Surgery (from Greek meaning ‘hand work’) is a critical aspect of medical treatment. The importance of medical devices in a procedure cannot be underestimated. That’s where we come in: we produce medical devices that are a cut above – by any reckoning. In the following pages, enter the world of medical devices at Lotus.
Lotus – a foreword

As an engineering / management professional with over 25 years’ experience in the Medical Device Industry, including the development of 7 facilities with Surgical Sutures as their primary product lines, it gives me great pleasure to introduce Lotus Surgicals Pvt Ltd.

Lotus’ ultra modern 60,000 square feet (5,574 square metres) facility in Dehradun, India is at par with the best of the Medical Device manufacturing facilities in the world. From the beginning, Lotus has been committed to creating a world-class manufacturing facility capable of delivering superior quality Sterile Medical Devices to domestic and international markets. In pursuit of this objective Lotus has spared no effort to select from the world market the highest quality manufacturing and testing equipment available. Unlike other competitors who typically utilize large Class 100,000 work areas, Lotus has chosen to create individual Class 10,000 Clean Rooms for the storage (critical components), preparation (sutures), assembly, packaging and sterilization of their products, as well as controlled warehouse and finished goods areas.

While competitors either ship their products to contract facilities for sterilization or have large EO Sterilization Chambers for processing their products, Lotus has chosen to utilize a unique state-of-the-art 100% EO Sterilizer from Anderson Sterilizer. This Sterilizer has the ability to process and monitor smaller individual lots and ensure better EO distribution. It is also equipped with an Abator that neutralizes the discharged EO into carbon dioxide and water prior to release, thus eliminating damage to the environment and EO exposure risk to the operators. The facility is also equipped with a Quality Assurance Laboratory and a separate isolated Microbiological Laboratory. To ensure that the manufacturing operations are uninterrupted by power outages, the facility has been equipped with a 725 KVA generator equipped with an MTU engine (Mercedes Benz).

Lotus’ commitment did not stop with the facility and equipment. It has chosen to select only the highest quality raw material components (sutures, needles, mesh, etc.) from the world market for use in the manufacture of the products. In addition they have developed user-friendly packaging in consultation with DuPont, clearly identified to minimize the opportunity for error while maintaining sterility and product stability.

In conclusion, I have no hesitation in saying that Lotus, through dedicated ownership and joint commitment to quality, has raised the bar for the medical device industry in India and will occupy a prominent place in the world market in the years to come.

Scott Henderson
Project Consultant and Director
Lotus Surgicals Pvt Ltd
The guiding principles at Lotus are **honesty, integrity** and **hard work**. The core team ensures that these values are **preserved and practised** down the line.

Any organization is only as good as the people who spearhead it. Lotus is lead by dynamic people with years of experience behind them.

**Mehernosh Daruwalla**

Mehernosh Daruwalla is the Managing Director of Lotus Surgicals Pvt Ltd. Starting his career with Pfizer in 1979, he has been associated with the medical profession for the past 28 years. He enjoys a high degree of credibility and acceptance in the medical fraternity. His vast experience, understanding of customer needs, and delivering solutions provides Lotus with the competitive edge.

Samara Capital, an India focused private equity fund with USD 500 million assets under management, has invested in Lotus to assist in the company’s next phase of growth. Samara is contributing towards strengthening systems and processes, introducing new product lines and taking the company global.
A clean room facility is one which has a defined environmental control of particulate and microbial contamination and is constructed, maintained and used in such a way as to minimize the introduction, generation, and retention of contaminants.

Lotus Surgicals has an ultra-modern Clean Room facility for manufacturing various medical devices. The infrastructure complies with the specifications, testing and validation norms of International Regulatory Agencies, such as ISO, WHO, USFDA and EU.

Some of the impressive operational and constructional features of the Lotus Clean Room facility are:

- The entire manufacturing area is designed to meet Class 10,000 cleanliness standard of US FED 209E (i.e. not more than 10,000 particles of size 0.5 microns per cubic feet of air) equivalent to ISO Class 7. This provides an environment which protects from external contamination.
- The air handling systems are designed to ISO requirements (ISO 14644), thus providing air of high quality with respect to particulates. The processing areas receive clean and filtered air with a minimum of 60 air changes per hour in the core process areas.
- All process areas have terminal High Efficiency Particulate (HEPA) Filters with an efficiency of 99.97% down to 0.3 micron.
- The air flow is unidirectional and in a laminar fashion across all workstations, lowering contamination risk.
- A differential pressure of 12 to 15 Pascals is maintained effectively between adjacent rooms to prevent ingress of particulates (viable and non-viable).
- Temperature and relative humidity control is provided through an energy efficient air conditioning system and dehumidifiers, ensuring stability of environmental condition during manufacturing, which is extremely important for synthetic absorbable sutures.

Clean rooms creating the right environment

Clean room construction from non-particle shedding modular panels ensures air tight rooms, better insulation and ease of maintenance.
The clean rooms have been constructed with non-particle shedding modular panels made of powder coated GI sheets with polyurethane foam at its core, ensuring airtight clean rooms, better insulation and ease of maintenance. Epoxy flooring and covings at all corners provide smooth surfaces and prevent generation and accumulation of dust. It also prevents settling and harboring of micro-organisms in corners and crevices.

- The clean room clothing is pre-sterilized (by autoclaving). It is provided to all personnel entering the clean room facility, thus minimizing contamination in the clean room areas.
- Raw material movement into the clean room facility is through well-designed air locks and dynamic pass boxes, thus minimizing the entry of contaminants into the clean room facility.
- All doors and windows are flushed with walls on both sides. The door and window frames are equipped with non-particle shedding gaskets to make them airtight.
- Door Interlocking System is provided in all critical areas to avoid cross contamination and to prevent unauthorized man-material entry.

All the above features contribute significantly in reducing the bio-burden and particulates on the product prior to sterilization. This helps us produce a risk-free, sterile product that can be used with confidence by the surgeons.

The 15,000 square feet manufacturing area has a total of 20 Class 10,000 clean rooms of varying sizes.
To achieve world-class standards in manufacturing, Lotus has imported from the US the suture preparation, needle attaching, sealing and automatic winding machines.

The cutting of the mesh into different shapes and sizes is done on a laser cutting machine. The mesh is double packed in DuPont Tyvek paper using a custom-built automatic packaging machine.

The manufacturing processes are handled by well-trained, skilled and dedicated personnel. The manufacturing personnel at Lotus have been imparted hands-on training by specialists from Japan and our Project Consultant, Scott Henderson of USA.

Ultra modern facility, combined with well trained personnel, ensures consistent quality in manufacturing.
Lotus, in consultation with DuPont, USA, developed a unique, hermetically sealed aluminium peel-off pouch for packaging the entire range of synthetic absorbable sutures.
Meeting the challenge of sterilization

One of the more difficult aspects of suture manufacturing has been the sterilization of synthetic absorbable sutures. Due to their hygroscopic nature and the tendency to bond effectively with EtO in the presence of moisture, they tend to degenerate and lose strength on storage, leading to serious implications for the patient and the surgeon.

The solution, therefore, was a sterilizer that delivered precise moisture levels for effective sterilization. Andersen uses a unique method for creating humidity. It employs a humidity chip that delivers precise humidity levels directly onto the load to be sterilized, compared to the older method of spraying distilled water into a chamber full of gas.

Andersen Sterilizers use less than 1/6th of the gas compared to other conventional sterilizers. As a result, less gas binds to the suture and is easy to recover at the end of the cycle. This also ensures that lesser amounts of gas are discharged into the environment. As opposed to this, conventional sterilizers using high amounts of gas make the complete recovery of EtO difficult, leading to the presence of residual EtO on the product that could lead to post-operative complications.

Lotus found the answer in a 100% EtO gas sterilizer from Andersen Products, USA. Andersen is a name to reckon with in the business of sterilization for the past 35 years and has more than 7,000 installations worldwide to its credit.

Andersen uses a unique method for creating humidity. It employs a humidity chip that delivers precise humidity levels directly onto the load to be sterilized, compared to the older method of spraying distilled water into a chamber full of gas.

As a responsible corporate citizen, Lotus is also committed to environment protection. To this end it has invested in an Abator provided by Andersen Products that neutralizes the discharged EtO into carbon-dioxide and water.

The Andersen Sterilizer delivers precise moisture levels through a humidity chip and utilizes less than 1/6th of the EtO used by conventional sterilizers.
At Lotus quality is never by accident – it’s by design, using the Quality Management System (QMS). Every quality aspect is reviewed periodically.

The Lotus facility is an integrated manufacturing facility, producing finished products as well as primary finished packaging itself.

The Quality Management System (QMS) is developed to provide assurance that all systems are designed and implemented as per the standard norms.

The QMS is based on the following strong pillars:

- Quality Policy
- Quality Risk Management
- Robust Technology
- Quality By Design
- Facility Designing as per international standards
- Standard Operating Procedures
- Compliance to Standard Operating Procedures
- Internal Audit System
- Role & Responsibility of Quality Assurance function
- Independent QA
- Well-equipped QC Laboratory
- Well-equipped Microbiology Laboratory
- Vendor Qualification & Approval
- Change Control Procedures
- Qualification & Validation

The Quality Management System is reviewed periodically to keep it updated with any changes in practices. This will be driven by Quality Assurance and reviewed by the Management periodically.

Such an effective Quality Management System is the current thinking of the industry.
At Lotus only the finest quality needles are selected and customized for each surgical specialty and procedure.

The Lotus range of products

### Surgical Sutures

Complete range of Absorbable and Non-absorbable, Braided and Monofilament Sutures catering to every specialty, including cardiovascular and plastic surgery.

#### Absorbable Sutures (Braided, Coated)
- **Lotus®**: Polyglycolic Acid
- **Lotus 910®**: Polyglaclin-910
- **Lotus 930 AM™**: Polyglaclin-910 with Antimicrobial (Chlorhexidine diacetate)
- **Lotus Swift®**: Short-term Polyglactin-910

#### Non-Absorbable Sutures (Braided, Coated)
- **Estrolus®**: Polyester
- **Silros®**: Black Braided Silk
- **Silk Reel**: Black Braided Silk Reels

#### Absorbable Sutures (Monofilament)
- **Monolux®**: Poliglycolide-co-caprolactone
- **Masor®**: Poly(Dl-lactide-co-glycolide)
- **Logut®**: Calgut Sutures

#### Non-Absorbable Sutures (Monofilament)
- **Prokis®**: Blue Polypropylene
- **Prokis®**: Blue Polysulfone
- **Nylors®**: Black Polynylde
- **Steed®**: 316 L Stainless Steel
The Lotus range of products

Other medical devices

- ProLux® Mesh - Polypropylene mesh for Hernia Repair
- ProLux® Lite - Light Weight Polypropylene Mesh for Hernia Repair
- ProLux® Ultra Lite - Ultra Light Weight Polypropylene Mesh for Hernia Repair
- Pro-Ag® - Partially Absorbable Light Weight Mesh for Hernia Repair
- Prosect® - Skin Stapler & Remover
- Haemosec® - Haemostatic Clips & Applicators
- Freedom® - Trans-obturator sling and needle system
- Procedural Kits - Hernia Kit, C-Section Kit, Abdominal Hysterectomy Kit
- Limbal Stitches - ProLux Mesh

Mesh in various shapes and sizes are available, laser cut and double wrapped with DuPont Tyvek Paper.
The earth is our only home – as it stands. Lotus feels responsible for the earth and the people who dwell on it.

The 'TONS' river flowing quietly behind our plant is symbolic of our concern for the environment. This gentle brook is clear and devoid of effluents. Which, again, underlines our eco-friendliness.

As a corporate manufacturing high quality medical devices, Lotus's responsibility extends far beyond its manufacturing activities. Which is why you'll find that we not only have an abiding concern for the environment but also deep regard for the people in our community.

No wonder all our equipments conform to the highest environmental standards, and the facilities for our employees are of the topmost order.

We ensure proper training for our people in operations, safety and environmental matters. And have a programme whereby their skills are constantly upgraded. More importantly, we have a strong affinity for the local populace and are providing employment opportunities to them.
Recognition for being a Symbol of Excellence in the Medical Device Sector

LOTUS SURGICALS PVT. LTD. is the recipient of the Economic Times "ET Best Healthcare Brand 2016". This award is among the most celebrated awards that seeks to recognize companies and individuals that have pushed the boundaries of excellence - rising above competition and demonstrating exceptional performance across India. Lotus has been recognised for this outstanding performance.

This is yet another testimony of Lotus’ efforts and success in delivering quality products year after year.

Within a short period Lotus has carved a niche for itself as a provider of high quality surgical products at affordable prices; thus blunting the aggressive branding and pricing of multinational companies. Today more and more surgeons are convinced that Lotus is the way forward and can be whole-heartedly trusted with patients’ lives.

Lotus Surgicals Pvt. Ltd. is also a recipient of the Frost & Sullivan "Indian Medical Consumables Company of the Year 2013" award.

It is important to state that these awards would not have been possible without the faith and support of thousands of doctors patronizing Lotus products.

We, at Lotus, rededicate ourselves to push the boundaries of excellence and further enhance our position in the industry year after year by focusing on innovation, research and development, quality, customer care and constantly keeping in mind that we are dealing with human life, which is precious.