

# DEPARTMENT OF ORTHOPAEDICS ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI - 110029

Dr. Rajesh Malhotra

Professor and Head, & Chief, Trauma Centre Ph. 011-26593341 011-26588407

Dated: 31/05/2019

Ref. No.

02/Ortho/Stores/Proprietary item/2019-20

Subject

"Drill Cover Hex System - 02 Unit" for the Department of Orthopaedics AIIMS, New Delhi - 110029 on proprietary basis: <u>Inviting comments thereon</u>

The Institute is in the process to purchase "<u>Drill Cover Hex System- 02 Unit</u>" for the Department of Orthopaedics, AIIMS, New Delhi from M/s. Arbutus Medical, Inc. 560-828, W, 10<sup>th</sup> Ave, Vancouver, Canada on proprietary basis. The proposal submitted by M/s. S. J. Mega Solutions, B-1341/42, GD Colony, Mayur Vihar, Phase-111, New Delhi - 110096 and PAC Certification are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding the proprietary nature of the equipment/item within 15 days giving reference no. <u>O2/Ortho/Stores/Proprietary item/2019-20</u>. The comments should be received of the office of Professor and Head, Department of Orthopaedics, 5<sup>th</sup> Floor, Teaching Block, AIIMS, New Delhi, failing which it will be presumed that any other vendor has no comment to offer and the case will be decided on the merits.

Yours sincerely,

Prof. Rajesh Malhotra Professor and Head

Dr. R. MALHOTRA
MBBS, MS (Ortho), FRCS, FACS, FICS, FIMSA
Professor & Head
Department of Orthopaedics
A.I.I.M.S., New Delhi-110029

Encl: Related documents enclosed

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#### **DrillCover Hex System**

Make: M/s. Arbutus Medical, Canada

- Should be Level 4 ANSI/AAMI PB70 barrier linen cover
- Should be Impermeable barrier to Blood, bodily fluids, bacteria and water
- Should be ANSI Level 4 medical textile cover meeting EN1395, ASTM1670, ASTM1671 Standards
- Should be Autoclavable linen cover against 75 cycles
- Should be Metal chuck adapter with chuck key
- ➤ Should be Drill variable speed 0-1050 RPM
- Should be Drill stall-torque of 27.2 in –lb (3.1 N-m)
- Should be 2 X lithium ion, rechargeable battery
- Should be 30 minutes continuous unloaded run time on full charge batteries
- ➤ Should be 920 gm weight of Drill
- Should be FDA certification for complete Hex System including Drill, cover and chuck
- Should be Canada Class-II Certification
- Should be ISO 13485 Manufacturing environment

Dr. R. MALHOTRA

MBBS, MS (Ortho), FRCS, FACS, FICS, FIMSA

Professor & Head

Department of Orthopaedics

A.I.I.M.S., New Delhi-110029

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DR. R. M. S. C. L. L. Salles as to 20 a

# ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI - 110029

### PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1.	The indent goods are manufactured by M/s.	M/s. Arbutus Medical, Canada
2.	Item Name	DrillCover Hex System
3.	Model/Part/Catalogue No.	Drill Hex System
4.	Reasons/Justification which makes the requirement proprietary	Proprietary Certificate Enclosed for M/s. Arbutus Medical, Canada
5.	It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfill the vital requirements of end user.	2
6.	It is certified that the purchase is proposed to be made on proprietary usage basis because any other material/equipment/instrument chemical, etc. if used will lead to deviation and affect the integrity/accuracy, validity or analysis of the assignment/patient care.	DrillCover Hex System is proprietary product (Principal Firm Certificate enclosed), and best of my knowledge the price quoted by the firm should be reasonable

Signature of Indentor	
SIGNATURE OF THE T.S.E.C.	
SIGNATURE OF THE T.S.E.C.	

PROFESSOR AND HEAD DEPARTMENT OF ORTHOPAEDICS

Dr. R. MALHOTRA

MBBS, MS (Ortho), FRCS, FACS, FICS, FIMSA

Professor & Head

Department of Orthopaedics

A.I.I.M.S., New Delhi-110029

# Note 1: T.S.E.C. should clearly mention that the item in question is required to standardization of machinery or spare parts to be compatible to the existing sets of equipment which is required to be procured only from one manufacturer mentioed in serial no. (i)

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DR. RANGERO PRESIDES

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Dated 31/05/2019

File No.

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#### "CERTIFICATE FOR REASONABLENESS OF PRICE"

It is certified that the goods/equipment i.e. "Drill Cover Hex System – 02 Units," (Item Name) to be purchased are of the requisite quality, quantity and specifications and has to be purchased after following due purchase procedure of Institute. The purchase price against above mentioned tender/PAC is reasonable and recommended for purchase for the department of ORTHOPAEDICS"

**Dr. Rajesh Malhotra**Professor and Head
Department of Orthopaedics

Dr. R. MALHOTRA

MBBS, MS (Ortho), FRCS, FACS, FICS, FIMSA
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DR. RAVI MITTAL

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January 11, 2019

#### PROPRIETARY CERTIFICATE

To Whom It May Concern:

Arbutus Medical has 1 patent pending (USPTO) on these product families and there is no other system in the world that matches these specifications:

- Level 4 ANSI/AAMI PB70 barrier linen cover
- Impermeable barrier to blood, bodily fluids, bacteria and water
- ANSI Level 4 medical textile cover meeting EN13795, ASTM1670, ASTM1671 standards Autoclavable linen cover against 75 cycles
- Metal chuck adapter with chuck key
- Drill variable speed 0-1050 RPM

- Drill stall-torque of 27.2 in-lbs (3.1 N-m)
- 2x lithium ion, rechargeable batteries
- 30-minute continuous unloaded runtime on full charge batteries
- 920 g weight of drill
- FDA certification for the complete Hex system including drill, cover, and chuck
- · Canada Class II certification
- ISO 13485 manufacturing environment

Signed for and on behalf of Arbutus Medical

Thank you,

Tyler Algeo

Director, Global Health Arbutus Medical, Inc

Dr. R. MALHOTRA

MBBS, MS (Ortho), FRCS, FACS, FICS, FIMSA

Professor & Head

Department of Orthopaedics

A.I.I.M.S., New Delhi-110029

Dept. of Ansari Nagar Assistant Professorics Dept. of Ansari Nagar A.I. Mew Delhi-110029

DR. RAVI-MITTAL
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Dr. VIJAY KUMAR

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