君华医疗
JUNHUA MEDICAL

AKSOPEEK®

Medical Grade Implantable PEEK

Changzhou Junhua Medical Technology Co.,Ltd.

About us

Changzhou Junhua Medical Technology specializes in implant-grade PEEK and carbon fiber-reinforced PEEK for medical use. Our AKSOPEEK®series is approved by the National Medical Products Administration.

With 18 years of expertise, we adhere to strict ISO13485 quality standards and have garnered certifications like FDA and ISO10993 for biocompatibility.

Our 1,200 square meter cleanroom facilities enable us to provide comprehensive services from material procurement to OEM manufacturing, including injection molding of PEEK implants.

Why Choose Junhua PEEK?

- 18+ years experience across 36 countries
- Innovative design and research expertise
- In-house ISO certified production facilities
- Single source integrated solution

AKSOPEEK®

TDS

AKSOPEEK® Medical Implant Grade PEEK

Changzhou Junhua Medical Technology Co., Ltd. has independently developed the AKSOPEEK® series of implant-grade PEEK materials, which have successfully passed the testing requirements of YY/T0660-2008 and ASTM F2026, and obtained third-party verification reports.

The Series includes the Following Grades:

AKSOPEEK®: Implant-grade PEEK material,

AKSOPEEK®HA: Implant-grade PEEK material with hydroxyapatite,

AKSOPEEK®CF: Implant-grade PEEK material reinforced with short carbon fibers,

AKSOPEEK®LCF: Implant-grade PEEK material reinforced with continuous carbon fibers,

AKSOPEEK®XR: Radiopaque implant-grade PEEK material.

Each grade represents different material properties and application directions, ensuring that specific medical implant needs are met.

AKSOPEEK® | Physical Property Table

Properties	Reference Standard	Unit	Standard Value	Measured Result
Color	-	-	Khaki	Khaki
Glass Transition Temperature T_g	ISO 11357-2	℃	125-165	147
Crystallization Temperature T_c	ISO 11357-3	℃	260-320	286
Melting Point T_m	ISO 11357-3	℃	320-360	340
Melt Flow Index	ISO 1133	g/10 min	6-15	8
Melt Viscosity	ISO 11443	Pa·s	200~400	389
Infrared Spectrum	YY/T 0660	-	The main absorption peak of the infrared spectrum of PEEK polymer coincides with the characteristic absorption peak of the standard control spectrum of the material	Pass
Total Heavy Metals, Lead Calculated as the Maximum Value/%	YY/T 0660	%	0.1	< 0.001
Heavy Metal ions (Ag, As, Bi, Cd, Cu, Hg, Mo, Pb, Sb, and Sn) max	ASTM F2026	ppm	100	5.8
Density	ISO 1183	kg/m^3	1280-1320	1308
Tensile Strength (instantaneous)	ISO 527	MPa	≥ 90	101
Tensile Strength (at break)	ISO 527	MPa	≥ 70	73
Elongation at Break	ISO 527	%	≥ 5	15
Flexural Strength	ISO 178	MPa	≥ 110	166
Flexural Modulus	ISO 178	GPa	≥ 3	4.0
Notched Impact Strength	ISO 180	kJ/m^2	≥ 4	6
In Vitro Cytotoxicity	ISO 10993-5	-	Pass	Pass

1. Moisture content is tested during packaging. Since AKSOPEEK® is hygroscopic, it needs to be dried before use.
2. Each batch needs to test the infrared (FTIR) to ensure that it is consistent with the AKSOPEEK® spectrum.
3. 0.001-0.003% calcium stearate can be added as lubricant.

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AKSOPEEK® HA | Physical Property Table

Properties	Reference Standard	Unit	Standard Value	Measured Result
Color	-	-	Khaki	Khaki
Density	ISO 1183	kg/m^3	1430~1490	1450
Glass Transition Temperature T_g	ISO 11357-2	℃	135~155	146
Melting Point T_m	ISO 11357-3	℃	330~350	342
Crystallization Temperature T_c	ISO 11357-3	℃	270~310	287
Infrared Spectrum	ASTM F2026	-	The main absorption peak of the infrared spectrum of PEEK polymer coincides with the characteristic absorption peak of the standard control spectrum of the material	Pass
Tensile Strength (instantaneous)	ISO 527	MPa	≥ 90	94
Tensile Strength (at break)	ISO 527	MPa	≥ 70	73
Elongation at Break	ISO 527	%	≥ 5	9
Flexural Strength	ISO 178	MPa	≥ 150	166
Flexural Modulus	ISO 178	GPa	≥ 3.8	4.3
Notched Impact Strength	ISO 180	kJ/m^2	≥ 3.5	6

AKSOPEEK® CF | Physical Property Table

Properties	Reference Standard	Unit	Standard Value	Measured Result
Color	-	-	BLACK	BLACK
Carbon Fiber Content	ASTM D3171	%	28-32	30.1
Melt Flow Index	ISO 1133	g/10 min	1-5	2.8
Glass Transition Temperature Tg	ISO 11357-2	℃	135-155	147
Crystallization Temperature Tc	ISO 11357-3	℃	270-310	286
Melting Point Tm	ISO 11357-3	℃	330-350	340
Infrared Spectrum	ASTM F2026	-	The main absorption peak of the infrared spectrum of PEEK polymer coincides with the characteristic absorption peak of the standard control spectrum of the material	Pass
Density	ISO 1183	kg/m^3	1380-1440	1410
Tensile Strength (at break)	ISO 527	MPa	≥180	224
Elongation at Break	ISO 527	%	≥1.2	2.8
Flexural Strength	ISO 178	MPa	≥ 280	327
Flexural Modulus	ISO 178	GPa	≥ 16	19
Notched Impact Strength	ISO 180	kJ/m^2	≥ 6	8.3
In Vitro Cytotoxicity	ISO 10993-5	-	Pass	Pass

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2. Each batch needs to test the infrared (FTIR) to ensure that it is consistent with the AKSOPEEK® spectrum.
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AKSOPEEK® LCF | Physical Property Table

Properties	Reference Standard	Unit	Measured Result
Carbon Fiber Mass Content	ASTM D3529	%	66
Density	ASTM D792	g/cm^3	1.58
Hardness	ASTM D785	/	104
Infrared Spectrum	ASTM F2026	--	Pass
Tensile Strength (at break)	ASTM D3039	MPa	880
Tensile Modulus	ASTM D3039	GPa	73
Flexural Strength	ASTM D7264	MPa	1400
Flexural Modulus	ASTM D7264	GPa	65
Compression Strength	ASTM D6641	MPa	670
Compression Modulus	ASTM D6641	GPa	60
Thermal Deformation Temperature	ASTM D648	℃	332
Compressive Strength After Impact	ASTM D7137	MPa	225
Type I Interlaminar Fracture Toughness	ASTM D5528	J/m^2	1410
Short Beam Strength	ASTM D2344	MPa	100
In-plane Shear Strength -0.5%	ASTM D3518	MPa	130
In-plane Shear Modulus	ASTM D3518	GPa	5.2

AKSOPEEK® XR | Physical Property Table

性 能	Reference Standard	Unit	Standard Value	Measured Result
Color	--	--	Khaki	Khaki
Glass Transition Temperature Tg	ISO 11357-2	℃	125-165	154.55
Crystallization Temperature Tc	ISO 11357-3	℃	260-320	269.55
Melting Point Tm	ISO 11357-3	℃	320-360	339.86
Infrared Spectrum	ASTM F2026	--	The main absorption peak of the infrared spectrum of PEEK polymer coincides with the characteristic absorption peak of the standard control spectrum of the material	Pass
Density	ISO 1183	kg/m^3	1485-1525	1503
Tensile Strength (instantaneous)	ISO 527	MPa	≥ 90	102
Tensile Strength (at break)	ISO 527	MPa	≥ 70	100
Elongation at Break	ISO 527	%	≥ 5	14.34
Flexural Strength	ISO 178	MPa	≥ 110	155
Flexural Modulus	ISO 178	GPa	≥ 3	4.28
Notched Impact Strength	ISO 180	kJ/m^2	≥ 4	6.45
In Vitro Cytotoxicity	ISO 10993-5	--	Pass	Pass

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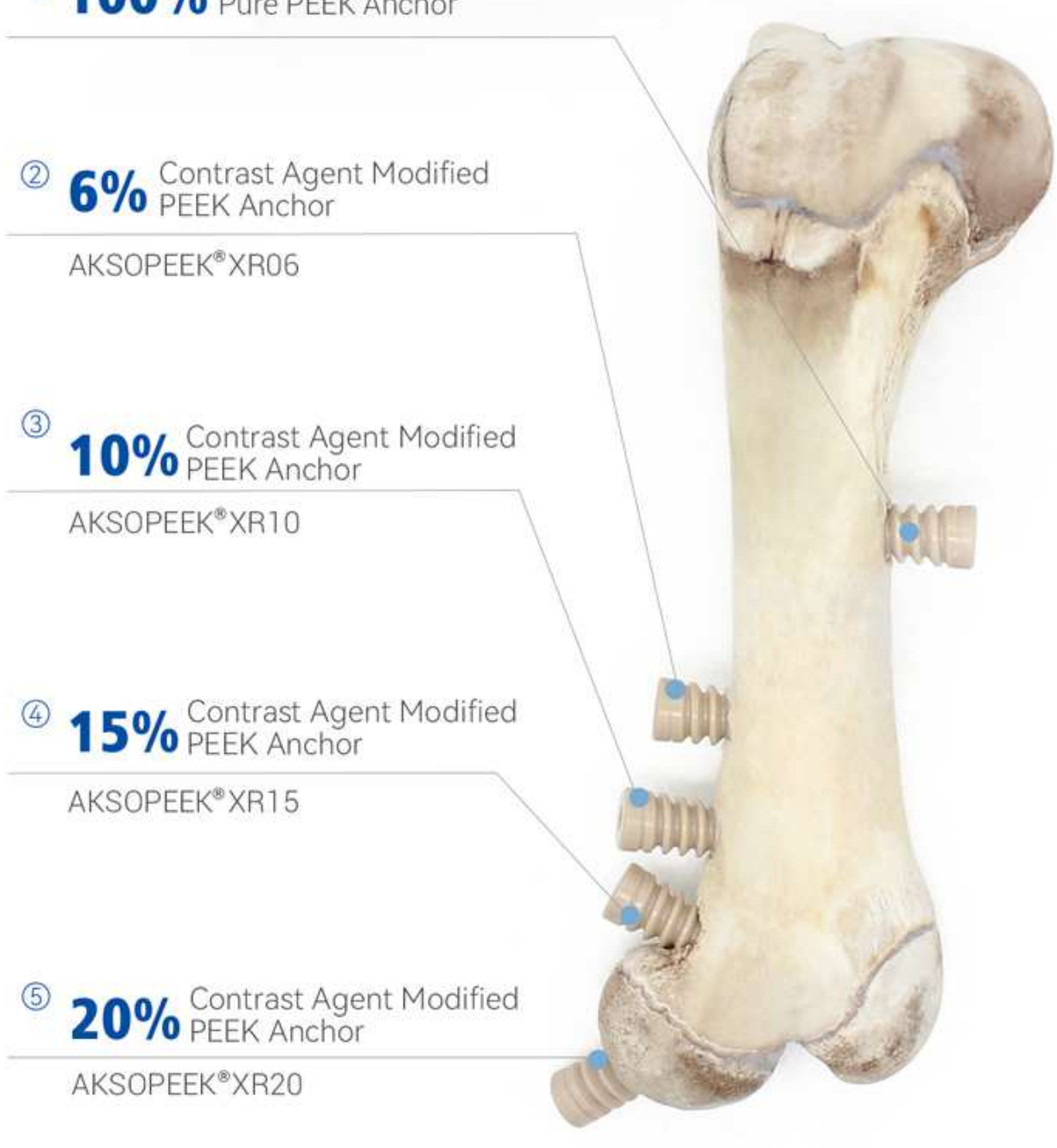
Visible Implant-grade PEEK Material

• Precision Reshaping and Positioning

During surgical procedures, physicians can utilize X-ray imaging technology to accurately locate and reshape PEEK implants, ensuring their precise placement in the intended location. This enhances the success rate of surgeries and improves patient recovery post-operation.

• Postoperative Monitoring and Evaluation

The visibility of PEEK material under X-rays facilitates convenient postoperative monitoring and evaluation. Doctors can timely monitor the position, stability, and surrounding tissue conditions of the implant through X-ray examinations, allowing for adjustments to the treatment plan or necessary interventions as needed.



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Biocompatibility

Test Reports

Biocompatibility Tests

Product Name	Test Tool	Test Items	Results
AKSOPEEK® Medical Implant Grade Material	ISO 10993- 3	Genotoxicity Test	Pass
		Ames Test	Pass
		Chromosomal Aberration Assay in Mammalian Cells in Vitro	Pass
	ISO 10993- 4	Hemocompatibility	Pass
	ISO 10993- 5	Cytotoxicity Testing	Pass
	ISO 10993- 6	Bone Implantation Test (26 Weeks)	Pass
		Muscle Implantation (26 Weeks)	Pass
	ISO 10993-10	Skin Sensitization Test	Pass
		Intradermal Reactivity Test	Pass
	ISO 10993-11	Pyrogen Test	Pass
		Acute Systemic Toxicity Test	Pass
		Subchronic Systemic Toxicity Test	Pass
	ISO 10993- 17	Toxicology	Pass
	ISO 10993- 18	Chemical Characterization	Pass

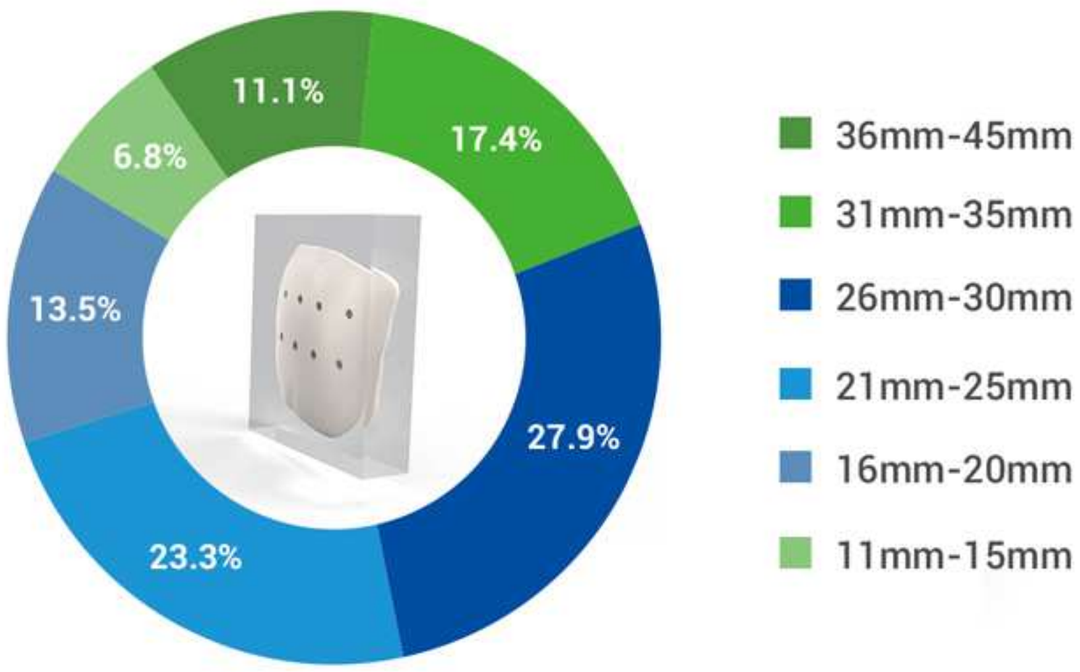
▼AKSOPEEK® Rods Dimensions

No.	Dia (mm)	No.	Dia (mm)	No.	Dia (mm)
1	φ6	7	φ18	13	φ32
2	φ8	8	φ20	14	φ35
3	φ10	9	φ22	15	φ38
4	φ12	10	φ25	16	φ45
5	φ15	11	φ28	17	φ50
6	φ16	12	φ30	18	φ55

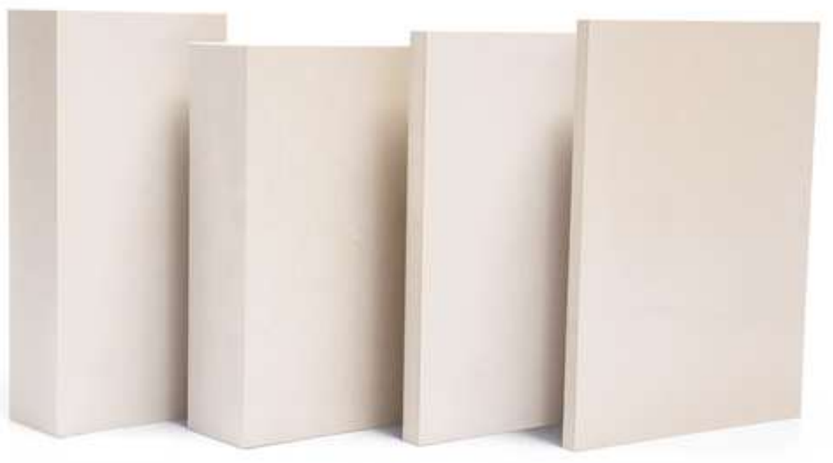
▼AKSOPEEK® Sheets Dimensions

No.	Max Length (mm)	Max Width (mm)	Thickness (mm)
1	1000	600	15
2	1000	600	20
3	1000	600	25
4	1000	600	30
5	1000	600	35
6	1000	600	40
7	1000	600	60

▼The frequency of use for AKSOPEEK®sheets of various thicknesses in cranial repair.



AKSOPEEK® offers a range of thicknesses to precisely match the needs of cranial repair, ensuring efficient material use and optimized cost.



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▼AKSOPEEK® Surgical Implants

PEEK Spinal Cages

PEEK Cranioplasty

Joints: PEEK Knee Ankle Body

Trauma: Continuous Carbon Fiber Reinforced PEEK Composites Bone Plate

Sports Medicine: PEEK Anchors

PEEK Sternal Strap

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Biocompatibility

Highly Machinable

X-ray Transparent

Implant Grade PEEK Filament for 3D Printing

Enhance Bioactivity and Bone Binding Efficiency

φ1.75mm

AKSOPEEK® is a high-tech material suitable for 3D printing in medical implants, processed using common extrusion-based 3D printing techniques. This material exhibits excellent biocompatibility and biostability, along with radiolucency to X-rays, enhancing the integration between bone and implant.

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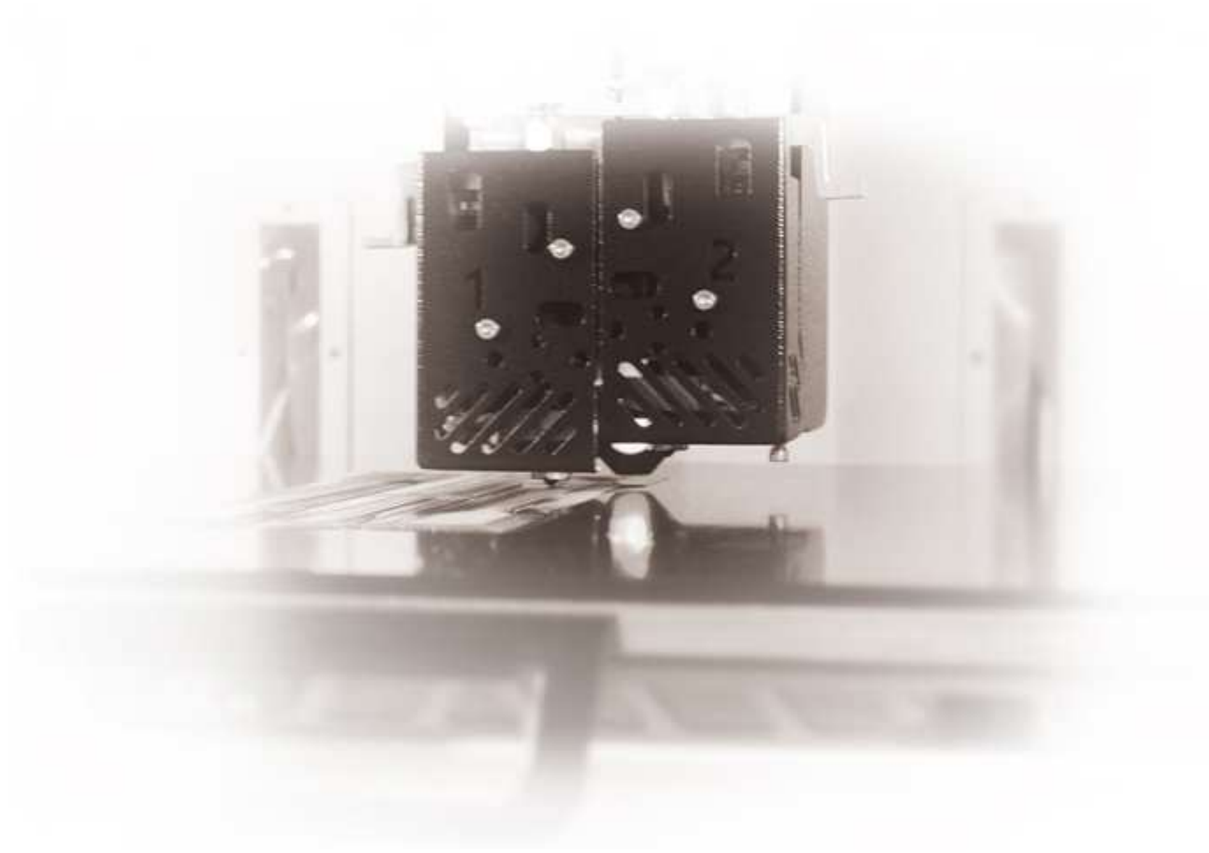
▼ The Product's Advantages Include

- Its ease of processing, allowing for stable printing within a 3D printer with good anti-warping properties.
- The ability to design and customize implant structures based on patient needs.
- Resistance to X-ray radiation.
- Superior wave transparency compared to metals.

▼ Performance Parameters of the Product

Properties	Unit	Test Tools	**Numerical Value** (X-Y direction) After Heat Treatment (200 /4 hrs)	**Numerical Value** (Z direction) After Heat Treatment (200 /4 hrs)
Mechanical Properties				
Tensile Modulus	MPa	ISO 527	2700	2590
Yield Stress	MPa	ISO 527	72	/
Yield Elongation	%	ISO 527	6	/
Ultimate Tensile Strength	MPa	ISO 527	63	51
Elongation at Break	%	ISO 527	13	/
Flexural Modulus	MPa	ISO 178	2590	2480
Simply Supported Beam Impact Strength	kJ/m^2	ISO 179	No Break	/



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Complies with ASTM F2026 Standard

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