

Corrigendum

In tender document Tender Enquiry No.24/Iplant/154/2016-RISH (ADMN)

Dated: 29-09-2016

As per schedule, Pre- Bid meeting of "Tender for Implant for Department of Cardiology" was held on 20-10-2016 at 03.00 PM, in the tender opening room.

After consideration by Store Purchase Committee following modification (deletions/additions/replacements) for Tender Enquiry No. 24/Implant/154/2016-RISH (ADMN) has been made.

Group B, Items no. 1 to 14 at page no. 21 to 23 now read as:-

GROUP B: VASCULAR STENTS/ PERIPHERAL

STENTS for Items no. 01 to 14 now may be read as:-

ITEM NO. 1: BALLOON EXPANDABLE (PREMOUNTED) VASCULAR STENTS USFDA APPROVED

Approved for pediatric and adult use

Available in various lengths and diameters

1a. Peripheral Stents dedicated for upper limb & lower limb arteries

1b. Carotid Stents

1c. Renal Stents

1d. Others

ITEM NO. 2: BALLOON EXPANDABLE (PREMOUNTED) VASCULAR STENTS- CE MARKED

Approved for pediatric and adult use

Available in various lengths and diameters

2a. Peripheral Stents dedicated for upper limb & lower limb arteries

2b. Carotid Stents

2c. Renal Stents

2d. Others

ITEM NO. 3: BALLOON EXPANDABLE (PREMOUNTED) VASCULAR STENTS- APPROVED BY DCGI

Approved for pediatric and adult use

Available in various lengths and diameters

3a. Peripheral Stents dedicated for upper limb & lower limb arteries

3b. Carotid Stents

3c. Renal Stents

3d. Others

ITEM NO. 4: BALLOON EXPANDABLE VASCULAR STENTS -USFDA APPROVED

Approved for pediatric and adult use

Available in various lengths and diameters

The stent must not be premounted on balloon

4a. Peripheral Stents dedicated for upper limb & lower limb arteries

4b. Carotid Stents

4c. Renal Stents

4d. Others

ITEM NO. 5: BALLOON EXPANDABLE VASCULAR STENTS- CE MARKED

Approved for pediatric and adult use

Available in various lengths and diameters

The stent must not be premounted on balloon

5a. Peripheral Stents dedicated for upper limb & lower limb arteries

5b. Carotid Stents

5c. Renal Stents

5d. Others

ITEM NO. 6: BALLOON EXPANDABLE VASCULAR STENTS- APPROVED BY DCGI

Approved for pediatric and adult use

Available in various lengths and diameters

The stent must not be premounted on balloon

6a. Peripheral Stents dedicated for upper limb & lower limb arteries

6b. Carotid Stents

6c. Renal Stents

6d. Others

ITEM NO. 7: SELF EXPANDING VASCULAR STENTS- FDA APPROVED

Approved for pediatric and adult use

Available in various lengths and diameters

7a. Peripheral Stents dedicated for upper limb & lower limb arteries

7b. Carotid Stents

7c. Renal Stents

7d. Others

ITEM NO. 8: SELF EXPANDING VASCULAR STENTS- CE MARKED

Approved for pediatric and adult use

Available in various lengths and diameters

8a. Peripheral Stents dedicated for upper limb & lower limb arteries

8b. Carotid Stents

8c. Renal Stents

8d. Others

ITEM NO. 9: SELF EXPANDING VASCULAR STENTS- APPROVED BY DCGI

Approved for pediatric and adult use

Available in various lengths and diameters

9a. Peripheral Stents dedicated for upper limb & lower limb arteries

9b. Carotid Stents

9c. Renal Stents

9d. Others

ITEM NO. 10: PTFE COVERED, PREMOUNTED BALLOON EXPANDABLE VASCULAR STENTS - 5-10 mm DIAMETER

Should be available in 5, 6, 7, 8, 9 & 10mm diameter sizes

Should be compatible with 6 – 7 Fr sheath

Should have low crossing profile

10a. Peripheral Stents dedicated for upper limb & lower limb arteries

10b. Carotid Stents

10c. Renal Stents

10d. Others

ITEM NO. 11: PTFE COVERED, PREMOUNTED BALLOON EXPANDABLE VASCULAR STENTS - 12-16 mm DIAMETER

Should be available in 12, 14 & 16mm diameter sizes

Should be compatible with 9- 11 Fr sheath

Should have low crossing profile

11a. Peripheral Stents dedicated for upper limb & lower limb arteries

11b. Carotid Stents

11c. Renal Stents

11d. Others

ITEM NO. 12: BALLOON EXPANDABLE VASCULAR STENTS PREMOUNTED ON BALLOON-IN-BALLOON (BIB) CATHETER

12a. Peripheral Stents dedicated for upper limb & lower limb arteries

12b. Carotid Stents

12c. Renal Stents

12d. Others

ITEM NO. 13: BALLOON EXPANDABLE COVERED VASCULAR STENTS PREMOUNTED ON BALLOON-IN-BALLOON (BIB)

CATHETER

13a. Peripheral Stents dedicated for upper limb & lower limb arteries

13b. Carotid Stents

13c. Renal Stents

13d. Others

ITEM NO. 14: SELF- EXPANDABLE COVERED VASCULAR STENTS

14a. Peripheral Stents dedicated for upper limb & lower limb arteries

14b. Carotid Stents

14c. Renal Stents

14d. Others

Following item is being added in Group B after Item no. 14:-

ITEM NO. 15: Vascular Mimetic Implant

To use in distal SFA & Popliteal arteries

ITEM NO. 16: Distal Embolic Protection Device/ filter to be used during Carotid Angioplasty & Stenting

16a. USFDA approved

16b. CE approved

16c. DCGI approved

ITEM NO. 17: Distal Embolic Protection Device/ Filter for SVG coronary grafts intervention 6F compatible

17a. USFDA approved

17b. CE approved

17c. DCGI approved

ITEM NO. 18: "Intra-aortic balloon catheter & insertion kit" (Complete IAB system) compatible with available machine

in cardiology department, i.e. "DATASCOPE, Maquet- CS 100."

- 7 Fr or above compatible

- IABP Balloon should be available in all sizes, eg. 25 cc, 34 cc, 40 cc, etc.

- Should include Intra-aortic balloon catheter & insertion kit and all other accessories needed.

GROUP D1 TO GROUP D18 at page no 29-32 NOW READ AS:-

GROUP D1: Pacemaker VVI/ AAI, USFDA APPROVED.

Advanced digital multi-programmable pacemaker with following features

>Single chamber pacemaker

>Digital signal processing

>Digital high sampling rates of P or R wave

Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting

>Algorithm to minimize ventricular pacing will be preferred

a) With 6F/7F compatible passive fixation tined leads or screws in lead & lead introducer.

b) Pulse generator only

c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D2: Pacemaker VVI/ AAI, CE APPROVED.

Advanced digital multi-programmable pacemaker with following features

>Single chamber pacemaker

>Digital signal processing

>Digital high sampling rates of P or R wave

Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting

>Algorithm to minimize ventricular pacing will be preferred

a) With 6F/7F compatible passive fixation tined leads or screws in lead & lead introducer.

b) Pulse generator only

c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D3: Pacemaker VVIR/AAIR, USFDA APPROVED.

Advanced digital multi-programmable pacemaker with following features

>Single chamber pacemaker

>Digital signal processing

>Digital high sampling rates of P or R wave

Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting

>Algorithm to minimize ventricular pacing will be preferred

a) With 6F/7F compatible passive fixation tined leads or screws in lead & lead introducer.

b) Pulse generator only

c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D4: Pacemaker VVIR/AAIR, CE APPROVED.

Advanced digital multi-programmable pacemaker with following features

>Single chamber pacemaker

>Digital signal processing

>Digital high sampling rates of P or R wave

Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting

>Algorithm to minimize ventricular pacing will be preferred

a) With 6F/7F compatible passive fixation tined leads or screws in lead & lead introducer.

b) Pulse generator only

c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D5: Pacemaker VDD, USFDA APPROVED.

Pace Advanced digital multi-programmable pacemaker with following features—

>Single and dual chamber pacemaker

>Digital signal processing

>Digital high sampling rates of P and R wave

>Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting

>Algorithm to minimize ventricular pacing will be preferred

a) With 7F/8F/9F compatible passive fixation tined lead or screw in lead & lead introducer.

b) Pulse generator only

c) 7F/8F/9F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D6: Pacemaker VDD, CE APPROVED.

Pace Advanced digital multi-programmable pacemaker with following features—

>Single and dual chamber pacemaker

>Digital signal processing

>Digital high sampling rates of P and R wave

>Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting

>Algorithm to minimize ventricular pacing will be preferred

a) With 7F/8F/9F compatible passive fixation tined lead or screw in lead & lead introducer.

b) Pulse generator only

c) 7F/8F/9F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D7: Pacemaker DDD, USFDA APPROVED.

Advanced digital multi-programmable pacemaker with following features—

- >Single and dual chamber pacemaker
- >Digital signal processing
- >Digital high sampling rates of P and R wave
- >Automated ventricular rate stabilization during AF
- >Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting
- >Algorithm to minimize ventricular pacing will be preferred
- a) With 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer.
- b) Pulse generator only
- c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D8: Pacemaker DDD, CE APPROVED.

Advanced digital multi-programmable pacemaker with following features—

- >Single and dual chamber pacemaker
- >Digital signal processing
- >Digital high sampling rates of P and R wave
- >Automated ventricular rate stabilization during AF
- >Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting
- >Algorithm to minimize ventricular pacing will be preferred
- a) With 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer.
- b) Pulse generator only
- c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D9: Pacemaker DDDR, USFDA APPROVED.

Advanced digital multi-programmable pacemaker with following features—

- >Single and dual chamber pacemaker
- >Digital signal processing
- >Digital high sampling rates of P and R wave
- >Automated ventricular rate stabilization during AF
- >Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting
- >Algorithm to minimize ventricular pacing will be preferred
- a) With 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer.
- b) Pulse generator only
- c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D10: Pacemaker DDDR, CE APPROVED.

Advanced digital multi-programmable pacemaker with following features—

- >Single and dual chamber pacemaker
- >Digital signal processing
- >Digital high sampling rates of P and R wave
- >Automated ventricular rate stabilization during AF
- >Quick single window patient data and pacemaker data for advanced diagnostic and troubleshooting
- >Algorithm to minimize ventricular pacing will be preferred
- a) With 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer.
- b) Pulse generator only
- c) 6F/7F compatible passive fixation tined lead or screw in lead & lead introducer only.

GROUP D11: Pacemaker DDDR, full body MRI COMPATIBLE with passive fixation steroid tipped tined leads or screw inleads with advanced features, USFDA APPROVED.

GROUP D12: Pacemaker DDDR, full body MRI COMPATIBLE with passive fixation steroid tipped tined leads or screw inleads with advanced features, CE APPROVED.

GROUP D13: Pacemaker VVIR, full body MRI COMPATIBLE with passive fixation steroid tipped tined leads or screw in leads with advanced features, USFDA APPROVED.

GROUP D14: Pacemaker VVIR, full body MRI COMPATIBLE with passive fixation steroid tipped tined leads or screw inleads with advanced features, CE APPROVED.

GROUP D15: Permanent pacing lead (ventricular/Atrial endocardialbipolar, passive fixation with tines), steroid eluting, IS-1 header,USFDA Approved.

GROUP D16: Permanent pacing lead (ventricular/Atrial endocardialbipolar, passive fixation with tines), steroid eluting, IS-1 header, CE Approved.

GROUP D17: Permanent pacing lead (ventricular/Atrial endocardial bipolar, active fixation with screws), steroid eluting, IS-1 header,USFDA Approved.

GROUP D18: Permanent pacing lead (ventricular/Atrial endocardialbipolar, active fixation with screws), steroid eluting, IS-1 header, CE Approved.

FOLLOWING GROUP IS BEING ADDED AFTER GROUP D18:-

GROUP D19: ICD SINGLE CHAMBER, USFDA APPROVED

- ICD should be small and physiological
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, USFDA Approved
- Device without leads, USFDA Approved

GROUP D20: ICD SINGLE CHAMBER, CE APPROVED

- ICD should be small and physiological
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, CE Approved
- Device without leads, CE Approved

GROUP D21: ICD SINGLE CHAMBER, MRI COMPATIBLE ,USFDA Approved.

- ICD should be full body MRI compatible
- ICD should be small and physiological
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, USFDA Approved
- Device without leads, USFDA Approved

GROUP D22: ICD SINGLE CHAMBER, MRI COMPATIBLE, CE Approved.

- ICD should be full body MRI compatible
- ICD should be small and physiological
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, CE Approved
- Device without leads, CE Approved

GROUP D23: ICD DOUBLE CHAMBER, USFDA APPROVED.

- ICD should be small and physiological
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, USFDA Approved.
- Device without leads, USFDA Approved.

GROUP D24: ICD DOUBLE CHAMBER, CE APPROVED.

- ICD should be small and physiological
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, CE Approved.
- Device without leads, CE Approved.

GROUP D25: ICD DOUBLE CHAMBER, MRI COMPATIBLE,USFDA Approved.

- ICD should be small and physiological
- Full body MRI compatible
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry
- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, USFDA Approved.
- Device without leads, USFDA Approved.

GROUP D26: ICD DOUBLE CHAMBER, MRI COMPATIBLE, CE Approved.

- ICD should be small and physiological
- Full body MRI compatible
- Algorithm to eliminate over –sensing of R wave, T wave, fractionated QRS and other extraneous signals
- Morphology bases SVT discrimination algorithm
- ATP during charging
- Wireless Telemetry

- Encourage intrinsic conduction
- More than 30 minutes of stored EGM,
- Device with all leads, CE Approved.
- Device without leads, CE Approved.

GROUP D27: Permanent defibrillation lead, bipolar endocardial steroid eluting active and passive fixation lead, USFDA Approved.

GROUP D28: Permanent defibrillation lead, bipolar endocardial steroid eluting active and passive fixation lead, CE Approved.

GROUP D29: BIVENTRICULAR PACING CRT-P, USFDA Approved.

- Device with all leads (Including LV leads), USFDA Approved.
- Device without leads, USFDA Approved.
- Device with full body MRI compatibility, USFDA approved
- Device without MRI compatibility, USFDA approved

GROUP D30: BIVENTRICULAR PACING CRT-P, CE Approved.

- Device with all leads (Including LV leads), CE Approved.
- Device without leads, CE Approved.
- Device with full body MRI compatibility, CE approved
- Device without MRI compatibility, CE approved

GROUP D31: BIVENTRICULAR PACING CRT-D COMBO, USFDA Approved.

- Device with all leads (Including LV leads), USFDA Approved.
- Device without leads, USFDA Approved.
- Device with full body MRI compatibility, USFDA approved
- Device without MRI compatibility, USFDA approved

GROUP D32: BIVENTRICULAR PACING CRT-D COMBO, CE Approved.

- Device with all leads (Including LV leads), CE Approved.
- Device without leads, CE Approved.
- Device with full body MRI compatibility, CE approved
- Device without MRI compatibility, CE approved

GROUP D33: LV leads, all types (Bipolar, Quadripolar, Multisite, etc.), USFDA approved

GROUP D34: LV leads, all types (Bipolar, Quadripolar, Multisite, etc.), CE approved

GROUP D35: LV lead delivery system (Dedicated catheter for engaging/hooks coronary sinus, CS subselector, etc.), USFDA approved

GROUP D36: LV lead delivery system (Dedicated catheter forengaging/hooks coronary sinus, CS subselector, etc.), CE approved

GROUP D37: "Leadless Pacemaker" with delivery system and all the necessary accessories, USFDA approved.

- Price should be quoted with all the necessary accessories & complete delivery system.

GROUP D38: "Leadless Pacemaker" with delivery system and all the necessary accessories, CE approved.

- Price should be quoted with all the necessary accessories & complete delivery system.

GROUP D39: Implantable Loop Recorder

- MRI Conditional with 1.5 T & 3.0 T System

- 3 years of longevity
- Ability to recorder AT/AF Burden
- Ability to record Brady , Tachy Episodes
- Patient triggered ECG Storage

GROUP D40: Implantable Loop Recorder - Miniaturize

- Implantable Loop Recorder < 1.5 cc
- MRI Conditional with 1.5 T & 3.0 T System
- Mass < 3.0 gram
- Injectable system to deploy
- 3 years of longevity
- 57 minutes of ECG Storage
- Ability to recorder AT/AF Burden
- Ability to record Brady , Tachy Episodes
- Patient triggered ECG Storage upto 30 minutes.

Note: Last date of submission of bids in respect of aforesaid tender is hereby extended till 09-12-2016 at 03:00 PM and Technical bid will be opened on same day at 03.30 PM.