# **ortho**materials<sup>TM</sup>

## 第六届ORTHOmaterials™骨科及齿科植入器械制造技术论坛

The 6th ORTHOmaterials™ Orthopeadic and Dental Devices Manufacturing Technology Forum



2023年9月7日-8日 7-8 September 2023



江苏常州中吴宾馆

Zhongwu Hotel, Changzhou, Jiangsu, China

## 会议日程

## **CONFERENCE AGENDA**

2023年9月7日		7 September 2023
08:00-09:30	签到	Registration
09:30 - 09:40	<b>欢迎辞</b> ORTHOMATERIALS 中国区负责人 翁益良	Welcome Speech ORTHOMATERIALS   China Regional Executive YiLiang WENG
09:40 - 10:10	骨科关节陶瓷材料及产品国产化研究 国家高性能医疗器械创新中心   研究员 张红斌	Ceramic Materials and Implants for Orthopedic Joints  National Innovation Center for Advanced Medical Devices    Principal Investigator HongBin ZHANG
10:10 - 10:40	<b>骨科植入物性能的计算机模拟</b> 西南交通大学 利兹学院院长&机械学院教授 靳忠民	Computational Simulation of Orthopaedic Devices Southwest Jiaotong University   Dean of the Leeds Joint School & Professor of Mechanical Engineering ZhongMin JIN
10:40-11:00	茶歇	Tea Break
11:00 - 11:30	骨科及齿科植入材料的表面生物 功能化改性与产业应用 中国科学院上海硅酸盐研究所 副研究员 钱仕	Surface Biofunctional Modification and Application of Orthopedic and Dental Implant Materials Shanghai Institute of Ceramics, Chinese Academy of Sciences   Associate Professor Shi QIAN
11:30 - 12:00	高性能医用钛合金材料及器械研发 国家高性能医疗器械创新中心 副研究员 胡楠	Research and Development of Advanced Ti-based Biomedical Materials and Devices  National Innovation Center for Advanced Medical Devices   Associate Professor Nan HU
12:00-13:00	午餐	Lunch

	分会场A: 先进材料和产品注册	Session A : Advanced Materials and Product Registration
13:00-13:40	聚醚醚酮增材制造用于植入器械的最新进展及产品介绍 英威宝(中国) 新业务开发经理 孙莉	PEEK Additive Manufacturing for Implant Device - Latest Progress and Product Introduction Invibio (China)   Business Development Manager Iris SUN
13:40 - 14:20	交联技术创新—供应困境下的新选择 三菱化学高新材料 植入聚合物技术高级经理 Jared TINKER	Advancements in Crosslinking Technologies that Bring Solutions to Supply Chain Headaches Mitsubishi Chemical   Global Technology MediTECH Senior Manager Jared TINKER
14:20 - 15:00	新一代长期植入级聚合物材料 – PEKK的 应用以及与传统同族材料对比 Seqens   医用高分子材料事业部 业务发展经理 Johan RIXTE	PEKK-The Next Generation Material for Medical Implants (polyetherketoneketone) Seqens   Medical Polymer Devision Business Development Manager Johan RIXTE
15:00 - 15:30	茶歇	Tea Break
15:30 - 16:10	改性聚丙烯PP – 骨科关节试模和器械加工 新型材料解决方案	Polypropylene – A Novel Materials Solution for Machined Orthopedic Joint Replacement Sizing Trials and Devices
	威斯莱科 医疗市场总监 Jim FAGAN	Westlake Plastics   Medical Marketing Director Jim FAGAN
16:10 - 16:50	威斯莱科 医疗市场总监 Jim FAGAN 新规下如何进行临床评价路径决策 和开展临床评价 奇敏儿信息咨询 医学部负责人 梁星	SWIN MARKET CONTRACTOR
16:10 - 16:50 16:50 - 17:30	新规下如何进行临床评价路径决策 和开展临床评价	Westlake Plastics   Medical Marketing Director Jim FAGAN  The Solution to deciding CER Feasibility and drafting CER
	新规下如何进行临床评价路径决策和开展临床评价 和开展临床评价 奇敏儿信息咨询 医学部负责人 梁星 创新可吸收骨科器械美国 FDA 510 (k) 上市 申请及策略解析	Westlake Plastics   Medical Marketing Director Jim FAGAN  The Solution to deciding CER Feasibility and drafting CER  QME Consulting   Manager of Medical Department Xing LIANG  US FDA 510 (k) Registration of Innovative Absorbable Orthopedic Devices and Strategy Analysis

	分会场B: 高效加工和精密测量	Session B : Efficient Processing and Precision Measuring
13:00 - 13:40	<b>骨钉高精度螺纹旋风铣</b> 号恩刀具(中国) 技术工程师 沈立宇	Bone Screw High Precision Thread Jet Whirling Horn Cutting Tools (China)   Technical Engineering LiYu SHEN
13:40 - 14:20	<b>植入物曲面高效加工</b> 德马吉精森机(中国) 医疗卓越中心负责人 言柏超	Efficient Machining of Implant Surfaces  DMG MORI (China)   Head of Excellence Center Medical  BoChao YAN
14:20 - 15:00	医疗解决方案的创新技术实现从编程、设置到加 工各环节的高效和安全 奥奔麦软件技术(中国)   应用工程师 张猛	Innovative Technologies of Medical Solution Make Sure the Processes of Programming, Set-up and Machining to be Safe and Efficient Open Mind Software Technologies (China)   Application Engineer Meng ZHANG
15:00 - 15:30	茶歇	Tea Break
15:30 - 16:10	<b>骨钉离线高效测量</b> 马波斯(中国) 产品经理 李鑫	Efficient Off-Line Measurement of Bone Screws Marposs (China)   Product Manager Xin Ll
16:10 - 16:50	高端精密多功能机床在骨科与齿科植入体中 的应用 威力铭-马科黛尔(中国) 销售经理 江勇军	Application in Orthopedic and Dental Implants by High Precision Multifunctional CNC Machine Willemin-Macodel (China)   Sales Manager YongJun JIANG
16:50 - 17:30	<b>骨科产品加工中高浓度油烟、油雾的处理方式</b> 艾博森空气净化(中国) 高级技术专家 何纪明	Treatment Methods for High Concentration Oil Smoke and Oil Mist in Orthopedic Product Processing Absolent Air Care (China)   Senior Technical Expert Steve HE
17:30-18:00	互动	Networking
18:00-20:00	晚宴	Dinner

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	分会场C: 合规检测和法规解析	Session C : Compliance Testing and Regulatory Analysis
09:00-09:40	<b>最小负担免临床全球上市实战分享</b> 北京贝马科斯技术 首席数据专家 马敏	Least Cost Clinical Trial Exemption Global Market Access Practical Sharing Beijing Baymax Technology   Chief Data Expert Min MA
09:40-10:20	<b>医疗器械分析和法规支持</b> 毅博科技(中国) 高级经理 杨丽洁	Medical Device Analysis and Regulatory Support Exponent (China)   Senior Manager LiJie YANG
10:20-10:40	茶歇	Tea Break
10:40-11:20	<b>可重复使用医疗器械—再处理确认要点</b> 通标标准技术服务(上海) 生命科学事业部 生物实验室主管 周言君	Reusable Medical Device Reprocessing Validation SGS-CSTC Standards Technical Service (Shanghai)   Life Science Services Bio Lab Supervisor Claudia ZHOU
11:20-12:00	<b>口腔类医疗器械生物相容性评估关注点</b> 药明康德中国医疗器械测试中心  生物相容性实验室技术负责人 徐彪	Key Points in Biocomptability Evaluation of Dental Medical Devices  Wuxi Apptec China Medical Devices Testing Center    Technical Director of Biocompatibility Laboratory Biao XU

	分会场D: 智能管理和数字制造	Session D : Intelligent Management and Digital Manufacturing
09:00-09:40	<b>医疗器械加工的刀具管理之痛</b> 诺而为工业技术 执行副总裁 肖晶月	The Pain of Cutting Tools Management in Medical Device Processing Knowhy Industrial Technical Service   Vice President JingYue XIAO
09:40-10:20	一次性使用 & 智能包装管理:小型植入物和医疗器械角度 卡尔托利 – 超净包装集团   亚太区总经理 Yannick RAVIER	Single Use & Smart Packaging Management: Small Implants & Procedure Instruments Perspective. Cartolux - Top Clean Packaging Group   Asia General Manager Yannick RAVIER
10:20-10:40	茶歇	Tea Break
10:40-11:20	<b>小批量、多品种医疗零部件生产的柔性解决方案</b> 爱路华(中国) 副总裁 市场销售&系统方案 胡劲宏	Flexible Solutions for Small Batch, Multi-Variety Medical Parts Production Erowa (China)   VP Marketing Sales & System Solution JinHong HU
11:20-12:00	高光束质量激光助力骨科器械精密加工 通快(中国)   医疗行业销售经理 郝浩然	High Beam Quality Laser-Assisted Precision Machining of Orthopedic Instruments Trumpf (China)   Medical Sales Manager Jacky HAO

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#### 金属材料 **METALLIC MATERIALS** Market leader in supplying precision stainless steel thin wall 提供符合医疗器械行业质量标准的精密薄 **Accu-Tube** 壁不锈钢管的市场领导者。 tubing that meets medical device industry quality standards. 提供 TC4/TC4ELI/TC20/TA1G/TA2G/ Professional medical titanium alloy material manufacturer TA3G/TA4G 棒、丝材的专业医用钛合金材 offering bars and wires in 料制造商。 TC4/TC4ELI/TC20/TA1G/TA2G/TA3G/TA4G. 高精度医用不锈钢和钛合金丝材、棒材、 Manufacture of wires, bars, sheets, and sections in medical 777 板材及型材制造。 stainless steel and titanium with high precision. EZM EDELSTAHLZIEHEREI MARK World's leading producer of cannulated bars in titanium and 金属中空材的全球领导者,提供用于创伤、 脊柱和运动医学等骨科植入物及手术器械 stainless steel for the production of orthopaedic implants and 应用的钛合金和不锈钢中空材、薄壁管和 surgical instruments in trauma, spine and sports medicine 实心棒的一站式金属解决方案,以及聚合 applications, as well as supply of thin wall tubing and solid 物系列植入物的注塑成型代工服务。 bars to offer one-stop solution of metallic materials, and also offering injection molding service of polymers for implants. 近百年历史的欧洲医疗产业原材料供应 Almost a century of European medical raw material supplier, 商,提供骨科植入物和手术医疗器械的钛 providing implantable and instrumental material ranges from **STAINLESS** 合金、钴铬钼及不锈钢原材料。 titanium alloys, CCM and stainless for medical market. 全球最大的全产业链钛材生产商,供应医 World's largest fully vertically integrated titanium producer, 疗用途的钛板和钛棒,并提供完整的仓储 providing titanium plates and bars for medical application as 物流和切割服务。 well as warehousing, logistics and cutting services. 非金属材料 NON-METALLIC MATERIALS Especially developed for resorbable orthopedic implant 可吸收骨科植入材料,具有的生物相容性 devices and serve as the matrix in a wide variety of applications 和生物降解性优势,在运动医学、外伤、 颅颌面等手术领域中,可作为治疗肌肉骨 to treat injuries such as sports medicine, trauma and spinal Corbion 骼系统损伤。 surgery. 生产和销售符合医疗行业严苛要求的医疗 Manufacture and sale of medical plastic sheets and rods which Ensinger **O** 级塑料板棒,同时提供塑料材料机加工和 are complied with stringent requirements of the medical 注塑服务。 industry, and providing plastic material machining and injection moulding services. A global leading supplier of high performance polymers for 提供植入级聚醚醚酮 VESTAKEEP®,植入级 medical application, including implantable PEEK 可降解聚合物 RESOMER®,以及医疗级尼 EVONIK 龙等高性能聚合物。 (VESTAKEEP®), bioresorbable polymers (RESOMER®), and PA12 etc. An industry-leading biomedical materials provider, serving 行业领先的生物医用材料供应商,为医疗 medical device and pharmaceutical manufacturers with 行业提供专业的技术和服务,包括:医用 改性塑料、植入材料、药物/聚合物混合、 professional technology and services. These include custom #FOSTER 溶液、型材,以及贸易和分销业务。 medical compounds, implantable materials, drug/polymer blends, solutions, profiles, and trading & distribution businesses. A global leader in providing high-performance implantable 为医疗器械制造商提供高性能可植入 PEEK Invibio PEEK solutions to medical device manufacturers. The 材料解决方案的全球领先企业,提供的产 品和服务用于脊柱、创伤和骨科医疗领域 company provides products and services for spine, trauma and 的组件的制造,旨在研发使用寿命更长的 orthopaedic and dental medical segments for the 植入式医疗器械。 development of long-term implantable medical devices. 生产和销售 AKSOPEEK 品牌植入级 PEEK 材 Manufacture and sale of AKSOPEEK Implant-grade PEEK, 料、植入级碳纤维增强 PEEK,医用碳纤维 Implant-grade carbon fiber reinforced PEEK, Medical carbon 增强 PEEK、PPSU、PEI 等医用高分子材料, fiber reinforced PEEK, PPSU, and PEI. One-stop services to 可配套客户完成从原料采购到制品代工的 customers from raw material procurement to product OEM. 一站式服务。 提供优质可植入 PEEK (聚醚醚酮) Offers a product range that includes both high quality PEEK MITSURISH (polyetheretherketone) Zeniva® PEEK and UHMW-PE Zeniva® PEEK 和 UHMW-PE (超高分子量聚乙 CHEMICAL GROUP 烯) - Chirulen® / Extrulen® UHMW-PE 型材。 (ultra-high molecular weight polyethylene) - Chirulen® / 三菱化学高新材料(上海)有限公司 Extrulen® UHMW-PE products.



提供植入级聚醚酮酮 IMPEKK®,植入级可降解聚合物 EXPANSORB®,以及植入级聚氨酯等其他高性能聚合物的定制服务。

A global leading supplier of high performance polymers for medical application, including implantable PEKK (IMPEKK®), bioresorbable polymers (EXPANSORB®), and Custom production of PU.



专注于医疗器械和生命科学领域。主要提供洁净室塑料注塑,后道加工及组装服务。同时,集团旗下 Orthoplastics 公司作为植入级 UHMWPE 制品的行业领导者,提供UHMWPE 材料的压缩成型及性能测试服务。

As a global medical device manufacturer, we provide injection molding, secondary process and assembly for medical devices. As a world leader in the development and supply of implantable-grade UHMWPE for orthopedics applications, we provide Direct Compression Moulding and Laboratory Services.



作为高性能热塑性塑料挤压和压缩成型技术的世界领先制造商,我们的先进技术使 我们能够将全系列的热塑性树脂转化为棒 材、片材和薄膜。 As a world leading manufacturer in extrusion and compression molding technologies of high performance thermoplastics, our advanced technologies allow us to convert the full range of thermoplastic resins into rods, sheets, and film.

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#### 包装材料

#### **PACKAGING MATERIALS**



作为欧洲医疗无菌包装解决方案领航者,我们可以帮助您提供包装设计到生产阶段的高品质无菌包装,包括医疗器械 CDMO,吸塑和注射包装,医疗精密部件和热封口机。

As Europe's leading packaging solution provider, we can assist you from the concept to the production phase to manufacture top quality sterile packaging, Includes Medical Device CDMO, Blister & Injected Packaging, Medical Precision Components, and Heat Sealing Machine.



专注于医用吸塑盒和 ProFlex Film™(TPU 医用包装)的研发与生产,在医疗领域里广泛应用于骨科植入器械及手术器械等。

Specializes in the research, development and production of medical blister packaging and ProFlex Film™ (TPU medical packaging), which is widely used in orthopedic implants and surgical instruments in the medical field.



专注于为医疗器械、齿科器械、健康 护理产品和实验室诊断仪器设备等应 用提供通用标准化和定制化硬质塑料 包装解决方案。 Focusing on providing universal standardized and customized hard-plastic packaging solutions for applications such as medical devices, dental devices, health care products, and laboratory diagnostic equipment.

## 工艺服务

#### **PROCESSING SERVICES**



为关节、脊柱、创伤和齿科种植体等骨科植入物和手术工具,提供专业等离子喷涂涂层服务,拥有喷涂纯钛、钛合金、羟基磷灰石、钽涂层等领先技术与品质。

Provider of advanced and high quality plasma coating service for orthopedic implants and surgical tools in the area of joints, spine, trauma and dental implants. Coating services include coating of pure titanium, titanium alloy, hydroxyapatite and tantalum coatings.

## **CASTPRO**

国内领先的人工关节植入物铸件供应商, 提供高品质高性能的股骨髁、胫骨托、股 骨柄、双极杯、球头、试模件等毛坯铸件。 Leading implant casting supplier in domestic market, providing high quality&performance casting parts such as Femoral Component, Tibial Baseplate, Hip Stem, Bi-polar cup, Hip Head, Femoral Trial, etc.



专为医疗器械提供表面处理代工服务,包括: 钛金属阳极氧化、不锈钢的钝化和电解抛光、适用于所有植入物的 HA<sup>nno</sup>(纳米羟基磷灰石)涂层。

Focus on providing surface finishing services for medical devices, including titanium anodizing, stainless steel passivation and electrolytic polishing, HA<sup>nano</sup> (Nano hydroxyapatite coating) for all implants.



提供满足全球医疗骨科行业及航空工业发 展需要的骨科植入物精密锻件、机加工成 品件及航空发动机关键零部件产品。 Provides orthopeadic precision forging parts, finished machining products and key components of aero plane engine to meet the fast development and huge demands of global medical and aviation industry.

#### ionbond

IHI GROUP

我们的 Medthin™系列涂层具有高硬度、良好的结合力、高断裂韧性、低摩擦特性,这些涂层现在广泛应用于医学植入物及手术器械中。

Our Medthin $^{\text{TM}}$  series of coatings features high hardness, excellent adhesion, fracture toughness and low friction that are widely used in medical implants and surgical instruments.



为种植体生产企业提供种植体、基台及其他种植体附件数控加工及表面处理(喷砂酸蚀,阳极氧化)的代工服务;为骨科生产企业提供脊柱创伤类产品的数控加工及表面氧化的代工服务;椎体成形工具、骨科手术工具、模具加工、注塑件加工等加工业务。

CNC machining and surface treatment (sandblasting, acid etching, anodizing) of implants, abutment and other implant accessories for implant manufacturers; Provide CNC machining and surface oxidation OEM services for orthopedic manufacturers of spinal trauma products; Vertebra forming tools, orthopedic surgery tools, mold processing, injection parts processing and other processing business.



向创伤、脊柱、关节、齿科种植体、工具 器械类产品的生产商提供全套超声波清洗 及各项表面处理工艺研发、代工服务、设 备及附属设施。 Total solution provider of ultrasonic cleaning, R&D of cleaning and surface treatment process and service of surface treatment for trauma, spine, joint, dental implant and instrument products.

# Lincotek

Medical

为脊柱、关节重建、运动医学、创伤和四肢市场提供全方位的医疗器械开发和制造服务;也是医疗领域铸造、机加工、等离子喷涂和增材制造方面的技术专家。

A fully-integrated, global contract manufacturer for spine, reconstruction, sports medicine & trauma and, extremities markets and a recognized expert in casting, machining, plasma spray coatings and additive manufacturing technologies in the medical field.



专注于金属材料高端热处理整体解决方案 及加工业务。公司主要服务于:汽车发动 机动力核心零部件热处理加工;精密磨具 的表面硬化处理;精密医疗器械及零部件 的光亮处理;航空零部件功能处理。 Focusing on high-end heat treatment solutions and processing business for metal materials. The company mainly serves: heat treatment processing of core components of automotive engine power; Surface hardening treatment of precision grinding tools; Bright treatment of precision medical devices and components; Functional processing of aviation components.



一站式灭菌解决方案提供商,业务包括灭 菌技术服务和实验室检测服务,聚焦于医 疗器械、医药包装、生物制品等行业。 One-stop sterilization solutions provider, business includes technical solutions and laboratory test, which is primarily specialized in medical device, pharmaceutical packaging, and biological products etc.



我们致力于满足医疗植入物公司对金属表面处理的需求,提供植入物和相关器械的 钛和铝阳极氧化服务。专业致力于高端表面处理技术的创新、研发、推广和应用。 By approaching the needs of medical implants companies for metal finishing, we are providing titanium and aluminum anodizing services of implants and instruments. We are committed to innovation, R&D, promotion, and application of high-end surface treatment techniques.

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## 咨询及检测服务

#### **CONSULTING AND TESTING SERVICES**





专注生物力学测试,涉及产品包括:骨科材料及植入物;牙科材料及植入物;运动 医学产品;各种金属、高分子、陶瓷以及 复合材料等。 Our experts assess strength, resistance, durability and ageing of various joint endoprosthesis, osteosynthesis products, trauma products, surgical instruments and PE/ ceramic and composite material.



HEALTHIER FOR ME

为国家卫健委发文允许向基层采集数据的业务系统之一的平台技术,采用真实世界研究(RWS)及临床评价的方法,助力产品获得上市许可。

As one of the business systems allowed by the National Health Commission to collect data from grass-roots organizations, a platform technology using Real World Research (RWS) and clinical evaluation methods to assist products in obtaining market approval.



美国FDA及欧盟CE全球取证一站式服务领航者。提供骨科化学表征及毒理学评价、生物相容性测试、动物实验、及欧美注册咨询服务。为全球知名第三方验证公司合作方并為亮宇OECD GLP国际级生物学实验室指定代表。

One-stop shop medical device consulting company providing the material chemical analysis and toxicology evaluation, biocompatibility and preclinical animal testing, US FDA and CE consulting service. We are the global third-party partner and agent of LEON OECD GLP biocompatibility laboratory.



整合了德国实验室、德国设备制造商及国内优秀资源的第三方植入物检测实验室,使用各类国际先进的检测设备,可以为客户提供各种产品注册检测服务和研发检测服务。

A professional third-party implant testing laboratory by integrating German test service provider, German equipment manufacturer and domestic excellent resources, using a large number of international advanced testing equipments, which can provide customers with various product registration testing services and R & D testing services.

## **EPINT**K

服务骨科齿科行业多年,服务项目包含: 法规咨询;临床前研究(新材料/产品性 能研究、磁共振兼容性、全套生物学、大 动物试验、工艺确认);注册检测;临床 试验,真正做到了全流程一站式服务。 Being serving the orthopedic and dental industry for many years with service projects including regulatory consulting; Pre clinical research (new material/product performance research, magnetic resonance compatibility, complete biology, large animal testing, process confirmation); Registration testing; Clinical trials, and have truly achieved one-stop service throughout the entire process.

## E<sup>x</sup>ponent®

在医疗器械领域我们提供MRI安全性和兼容性测试、失效分析、实验设计和测试、有限元分析、工厂审核、美国和欧盟监管文件提交、植入物取出分析、产品召回相关的技术咨询服务。

As an engineering and scientific consulting firm, we provide technical services including MRI safety and compatibility test, failure analysis, experimental design and testing, finite element analysis, quality assurance and factory audit, regulatory submissions in USA and Europe, explanted device analysis and product recalls in medical device industry.

## Kerbio 科标医学

专业第三方检验检测服务平台,为全球医疗器械生产研发公司提供生物相容性试验、微生物检测、医疗器械包装验证等测试服务。

As third-party professional testing service platform, we provide biocompatibility testing, microbiological testing, medical device packaging verification for medical device manufacturing and research worldwide.



作为一家服务于中高端、创新型医疗器械的第三方检测服务公司,为全球医疗器械研发生产企业提供专业的临床前大动物实验、生物相容性测试、国内外法规注册咨询、临床研究、体系与技术定制化培训等服务。

A strategic project integration management platform providing medical device manufacturers with professional preclinical performance testing in vivo, biocompatibility testing, international registration consulting, clinical research, customized quality and customized trainings, etc.



为医药企业提供全生命周期服务的专业公司并拥有18年的行业经验。我们的检测机构是首家获得国家级资质的非公有制机构并拥有多样的检测能力。我们的咨询机构为客户定制策略,加速上市。

Professional services provider for medical enterprises with 18 years experience. Testing lab is the first non-public institution that obtains ChinaLaboratory Mandatory Approval with strong testing capacity. Consulting service assists client to establishglobal market strategy and speed the access to the market.



全球唯一的医疗器械研究组织及ISO-10993 标准的奠基人,为全球医疗器械企业提供 上市前和上市后的测试、法规咨询和临床 服务。 The only medical device research organization (MRO), the founder of ISO-10993, providing pre-& post-market testing, consulting and clinical services to medical device companies worldwide.



外科植入物力学性能检测的第三方检测平台,拥有自主研发的检测设备,具有ISO17025等资质,报告可提交至NMPA、CE、FDA进行产品注册。

The third-party testing platform for Mechanical properties testing of surgical implants, has self-developed testing equipment and ISO 17025 certification. Reports can be submitted and used to NMPA, CE, and FDA for product registration.



临床试验服务,为医疗器械企业提供一站 式解决方案,帮助客户实现可持续的竞争 优势。我们精通中国及欧美等国际医疗器 械注册法律法规、技术规范,在法规解 读、标准理解、申报文件编写、临床试验 等方面具有明显的优势。

2004年成立,专注于全球医疗器械注册和

registration and medical device clinical trial services, to provide one-stop solutions for medical device manufacturers and dealers, and help customers achieve sustainable competitive development. We are proficient in NMPA and international medical device registration regulations. With customer-oriented service idea, we have supported almost 1000 clients all over the world and achieved more than 3800 NMPA certificates successfully.

Founded in 2004, being specialized in global medical device



外科植入物第三方检测(CMA/CNAS)服务平台。以专业技术为驱动,以客户服务为核心,为国内外客户提供检测、研发、注册咨询及临床比对服务。

A professional service platform specializing in third-party testing (CMA/CNAS) for surgical implants. Driven by expertise and customer service, we provide testing, research and development, registration consulting, and clinical comparison services to clients both domestically and internationally.



国际领先的第三方测试、检验、认证机构。我们的使命是提供专业和独立的临床研究和生物/制药和医疗器械的质量控制测试服务和测试研究,为我们的客户和世界各地的患者创造价值、以保证药品/医疗器械质量。现拥有高水准的GMP/GLP合规实验室服务网络。

A world-leading institution in third-party testing, inspection and certification headquartered. Our mission is to safeguard the quality of medicines/medical devices by providing professional and independent services in clinical research, biologics characterization, analytical development, and quality control testing of pharmaceuticals, biopharmaceutical and medical devices creating value for our clients and patients worldwide, now with a state-of-the-art clinical pharmacology unit and the global network of GMP/GLP-compliance laboratories.



<mark>苏 大 检 测</mark> SUDATEST 始于1984年,源于苏州医学院,检测行业学院派。为全球医疗器械研发生产企业提供清洗验证、动物实验、生物相容性、包装验证、化学表征等检测服务,报告符合NMPA、FDA、CE注册要求。

Being deep-rooted in Suzhou Medical College since 1984, traditional academic testing facility. Provide global medical device R&D and production enterprises with cleaning verification, animal experiments, biocompatibility, packaging verification, chemical characterization and other testing services. Report fully meets requirement of NMPA, FDA, CE registration.



拥有丰富的医疗器械测试经验,提供从研发到市场化的一站式医疗器械测试服务商。所有服务流程均遵从且满足CMA、ISO/IEC 17025、US FDA GLP、欧盟成员国比利时0ECD GLP、IS013485、A2LA及相关IS0标准的要求。提供八大核心业务:大动物实验、化学测试、毒理学风险评估、生物相容性、生物学评价、微生物测试、病理学平台和注册及临床等。

With rich experiences in medical device testing experience, we can provide a one-stop medical device testing service from R&D to marketization. All service processes comply with and meet the requirements of CMA, ISO/IEC 17025, US FDA GLP, EU Member State Belgium OECD GLP, ISO13485, A2LA and related ISO standards. Providing eight core businesses: large animal research, chemical testing, toxicological risk assessment, biocompatibility, biological evaluation, microbiological testing, pathology services and registration and clinical services, etc.

# 第六届ORTHOmaterials™骨科及齿科植入器械制造技术论坛 The 6th ORTHOmaterials™ Orthopeadic and Dental Devices Manufacturing Technology Forum



加工设备	MACHINING EQUIPMENTS	
∧bsolent	提供超高效油烟、油雾过滤系统,应用于 骨科植入材料加工;如:走心机、磨床等 高污染环境,防止污染空气影响设备寿命 及人员健康。	Provide ultra efficient oil smoke and oil mist filter systems for orthopedic implant material processing; For example, high pollution environments such as centrifuges and grinders can prevent air pollution from affecting equipment lifespan and personnel health.
A.HAA5	提供骨科磨削方案的五轴数控磨床制造 商,全球医疗领域磨削应用的领跑者。	5 axes grinding machines manufacturer and solution provider for orthopaedics, a global leading company in grinding application for medical industry.
CHIRON <b>Group</b>	德国高端数控机床与自动化方案的可靠供 应商,凭借丰富经验为医疗行业提供植入 体与器械等产品的高精度加工与生产解决 方案。	As a reliable supplier of high-end CNC machine tools and automation, we provide high precision machining centers and production solutions for implants and instruments in the medical industry with our rich experience.
DARDI 大地水刀 WATER CUTTER	高精度超高压五轴水刀,IGEMS-3D 软件, 快速、智能套料,切割精度达 ±0.02mm。 国内首创,为钛合金骨科植入体等医疗器 械提供高效自动化加工方案。	High accuracy and ultra-high pressure X5 waterjet cutting machine with IGEMS-3D software, to cut the material faster and intelligently, achieving cutting accuracy up to ±0.02mm. Providing efficient automatic processing solution for titanium alloy orthopedic implants and other medical devices.
DMG MORI	提供包括车削、铣削以及先进加工技术, 例如超声加工技术、激光加工技术和增材 制造技术等全方位医疗产品加工行业方 案。	Medical full-service provider for turning Technology, milling technology as well as new technologies (Ultrasonic, LaserTec, Additive Manufacturing).
GROB	无论是植入物、假体,还是医疗器械,格 劳博五轴联动通用加工中心可满足医学工 程行业的最高要求,确保精密工件的完美 制造。	Whether implants, prostheses or medical devices, GROB 5-axis universal machining centers meet the highest demands of the medical engineering industry and ensure the perfect manufacture of precision parts.
INDEX	为医疗产品加工提供高效高精解决方案的 多轴自动机床、自动走心车床、车铣中心、 和通用车床等。	Providing high efficient and high precision technology solutions for medical products by Multi-spindle automatics, sliding headstock automatic lathes, turn-mill centers and universal turning machine.
北京精雕集团 BEIJING JINGDIAD GROUP	主要生产精密五轴高速加工中心和磨削中心,提供骨科植入物、精密微创手术器械、 心外科手术器械、齿科零件的整体加工方 案。	The company mainly produces precision five-axis high-speed machining centers and grinding centers, providing overall processing schemes for orthopedic implants, precision minimally invasive surgical instruments, cardiac surgical instruments and dental parts.
KNOLL .lt works	为医疗行业提供冷却液过滤、排屑、碎屑、 泵抽设备、磨削超精过滤系统、工业废水 零排放系统、设备维护和运行管理软件系 统。	Provides the medical industry with world-leading coolant filtration, chip removal and crushing, pumping equipment and solutions, as well as super precision filtration system for grinding applications, industrial wastewater zero discharge system, equipentn maintenance and operation management software system.
Mazak	诞生于我们的数字化工厂的五轴加工中 心、车铣复合加工机等,满足医疗行业客 户加工的多样化需求。	5-axis machining center and multi-tasking machines manufactured in our iSMART Factory, fully meet the diversified needs of customers in the medical industry.
starrag	通过超高性能运动学和 5 轴联动加工,为 医疗产品带来了高效可靠的整体高精加工 解决方案。	Providing an efficient and reliable complete high-precision machining solutions for medical products through the ultra-high performance kinematics with five simultaneous axes machining.
TORNOS	移动式主轴箱技术及瑞士型自动车床的发明者及行业领导者。我们凭借在整个医疗技术生产链中的丰富经验、全面的解决方法、完整的生产计划和全球性业务,成为医疗器械和仪器制造商及其供应商的完美合作伙伴。	The inventor and a pioneer of sliding headstock technology and the Swiss-type automatic lathes. Vast experience throughout the medtech production chain, a holistic approach, a complete production program and a global presence make us the perfect partner to medical device and instrument manufacturers and their suppliers.
Turbo-Separator  • Like intendiced corpus	有着 60 多年技术经验的工业液体过滤技术权威,一直致力为不同应用领域提供最先进的无耗材过滤系统。	With more than 60 years of technical experience in the industrial liquid filtration technology authority, committed to providing the most advanced non consumable filtration system for different applications.
WILLEMIN-MACODEL YOUR ADVANCED MACHINERS SOLUTIONS	为全球医疗领域提供创新加工方案的多轴 数控机床制造商。	An innovative machining solutions provider of 5+ axes CNC machines in global medical industry.
后道处理设备	POST-PROCESSING EQUIPMENT	rs
	全球领先的超声波清洗设备制造商,为医 疗器械和植入物等行业提供非标钝化和清	The world's leading manufacturer of ultrasonic cleaning equipment, providing customized passivation and cleaning
FOBA	洗设备。 用于医疗器械产品直接标识的激光打标 机	equipment for medical devices, implants and other industries.  Laser marking system for direct marking of medical device.
Laser at your service	机。	We provide finishing processes and equipments as well as
RÓSLER° finding a better way	用品提供各种表面光饰工艺、设备以及相配套的工艺水处理及光饰耗材。	process water treatment and consumables for a variety of surface finishes on orthopaedic implants, medical devices and other engineered medical products.
TEGUANG·SH 金属表面处理 上海特光机械	主要提供用于关节类产品、骨板、骨螺 钉、心血管支架、手术器械等表面抛光 处理设备及相应耗材,并全程提供技术 支持服务。	Mainly provides surface polishing equipment and corresponding consumables for joint products, bone plates, bone screws, cardiovascular stents, surgical instruments, etc., and provides technical support services throughout the process.

process.

welding and 3D printing.

polishing process of medical implant.

As a high-tech company we provide solutions for the medical

industry such as anti-corrosion marking, laser cutting, laser

Provides polishing machines, polishing media and polishing

compounds, and also offers the total solution for the final

为医疗行业提供抗腐蚀打标、激光切

割、激光焊接以及3D打印等解决方案的

主营研磨抛光设备、研磨耗材、研磨添加剂,以及医疗植入物后道研磨抛光的 整体解决方案。

高科技公司。

TRUMPF

欣优亮

## **ortho**materials<sup>TM</sup>

## 第六届ORTHOmaterials™骨科及齿科植入器械制造技术论坛

The 6th ORTHOmaterials™ Orthopeadic and Dental Devices Manufacturing Technology Forum

参展企业 EXHIBITORS LIST

## 设备附件及耗材

#### **EQUIPMENT ACCESSORIES AND CONSUMABLES**



全球金属加工液领域活跃的制造商,致力 于高质量的切削液和磨削油的研发及生 产。 A globally active company in the metalworking fluid sector, developing and producing high-quality cutting and grinding fluids.



主要提供辐照、环氧乙烷、高压蒸汽、过氧化氢等灭菌方式的灭菌检测耗材,其中灭菌化学指示剂、生物指示剂销往全球100多个国家。

Mainly provides sterilization testing consumables for sterilization methods such as irradiation, ethylene oxide, high-pressure steam, and hydrogen peroxide. Among them, sterilization chemical indicators and biological indicators are sold to more than 100 countries around the world.



深入研究和应用前沿的精密小零件加工解 决方案,帮助中国骨科植入物和种植牙客 户解决各种加工难题,实现降本增效的目 标。 Making a profound study and applying cutting-edge precision small part processing solutions, to help Chinese orthopedic implant and dental implant customers to solve various processing problems and achieve the goal of cost reduction and efficiency increase.



致力于工装夹具系统、预调测量设备、机 器人、工作管理软件的研发和生产。 A global operating organization dedicated to the development and production of tooling system, presetting & measuring device, robot loading system and job management software.



全球金属切削技术领导者,以高性能切削 刀具、创新研发及贴近客户需求的特质在 全球市场获得成功。 "PASSION FOR PRECISION - 精益求精"是我们

的承诺与主旨。

As a leader of the global cutting technology, the high-performance cutting tools, inventiveness, and customer focus are the three factors that have made us a success on the world market for cutting tools. PASSION FOR PRECISION is our

commitment and keynote.



创建于 1969 年,专注于硬质合金刀具的设计和生产,特别在槽加工领域。我们在整个全球的汽车、航空航天、工程机械、液压、能源、医疗行业都有很高的市场份额和客户赞誉度。非标刀具领域更是我们的强项。

Established in 1968, we've been dedicated our resources to the design and manufacture of tooling specifically for grooving applications. We have good global market share on industrials of Automotive, Aerospace, Machinery, Hydraulic, Energy, Medical and trusted and praised by our customer. Especially customized tools are our strengths.



专业配套三、四、五轴机床的零点快换系 统和工件高精密浮动装夹系统;提供医疗 器械及人体植入物零件加工和自动化生产 整体解决方案。 Zero-point quick-change system and high precision floating clamping system for 3-, 4- and 5-axis machine tools; Provide total solutions for processing and automated production of medical devices and human implant parts.



在医疗行业拥有成功的合作案例的刀具整 包管理服务提供商,针对高端医疗、机械 替代性医疗等,均有丰富的刀具管理服务 经验。 Outsourcing management service provider of cutting tools with successful cooperation cases and abundant of service experience in high-end medical products and mechanical alternative medical products areas.



致力于专业开发、生产五轴机床配套的零 点快换系统、工件夹持系统。提供植入物 及器械零件加工自动化一体化方案。

专门生产用于不锈钢、钛、高温合金和

Focus on the development and production of QuickPoint and Workholding system for 5-axis machine. We supply the complete module or special automation solution to the trauma, spine, joint parts and other field components.

Specializes in in high performing carbide cutting tools for

## In MIKRON TOOL

CoCr 合金的高性能硬质合金刀具,并为医疗和牙科技术等行业提供高效的加工解决方案和工程服务。该产品组合包括直径范围从 0.1-8.00 mm(定制最大直径微 32 mm)的工具,用于定心、倒角、钻孔(最大 50 x d)-铣削、铰孔和去毛刺。保证了高切削速度、工艺可靠性和 μ 级范围内的可重复性。

stainless steel, titanium, superalloys and CoCr alloys and offers highly efficient machining solutions and engineering services for industries such as the medical and dental technology. The portfolio includes tools in the diameter range from 0.1 - 8.00 mm (customized up to 32 mm) for centering, chamfering, drilling - up to 50 x d -, milling, reaming and deburring. High cutting speeds, process reliability and repeatability in the  $\mu\text{-}\text{range}$  are guaranteed.



以"切削液公司"著称,我们作为水溶性 切削液的顶级专家,为全球客户提供个性 化订制解决方案。 As "The Coolant Company", we specialize in water-miscible coolants, and we provide individual, tailor-made solutions for your business all over the world.



我们提供加工各种材料的零件的完整 CAM 解决方案,例如医疗器械、骨科植入物、 牙科个性化基台、种植桥、种植杆卡等。

-家拥有 73 年历史的瑞士家族企业,专

The complete CAM solution for the components machining in diverse materials, such as medical instruments, orthopaedic implants, customized abutments, implant bridges and bars.

A family-owned Swiss company with a history spanning 73

## REGO-FIXA

注于高精度刀具夹持系统的研发和生产。 我们产品系统中的 powRgrip® 冷压夹持 系统以其卓越的精度和强大的夹持力,可 显著提升骨科植入物的生产质量和效率, 优异的兼容性和一致性降低了生产成本, 是制造高精度医疗器械的理想之选。 years, specializing in the research and production of high-precision tool holding systems. Our product line, the powRgrip® tool holding system, stands out with its excellent precision and powerful clamping force, significantly enhancing the quality and efficiency of orthopedic implant manufacturing. With outstanding compatibility and durability, it effectively reduces production costs, making it the ideal choice for manufacturing high-precision medical equipment.



我们对医疗植入物喷砂工艺有着深入的理解,始终如一地为客户提供可靠的高性能陶瓷喷砂介质,包括氧化锆珠、氧化铝砂和锆刚玉。

We have developed an in-depth understanding of media behavior on medical implant, and been consistently delivering reliable supply of high-quality ceramic blasting media including zirconia beads, alumina grits, alumina-Zirconia grits with maximized performance and efficiency.



行业领先的夹持技术和抓取系统供应商, 针对骨关节内植入物、小型手术器械、齿 科植入物加工等提供系列广泛的工件和刀 具夹持产品。 International technology leader in clamping technology and gripping systems. The company provides wide range of workholding and toolholding solutions for orthopedic and dental implant, as well as surgical instruments.



全球刀具领袖之一,作为" 铣削之王", 在航空、医疗、能源等领域享有盛誉。通 过与全球医疗器械商的多年紧密合作,我 们已成为富有经验和创新精神的整体解决 方案提供者,助您取得成功。 With an established reputation as a leading manufacturer and supplier of carbide cutting tools and associated equipment. As the medical industry continues to innovate and grow, we are here to help you understand and overcome the metal cutting challenges you encounter.



专注于走芯机医疗小零件加工,提供包括 软件、刀具、夹具、切削液、加工方案设计、 试切等系统解决方案。 Focus on CNC machining of medical small parts, providing system solution of software, cutting tools, fixtures, cutting fluid, processing scheme design, product trial cutting etc.

Since foundation in 1915 it has been our declared goal to



自 1915 年成立以来,致力于在骨科植入物、器械、关节及齿科产品加工领域提供高效率、高精度切削刀具。我们的产品在钛合金、不锈钢、钴铬钼以及镍钛合金加工都有极其显著的优势。

forge ahead in the production of high performance and precision cutting tools for implant, instruction, knee and teeth industry. Our products have particular advantages in the finish machining of titanium, stainless, CoCrMo and Nitinol.



我们致力于研发和生产高精密的零点定位 系统和定心虎钳系统,为医疗器械制造商 提供完善的骨板类零件自动化夹持方案。 We are committed to the development and production of high-precision zero point clamping systems and centering vise systems, providing medical device manufacturers with complete automatic clamping solutions for bone plate parts.

## 第六届ORTHOmaterials™骨科及齿科植入器械制造技术论坛

The 6th ORTHOmaterials™ Orthopeadic and Dental Devices Manufacturing Technology Forum

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## 测量及检测设备

#### MEASURING AND TESTING MACHINES



为骨科和齿科提供从 BIOVIA Materials Studios 分子级材料设计模拟到 Abagus 仿真及各种原位、非原位力学试验加载与 测量系统的虚实一体的生物力学科研平

Provides an integrated biomechanical research platform for orthopedics and dentistry, from BIOVIA Materials Studios molecular-level material design simulation to Abaqus structural simulation software and various in-situ and non-in-situ mechanical test loading and measurement systems.



外科植入物动态力学解决方案服务商,包 括骨钉、接骨板、椎间融合器、髋关节等。

Dynamic mechanical solutions for surgical implants service provider. Consist of metallic medical bone screws, metallic bone plates, intervertebral body fusion device, hip joint prostheses, etc.



授权经销商

德国蔡司在中国的合作伙伴,专业提供成 套光学三维扫描和变形测量方案,以及技 术咨询和测试服务。

The partner of German ZEISS in China, specializing in providing complete sets of optical 3D scanning and deformation measurement solutions, as well as technical consulting and testing services.

动态试验机集成专利高性能直线电机,广 泛适用于骨科植入物及材料的动态力学性 能测试和多自由度多轴定制化动态测试。

Dynamic test platform integrates patented high-performance linear motor, which can be widely used in dynamic mechanical properties test of various materials and orthopedic implants, as well as customized multi-axis dynamic test.



拥有 200 多年的精密计量经验,以及对智 能制造领域先进技术的重组,为医疗行业 提供贯穿产品全生命周期的质量提升解决 方案。

Provides quality improvement solutions throughout the product life cycle for the healthcare industry, with more than 200 years of experience in precision metering and reengineering advanced technologies in intelligent manufacturing.

## **MARPOSS**

光学测量技术可控制同一个骨钉零件的多 项质量指标,是骨钉检测的理想选择。不 仅可以对植入物进行尺寸检测,也可做相 关的功能测试。

The optical measurement technique controls several quality indicators of the same bone screws part and is ideal for bone screws inspection. Not only can the implant be inspected for its dimensions, but also for related functional test.

## **Mitutoyo**

一家提供 8 大种类逾 5500 款产品的全球 综合性测量仪器制造商,针对医疗行业可 提供多元可靠的测量解决方案。

A global manufacturer of comprehensive measurement instruments offering more than 5500 products in eight categories, providing a wide range of reliable measurement solutions for the medical industry.



在光学检测表面形貌的领域有超过 15 年 的经验,纳米精度、一键式采集功能、自 动化数据分析等优势为用户提供各种医疗 样品的 3D 形貌检测。

With over 15 years of experience in the field of optical inspection of surface topography, we offer users 3D surface detection of various medical samples with advantages such as nanometer precision, one-click acquisition function, and automated data analysis.



来自德国的精密测量设备制造商,针对外 科植入物的尺寸测量提供复合式三坐标或 CT 解决方案。

Precision measurement equipment manufacturer from Germany, providing multi-sensor coordinate measuring or CT measuring solutions for surgical implants.



Seeing beyond

我们的医疗行业质量解决方案覆盖金属加 工、注塑及增材制造等多种工艺,满足医 疗产业对产品质量管控各环节所提出的更 多样化需求,赋能客户跨越医疗质量检测 难关,为生命健康护航。

Our medical industry quality solutions cover a wide variety of processes such as metal processing, injection molding and additive manufacturing, we will fulfill various demands from medical industry for quality control, and support our customers to overcome the challenges for medical quality control.



全球技术领先的材料试验机供应商,为 20 多个工业领域的研发及质量保证提供 全面的材料试验解决方案。

A worldwide leading supplier of materials testing machines, provides testing solutions for test methods in R&D, as well as for quality assurance in more than 20 industries.

## 合约制造

## CONTRACT MANUFACTURE



各类牙科钻头、丝锥等医疗工具代工及协 同开发服务。

提供各式骨科钻头、骨锉、铰刀、丝锥及 Specialized in providing professional orthopedic instrument OEM and R&D support service, supplying various kinds of orthopedic instrument such as drills, broaches, reamers, taps. Dental drills and taps are also our strength products.

# autocam medical

全球化的合约制造商,精密制造加工骨科 手术钻头、起子、螺钉、骨板、切割工具, 以及其他复杂、高度工程化的外科植入物、 器械和手件等。

A global contract manufacturer of precision-machined surgical drill bits, drivers, screws, plates, cutting tools and other complex, highly engineered surgical implants, instruments, and handpieces, as well as other device components.



ODM 服务商,提供口腔种植、运动医学、 骨科器械、器械盒设计开发、协同开发及 受托生产服务。在刃具切削、产品耐腐蚀 方面方案卓越。

ODM supplier providing design, collaborative development and contract manufacture of dental implants, sports medicine, orthopaedic instruments, cases and trays with excellent solutions in sharp tool cutting and product corrosion resistance.



我公司为美国、欧洲著名医疗客户提供优 质的 OEM 服务,产品包括螺钉、骨板、 改锥及器械等,广泛应用于医疗设备、医 疗工具、以及脊柱、创伤、牙科、运动医学、 颅颌面、眼科、心脏起搏器。

We provide OEM service for the most famous medical customers in USA and Europe. Our products, which include screws, plates, drivers and instruments, are widely used in trauma, spine, dental, sports medicine, cranial maxillofacial, ophthalmic surgery and components of pacemaker.

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## 主办机构 Organizer

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主办方联系人