



INTELLIGENT PROXIMAL FEMUR
COMBINED COMPRESSION
INTRAMEDULLARY NAIL

智能型股骨近端联合加压髓内钉

江苏双羊医疗器械有限公司

Jiangsu Shuangyang
Medical Instrument Co., Ltd.



www.jsshuangyang.com





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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、胸腰后路钉棒系统、椎板固定板系统、金属带锁髓内钉、外固定支架、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.

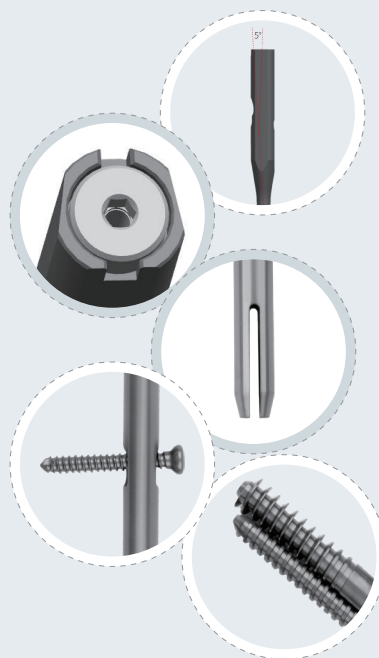
Thanks to meticulous guidance and supports from distinguished orthopaedic specialists, professors and clinicians, we have launched numerous leading products customized for different human skeletal parts, including locking bone plate fixation system, titanium bone plate fixation system, titanium cannulated bone screw & gasket, titanium sternocostal system, locking maxillofacial internal fixation system, maxillofacial internal fixation system, titanium binding system, anatomic titanium mesh system, posterior thoracolumbar screw-rod system, laminoplasty fixation system, interlocking intramedullary nail, external fixator 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

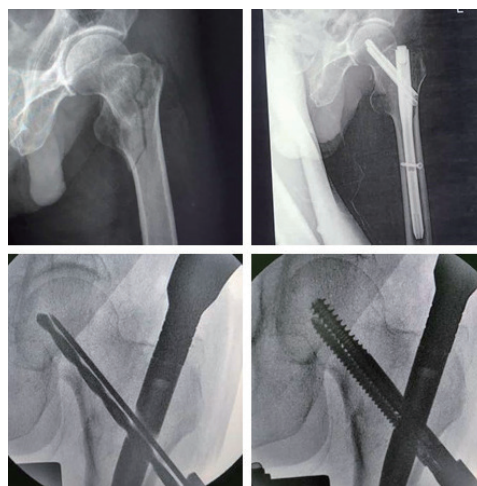
- ◎ 5° 外翻角提供大粗隆顶点微创入路
- ◎ 近端梯形截面设计，增强了股骨近端的稳定性
- ◎ 远端独特的发夹形分叉设计，以降低应力集中，避免远端假体周围骨折。
- ◎ 远端钉孔可选择动态或静态锁定
- ◎ 独特的联合加压交锁钉设计提供了良好的稳定性及抗旋能力，可控的线性加压效果

- ◎ 5° valgus angle provides minimally invasive approach to the apex of greater trochanter.
- ◎ The proximal trapezoidal section enhances the stability of the proximal femur.
- ◎ Unique hairpin bifurcation design at the distal end to reduce stress concentration and avoid fractures around the distal prosthesis.
- ◎ Dynamic or static locking can be selected for distal nail.
- ◎ Unique combined compression interlocking nail design provides good stability and anti-rotation ability, controllable linear pressure effect.



适应症 Indications

- ◎ 股骨颈骨折
- ◎ 股骨颈底骨折
- ◎ 粗隆间骨折
- ◎ 股骨干骨折
- ◎ Fracture of neck of femur
- ◎ Fracture of femoral neck base
- ◎ Intertrochanteric fracture
- ◎ Fracture of femoral shaft



主钉 Main nail

短款 Short section



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.19.02.07090185	9.0	185
14.19.02.07090200		200
14.19.02.07090215		215
14.19.02.07100185	10.0	185
14.19.02.07100200		200
14.19.02.07100215		215
14.19.02.07110185	11.0	185
14.19.02.07110200		200
14.19.02.07110215		215
14.19.02.07120185	12.0	185
14.19.02.07120200		200
14.19.02.07120215		215



长款（左） Long section (left)



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.19.12.07090260	9.0	260
14.19.12.07090280		280
14.19.12.07090300		300
14.19.12.07090320		320
14.19.12.07090340		340
14.19.12.07090360		360
14.19.12.07090380		380
14.19.12.07090400		400
14.19.12.07090420		420
14.19.12.07100260	10.0	260
14.19.12.07100280		280
14.19.12.07100300		300
14.19.12.07100320		320
14.19.12.07100340		340
14.19.12.07100360		360
14.19.12.07100380		380
14.19.12.07100400		400
14.19.12.07100420		420
14.19.12.07110260	11.0	260
14.19.12.07110280		280
14.19.12.07110300		300
14.19.12.07110320		320
14.19.12.07110340		340
14.19.12.07110360		360
14.19.12.07110380		380
14.19.12.07110400		400
14.19.12.07110420		420
14.19.12.07120260	12.0	260
14.19.12.07120280		280
14.19.12.07120300		300
14.19.12.07120320		320
14.19.12.07120340		340
14.19.12.07120360		360
14.19.12.07120380		380
14.19.12.07120400		400
14.19.12.07120420		420

长款 (右) Long section (right)



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.19.22.07090260	9.0	260
14.19.22.07090280		280
14.19.22.07090300		300
14.19.22.07090320		320
14.19.22.07090340		340
14.19.22.07090360		360
14.19.22.07090380		380
14.19.22.07090400		400
14.19.22.07090420		420
14.19.22.07100260	10.0	260
14.19.22.07100280		280
14.19.22.07100300		300
14.19.22.07100320		320
14.19.22.07100340		340
14.19.22.07100360		360
14.19.22.07100380		380
14.19.22.07100400		400
14.19.22.07100420		420
14.19.22.07110260	11.0	260
14.19.22.07110280		280
14.19.22.07110300		300
14.19.22.07110320		320
14.19.22.07110340		340
14.19.22.07110360		360
14.19.22.07110380		380
14.19.22.07110400		400
14.19.22.07110420		420
14.19.22.07120260	12.0	260
14.19.22.07120280		280
14.19.22.07120300		300
14.19.22.07120320		320
14.19.22.07120340		340
14.19.22.07120360		360
14.19.22.07120380		380
14.19.22.07120400		400
14.19.22.07120420		420



拉力螺钉 Lag screw



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.23.14.04100075	10.0	75
14.23.14.04100080		80
14.23.14.04100085		85
14.23.14.04100090		90
14.23.14.04100095		95
14.23.14.04100100		100
14.23.14.04100105		105
14.23.14.04100110		110
14.23.14.04100115		115
14.23.14.04100120		120

加压螺钉 Compression screw



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.23.03.02064070	6.4	70
14.23.03.02064075		75
14.23.03.02064080		80
14.23.03.02064085		85
14.23.03.02064090		90
14.23.03.02064095		95
14.23.03.02064100		100
14.23.03.02064105		105
14.23.03.02064110		110
14.23.03.02064115		115

封帽 Cap



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.24.02.01012005	12.0	5
14.24.02.01012010		10
14.24.02.01012015		15

防旋螺钉 Anti-rotation screw



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.24.01.04008010	8.0	10

锁钉 Locking screw



订货编码 Item No.	直径 (mm) Diameter	长度 (mm) Length
14.22.01.02048025	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

* 本规程以短款操作为例

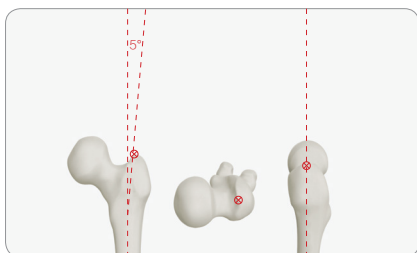
This operation manual takes the short section as an example

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。

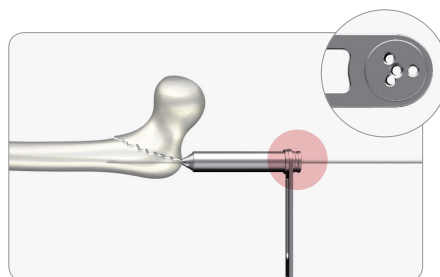
Sagittal view: located at the apex of the greater trochanter or slightly outside, at 5° to the axis of the medullary cavity.

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

02

插入导针

Insert guide needle



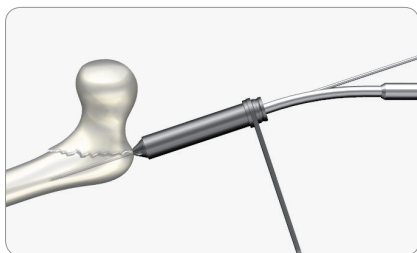
插入导钻导套，植入 $\Phi 3.2$ 导针。

Insert $\Phi 3.2$ bone guide needle with the drill guide sleeve along the opening.

03

近端开口

Proximal opening



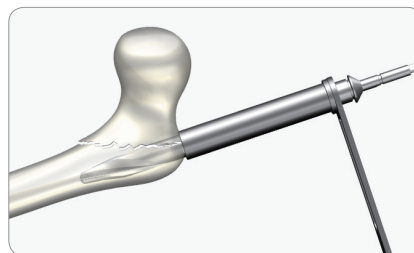
沿导针在开口用导套内插入开口锥，打开髓腔。

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



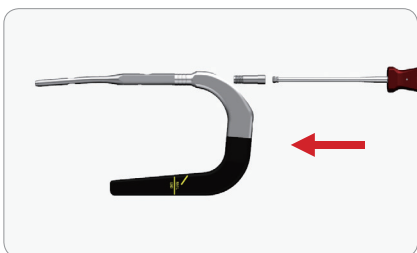
使用 $\Phi 16.5$ 空心扩髓钻沿导针在开口用导套内打开近端髓腔。

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



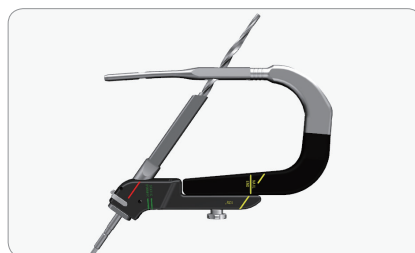
将髓内钉用吊紧螺栓连接到瞄准臂上，用 SW8.0 螺丝刀拧紧。

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

06

体外确认

External confirmation



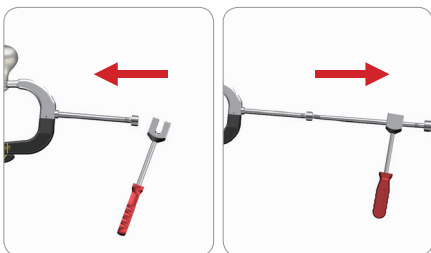
安装上近端瞄准架，锁紧螺母；将拉力螺钉导钻插入瞄准臂孔，拉力螺钉钻头在套筒内应当能顺利通过髓内钉上的孔。

Install aiming arm, lock the nut; insert the drill guide of lag screw into the aiming arm hole, and the drill bit of lag screw what in the drill sleeve should pass through the hole in the intramedullary nail well.

07

髓内钉的植入

Implantation of intramedullary nail



旋转着插入髓内钉，若需敲击，则拧入主钉打入器/取出器，利用滑锤敲击或拔出，使得髓内钉进入最佳位置。

注意：禁止敲击瞄准臂。

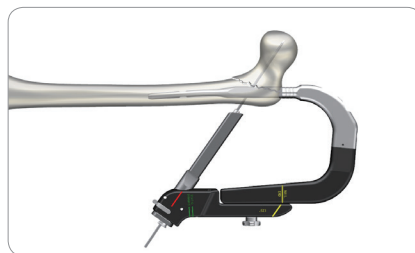
Rotate and insert the intramedullary nail. If it needs to be tapped, screw in the 'advance & retreat puller' of main screw, and use the sliding hammer to knock or pull out, so that the intramedullary nail enters the optimal position.

Note: Do not tap the aiming arm.

08

插入拉力钉导针

Insert the guide needle of lag screw



将拉力螺钉导钻插入瞄准臂孔内，通过克氏针导钻植入 $\Phi 3.2$ 骨导引针。

Insert lag screw guide drill into the aiming arm hole, and implant $\Phi 3.2$ bone guide needle through Kirschner wire guide drill.

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。
(以图示为例)

例如：测深长度 100mm

非加压模式：

拉力螺钉长度 100mm

加压螺钉长度 95mm

加压模式：

加压距离 5mm

拉力螺钉长度 95mm

加压螺钉长度 90mm

(本规程以加压模式为例)

Insert the probe sounder and read the value based on the tail of the guide pin. (take the illustration as an example).

For example: The sounding length is 100mm

Non compression mode:

Take lag screw length in 100mm

Take compression screw length in 95mm

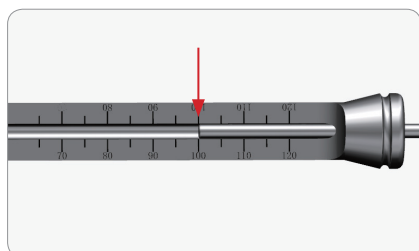
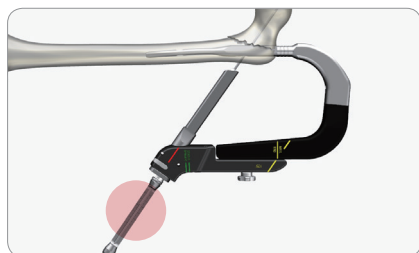
Compression mode:

If the compression length in 5mm,

Take lag screw length in 95mm

Take compression screw length in 90mm

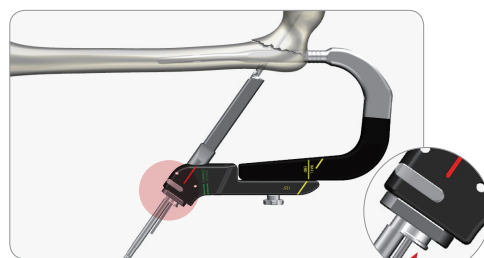
This procedure takes compression mode as an example.



10

打开皮质骨

Drill cortical bone



此处限位
Depth limited point

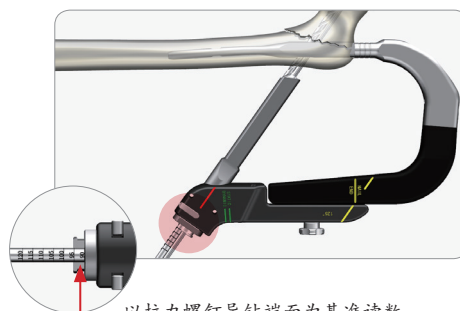
将开口钻头沿克氏针导钻下方钻入，直至限深处。

Opening drill bit go into along the lower part of k-wire guide drill.

11

加压螺钉钻头钻孔

Drill for compression screw



以拉力螺钉导钻端面为基准读数

Value reading based on the lag screw guide drill

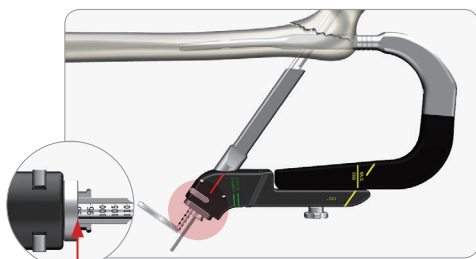
加压螺钉钻头钻至相应刻度位置。

Drill the compression screw bit to the corresponding scale position.

12

安装防旋把手

Install anti-rotation handle



以拉力螺钉导钻端面为基准读数
Value reading based on the lag screw guide drill

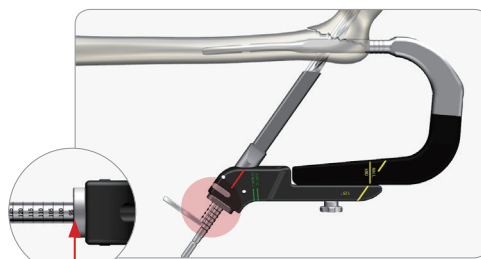
移除加压螺钉钻头，在钻好的孔内插入防旋把手。

Remove the compression screw drill bit and insert the anti-rotation handle.

13

拉力螺钉钻头钻孔

Drill for lag screw



以拉力螺钉导钻端面为基准读数
Value reading based on the lag screw guide drill

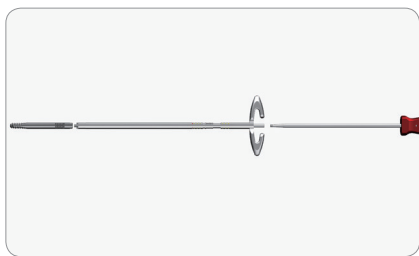
移除克氏针导钻，拉力螺钉钻头钻至相应刻度位置。

Remove the Kirschner wire guide drill, and lag screw drill bit should drill to the appropriate scale.

14

组装拉力螺钉

Install lag screw



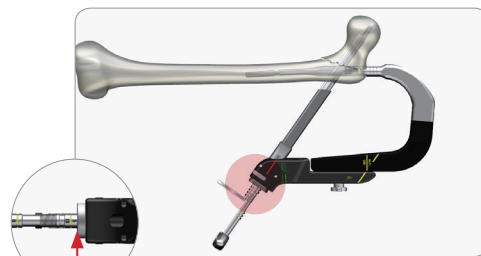
将拉力螺钉与拉力螺钉上钉器相连接，通过SW3.5改锥拧紧。

Connect lag screw with screw in tool, and tighten them with SW3.5 screwdriver.

15

植入拉力螺钉

Implant lag screw



加压距离为 5mm
Compression distance is 5mm.

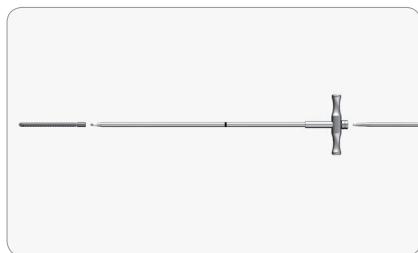
沿螺纹导针拧入拉力螺钉，根据预加压距离确定拧入深度，直至上钉器上加压刻度线与拉力螺钉导钻端面齐平。

Insert the lag screw along the thread guide needle and determine the depth according to the pre-compression distance until the scale of screw in tool is level with lag screw drill guide.

16

组装加压螺钉

Install compression screw



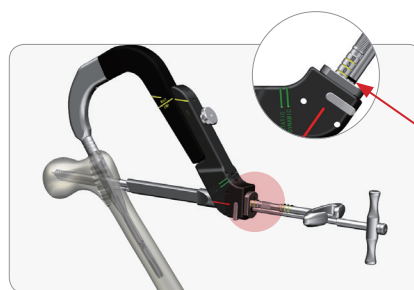
将加压螺钉与加压螺钉上钉器相连接，通过 SW3.5 改锥拧紧。

Connect compression screw with screw in tool, and tighten them with SW3.5 screwdriver.

17

植入加压螺钉

Implant compression screw



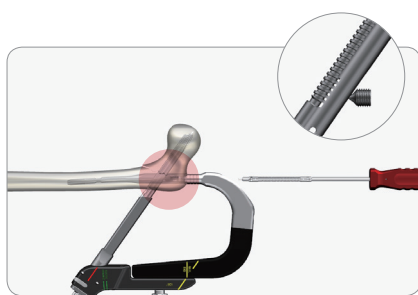
移除防旋把手，拧入加压螺钉，直至加压螺钉上钉器上黑色的标志线与拉力螺钉上钉器上的“0”刻度标志线齐平

Remove anti-rotation handle, insert compression screw until the black mark on screw in tool of compression screw is level with "0" scale on screw in tool of lag screw.

18

植入防旋螺钉

Implant anti-rotation screw



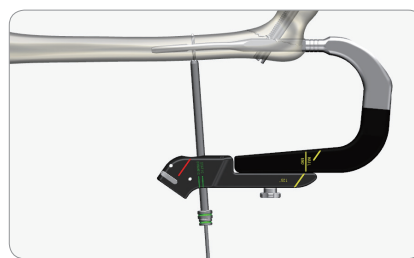
用 SW3.5 万向六角改锥拧入防旋螺钉。

Use SW3.5 multi-axial hexagon screwdriver to screw in the anti-rotation screw.

19

远端钻孔

Distal drilling



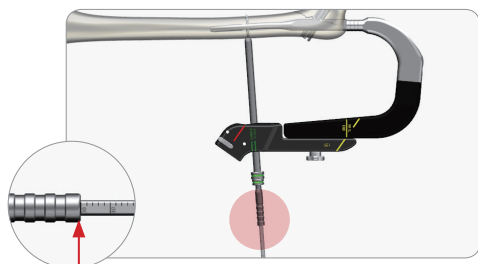
将绿色标记导钻插入瞄准臂孔，用 $\Phi 4.3$ 钻头钻透双侧皮质骨。

Insert the green mark guide drill into the aiming arm hole and drill through the cortical bone on both sides by using $\Phi 4.3$ drill bit.

20

远端测深

Distal depth measuring



以套筒尾端为基准读数

Value reading based on the end of the sleeve

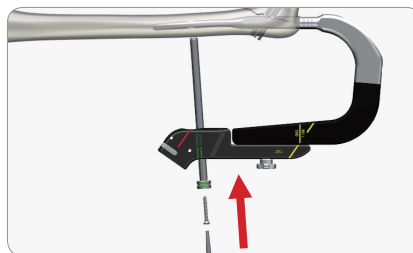
测深器通过导套钩住对侧皮质骨，测量深度。

Depth gauge go through the sleeve and hook contralateral cortical bone, then gauge the depth.

21

远端上钉

Distal screwing



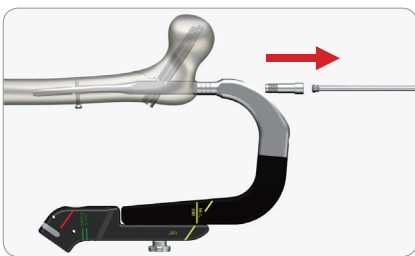
选择合适长度螺钉，用 SW3.5 改锥完成上钉。

Choose screw with appropriate length, finish screwing in by using SW3.5 screwdriver.

22

取下瞄准臂

Remove the aiming arm



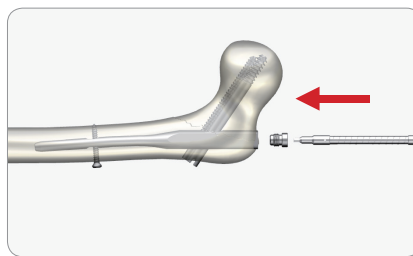
用 SW8.0 六角改锥拧下吊紧螺栓，取下瞄准臂。

Unscrew the lifting bolt with 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 with SW3.5 multi-axial hexagon screwdriver.



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