



WELCOME TO

**DKSORTHO & SHARMA**  
PHARMACEUTICAL PVT. LTD

**PolyNpixel**

[www.dksortho.com](http://www.dksortho.com)





# DELIVERING QUALITY SINCE 1992

Dksortho & Sharma Pharmaceutical Pvt.

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- 32 Years of Excellence in Orthopedic Solutions
- Reached 93 Countries Worldwide
- Registered in Over 32 Countries
- Comprehensive Product Range: Total Hip Replacement, Total Knee Replacement, Spine, Sports Medicine and Trauma Products
- Advanced Manufacturing with State of the Art High Speed Machines
- Trusted by Medical Professional Globally
- Dedicated to Quality, Innovation, and Patient Care.

# 33 YEAR OF ORTHOPEDIC EXCELLENCE: THE DKSORTHO.COM

**2008:** EXPANDING INTO THE JOINTS REPLACEMENT WITH TOTAL KNEE REPLACEMENT WITH PRECISION AND INNOVATION Getting eruropen CE certificate

**2006:** Importing Six New MACHINES from TAIWAN to BEGIN TOTAL HIP REPLACEMENT Production for the Orthopedic Market

**2004:** VENTURING INTO EXPORTS IN 2004: Paving the way for Global Reach and Expansion.

**2003:** Introducing the Locking Plate System under the Brand Name SPCPL MARKS A PIONEERING MILESTONE, BRINGING ADVANCED ORTHJOPEDIC TECHNOLOGY TO INDIA FOR THE FIRST TIME.

**2002:** 5: CNC MACHINE 2: WIRE CUT MACHINE 2: VMC MACHINES WITH CADCAM

**1992:** SHARMA PHARMACEAUTIAL spotted our footprints in Indian orthopedic industries. The Manufacturing Unit started with a few manual machines for DCP PLATES and CORTICAL SCREWS.

**1993:** Introducing the Locking Plate System under the Brand Name SPCPL MARKS A PIONEERING MILESTONE, BRINGING ADVANCED ORTHJOPEDIC TECHNOLOGY TO INDIA FOR THE FIRST TIME.

1989

Starting an idea for the small orthopedic product manufacturing process in Mumbai in 1989 must have been quite a journey.

1995

Introducing CNC machines to the orthopedic implant industry in India.

2015

20 new CNC machines installed for production boost: big step forward

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2018

2023

DKSortho making India proud by operating in 91 countries and winning India's Best 500 Brand in 2023. 400+ CHANNEL PARTNERS IN INDIA 600000 SURGERYS IN TRUMA FOR A YEAR 30000 SURGERYS IN JOINTS FOR A YEAR

2010

ACQUIRING NEW FIVE DIFFRENT MACHINES FROM THE USA ,GERMANY, AND JAPN FOR PRODUCT DEVELOPMENT. GETTING ISO13485:2016

**2014:** The use of CMM 3D scanner machines for medical devices from Germany showcases a commitment to precision and quality in the healthcare sector.

**2013:** INDIA'S FIRST ORTHOPEDIC COMPANY TO INSTAL US RIVERSE ENGINEERING SOFT WARE ;INNOVATIVE MOVE. 2012

**2009:** Gujrat 1st company and India's 3rd company to get FDA licence. GETTING ISO9001:2015 MANUFACTURING LICENSE - FOOD& DRUGUS CONTROL ADMINISTRATION (

Opening a new joint venture in Mexico, DKSORTHOMX, in 2024 expands DKSORTHO's global presence and signifies its commitment to growth and innovation.

2024

We would like to take this opportunity to briefly introduce our company DKSORTHO & SHARMA PHARMACEUTICAL PVT. LTD. as a foremost manufacturer and exporter in orthopedic implants and instruments. We would like to explore our products globally with well expertise, specialized and well renowned orthopedic surgeons. We are serving the orthopedics market globally with the best quality of orthopedic implants and instruments since 1992

## OUR PRODUCTS :( STAINLESS STEEL & TITANIUM

1. Arthroplasty (total knee replacement, total hip replacement, shoulder replacement etc.
2. Hemi-arthroplasty (modular bi-polar hip, bi-polar hip, amp, Thompson prosthesis etc.
3. Arthroscopy implants
4. Spinal implants (cervical, thoracolumbar & lumbosacral) Plates (titanium and PEEK)
5. Cannulated cancellous screws
6. External fixator
7. Pins and wires
8. Oral & maxillofacial implants
9. Bone plates and bone screws (locked system and non-locked systems)
10. Interlocking nails, locking bolts and accessories
11. General instruments

Quality Parameters: DKSORTHO & SHARMA PHARMACEUTICAL PVT. LTD. is well certified & approved with ISO 9001:2015, ISO 13485:2016, CE Mark and Indian FDA. This credential gives us an edge to supply our products all over the world. Also we do maintain the international standards in the terms of Quality and services. We provide flexible supports that assist companies and individuals to meet their objectives by giving the best possible service at an affordable price.

## MR. DAYANAAND SHARMA (CEO)

Mr. Dayanand Sharma, the CEO of Dksortho & SharmaPharmaceutical Pvt. Ltd is responsible for the brand DKSORTHO". He has an insatiable appetite for success and innovation which has led to the cultivation of the brand DKSORTHO" as an eminent player in the orthopedic sector, serving millions of patients world wide with quality oriented Orthopedic Implants. He has started his career with various odd jobs including working long hours on manually operated conventional machines and assembly of the orthopedic implants. He bought all kind of technical changes, process up-gradations and mastered the art of innovative manufacturing of orthopedic implants. He travelled across the globe in search of business and learned dynamics of international business. Mr. Sharma has got more than 29+ years of core experience of working with Orthopedic Implants. He has successfully expanded "DKSORTHO" presence in India as well as more than 60+ countries across the world. Under his leadership "DKSORTHO" is developing as a global leader in Orthopedic Industries. Dksortho & Sharma Pharmaceutical Pvt. Ltd is one of the fastest growing orthopedic implant manufacturing company in India and the company manufactures over thousands of different orthopedic implants and exports to various countries.

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# QUALITY & CERTIFICATIONS

**CERTIFICATE OF COMPLIANCE**

PRODUCT CERTIFICATE  
EC Attestation of Conformity

**PROGRESSIVE**

The Governing Board of  
Progressive International Certifications Limited hereby grant to:

**DKSORTHO & SHARMA PHARMA CEUTICAL PRIVATE LIMITED**  
ADDRESS : 444, GIDC ESTATE, WAGHODIA - 391760, VADODARA, GUJARAT, INDIA.

has been assessed by QVA and found to comply with the requirements of:

**U.S. FDA**  
(US FDA Regulatory Guidelines for Scientific and Medical Instruments)

For the following Scope:  
DESIGN & DEVELOPMENT, MANUFACTURE & SALES OF ORTHOPEDIC IMPLANTS: JOINT PROSTHESIS (HIP, KNEE AND SHOULDER) AND ORTHOPEDIC REUSABLE INSTRUMENTS AND ACCESSORIES.  
The product is in full compliance with all provisions of US FDA.  
This certificate is only valid for products described above and based upon technical file submitted by client.

Registration No.: PICL/USFDA/0525/0074  
Certificate Issue Date: 05.05.2025  
1st Surveillance: 05.2026  
2nd Surveillance: 05.2027  
Certificate Renewal Date: 04.05.2028

**PROGRESSIVE** **FDA**

Head of Certificate

This Certificate of Registration is granted subject to the Regulations approved by the Board.  
**PROGRESSIVE INTERNATIONAL CERTIFICATIONS LTD.**  
Office 4, 219, Kensington High Street, Kensington, London, W8 6BD, England.  
E-mail: info@picl.com, Website: www.picl.com  
For current validity of this certificate, Please visit our website

USE OF ACCREDITATION MARK INDICATES ACCREDITATION IN RESPECT OF THE ACTIVITIES COVERED BY ACCREDITATION INSTITUTE ASSESSMENT BODY (EUROPE) CERTIFICATION NUMBER 004

CERTIFIED FOR EXCELLENCE IN

Orthopaedic & Trauma Implants  
Spinal & Arthroscopy Solutions

**QRO**  
QUALITY RESEARCH ORGANIZATION

**Certificate of Registration**

This is to certify that

**DKSORTHO & SHARMA PHARMACEUTICAL PRIVATE LIMITED**  
444, GIDC ESTATE, WAGHODIA - 391760, VADODARA, GUJARAT, INDIA

has been independently assessed by QRO and is compliant with the requirement of:

**ISO 13485:2016**  
Quality Management System for Medical Devices

For the following scope of activities:  
**DESIGN, DEVELOPMENTS, MANUFACTURE & SALES OF ORTHOPEDIC IMPLANTS: BONE PLATES, BONE SCREWS, INTRAMEDULLARY NAILS, SPINAL IMPLANT, JOINT PROSTHESIS (HIP, KNEE AND SHOULDER) AND ORTHOPEDIC REUSABLE INSTRUMENTS AND ACCESSORIES.**

Date of Certification: 12th September 2024  
1<sup>st</sup> Surveillance Audit Due: 11th September 2025  
2<sup>nd</sup> Surveillance Audit Due: 11th September 2026  
Certificate Expiry: 11th September 2027

Certificate Number: 305024091245MD

**QRO** **EGAC** **IAF**

Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended / withdrawn).  
The Validity of this certificate can be verified at [www.qrocert.org](http://www.qrocert.org).  
This certificate of registration remains the property of QRO Certification LLP, and shall be returned immediately upon request.

India Office : QRO Certification LLP  
142, 1<sup>st</sup> Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)  
Website : [www.qrocert.org](http://www.qrocert.org), E-mail : [info@qrocert.org](mailto:info@qrocert.org)

OUR CERTIFICATIONS INCLUDE

ISO 13485:2016  
WHO-GMP

Confirms that DKSORTHO follows standardized manufacturing systems for medical implants and instruments. This certification ensures consistent production, controlled processes and regulatory manufacturing practices.



- **CE Certification**  
European conformity for medical devices
- **WHO-GMP Certification**  
Good Manufacturing Practice compliance

# OUR PRODUCTS

## ( STAINLESS STEEL & TITANIUM)

1. Arthroplasty (total knee replacement, total hip replacement, shoulder replacement etc. (cemented & uncemented))
2. Hemi-arthroplasty (modular bi-polar hip, bi-polar hip, amp, Thompson prosthesis etc. (cemented & uncemented))
3. Arthroscopy implants
4. Spinal implants (cervical, thoracolumbar & lumbar) **PolyNpixel** & cages (titanium and PEEK)
5. Cannulated cancellous screws
6. External fixator
7. Pins and wires
8. Oral & maxillofacial implants
9. Bone plates and bone screws (locked system and non-locked systems)
10. Interlocking nails, locking bolts and accessories
11. General instruments



# ARTHROPLASTY

TOTAL KNEE REPLACEMENT SYSTEM (IGEN)



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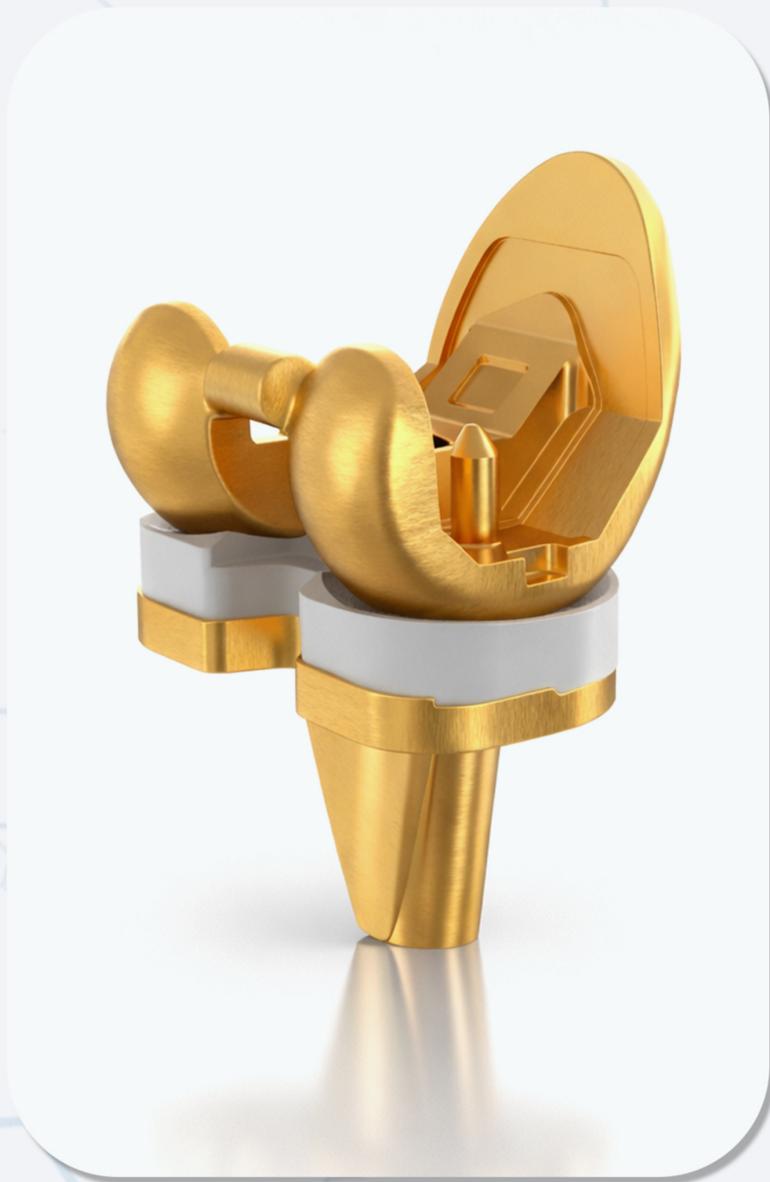




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# ARTHROPLASTY

Prathmesh PS knee replacement system (GEN II)

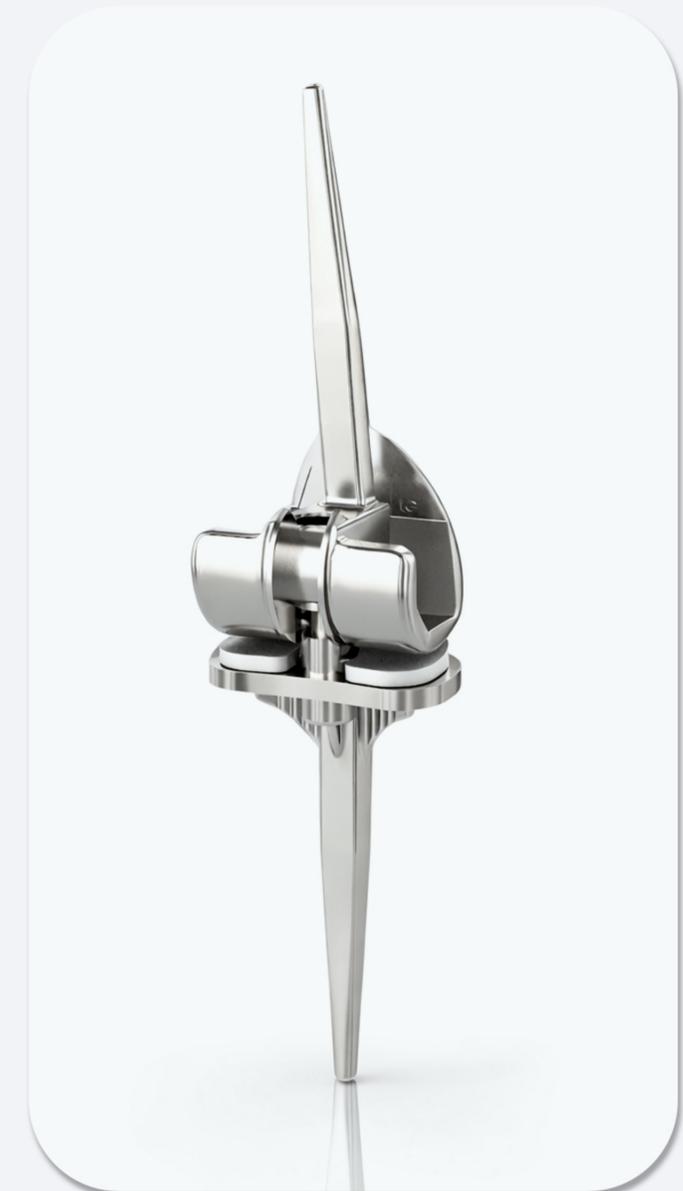


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# ARTHROPLASTY

TOTAL KNEE REPLACEMENT (III GEN) GOLD

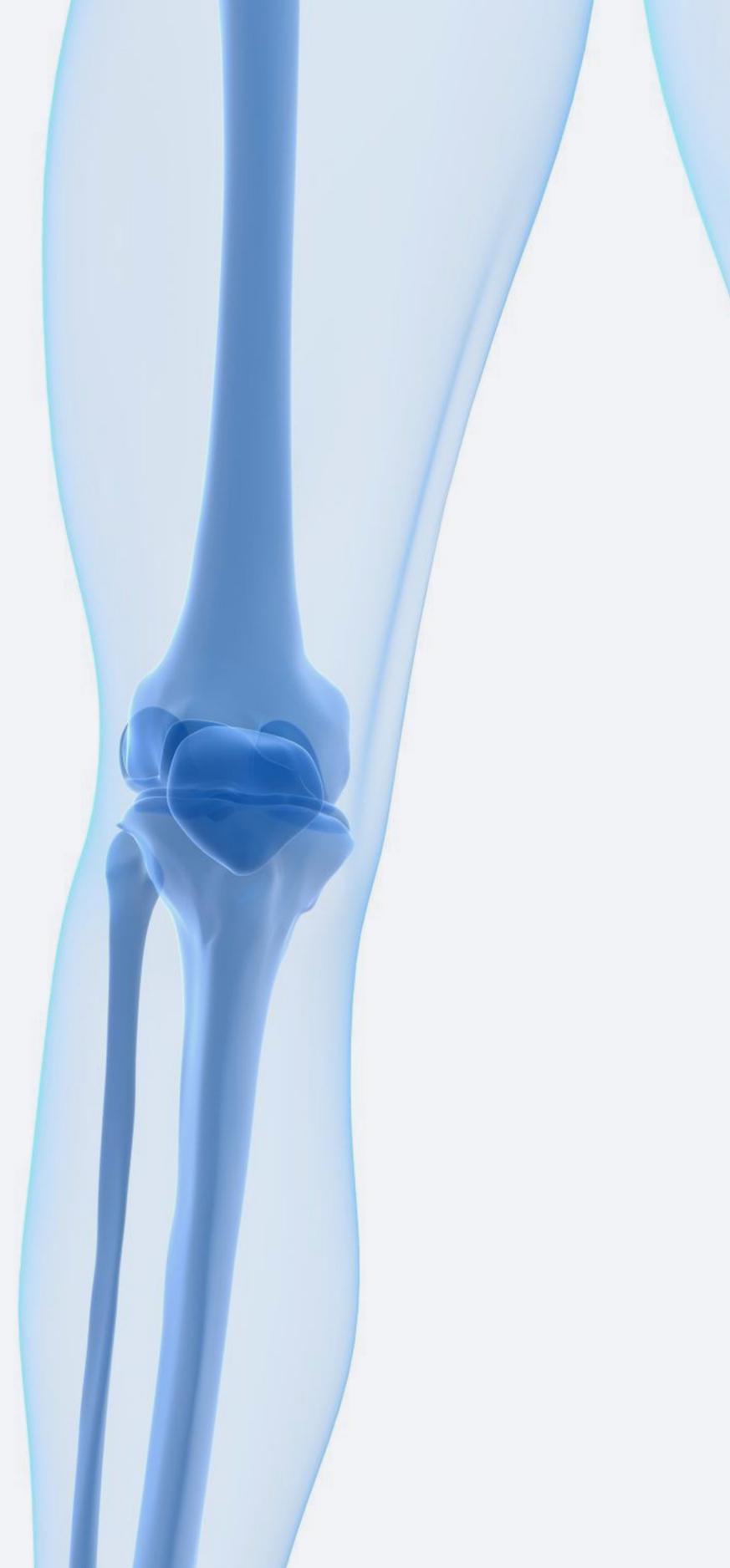


# ARTHROPLASTY

Prathmesh PS knee replacement system (GEN IV)

# MEGA PROSTHESIS

(LOWER LIMB & UPPER LIMB)

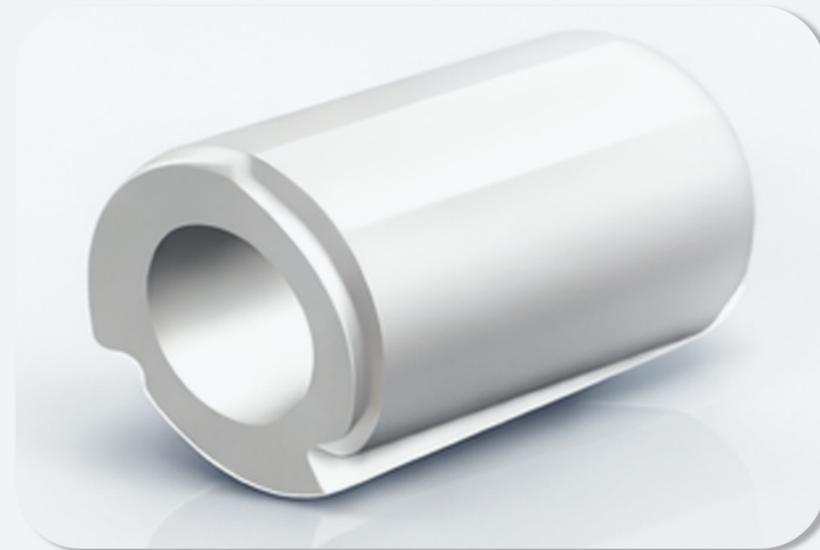


# ARTHROPLASTY

TOTAL HIP REPLACEMENT (CEMENTED)



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# TOTAL HIP REPLACEMENT (UNCEMENTED)

REVISION & CEMENTED AND ADVANCE DUAL



# REVISION & CEMENTED AND ADVANCE DUAL MOBILITY



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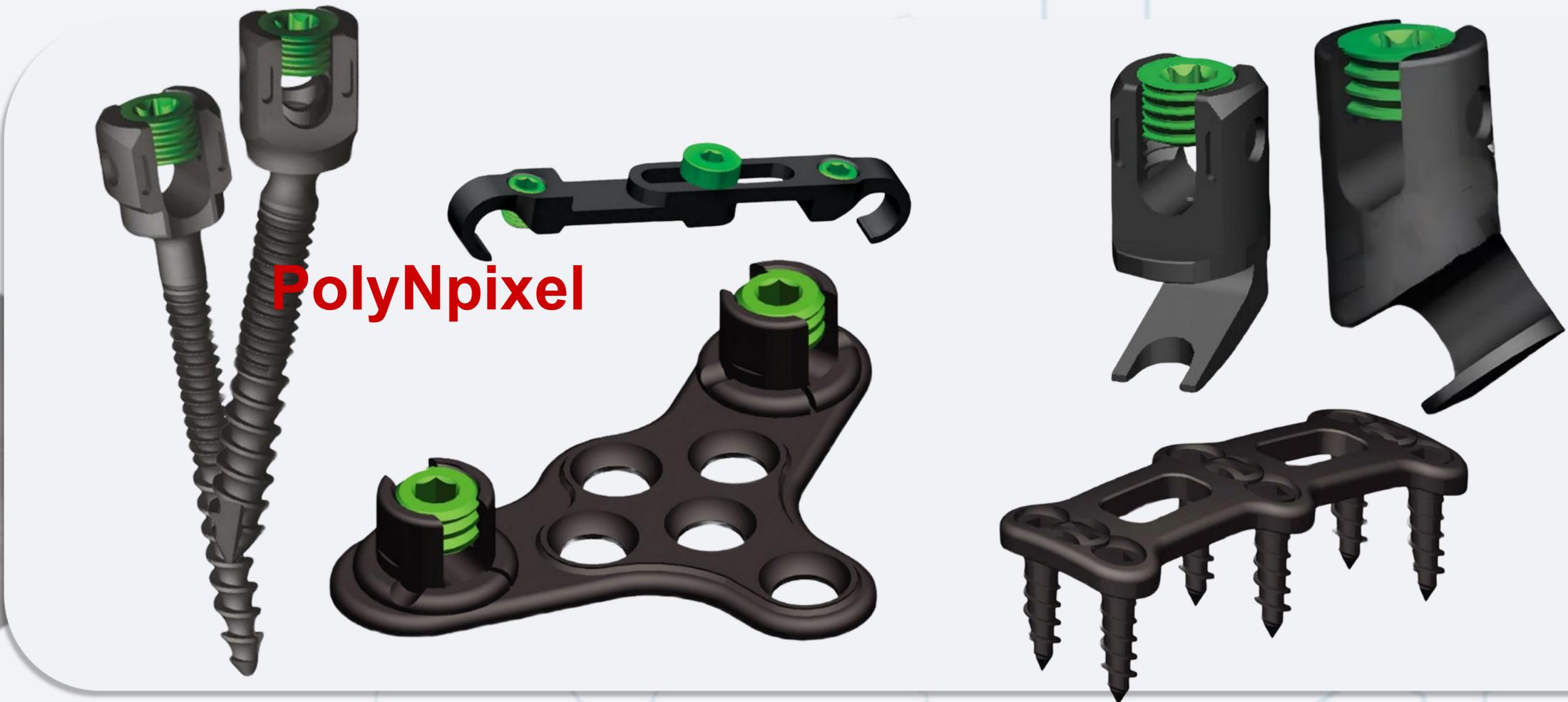
# HEMI SHOULDER PROSTHESIS & REVERSE SHOULDER



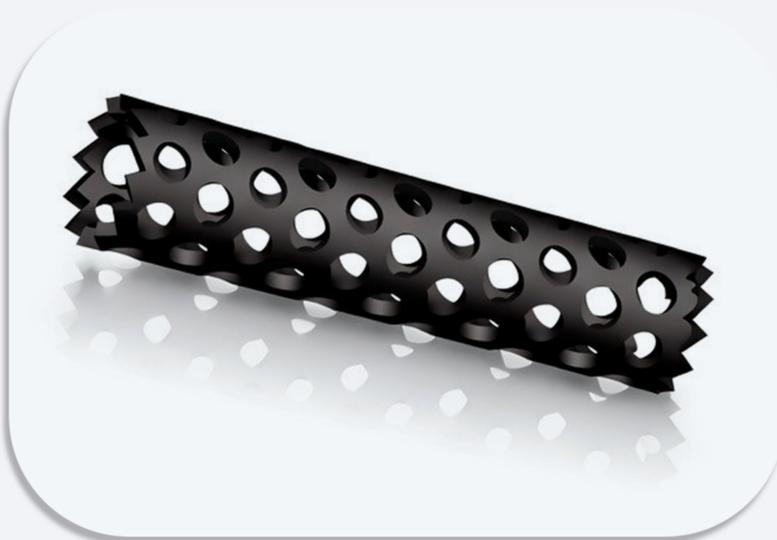
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# SPINAL IMPLANTS (CERVICAL, THORACOLUMBER & LUMBOSACRAL)



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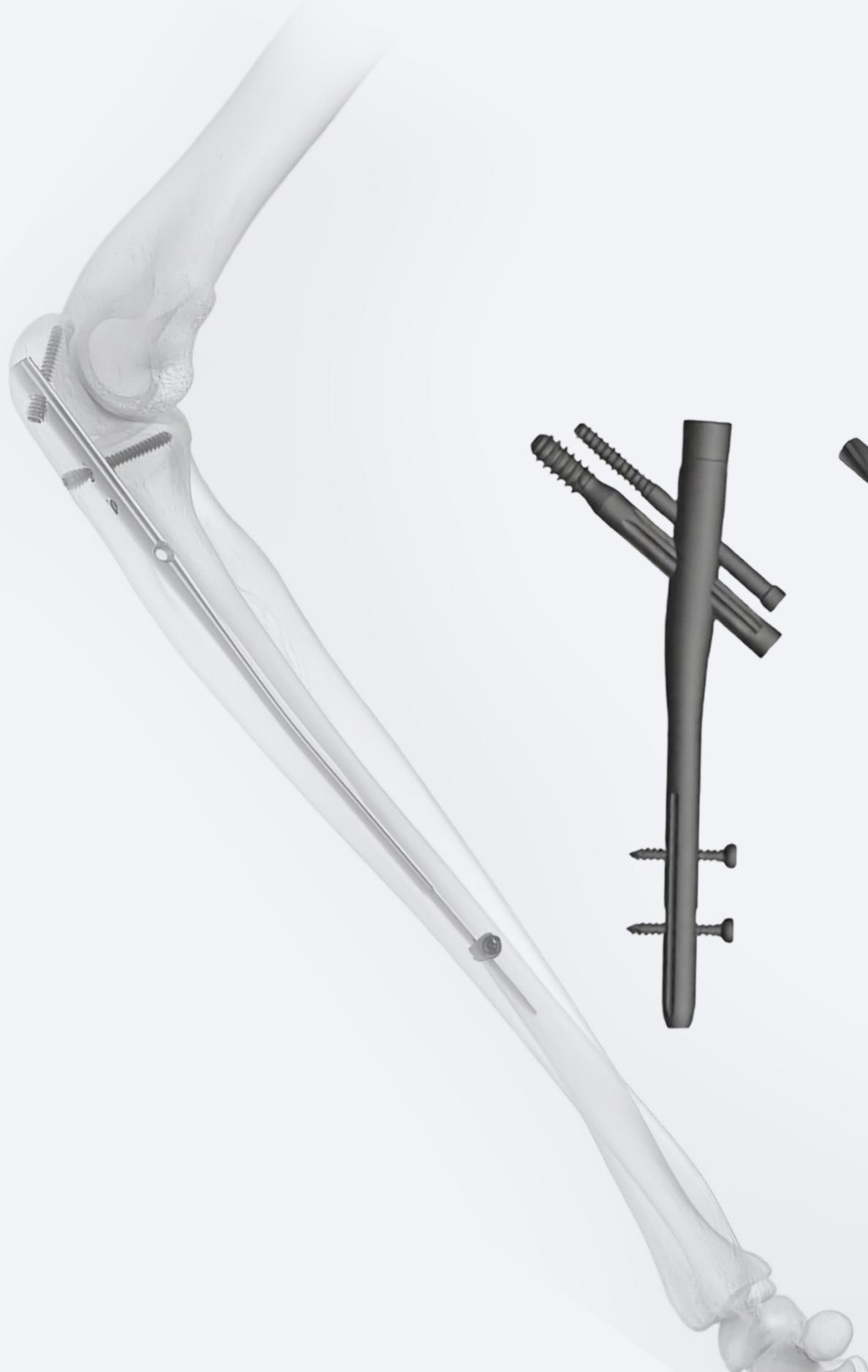
**SPINAL IMPLANTS**  
(CERVICAL, THORACOLUMBER & LUMBOSACRAL)

# BONE PLATES AND SCREWS SYSTEMS

(LOCKED SYSTEMS AND NON LOCKED SYSTEMS)



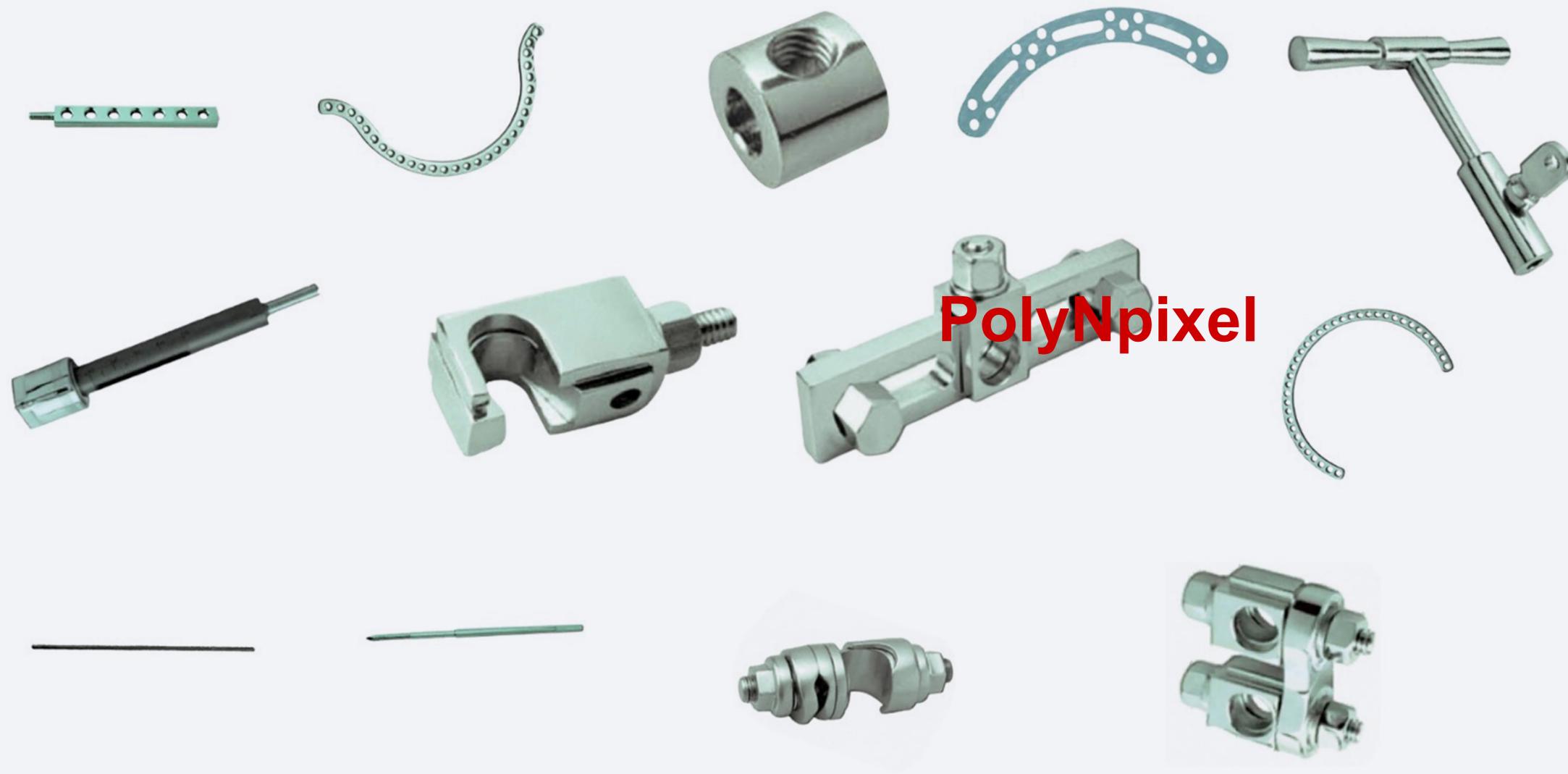
# INTRAMEDULLARY Nailing systems



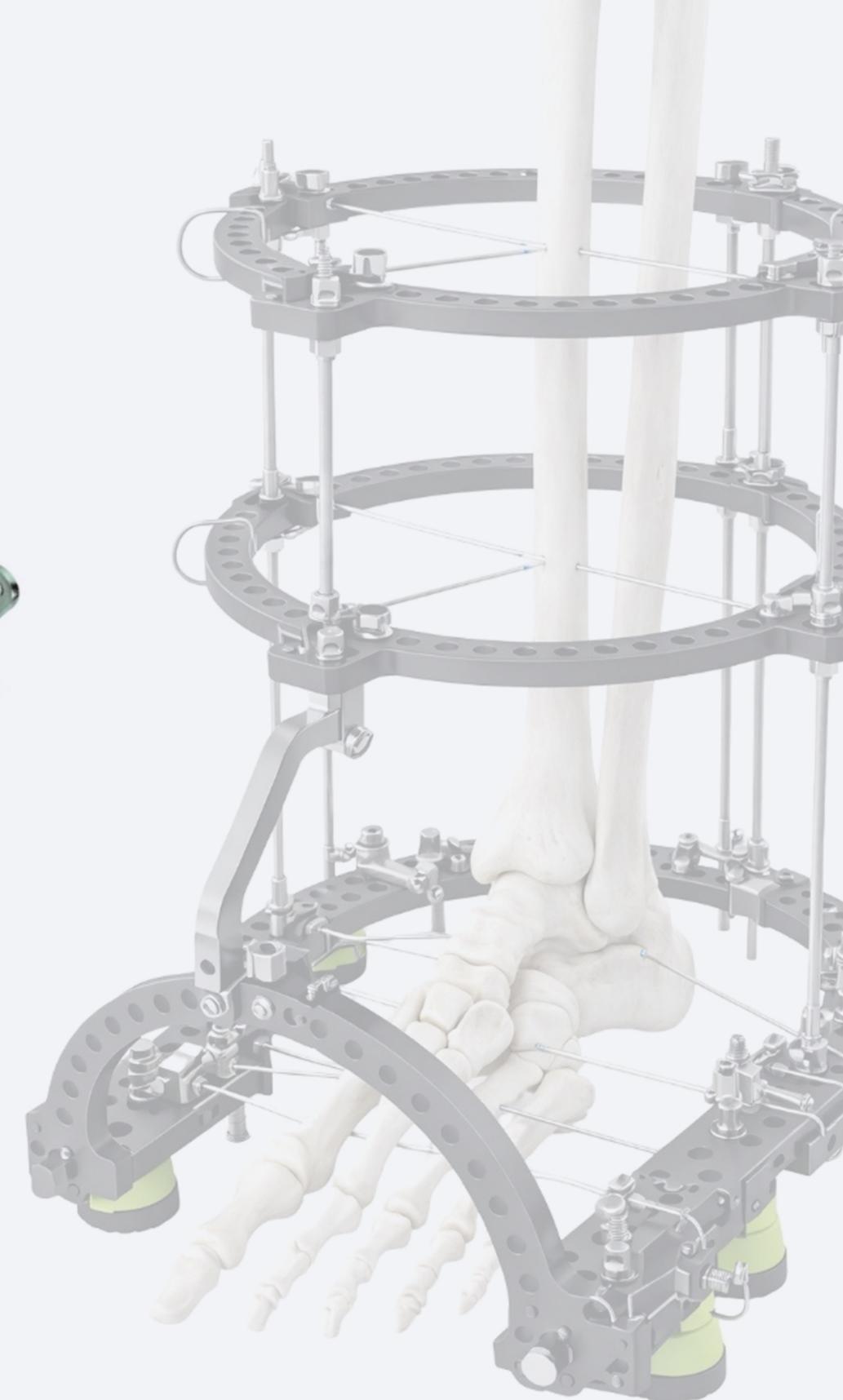
**PolyNpixel**



# EXTERNAL FIXATOR:



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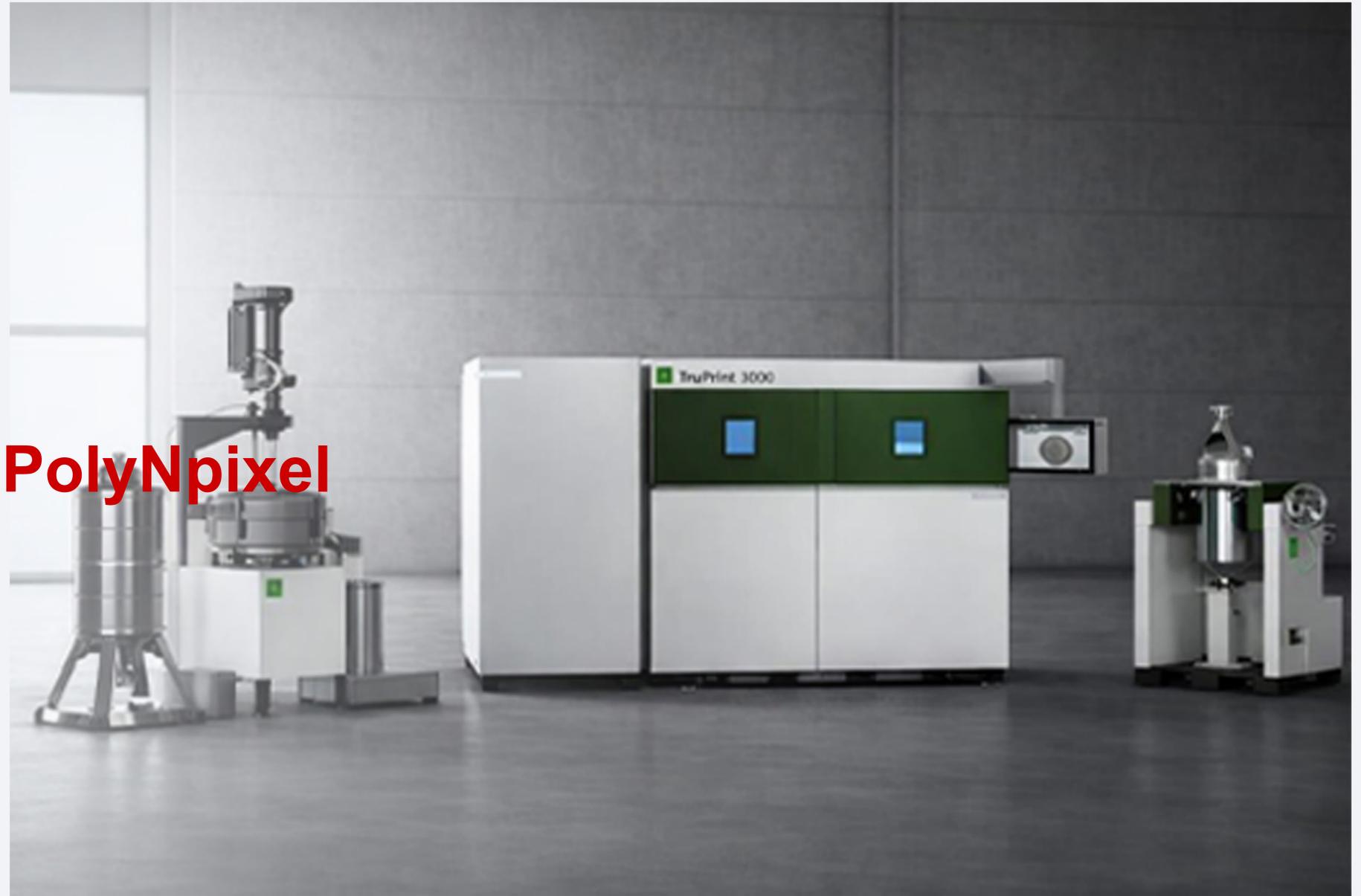
# ORAL & MAXILLOFACIAL IMPLANTS

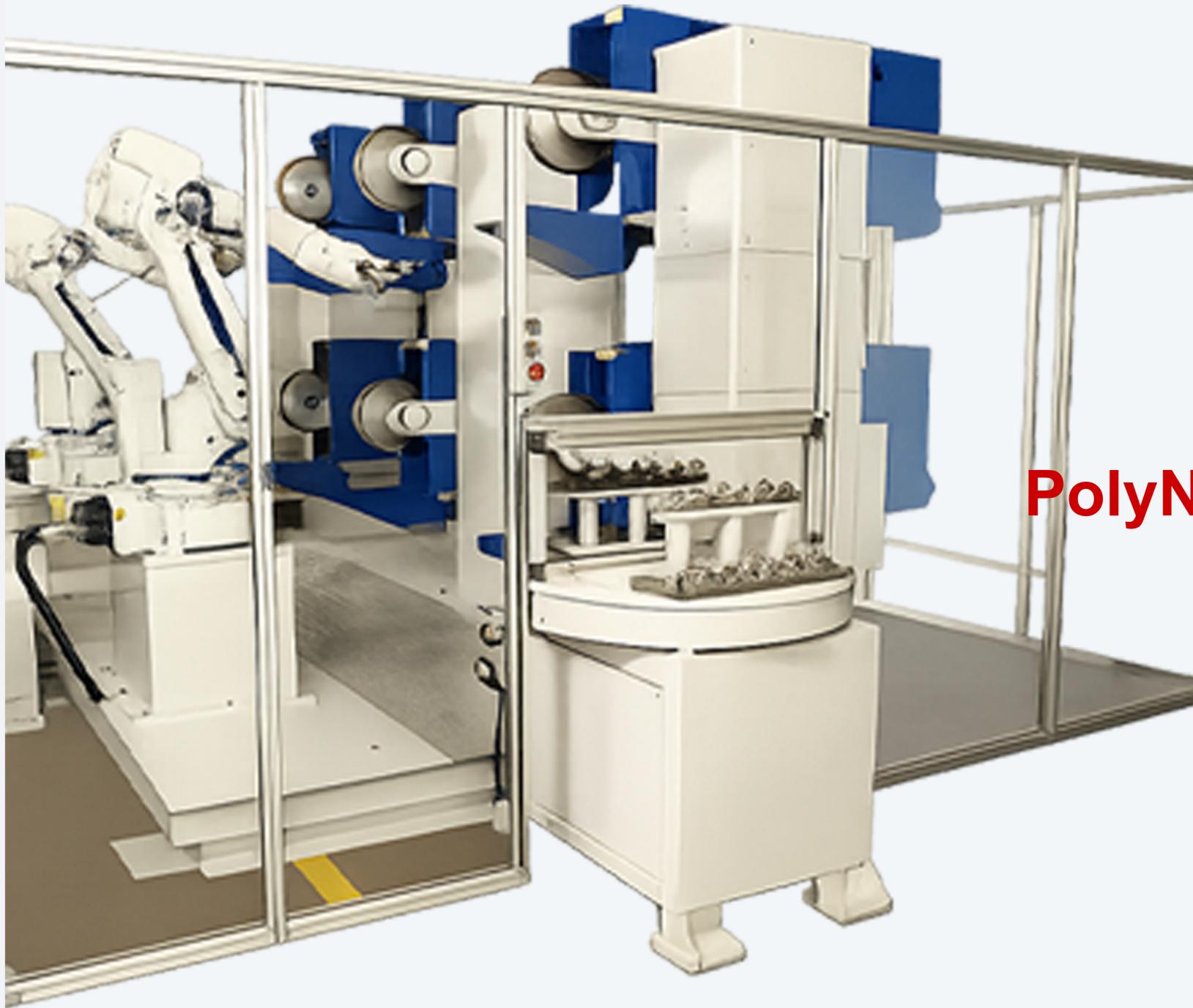


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# 3D PRINTING MACHINE

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Polishing Machine



PolyNpixel



**ROBOTE**  
**POLISHING MACHINE**

# MANUFACTURING EXPERTISE

We hold The Latest Technology Manufacturing Machines. Our Computer controlled as well as Hand Crafted Machines make us capable of producing Quality Products with high tolerance and exceptional surface integrity. Our Production Staff ensures top quality and reliable products through a single step manufacturing process i.e. from raw materials to finished products.

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We have people with rich experience in manufacturing of Orthopedic implants and instruments.



# MANUFACTURING EXPERTISE



Our current location holds more than 40 automatic machines (MADE IN USA/GERMANY/JAPAN) with modern technology and fully automatic such as

Machine,  
Water Jet Cutting Machine,  
Ultrasonic Cleaning Machine,  
Laser marking Machine Conventional Lathe & Milling machines

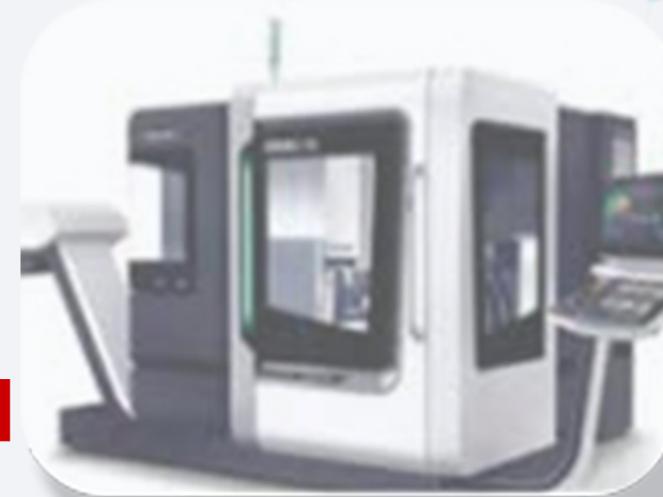
CNC Swiss Turn, Vertical  
Machining Centre CNC 5 Axis,  
CNC 4 Axis, CNC 3 Axis CNC  
(Thread Milling Machine & Turning

QUALITY INSPECTION MACHINES : Venire Calipers, Micro Meter, Height Gauge, Profile Projector, Coordinate Measurement Machine which ensure the pinnacle quality and consistent products through a single step of manufacturing.

# MANUFACTURING CAPACITY



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# 3D SCANNER

Quality Control Instruments



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CMM



# HARDNESS TESTER



VMM MACHINE

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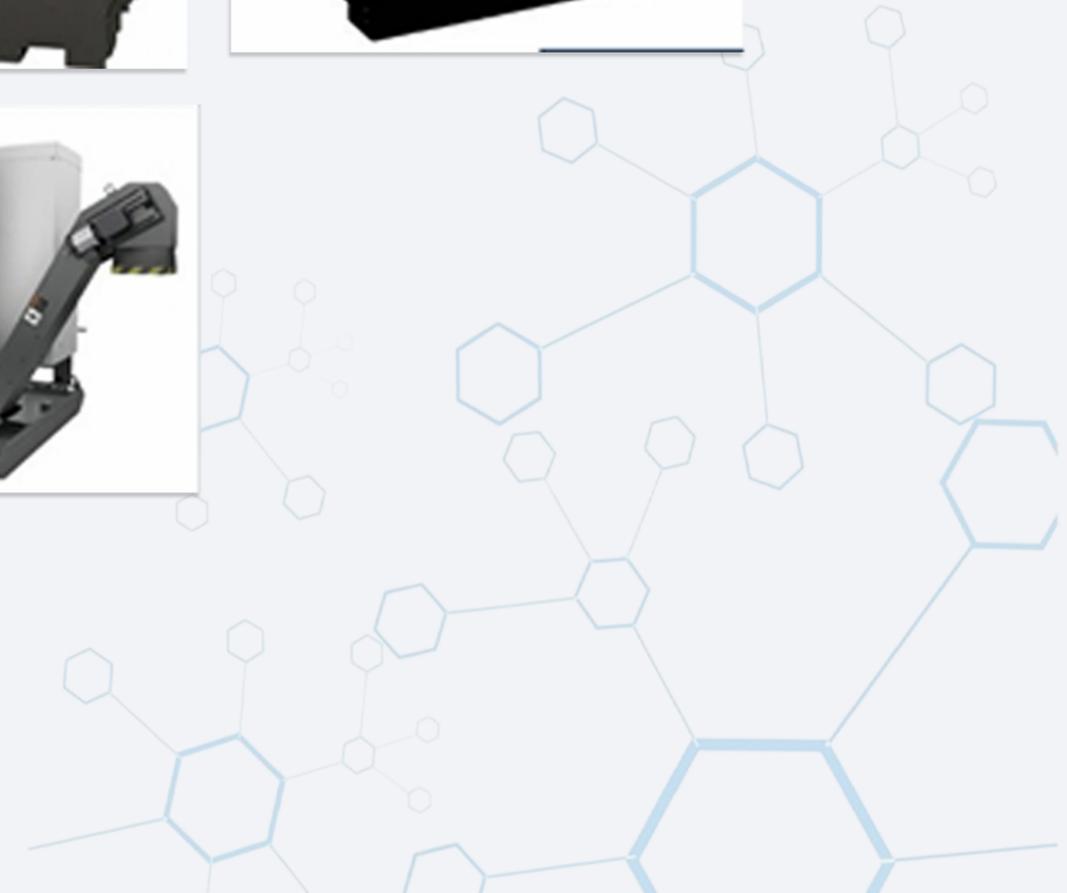


VARNIER CLIPPER

# QUALITY CONTROL Instruments



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# MANUFACTURING INFRASTRUCTURE



**QUALITY  
CONTROL** PolyNpixel  
**INSTRUMENTS (CLEANROOM)**

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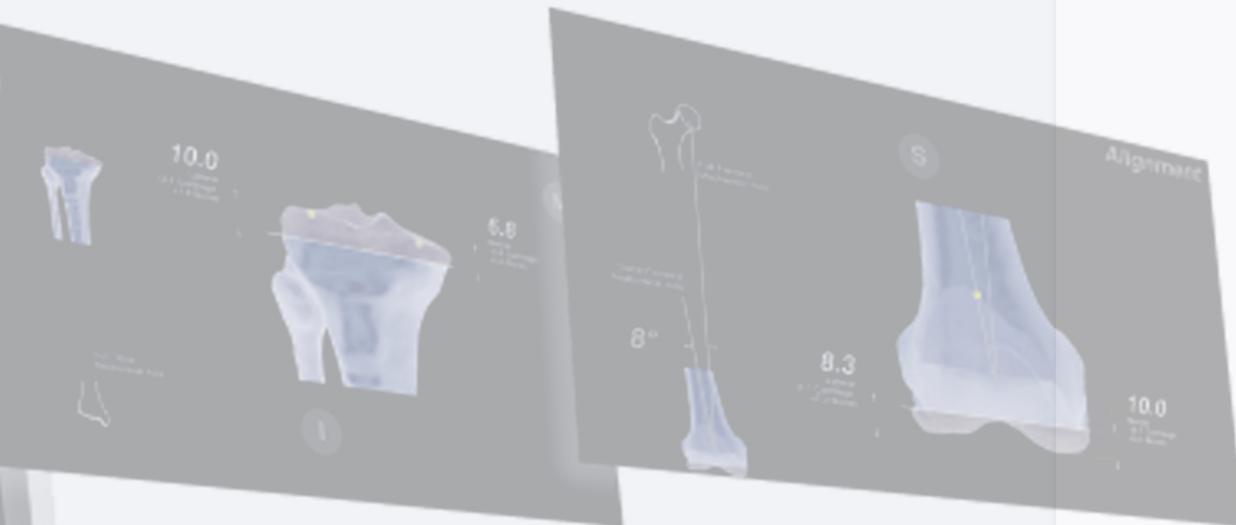


# DESIGN AND DEVELOPMENT

Designs are developed from the time tested and well established products which are already available in the markets using advanced CAD/CAM software's. Further designs are developed and modified based on guidance & feedback from our valued Surgeons.

## DESIGN STRATEGIES

- Concept Creation
- Brainstorming
- Refinement of Design
- Product Development, Verification & Validation
- Creation & Support of Quality Systems
- Generation of Necessary Quality & Regulatory Documentation



**PolyNpixel**

"A NEW VISION FOR BONE"

SHALL WORK  
TOWARDS A COMMON  
GOAL OF ACHIEVING  
TOTAL CUSTOMER  
SATISFACTION BY  
PROVIDING QUALITY,  
SUPPORT & SERVICES,  
ACCORDING TO  
ISO 13485 NORMS.

THIS WILL BE  
ACHIVED  
BY OUR TOTAL  
COMMITMENT TO

## Quality Policy

- ✚ **Contuinuous review and upgrading of Systems.**  
सिस्टम की निरंतर समीक्षा और उन्नयन।
- ✚ **Enhance the expertise of our people by periodic training.**  
आवधिक प्रशिक्षण द्वारा हमारे लोगो की विशेषज्ञता में वृद्धि।
- ✚ **By continually improving effectiveness of quality management system through developing.**  
समातार गुणवत्ता की प्रभावशीलता में सुधार करके विकास के माध्यम से प्रबंधन प्रणाली।
- ✚ **Manufacturing and supplying medical devices for Domestic and International Market.**  
विनिर्माण और चिकित्सा उपकरणों की आपूर्ति के लिए राष्ट्रीय और अंतर्राष्ट्रीय बाजार।
- ✚ **No compromise in quality,safety,Efficiency and Technical support while meeting applicable statutory and regulatory requirement.**  
गुणवत्ता, सुरक्षा, दक्षता और तकनीकी सहायता में कोई समझौता नहीं सांविधिक और विनियामक आवश्यकताएं।
- ✚ **We Deliever products to customers in the Right Quality with Right Quantity on Time,Every Time.**  
हम समय पर सही गुणवत्ता और सही मात्रा में ग्राहकों को उत्पाद वितरित करते हैं।
- ✚ **Continuous updating and technical competence.**  
निरंतर अद्यतन और तकनीकी क्षमता।

  
MR. D.K. SHARMA [CEO]  
Date : Jan - 2019

QUALITY  
& POLICY

ISO CLASS 7  
**CLEAN**  
ROOM AREA

**PolyNpixel**





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# MICROBIOLOGY LAB



The background of the image is a blurred photograph of a laboratory hallway. On the left, a white door is slightly ajar. In the center, a whiteboard is mounted on a light-colored wall. On the right, a bright blue door is closed. Overlaid on the whiteboard and the wall are several faint, light blue chemical structures, including various rings and molecular frameworks. The text 'MICROBIOLOGY' is written in a large, bold, dark blue font across the middle of the image. Below it, the word 'LAB' is written in a large, bold, light blue font. The text 'PolyNpixel' is written in a smaller, red font, positioned between the two main lines of text.

# MICROBIOLOGY

# LAB

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# QUALITY CONTROL PRODUCT ANALYSIS



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# PACKING OF PRODUCTS

- Non-Sterile implants are packed in a Low Density Polyethylene (LDPE) pouches. These pouches are further packed in another Low Density Polyethylene pouch.

ULTRA IS USED AS PRIMARY PACKAGING FOR SUPPLYING STERILE ORTHOPAEDIC IMPLANTS. IT IS ONE SIDE LAMINATED

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(printed) and other side is porous material (polyolefin). It comprises of top web blue laminate sandwich printed, made of 12µm polyester / 38µm polypropylene "Peel" and bottom web 93g/m<sup>2</sup> polyolefin. It has 5 years shelf life from date of manufacturing.

- Following the QC tests and Laser marking, QC passed implants are packaged in Ultra Roll which is further sealed. Each unit is packed separately in the ultra rolls which is cut and sealed as per the packaging material manufacturer's specification. Primary Label is applied on the back side of the primary packing.
- Tertiary packed material is finally packed in a box. Box is closed and Label is applied on the carton box. This box is further sealed by a thin polyethylene film

# REGULATORY AFFAIRS

- Ensures compliance with all regulations and laws pertaining regulatory agencies and personnel on specific issues affecting business. REGULATORY AFFAIRS to business

# WORKING WITH DIFFERENT

regulatory agencies and personnel on specific issues affecting business

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# REGISTERED COUNTRIES

- PERU
- NICARAGUA
- MEXICO
- COLOMBIA
- ECUADOR
- EGYPT
- ETHIOPIA
- MOROCCO
- MYANMAR
- SRI LANKA
- KENYA
- ALGERIA...ETC

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# STRENGTHS OF MARKETING

Currently, We capture approximately more than 30% of Orthopaedic Implant Market share in India. Our Strong Marketing Team enables in all the 29 Indian States and 7 union territories.

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# MOTTO

## DKSORTHO

Believes in providing the best quality & service to everyone associated with us

## DKSORTHO

Hopes that we can work closely with your organization and build a strong long-term relationship to develop the world of orthopedics.

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# REGISTERED COUNTRIES

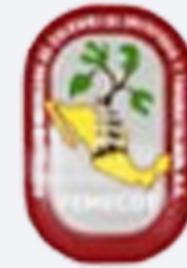


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# EXHIBITION PARTICIPATION

PRODUCT PROMOTIONS AROUND THE **PolyNpixel**

To strongly promote our products, we participate in various Conferences and seminars round the clock & round the globe. A renowned team of doctors and their associates conduct seminars and training sessions on our products in India and various parts of the world.



**XXXII CONGRESO  
MEXICANO DE  
ORTOPEDIA y TRAUMATOLOGÍA**



**WHX Miami**  
Formerly FIME

**AAOS**  
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

**WHX Dubai**  
Formerly Arab Health



# THANK YOU!

PolyNpixel



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[www.dksortho.com](http://www.dksortho.com)



[vivek.gbm.dksortho.com](mailto:vivek.gbm.dksortho.com)