



INTELLIGENT PFNA INTRAMEDULLARY NAIL

智能型 PFNA 髓内钉

江苏双羊医疗器械有限公司

Jiangsu Shuangyang
Medical Instrument Co., Ltd.



www.jsshuangyang.com





江苏双羊医疗器械有限公司
Jiangsu Shuangyang Medical Instrument Co., Ltd.

企业简介

Company Introduction

江苏双羊医疗器械有限公司，创建于 2001 年，占地面积 18000 平方米，建筑面积 15000 多平方米，注册资金 2000 万。是一家从事骨科植入物产品的研发、制造、销售和服务的民族企业，获得多项国家级专利。

公司选择钛及钛合金为原材料，严把质量关，选择国内外知名企业宝钛、ZAPP 等作为原材料供应商，并配备世界一流的加工中心、纵切车床、数控铣床、超声波清洗等生产设备和装置，以及万能试验机、电子扭转机、数字投影仪等精密的量具。公司拥有完善的管理体系，先后通过了 ISO9001:2015 质量管理体系认证，ISO13485:2016 医疗器械质量管理体系认证，TUV 的 CE 认证，并于 2007 年率先通过国家局组织的《医疗器械生产质量管理规范植入性医疗器械实施细则（试点）》检查。



公司针对人体各个骨骼部位的特点，在著名骨科专家、教授、临床医师的悉心指导与帮助下，推出众多主导产品：锁定接骨板固定系统、钛质接骨板固定系统、钛质空心接骨螺钉及垫片、钛质胸肋骨系统、锁定颌面内固定系统、颌面内固定系统、钛质捆绑系统、解剖型钛网系统、基础工具系列等，并拥有专业的配套手术器械包，以满足临床不同的需求。公司的产品因设计可靠、加工精细、医生临床使用方便、患者愈合期短而受到了许多临床医师和患者的高度评价。

中国梦，双羊梦！双羊作为一个有使命感、有责任心、有抱负、有人文情怀的公司的初衷不会变，始终以“以人为本，诚信至上，不断创新，追求卓越”的理念不会变，争创医疗器械领域民族品牌领头羊的决心不会变。愿更多有志者与双羊共同创造美好的未来！



Jiangsu Shuangyang Medical Instrument Co., Ltd. was founded in 2001, covers an area of 18,000 m², including a floor area of over 15,000 m². Its registered capital reaches 20 million Yuan. As a national enterprise dedicated to the R&D, manufacturing, sales and service of orthopaedic implants, we have obtained several national patents.

Titanium and titanium alloys are our raw materials. We perform strict quality control, and select domestic and international famous brands, such as Baoti and ZAPP, as our raw material suppliers. Meanwhile, we are equipped with world class production equipment and devices including machining center, slitting lathe, CNC milling machine, and ultrasonic cleaner, etc., as well as precise measuring implements including universal tester, electronic torsion tester and digital projector, etc. Thanks to a sophisticated management system, we have acquired ISO9001: 2015 Certificate of Quality Management System, ISO13485:2016 Certificate of Quality Management System for Medical Devices, and CE certificate of TUV. We are also the first to pass the inspection according to the *Enforcement Regulation (Pilot) for Implantable Medical Devices of Good Manufacturing Practice for Medical Devices* organized by the National Bureau in 2007.

Thanks to meticulous guidance and supports from distinguished orthopaedic specialists, professors and clinicians, we have launched numerous leading products customized for different human skeletal parts, including locking bone plate fixation system, titanium bone plate fixation system, titanium cannulated bone screw & gasket, titanium sternocostal system, locking maxillofacial internal fixation system, maxillofacial internal fixation system, titanium binding system, anatomic titanium mesh system, and basic tool series, etc. We also have professional supporting surgical instrument sets to meet various clinical needs. Extensive acclaims have been received from clinicians and patients for our easy-to-use products with reliable design and fine machining, which can bring a short healing period.

China dream and Shuangyang dream! We will stick to our original intention to be a mission-driven, responsible, ambitious and humanistic company, and adhere to our idea of “people orientation, integrity, innovation, and excellence”. We are determined to be a leading national brand in the medical Instrument industry. At Shuangyang, we always welcome aspiring talents to co-create a bright future with us.

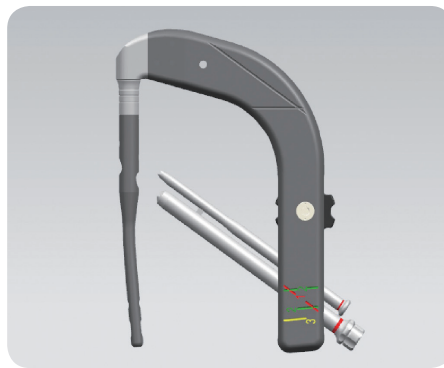
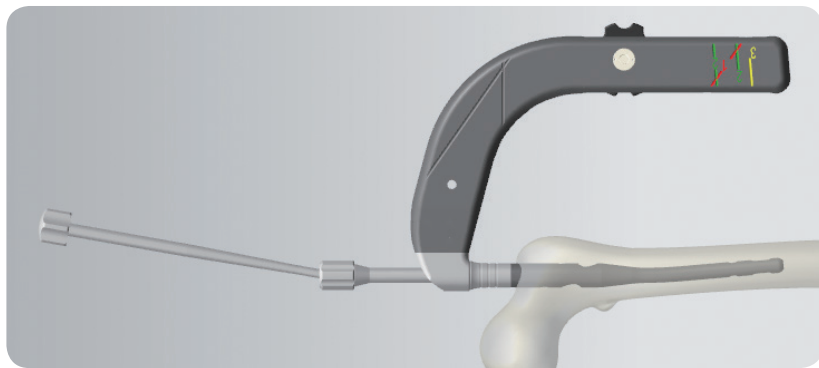


产品特点 Product features

- ◎ 空心髓内钉，近端外展 5° 角使得粗隆顶点进钉更为顺利；
 - ◎ 拉力钉有螺纹式和刀片式两种可选；
 - ◎ 防旋螺钉设计能有效防止退钉和滑钉；
 - ◎ 拉力钉杆部有不对称凹槽，可顶住防旋螺钉，防止滑动；
 - ◎ 螺纹式拉力钉能更好的适应年轻患者；
 - ◎ 刀片式拉力钉的旋入对松质骨产生挤压增加骨密度；
 - ◎ 刀片式拉力钉头部骨水泥孔设计增加螺钉抗拔出力，为骨质疏松患者提供稳固固定。
-
- ◎ Cannulated intramedullary nail adopts the design of 5° angle of proximal abduction to make nail into the apex of the trochanter more smoothly.
 - ◎ Lag screw is optional in blade and threaded types.
 - ◎ Anti-rotation screw design can prevent the nail off and nail slipping.
 - ◎ The shank of the lag screw has an asymmetrical groove to resist the anti-rotation screw and prevent slippage.
 - ◎ Threaded lag screw is better adapted to young patients.
 - ◎ The squeezing of the blade lag screw causes compression to cancellous bone to increase bone density.
 - ◎ The bone cement hole design of the blade lag screw head increases the pullout resistance of the screw and provides a firm fixation for patients with osteoporosis.



器械特点 Instrument features



- ◎ 可透光瞄准臂；
 - ◎ 特殊的打入架能起到现场调节作用；
 - ◎ 万向打、拔导向杆设计，可以方便控制髓内钉插入深度；
 - ◎ 符合人体工程学的瞄准臂形状，有效的解决了体位阻挡的问题；
 - ◎ 工具用不同的颜色表示，方便术中操作；
 - ◎ 套筒上的螺纹设计防止术中工具脱落。
-
- ◎ Light transmissive aiming arm.
 - ◎ Special punching frame can play a role in on-site mediation.
 - ◎ Multi-axial swing and dial guide design for easy control of the insertion depth of the intramedullary nail.
 - ◎ Ergonomic aiming arm design effectively solves the problem of body position blocking.
 - ◎ Tools are marked in different colors for easy intraoperative operation.
 - ◎ The thread design on sleeve prevents the tool from falling out during surgery.

PFNA

130° 金属带锁髓内钉
130° metal interlocking intramedullary nail

主钉 Main nail

短款 Short section

订货编码 Order code	直径 (mm) Diameter	长度 (mm) Length
14.19.02.08090185	Φ 9	185
14.19.02.08090200		200
14.19.02.08090215		215
14.19.02.08100185	Φ 10	185
14.19.02.08100200		200
14.19.02.08100215		215
14.19.02.08110185	Φ 11	185
14.19.02.08110200		200
14.19.02.08110215		215





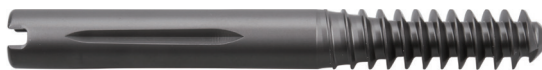
主钉 Main nail



长款 Long section

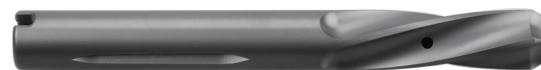
订货编码 Order code		直径 (mm) Diameter	长度 (mm) Length
左 Left	右 Right		
14.19.12.08090260	14.19.22.08090260	Φ 9	260
14.19.12.08090280	14.19.22.08090280		280
14.19.12.08090300	14.19.22.08090300		300
14.19.12.08090320	14.19.22.08090320		320
14.19.12.08090340	14.19.22.08090340		340
14.19.12.08090360	14.19.22.08090360		360
14.19.12.08090380	14.19.22.08090380		380
14.19.12.08090400	14.19.22.08090400		400
14.19.12.08090420	14.19.22.08090420	Φ 10	420
14.19.12.08100260	14.19.22.08100260		260
14.19.12.08100280	14.19.22.08100280		280
14.19.12.08100300	14.19.22.08100300		300
14.19.12.08100320	14.19.22.08100320		320
14.19.12.08100340	14.19.22.08100340		340
14.19.12.08100360	14.19.22.08100360		360
14.19.12.08100380	14.19.22.08100380		380
14.19.12.08100400	14.19.22.08100400	Φ 11	400
14.19.12.08100420	14.19.22.08100420		420
14.19.12.08110260	14.19.22.08110260		260
14.19.12.08110280	14.19.22.08110280		280
14.19.12.08110300	14.19.22.08110300		300
14.19.12.08110320	14.19.22.08110320		320
14.19.12.08110340	14.19.22.08110340		340
14.19.12.08110360	14.19.22.08110360		360
14.19.12.08110380	14.19.22.08110380		380
14.19.12.08110400	14.19.22.08110400		400
14.19.12.08110420	14.19.22.08110420		420

拉力螺钉 Lag screw



螺纹式 Threaded type

订货编码 Order code	直径 (mm) Diameter	长度 (mm) Length
14.23.04.04100075	Φ 10	75
14.23.04.04100080		80
14.23.04.04100085		85
14.23.04.04100090		90
14.23.04.04100095		95
14.23.04.04100100		100
14.23.04.04100105		105
14.23.04.04100110		110
14.23.04.04100115		115
14.23.04.04100120		120



刀片式 Blade type

订货编码 Order code	直径 (mm) Diameter	长度 (mm) Length
14.23.02.04100075	Φ 10	75
14.23.02.04100080		80
14.23.02.04100085		85
14.23.02.04100090		90
14.23.02.04100095		95
14.23.02.04100100		100
14.23.02.04100105		105
14.23.02.04100110		110
14.23.02.04100115		115
14.23.02.04100120		120

锁钉 Locking screw



订货编码 Order code	直径 (mm) Diameter	长度 (mm) Length
14.22.01.02048025	Φ 4.8	25
14.22.01.02048030		30
14.22.01.02048035		35
14.22.01.02048040		40
14.22.01.02048045		45
14.22.01.02048050		50
14.22.01.02048055		55
14.22.01.02048060		60
14.22.01.02048065		65
14.22.01.02048070		70

封帽 Cap



订货编码 Order code	直径 (mm) Diameter	长度 (mm) Length
14.24.02.01014002	Φ 14	15

防旋螺钉 Anti-rotation screw



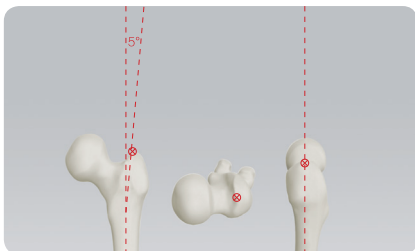
订货编码 Order code	直径 (mm) Diameter	长度 (mm) Length
14.24.01.04008020	Φ 8	20

操作步骤 Operation manual

01

确定进钉点

Determine the entry point



正面片：位于大转子顶点或稍偏外侧，与髓腔轴线成 5°。

侧面片：进钉点与髓腔中央成一条直线。

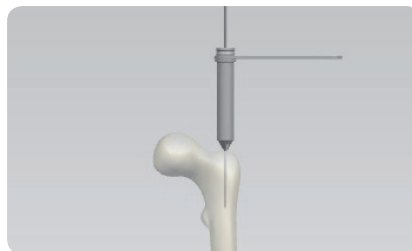
Sagittal view: located at the apex of the greater trochanter or slightly outside, at 5° to the axis of the medullary cavity.

Coronal view: the entry point is in line with the center of the medullary cavity.

02

插入导针

Insert guide needle



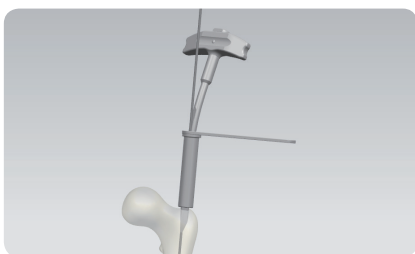
插入导钻导套，植入 $\Phi 3.2$ 导针。

Insert the guide bushing and insert the $\Phi 3.2$ guide needle.

03

近端开口

Proximal opening



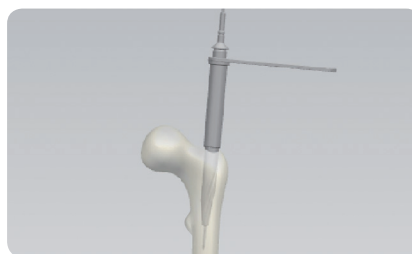
沿导针在开口用导套内插入开口锥，打开髓腔。

Insert the opening cone along the guide needle in the opening guide sleeve to open the medullary cavity.

04

近端扩髓

Proximal reaming



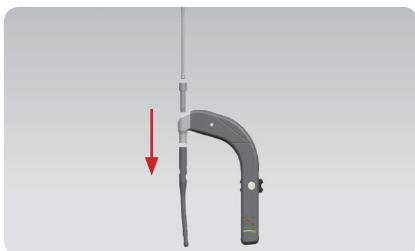
使用 $\Phi 16.5$ 空心扩髓钻沿导针在开口用导套内打开近端髓腔。

Use the $\Phi 16.5$ cannulated medullary drill to open the proximal medullary cavity along the guide needle in the opening guide sleeve.

05

组装髓内钉

Install intramedullary nail



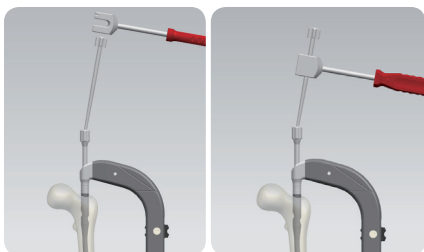
将髓内钉用吊紧螺栓连接到瞄准臂上，用 SW8.0 螺丝刀拧紧。

Connect the intramedullary nail to the aiming arm with the lifting bolt and tighten by the SW8.0 screwdriver.

07

髓内钉的植入

Implantation of intramedullary nail



旋转着插入髓内钉，若需敲击，则拧入特色可进退打拔器，利用滑锤敲击或拔出，使得髓内钉进入最佳位置。

Rotate and insert the intramedullary nail. If it needs to be tapped, screw in the unique advance & retreat puller, and use the sliding hammer to knock or pull out, so that the intramedullary nail enters the optimal position.

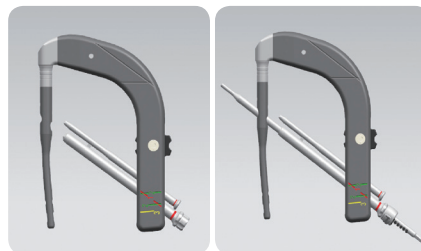
注意：禁止敲击瞄准臂。

Note: Do not tap the aiming arm

06

体外确认

External confirmation



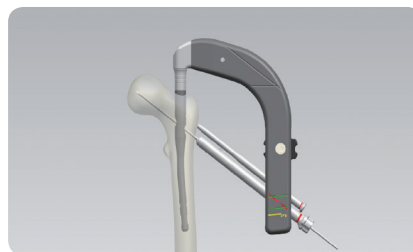
将导钻套筒插入瞄准臂孔，锁紧螺母，拉力钉钻头在套筒内应当能顺利通过髓内钉上的孔。

Insert the drill sleeve into the aiming arm hole, then lock the nut, and the drill bit of lag screw should pass through the hole in the intramedullary nail well in the drill sleeve.

08

插入拉力钉导针

Insert the guide needle of lag screw



将导钻套筒插入瞄准臂孔，锁紧螺母，打入 $\Phi 3.2$ 导针。

Insert the drill sleeve into the aiming arm hole, then lock the nut, and insert the $\Phi 3.2$ guide needle.

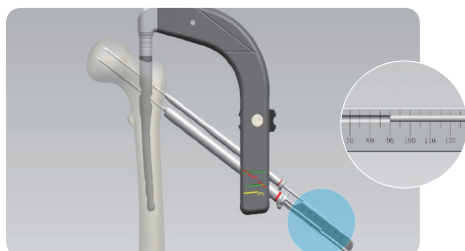
注意：如需要可打入两枚导针以起到防旋作用。

Noted: If necessary, two needles can be inserted to prevent rotation

09

测量拉力钉长度

Measure the length of lag screw



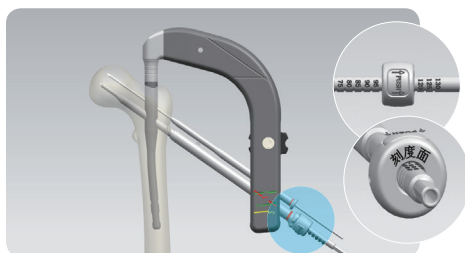
插入导针测深器，以导针尾部为基准读取数值。

Insert the guide needle depth gauge and read the value based on the tail of the guide needle.

11

拉力钉钻头钻孔

Drill for lag screw



调整钻头限位卡座至相应数值，沿着导针钻孔至限深处。

Adjust the drill limited holder to the corresponding value and drill along the guide needle to the limited depth.

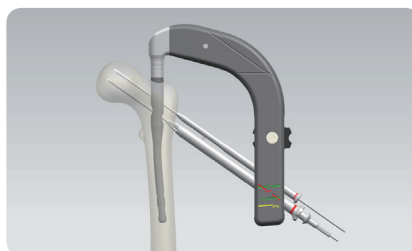
注意：限位卡座必须按箭头所指方向安装，读数必须按打标“刻度面”所示位置读取。

Note: The limit holder must be installed in the direction indicated by the arrow. And must be read at the position indicated by the marked "scale".

10

打开皮质骨

Open cortical bone



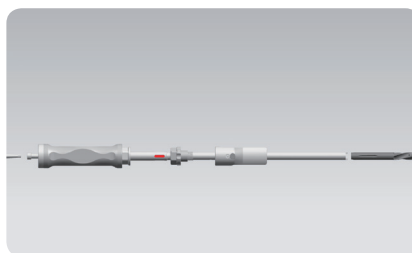
沿导套插入 $\Phi 10.2$ 开口钻头，打开近端皮质骨。

Insert the $\Phi 10.2$ open drill bit along the guide sleeve to open the proximal cortical bone.

12

安装拉力钉（刀片式）

Install lag screw (blade type)



连接拉力螺钉于打入架上，用 SW3.5 六角改锥拧紧不得有松动。

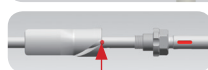
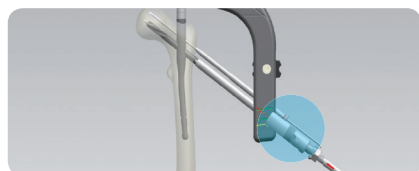
Connect lag screw to the driving frame and tighten with the SW3.5 hex screwdriver.

注意：应将加压螺母拧在最后位置（靠近手柄处）不得影响加压。
若选择螺纹式拉力螺钉直接跳转至第 16 步。

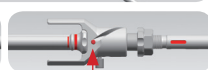
Note: The nut should be screwed to the final position (near the handle) and should not affect the pressurization.
If you choose the threaded type lag screw, please directly see the 16th step.

13 植入拉力钉（刀片式）

Implant lag screw (blade type)



敲击前销钉位置
tap the position of
the front pin



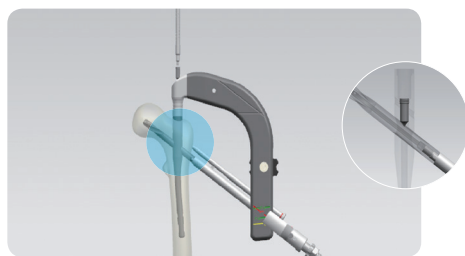
敲击后销钉位置
tap the position of
the rear pin

将打入架插入套筒，旋转手柄使得如图圆柱销滑入弧形槽，用滑锤轻轻敲击手柄尾部直至圆柱销滑入槽的顶端，完成上钉。

Insert the punching frame into the sleeve, rotate the handle so that the cylinder pin slides into the curved groove as shown in the figure, and gently tap the tail of the handle with the slide hammer until the cylinder pin slides into the top of the groove, to complete the implantation.

15 植入防旋螺钉

Implant anti-rotation screw

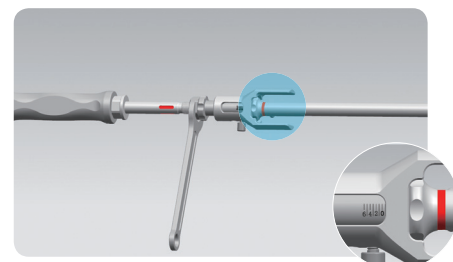


用 SW3.5 万向六角改锥将防旋螺钉拧入髓内钉，转动打入架确保防旋螺钉落入拉力钉凹槽内。

Put anti-rotation screw into intramedullary nail with the SW3.5 Multi-axial hexagon screwdriver. Turn the driving frame to ensure that the anti-rotation screw falls into the groove of lag screw.

14 拉力钉加压（刀片式）

Lag screw pressurization (blade type)

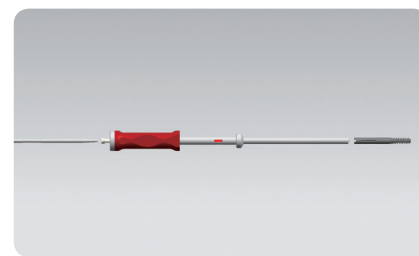


转动加压螺母至固定座顶端，此时滑套上显示为 0mm，继续转动开始加压，注意刻度线位置，谨防过度加压。

Rotate the nut to the top of the fixed seat. At this time, the sliding sleeve shows 0mm. Continue to rotate and start to pressurize. Pay attention to the position of the scale line. Be aware of over pressurization.

16 安装拉力钉（螺纹式）

Install lag screw (threaded type)



连接拉力螺钉于上钉器上，用 SW3.5 六角改锥拧紧不得有松动。

Connect lag screw to the nailer and tighten with the SW3.5 hexagon screwdriver.

17 植入拉力钉（螺纹式）

Implant lag screw (threaded type)



将上钉器插入套筒，顺时针旋转手柄至限位座与套筒贴合，完成上钉，继续旋转完成加压。

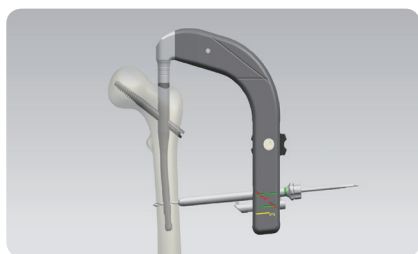
Insert nailer into the sleeve, rotate the handle clockwise to the limit seat and fit the sleeve, complete the implantation. Continue to rotate to complete the pressurization.

注意：加压完成后必须保证涂色凹槽面对正上方，否则防旋螺钉无法锁紧。

Note: After completing the pressurization, please ensure that the coloring groove faces directly above, otherwise the anti-rotation screw can not be locked.

19 远端钻孔

Distal drilling

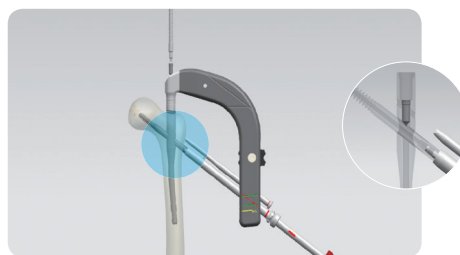


将绿色标记套筒插入瞄准臂孔，用 $\Phi 4.3$ 钻头钻透双侧皮质骨。

Insert the green mark sleeve into the aiming arm and drill the bilateral cortical bone with one $\Phi 4.3$ drill bit.

18 植入防旋螺钉

Implant anti-rotation screw

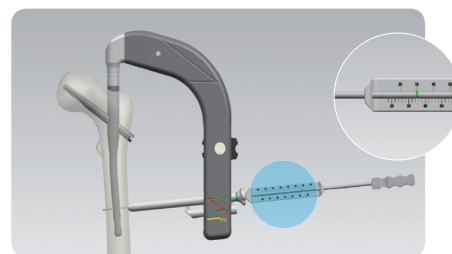


用 SW3.5 万向六角改锥将防旋螺钉拧入髓内钉，转动打入架确保防旋钉落入拉力钉凹槽内。

Put anti-rotation screw into intramedullary nail with the SW3.5 Multi-axial hexagon screwdriver. Turn the driving frame to ensure that the anti-rotation screw falls into the groove of lag screw.

20 远端测深

Distal depth measuring



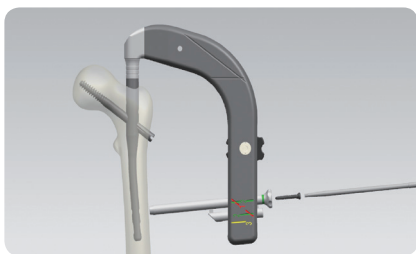
将钩针型测深器通过套筒钩住对侧皮质骨，以绿色标记处为基准读数。

Fix the hook type depth gauge through the sleeve to the bilateral cortical bone, refer the green mark as the exact measurement.

21

远端上钉

Distal screwing



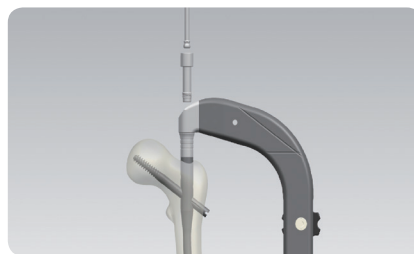
用 SW3.5 改锥通过套筒完成上钉。

Use the SW3.5 screwdriver to complete the screwing through the sleeve.

22

取下瞄准臂

Remove the aiming arm



用 SW8.0 六角改锥拧下吊紧螺栓，取下瞄准臂。

Unscrew the lifting bolt with the SW8.0 hexagon screwdriver and remove the aiming arm.

23

植入封帽

Implant cap



用 SW3.5 万向六角改锥拧入封帽。

Screw cap into intramedullary nail with the SW3.5 Multi-axial hexagon screwdriver.



不断创新 · 追求卓越

INNOVATING CONSTANTLY
KEEP STRIVING FOR EXCELLENCE

www.jsshuangyang.com

地址: 江苏省张家港市杨舍镇包基双羊大厦 邮编 Postcode: 215600

ADD: Shuangyang Building, Baoji, Yangshe Town, Zhangjiagang City, Jiangsu Province, China

电话 Telephone: 0512-58268332 传真 FAX: 0512-58268337 E-Mail: shuangyang@jsshuangyang.com



微信号: shuangyang8

由于印刷的关系, 可能与实际产品的颜色有所差异, 使用时请以实物颜色为准。

Because of the printing, it may vary with the color of the actual product, please subject to the product color when using.

仅供医疗器械专业技术人员、临床医师参考阅读, 最终解释权归江苏双羊医疗器械有限公司所有。

Only for the medical professional technical personnel and the clinician reference reading, the final interpretation right of this event is reserved by Jiangsu Shuangyang Medical Instrument Co., Ltd.