



FDA U.S. FOOD & DRUG
ADMINISTRATION



Certified Company



34 Years of
Dedication



pain was past

make pain free life your future

34 Years of
Dedication



XLO, established in 1992, has emerged as a pioneering force in the field of orthopaedic implants. The company is dedicated to enhancing patient outcomes and improving quality of life through innovative solutions in orthopaedics.

With a strong emphasis on quality and precision, **XLO a US FDA, CE, ISO13485:2016, WHO:GMP, ISO 9001:2015 & Indian FDA** has positioned itself as a leader in the design, development, and manufacturing of advanced orthopaedic implants.

XLO offers the most extensive range of Cementless & Cemented Joint Replacement Implants, Trauma Implants, 3d Printed Patient Specific Implants & Instruments along with Bone Cement with a state-of-the-art manufacturing facility located in New Delhi, India. This facility is equipped with advanced technology that supports the production of high-quality orthopaedic implants while adhering to strict regulatory standards.

The company has established a pan-India presence, ensuring that its products are accessible across the country. Furthermore, XLO exports its innovative solutions worldwide, contributing significantly to global healthcare advancements in orthopaedics.



Vision

To become India's First Professionally managed MNC in Orthopaedics.

We are a diversified healthcare company applying innovative science to develop specialty Orthopaedic products that save and Support patients' lives.

Mission

As one of the most respected company in Orthopaedics, we are committed to be :

- One of the top three Orthopaedic devices company in India
- A preferred partner in improving quality and access to healthcare
- An innovator in science and technology
- Recognized and trusted worldwide
- A high-quality investment
- A rewarding place to work and develop
- A one stop solution for Orthopaedic speciality



Company Snapshot



- More than 34 years of market experience driven as well-recognized Indian brand.
- Widest range of Orthopaedic Implants.
- Approximately 70% of sales from products with leading market positions.

Company History



- 01**
The first to Launch Uncemented Dual Porous Coated Implants as an Indian manufacturer.
- 02**
The first to get Manufacturing CE for all products.
- 03**
The first to make Bone Cement in active collaboration.
- 04**
The first to get CE, EN:ISO13485, WHO:GMP, ISO 9001: 2015 certifications.
- 05**
The first to make Expandable Tumor Implants in India.
- 06**
The first to provide Pre-Sterilized Products..
- 07**
The first over 16 years Follow-ups for Hips.

Company History



- 08 *The first to provide complete basket of Orthopaedic Implants & Instruments.*
- 09 *The first and Only Indian company to have maximum range of Tumor Implants.*
- 11 *The first to launch CERAMIC 36mm heads.*
- 13 *The first A leader in Customization of Implants in the shortest possible time.*
- 08 *The first to provide complete basket of Orthopaedic Implants & Instruments.*
- 10 *The first to launch Collarless Hip Replacement stem.*
- 12 *The first to launch Large Diameter Acetabular Cups.*
- 14 *3D Printing.*



xlo Strengths

- Strong values-based culture.
- Passionate team with significant depth of talent and expertise.
- Innovation.
- Customization.
- Manufacturer of 3rd Generation Implants.
- Significant capabilities in manufacturing, distribution and direct selling.
- Strong patient and customer relationships.
- Strong scientific and technological expertise.
- To cater to 80% of India's needy patient population.
- Experienced management team with immense experience in Orthopaedics.

Materials



All our products are fabricated using high grade raw materials like Titanium Ti6Al4V Grade 5 and Stainless Steel 316L that adhere to ASTM Standards.

All our products are manufactured by using CNC (Computer Numerical Control) machines.

**GLOBAL
PRESENCE
IN MORE THAN
30
COUNTRIES**



Academic and International Partner's



UNIVERSITY
of York



UNIVERSITY OF LEEDS



THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA



Maulana Azad Medical College

TUDelft
Delft
University of
Technology



Academic and International Partner's



Global Health Research Group
Surgical Technologies

ONLY INDIAN COMPANY CHOSEN TO PARTNER WITH UNIVERSITY OF LEEDS FOR RAIS PROJECT



“

Little by little, day by day, the project for WID is moving in the right direction.





XL-ARE , A Division of XLO Institute for Surgeons is a research and education based platform specializing in surgical treatment of Joints, Trauma, Spine and Musculoskeletal disorders via constant research and innovation. Being medical guide a non-profit organization, XL-ARE strives to coordinate with a global network of specialists surgeons and plan to be the leading educational platform for all.

Past Sawbone Journey



trusted by
Orthopaedics



XL-ACADEMY OF RESEARCH AND EXCELLENCE
A Division of XLO I Ortho Life Systems

Past Sawbone Journey



BOSCON 2024
Dhaka, Bangladesh



trusted by
Orthopaedics



Past Sawbone Journey



Past Sawbone Journey



Adyar Cancer Institute Chennai, Tamil Nadu



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trusted by
Orthopaedics

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Past Sawbone Journey



XL-ARE
Dhaka, Bangladesh



trusted by
Orthopaedics



Past Sawbone Journey



RAIS
Cadaver
Lab UK

UK
Award
RAIS



UNIVERSITY OF LEEDS

xlo pd-m RAIS



xlo
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Past Sawbone Journey



**RAIS Kenya
& Uganda**

NZOACON



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Cadaver workshop- Megaprosthesis



**Swami Rama
Himalayan University**
Sangatiya Walakhur, Uttarakhand



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A Division of XL O | Ortho Life Systems



Deborah Maufi MBBS, MBA

Improving access to health information and care services where it's needed most | Women's Health | Healthcare Project Manager | Health Innovations

“

The future lies in gasless laparoscopy, offering numerous benefits including reduced costs, improved accessibility, fewer complications, and enhanced sustainability in minimally invasive surgery.



LORESA

47 followers

1mo • Edited •

✓ Following

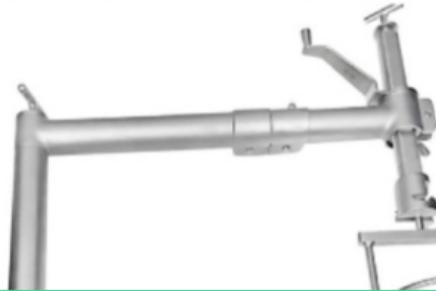
• Innovating for Impact: Gasless Laparoscopy in Resource-Limited Settings

In the world of healthcare, innovation often stems from a need to bridge gaps and overcome challenges. In many parts of the world, access to advanced medical facilities is limited, making complex surgical procedures a daunting task. Traditional laparoscopic surgery, which relies on carbon dioxide insufflation, poses challenges in resource-constrained environments. Enter Retractor for Abdominal Insufflationless Surgery (RAIS), a groundbreaking solution designed to eliminate the need for gas insufflation during laparoscopy.

We're pushing the boundaries of medical technology and bringing transformative change to the world of surgery. Stay tuned for more updates on RAIS and its impact on global healthcare.

#HealthcareInnovation #SurgicalTechnology #GlobalHealth
#ResourceLimitedSettings #RAIS #Laparoscopy #gaslesslaparoscopy

University of Leeds Pete Culmer @Noel Aruparayil Anurag Mishra Sundeep Singh Sawhney Deborah Maufi MBBS, MBA Richard Hall MSc, BA(Hons), CMgr MCMI, FRSA Pd-m International Tamandeep Singh Kochhar

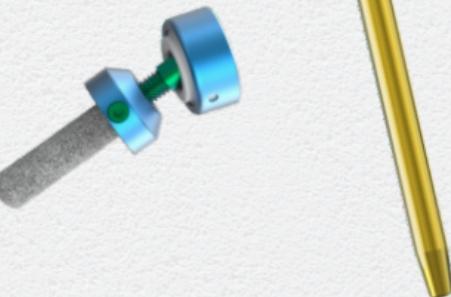




India's Only Company with the most extensive range of
Cementless & Cemented Joint Replacement Implants,
3d Printed Patient Specific Implants,
Trauma Implants & Instruments.



xlo trusted by
Orthopaedics



XLO Products

Excellence and our company manufactures wide range of products, which comprises of following categories :

- Trauma Extremities (Locking Plates & Screws, Non Locking Plates, Intramedullary Nails)
- Arthroscopy Implants & Instruments
- Spine Implants & Instruments
- External Fixation systems including illizarov (Steel & Carbon) & Special Fixators
- Joint Replacement – Complete Range of Cemented & Cementless Hips, Elbow , Shoulder, Radial Head, Ankle etc.
- Custom made & 3D printed implants
- Bone Cement (Antibiotic & Non Antibiotic)
- Cement Gun & Disposables
- Limb Salvage Implants

Range of Limb Salvage Implants:

- Distal femur Titanium (Non Rotating) with HA Collar stem
- Distal femur Titanium (Rotating Platform) with HA Collar stem
- Proximal Tibia (Non Rotating) with HA Collar stem
- Proximal Tibia (Rotating Platform) with HA Collar stem
- Proximal Humerus/Modular Shoulder
- Complete Humerus Expandable Prosthesis
- Proximal Femur with HA Collar stem
- Distal Complete Tibial & Femoral Modular Knee Prosthesis
- Distal Tibial / Ankle Modular Knee Prosthesis
- Distal Femur Expandable Prosthesis
- Proximal Tibia Expandable Prosthesis
- Periacetabular /Saddle Modular Prosthesis
- Arthrodesis Modular Knee Prosthesis
- Proximal Tibia Epiphyseal Limb Sparing Prosthesis
- Acromium Prosthesis
- Growing Implants for Pediatric Patients

Implants available in SS316L, SS316LVM, CoCr, Titanium Grade 5Eli

XLO range of Innovative products

xl-axenture

Cementless Total Hip Replacement System

xl-foundation™c

Cemented Modular Bi-polar & Total Hip Replacement System

xl-advance evolve

Cementless Modular Elbow Replacement Systems

xl-spine innovations

Spine Systems

xl-nex gen

Modular Cementless Radial Head Replacement Systems

xl-momentum

Limb Salvage - Next Generation Systems

xl-lock fx

Sterile Locking Trauma Extremities Systems

xl-infinity

Modular & Customized Limb Salvage Systems

xl-triniti™

Total Knee Replacement Systems

xl-syNergy

Cementless Modular Shoulder Replacement Systems

xl-elite

Modular Ankle Replacement Systems

xl-optima solutions

Arthroscopy Systems

xl-ace

Nailing Systems

xl-creations

3D Printing & Customized Solutions

xl-ex fix

External Fixator

xl-surgical solutions

Acrylic Bone Cement, Disposable Syringe Kit & Cement Gun

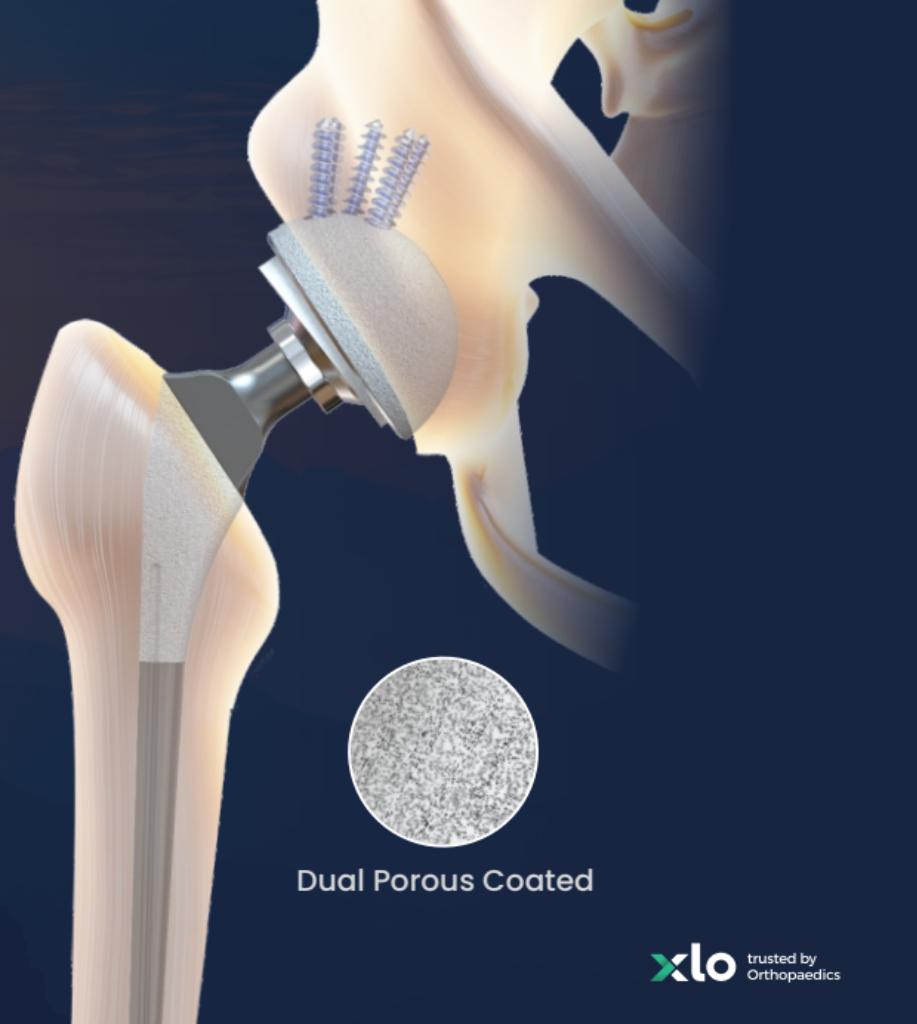
Multifunctional Power Tools

xl-axenture

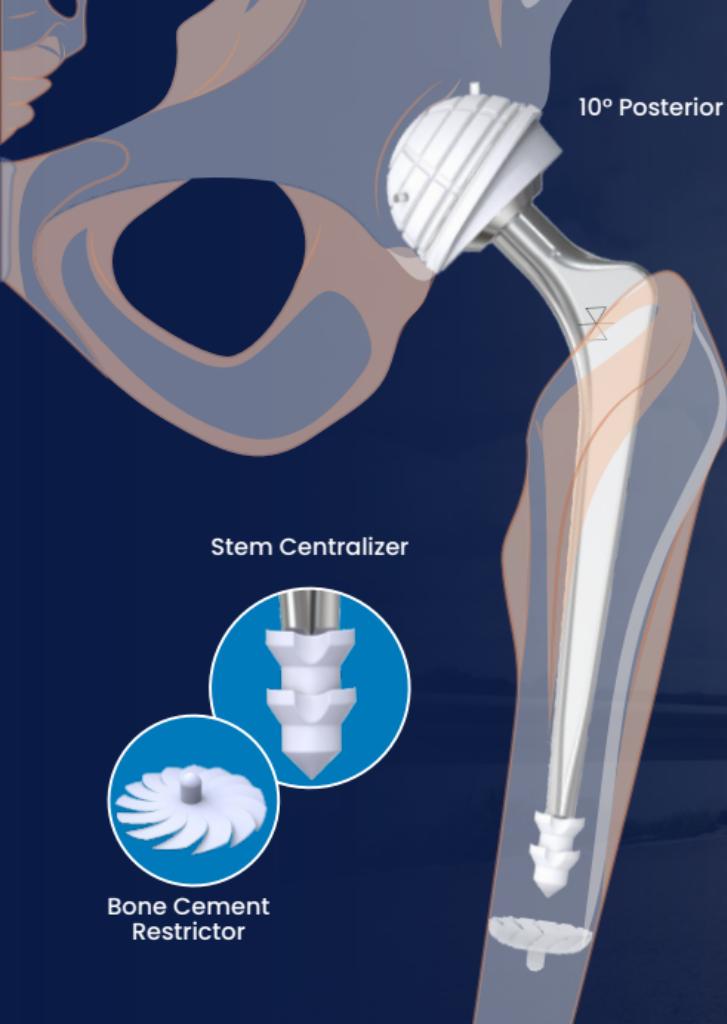
Cementless Total Hip Replacement System

for Inquiry please email us @

- Domestic : info@xlo.in
- Export : exports@xlo.in



Dual Porous Coated



10° Posterior Wall Cup

Stem Centralizer



Bone Cement
Restrictor

xl-foundation™“c”

*Cemented Modular Bi-polar & Total Hip
Replacement System*

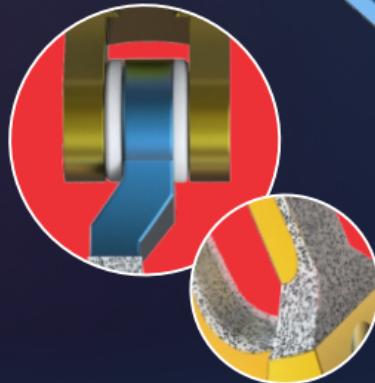
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India's First Indigenous **xl-advance evolve**

Cementless Modular Elbow Replacement Systems



Dual Porous Coated

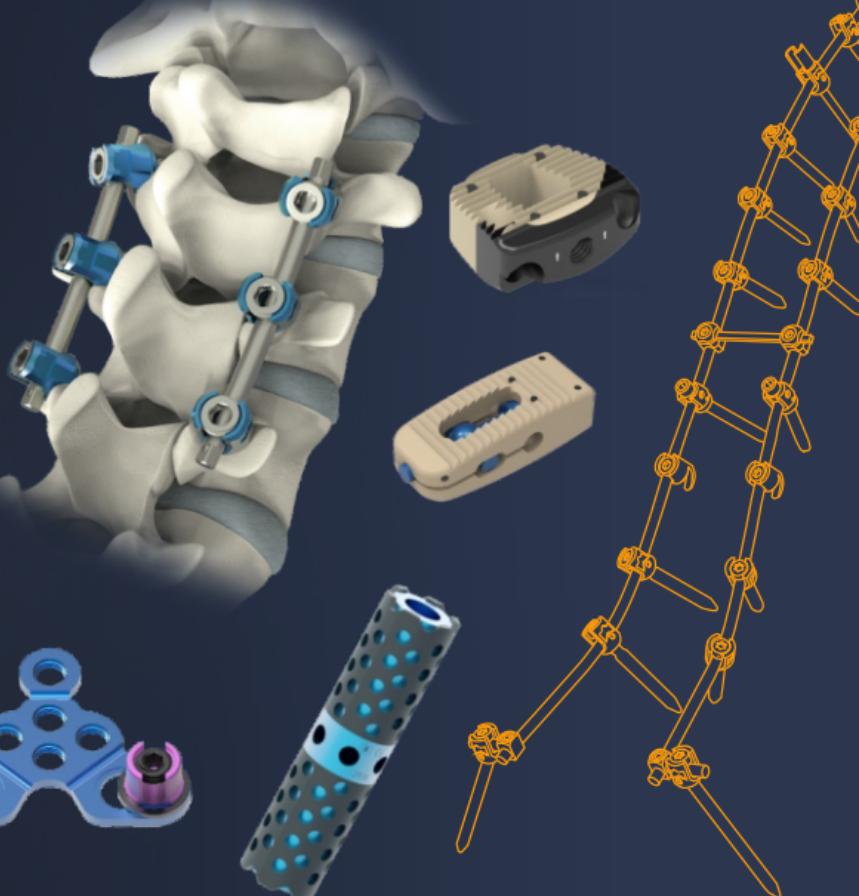
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xl-spine innovations

Spine Systems



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xl-nex gen

*Cementless Modular Radial Head
Replacement Systems*

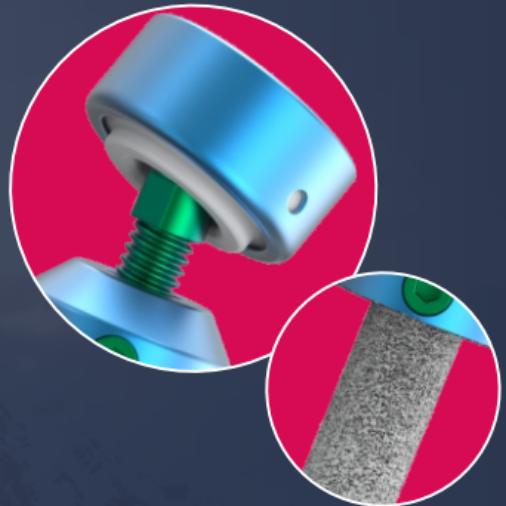
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- 15° Bipolar Range of Motion

- Telescope Feature from 2mm to 10mm in 2mm Increments



Dual Porous Coated

xl-momentum

Limb Salvage - Next Generation Systems



Dual Porous Coated

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xl-lock fx

Sterile Locking Trauma Extremities Systems

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xl-infinity

Modular & Customized Limb Salvage Systems

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Launching Soon...

xl-trinity

Total Knee Replacement Systems



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xl-synergy

*Cementless Modular Shoulder
Replacement Systems*

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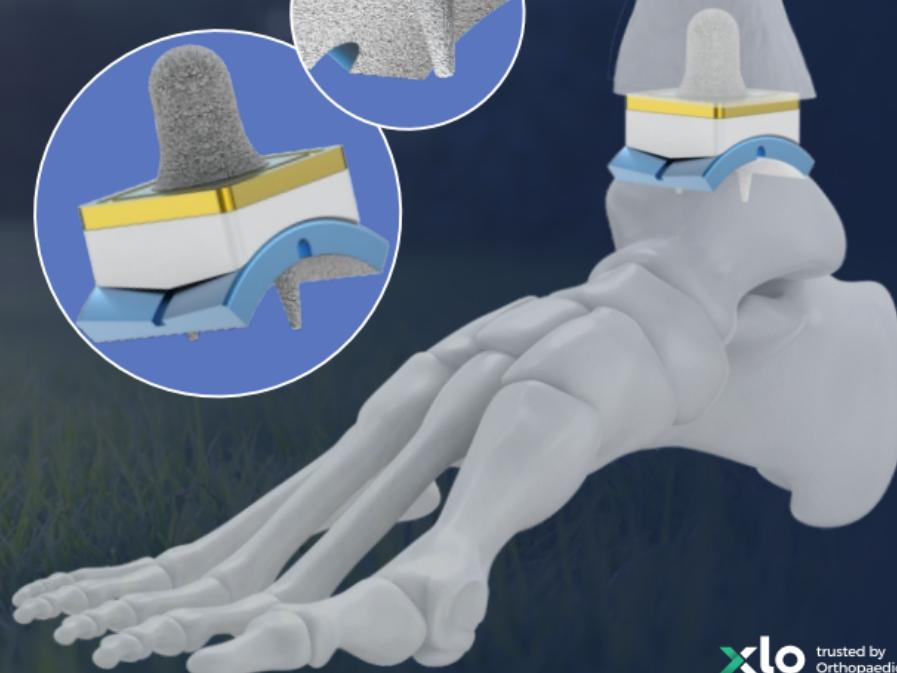
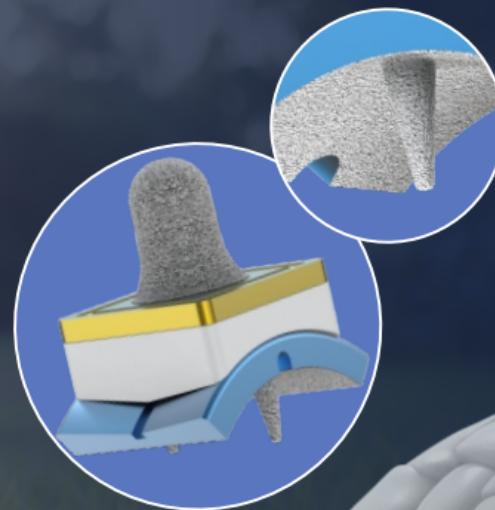


xl-elite

Modular Ankle Replacement Systems

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Dual Porous Coated



xlo trusted by
Orthopaedics

xl-optima solutions

Arthroscopy Systems



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xl-ace

Nailing Systems

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XL-surgical solutions

Acrylic Bone Cement, Disposable
Syringe Kit & Cement Gun



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A dark, semi-transparent background image of two surgeons in blue scrubs and caps, focused on a procedure. In the foreground, a surgeon's gloved hands are visible, holding surgical instruments.

Multifunctional Power Tools



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xl-ex fix

External Fixators



for Inquiry please email us @

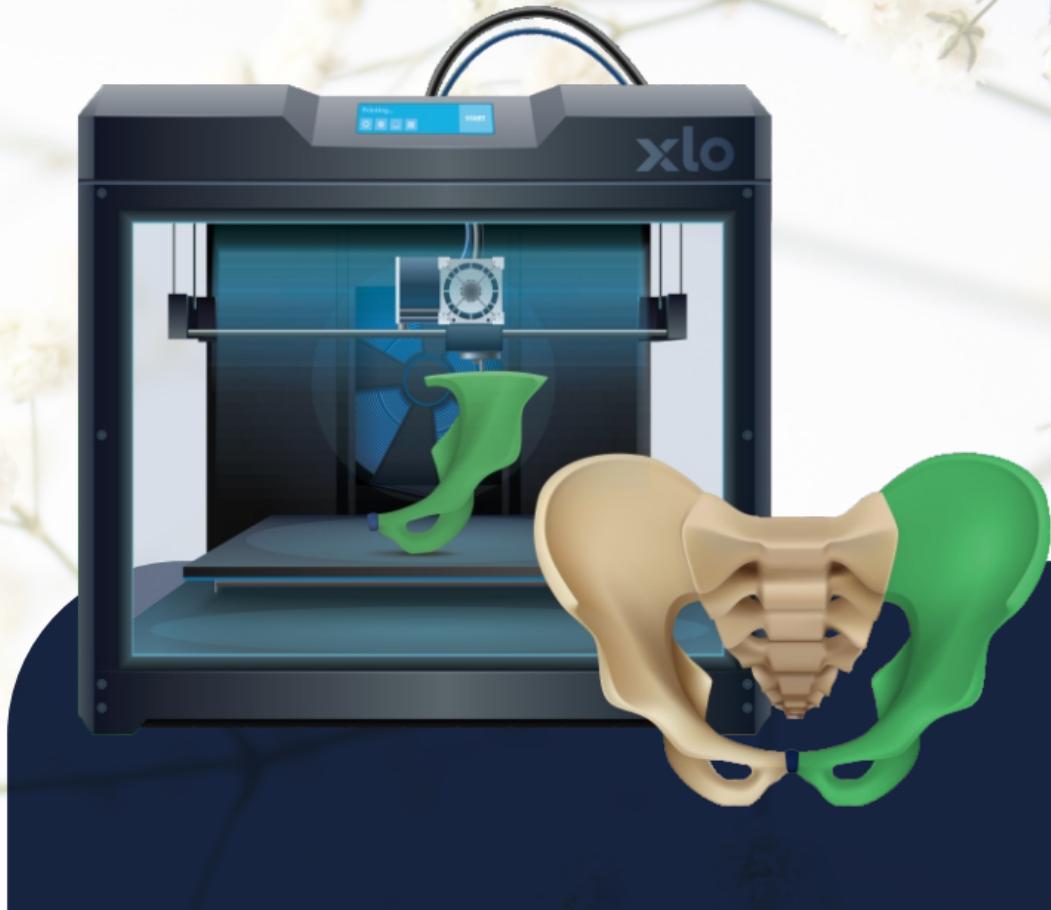
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xl-creations Patient Specific Implants (PSI)

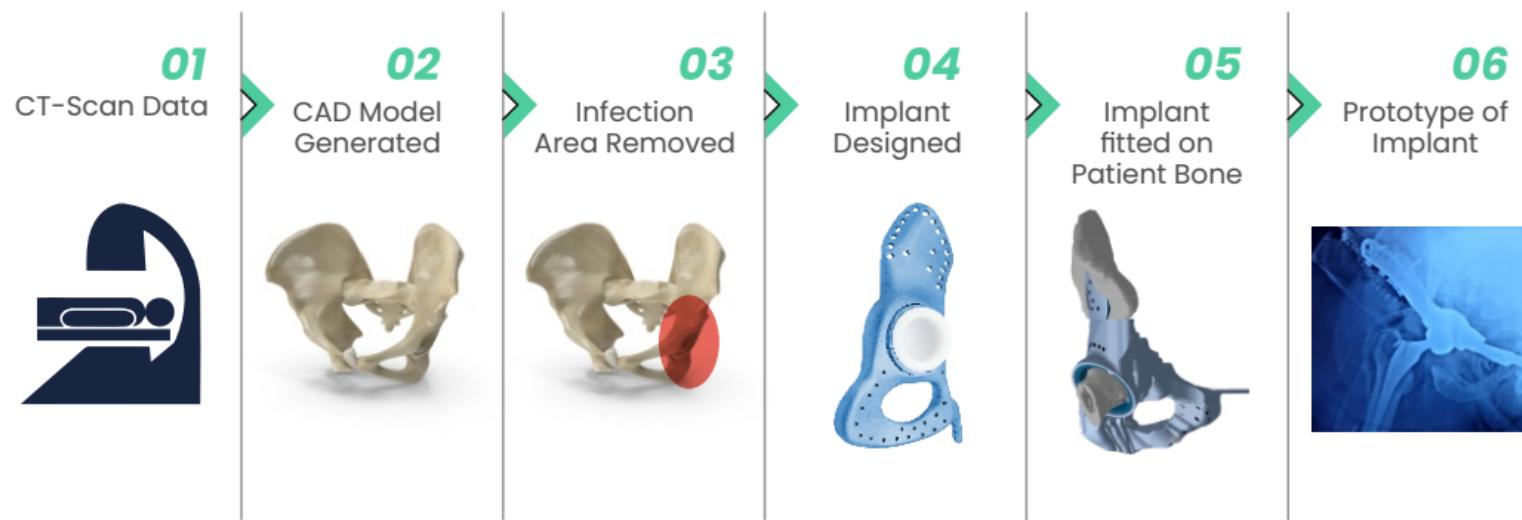
3D Printing Patient-specific Implants & Jigs Designed To Fit Each Patient

XLO offers a complete, effective, and clinically-validated software solutions to create high-quality patient specific implants. Jigs, etc. faster and at lower costs. The XL-Creations provide patient specific solutions and flexible services to integrate easily with your existing work flow resulting in a frictionless experience loved by surgeons as well as their patients.

3D Patient Solutions is a consultative, concierge level service provided by XLO. Design brings the level of expertise and surgical planning you demand in complex cases. The interactive experience enables a personalized planning approach for each patient allowing you to better manage pre & post operative outcomes.



Workflow Patient Specific Implant Design



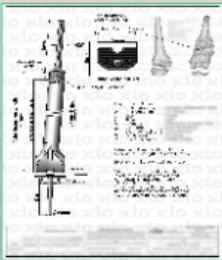
xl-creations

Distal Growing Prosthesis

A Team of Specialists working in close partnership with the surgeons



Three-dimensional reconstruction of the bone defect



Patient Template



Surgery Photo



Post-Operative x ray



Actual Implant

50+
Cases

xlo

xlo

15+
Cases

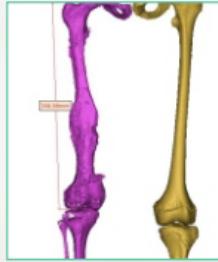
Actual Implant



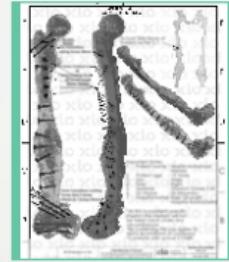
xl-creations

Customized Distal Femur Plate

A Team of Specialists working in close partnership with the surgeons



Three-dimensional
reconstruction of
the bone defect



Patient Template



Three-dimensional
rendering of the
implant

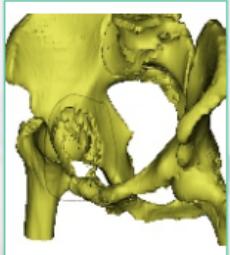


Post-Operative
x ray

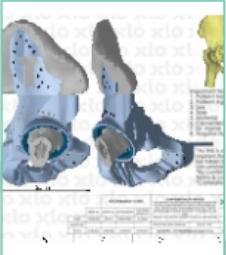
xl-creations

Hemi-pelvic Endoprosthetic Replacement

A Team of Specialists working in close partnership with the surgeons



Three-dimensional reconstruction
of the bone defect



Patient Template



Surgery Photo



Pre-Operative
x ray



Post-Operative
x ray

Actual Implant



05+
Cases

xlo

10+ Cases



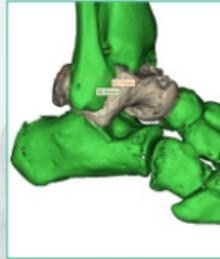
xlo

Actual Implant



xl-creations
Talus Prothesis

A Team of Specialists working in close partnership with the surgeons



Three-dimensional
reconstruction of
the bone defect



Patient Template



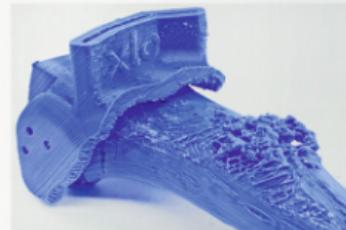
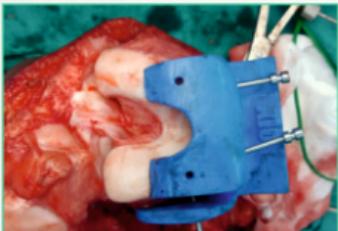
Pre Operative
X-Ray



Surgery Photo



Post-Operative
x ray



Surgery Photo

Instrument set: Graphic case



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Sterile Packaging

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INTERNATIONAL PRESENCE

Every year we participate in the international exhibitions such as:



Arab Health (UAE)



Ethio Health (Africa)



FIME (USA)



Pharmatech East (Africa)



Nepal Medical Show
(Kathmandu, Nepal)



Medica (Germany)

DOMESTIC PRESENCE

Every year we participate in the domestic exhibitions such as:



WIROC MAX (BKC, Mumbai)



NZOACON (GMCH
Hospital, Chandigarh)



7th BMCON
BMORTHOONCOCON
(Jaipur)



Insight 13th Annual CME
(Trivandrum)



Annual Scientific Conference
Of Indian Orthopaedic Association
(Lucknow)



Annual conference of
Maharashtra Orthopedic
Association (Mumbai)



Our Certification


Ortho Life Systems Private Limited
Tamandeep Kochhar
Director
D-111, Okhla Industrial Area, Phase 1
New Delhi
Okhla, Delhi 110020
India

April 26, 2024

Re: K233873
Trade Device Name: XLO Brand of Locking Distal Humerus Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 28, 2024
Received: March 28, 2024

Dear Tamandeep Kochhar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some clearest products may be considered as medical products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/cder/ob/510k/presets/pma.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note, CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 894. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99732/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99783/download>).

U.S. Food & Drug Administration
2000 Rockville Pike, Bethesda, MD 20892
www.fda.gov


Certificate of Compliance


We hereby declare that the technical files of all the items in each product group of complied with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-20116

Manufacturer : Ortho Life Systems Pvt. Ltd.

Address : D-111, Okhla Industrial Area, Phase 1, New Delhi 110020 (India)

Products : Orthopaedic Implants (Sterile/Non-Sterile) & All Types of Instruments

Complies with the requirements applicable to it

The Certificate is issued for the performance of the quality system covering the design, manufacture and final inspection of the medical products. The medical system has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

This certificate is issued under the following conditions:

- It applies only to the quality system maintained in the manufacture of above referenced products. If any changes are made to the design or type/variety of products, permission is required.
- The certificate remains valid until the manufacturing conditions or the quality system are not changed.
- The certificate validity is conditioned by positive results of surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after making a declaration of conformity with all relevant EC Directives. This statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	17th June 2024
1 st Surveillance Audit Due	16 th June 2025
2 nd Surveillance Audit Due	16 th June 2026
Certificate Expiry (subject to the company maintaining its system to the required standard)	16 th June 2027


Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
75-77 Melton Street, Covent Garden, London, WC2H 9QZ, United Kingdom
Website: www.ukcertifications.org.uk, email: info@ukcertifications.org.uk
Company No. 1148705





Our Certification



Contact



ORTHO LIFE SYSTEMS PVT. LTD.

Corporate Office & Works:

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New Delhi-110020, India

Tel: +91-11-41324393

+91-11-42851229

Toll Free: 1800 121 1190

Sales Office:

49, Church Road, Bhogal, Jangpura,
New Delhi-110014, India

info@xlo.in

www.xlo.in