Subject: Purchase of Swan Gang VIP catheter Consumable, Edward Life Sciences Ltd for the department of Cardiac Anaesthesia at AIIMS, New Delhi-29 on proprietary basis- Inviting comments thereon.

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The request received from Dr. Arindam Choudhury, Deptt. of Cardia Anesthesia by M/s. Edward Life Sciences Ltd on proprietary basis. The proposal is submitted by M/s Edward Life Sciences Ltd and PAC certifications are attached.

The above documents are being uploaded for open information and to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 7 days of issue of giving reference No. 01/Stores/ Cardiac Anaesthesia/PSC/Proprietary/2012-13. The comments should be received by office of Stores Officer, Research Section at AIIMS on or before 25.03.2013 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.

Yours faithfully,

Encl: Related documents enclosed.

PAC Certificate enclosed.

Specification of the item.

Dr Arindam Choudhury
Principal Investigator

Asstt. Professor, AIIMS
**SPECIFICATIONS:**

**Swan Ganz Thermadilution VIP Catheter**

Flow directed 5 lumen pulmonary artery catheters. 7.5 F in diameter & 110 cm in length with guide wire & single handed insertion device.

It should have a coating of Heparin as well as antimicrobial material (Benzalkonium Chloride) on entire catheter surface.

Should be able to give Cardiac output using Thermo dilution method.

Should be able to give PA pressure, PAWP & RA Pressure when transduced.

Should have proximal infusion & proximal injectate ports at 31 cm & 30 cm respectively.
Proprietary Article Certificate

March 20, 2013

To Whomsoever It May Concern:

I hereby certify that Edwards Lifesciences Technology Sarl, State Road 402, Km 1.4, Industrial Park, Anasco, PR 00610-1577 is the sole manufacturer of model 831HF75.

Description
The Swan-Ganz Thermodilution Catheters provide diagnostic information to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer.

Swan-Ganz Hi-Shore, CardioCath, and “S” Tip Thermodilution Catheters (Models 141F7, 141HF7, 143HTF7, 151F7 and 151HF7, respectively) have the same functions as the standard Swan-Ganz Thermodilution Catheter (Models 131HF7, 131HVF7 and 131HVLF7). The “S” Tip catheter (Models 151F7 and 151HF7) is designed for femoral vein Insertion. The Swan-Ganz Hi-Shore Thermodilution Catheter (Models 141F7 and 141HF7) is slightly stiffer than the standard Swan-Ganz catheter, and may be used when more torque control and maneuverability are needed (i.e., from the femoral approach). The CardioCath Thermodilution Catheter (Models 143TF7 and 143HTF7) is made from the same material as the Swan-Ganz Hi-Shore TD Catheter but is even stiffer due to the stiffening rod in one lumen. CardioCath has a “C” tip bend. In addition to the standard distal (pulmonary artery) and injectate lumens, the Swan-Ganz VIP Thermodilution Catheter (Models 831F75, 831HF75, 831HVF75, 831HVLF75, 831VF75G, and 831VF75G) has an additional lumen that provides direct access to the right atrium. The Swan-Ganz VIP+ Tri-Lumen Infusion Thermodilution Catheter (Models 834HF75 and 834F75) is equipped with a right atrium lumen and an additional lumen. The catheter’s right ventricular (RV) lumen terminates 10 cm from the catheter tip and the right atrial (RA) lumen terminates at 31 cm. The VIP lumen allows for continuous infusion, even during cardiac output determinations. The True Size Thermodilution Catheter (Model 132FS) is designed for pediatric use. Different models are available for use in adult or pediatric patients and for different insertion sites.

Certain catheters are treated with the AMC THROMBOSHIELD antimicrobial* heparin coating (Refs. 1 & 25). Significant antimicrobial activity associated with the AMC THROMBOSHIELD coating has been demonstrated using in vitro diffusion agar assays against the following organisms: Staphylococcus epidermidis, S. aureus, Streptococcus faecalis, Candida albicans, Escherichia coli, Serratia marcescens, and Acinetobacter calcoaceticus. Catheters with the AMC THROMBOSHIELD coating are denoted by an “H” in the model number (i.e. 831HF75).

Catheters with a contamination shield pre loaded on the catheter are denoted by a “V” in the model number; a “VL” denotes a locking contamination shield (i.e. 831VLF75) compatible with Edwards Introvers introducers.

Indications
Swan-Ganz Thermodilution Catheters are indicated for the assessment of a patient’s hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions.
The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

For Edwards Lifesciences LLC

[Signature]

Tom D. Mead
Director, Regulatory Affairs
State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 20th day of March, 2013, by Tom D. Mead, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

[Signature of Notary Public]

ELAINE E. MC CLAIN
Commission # 1940952
Notary Public - California
Orange County

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