 (Founder President)
•Past President of SWAAC ELSO 2018
•International ELSO – FELSO award –
ELSO ECMO fellow - 2020

Outsourced Manufacturing Partner Director Details

Prathima Deepthi

Founder & Director



Prathima Deepthi is the Founder and Director of **Sree Guravey Life Sciences (SGLS)**. With a Bachelor's degree in Electrical Engineering and over 15 years of experience in the medical device industry, she has played a pivotal role in the design, development, and commercialization of both active and non-active medical devices. She has successfully built and led cross-functional teams that have brought innovative and life-saving technologies to market.

SGLS – SREE GURAVEY LIFE SCIENCES

Rajesh Kalavalapally

Chairman & Non-Executive Director

Engineering Manager – 2007 to 2012
Burpee Materials Technology
Burpee Med Systems
(bought by Seisa Medical)
Founder/CEO/VP of Engineering .
MAJiK Medical Solutions
(www.majikmed.com)
GRK Medical Devices
(www.grkmedical.com)



Facility details



Class 8



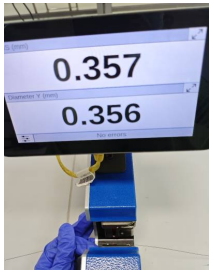
Class 7



ETO



Stability



Laser Mic



UTM



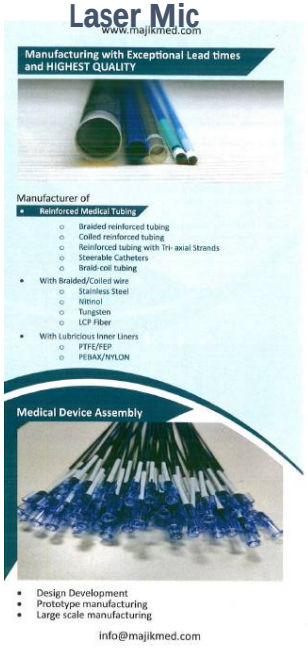
Dip coating



Molding

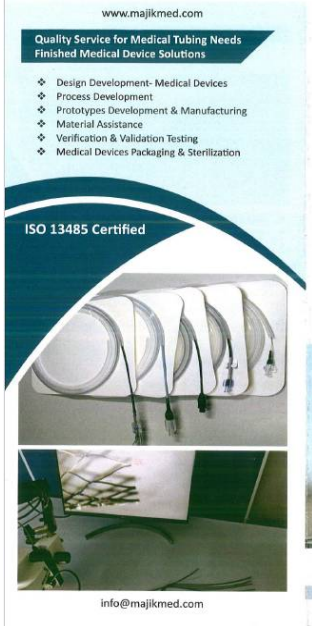
Plot No 55, ALEAP Industrial Estate, Pragathi Nagar, Hyderabad, Telangana 500090















CDSCO
Central Drugs Standard Control Organization

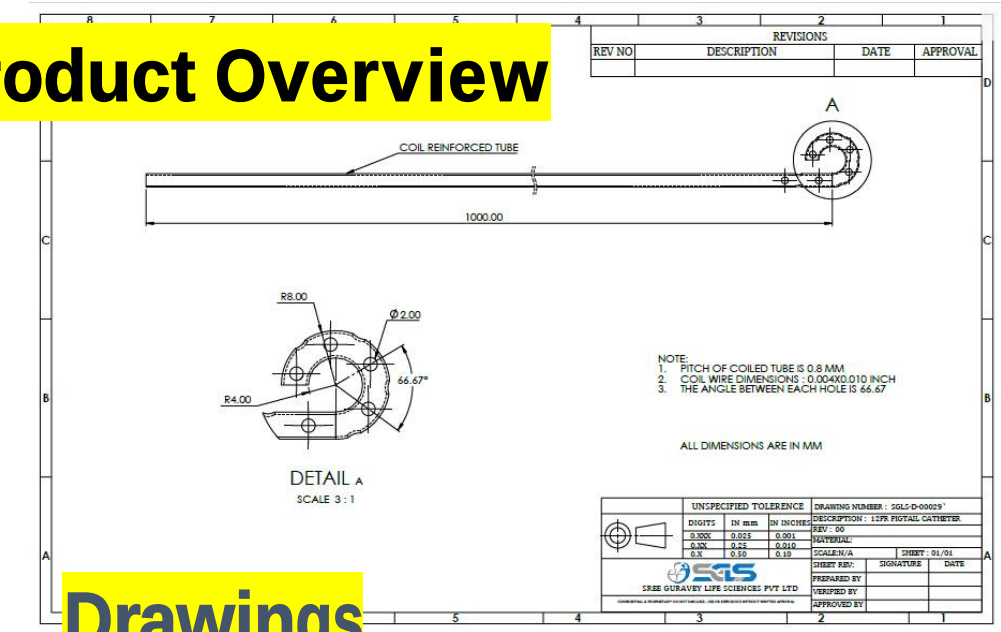
ISO
14644-1:2015 14644-2:2015

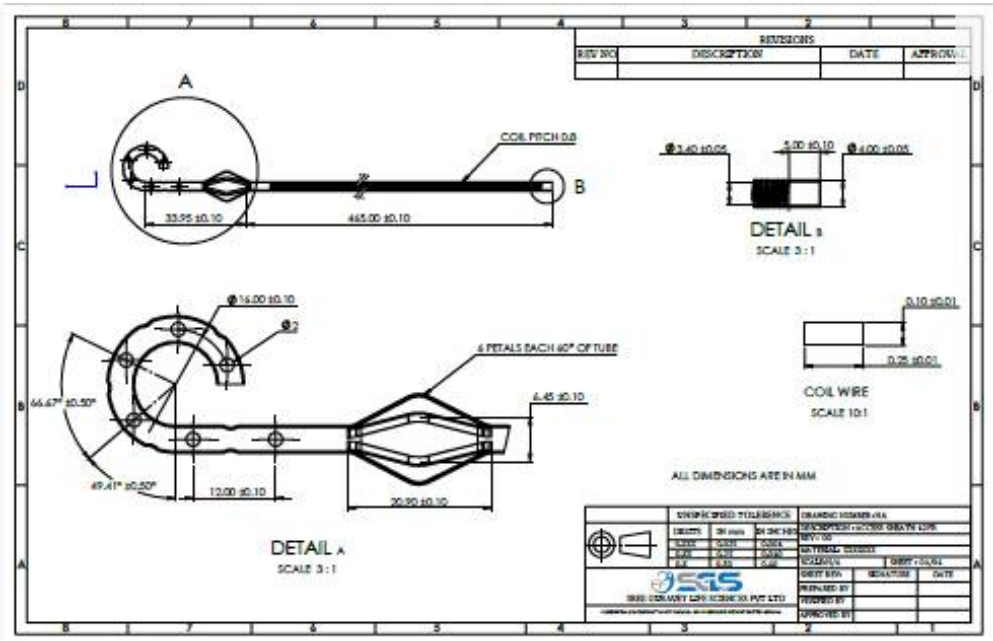
International Organization for Standardization
ISO
14971
Risk Management

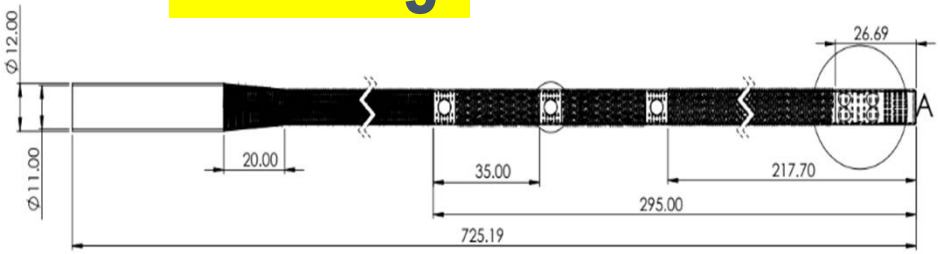
International Organization for Standardization
ISO
13485
Quality Management System

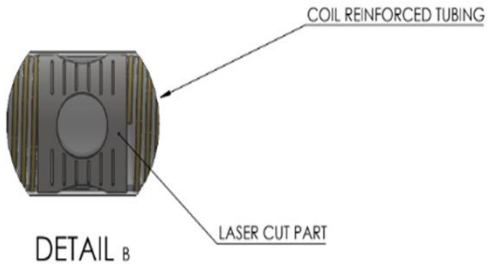
Product Overview

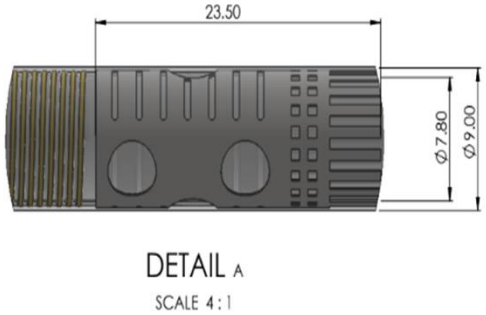
Drawings

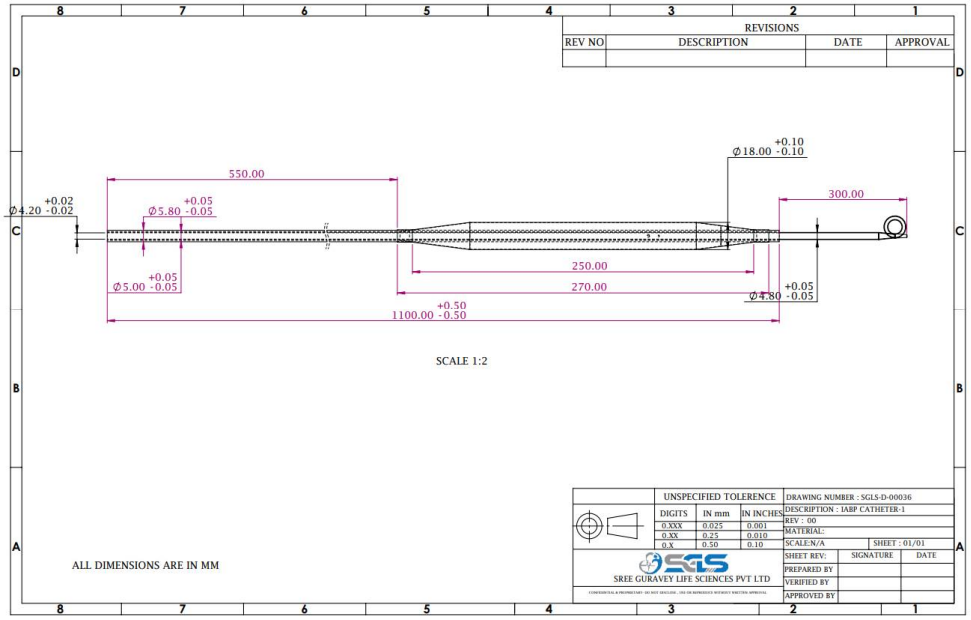






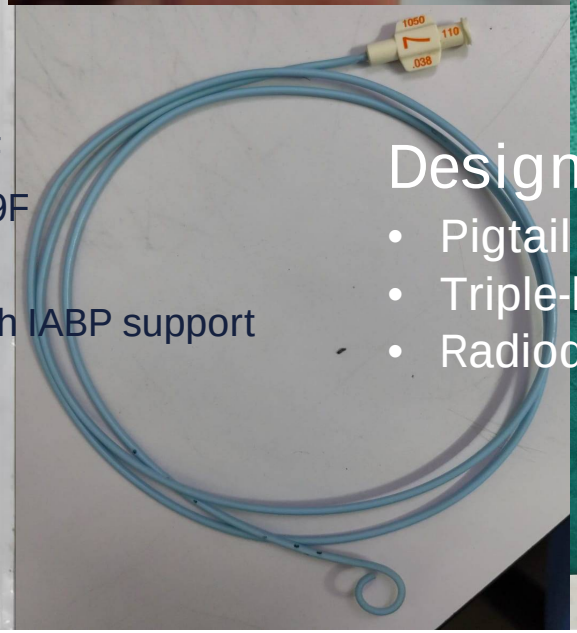






Conventional pigtail catheter available in the market

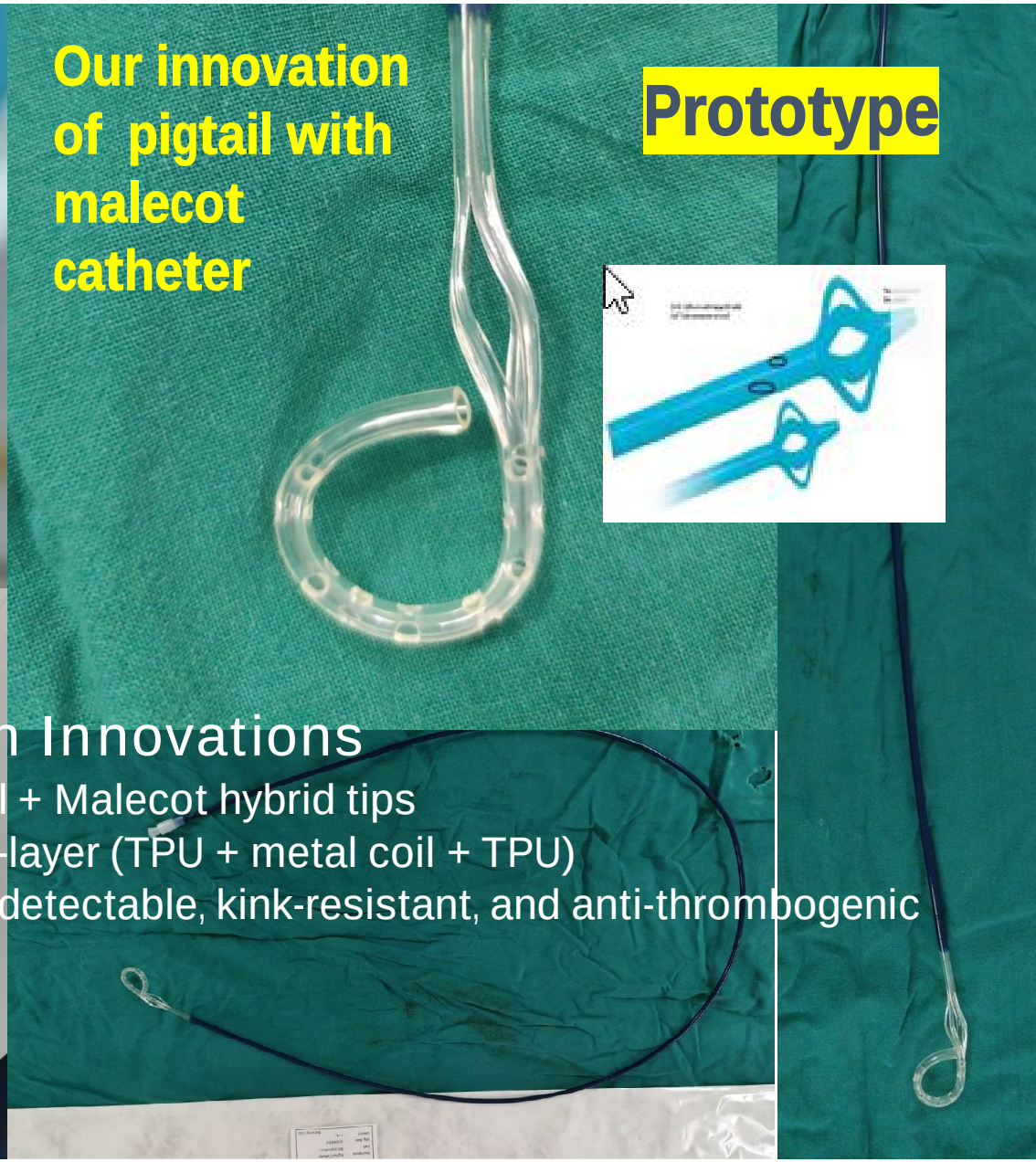




Cannula Types

- Arterial Cannula: 9F - 21F
- Venous Cannula: 12F - 29F
- Double Lumen Cannula
- GO VENT LV Cannula with IABP support

Our innovation of pigtail with malecot catheter



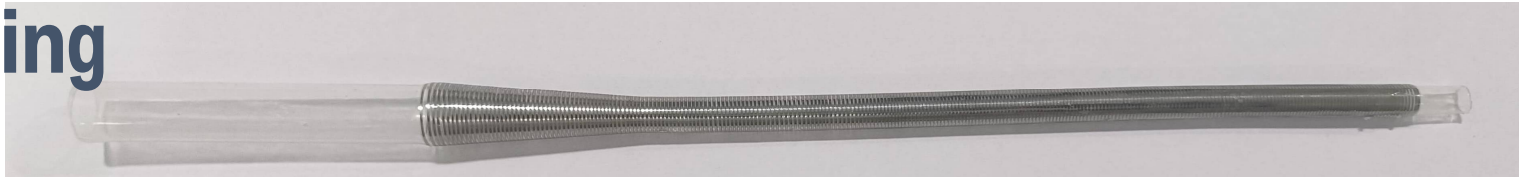
Prototype

Design Innovations

- Pigtail + Malecot hybrid tips
- Triple-layer (TPU + metal coil + TPU)
- Radiodetectable, kink-resistant, and anti-thrombogenic

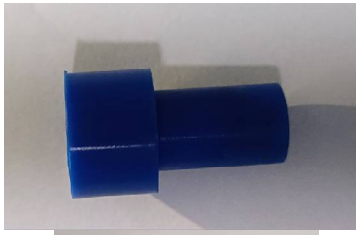
Test Manufacturing







Prototype





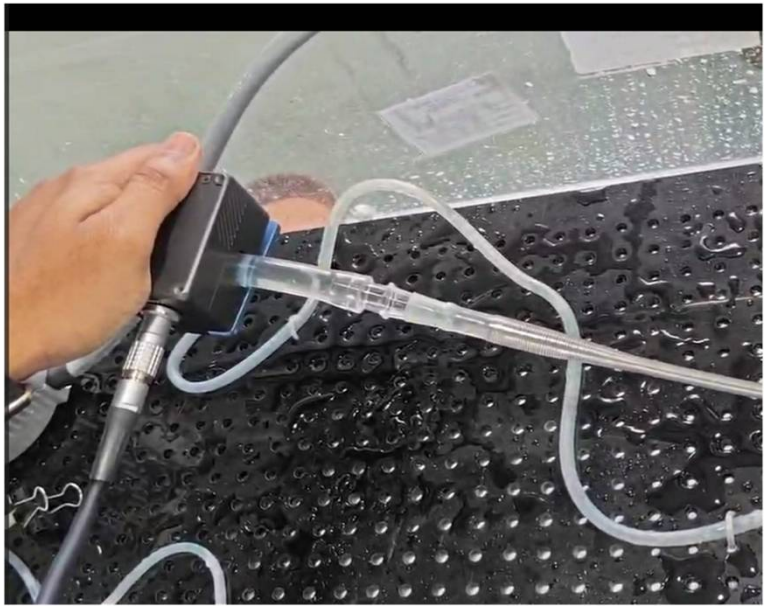




Testing

ISO 18193:2021 Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation





- Flow rate analysis
- Pressure Drop
- Collapse resistance
- Kink Resistance
- Pull strength
- External surface
- Radiodetectability

Yet to Perform

- Blood cell damage
- Plasma free hemoglobin

Certificates

Patents applied

Test manufacturing

ECMO Cannula Development Phases

1. Product Design and Analysis
2. Design Feasibility Phase- Technical and Financial
3. Clinical inputs and Improvements
4. Design Inputs- Regulatory& Statutory requirements
5. Design outputs & Pilot production
6. Pilot lot Verification
7. Pilot lot Validation
8. Regulatory Documentation
9. Manufacturing License
10. Commercialization

Problem Statement

- ECMO (Extracorporeal Membrane Oxygenation) therapy is vital but underutilized in India.
- There is no Indian manufacturer for ECMO systems, increasing reliance on imports.
- ECMO disposables like cannulae are expensive (₹25,000+), limiting use to elite hospitals.
- Supply chain breaks during crises (e.g., COVID-19) caused critical shortages.
- **Over 90% of patients in India cannot afford ECMO.**

Our Solution

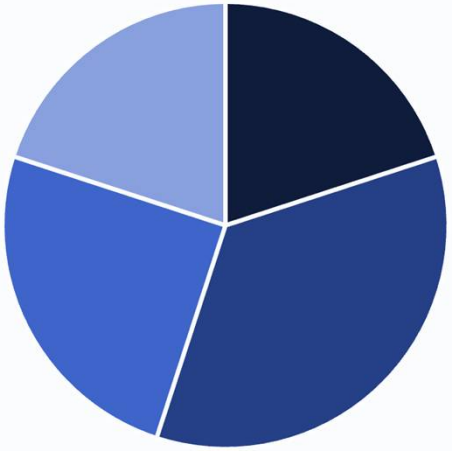
- Design, develop, and manufacture **indigenous ECMO cannulae**.
- Tailored to Indian demographics: pediatric, adult, and neonatal variants.
- Materials: Biocompatible polymers (TPU/PTFE), triple-layer design for safety.
- Price point: **₹ 20,000 MRP**, 30-40% cheaper than imported alternatives.
- Enables access to Tier-2 and Tier-3 ICUs.

PROJECT UTILITY, FEASIBILITY & MARKET ECONOMICS

Market Opportunity

- ECMO-related consumables market in India: ₹500–700 crore.
- Cannula share: 15–20% (₹75–140 crore).
- **Growing demand** due to cardiac, pulmonary, and transplant cases.
- India has 3,00,000+ ICU beds, 200+ ECMO centers.
- High potential in export markets: Asia, Africa, SAARC nations.

Other ECMO components



SOCIO ECONOMICS - India needs ecmo

Each tertiary care hospital at least have one ECMO case every month
29 states & 7 union territories, at least on an average 50 well furnished tertiary care hospital in each state.
If we extrapolate it will be 750 ECMO cases in a month & 9000 cases/year
Even if survival is 50%, one can save 4500 lives/year, 375/month, 12.5/day

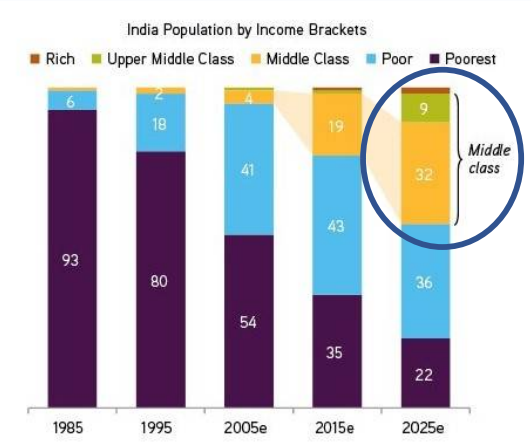
COST IMPACT on ECMO application ECMO is a costly business

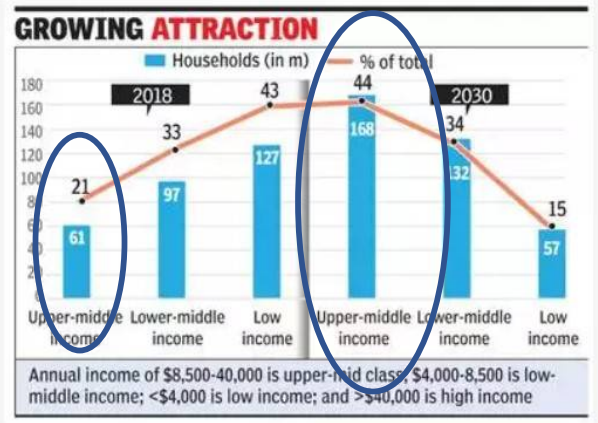
PROBLEM

9 /10 patients cannot afford ECMO in India
The cost of ECMO therapy is
Heart patients - 5 lacs to 15 lacs over 1 week
Lung patients - 15 lacs to 35 lacs over 1 month

SOLUTION

The only way **is better economy (GDP) of our population,** **so they can themselves fund the ecmo cost,** as health is a still a self funded affair in our country
Alternative is **indigenous manufacturing of ECMO system in our country which will reduce the ECMO cost by 50 %**





Proof of concept: (already done)

Objective: To validate the design, performance, and market viability of locally manufactured, cost-effective ECMO cannula tailored for the Indian healthcare market.

Key Steps in PoC:

1. Research & Design:
Develop prototypes of venous and arterial ECMO cannula using biocompatible materials.
Focus on flow efficiency, thrombosis prevention, and patient comfort (e.g., pediatric and adult designs).

2. Bench Testing:
Conduct simulations to evaluate flow dynamics, durability, and material compatibility.
Test against international standards (ISO 7198 for vascular prostheses and biocompatibility).

3. Pilot Manufacturing:
Partner with a local medical device manufacturer for small-batch production.
Ensure compliance with Indian regulatory standards (CDSCO) and obtain necessary certifications.

4. Clinical Validation:
Collaborate with 2-3 leading hospitals (e.g., AIIMS, Medanta, RVMH) for limited clinical trials.
Measure clinical outcomes, ease of insertion, and post-procedural complications.

5. Cost-Effectiveness Analysis:
Compare production and selling costs with imported cannula.
Highlight cost savings for hospitals using local cannula (~30-40% cheaper).

6. Stakeholder Feedback:
Gather input from intensivists, ECMO specialists, and perfusionists for design optimization.
Address pain points like delivery time, inventory management, and affordability.

7. Market Validation:
Present results to hospital procurement teams and government healthcare bodies.
Secure initial orders and demonstrate potential demand through MOUs with distributors.

Deliverables:
Functional prototypes that meet clinical and regulatory benchmarks.
Positive feedback and measurable clinical outcomes from pilot trials.
Cost-benefit analysis showing significant savings over imported alternatives.
Stakeholder endorsements and initial purchase commitments.

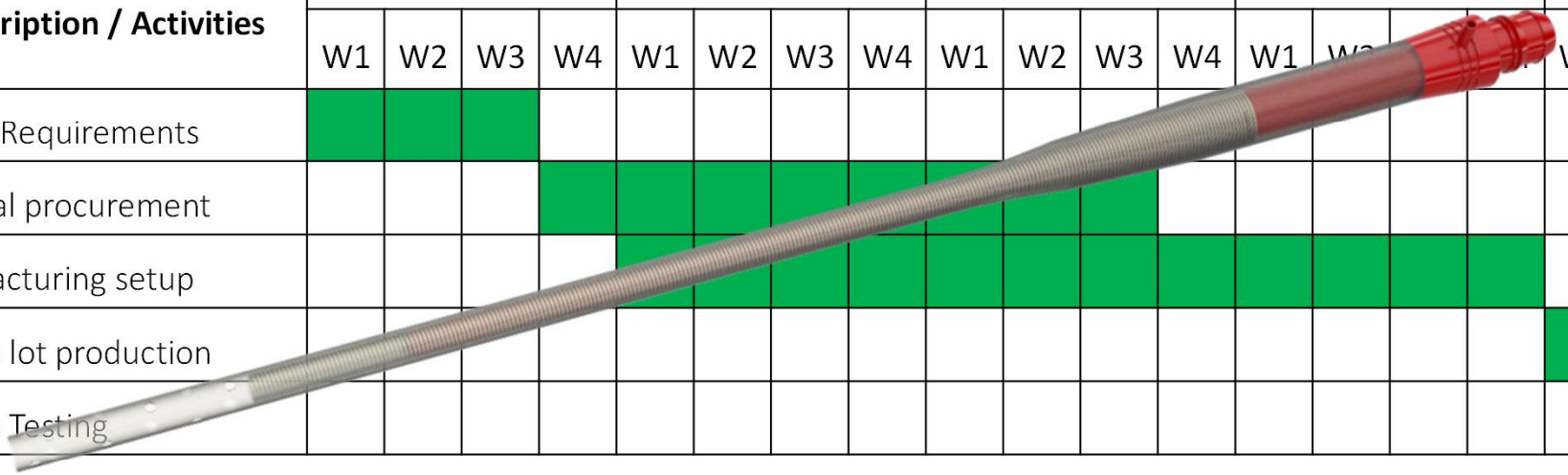
Timeline:
0-3 Months: Research, design, and prototype development.
4-6 Months: Bench testing and pilot manufacturing.
7-9 Months: Clinical validation and stakeholder engagement.
10-12 Months: Final report, certifications, and market launch.

This PoC demonstrates feasibility, clinical reliability, and commercial viability, paving the way for scaling production and market penetration.

ECLS BHARAT – GO REALISM PL - ECMO Cannula development project

Phase 1- Current Progress

Task No.	Description / Activities	Month 1				Month 2				Month 3				Month 4				Month 6			
		W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4
01	Design Requirements																				
02	Material procurement																				
03	Manufacturing setup																				
04	Sample lot production																				
05	Sample Testing																				



Phase 2 Scheduled Activities

Task No.	Description / Activities	Month 7				Month 8				Month 9				Month 10				Month 11			
		W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4
01	Pilot Lot Run																				
02	Pilot Lot Verification																				
03	Biocompatibility & Stability																				
04	Regulatory Documentation																				

Traction

Prototype Development

Developed multiple prototypes and validated with clinical experts.

Licensing & Patents

Obtained test licenses and filed for patents.

Testing

Completed flow, kink, and pressure tests.

Training Ecosystem

1,000+ consultants trained across 70+ hospitals.

Recognition

National recognition through ESOI and IJE.

Unique Selling Proposition (USP)



Cost-effective

₹15,000 vs ₹25,000+ imported price.



Made in India

Faster delivery, no forex dependence.



Custom Designed

Based on Indian ICU feedback.



Inclusive Access

Affordable for 90% of the population.

Target Market Customer Segments: B to B, B to C



Tier-1 corporate hospitals

Apollo, Fortis, Max



Tier-2/3 hospitals and ICUs



Pediatric and neonatal ICUs



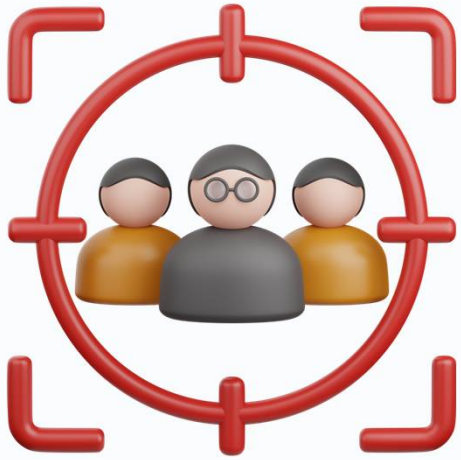
Transplant centers

Additional targets: Government hospitals under Ayushman Bharat and export markets including Nepal, Bangladesh, Sri Lanka, South Africa



Market Potential: First-year sales projected at 1,000 cannulas (₹1 crore), growing to 5,000 cannulas (₹5 crore) by Year 5, targeting 200 ECMO centers and 75,000 ECPR patients.

Global Reach: Leveraging 3,00,000 ICU beds in India and expanding to underserved regions like South Asia, Africa, and the Middle East.



Business & Revenue Model: Pricing Model

₹5,000 Production cost

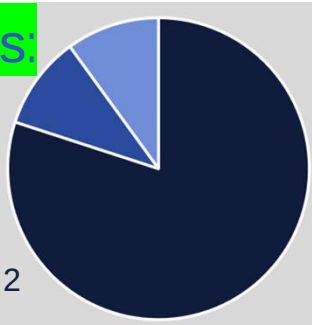
₹10,000 Distributor price

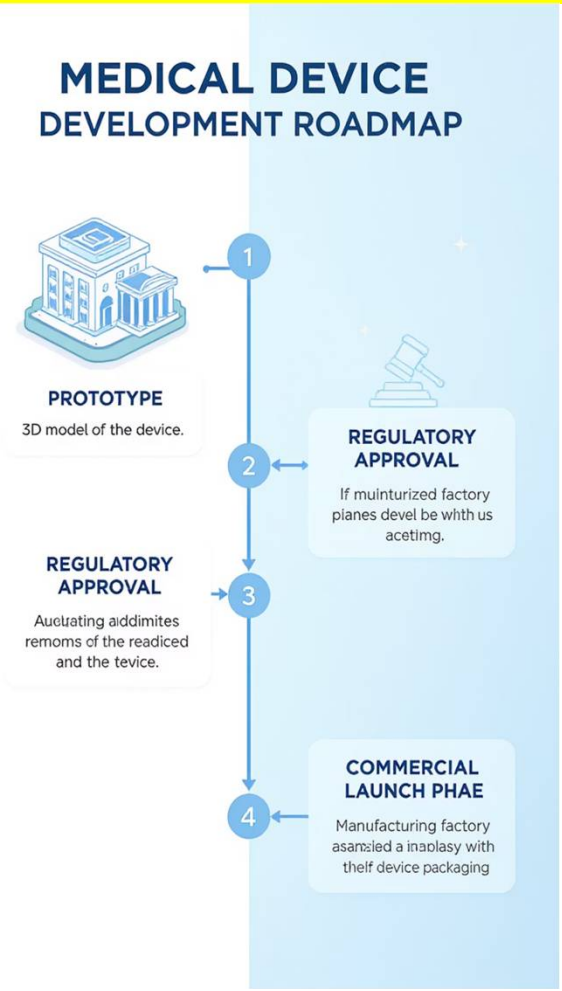
₹20,000 MRP

Revenue Streams:

- Cannula sales
- Exports
- Training & support

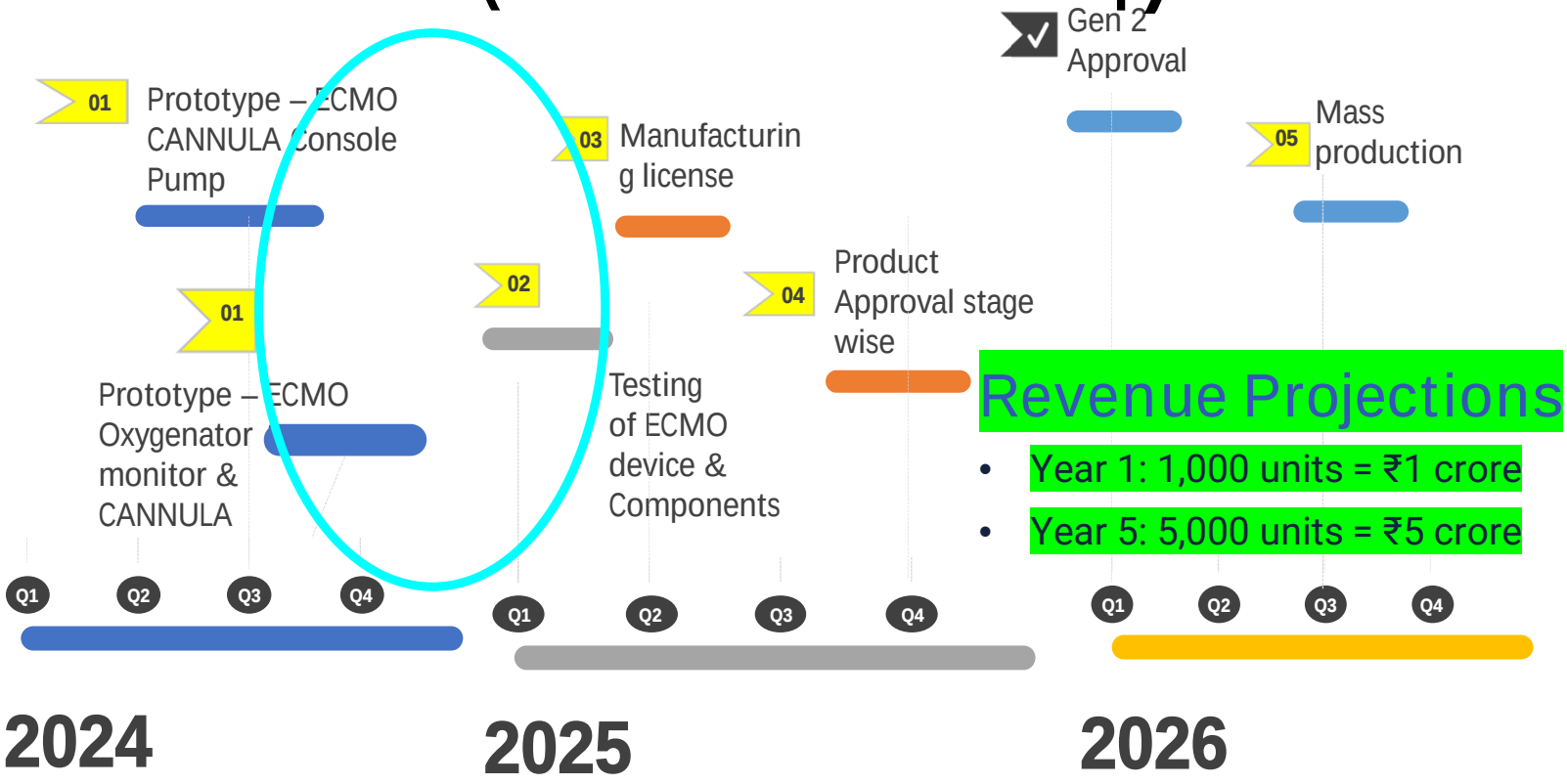
Exports begin from Year 2





Roadmap & Milestones

TIME LINE (ECMO CANNULA Roadmap)



Revenue Projections

- Year 1: 1,000 units = ₹1 crore
- Year 5: 5,000 units = ₹5 crore

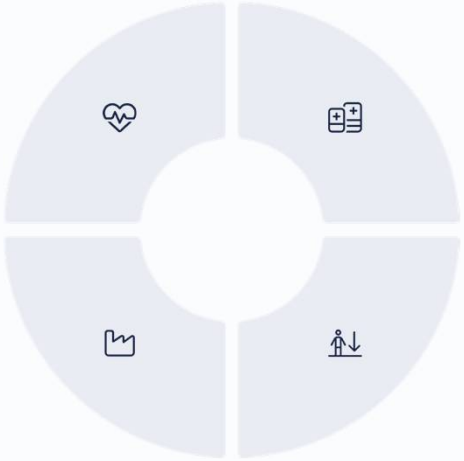
Competitive Landscape

Company	Local Manufg	Cost Efficiency	Design Innovation	Delivery Speed
GO Realism	Yes	High	High	Fast
Meditronics	Yes	Medium	Medium	Medium
GRK Medical	No	Low	Low	Slow
Imported Brands	No	Very Low	Medium	Very Slow

Impact & Vision

Lives Saved

Saving over 2.5 lakh lives annually through accessible ECMO.



ICU Empowerment

Empowering Indian ICUs with affordable, quality technology.

Make in India

Enabling "Make in India" in critical care.

Self-Reliance

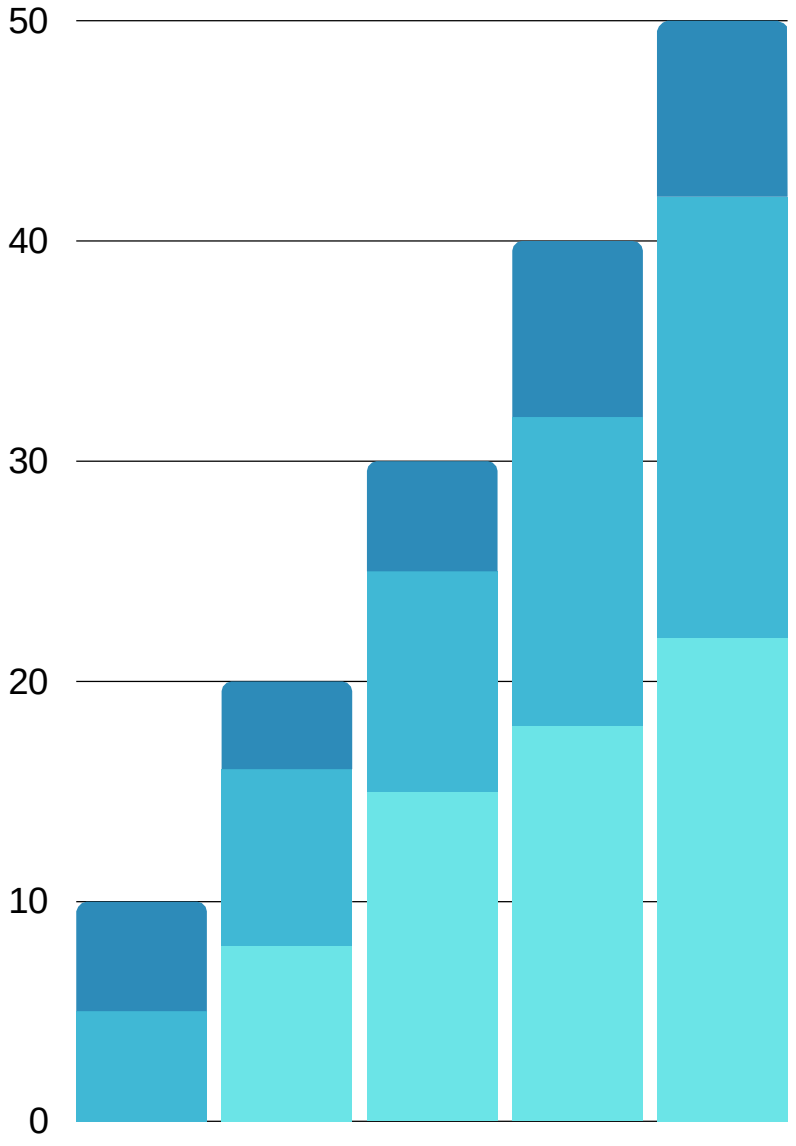
Reducing national dependency on imports.

GO-TO-MARKET STRATEGY

- Leading ECMO Education: Since 2010, we have trained over 1,000 professionals from 70 corporate hospitals across 20 states, running fellowship programs and publishing the Indian Journal of ECMO (IJE).

- Trusted Authority: As pioneers in ECMO science in India, our initiatives, including plans for an Indian College of ECMO, have earned national recognition and trust.

- Unique Market Position: strong mentor-student network and anticipation for our economical, multifunctional, Made in India ECMO circuit, we are set to redefine the industry.



Go-to-Market Strategy

ECMO Network

Leverage ECMO training network and fellowships.

Hospital Engagement

Engage Tier-1 hospitals through workshops and demo.

Government Tenders

Government tender applications (PMJAY, ESIC).

Medical Outreach

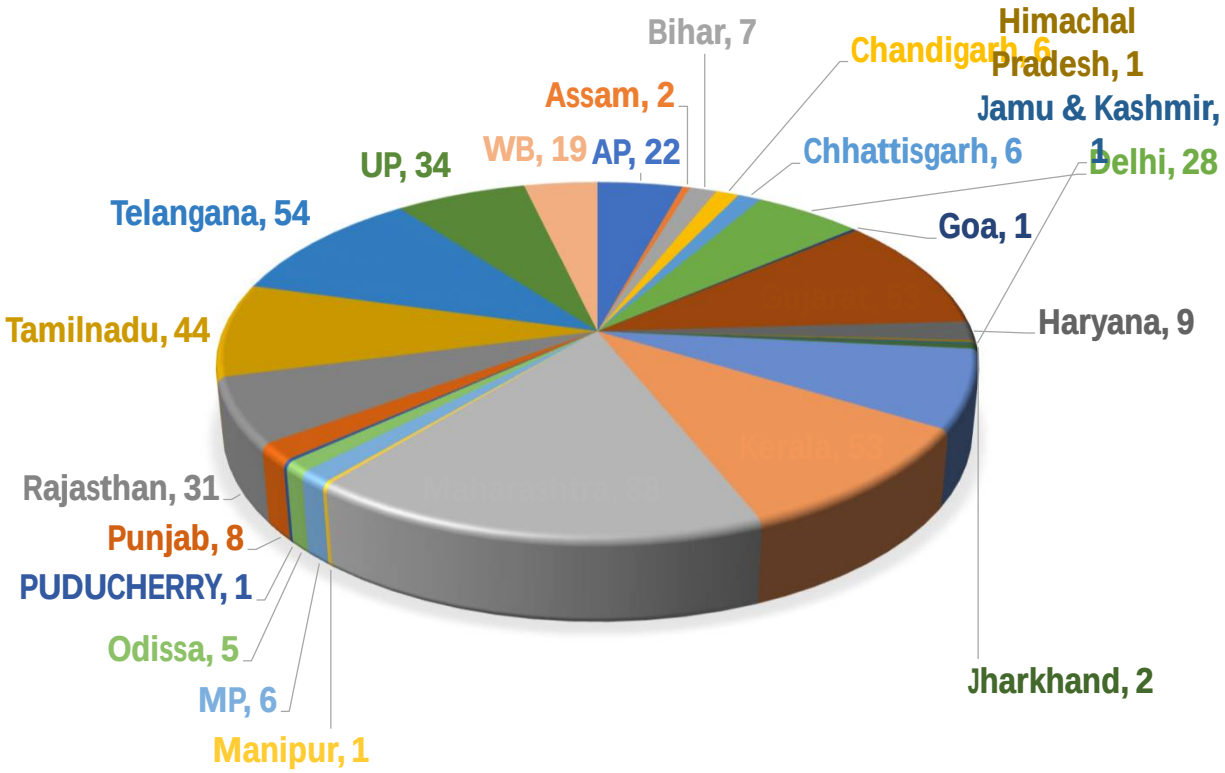
Medical conferences, CME, and journal advertising.

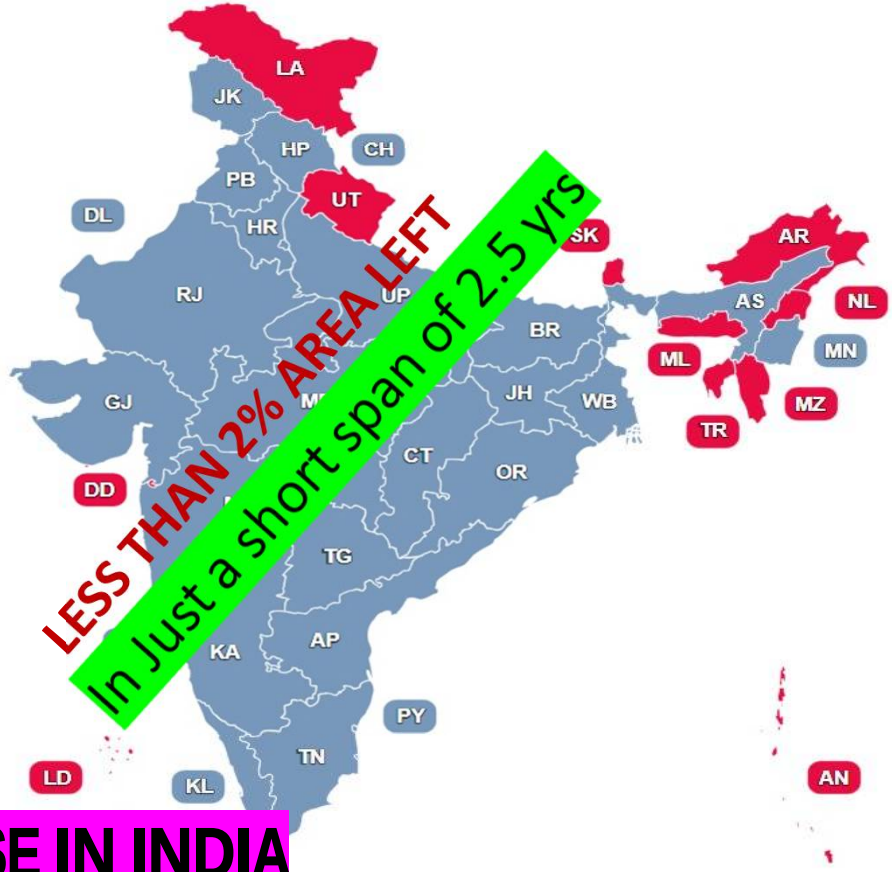
Export Markets

Export distributors in Africa & Asia.

Digital Strategy

Targeted digital marketing and educational webinars.





ESOI - ELSO ENDORSED OUT REACH COURSE IN INDIA

Revised Budget – 011224
ECMO components Manufacturing

At present manufacturing is outsourced to SGLS Pvt Ltd, Hyderabad
then – Indigenous manufacturing plant at Mumbai

SN	Product name	Rough estimate (in Lakhs)
1	ECMO Console – Prototype, Raw material,	50
2	ECMO PUMP – Prototype making, Raw material, mold making	100
3	ECMO Oxygenator – Prototype, Raw material & mold making	100
4	Automation for Oxygenator	25
5	ECMO heater unit - Prototype, Raw material & mold making	50
6	ECMO Circuit - Prototype, Raw material & mold making	45
7	ECMO Monitor – Prototype & Designing manufacturing	50
8	ECMO Cannula - Prototype & Designing manufacturing	100
9	Digital Blender	25
10	Device approval & market Launch	55
	Total	600

6. Revenue model

- Financial Income source ------- ------ SELF FUNDING
  - Sale of cannula
- Channels of revenue
  - Self Funding
  - Bank Loans
  - Start up Schemes & SEED Funding
- Pricing model being charged to the target customer
  - End user – MRP - Rs 15,000 / piece which is less than international brands (Say Rs 25000),
  - Stockist / Distributor (Purchase Price – Rs 10,000 / piece)
  - Around Rs 20000– 40000 profit per cannula
- Pricing slabs for different customer segments
  - Export to Asia & Africa
- Cost-Effectiveness Analysis:
  - Comparison of pricing with that of competitors absolutely needed
  - Compare production and selling costs with imported cannula.
  - Highlight cost savings for hospitals using local cannula (~30-40% cheaper).

- Projected Revenue overhead expenses in 3 years
  - Revenue Diversification
    - Cannula Sales: 80% of revenue.
    - After-Sales Support and Training: 10%.
    - Exports: 10% (from Year 2 onward).
    - This model leverages India's growing healthcare market and the need for cost-effective ECMO solutions.

Business Plan – Revenue Target for ECMO Cannula

Our target customers include:

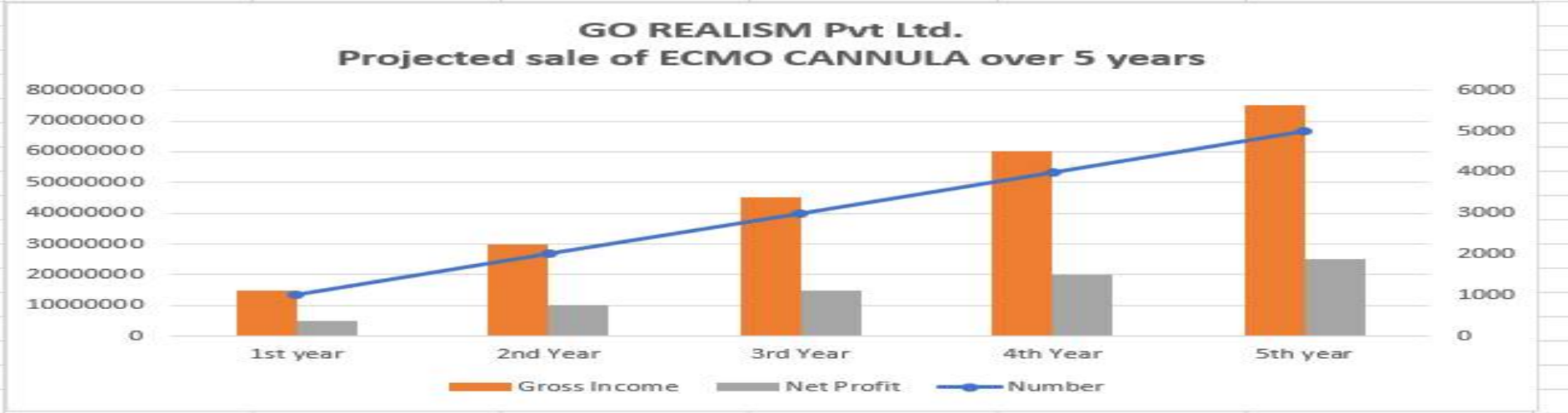
• All Corporate & private Critical centres with ECMO facility in India

• Government & semi government hospitals with tertiary care set up in India

•Exporting ECMO & related disposables in Resource limited countries

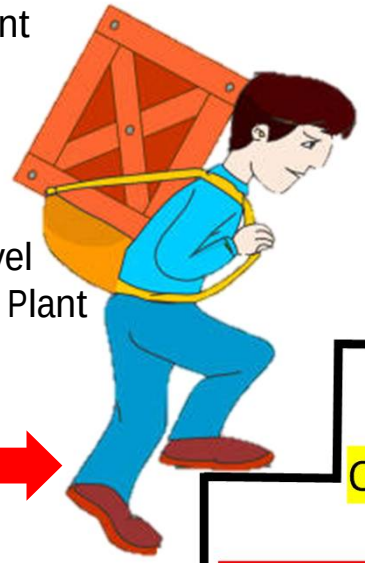
Projection Report of sale of ECMO cannula (@15000 / cannula)

Year	1st year	2nd Year	3rd Year	4th Year	5th year
Number	1000	2000	3000	4000	5000
Gross Incon	15000000	30000000	45000000	60000000	75000000
Net Profit	5000000	10000000	15000000	20000000	25000000



Medical Science based Deep Tech Start up Journey for Human Application

No workshop
Team under development
Initial Outsourcing
80 % Time wastage
Limitations of work
Reinvent the wheel
Component level
Manufacturing Plant
Mission to practice
– cost economy



WE ARE HERE

Final production and assembly under one roof

Indigenous Components development

Class C products, Clinical Trials, CDSCO approval

Outsource manufacturing and imports to meet standards (Make in India)

Product – 2 stages - A. Market level (90%) B. Innovation (10%)

Prototype – Patents – Test Licenses – Regulatory
(Self Funded)

Ideation – Proof of Concept (Self Funded)

Doctors to Entrepreneurs (Engineers)



Plan of action

Looking for grants to pursue our MISSION

Call to Action

Contact: eclsbharatpl@gmail.com

Website: www.eclsbharat.com

Contact ...

Visit Website

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