



JORDAN ARMED FORCES

The DIRECTORATE OF ROYAL MEDICAL SERVICES
THE INSTITUTE OF BIOMEDICAL TECHNOLOGY



Item #	Thorascopic surgical instrument set	Qty. (t)
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IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	
FDA/CE clearance	

	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
1.	<p><u>Damico biopsy forceps:</u></p> <p>should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft.</p> <p>6mm width serrated oval ring jaws atraumatic curved without ratchet, made from medical stainless steel, shaft width (5-7) mm, working length (23-28) cm, total length (33-38) cm, used for both dissector and biopsy forceps.</p>		



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	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
2.	<p><u>Forester lung grasping clamp:</u> should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft.</p> <p>Curved left (20) mm oval ring jaws serrated tapered atraumatic with ratchet, made from medical stainless steel, shaft width (5-7) mm, working length (23.5) cm, total length (33.5) cm.</p>		
3.	<p><u>Duval lung grasping clamp:</u> should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft.</p> <p>Curved left jaws (1.0 cm) serrated atraumatic with ratchet, made from medical stainless steel, shaft width (10) mm, working length (23.5) cm, total length (34) cm.</p>		
4.	<p><u>Node grasping clamp:</u> should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft.</p> <p>Curved jaw (11) cm oblong ring jaws without ratchet serrated atraumatic curved, made from medical stainless steel, shaft width (5) mm, working length (23) cm, total length (33) cm.</p>		
5.	<p><u>Damico debakey clamps:</u> should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft.</p> <p>Curved left jaws tapered (1*2) debakey jaws style, (11) cm jaw length without ratchet, made from medical stainless steel, shaft width (10) mm, working length (27) cm, total length (37.5) cm.</p>		



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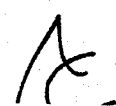


	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
6.	<p><u>Chitwood debakey clamps:</u> should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft. (6.5-10) cm jaw length (1*2) debakey jaws style, curved left with ratchet, made from medical stainless steel, shaft width (10) mm, working length (23-24.5) cm, total length (32.5-36) cm.</p>		
7.	<p><u>VATS MIS Scissors:</u> should be made as a single unit (one piece) and detachable part is not accepted.</p> <p>Dual pivot point, ring handle sliding shaft. Surgical scissor with rounded blunt blades, curved blade length (3.5) cm, made from medical stainless steel, shaft width (10) mm, working length (19.5) cm, total length (29) cm.</p>		
8.	<p><u>Dennis suction:</u> should be made as a single unit (one piece) and detachable part is not accepted. made from medical stainless steel.</p> <p>Variable suction curved blunt tip yankauer style with (7.5) mm tip width, shaft width (5) mm, working length (32) cm, total length (45.5) cm, yankauer style handle with tear shaped regulator.</p>		

مراقبه


Special Terms for Surgical Instruments

1. *Offers not complying with any of the special terms or the technical specifications will be considered as non-conforming.*
2. *Any vendor providing FORGED documents will be disqualified from the current tender and any future RMS tenders or purchase orders.*
3. *Bidder must provide a copy of the certificates of the following standards formally endorsed by the chamber of commerce of the manufacturing origin with the technical offer:*
 - A *EN ISO 13485:2012*
Standard to measure the quality of medical equipment, medical instruments and medical technology.
 - B *ISO 9001:2008*
Specifies requirements for a quality management system.
 - C *ISO 7153-1:1991*
This second edition cancels and replaces the first edition (ISO 7153-1:1983): it has been extended to include dental instruments.
 - D *ISO 7151:1988*
Specification of basic requirements for as well physical characteristics as workmanship, of the steel grades used and heat treatment of component parts, excluding rivets, screws.
 - E *ISO 7740:1985*
Lays down the dimensions of two sizes of fitting features for detachable scalpel blades and the handles with which they are used.
 - F *ISO 7741:1986*
This standard deals with materials, heat treatment and hardness of component parts, corrosion resistance, workmanship and cutting ability of scissors and shears used in the surgery and defines the test methods.



G ISO 13402:1995

Describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure.

H EN ISO 14001: 2004

ISO 14001 sets out the criteria for an Environmental Management System (EMS).

I 2007/47/EC

Is intended to harmonize the laws relating to medical devices within the European Union.

4. Bidder must submit samples with the technical offer from each brand that was submitted in the offer to be assessed and /or evaluated by RMS.

- *Offers which do not include such samples will be considered non-conforming.*
- *Offers which fail the evaluation/assessment process will be excluded from the tender.*
- *Samples will be returned to the Bidder at the end of the evaluation/assessment process except for samples from Bidders winning the final award where they will be the property of RMS and will be kept as a reference for the receiving committee.*

5. Required certificates:

- A. For instruments of USA origin, a copy of a certificate of FDA approval must be submitted with the technical offer.**
- B. For instruments of other origins, a copy of either a CE certificate (MDD)/TÜV OR a certificate of FDA approval must be submitted with the technical offer.**
- C. Where applicable, a copy of declaration of conformity certificate is accepted.**
- D. With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent / distributor for the offered item.**
- E. In all of the above cases (except D) certificates must be formally endorsed by JFDA.**

6. Country of origin:

The origin and the manufacturing plant for each set must be one of the following countries:

USA, UK, Sweden, Switzerland, Germany, France, Austria & Czech Republic.

- All offered items must be approved for sale in the same country of origin (an original and officially endorsed free-sale certificate from an authorized body must be included in the offer).

- 7. All items should be engraved or etched with manufacturing origin, company logo and code number.*
- 8. Each instrument set will be awarded as a whole set.*
- 9. Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first third of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period will be rejected.*
- 10. The supplier must furnish DRMS with a guarantee letter stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for twenty four months from the date of final acceptance of the equipment by DRMS which shall cover rusting, manufacturing defects, wear and tear and corrosion.*
- 11. Offers must include clear original catalogues for all offered items. Images and part numbers of offered items must be provided, highlighted and outlined clearly.*
- 12. Offers must include fully detailed information as a soft copy (either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact model/catalogue number and country of origin of the offered item(s), full description/specifications.*
- 13. Any accessories and consumable items necessary for the proper operation of surgical sets must be included in the offer. Bidder will bear any responsibility resulting from the awarding of insufficient items or sub-items.*
- 14. Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores and warranty.*
- 15. Custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port's corporation (including expenses caused by delay in presenting the necessary shipment documents for either*

clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).

16. DRMS has the right to increase or decrease the awarded quantities by a percentage not exceeding 30% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.

17. For offers submitted in Jordanian dinars, payment will be either by wire transfer or by cheque after final acceptance of goods, Any other way of payment will be rejected.