

No. IV-21011/19/2010-Prov-I
Government of India
Ministry of Home Affairs

26, Man Singh Road, Jaisalmer House,
New Delhi, 1.12.2010


To
The ADG (Medical), Central Paramilitary Force Medical Services,
ITBP, TIGRI,
PO Madangir,
New Delhi-110016

Subject:- Specifications for Arthroscope Complete for CPMFs Hospitals- approval thereof.


Sir,

The Specifications for the Arthroscope Complete for CPMFs Hospitals have been approved by the Competent Authority in MHA and the same are enclosed for information and Record.

Yours faithfully,


(S.B.Nanda)
Under Secretary

Encl. as above


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Technical Specification of Arthroscope Complete

For Knee Arthroscopy Including ACL & PCL set with Full HD Camera System, Shaver And Pump Systems including Instrument for Shoulder Arthroscopy, Hip Arthroscopy, Small Joints and Data management System

Arthroscope: Autoclavable	Qty one each
➤ Wide angle Forward-Oblique and lateral scope	
➤ Field of view:	
➤ Angle of View: 30° and 70°	
➤ Diameter 4 mm	
➤ Length 16 cm to 18 cm	
➤ Fibre Optic light transmission incorporated	
➤ Standard ocular window for coupling camera head	
➤ Scratch resistance sapphire coated tip lens	
➤ Rod lens system for optimum brightness, contrast and definition	
Arthroscope Sheath, rotatable	Qty - 1
➤ Diameter 5.5 to 6 mm	
➤ Working length 12 cm	
➤ With 2 rotatable stopcocks	
➤ Autoclavable, for use with telescope 30° and 70°	
Semi Sharp Obturator	Qty - 1
Use with arthroscopy sheath, working length 12 cm	
Hook Probe	Qty - 1
Graduated	

CAMERA SYSTEM

Specifications for Full HD Digital Camera

The system should be truly Digital Full HDTV Endoscopic Video Camera. The system should quality all the essential criteria for full HDTV system
➤ Maximum resolution of 1920 X 1080 Pixels
➤ Progressive scan
➤ Consistent use of 16:9 format for input & Output to guarantee genuine HDTV
The system should have the following Features
➤ CCD sensing chip should optimizes image quality & Digital Source Sampling for maximizing hi-fidelity image transmission
➤ Optimizes to Any size: The system should have optical zoom to enhance the quality of image size & cross speciality standardization of the camera system, regardless of telescope used
➤ The system should automatically optimize all settings. The system should be ready-to-use as soon as it is connected to the camera control unit
➤ The system should be menu driven, thus allowing the surgeon to program the camera head functions as per surgical need & requirement
➤ The system should have the following Digital O/Ps
➤ HDTV signal to DVI-D Socket

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- Digital SDI Signal
- DV/USB For Digital recording

Technical Specifications

Image Sensor	3 X 1/3" CCD-Chip
Pixels	1920 (H) x 1080 (V) Pixels per chip
Camera Head Weight	150-250 gms
AGC	Micro-processor Controlled 55-65 dB
Lens	Optical Zoom Lens with desirable range f-12-35 mm
Video output	Composite signal to BNC Socket S-Video signal to 4-pin Mini DIN Socket (2x) RGB Signal HDTV Signal to DVI-D socket (2x) Digital SDI Signal to BNC socket DV signal to DV socket

Certified to: TEC-601-1, CE according to MDD, protection class I/CF

TFT Flat Screen Monitor

The system should have Qty -1

- Full HDTV medical grade monitor size: 26 inch
- To accept DVI-D, DV and SDI video inputs
- Compact & Lightweight design
- Drip water protected, dustproof housing
- Screen Diagonal 26 inch
- Resolution 1920 X 1080p

XENON LIGHT SOURCE AND LIGHT CABLE

Specifications

High Intensity Xenon light source with spare xenon lamp

Special Features

- High light intensity with 300 watt Xenon lamp
- High colour temperature- more than 6000 K corresponds to brightness of sunlight resulting in high visual and photographic clarity for colour rendition
- Monitoring of lamp function

Technical Specifications

Lamp type	Xenon lamp 300 watt
Colour temperature	Approx 6000 K
Light outlets	1
Light intensity adjustment	Continuously adjustable from 0 to 100% manually

Qty-1

FIBRE OPTIC CABLE

Specifications

Should be 3.5 mm & length: 230 Cm Qty 2

Specifications of Arthroscopy Shaver

High speed shaver system with:

- Stable torque throughout entire speed range
- Optionally available high speed shaver hand pieces with rotational speed ranging from 1000 rpm to 15000 rpm
- Oscillation of shaver within rotation speed from 500 rpm to 3000

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rpm	
<ul style="list-style-type: none"> Choice between hand controls, control via footswitch or control from the console via LCD touch screen Drill and saw hand piece can be used 	
Light weight handle with switches for	
<ul style="list-style-type: none"> Selection with rotation (clock wise, anti clock wise and oscillation) Control to increase or decrease the rotation speed. Suction control, on the handle itself High speed hand piece with not more than 8000 rpm Autoclavable 	
Unit should be supplied with foot switch and Shaver handle	Qty -1
Specification for Shaver blades preferably reusable	Qty- 1 each
<ul style="list-style-type: none"> Aggressive cutter 4.5 mm, reusable Full radius Resector 4.5 mm, reusable Curved aggressive full radius resector, distal tip curved 15 deg up to 4.2 mm, reusable Round Burr 5.5 mm, reusable Finnish barrel burr 5.5 mm, reusable 	
FLUD PUMP MANGEMENT SYSTEM	
<ul style="list-style-type: none"> Irrigation pressure and flow rate are electronically controlled Flow rate 1-2 lts/min Display of operating parameters set points and actual performance data The unit should be compact with front panel display of critical parameters like flow-reset and actual with audible alarm system in case of overpressure. 	
Unit should be supplied with foot switch	Qty-1
Preferably Reusable tubing set	Qty-2
HAND INSTRUMENTS	
All hand instruments should have one piece outer shaft with excellent control over the cutting process	
Punches	
All purpose, low profile not more than 3 mm enables access to structures in narrow joint areas with large aperture angle allows efficient resection. Should have and ergonomic handle for controlled, measured and non tiring cutting	
(A)	Qty- 1 each
➤ Straight cutting width 2.7 mm, shaft diameter 3.5 mm Working length 13 cm	
➤ Upturned 15 deg Cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13cm	
➤ Jaws curved 30 deg left Cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13cm	
➤ Jaws curved 30 deg right Cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13cm	

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➤ Jaws curved 90 deg right Cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13cm	
➤ Jaws curved 90 deg right Cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13cm	
(B)	Qty- 1 each
➤ Straight Cutting width 3.4 mm, shaft diameter 3.5 mm, working length 13 cm	
➤ Upturned 15 deg Cutting width 3.4 mm, shaft diameter 3.5 mm, working length 13 cm	
➤ Jaws curved 30 deg left Cutting width 3.4 mm, shaft diameter 3.5 mm, working length 13 cm	
➤ Jaws curved 30 deg right Cutting width 3.4 mm, shaft diameter 3.5 mm, working length 13 cm	
➤ Jaws curved 90 deg right Cutting width 3.4 mm, shaft diameter 3.5 mm, working length 13 cm	
➤ Jaws curved 90 deg right Cutting width 3.4 mm, shaft diameter 3.5 mm, working length 13 cm	
(C) Scissor Punch	Qty- 1 each
➤ Straight Cutting width 1.5 mm, shaft diameter 3.5mm, working length 23 cm;	
➤ Shaft curved left Straight Cutting width 1.5 mm, shaft diameter 3.5mm, working length 23 cm;	
➤ Shaft curved right Straight Cutting width 1.5 mm, shaft diameter 3.5mm, working length 23 cm	
(D) Grasper	Qty- 1 each
➤ Straight spoon shaped jaws Shaft diameter 3.5 mm, Working length 13cm;	
➤ Aggressive foreign body grasper Shaft diameter 3.5 mm, Working length 13cm;	
➤ 30 deg upturned spoon shaped Shaft diameter 3.5 mm, Working length 13cm;	
(E) Rasp and Curette;	
➤ Oval curette curved 10 deg, length 13 cm	
➤ Oval curette curved 30 deg, length 13 cm	
➤ Rasp straight, narrow, fine working length 13 cm	
➤ Rasp narrow curved, Working length 13 cm	
Specifications of ACL set	
Instruments set for bone tendon bone as for soft tissues	
• Tribal tunnel Guide Anterior Cruciate Ligament	Qty- 1
➤ Variable angle, tunnel angle between 40 deg and 60 deg	
➤ With specially designed tip for viewing the exit of the target wire from above before placement	
➤ With special fixation mechanism for secure and continuous fixation of the guide pin in every position	
➤ The guide should have stable construction which prevents winding and torsion of the guide and provides extremely high target precision	
➤ Design should be sturdy allows absolutely no area for play between angles	

➤ Tendon Striper 6-7 mm.

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<ul style="list-style-type: none"> • Drill Wire ➢ Diameter 2.4 mm ➢ Length 32 cm, pyramidal shape 	Qty-10
<ul style="list-style-type: none"> • Headed Bone Drill ➢ Diameter 4.5, 7, 8, 9, 10 and 11 mm ➢ Should have marking ➢ Cannulated, for use with drilling wire, diameter 2.4 mm ➢ Tendon Stripper ➢ Diameter 7 mm ➢ Length 30 cm ➢ Should have length marks on the stripper for measurement of the length of the graft 	Qty-1 each
<ul style="list-style-type: none"> • Tendon thickness Tester ➢ For determination of tendon thickness from 6 mm to 10.5 mm in 0.5 mm increments ➢ Should provide precise thickness measurement with a flap mechanism to measure the graft when it is tensed on the graft board ➢ No threading through the tendon or the bone block should be required 	Qty-1
<ul style="list-style-type: none"> • Femoral tunnel Guide, Anterior Cruciate Ligament Should consist of ➢ Handle ➢ Attachments for 4.5, 6, 7, 8 mm offset 	Qty-1
• Curette, oval, large, curved 10 deg, length 13 cm	Qty-1
• Rasp narrow curved, fine serration, length 13 cm	Qty-1
• Tendon hook	Qty-1
<ul style="list-style-type: none"> • Tendon Board for cleaning and preparing the graft ➢ Graduated scale for measurement of the graft ➢ Facility for preparation and initial tensioning of the graft ➢ Marking for the determination of the graft portion in the femoral tunnel intraarticular and tibial tunnel ➢ Including a retainer for femoral fixation button 	Qty-1
• Thread Clip	Qty-1
<ul style="list-style-type: none"> • Length Gauge ➢ Graduated ➢ Length 23 cm 	Qty-1
• Thread Hook	Qty-1
<ul style="list-style-type: none"> • Drilling wire with eye ➢ Diameter 2.4 mm ➢ Length 38 cm, spiral-shaped polishing 	Qty-5
Specifications of PCL Instruments	
• Tibial target guide for PCL	Qty-1
• Femoral PCL aimer, graduated, length 14.5 cm	Qty-1
• AWI for PCL, 1.5 mm dia 4mm, length 20 cm	
• Raspatory, crescent shape, length 13 cm	Qty-1
• Blunt spoon for PCL with T shaped handle	Qty-1
• Suture retriever for PCL with T shaped handle	Qty-1

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Instruments for meniscus repair

All inside techniques of meniscus repair for posterior horn area of lateral and medial meniscus. Suture material used with the set should be monofilament 2-0 to 2

- Handle for suture attachments
- Wheel attachment to roll suture
- Suture attachment straight, hook shaped, length 13 cm
- Suture attachment angled 180 deg right, , length 13 cm
- Suture attachment angled 180 deg left, , length 13 cm
- Suture attachment angled 360 deg right, , length 13 cm
- Suture attachment angled 20 deg upward, , length 13 cm
- Suture attachment angled 20 deg upward, length 14 cm
- Cannula to use with suture attachment
- Obturator Cannula
- Knot pusher
- Suture curette, for retinaculum suture with handle
- Thread grasping forceps

Mobile Video Trolley

- Mobile video trolley rides in 4 antistatic dual wheels
- Wheel diameter not less than 12 cm
- Two equipped with locking breaks
- One camera head mount
- Integrated power board provides connection to all units
- Channel inside the stands to avoid hanging of the cables
- One drawer with lock
- Should have inbuilt arm for 26 inch TFT monitor
- One adjustable swivel arm for monitor can be mounted either on left or on right stand for touch screen

Arthroscopy Leg holder

- Arthroscopy Leg holder, with
 - Clamp 25mm and 30 mm
 - Cushion
 - Strap for tightening

Qty-1

Data Management System

The system should have

- Digital storage of still images, Video sequences & Audio Files in full HD format
- Sterile, Ergonomic operation via touch screen, camera head buttons & foot switch
- Efficient archiving on DVD or CD-ROM, both multi-session and multi patient
- Should be able to record full HD format
- Automatic creation of standard reports
- Computer and monitor to be used in OR should be certified
- All required accessories should be supplied with the system
- 15" touch screen should be supplied with the system
- The unit should be compact and should be medical grade

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computer

Shoulder Arthroscopy instruments

- **Cannula system for Shoulder Arthroscopy**

Diameter not more than 8.25 mm, working not less than 70 mm preferably with reusable metal cannulas and transparent plastic cannulas

The system should be supplied with the following items for an optimum control of the direction and position of the portal under vision. The system provides a portal to the joint by merely dilating the soft tissue without injuring.

- Six Positioning needle
- Six Obturator for positioning needle
- Six guide wire diameter 0.9mm
- One cannulated dilator
- One handle for dilator
- Two housing for use with metal and transparent cannula
- Ten set of gaskets, double flap to avoid intra articular pressure
- One handle for introducing cannula
- One obturator for cannula
- Two metal cannula, reusable
- Ten Transparent Cannula, Diameter not more than 8.25 mm, Working length not less than 70 mm

Qty-10

Should be compatible with obturator and introducer

- Changing rod, length 35 cm
- Knot pusher
- Suture retrieval forceps
- Punch, Working length 18 cm
- Hook Scissors, Working length 18 cm
- Grasping Forceps, Working length 18 cm
- Crochet hook, Working length 15 cm
- Suturing instruments for Rotator Cuff, the system should consist of
 - Handle
 - Wheel attachment for suture size 1-2 mono and multifilament
 - Suture attachment straight, distal tip curved, 7mm in height
 - Suture attachment straight, distal tip curved like hook, not less than 8.7 mm in height
 - Suture attachment straight, distal tip curved like hook, not less than 10 mm in height
 - Suture attachment angled 30 deg to the right, not less than 8 mm in height
 - Suture attachment angle 30 deg to left, not less than 8 mm in height
- Hook and retractor graduated, Diameter 3.5 mm, working length 18 cm, length of hook 3cm

Qty-1

Qty-1

Qty-1

Qty-1

Qty-1

Qty-1

Qty-1

Qty-1 each

Qty-1

- Croche hook.

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• Threaded Drill for preparation of tunnel for anchor	Qty-1
• Glenoid drill guide	Qty-1
• Suture shuttle instrument curved downward, tip opens downward	Qty-1
• Rap working length 7 cm Shaft diameter 5.5 mm	
➢ For Glenoid	
➢ For SLAP	
• Elevator working length 17 cm Shaft diameter 6 mm	
➢ 30 deg curved	
➢ 15 deg curved	
<u>Hip Arthroscopy Set</u>	
• Arthroscope : Autoclavable	Qty-1
➢ Wide angle Forward-Oblique and lateral scope	
➢ Field of view:	
➢ Angle of View: 30° and 70°	
➢ Diameter 4 mm	
➢ Length 16 cm to 18 cm	
➢ Fibre Optic light transmission incorporated	
➢ Standard ocular window for coupling camera head	
➢ Scratch resistance sapphire coated up lens	
➢ Rod lens system for optimum brightness, contrast and definition	
➢ Arthroscope Sheath, Quick Coupling	One
➢ Diameter 5.5 mm	
➢ Working length 12 cm	
➢ With 2 rotatable stopcocks	
➢ Autoclavable, for use with telescope 30° and 70°	
• Blunt obturator, Autoclavable; for use with arthroscope sheath diameter 5.5 working length 12 cm	One
• Handle with cannulated obturator for use with arthroscopy sheath	One
• Hook and Retractor	One
➢ Straight, graduated, diameter 3.5mm, working length 8.5 cm, length of hook 2mm	
➢ Shaft curved 30 deg, graduated, diameter 3.5 mm, working length 8.5 cm, and length of hook 2 mm	
➢ Shaft curved 70 deg, graduated, diameter 3.5mm, working length 8.5 cm, and length of hook 2 mm	
Working instruments	
• Positioning needle with stylet, dia 2.1 mm, length more than 20 cm	
• Guide wire, 1.5 mm, length not less than 40 cm	
• Cannulated dialator for use with guide wire, length not less than 30 cm	
• Set of working Cannula	
➢ Threaded cannula, transparent, inner dia not less than 8 mm, working length not less than 90 mm	
➢ Handle for cannula	

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<ul style="list-style-type: none"> > Cannulated obturator for use with handle > Housing for gasket > Set of gaskets for housing 	
<ul style="list-style-type: none"> • Punch, jaws curved 15 deg up, working length 20 cm, cutting width 3.4 mm • Punch, shaft curved 15 deg up, working length 20 cm, cutting width 3.4 mm • Grasper, aggressive, working length 20 cm • Currette, curved upto 20 deg • Knife, curved, sharp double ended, working length 20 cm • Aimer for portal placement <ul style="list-style-type: none"> > Aimer with attachment for bullet > Bullet short, 10.5 cm > Bullet long 14.5 cm 	
<u>Instruments for small joint</u>	
<ul style="list-style-type: none"> • Small Joint Arthroscope <ul style="list-style-type: none"> > Wide angle Forward-Oblique scope > Field of view > Angle of View: 30° > Diameter 2.4 mm > Length not more than 10cm > Fibre Optic light transmission incorporated > Standard ocular window for coupling camera head > Scratch resistance sapphire coated tip lens > Rod lens system for optimum brightness, contrast and definition > Arthroscope Sheath, rotatable <ul style="list-style-type: none"> > Diameter 3.5 mm > Working length 6-7 cm > With 2 rotatable stopcocks > Autoclavable, for use with telescope 30° and 70° 	
<ul style="list-style-type: none"> • Blunt obturator, Use with arthroscopy sheath 	Qty -1
<ul style="list-style-type: none"> • Instruments for Small Joint <ul style="list-style-type: none"> > Punch, straight, dia 2.3 mm, length 10 cm > Punch, 15 deg upward angled, dia 2 mm, length 10 cm > Biopsy Forceps, spoon shaped jaws, dia 2.3 mm, length 10 cm > Grasping forceps, dia 2.3 mm, length 10 cm > Hook retractor 	Qty -1 each
<p>System must be having five years standard warranty and next five years CMC price must be given</p>	

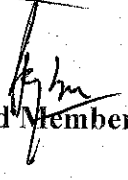
system must be FDA or CE, ISO approved.

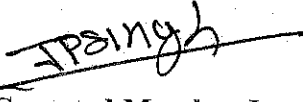
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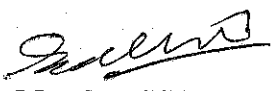

Member ITBP



Member CBPF


Member BSF


Co-Opted Member-II

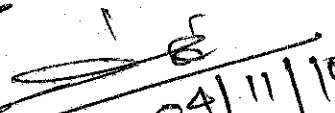

Co-opted Member-I


Member SSB


Co-opted Member-III

Technically approved/not approved

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ADG (Medical), CPMFs