

# Inspire the Life





#### 普霖医疗科技(广州)有限公司 Princeton Medical Scientific Co., Ltd

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**OEM Service** 

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#### Manufacturing



### 关于我们About us

普霖医疗科技(广州)有限公司成立于2011年9月,专注高端微创介入医疗器 械研发生产,产品覆盖心血管、外周血管、骨科、泌尿微创等领域。公司GMP厂房面 积近3538平方米,拥有4项发明专利、12项实用新型专利及多项医疗器械注册证。 部分产品获CE认证。多年来,公司成果显著,通过广州市企业研发机构、科技小巨人 等认定。2016年获全国创新大赛广东省赛生物医药企业组三等奖,2016、2020年通 过瞪羚培育认定,2021、2022年通过瞪羚认定,2016、2019、2022年获高新技术企 业认定,2022年被认定为广东省专精特新企业。

Princeton Medical Scientific Co., Ltd. was established in September 2011. It focuses on the research and development and production of high-end minimally invasive interventional medical devices. Its products cover fields such as cardiovascular minimally invasive, peripheral vascular minimally invasive, orthopedic minimally invasive, and urological minimally invasive. The company's GMP plant has an area of nearly 3,538 square meters. It has 4 invention patents, 12 utility model patents and a number of medical device registration certificates. Some products have obtained CE certification . Over the years, the company has achieved remarkable results and has passed the certifications of Guangzhou enterprise research and development institutions, technology little giants and so on.

#### • 代加工服务 OEM Product and Service -

- 介入鞘管 Interventional sheath
- 编织 / 弹簧管 Braided/coiled tubing
- 球囊导管 Balloon catheter
- 椎体成形工具 Kyphoplasty tool kit
- 覆膜支架 Stent graft
- 导丝
  Guidewire

#### • CE自主品牌系列, 持续更新中 Private label products (CE mark)Ongoing update.

- 椎体成形工具 Kyphoplasty tool kit
- PTA球囊导管 PTA balloon catheter
- 输尿管球囊导管 Ureteral balloon catheter
- 输尿管导引鞘 Ureteral access sheath
- 支持导管 Support catheter

#### ● 生产优势 Our Fully Integrated Manufacturing Capability——

- 万级、十万级洁净车间 Class 10,000 and 100,000 clean rooms
- ISO13485质量管理体系 ISO13485 quality management system.
- 生产线:球囊导管、输送导管、椎体成形工具、挤出注塑 Production lines:
- balloon catheters, delivery catheters, vertebroplasty tools, extrusion
- and injection molding.
- R&D技术团队&品控团队 R&D engineering team & quality control team.



## **OEM** 介入导管/鞘管 Interventional Sheath

• 生产线 Production Line -



• 代加工服务 Process of Quality Control



#### • 资质证书 Certificates -







Specification

外径 OD	3Fr~24Fr
外径公差 Tolerance of ID/OD	+/-0.01~0.08
最大值长度 Maximum length of sheath	2600mm
材料 Tube material	PTFE/Pebax/PE/Nylon/PU/SUS/Ptlr
结构 Strengthen structure	Coiled/Braided/Nylon wire
表面处理 Surface treatment	Hydrophilic coating
产品分类 Product catagories	Vascular sheath/Ureteral sheath/Guiding catheter/Microcatheter



## **OEM** 编织/弹簧导管 Braided/Coiled Tubing

## **0EM&CE** mark

### 输尿管导引鞘 Ureteral access sheath



#### Specification

2F-30F
2600mm
Nylon, Pebax and custom blends
304 Stainless steel
As specified by customer
Regular braid pattern/Diamond braid pattern/Half load

- 用途:微导管、导引导管、电生理导管、输送鞘管(支架输送系统、封堵器输送系统等)
- 结构:编织鞘、弹簧鞘、可控鞘等
- Purpose: Microcatheter, guiding catheter, electrophysiological catheter, delivery sheath (stent delivery system, occluder delivery system, etc.)
- Structure: Braided sheath, spring sheath, controllable sheath, etc.

- 输尿管导引鞘用于泌尿外科内窥镜检查和手术,用以辅助内窥镜和手术器械进入泌尿道, 可以提高输尿管狭窄、管腔狭小患者的进镜成功率,提高检查和治疗的有效性和安全性, 显著减少输尿管损伤。
- Purpose: Microcatheter, guiding catheter, electrophysiological catheter, delivery sheath (stent delivery system, occluder delivery system, etc.) Structure: Braided sheath, spring sheath, controllable sheath, etc.

#### Specification

尺寸 Size	10Fr,11Fr,12Fr,13Fr,14fr
有效长度 Effective Length	265mm,365mm,415mm,465mm,565mm
接头类型 Connector	Y type/S type
材质 Material	PTFE、PEBAX、PE、Nylon、PU

## **OEM&CE mark** 支持导管 Support catheter

## **OEM&CE mark** 球囊导管 Balloon Catheter



#### Specification

尺寸 Size	2.3F/2.6F/4.0F or customized sizes
长度 Length	65cm/90cm/135cm/150cm
外层材质 Outer layer	Pebax
内层材质 Inner Liner	PTFE
线材质 Wire material	304 stainless steel, Nitinol
加固类型 Reinforcement	Braided/Coiled

#### Features

- ●支持导管用于小血管或超选择性解剖结构进行诊断和介入操作,可用于外周血管,并可用于 注射诊断性药物和造影剂。
- Support Catheter is intended for use in small peripheral vessel or super selective anatomy for diagnostic and interventional procedures.

- 球囊导管可以用于扩张狭窄的动脉,恢复肢体的血液供应。
- Balloon catheters can be used to dilate narrowed arteries and restore blood supply to the limbs.

	PTA	PTCA
Balloon diameter(mm)	1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10	1.5, 1.75, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0
Balloon length(mm)	20, 40, 80,120, 150, 210	9, 10, 12, 14, 15, 16, 20, 24, 25, 30
Nominal pressure(atm)	8	6
Rated burst pressure (atm)	14	16
Guidewire compatibility(inch)	0.014", 0.018", 0.035"	0.014"
Catheter length(mm)	800, 1200, 1300, 1500	1400
Sheath compatibility(F)	5, 6, 7	2.7
Proximal catheter diameter(mm)	0.89, 1.2, 1.75	0.0165

#### 输尿管Ureteral

Balloon diameter(mm)	4-10
Balloon length(mm)	40-100
Nominal pressure(atm)	8
Rated burst pressure (atm)	20
Guidewire compatibility(inch)	0.038''
Catheter length(mm)	850
Sheath compatibility(F)	6-7
Proximal catheter diameter(mm)	1.96

# **0EM&CE** mark

## **0EM&CE** mark

### 椎体成形工具 Kyphoplasty Tool Kit



#### Specification

穿刺针 Puncture needle	OD: 2. 5mm/3.0mm/3. 7mm/4. 2mm/Length: 120mm
扩张器 Working cannula	OD: 3.7mm/4.2mm/Length: 120mm
导丝 Guide wire(Round tip)	OD: 1.6mm/Length: 270mm
精细钻 Bone drill	OD: 3.0mm/3.6mm/Length: 204mm
骨水泥推送器 Bone cement filler	OD: 3.0mm/3.5mm/Length: 189mm
包装方式 Package	Bulk package/Sterilized package

- ●椎体成形工具用于通过微创手术将骨水泥或其他填充材料注入骨折的椎体,这有助于稳定患 者椎体、缓解疼痛。
- Vertebroplasty&kyphoplasty tools are used to inject bone cement or other filling materials into fractured vertebrae through minimally invasive surgeries. This helps to stabilize the patient's vertebrae and relieve pain.

#### • 椎体球囊 Kyphoplasty Balloon Catheter -



#### pecification 球嚢直径 Balloon diameter(mm) Salloon length(mm) 加-15-20mm 10-15-20mm 10-15-20mm 300psi 300psi 2-6ml 管径 Shaft diameter(mm)

- ●椎体后凸成形术球囊是为治疗脊柱压缩性骨折的微创手术而设计的,用于稳定和强化 骨骼,避免进一步压缩并缓解背部疼痛。
- kyphoplasty balloon are designed for minimally invasive procedure to treat compression fractures of the spine to stabilize and strengthen the bone to avoid further compression and relieve back pain.

#### ● 压力泵 Inflation Device -



●压力泵在介入手术中,它用于控制球囊导管内的压力,精确地给球囊充气和放气。

• In interventional surgeries, the pressure pump is used to control the pressure inside the balloon catheter and inflate and deflate the balloon accurately.

## **OEM** 经皮肾穿刺套件 Percutaneous Nephrostomy Kit



- ●供临床对肾结石或肾积水患者做经皮肾穿刺扩张引流和腔镜手术器械置入时进行扩张,建立 通道时使用。
- It is used for clinical dilatation and channel establishment in patients with renal stones or hydronephrosis during percutaneous renal puncture expansion and drainage as well as endoscopic surgical instrument placement.

#### Specification

扩张器 Dilator	8F, 10F, 12F, 14F, 16F, 18F, 20F, 22F
可撕裂鞘管 Tear-Away Introducer Sheath	8F, 10F, 12F, 14F, 16F, 18F, 20F, 22F
穿刺针 Puncture Needle	18G, 22G
弹簧导丝 Spring Guidewire	0.035″
材质 Material	304stainless steel、HDPE、BaSo4、 PTFE、Nickel-titanium alloy



- ●用于引导器械,泌尿外科手术时进入非血管腔道一次性使用。
- Used for guiding instruments and for single use when entering non-vascular lumens during urological surgeries.

#### Specification

产品名称 Product name	斑马导丝 Zebra Urological Guidewire	亲水导丝 Hydrophilic guide
有效长度 Effective length(mm)	1500	1500
外径 Outer diameter (+0.02/-0.1)	0.89mm/0.035inch、 0.81mm/0.032inch、 0.71mm/0.028inch	0.64mm/0.025inch、 0.71mm/0.028inch、 0.81mm/0.032inch、 0.89mm/0.035inch
尖端类型 Tip type	直型 Straight	直型 弯型 Straight Angle
亲水涂层 Hydrophilic	软头部位 Soft tip part	整体全覆盖 Overall full coverage
材质 Material	PTFE、Niti core wire	Polymers、Niti core wire

OEM

## **OEM** 取石网篮 Stone retrieval basket



- ●供诊疗泌尿系统时在内窥镜下抓住、操控和取出结石以及其他异物用。
- For grasping, manipulating and removing stones and other foreign bodies under endoscope during diagnosis and treatment of urinary system.

#### Specification

网篮类型 Basket type	半圆 Round(A1)、折线 shape line(B1)
鞘管外径 Sheath tube OD	1.9Fr、 2.2Fr
材料 Material	ABSDPolyimide、nickel-titanium alloy
工作长度 Working length	110cm
网篮打开幅度 Width of opened basket	8mm、11mm

- ●输尿管支架放置于肾盂与膀胱之间,用于对人体输尿管进行支撑和引流。
- The ureteral stent is placed between the renal pelvis and the bladder and is used for supporting and draining the human ureter.

#### Specification

支架类型 Stent type	A=近端开口弯,远端开口直 Proximal opening is curved, distal opening is straight. B=近端闭口弯,远端开口直 Proximal end is closed and curved, distal end is open and straight. C=近端闭口弯,远端开口弯 Proximal end is closed and curved;distal end is open and curved. D=近端开口弯 Proximal opening is curved, distal opening is curved.
支架管外径 Stent tube OD	4.0Fr、4.7Fr、5.0Fr、6.0Fr、7.0Fr、8.0Fr
支架管长度 Stent tube Length	16cm、18cm、20cm、22cm、24cm、26cm、28cm、30cm
材质 Material	Polyurethane