

## Alfa Corpuscles develops indigenous yet affordable key surgical technology

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The most critical component of any laparoscopic surgery is the trocar, which is used to gain access to the abdomen for inserting the laparoscope and surgical instruments. To address to the risk of infections and injury due to the reuse of trocars, increasing number of surgeons prefer using disposable trocars, but high cost of the imported products leads to the malpractice of reuse of single use devices.

But now the New Delhi based Alfa Corpuscles, with financial assistance from the Technology Development Board, has commercialized endoXS, the First Indigenously designed 'Disposable Trocar for Laparoscopy' that has been developed from inputs from over 150 Surgeons, conforms to all international standards and has innovative features that leads to significant cost reduction. The product is manufactured in a GMP Facility, has a CE marked and has an ISO 13485 and CMDCAS Certification and bears Indian Patent Application Number 2032/DEL/2014.

Unique Features of endoXS are 'bladeless separator tip' for access with minimal tissue damage, 'angulated fascial thread' for superior abdominal wall retention, 'inbuilt adaptive flexi-seal' to maintain abdominal insufflations while accommodating a wide range of instrument sizes (4.7mm to 12.9mm) and 'optical access technology', enhancing safety during insertion by enabling visualization of the tissue layers.

"The sales of endoXSTM have already been promising with a lot of surgeons expressing interest and acknowledging the ease of operation with the device. With the introduction, widespread use and disposal of low cost disposable trocars such as endoXSTM there shall be a reduction in overall cost of laparoscopic surgery, reduced incidents of injury or infection due to reuse and adherence of ethical practices in relation to the device by doctors and hospitals," mentioned the company's spokesperson.

On what lies ahead, he added further, "Keeping up the spirit of Make in India campaign and with the positive encouragement of the Indian Government, we hope our product, endoXSTM, would be readily taken up by various hospitals and clinical

institutions, and appreciated for its low cost and quality which is at par with various imported products presently in the market."

The company believes that in the coming years, with the availability of endoXSTM, there would be reduction in overall cost of laparoscopic surgery, reduced incidents of injury or infection due to reuse and adoption of ethical practices of disposing single use devices by doctors and hospitals. Minimal Access (Laparoscopic) Surgery has come to be the mainstay treatment for a majority of surgically correctable diseases. One of the most critical components of any laparoscopic surgery is the trocar. Trocar injuries and infections can prove disastrous to the patient's health and surgeons' reputation.

The currently available forms of the trocars are either metallic (reusable) or plastic (disposable).

The metallic trocars are capital intensive, require frequent servicing, sharpening and are more prone to causing injury (both mechanical and electrical). Also, being complex lumened (hollow) devices are difficult to clean and nearly impossible to sterilise with conventional methods such as autoclave. Heating of water to produce steam in autoclave also releases the dissolved air giving rise to a non-condensable gas fraction.

The plastic (disposable) trocars, are marked for single use, which are expensive, hence they are frequently reused to justify or recover cost. These are usually subject to formalin vapour or glutaraldehyde (QAC) exposure, but due to the inaccessible inner chambers cannot be cleaned or sterilised effectively and reprocessing of single use devices stays as an issue of debate. Larger centres often use ethylene oxide or Sterrad for reprocessing of single use devices but pay little heed to validation of sterilisation and material disintegration that often leads to device failure and patient harm.

The disposable trocar has clear advantage both in terms of features and safety over the metallic and the use of such as a single use device is both safe and ethically correct, but the medical device industry needs to effectively design and produce low cost products to encourage disposal after use.