



विशेषी चरुणुडु, प्ररुणुडु ररुडु  
Free Quality Critical Care  
For Low Income Families

Government Medical College & Hospital, Nagpur  
शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, नागपूर

**Mahatma Jyotirao Phule Jan Arogya Yojana**  
महात्मा ज्योतिराव फुले जन आरोग्य योजना

कररुणुडुडुडु डुडुडु : औषधलडुडुडु डुडुडु, शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, नागपूर फोन क. ०७१२-२७०११०० Mail : nagpur.hospital5@gmail.com

No.GMCHN/MJPJAY/Quotation/Ortho/ Implants/ 1154 /2021

Date:- 05.08.2021

**Quotation Enquiry.**

To,

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**Subject :- Quotation Enquiry for " Implants " , Orthopedic Dept. GMCH, Nagpur , under Two Envelope (Two bid) 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.

- 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) **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.
- 3) **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.
- 4) **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 on even though lowest.
- 5) The quotation submitted will be valid for a period of **one year** only from the date of acceptance.
- 6) Loose packing of material will not be acceptable in any condition.
- 7) The quotation should be submitted in inward section of Hospital. 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 or receiving date of the quotation is **07.08.2021** up to 5.00 p.m.
- 8) Condition of advance payment through Bank, part payment etc. will not be accepted.
- 9) **Supply should be made from WHO GMP / FDA certified company only.**
- 10) Quotations if asked with samples, if not accompanies with sample will be liable for rejection even they are lowest. Samples should be sent with a labels attached quoting our ref. no of enquiry and item no etc.



11) 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.

**12) Very Important :-** Please provide valid copy of FDA approval for Vendor as well Manufacturer.

13) Once in a year along with the quotation please provide attested photocopies of renewed PAN No, GST/CGST/SGST, VAT, CST, Shop establishment, Drug licence, Income tax clearance & etc.

- IMP.:**
- 1) Submit sealed quotation under Two Envelope (Two bid) system for supply of implants.
  - 2) Envelope No. 1 (Technical Bid : Specifications), Compliance Chart & Authorization letter, Other Certifications & Necessary Documents.
  - 3) Envelope No. 2 (Price Bid)
  - 4) Specifications available at MJPJAY Office in working hours.

**Required Certificates/ Documents and Terms & Conditions:-**

- 1) FDA certificate of manufacturing of Implant Company.
- 2) FDA certificate of distributor/dealer for stocking and selling of implant.
- 3) Exclusive Certificate of authorized dealership/distributorship.
- 4) CE (European) certificate is desirable.
- 5) Shop gumasta/D.Pharm of the pharmacist.
- 6) GST/IT for last three years
- 7) Raw material quality certificate.
- 8) All implant should have embossed batch number, company name, CE number.
- 9) Implant supplier to provide the implants on Patient to patient basis.
- 10) Implant supplier to provide complete instrumentation set for the implant on loaner basis in each case.
- 11) Implant supplier to get the delivery memo signed by the nursing staff on duty at the time of giving the material.
- 12) Implant suppliers must supply the implants of the quoted company and no other company implant will be entertained.
- 13) If the L1 of particular implant is unable to supply the implant then the issue is to be immediately resolved by giving order to L2 to supply implant at the rate of L1, so that the patient's surgery is not delayed.



	<u>Technical Specification</u>	Quoted/Not Quoted
Sr No	PRIMARY HIP REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNISED MULTINATIONAL STANDARD COMPANY WITH COMPULSARY US-FDA APPROVAL)	
1	Metal on poly, imported, uncemented Total Hip Replacement Set Includes 1 Stem, 1 Acetabular cup, Compatible Liner, Atleast Two screws (globally recognized multi national standard company with CompulsoryUSFDA approval)	
2	Imported uncemented THR, metal on poly with SMALL STEM for small anatomy femur(globally recognized multi national standard company with CompulsoryUSFDA approval)	
3	Imported THR Hybrid ( Cemented cup + Uncemented stem)with 40gm cementwith CompulsoryUSFDA approval .	
4	Imported Uncemented THR with Large Head – Metal on poly (Titanium/Corail/HA Type) Head size 32- size 36 UHMWPE Includes 1 Stem, 1 Acetabular cup, Compatible Liner, Atleast Two screws wherever required	
5	Cemented THR – metal on poly (Titanium/Corail/HA Type) - 2 Packs 40gm bone cement - Cement restrictor and cement gun - Stem Centralizer	
	<b>REVISION HIP REPLACEMENT/ DIFFICULT PRIMARY WITH IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH COMPULSORY US-FDA APPROVAL)</b>	
6	Imported hybrid THR with acetabular mesh with cemented cup with uncemented stem with 40 gm cement with multiple Screws wherever necessary	
7	Imported hybrid THR with acetabular cage with cemented cup with uncemented stem with 40 gm cement with multiple Screws wherever necessary	
8	Femoral long stem- Wagner type stem all sizes with standard Acetabular cup, liner, head and Screws	
9	Femoral long stem Modular S-ROM type(should have variable neck length and variable offset both) stem of all sizes with standard Acetabular cup, liner, head and Screws	
10	JumboAcetabular cup with compatible Liner with femoral stem, Head and Screws	



11	Jumbo Acetabular cup with Acetabular constrained liner with femoral stem, Head and Screws	
12	Mesh/Cage Acetabular plus Constrained Liner plus Revision Femoral stem like S-ROM/Wagner	
	<b>PRIMARY/REVISION KNEE REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH COMPULSORY US-FDA APPROVAL)</b>	
13	Metal Backed Tibia, CS TKR (Imported) includes Femoral Component, Tibial tray with highly cross linked ultra high molecular weight Polyethylene Liner and Patella	
14	All poly tibia with CS TKR (Imported) includes Femoral Component and all poly Tibial component with Patella	
15	Imported TKR with Metal Backed Tibia with Tibial Extension rod of all sizes- one with Femoral Component polyethylene liner and Patella	
16	Imported TKR with Metal Backed Tibia with femoral Extension rod with Tibial component, polyethylene liner and Patella	
17	Imported TKR with Metal Backed Tibia with femoral + tibial Extension rod (with various femoral and tibial augments for ex metal blocks, wedges, screws and cones)	
	<b>SHOULDER AND ELBOW REPLACEMENT IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH US-FDA APPROVAL)</b>	
18	Total shoulder arthroplasty (imported) Modular with cement	
19	Reverse Total shoulder arthroplasty (imported) Modular with cement	
20	Total Elbow arthroplasty (imported) Modular with cement	
21	Radial head Prosthesis (imported) Modular with cement	
22	Shoulder Hemiarthroplasty (imported) Modular with cement	
	<b>HIP HEMI-ARTHROPLASTY IMPORTED IMPLANT (GLOBALLY RECOGNIZED MULTI NATIONAL STANDARD COMPANY WITH COMPULSORY US-FDA APPROVAL)</b>	
23	Uncemented hemiarthroplasty (Imported)- MODULAR	
24	Cemented hemiarthroplasty (Imported)-MODULAR	
	<b>INDIAN IMPLANT FROM A STANDARD INDIAN COMPANY WITH EITHER USFDA AND/OR with EUROPEAN CE CERTIFICATE</b>	
25	Metal on poly Indian uncemented THR (Titanium blasted/corail/HA coated) with highly cross linked ultra high molecular weight Polyethylene Liner	
26	Total Elbow arthroplasty (Indian)	



27	Radial head prosthesis (Indian)	
28	Uncemented Hemiarthroplasty (Indian) – Modular	
	<b>TRAUMA</b>	
29	Proximal femur osteotomy plate with screws	
30	2.7 mm Mini plate with screws straight all sizes (Simple)	
31	Radial Head prosthesis (modular) with cement	
32	2.4/2.7 mm proximal radius head plate (rim/ head neck)	
33	Curved reconstruction plates with screws 3.5/4.5 mm	
34	Curved low profile locking reconstruction plates with screws 3.5mm (straight/ curved/ J- plate)	
35	Proximal femoral locking hook plate with screws	
36	Condylar distal femoral plates with screws	
37	Medial distal Femoral plates (Simple)	
38	Condylar angled blade plates with screws	
39	Headless compression screws 2.4 mm -3.5 mm	
40	TSF (Taylor spatial frame)	
41	J nail	
42	V nail	
43	K nail	
44	HTO plates (puddu plates )	
45	Bone staples (small, medium, large)	
46	Pelvic Trauma Plates- AO type	
47	Pubic Symphysis Plate – AO type	
48	7.5 mm cancellouscannulated screws partially threaded – AO type (Stainless Steel)	
49	7.5 mm cancellouscannulated screws fully threaded – AO type (Stainless Steel)	
50	7.5 mm cancellouscannulated screws partially threaded – AO type (Titanium)	
51	7.5 mm cancellouscannulated screws fully threaded – (Titanium)	
	<b>SPINE</b>	
52	Vertebroplasty kit with cement	
53	Artificial cervical disc small, medium, large	
54	Odontoid fixation screw	
55	Titanium 20 pedicle screws and 2 connecting rods with 2 pedicle hooks	
56	Titanium 20 pedicle screws and 2 connecting rods with 2 laminar hooks	
57	Fenestrated pedicle screw for osteoporotic bone, 8 screws + 2 rods + 1 packet of acrylic bone cement	
58	Fenestrated pedicle screw for osteoporotic bone, 5 screws + 2 rods + 1 packet of acrylic bone cement	
59	Laminoplasty plates with screws	
60	20 pedicle screws + 2 rods + 6 pedicle hooks	
61	Kyphoplasty kit	
62	8 pedicle screws + 2 rods + thoracolumbar expandable cage	
63	4 lateral mass screws + 2 rods + 2 C1-C2 spacer cage	



64	Spine radiofrequency probe (disposable)	
65	Bone substitute spacer for laminoplasty	

Sr.No	Neurosergery	Quoted /Not Quoted
66	Wire for C1, C2 Fixing	
67	Occipital plate with screw	
68	V.P. shunt Low Pressure	
69	V.P.shunt Medium Pressure	
70	V.P. shunt High Pressure	
71	Lambo peritoneal shunt	
72	Cervical peek cage	
73	G Patch 8x10	
74	External Ventrical Drainage Device	
75	Quantum	

### 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 polyethelene, other polyethelene 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.
- Head implants with trials of sizes ranging from 22 mm to 40 mm must be provided.



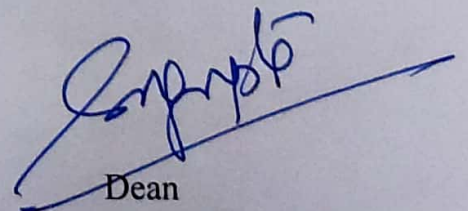
- Box cutter, canal finder, serial reamers with variable broaches (small/ medium/ large) corresponding to the stem implant must be provided.
- Quick coupling mechanism should be present for easy placement of head and stem.
- Femoral head impactor should be included in the set.
- The instruments and implants 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.
- Instruments with quick coupling mechanism should be provided for easy trial/ implant placement, positioning or removal.
- Highly crossed linked patellar button should be provided with variable sizes.
- Distributer should provide high viscosity bone cement (PALACOS) 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.



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