# **TENDER FOR**

# LAPAROSCOPIC SIMULATOR

# **AT**

# NATIONAL INSTITUTE OF AYURVEDA, JAIPUR

NIT ISSUE DATE	:	07-01-2022 ( 2:00 PM)
NIT NO.	:	NIA/CS/S.T/2021/(1)59
LAST DATE OF SUBMISSION	:	17-01-2022 (2:00 PM)
BID OPENING DATE	:	18-01-2022 (2:00 PM)
TENDER COST	:	2500/-



# NATIONAL INSTITUTE OF AYURVEDA

(Deemed to be University) MINISTRY OF AYUSH GOVT. OF INDIA JORAWAR SINGH GATE AMER ROAD, JAIPUR

## LAPAROSCOPIC SIMULATOR NIA/CS/S.T/2021/(1)59

National Institute of Ayurveda, Jaipur an autonomous body under the Ministry of AYUSH, Government of India invites **online bids in two bid system for** tenders for supply & installation of *Laparoscopic Simulator*. Best offers are invited along with the complete details of specifications, terms & conditions.

S.N.	ITEM DESCRIPTION	QTY	EMD (RS.)
1	Laparoscopic Simulator	01	4,00,000/-

#### **INSTRUCTIONS:**

- 1. Bids shall be submitted online at CPPP website: <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a>
- 2. The complete bidding process is online Bidders should be in possession of valid digital Signature Certificate (DSC) of class II or III for online submission of Bids, Prior to bidding DSC need to be registered on the website mentioned above.
- **3.** Tenderer/Contractor/Bidders are advised to follow the instructions provided in the instructions to the contractors/Tenderer/Bidders for the e-submission of the bids online through the Central Public Procurement Portal for e-Procurement at <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a>.
- **4.** Bid documents may be scanned with 100 dpi in black and white option which helps in reducing size of the scanned document.
- 5. Tenderer /Contractor/Bidders are advised to submit Technical Bid Document photo copy before last date of bid submission.

#### 6. EMD Payment:

The Bidder shall be required to submit the Earnest Money Deposit (EMD) for an amount of *Rs. 4,00,000 (Rupees Four Lacs Only)* by the way of demand drafts only. The demand drafts shall be drawn in favor of *"Director, National Institute of Ayurveda"* Payable at Jaipur. The EMD of the Successful Bidder shall be returned after the successful submission of Bank Guarantee/Security Deposit and for unsuccessful Bidder(s) it would be returned after award of the Contract. *The demand Drafts for EMD must deliver to Director, NIA, Jaipur on or before last date /time of Bid Submission*.

- a) Tenderer shall not be permitted to withdraw his offer or modify the terms and conditions thereof. In case the tenderer fails to observe and comply with stipulation made herein or back out after quoting the rates, the aforesaid amount of earnest money will be forfeited.
- b) The firm who are registered with National Small industries corporation (NSIC) or Small Scale Industries (SSI) are exempted to submit the EMD(Copy of registration must be provided along with Technical Bid) Registration proof and Udyog Aadhar Certificate should be enclosed with Technical Bid.
- c) Bidders are not allowed to submit more than one bid anytime during the tendering process for the same/similar tendered item else all his bids shall be cancelled thereby making him disqualified in addition to the forfeiture of the EMD.
- d) The EMD, in case of unsuccessful Bidders shall be retained by NIA, Jaipur till the finalization of the Tender. No Interest will be payable by NIA, Jaipur on EMD.
- e) EMD is required to protect the purchaser against the risk of Bidders conduct. The EMD will be forfeited if the bidder withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to the notice that the information/ documents furnished in its tender is incorrect or false.

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f) The EMD/PBG shall be forfeited if successful bidder fails to supply the goods/equipment in stipulated time or fails to comply with any of the terms & conditions of the contract or fail to sign the contract.

#### 7. Submission of Tender:

The tender shall be submitted online in two parts, viz., Technical Bid and Financial Bid (BOQ). All the pages of bid being submitted must be signed and sequentially numbered by the bidder irrespective of nature of content of the documents before uploading.

The Bidder shall quote the Technical and Financial Bids as per the format enclosed with tender document. *The Bidders should submit their all relevant documents (Technical bid document and EMD proof etc.) before last date and time of bid submission.* 

### <u>The offers submitted by Telegram/Fax/email shall not be considered. No correspondence will</u> <u>be entertained in this matter.</u>

#### 8. <u>Technical Bid:</u>

#### All pages of the Tender should be numbered and indexed.

The bidder shall provide in its tender the required as well as the relevant documents like technical data, literature, drawings etc. to establish that the goods and services offered in the tender fully confirm to the goods and services specified by the purchaser in the tender documents. For this purpose, the bidder shall also provide a clause-by-clause commentary on the technical specifications and other technical details incorporated by the purchaser in the tender documents to establish technical responsiveness of the goods and services offered in its tender duly indicating relevant page numbers in the product literature.

The following documents are to be furnished by the contractor/Bidder along with Technical Bid as per the Tender Document:

- a) Signed and scanned copy of appropriate value of valid registration certificate (if any), experience certificate as per the tender notice, PAN, GST registration certificate and Tender Acceptance Letter.
- b) Signed and Scanned Copy of make and model of all systems, sub systems and additional items should be mentioned in the technical bid and complete technical details should be provided in the form of Brochures and write-ups.
- *c)* The bidders are required to submit user certificate for the relevant equipment on the letter head of the institution (Government/ Private)
- *d*) Signed & stamped compliance sheet of the technical specification of the goods with technical printed literature must be enclosed with the bid

### e) Manufacturer Authorization:

The bidder (if not original equipment manufacturer must submit Original Equipment Manufacturer authorization certificate that the tenderer is authorized for selling and maintain the equipment quoted for.

### 9. <u>Financial Bid:</u>

Price Schedule(s)as per BoQ format filled up with all the details including Make, Model etc. of the goods offered to be uploaded.

While filling up the columns of the Financial Bid, the following aspects should be noted for compliance:

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#### Price should include:

- a) Duties and fees, if any
- b) Charges towards Packing & Forwarding, Inland Transportation, Insurance, Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Financial Bid
- c) The price of annual CMC, as mentioned in List of Requirements, Technical Specification and Financial Bid
- d) GST will be payable separately as per applicable rate.

#### Schedule of price bid in the form of BOQ\_XXXX .xls

The below mentioned price bid format is provided as BoQ\_XXXX.xls along with this Tender Enquiry Document at https://eprocure.gov.in/eprocure/app . Bidders are advised to download this BoQ\_XXXX.xls as it is and quote their offer/rates in the permitted column and upload the same in the commercial bid. Bidder shall not tamper/modify downloaded price bid template in any manner. In case if the same is found to be tempered /modified in any manner, tender will be completely rejected and tenderer is liable to be banned from doing business with NIA, Jaipur.

- **10.** The authorized signatory of the bidder must digitally sign the bid. Individuals digitally signing the bid or other documents connected with a contract must specify whether he signs as:
  - a) A 'Sole Proprietor' of the firm or constituted attorney of such Sole Proprietor
  - b) In case of partnership firm he must have authority to quote & to refer to arbitration dispute concerning the business of the partnership either by virtue of the partnership agreement or a power of attorney
  - c) Constituted attorney of the firm if it is a company.
- 11. <u>Turnover</u>

The Firm/Agency should have an annual minimum turnover of Rs. 2 Cr. during last 3 Years (2018-19, 2019-20, 2020-21) to be eligible for consideration.

12. <u>Validity:</u>

The quoted rates must be valid for a period for 180 days from the date of closing of the tender. The overall offer for the assignment and bidder(s) quoted price shall remain unchanged during the period of validity. If the bidder quoted the validity shorter than the required period, the same will be treated as unresponsive and it may be rejected.

- 13. The bidding firm should be continuously engaged (with Valid License/Registration) in the same business at least for last 3 Years. The bidding firm should have at least 1 similar contract with Central Government/State Government/Public Sector Undertakings/ Universities/ Deemed to be universities/ Autonomous Bodies/Reputed Medical Institute or Organizations in last 3 Years.
- **14.** The bidder shall provide a list of major Government and Private Institutions where its relevant bid item has been supplied during last 3 years along with order copies
- 15. <u>The bidder firm should not have been blacklisted by any Ministry/Department of Govt. of</u> <u>India/State Government/any PSU's etc. The Performance Security Deposit will be forfeited</u> <u>after awarding the Bid, in case the bidding firms found black listed by Central</u> <u>Government/State Government/PSU's/Universities/Deemed to be Universities/Autonomous</u> <u>Bodies at any point of time.</u>
- 16. <u>The Director, National Institute of Ayurveda reserve the right to accept or reject any/all</u> <u>tenders without assigning any reason thereof.</u>

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#### 17. Availability of Funds:

Expenditure to be incurred for the proposed purchase will be met from the funds available with the purchaser/consignee

#### 18. Delivery and Installation:

#### For goods supplied from India:

- a) All the goods ordered shall be delivered and Installed at NIA, JAIPUR within **30 days** from the date of issue of supply order. All the aspects of safe delivery, installation and commissioning shall be the exclusive responsibility of the supplier. If the supplier fails to deliver, install and commission the goods on or before the stipulated date, then a penalty at the rate of 0.5% per week or a part thereof of the total order value shall be levied subject to maximum of 10% of the total order value. The successful tenderer will also provide required training for supplied items at NIA.JAIPUR. The goods should be manufactured after adoption of latest technology. If at any time during the currency of the contract, the supplier encounters conditions hindering timely supply of the goods and performance of services, the supplier shall promptly inform the NIA, JAIPUR for extension of the delivery schedule accordingly.
- b) On receiving the supplier's communication, NIA, JAIPUR shall examine the situation as soon as possible and, at its discretion, may agree to extend the delivery schedule, with or without liquidated damages for completion of supplier's contractual obligations by issuing an amendment to the contract. In the case of package supply where the delayed portion of supply materially hampers installation and commissioning of the systems, liquidated damages charges shall be levied as above on the total value of the concerned package of the purchase order. Quantum of liquidated damages assessed and levied by the purchaser shall be final and not challengeable by the supplier.

#### 19. Signing the Contract:

The successful bidder shall be required to execute the Contract Agreement accepting all terms and conditions stipulated herein on a non -judicial stamp paper of Rs. 500/ - (Rs. Five Hundred only) along with performance security within fifteen days of the issue of the Letter of notification of a ward. In the event of failure on the part of the successful bidder to sign the Contract within the period stipulated above, the EMD shall be forfeited and the acceptance of BID shall be considered as cancelled.

#### 20. Performance Security:

As a guarantee towards due performance and compliance of the contract work, the successful bidder (contractor) will deposit an amount equal to 3% of order value and should be kept valid for a period of 60 day beyond completion of all the contractual obligation, including CMC period towards security deposit by way of demand draft/ bank Guarantee in favour of "<u>DIRECTOR NIA</u>, <u>JAIPUR</u>" drawn on any Nationalized Bank/Scheduled Bank and payable at JAIPUR within fifteen days of the issue of the Letter of notification of award along with non-judicial stamp paper of Rs. 500/- (Contract agreement).

#### 21. Incidental Services:

The supplier shall be required to perform the following services: -

- a) Installation & Commissioning, Supervision and Demonstration of the goods.
- b) Providing required jigs and tools for assembly, minor civil works required for the completion of the installation.
- c) On Site Training to Doctors/ Technicians/ Staff is to be provided by Supplier for operation and maintenance of the equipment for a period of 30 working days after successful installation of the machine, as per direction of user department.

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- d) Supplying required number of operation & maintenance manual for the goods.
- e) To provide non-locked open software and standard interface inter-operability conditions for networked equipment's in hospital management information system, wherever applicable.

#### 22. After Sales Service:

After sales service Centre should be available on 24 (hrs.) X 7 (days) X 365(days) basis. Complaints should be attended properly, maximum within 24 hrs. to ensure an uptime of minimum 95%, wherever applicable, failing which the necessary penalty measures shall be enforced.

#### 23. Inspections:

- a) NIA, Jaipur shall have the right to inspect and/or to test the goods to confirm their conformity to the NIT Specifications at no extra cost to the Purchaser.
- b) NIA, Jaipur right to inspect, test and, where necessary, reject the Goods after the goods arrival at the final destination shall in no way be limited or waived by reason of the Goods having previously been inspected, tested and passed by NIA, JAIPUR prior to the goods shipment.
- c) The Director, NIA, JAIPUR shall be the final authority to reject full or any part of the supply which is not confirming to the specification and other terms and conditions
- d) No payment shall be made for rejected items and those must be removed by the Bidders within two weeks of the date of rejection at their own cost and replaced immediately. In case these are not removed, these will be auctioned at the risk and responsibility of the suppliers without any further notice.

#### 24. Payment Terms:

Payment of the total order value shall be released after the successful installation/ commissioning and tanning of the ordered goods against the submission of the inspection report.

#### 25. Guarantee / Warrantee Period:

The Tenderers must quote for 5 year comprehensive warranty (including all Spares, Accessories and Labor) from the date of completion for satisfactory installation. The Warranty Charges shall not be quoted separately otherwise the offer shall be summarily rejected.

#### 26. Breach of Terms and Conditions:

In case of breach of any terms and conditions as mentioned above, the Competent Authority, will have the right to cancel the work order/ job without assigning any reason thereof and nothing will be payable by NIA, Jaipur in that event the security deposit shall also stands forfeited

#### 27. Insolvency etc.:

In the event of the firm being adjudged insolvent or having a receiver appointed for itby a court or any other order under the Insolvency Act made against them or in the case of a company the passing any resolution or making of any order for winding up, whether voluntary or otherwise, or in the event of the firm failing to comply with any of the conditions herein specified NIA, Jaipur shall have the power to terminate the contract without any prior notice

#### 28. Force Majeure:

If, at any time during the subsistence of this contract, the performance in whole or in part by either party of any obligation under this contract is prevented or delayed by reasons of any war or hostility, act of public enemy, civil commotion, sabotage, fire, floods, explosion, epidemics,

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quarantine restriction, strikers lockout or act of God (herein after referred to as events) provided notice o happening of any such eventuality is given by part to other within 21 days from the date of occurrence thereof, neither party shall by reason of such event be entitled to terminate this contract nor shall either party have any claim for damages against other in respect of such non -performance or delay in performance, and deliveries have been so resumed or not shall be final and conclusive. Further, that if the performance in whole or in part of any obligation under this contract is prevented or delayed by reason of any such event for a period exceeding 60 days, either party may, at least option to terminate the contract.

- **29.** Bidder shall submit a copy of the tender document and addenda thereto, if any, with each page of this document should be signed and stamped to confirm the acceptance of the entire terms & conditions as mentioned in the tender enquiry document.
- **30.** After due evaluation of the bid(s) Institute will award the contract to the lowest evaluated responsive tenderer.
- **31.** Conditional bid will be treated as unresponsive and it may be rejected.

#### 32. Demonstration:

NIA, Jaipur reserves the right to ask the tenderers for arranging demonstration of their equipment for which rates have been quoted, to the concerned committee, if required.

**33.** The Institute reserves the right to accept in part or in full or reject any or more tender(s) without assigning any reasons or cancel the tendering process and reject all tender(s) at any time prior to award of contract, without incurring any liability, whatsoever to the affected bidder or bidder(s)

#### 34. Applicable Law:

The contract shall be governed by the laws and procedures established by Govt. of India, within the framework of applicable legislation and enactment made from time to time concerning such Commercial dealings / processing

Any disputes are subject to exclusive jurisdiction of Competent Court and Forum in Jaipur, Rajasthan, India only

The Arbitration shall be held in accordance with the provisions of the Arbitration and Conciliation Act, 1996 and the venue of arbitration shall be at Jaipur. The decision of the Arbitrator shall be final and binding on both the partied

Force Majeure: Any delay due to Force Majeure will not be attributable to the supplier.

### NIA/CS/S.T/2021/(1)59 <u>Technical Bid</u>

1.	Name of Tendering Company/Firm/Agency		:		
2.	Name of Owner/Partners/Directors		:		
3	Full Particulars of the Head Office		:		
	Address		:		
	Telephone No.		:		
	• Fax No.		:		
	E-mail address		:		
	Full Particulars of the Bankers of the		:		
4	Company/Firm/Agency, with full Address/Tel. No	).			
	Name of the Bank		:		
	Address of the Bank		:		
	Telephone No.		:		
	• Fax No.		:		
	E-mail address		:		
5	Registration Details:		:		
	Copy of Firm/Agency's Registration No.		:		
	PAN/GIR NO.		:		
	GST Registration No		:		
	Aadhar No. of Owner/Partners/Directors		:		
6	Details of Earnest Money Deposit		:		
	Amounts (Rs.)		:		
	DD/PO No. and Date		:		
	Drawn on Bank		:		
	Valid upto		•		
7	Details of Tender Fee		· :		
/	Amount		· :		
	DD/PO No.				
			:		
	Drawn on Bank				
	Valid upto		:		Mith Due of duly contified by Chentoned
_	Annual Turnover of the Company/Firm/Agency for				
8	Accountant/Auditor) Last 03 Years balance sheet a Conditions	and cop	ies of	rincor	ne tax returns for 3 Years as stated in Terms &
	2018-2019				
	2013-2019		:		
	2020-2021		:		
		Scala	:		
	The Firm who are registered with NSIC or Small Industry/Or MSME are exempted to submit the te				
9	fee or EMD (Copy of Registration certificate mu				
	provided along with Udyog Addhar)				
10	Similar supplies in last 3 Years (with Proof)			1	
	Experience in the field for the minimum 3years				Similar 1 Government Running Contract with Central Government /State Government/Public Sector Undertakings /Universities/ deemed to be universities / Autonomous Bodies / Reputed Medical Institute or Organizations in last 3 Years.
				1	

NIA/CS/S.T/2021/(1)59 Certificate (To be submitted with the Technical Bid)

The Annual Turnover of M/s.

\_\_\_\_\_ for the last 3 Years

are given below and it is certified that the Statement is true and correct:

S.N.	Year	Turnover (in Rs.)
1	2018-2019	
2	2019-2020	
3	2020-2021	
	Total	RsLacs

Average Turnover Per Annum: Rs.\_\_\_\_\_ Lacs.

Signature of Chartered Accountant/Auditor with Seal

# LAPAROSCOPIC SIMULATOR NIA/CS/S.T/2021/(1)59

### MANUFACTURER'S/PRINCIPAL'S AUTHORIZATION FORM

TO,
Director
National Institute of Ayurveda
Jaipur
Sir,
Tender:

We	who are establis	hed a	nd reputa	able	manufactur	er of
having factories at	and				, he	reby
authorize Messrs	(name	and	address	of	agent(s)to	bid,
negotiate and conclude the contract with you against	Tender.					

No----- for the above goods manufactured by us. No company or firm or individual other than Messrs. ------ are authorized to bid, negotiate and conclude the contract in regards to this business against this specific tender.

We hereby extend our full guarantee and warranty as per the conditions of tender for the goods offered for supply against this tender by the above firm.

The authorization is valid upto ------

Yours faithfully,

For and on behalf of Messrs.'-----

(Name of manufacturers) principal

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## **Technical Specifications:**

# LAPAROSCOPIC SIMULATOR

- The system should be fully computerised and interactive.
- Should have PC and virtual reality simulation processor with 24" flat LCD touch screen
- Should have elevation mechanism for height adjustment
- Should have foot switch for electrosurgical coagulation
- Should have high performance force feedback with three (3) degrees of freedom
- Should have tool tracking with five(5) degrees of freedom
- Should be High performance and precision
- Should have a variety of optical angles : 0, 30 and 45
- Should have adapted instrument handles (graspers)
- Should have interchangeable suturing handles with suturing module
- The system should be able to provide comprehensive training in the field of laparoscopic surgery.
- The system should allow for individual training and allow Team Training by plug-and playconnection of the portable system. "Team training is performed using a combination of haptic and non-haptic systems".
- The system should contain at least 19 modules.
- The system should have multiple parameters to evaluate trainee.
- The system should have Web based Simulator Curricula Management System, providing the optimal solution for managing simulation based training and education needs
  - Should facilitate performing the administrative tasks of running a training course or workshop.
  - Should offer extensive library of courses including a library of ready-to-use simulator based courses and a platform to design new ones. Courses may include online didactic content, performance review and assessment with benchmarks in selected modules.
- Should have Virtual selection of pre-set trocar positions in certain modules.

## Virtual operating Room Setting – VR-OR (in selected modules)

- The system should have a setting of the fully immersive environment of the Virtual Operating Room using Oculus headset for the following modules: Inguinal Hernia, LAP Chole, Appendectomy and Hysterectomy
- The Virtual Operating Room setting should allow performance of the procedure in a virtual operating room with a virtual team, equipment and operating room sounds.
- VR OR should include optional tool selection instructions by Nurse in certain modules.
- VR OR should include the Surgical Mentor capability Surgical mentor provides procedural comments and tips in certain modules.

### Modules

- The system should have the following practice modules :
  - Basic Laparoscopic Skills including:
    - Camera manipulation, Eye-Hand Coordination
    - Clip Applying, Clipping and Grasping
    - Two handed Manoeuvres, Cutting and Electrocautery
    - Translocation of Objects

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### Basic and advanced suturing skills

- The advanced Suturing Module should include, Backhand technique, U-stitch, Curved suture line, Anastomosis, Slanted plane Suture line, Upper plane suturing and Hexagonal suture line.
- The Basic and advance Suturing, should include, detailed interactive tutorials to enable independent training.

### **Essential skills Module**

• Should have Essential tasks similar to Fundamentals of Laparoscopic Skills developed by SAGES.

### The system should enable trainee to practice simulation of the following procedures: Lap Cholecystectomy skills and full procedures—

- Should have procedural task module to guide the trainee through the critical steps involved in the Lap Chole procedure with displayed guidance.
- Should have Full procedures for cholecystectomy of at least 6 virtual patient cases with 16 anatomical variations enabling hands on in an unrestricted anatomical environment.
- Should have task Expert's "Critical View of Safety" which allows to perform a dissection of the cystic duct and artery using a reference of the expert's dissection.

## <u>Lap Incisional Hernia –</u>

- Should have at least 6 easy to difficult hernia repair cases.
- Should feature cases of hernia removal using simulated tools common to real surgeries such as the Harmonic Scalpel.
- The module should have simulated mesh, fixation devices, touch screen capabilities with external body view.
- $\circ\,$  The module should have an ability to control an abdominal cavity insufflation pressure.

## Lap Inguinal Hernia Module-

- The Module should provide virtual-reality hands-on simulation for Inguinal Hernia.
- The module should allow users to practice the key steps of the Laparoscopic Transabdominal Preperitoneal (TAPP) Inguinal Hernia repair for the right direct defect.
- Should include anatomy identification, peritoneal incision and dissection and sac reduction steps.
- Should include mesh placement, closure and fixation of the peritoneum task.

## Lap Appendectomy skills and full procedures-

- Should have a complete laparoscopic appendectomy curriculum.
- Should include at least two guided tasks, three guided techniques and four complete procedures with different levels of appendix inflammation and anatomical variations.
- Anatomy variations should include: retrocecal appendix, regular appendix, gangrenous pre-ileal appendix and perforated appendix.
- Should include ability for complete exposure, dissection and clipping of the appendicular artery.
- Should be able teaching surgical residents the basic steps of an appendectomy procedure and its techniques.
- Should include
  - i)Inspection of the abdominal cavity,
  - ii)Pus removal (in perforated and gangrenous cases),
  - iii)Exposure of the retrocecal appendix,
  - iv) Cecum mobilization (in retrocecal case) and Division of the mesoappendix,

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vi) Control of the appendicular artery, division and extraction of the appendix and irrigation and inspection of the abdominal cavity.

- Trainees should be able to learn to prevent potential complications such as perforation of the appendix and injury to the surrounding structure.
- Should have anatomical 3d Map and real life video.
- Should include "Proctor Mode"- capability enabling real-time modification of mesoappendix blunt dissection difficulty.
- Should include "Proctor Mode "– capability enabling real-time trigger of injury to the appendicular artery and bleeding control.
- Should include "Proctor Mode capability that allows to enable/disable a specific tool from the tools menu in real time.
- Should include Nurse Tool Selection capability that enables the selection of instruments during the case by a nurse
- The Appendectomy module should be validated.

### **Cholangiography Module-**

- The module should feature realistic visualization of the Cholangiography procedure.
- Should have didactic step by step guidance to lead the trainee through this complicated procedure.

### Nissen Fundoplication

- The module should offer **hands-on practice** with highly realistic graphics allowing users to practice the key steps of the Laparoscopic Nissen Fundoplication procedure for treatment of Gastro-Esophageal Reflux Disease (GERD)
- Should include dissection of peritoneal ligaments, and dissection of the short gastric vessels.
- Trainee should learn to prevent potential complications such as bleeding from various vessels and damage to the esophagus, crura, stomach and spleen.
- Should have at least Two Tasks
  - Task 1- Incision of the Gastrohepatic ligament and revealing Esophagus and Crura
    - The task should allow for practicing accurate peritoneal incision and dissection.
    - Should provide the trainee an opportunity to incise a window into the gastrohepatic ligament, safely dissect the peritoneum, separating the esophagus and crura, and release the esophageal circumference by dissecting the phrenoesophageal ligament.

Task 2 – Division of the Short Gastric Vessels

 The task should allow for practicing an accurate and safe dissection of the gastrosplenic ligament, including its short gastric vessels, in order to later mobilize the stomach fundus.

## Lap Full Gastric Bypass-

- Should help the trainee to understand and practice to complete a gastric bypass in its four primary steps.
  - i) Creation of the gastric pouch, Measurement and division of the jejunum,
  - ii) Gastrojejunal anastomosis
  - iii) Enteroenterostomy anastomosis with 2 anatomical positions

## Lap Sigmoidectomy and full procedure-

- Has to be full procedure module and Module should help the user to identify anatomy such as the ureter, IMA, IMV, gonadal,
- Should include

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- i) incise the peritoneum,
- ii) dissect in the correct tissue planes,
- iii) expose and dissect vessels, and
- iv) perform distal division and anastomosis.
- The Sigmoidectomy module should be validated.

### Lap Lobectomy Module-

• The module should provide a unique opportunity to practice the complicated steps. i) The hilar dissection

ii) Dissection and division of the blood vessels and bronchus, fissures division in order to separate the upper right lobe.

- Should simulate complications such as
  - i) injury to the pericardium, pulmonary artery and vein branches, phrenic nerve and azygos vein
- Virtual cases Should have
  - i) 3D anatomy atlas, step by step tutorials, experts video
  - ii) A fully guided case, Breathing and pulse movements
- Should have objective performance metrics that enhance the learning experience.
- The system should have options of selecting various hand instruments.
- Should have a "Proctor Mode" capability enabling real-time modification of the tissue stiffness during blunt dissection.
- Should have "Proctor Mode" –Capability enabling real-time trigger of mild and major injuries to the vessels and injuries control.
- Should have "Proctor Mode" capability that allows to enabling /disabling a specific tool from the tools menu in real time.
- Should include Nurse Tool Selection capability that enables the selection of instruments during the case by a nurse

### Lap Nephrectomy and full procedure-

- Has to have full procedure module of Transperitoneal Laparoscopic Radical Left Nephrectomy
- Trainee should be able to identify the anatomy such as the ureter, gonadal vein, renal vein, renal artery,
- o Should allow trainee to decide about the adrenal gland and
  - i) perform the Hilar Dissection
  - ii) Perform the Colon Mobilization with a complete instrument set.
  - iii) Perform mobilization of the upper pole

### <u>Lap Gyn – salpingostomy, oophrectomy etc. procedures –</u>

- Should have at least 7 cases to encounter a range of patient pathologies and gain experience with various techniques and surgical instruments.
- Should include variety of complications and emergency situations.
  - i) bleeding at the implantation site,
    - ii) a ruptured fallopian tube
  - iii) a blood filled abdominal cavity.
- Should allow trainee to make decision in a unrestricted clinical environment to perform
- i) Salpingostomy
- ii) Salpingectomy
- iii) Salpingo-Oophorectomy
- iv) Tubal sterilization

The module has to be validated in clinical studies

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## Lap Hysterectomy skills and full procedure -

- Should offer complete hysterectomy procedure including
  i) Ureter exposure, ii) Uterine manipulation, iii) Superior pedicles division,
  iv) Bladder mobilization, v) Exposure and division of the uterine artery, and
  vi) Colpotomy.
- The course of the ureters may be visualized transperitoneally, or through a retroperitoneal dissection
- Should have an option to allow the infrared illumination of the ureters for ureters's course identification.
- Should have an option to perform, hysterectomy with or without a preservation of the fallopian tubes and ovaries.
- Should include the option of ischemic appearance of the uterus after the division of the uterine vessels.
- Should include an option of "Proctor Mode" –capability enabling real-time triggering of injuries to the vessels and bleeding control.
- Should include an option of "Proctor Mode" capability that allows to enable/disable a specific tool from the tools menu in real time.
- Should include Nurse Tool Selection capability that enables the selection of instruments during the case by a nurse

### Vaginal Cuff Suturing-

- The module should provide a unique opportunity to practice vaginal cuff suturing using unidirectional and bidirectional Barbed Sutures.
- Should include a variety of potential complications such as suspected injury to the bladder, ureters, colon and iliac vessels.
- Should offer both visually guided suturing techniques and free-hand training

## **MYOMECTOMY SUTURING MODULE**

- The module should provide to practice and refine the suturing skills required for an upper myometrium and serosal closure using a continuous running suture.
- Training should include a variety of potential complications such as suspected injury to the bladder, ureters, colon and iliac vessels.
- Should have Real suturing handles allow for the life-like practice of suturing skills.
- Should have educational aids including videos of the real procedure, procedural instructions, 3D anatomical atlas and comprehensive performance reports.
- The system should be CE and ISO certified.
- 3D anatomical maps with an ability to filter out different organs for better understanding of anatomy should be available on certain modules.
- Should have feature of split screens of the procedure and of the anatomical atlas (that also have the capability to follow the user's camera movement on both sides of the split screen) in certain modules.
- Should have short video of real-life procedures in certain modules for self-learning
- Should have custom building of training courses for learners of all levels.
- Should have viewing and exporting of performances reports to facilitates learning, analysis of training effect, showing the learning curve, research and future certification.
- Should have technical Skills Reporting and Assessment :
  - Time and economy of movements.
  - $\circ$  Safety and electrosurgical dissection per relevant modules.
  - Procedural errors.

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- Procedure specific checklist items relating to knowledge of procedures, handling of instruments and many more.
- Should facilitate web based simulator curricula management system, providing the optimal solution for administration of users, Curricula design, Pre-preparation with didactic learning, Simulation and Reporting and assessment remotely.
- Should have ready to use designed Curricula from famous institutes.
- Should have a facility to access, assign, evaluate and administer the data of users remotely. Should have ready to use simulator based courses.
- Should have implementation of the ACS/APDS curricula.
- The system should have an option to be fully integrated online.
- The system should have an option for online centralized management of one or more simulators. The system should have an option for online user and group registration and administration
- The system should have an option for online access to didactics content: descriptions, objectives module books, tutorials and real life videos.
- The system should have an option for online access to ready to use course
- The system should have an option for online access to the performance reports.
- The system should have an option for online export of reports to files.
- The system should have an option for online capability to create and modify benchmarks.

## **Team Training**

- Should have Team Training capability in Hysterectomy Module allowed by a plug and play connection of the portable LAP Express system to the haptic LAP Mentor.
- Should have Camera Assistant capabilities in LAP Chole and Appendectomy modules allowed by a plug and play connection of the portable LAP Express system to the haptic LAP Mentor.
- The camera control in the Team Training case in the Hysterectomy module should be easily switched between users during a procedure.
- The camera control in the Camera Assistant setting in the LAP Chole Full Procedures module should be easily switched between users during a procedure.
- In the Hysterectomy Team Training case several trainees should be able to work simultaneously on the same case: the main surgeon operates 2 tools. The first assistant operates the third assisting tool and the second assistant manipulates the uterine manipulator.
- Should offer Nurse Tool Control capability that enables the selection of instruments during the case (in Appendectomy, Hysterectomy and Lobectomy modules)

### <u>Curricula</u>

- Should offer an implementation of the validated Proficiency Based Curriculum for the Cholecystectomy module
- Should offer an implementation of the SORTED Bariatric Curriculum
- Should offer an implementation of The Patient Safety Course for OR Nurses
- Should offer an implementation of the 1<sup>st</sup> MSMU (I.M.Sechenov First Moscow State Medical University) Scoring course.
- Should offer an implementation of the LSS (Laparoscopic Surgical Skills) Curriculum Grade 1 –Level1.

### **Associations**

• Should be used exclusively for the simulation based assessment for the European Laparoscopic Skills Curriculum (LSS) - Endorsed by EAES.