



Medical College & Hospital, Nagpur

शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, नागपूर
Mahatma Jyotirao Phule Jan Arogya Yojana

महात्मा ज्योतिराव फुले जन आरोग्य योजना

कार्यालयचा पत्ता : औषधालयाचे बाजूला, शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, नागपूर पिन क्र. ४४१२-२७०११००

No.GMCHN/MJPJAY/Ortho/Quot/ Orthopaedic Implants / 650/2025
Quotation Enquiry.

Date: 18 /03 / 2025

To,

Subject: - Quotation Enquiry for "Orthopaedic Implants" under Two Envelope system

The undersigned invited sealed quotations for the items mentioned below/on/reverse or as per enclosed statement for the use of the MJPJAY, Govt. Medical College & Hospital, Nagpur under Two Envelope (Two Bid) system on the following terms & conditions.

Whole tender procedure is being conducted by MJPJAY office for supply of Implants required for MJPJAY beneficiary patients.

- 1) The prices quoted should be free delivery to MJPJAY Store, Govt. Medical College & Hospital premises purely on patient-to-Patient basis for local dealers and F.O.R. Destination for outsiders.
- 2) Approved (L₁) Implant and its complete instrument sets should be made available by 3pm one day prior to surgery for elective cases.
- 3) Approved (L₁) Implant and its complete instrument sets should be available Immediately for emergency cases under ETI
- 4) L₂, L₃ or other approved vendors should supply implant in case L₁ is not able to supply the Implant. (As per Government Rule)
- 5) The Price quoted should be inclusive of all taxes, duties if payable like customs, excise, GST. The GST number should be quoted in your letter while quoting the rates. Exemption of taxes, if on A.F. Forms etc. be separately stated.
- 6) The serial number of the items should not be changed while quoting rates. You may drop the Item if not interested & List should be prepared in printed copy only, otherwise it may be rejected.
- 7) Rates should be quoted strictly for the item specified in the list provided and for standard quality of goods. In case of alternate offer, the detailed specifications, name of manufacturer or make etc must invariably be stated. Specifications other than specified in the schedule may be liable for rejection even though lowest.
- 8) The quotation submitted will be valid for a period of One Year only, from the date of acceptance.
- 9) Loose packing of material will not be acceptable in any condition.
- 10) The quotation received after due date will not be accepted. The quotation should be submitted in sealed cover. Unsealed quotations, which are not properly sealed, will not be accepted. The last receiving date of the quotation is 24.03.2025 up to 5.00 p.m.
- 11) Material Should be supply In store (MJPJAY) & Your Invoice and challan should have the certification that, the drug/material supplied under this challan & Invoice are of required Pharmacopelal standard and any defect found in future shall be sole responsibility of supplier.
- 12) The Dean, Govt. Medical College & Hospital, Nagpur does not pledge himself to accept the lowest or any quotations and reserves to himself right of acceptance or rejection any of quotations which does not suit to his requirements.
- 13) Vendor should have a Authorization certificate from the manufacturer.
- 14) Supply should be made from WHO GMP / FDA certified company only.
- 15) Please provide attested photocopies of renewed PAN No, GST/CGST/SGST, VAT, CST, Shop establishment, Drug license, Income tax returns for FY 23-24.
- 16) Please provide valid copy of FDA/ISO approval certificate for Vendor as well Manufacturer.
- 17) Please provide Metallurgy certificate of Implants quoted.
- 18) Vendor should have enough experience and capability to supply to college/hospital of this level having such number of beds and patients load
- 19) Vendor should quote only for one company for each Item.
- 20) Vendor should make provision for separate instrument and implant sets exclusively reserved only for this hospital. He should also supply additional sets if multiple patients with similar fracture are posted on same day.
- 21) If L1 vendor is unable to supply the implant for any reason within given time period, they should accordingly inform the office in writing. MJPJAY office has right to give order to L2 vendor, If L1 vendor does not give in writing and is also not supplying implant as per requirement then the order will be given to L2 without informing L1 vendor.
- 22) Supplier should only supply implants of the company quoted in tender, any discrepancy is not acceptable and

- 23) All supplied implant should have embossed company name and batch number on it.
- 24) Order of implant will be given telephonically by the doctor of orthopaedics department. Implant/sets are to be supplied one day before the date of surgery up to 3pm. No sets will be accepted after 3pm and will be considered as Deficiency of service.
- 25) Supplier should supply implant only for the pre-authorization approved patients. Supplier should confirm pre-authorization approval number at MJPJAY office before delivery of implant at OT.
- 26) In case of deficiency in Quality/service of the supplied sets, supplier will be debarred for one year after 3 complaints and supplier with second lowest rate will be selected for supply. Adequacy of quality/service will be decided by end user department in consultation with MJPJAY office.
- 27) Incomplete sets including implants which are short of sizes or screws or absence of Important Instruments will not be accepted and will be considered as deficiency in service. 3 such Incidents If documented by the user department will make the vendor Invalid for the given set.
- 28) Supplier should submit the certified copy of DM at MJPJAY office within 7 days from the date of supply. Certification of DM should only be done by the Incharge of the respective unit. If supplier fails to submit the certified DM within 7 days respective order will be treated as cancelled and payment will not be processed.

- IMP.: 1) Submit sealed quotation under Two Envelope (Two bid) system for supply of Implants.
2) Envelope No. 1 (Technical Bid : Specifications), Compliance Chart & Authorlzation letter, Other Certifications & Necessary Documents.

Sr No	Item Name	Manufacturer

- 3) Envelope No. 2 (Price Bid) submit Items in format mentioned below.

Sr No	Item Name	Manufacturer	Rates per unit (Including GST)

LIST OF ORTHOPEDIC IMPLANT ITEMS for MJPJAY : 2025

ARTHROPLASTY

Sr. No	Item Name	Manufacturer	Rate per unit Including GST)
	PRIMARY HIP REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)		
1	Metal on poly imported UNCEMENTED THR(globally recognized multi national standard company WITH USFDA APPROVAL)		
1a	Imported UNCEMENTED THR with ceramic head (globally recognized multi national standard company WITH USFDA APPROVAL)		
2	Imported uncemented THR, metal on poly with small stem for small anatomy femur(globally recognized multi national standard company WITH USFDA APPROVAL)		
3	Imported THR Hybrid (Cemented cup + Uncemented stem)WITH 40gm cement		
3a	Imported THR reverse Hybrid (uncemented cup + Cemented stem)WITH 40gm cement		
	REVISION HIP REPLACEMENT/ DIFFICULT PRIMARY with IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)		
4a	Imported Hybrid THR with Acetabular MESH WITH CEMENTED CUP WITH UNCEMENTED STEM with 40 gm cement		
4b	Imported Hybrid THR with Acetabular multihole CAGE WITH CEMENTED CUP WITH UNCEMENTED STEM with 40 gm cement		
4c	Imported Hybrid THR with Acetabular multihole CAGE WITH CEMENTED CUP WITH UNCEMENTED LONG STEM with CABLES and 40 gm bone cement		
5a	Imported Cemented THR – metal on poly (Titanium/Corail/HA Type) with 2 Packs 40gm bone cement ,cement restrictor and centralizer		
5b	Femoral long stem-wagner stem		

5c	Femoral long stem Modular S-ROM stem		
5d	Jumbo cup		
5e	Acetabular constrained liner		
	PRIMARY KNEE REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)		
6	Metal Backed Tibia, CS TKR (imported)		
7	All Poly TIBIA WITH CS TKR (Imported)		
7a	Imported TKR with Metal Backed Tibia with Tibial Extension rod- one (with various tibial augments for ex metal blocks, wedges, screws)		
7b	Imported TKR with Metal Backed Tibia with FEMORAL Extension rod (with various femoral augments for ex metal blocks, wedges, screws)		
	REVISION KNEE REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)		
8	Revision TKR WITH METAL BACKED with various augments, wedges and cones. Supplied with pulse lavage		
	SHOULDER AND ELBOW REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)		
9	Total shoulder arthroplasty (imported)		
10	Reverse Total shoulder arthroplasty (imported)		
11	Total Elbow arthroplasty (imported)		
12	Radial head Prosthesis (imported)		
13	Shoulder Hemiarthroplasty (imported)		
	HIP HEMI-ARTHROPLASTY IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)		
14	Uncemented hemiarthroplasty (Imported)- modular		
15	Cemented hemiarthroplasty (Imported)-MODULAR		
	INDIAN IMPLANT FROM A STANDARD INDIAN COMPANY WITH EITHER USFDA AND/OR with EUROPEAN CE CERTIFICATE		
16	Metal on poly Indian uncemented THR (Titanium blasted/corall/HA coated)		
17	Cemented THR Indian with 2 packs bone cement 40gm, cement restrictor, centralizer		
18	Total Elbow arthroplasty (Indian)		
19	Radial head prosthesis (Indian)		
20	Shoulder hemiarthroplasty (Indian)		
21	Uncemented Hemiarthroplasty (Indian) – Modular		


 DEAN
 GOVERNMENT MEDICAL COLLEGE AND HOSPITAL
 NAGPUR

Specifications for uncemented THR

- The system should have acetabular system and femoral stem system separately with accurate fit between acetabular and femoral components.
- Both the acetabular component and femoral component must be of same manufacturer.
- All the products must be US FDA approved compulsorily.
- FDA certificate of distributor/ dealer for stocking and selling of implant must be there.
- Certificate of authorized dealership/ distributorship must be there.
- All implants must have embossed batch number, company name, CE number with Barcoding.
- Implant supplier must supply implant on case-to-case basis.
- Distributer must provide complete instrumentation set for the implant in each case. Implant sizes must be complete WITHOUT FAIL EVERYTIME. Any repetitive absence of implant sizes during Surgery will be considered as a ground for blacklisting of supplier.
- Distributer must supply implant of the company quoted and no other company implant will be accepted.
- Instrument set should be supplied before 4 pm a day prior to surgery.
- Regular implants shall be supplied on same day notice.
- Revision Implants shall be supplied not more than 3 days later
- Local dealership/Distributorship within 10 kms of GMCH Nagpur. Distributer without office in Nagpur will be rejected.
- The acetabular shell, and femoral stem should be made up of surface coated (grid blasted/ plasma sprayed) titanium alloy or trabecular metal/ Hydroxyapatite coated.

- **The acetabular system** should have metal (surface coated titanium alloy) shell of variable sizes ranging from 40 mm to 70 mm with maximum 2 mm increments, 1mm increments will be preferred.
- Poly in all imported implants should be ultra high molecular weight highly crosslinked polyethylene, other polyethylene liners will not be accepted
- Variety of shells according to mode of fixation should be there like, one holed, cluster holed, multi-holed, and spiked holed.
- The shell inserter with adapter with rotational control, ball hex driver, and the provisional shells of sizes corresponding to original shells should be included.
- Cup positioner with alignment guide for lateral and supine position (A frame, Gunsight) should be there to aid in accurate cup positioning.
- Adequate number of screws (at least six) with flexible screwdriver (15mm, 30mm, and 45mm) must be provided in the set.
- Non modular straight screwdriver, screw hole plug instrument, universal handle, ratcheting modular handle, straight/ U joint/ modular flex shaft, adjustable drill guide, hex wrench, depth gauge, and screw holding forceps should be there in the system.
- Each acetabular system must include a polyethylene liner of variable sizes ranging from 22 mm, 26 mm, 32 mm, 38 mm, and 40 mm.
- The material of liner should be of highly crosslinked polyethylene with minimum thickness of 5 mm.
- The outer edge of liner should have variable inclination options like, neutral, 10°, and 20° elevation. 7 mm offset option in liner is desirable.
- Locking mechanism for stability of liner with the shell should be there.

- Liner inserter with dome impactor or hard bearing rim impactor of sizes corresponding to head sizes and disposable suction cup should be included for proper placement of liner.
- Provisional liner with provisional locking system must be there in a separate tray than the implant.
- All instruments for shell and liner placement must have quick release- locking mechanism.
- Removal instruments should be there in case intraoperative removal of liner and/or shell is needed.
- All the implants and instruments of acetabular system must be provided in a stainless steel, autoclavable case with lid.
- *The femoral system* should have stems made of surface coated titanium alloy as mentioned above with length up to 170 mm with variable width and provisional counterpart stem should also be there.
- Collarless/ collared, standard/ tapered, high offset/ varus stem option must be there.
- Fully polished, tapered, and trapezoidal neck must be there with modular option for length and offset according to head sizes.
- Insert hole on the stem for rotation control and threaded femoral inserter during stem insertion must be there.
- Magnetic trunnion of variable sizes should be provided in the set.
- Femoral head should be made up of cobalt chromium molybdenum alloy or oxynium or ceramic.
- Head implants with trials of sizes ranging from 22 mm to 40 mm must be provided.

- Box cutter, canal finder, serial reamers with variable broaches (small/ medium/ large) corresponding to the stem implant must be provided.
- Quick coupling mechanism should be present for easy placement of head and stem.
- Femoral head impactor should be included in the set.
- The instruments and implants should be provided in separate stainless steel, autoclavable case with lid with separate trial tray.
- **Templates for acetabular component and femoral component should be provided for preoperative planning.**
- Implant supplier must supply drill/ saw in each case.

Specifications for imported TKR

- The system should have femoral and tibial component system separately with accurate fit.
- Options for constrained/ semi constrained, PCL sacrificing, standard/ high flex knee system should be there.
- Both the components must be of same manufacturer.
- All the products must be US FDA approved compulsorily.
- FDA certificate of distributor/ dealer for stocking and selling of implant must be there.
- Certificate of authorized dealership/ distributorship must be there.
- All implants must have embossed batch number, company name, CE number with Barcoding.
- Implant supplier must supply implant on case-to-case basis.
- Distributer must provide complete instrumentation set for the implant in each case. Implant sizes must be complete without fail.
- Distributer must supply implant of the company quoted and no other company implant will be accepted.
- Instrument set should be supplied before 4 pm a day prior to surgery.
- Regular implants shall be supplied on same day notice.
- Revision Implants shall be supplied not more than 3 days later
- Local dealership/Distributorship within 10 kms of GMCH Nagpur. Distributer without office in Nagpur will be rejected.
- The femoral and tibial component should be made of fully polished cobalt- chromium alloy.
- ***The femoral components*** should have variable range of sizes with its trial counterpart.

- Instruments with quick coupling mechanism should be provided for easy trial/ implant placement, positioning or removal.
- **The tibial component** should have variable component sizes, stem length should be there with the trial counterpart.
- Tibial insert of highly cross-linked polymer must be there with various thicknesses with its matching trial components.
- Highly crossed linked patellar button should be provided with variable sizes.
- Distributer should provide antibiotic impregnated high viscosity bone cement with each case.
- The implants for femur, tibia should be given in separate autoclavable trays and trials and instruments should be provided in separate tray.
- Implant supplier must supply drill/ saw in each case.