



FDA U.S. FOOD & DRUG
ADMINISTRATION



Certified Company



35
— Years of —
Dedications

xlo trusted by
Orthopaedics

pain was past

make pain free life your future

35

— Years of —
Dedications



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 35 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

02
The first to get Manufacturing CE for all products.

04
The first to get CE, EN:ISO13485, WHO:GMP, ISO 9001: 2015 certifications.

06
The first to provide Pre-Sterilized Products..

01
The first to Launch Uncemented Dual Porous Coated Implants as an Indian manufacturer.

03
The first to make Bone Cement in active collaboration.

05
The first to make Expandable Tumor Implants in India.

07
The first over 16 years Follow-ups for Hips.

Company History

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.

15
The first to launch Modular Growing Prothesis Implants

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.



Academic and International Partner's



Maulana Azad Medical College



Academic and International Partner's



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



Maulana Azad Medical College



SUPPORTED BY
NIHR | National Institute
for Health Research

Global Health Research Group
Surgical Technologies





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



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



IMSOS 2025
TAJ Cidade de Goa



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Past Sawbone Journey



BOSCON 2024
Dhaka, Bangladesh



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Past Sawbone Journey



IMSOS 2023
Chennai



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xl-aire
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A Division of XLO | Ortho Life Systems

Past Sawbone Journey



Adyar Cancer Institute
Chennai, Tamil Nadu



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Past Sawbone Journey



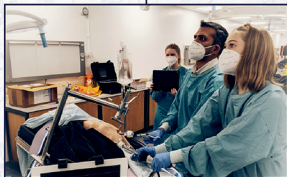
XL-ARE
Dhaka, Bangladesh



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xl-are
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A Division of XLO | Ortho Life Systems

Past Sawbone Journey



**RAIS
Cadaver
Lab UK**



**UK
Award
RAIS**



Past Sawbone Journey



**RAIS Kenya
& Uganda**



NZOACON



Cadaver workshop- Megaprosthesis



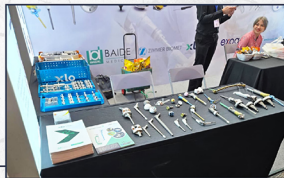
**Swami Rama
Himalayan University**
Sangatiya Walakhur, Uttarakhand



Past Sawbone Journey



**MOA with
Ortho Association**
Penang, Malaysia



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

Cadaver workshop- Megaprosthesis



**Maulana Azad
Medical College**
New Delhi





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 📺

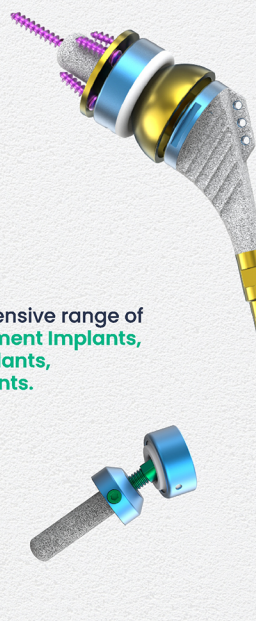
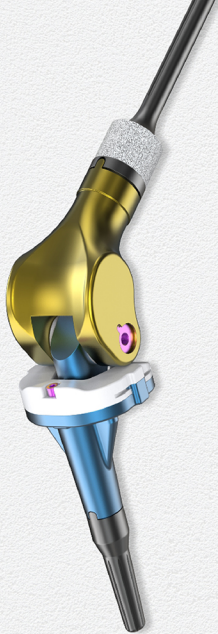
In the world of healthcare, innovation often stems from a need to bridge gaps and overcome challenges. In many parts of the world, access to advanced medical facilities is limited, making complex surgical procedures a daunting task. Traditional laparoscopic surgery, which relies on carbon dioxide insufflation, 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

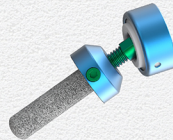




India's Only Company with the most extensive range of
Cementless & Cemented Joint Replacement Implants,
3d Printed Patient Specific Implants,
Trauma Implants & Instruments.



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-m^omentum**
Limb Salvage – Next Generation Systems

○ **xl-lock fx**
Sterile Locking Trauma Extremities Systems

○ **xl-infinity**
Modular & Customized Limb Salvage Systems

○ **xl-trinity**
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**

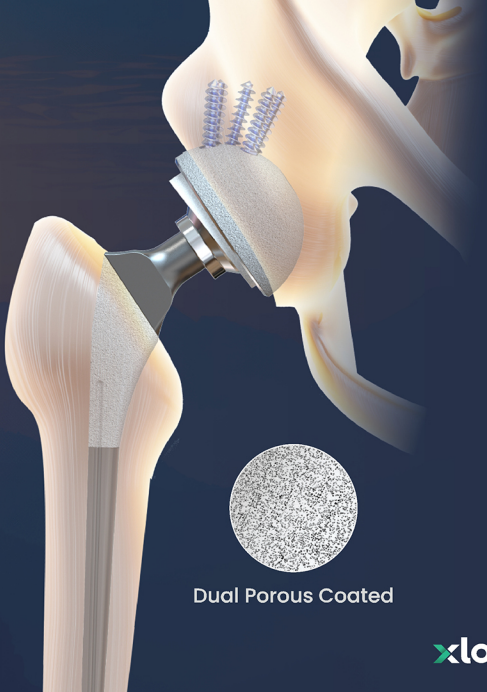


xl-axenture

Cementless Total Hip Replacement System

for Inquiry please email us @

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



Dual Porous Coated

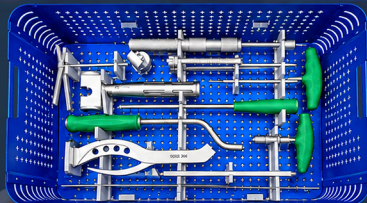
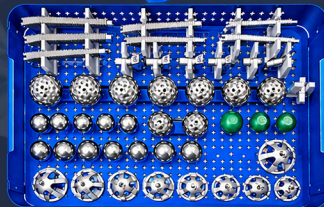
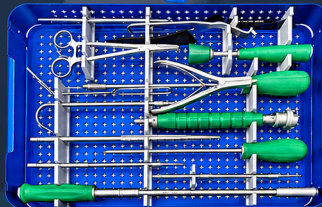
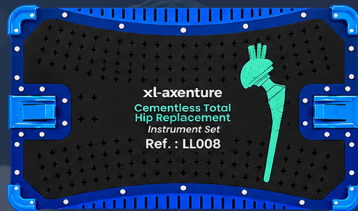
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Orthopaedics

xl-axenture

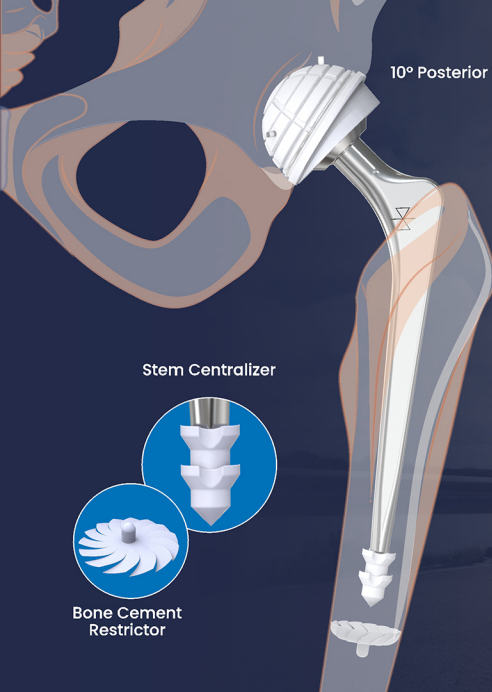
Cementless Total Hip Replacement
Instrument Set

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10° Posterior Wall Cup

Stem Centralizer



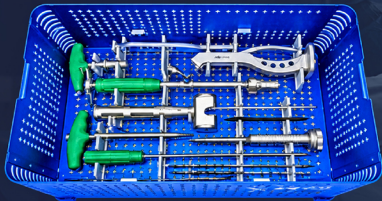
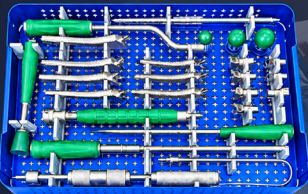
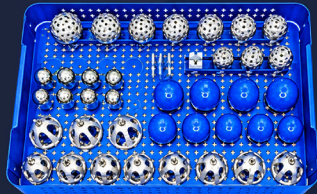
Bone Cement
Restrictor

xl-foundation[®]c

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

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xlo foundation "c"

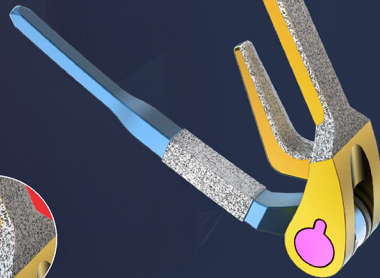
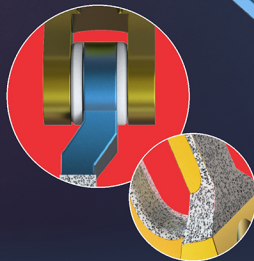
Cemented Modular Bi-polar & Total Hip Replacement Instrument Set

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India's First Indigenous
xl-advance evolve

Cementless Modular Elbow Replacement Systems



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Dual Porous Coated

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xl-spine innovations

Spine Systems

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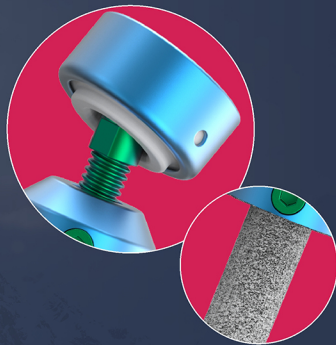
xl-nex gen

Cementless Modular Radial Head
Replacement Systems

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- 15° Bipolar Range of Motion
- Telescope Feature from 2mm to 10mm in 2mm Increments

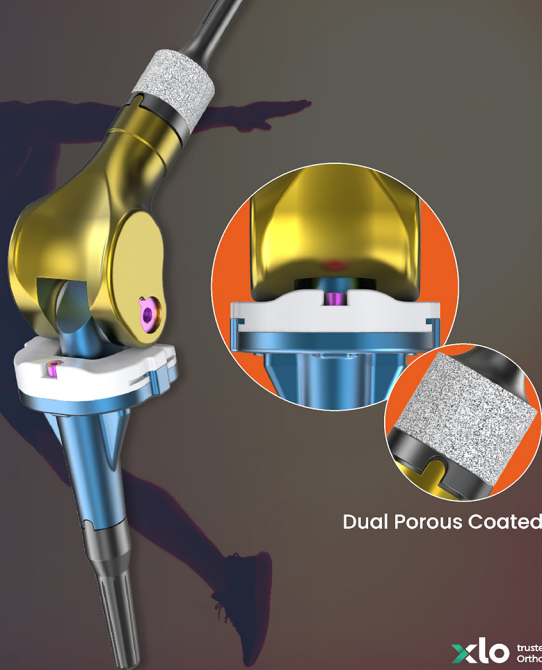


Dual Porous Coated

xlo trusted by
Orthopaedics

xl-momentum

Limb Salvage - Next Generation Systems



Dual Porous Coated

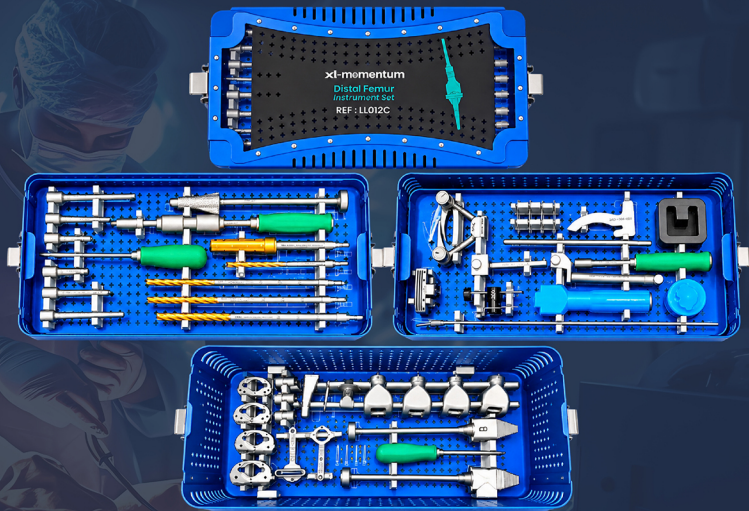
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xl-momentum

Distal Femur Instrument Set



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xl-lock fx

Sterile Locking Trauma Extremities Systems

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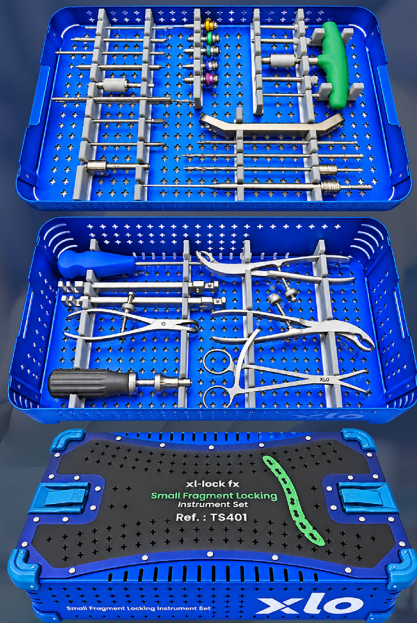
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xl-lock fx

Small Fragment Locking Instrument Set



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xl-infinity

Modular & Customized Limb Salvage Systems

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xl-trinit7

Total Knee Replacement Systems

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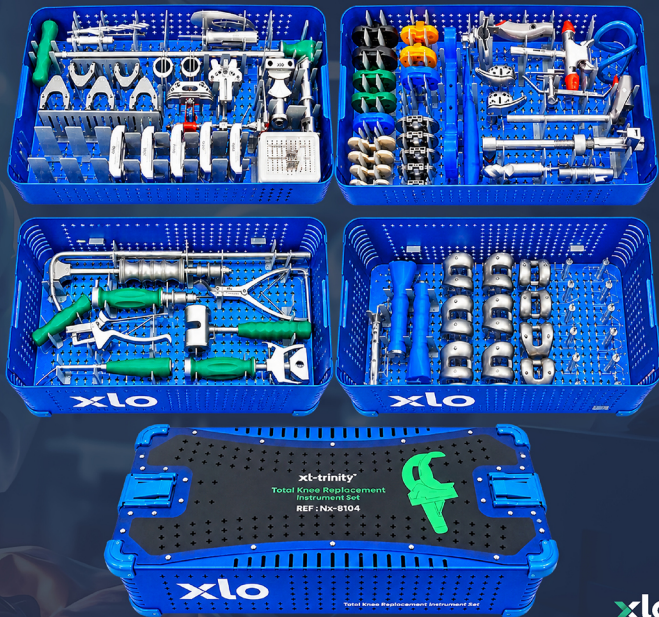
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xl-trinity

Total Knee Replacement
Instrument Set



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Orthopaedics

xl-synergy

Cementless Modular Shoulder
Replacement Systems



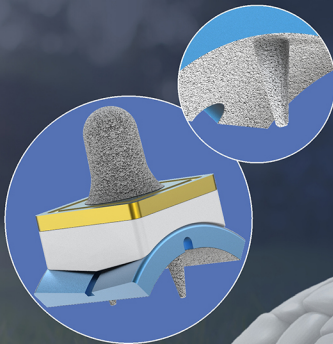
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xl-elite

Modular Ankle Replacement Systems

Dual Porous Coated



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xl-optima solutions

Arthroscopy Systems



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xl-ace
Nailing Systems

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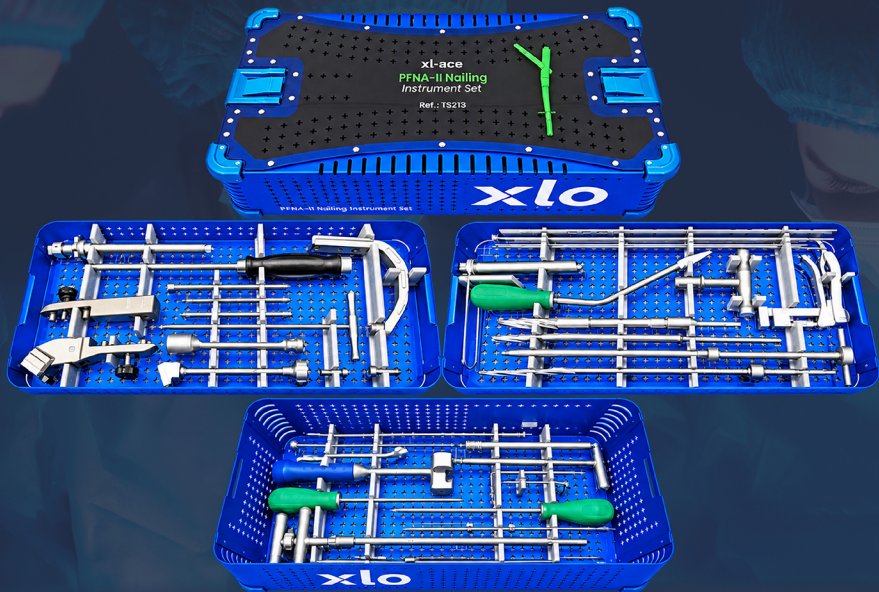
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- Export : exports@xlo.in

xl-ace

PFNA-II Nailing
Instrument Set

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xl-surgical solutions

*Acrylic Bone Cement, Disposable
Syringe Kit & Cement Gun*

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Available in:
Antibiotic &
Non Antibiotic

Designed &
Formulated
in **Germany**



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Multifunctional Power Tools



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xl-ex fix

External Fixators



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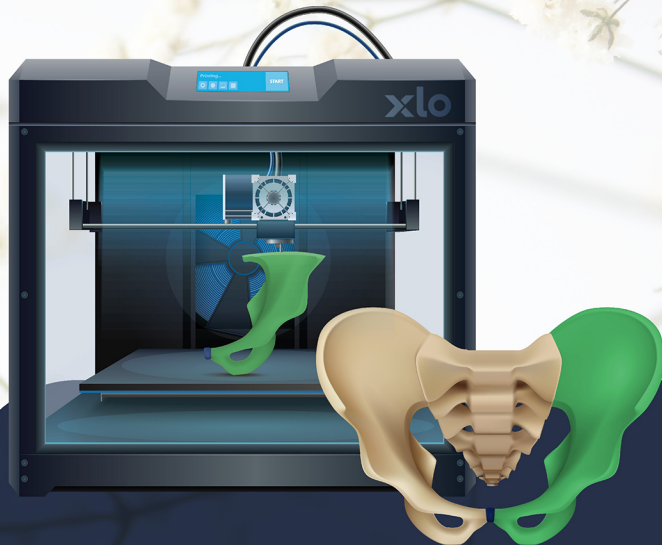
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xl-creations Patient Specific Implants (PSI)

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

01
CT-Scan Data



02
CAD Model
Generated



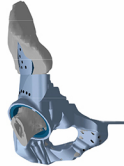
03
Infection
Area Removed



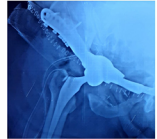
04
Implant
Designed



05
Implant
fitted on
Patient Bone



06
Prototype of
Implant

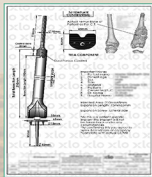


xl-creations Distal Growing Prosthesis

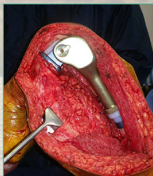
A Team of Specialists working in close partnership with the surgeons



Three-dimensional
reconstruction
of the bone defect



Patient Template

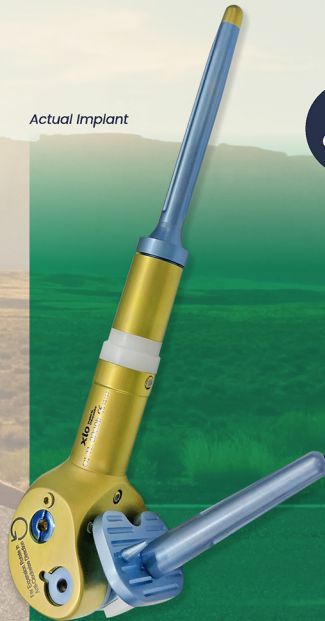


Surgery Photo



Post-Operative
x ray

Actual Implant



70+
Cases

xlo



20+
Cases



Actual Implant

xlo

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



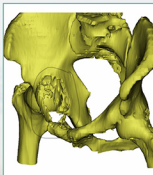
Three-dimensional
rendering of the
implant



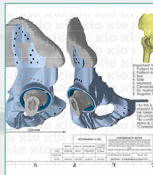
Post-Operative
x ray

xl-creations Hemi-pelvic Endoprosthetic Replacment

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

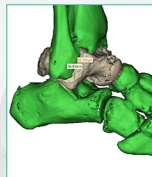


07+
Cases

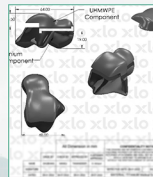
xl-creations Talus Prosthesis

A Team of Specialists working in close partnership with the surgeons

15+
Cases



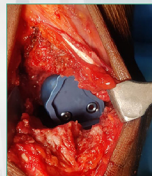
Three-dimensional
reconstruction of
the bone defect



Patient Template



Pre Operative
X-Ray



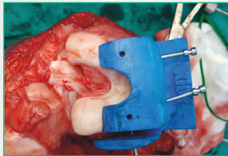
Surgery Photo



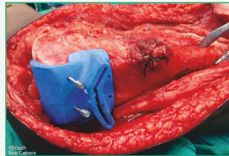
Post-Operative
x ray

xl-creations

Actual Implant



Surgery Photo



Instrument set: Graphic case



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Sterile Packaging

for Inquiry please email us @

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Export: exports@xlo.in

INTERNATIONAL PRESENCE

Every year we participate in the international exhibitions such as:



WHX Arab Health (UAE)



Ethio Health (Africa)



WHX 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
BMORTHONCOCON
(Jaipur)



Insight 13th Annual CME
(Trivandrum)



Annual Scientific Conference
Of Indian Orthopaedic Association
(Lucknow)



Annual conference of
Maharashtra Orthopaedic
Association (Mumbai)



Our Certification



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

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 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 cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/pmn/pmn.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 898. 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/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

U.S. Food & Drug Administration
2005 New Hampshire Avenue
Silver Spring, MD 20910
cderr@fda.gov

April 26, 2024



Certificate of Compliance



We hereby declare that the technical files of all the items in each product group of comply with the requirements of the Council Directive on Medical Devices 90/269/EEC as Amended 2007/47/EC.

Certificate No.: CE-20116

Manufacturer
Name : Ortho Life Systems Pvt. Ltd.
Address : D-111, Okhla Industrial Area, Phase I, New Delhi-110020 (India)
Products : Orthopaedic Implants (Sterile/Non-Sterile) & All Types of Instruments

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 90/269/EEC as Amended 2007/47/EC.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedure, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are not changed.
3. 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 completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The 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	17 th 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.
71-73 Station Street, Covent Garden, London, WC2E 0AH, United Kingdom
Website: www.ukcertifications.org.uk, email: info@ukcertifications.org.uk
Company No: 1184781

xlo trusted by
Orthopaedics

Our Certification



Contact



ORTHO LIFE SYSTEMS PVT. LTD.

INDIA

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New Delhi-110020, India**

Sales Office:
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New Delhi-110014, India**

Dubai, UAE

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**Customer Care No:
1800 121 1190**

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