ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110029
(HOSPITAL STORES)

Dated: - 15.04.2024

Ref. No.04/H/Consumable (Intraosseous Vascular Access Needle)/PAC/SSK-II/24-25

Sub: Purchase of Intraosseous Vascular Access Needle for department of Emergency Medicine, AIIMS on proprietary basis – reg.

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The institute is in the process for the procurement of Intraosseous Vascular Access Needle for department of Emergency Medicine, AIIMS on proprietary basis being close system. The proposal submitted by M/s. MGM Associates authorized distributor of M/s. Teleflex Medical Pvt. Ltd. and PAC Certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days from day of issue/uploading of the notification giving reference No.04/H/Intraosseous Vascular Access Needle/PAC/SSK-II/24-25. The comments should be received by office of Stores Officer, Main Hospital Store, at AIIMS on or before 01.05.2024 upto 12.30 P.M., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Encl: Related documents enclosed.

STORES OFFICER (H)र) Store Officer (Hospital Stores) अ.भा.आ.सं., अंसारी नगर, नई दिल्ली-29 A.L.I.M.S., Ansari Nagar, New Delhi-29

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## PROPRIETORY ARTICLE CERTIFICATE (PAC)

(for chemicals, spare parts, reagents, consumables etc.)

- (i) The indented goods are manufactured by M/s Teleflex, USA
- (ii) Item Name: Consumable (Intraosseous Vascular Access Needle)
- (iii) Model/Part/Catalogue No Arrow EZ-IO
- (iv) Reasons/Justification which makes the requirement proprietary## This item is proprietary and no other similar item is available with the power driver.
  - 1. 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. 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.

डॉ॰ नायर जमसेन्/Dr. Nayer Jamshed अपर अपनार्थ /Additional Professor अपनार्थात विशेष्य विश्वास विश्वास

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**Teleflex**®

Teleflex Medical IDA Business and Technology Pa Dublin Road Alhlone, Co. Westmeath trained

## **Proprietary Certificate**

To Whom it may Concern:

"Teleflex Medical", having offices at IDA Business and Technology Park, Dublin Road, Athlone, Co. Westmeath, Ireland, hereby confirms and verifies that following:

- 1. "Teleflex Medical" and/or its affiliated companies own or license all rights title and interest in and to the patents, trademarks, trade names, inventions, copyrights, know how, trade secrets and other intellectual property of the Arrow EZ-IO Intraosseous Vascular Access, to help permit intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent or medically necessary cases in adult and pediatrics.
- 2. Arrow EZ-IO Intraosseous Vascular Access System is a safe,<sup>1</sup> fast,<sup>2,3\*</sup> and effective<sup>4</sup> solution and provides peripheral venous access with central venous catheter performance.<sup>4-5,6</sup>
  - a. 97% first-attempt success rate<sup>7</sup>
  - b. Achieve vascular access within 10 seconds<sup>2</sup>
  - c. Safe; <1% serious complication rate<sup>1</sup>
  - d. 3 seconds to heart with medication/fluids3\*
- 3. **EZ-IO Power Driver:** Enables clinician control of the insertion with proven tactile feedback<sup>8</sup>.
- 4. **EZ-Stabilizer Dressing:** Designed to provide flexible securement of the EZ-IO Catheter, good adhesion and decreased risk of dislodgement.
- 5. **EZ-Connect Extension Set:** Must be primed with 1 ml of fluid prior to use
- 6. **EZ-IO Needles:** Diamond needle tip designed to deliver a fast and gentle insertion, and allow for manual insertion if needed
  - 45 mm 15 gauge: ≥40 kg, excessive tissue, humerus
  - 25 mm 15 gauge ≥3 kg
  - 15 mm 15 gauge 3–39 kg

The following are the details of the product:

Brand Name	Generic Name	New Men
Arrow EZ-IO Intraosseous Vascular Access System	Needle Sets	Ansals Majes

 "Teleflex Medical Pvt. Ltd.", having a registered office at the Building Embassy Vogue, 1st floor, Palace Road Ward No. 78, Bangalore, Karnataka-KA, India 560052, and "Teleflex Medical" are wholly-owned, indirect subsidiaries of Teleflex Incorporated (NYSE:TFX); and







Teleflex Medical IDA Business and Technology Park Dublin Road Alhione, Co. Westmeath Ireland

8. "Teleflex Medical Pvt. Ltd." is the sole authorized entity to import and market the above referenced product in India.

Yours Faithfully,

Rachel Rehl

Senior Regulatory Affairs Specialist

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Teleflex Medical

14 October 2022

## References:

1. Teleflex Internal Data on File 2014.

2. Davidoff J, Fowler R, Gordon D, Klein G, Kovar J, Lozano M, Potkya J, Racht E, Saussy J, Swanson E, Yamada R, Miller L. Clinical evaluation of a novel intraosseous device for adults: prospective, 250-patient, multi-center trial. *JEMS* 2005;30(10):s20-3. Research sponsored by Teleflex Incorporated.

3. Montez D, Puga T, Miller LJ, et al. Intraosseous Infusions from the Proximal Humerus Reach the Heart in Less Than 3 Seconds in Human

Volunteers. Annals of Emergency M edicine 2015;66(4S):S47. Research sponsored by Teleflex Incorporated.

4. Hoskins SL, Nascimento P Jr., Lima RM, Espana-Tenorio, JM, Kramer GC. Pharmacokinetics of intraosseous and central venous drug delivery during cardiopulmonary resuscitation. *Resuscitation* 2011; doi: 10.1016/j.resuscitation.2011.07.041. Research sponsored by Teleflex Incorporated. (preclinical study)

5. Hoskins SL, Zachariah BS, Copper N, Kramer GC. Comparison of Intraosseous proximal humerus and sternal routes for drug delivery during CPR. Circulation 2007; 116:II\_993. Research sponsored by Teleflex Incorporated. (preclinical study)

6. Based on Adult Proximal Humerus EZ-IO System Insertion data

7. Cooper BR, Mahoney PF, Hodgetts TJ, Mellor A. Intra-osseous access (EZ-IO) for resuscitation: UK military combat experience. J R Army Med Corps. 2007;153(4):314-316

8. Miller L, Philbeck T, Bolleter S, Garcia G. Tactile feedback comparison of three types of intraosseous access devices for needle insertion accuracy.

Ann Emerg Med 2010;56 (3):S133. Research sponsored by Teleflex Incorporated.

