中研股份
ZYPEEK
证券代码：688716

PEEK-LISCIEX

医用植入级聚醚醚酮

Implantable Grade PEEK

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吉林省中研高分子材料股份有限公司
JILIN JOINATURE POLYMER CO.,LTD

关于中研 *ABOUT US*

吉林省中研高分子材料股份有限公司，简称中研股份，是集聚醚醚酮(PEEK)研发、生产和销售为一体的高新技术企业。中研股份研发团队已经在PEEK化学合成、提纯、复合改性、注塑加工、型材加工、应用技术等领域积累了丰富经验。在此基础上，中研股份将PEEK的应用从工业领域拓展到医疗领域，实现了医用植入级聚醚醚酮国产化。

中研股份已经建设了1140.72平方米万级洁净GMP车间，车间内设置了颗粒生产车间、型材生产车间、微生物实验室等。在这些先进硬件设施的基础上，建立了ISO 13485质量管理体系，具备医用植入级聚醚醚酮产业化生产能力。

Jilin Joinature Polymer Co., Ltd (ZYPEEK) is a high-tech enterprise integrating PEEK research and development, production and sales. Our R&D team has accumulated rich experience in various fields of PEEK such as its polymerization, purification, compounding, injection molding, stock shapes processing and application technology. On this basis, we've expanded PEEK applications from industrial to medical field and realized domestic production of implantable grade PEEK.

We have built 10,000-grade GMP standard workshops of 1140.72m^2 for granules and stock shapes production, etc, as well as microbiology lab. Besides, we have established a quality management system in accordance with ISO13485 and possessed industrialized production capacity for implantable PEEK.

1140.72m^2
万级洁净GMP车间
10,000-grade GMP standard workshops

- 颗粒生产车间 Granule Production Workshop
- 型材生产车间 Stock Shapes Workshop
- 微生物实验室 Microbiology Lab

产品介绍

医用植入级聚醚醚酮
PEEK-LISCIEX

二十世纪八十年代

PEEK因其弹性模量与人体皮质骨相近，开始进入骨科医生的视野。

1998年

PEEK正式成为商业化生物材料，应用于整形外科和创伤外科。

2022年

中研股份推出PEEK-LISCIEX系列产品。

PEEK-LISCIEX，LISCIEX意涵Life Science X，即在生命与科学领域创造无限可能性。

产品特点

医用植入级聚醚醚酮
PEEK-LISCIEX

关键特性

生物相容性

植入后保持相对稳定不被排斥和破坏

弹性模量

接近人体皮质骨，减少应力遮挡

影像学兼容性

植入后核磁检查安全，术后检查无伪影

个性化匹配

易于加工，可一次设计成型，实现较高吻合度

安全性&舒适性

不易变形，暴露风险小；导热系数低，不易受冷热环境影响

Product Introduction

医用植入级聚醚醚酮
PEEK-LISCIEX

1980s

Since its elastic modulus is similar to that of human cortical bone, PEEK started to enter the visual field of orthopedists.

1998

PEEK formally became a commercialized biomaterial applying to/used in orthopedics and trauma.

2022

ZYPEEK launched a series of PEEK-LISCIEX products

PEEK-LISCIEX, LISCIEX means “Life Science X”,which means to create infinite possibilities in the field of life and science.

Product Characteristics

医用植入级聚醚醚酮
PEEK-LISCIEX

Key properties

Biocompatibility

Remains relatively stable;
Not rejected and destroyed

Elastic modulus

Modulus similar to bone;
Reduced stress shielding

Imaging compatibility

Radiolucent and artifact-free imaging on CT and MRI, facilitating post-operative monitoring

Customizable design

Eminently compatible with milling processes, for a more precise implant fixation;
Allowing intra-operative fine-tuning of contours

Safety&Comfort

Lower rates of exposure; Lower implant failure rates;
Low thermal conductivity and high patient satisfaction

产品目录

医用植入级聚醚醚酮
PEEK-LISCIEX

纯树脂颗粒　型号: ZR3G、ZR7G

加工方式:注塑或挤出。

可分别应用于胸骨固定带等医疗器械注塑制品、3D打印丝材、型材挤出等。

棒　材　型号: ZR7

棒材(R)标准长度为1000mm，直径为16/20/25/30mm
(其他尺寸可根据客户需求提供)

可应用于椎间融合器等机加工医疗器械制品。

板　材　型号: ZR7

板材(PL)标准尺寸为1000*620mm，厚度为30/40mm
(其他尺寸可根据客户需求提供)

可应用于颅骨等机加工医疗器械制品。

Products

医用植入级聚醚醚酮
PEEK-LISCIEX

Pure resin granules

Model: ZR3G, ZR7G

Processing mode: Injection molding or extrusion.
Applied to injection-molded medical devices (e.g. sternum fixation strap),3D filaments, stock shape extrusion, etc.

Rods

Model: ZR7

Standard length:1000mm,
Standard diameter:16/20/25/30mm
(Length is customizable)
Applied to machined medical devices (e.g. interbody fusion cage)

Plates

Model: ZR7

Standard length: 1000mm
Standard width: 620mm
Standard thickness: 30/40mm
(The dimension is customizable)
Applied to machined medical devices (e.g. CMF implants)

产品物性表

医用植入级聚醚醚酮
PEEK-LISCIEX

性 能		测试标准	单 位	ZR3G	ZR7G	ZR7 R25	ZR7 PL30
拉伸强度（屈服）		ISO 527-1&2 50 mm/min	MPa	110	100	110	110
拉伸强度（断裂）		ISO 527-1&2 50 mm/min	MPa	75	75	80	80
断裂伸长率		ISO 527-1&2 50 mm/min	%	25	45	15	15
切口冲击强度（悬臂梁）		ISO 180	kJ/m^2	5	7.5	5	5
弯曲模量		ISO 178	GPa	4.3	4.1	4	4
弯曲强度		ISO 178	MPa	175	165	175	175
密 度		ISO 1183 (A) Type	kg/m^3	1300	1300	1300	1300
黏 度		ISO 11443	Pa·s	160	380	380	380
DSC	Tg	ISO 11357	°C	143	143	143	143
	Tc			300	300	300	300
	Tm			343	343	343	343
重金属总量（以铅计，最大值）		USP 231	%	<0.1	<0.1	<0.1	<0.1
红外光谱		YY/T 0660	-	红外光谱的主要吸收峰与该材料标准对照图谱的特征吸收峰相吻合			

*上述数值是代表值，并非保证值。

中研可提供PEEK-LISCIEX产品的稳定性研究试验报告，为产品的货架有效期提供科学依据；可提供不同灭菌方式（湿热灭菌、环氧乙烷灭菌、伽马射线灭菌）对PEEK-LISCIEX产品的影响报告，为产品的耐灭菌稳定性提供有力证据。

Typical Material Properties

医用植入级聚醚醚酮
PEEK-LISCIEX

Properities		Test Method	Units	ZR3G	ZR7G	ZR7 R25	ZR7 PL30
Tensile Strength (Yield)		ISO 527-1&2 50 mm/min	MPa	110	100	110	110
Tensile Strength (Break)		ISO 527-1&2 50 mm/min	MPa	75	75	80	80
Tensile Elongation (Break)		ISO 527-1&2 50 mm/min	%	25	45	15	15
Impact Strength (Notched Izod)		ISO 180	kJ/m^2	5	7.5	5	5
Flexural Modulus		ISO 178	GPa	4.3	4.1	4	4
Flexural Strength		ISO 178	MPa	175	165	175	175
Density		ISO 1183 (A) Type	kg/m^3	1300	1300	1300	1300
Viscosity		ISO 11443	Pa·s	160	380	380	380
DSC	Tg	ISO 11357	°C	143	143	143	143
	Tc			300	300	300	300
	Tm			343	343	343	343
Total heavy metals as lead, max		USP 231	%	<0.1	<0.1	<0.1	<0.1
Infrared Spectrum		YY/T 0660	-	Main absorption peak of infrared spectrum coincides with characteristic absorption peak of standard control spectrum for this material.			

* Above value is a representative value but not an ensured value.

We can provide test report on PEEK-LISCIEX product stability, which offers scientific basis for its shelf life. We can provide the report on the effect of different sterilization ways (steam sterilization, ethylene oxide (ETO) sterilization and gamma sterilization) on PEEK-LISCIEX products, which offers assertive evidence for its sterilization-resisting stability.

生物相容性检测

医用植入级聚醚醚酮
PEEK-LISCIEX

检测标准	检测项目	PEEK-LISCIEX
GB/T 16886.3	遗传毒性 (Ames试验/小鼠淋巴瘤试验)	通过
GB/T 16886.5	体外细胞毒性	通过
GB/T 16886.6	骨植入26周	通过
GB/T 16886.10	皮肤致敏反应	通过
GB/T 16886.10	皮内反应	通过
GB/T 16886.11	急性全身毒性	通过
GB/T 16886.11	亚急性全身毒性	通过
GB/T 16886.11	亚慢性全身毒性	通过
GB/T 16886.11	热原试验	通过
GB/T 16886.18	化学表征与毒理学评估	通过

ISO 9001:2015
通过ISO 9001质量管理体系认证

YY/T 0660-2008
符合外科植入物用聚醚醚酮(PEEK)聚合物的标准规范

完成医疗器械主文档登记

ISO 13485:2016
获得ISO 13485质量管理体系证书

ASTM F2026:2017
符合ASTM F2026:2017标准

提供全方位技术服务与支持

Biocompatibility Test

医用植入级聚醚醚酮
PEEK-LISCIEX

Test Method	Test Item	PEEK-LISCIEX
GB/T 16886.3	Genotoxicity (Ames test / mouse lymphoma test)	Passed
GB/T 16886.5	*In vitro* cytotoxicity	Passed
GB/T 16886.6	26 weeks after bone implantation	Passed
GB/T 16886.10	Skin sensitization	Passed
GB/T 16886.10	Intradermal reaction	Passed
GB/T 16886.11	Acute systemic toxicity	Passed
GB/T 16886.11	Subacute systemic toxicity	Passed
GB/T 16886.11	Subchronic systemic toxicity	Passed
GB/T 16886.11	Pyrogen test	Passed
GB/T 16886.18	Chemical characterization and toxicological assessment	Passed

ISO 9001:2015
Passed ISO 9001 Quality Management System Certification

ISO 13485:2016
Obtained ISO 13485 Quality Management System Certificate

YY/T 0660-2008
Conform to standard specification of PEEK polymers for surgical implants

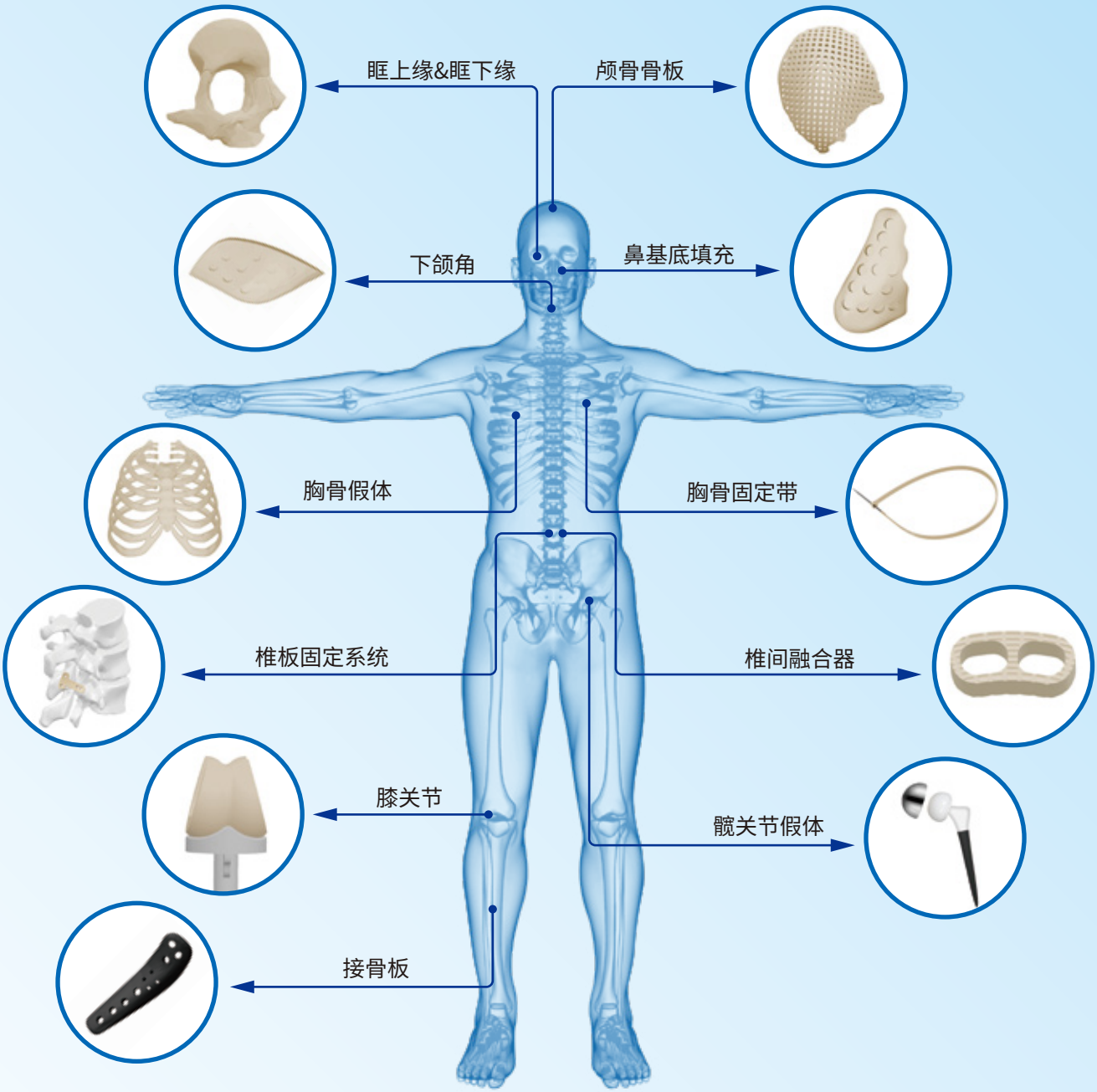
ASTM F2026:2017
In conformity with ASTM F2026:2017 standard

Completed Medical Device Master Files Registration

Deliver our full technical service and support

PEEK人体植入应用

医用植入级聚醚醚酮
PEEK-LISCIEX



界面螺钉

带线锚钉

连接片

等其他植入应用

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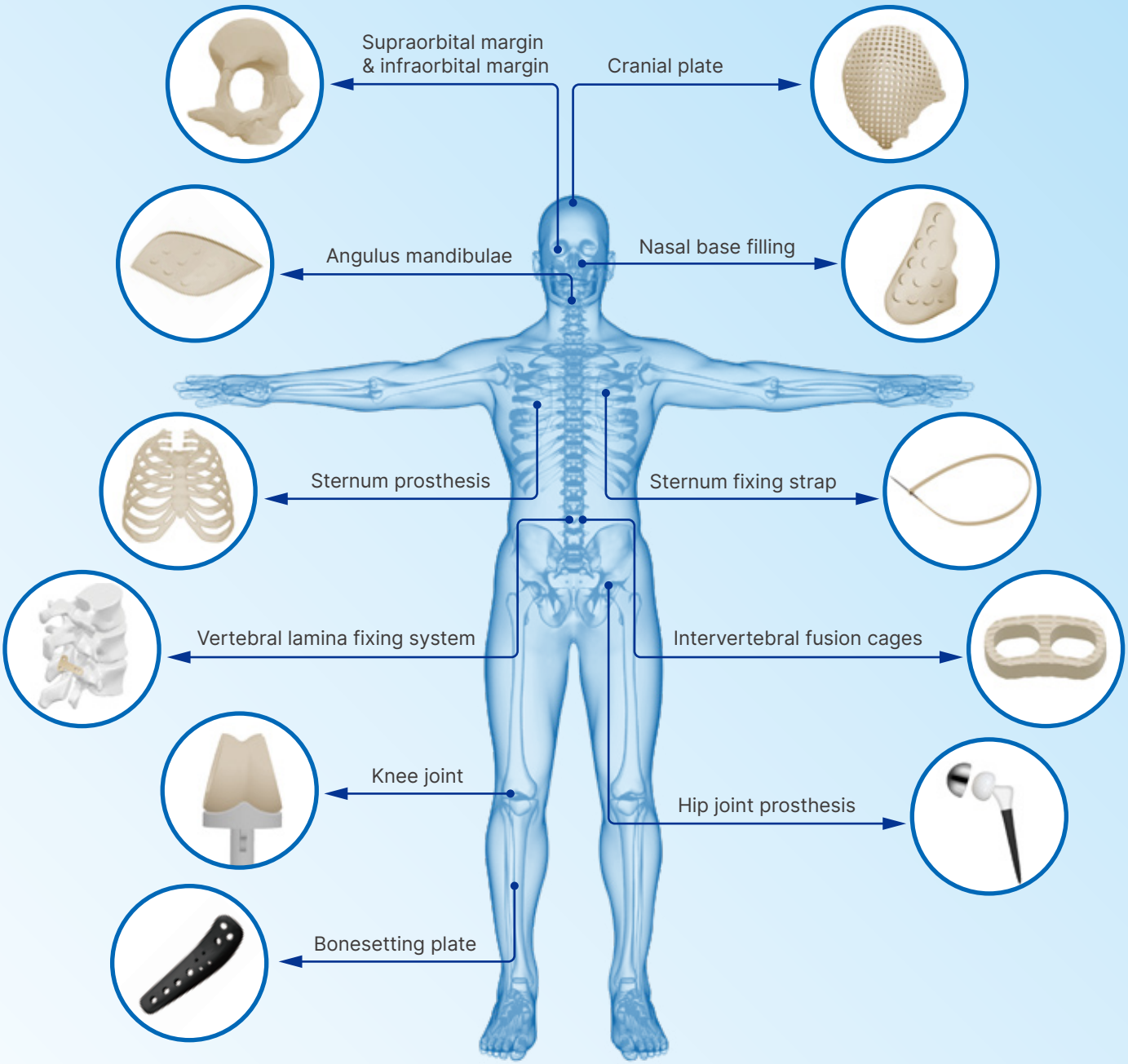
Application of PEEK Human Implantation

医用植入级聚醚醚酮
PEEK-LISCIEX



Interference screw

Threaded anchor nail

Connecting sheet

And other applications
for implantation
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