TECHNICAL SPECIFICATIONS

Temporary Percutaneous Mechanical Circulatory Support (pMCS) / Intravascular Microaxial Blood Pump System

Department: National Cardiac Centre (NCC), IGMH/MCGH
Purpose: Protected PCI and Cardiogenic Shock Program

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1. SYSTEM OVERVIEW

The offered system shall be a catheter-based temporary mechanical circulatory support platform designed to provide active ventricular unloading and forward blood flow support in patients with:

1. High-risk/complex Protected Percutaneous Coronary Intervention (PCI)
2. Acute cardiogenic shock of various etiologies including:
    - Acute myocardial infarction-related cardiogenic shock
    - Acute decompensated heart failure
    - Post-cardiotomy shock
    - Myocarditis
    - Bridge to recovery
    - Bridge to decision
    - Bridge to advanced therapy

The system shall provide:

- Left ventricular support
- Right ventricular support
- Escalation capability for higher circulatory support when required
- Real-time hemodynamic monitoring
- Intelligent positioning and alarm management
- Transport capability between ICU, cath lab, OT and imaging areas

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2. CONSOLE / AUTOMATED CONTROLLER SPECIFICATIONS

The system shall include an intelligent automated controller with:

User Interface

- Medical-grade touchscreen display
- Minimum 10-inch color display
- Intuitive graphical user interface
- Real-time display of:
    - Pump flow
    - Pump speed
    - Motor current

    - Pressure waveforms
    - Placement signals
    - Purge parameters
    - Alarm status
    - System diagnostics

Power Supply

- AC power operation
- Integrated rechargeable battery
- Battery backup minimum: ≥60 minutes
- Capability for uninterrupted patient transport

Data Storage

System shall provide:

- Continuous recording of hemodynamic data
- Minimum storage capacity: ≥24 hours
- USB/export capability
- Network connectivity capability
- Remote monitoring capability

Safety Features

Automated detection of:

- Suction events
- Pump malposition
- Reduced flow
- Purge failure
- Motor malfunction
- Pressure abnormalities
- System disconnection

Alarm system shall include:

- Audible alarms
- Visual alarms
- Priority-based alarm hierarchy

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3. PUMP CATHETER SPECIFICATIONS

System shall support multiple catheter options including:

Left Ventricular Support Pumps

Must provide:

- Peak flow ≥3.5–5.5 L/min depending on model
- Active ventricular unloading

- Forward systemic circulation support

Right Ventricular Support Pumps

Must provide:

- Flow ≥4.0 L/min

Pump Technology

Pump shall include:

- Distal microaxial motor
- Integrated impeller
- Continuous flow mechanism
- Flexible atraumatic distal segment
- Radiopaque markers

Catheter Characteristics

Catheter system shall:

- Be suitable for percutaneous vascular access
- Support femoral and/or axillary approaches
- Include dedicated introducer kits
- Include guidewire compatibility
- Include hemostatic access systems

Duration of Support

System shall support:

- High-risk PCI: ≥6 hours
- Cardiogenic shock support: up to 14 days or manufacturer's maximum approved duration

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4. HEMODYNAMIC INTELLIGENCE PLATFORM

System shall provide advanced monitoring including:

Real-time calculations:

- Cardiac output
- Cardiac power output (CPO)
- Mean arterial pressure
- Heart rate
- LVEDP trend
- Flow trend analysis

Smart positioning assistance:

System shall include:

- Placement guidance
- Position verification
- Stability indicators
- Automatic position monitoring

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5. CONSUMABLES

Bidder shall provide sterile single-use consumables:

Pump Catheters

Including:

- Standard support pump
- High-flow pump
- Right ventricular support pump

Access Kits

Including:

- Introducer sheaths
- Dilators
- Peel-away systems
- Hemostatic valves

Guidewires

Including:

- Shapeable guidewires
- Ventricular placement wires

Purge System Components

Including:

- Sterile purge cassette
- Tubing
- Accessories

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6. CLINICAL APPLICATIONS

System shall be approved/indicated for:

Protected PCI

Including:

- Unprotected left main intervention
- Last remaining vessel
- Severe LV dysfunction
- Complex multivessel PCI
- Atherectomy-supported procedures

- CTO interventions
- Complex bifurcation intervention

Cardiogenic Shock

Including:

- AMI cardiogenic shock
- Acute decompensated heart failure
- Myocarditis
- Bridge-to-recovery
- Bridge-to-decision

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7. TRAINING REQUIREMENTS

Vendor shall provide:

Clinical Training

- Initial physician training
- Cath lab nurse training
- ICU nurse training
- CVT training
- Biomedical engineer training

Minimum:

- 5 days on-site training

Proctorship Support

Vendor shall provide:

- Initial case support
- Clinical application specialist support
- Emergency remote support

Minimum: First 5-10 cases

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8. WARRANTY AND AFTER-SALES SUPPORT

Vendor shall provide:

Warranty

Minimum:

- One-year comprehensive warranty

Covering:

- Console
- Accessories
- Parts
- Labor

Service Requirements

- Preventive maintenance twice yearly
- Maximum service response time: ≤24 hours
- Availability of spare parts: Minimum 10 years
- Local or regional technical support availability

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9. DOCUMENTATION REQUIREMENTS

Bidder shall provide:

- CE and/or FDA approval
- Product catalogue
- Technical data sheets
- User manuals
- Installation requirements
- Consumable list with item codes
- Clinical evidence/publications
- Regulatory certificates

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10. BID EVALUATION PREFERENCE (OPTIONAL SECTION)

Preference may be given for systems with:

- Ability to escalate support without console replacement
- Integrated right ventricular support platform
- Smart sensor technology
- Axillary ambulatory support capability
- Remote monitoring capability
- Established international shock program experience
- Demonstrated clinical evidence for Protected PCI and cardiogenic shock