Technical Specifications

Tender for Coronary Intravascular Lithotripsy (IVL) System and Catheters

National Cardiac Centre (NCC) / IGMH / Dharumavantha Hospital

Purpose:
Procurement of a Coronary Intravascular Lithotripsy (IVL) System including generator, connectors, accessories, and disposable IVL catheters for the treatment of severely calcified coronary artery disease during percutaneous coronary intervention (PCI).

The system offered may be from any internationally recognized manufacturer compliant with applicable regulatory and safety standards. Equivalent technologies meeting the specifications below shall be accepted.

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1. GENERAL REQUIREMENTS

1.1 The offered device shall be specifically designed for treatment of severely calcified coronary artery lesions prior to stent implantation.

1.2 The system shall utilize sonic pressure wave / lithotripsy energy technology to fracture intimal and medial coronary calcium while allowing low-pressure balloon dilatation.

1.3 The system shall be approved by at least one of the following:

- US FDA
- CE Mark (European Union)
- UKCA
- PMDA Japan
- Other internationally recognized regulatory authority

1.4 The manufacturer shall have established clinical evidence and published data supporting safety and efficacy in coronary artery calcification treatment.

1.5 Vendor shall provide:

- Product brochures
- IFU (Instructions for Use)
- Clinical literature/publications
- Regulatory certificates
- Warranty documentation

2. SYSTEM REQUIREMENTS

2.1 IVL Generator / Console

The system shall include a reusable IVL generator/console capable of delivering lithotripsy pulses to coronary IVL catheters.

The generator shall:

- Be compact and cath-lab compatible
- Operate on standard hospital electrical supply
- Have touchscreen or digital user interface
- Display:
    - Number of delivered pulses
    - Remaining pulses
    - Treatment status
    - System alerts/errors
- Include audible and visual alarms
- Allow rapid setup and operation during PCI procedures
- Include foot pedal or hand activation mechanism if applicable
- Be compatible with all supplied catheter sizes

Safety Features

- Automatic pulse counting
- Overpressure protection
- Self-system diagnostic checks
- Electrical safety certification compliant with IEC standards

Accessories

Vendor shall include:

- Connecting cables
- Charging modules/power supply
- Transport/storage accessories

- User manuals
- Backup connectors as required

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3. CORONARY IVL CATHETER REQUIREMENTS

3.1 General Specifications

The catheter shall:

- Be specifically designed for coronary artery use
- Be rapid exchange (RX/monorail) type
- Be compatible with standard 0.014" coronary guidewires
- Be compatible with 6F guide catheters or smaller where applicable
- Permit low-pressure balloon inflation during lithotripsy
- Have integrated lithotripsy emitters within balloon segment
- Be sterile and single use
- Be individually packed

3.2 Balloon Characteristics

The balloon shall:

- Be semi-compliant or equivalent design suitable for coronary IVL
- Be capable of delivering lithotripsy pulses circumferentially
- Allow inflation at low nominal pressures
- Have radiopaque markers
- Have hydrophilic coating or equivalent deliverability enhancement
- Be designed for tortuous and calcified anatomy
- Have enhanced crossing profile suitable for complex lesions

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3.3 Sizes Required

The vendor shall supply multiple sizes including but not limited to:

Diameter	Length
2.5 mm	12 mm
3.0 mm	12 mm
3.5 mm	12 mm
4.0 mm	12 mm

Equivalent or additional sizes may also be quoted.

3.4 Technical Requirements

The catheter shall preferably have:

- Crossing profile ≤ 0.050"
- Working length approximately 135–140 cm
- Tip profile optimized for lesion crossing
- Multiple lithotripsy emitters
- Minimum 80–120 pulses per catheter
- Capability for multiple treatment cycles
- Flexibility suitable for distal vessel delivery

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4. CLINICAL PERFORMANCE REQUIREMENTS

The offered system should demonstrate:

- Effective calcium modification in severely calcified coronary lesions
- Facilitation of optimal stent expansion
- Reduced need for high-pressure balloon inflations
- Compatibility with imaging-guided PCI (IVUS/OCT)
- Suitability for:
    - Left main PCI
    - Bifurcation lesions
    - Long calcific lesions

- Underexpanded stents (if IFU approved)
- High-risk PCI

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5. TRAINING & SUPPORT

Vendor shall provide:

- Initial onsite clinical training
- Physician education and proctorship support if required
- Cath lab staff training
- Biomedical engineering orientation
- Application specialist support during initial cases

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6. WARRANTY & SERVICE

Generator Warranty

- Minimum 2-year warranty

Service Requirements

Vendor shall provide:

- Preventive maintenance
- Technical support
- Availability of spare parts
- Service response time declaration
- Local or regional technical support details

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7. DOCUMENTATION REQUIRED WITH BID

Bidders shall submit:

- Technical compliance sheet
- Product catalogues/brochures
- Regulatory approvals

- IFU documents
- Clinical evidence/publications
- Warranty declaration
- List of installations in region/internationally

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8. COMPLIANCE STATEMENT

Bidders must provide a point-by-point compliance statement against each technical specification indicating:

- “Comply”
- “Partially Comply”
- “Does Not Comply”

Supporting documentary evidence shall be attached.

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9. OPTIONAL PREFERABLE FEATURES

Preference may be given to systems with:

- Enhanced deliverability technology
- Shorter recharge/pause time between pulse cycles
- Improved re-crossing/re-wrap capability
- Advanced hydrophilic coating
- Lower crossing profile
- Clinical data from large multicenter studies
- Compatibility with contemporary complex PCI techniques