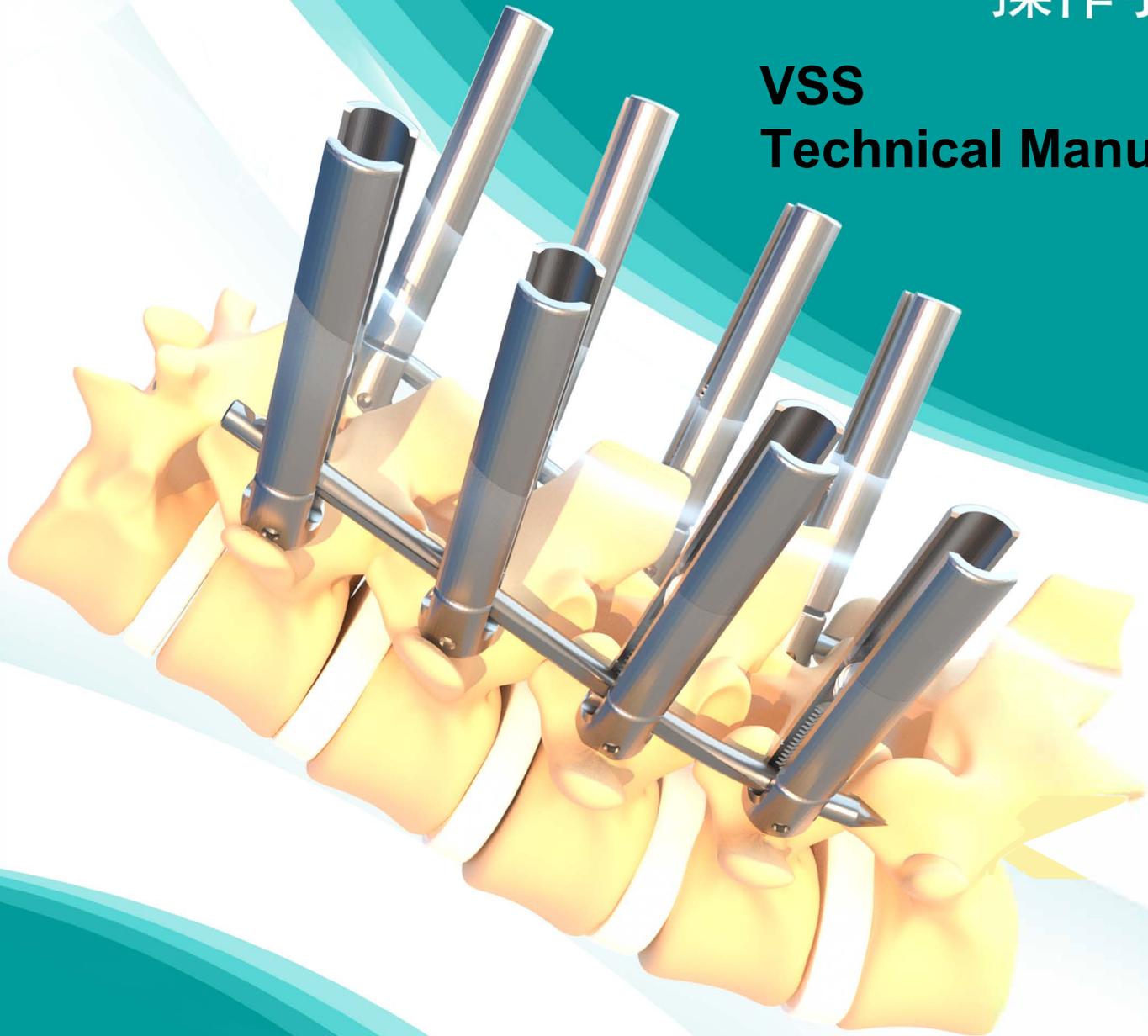
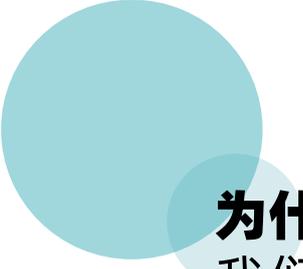


VSS II 85mm 加长臂微创系统 操作手册

VSS
Technical Manual





为什么选择富乐？ Why Choose Fule? 我们的优势 Fule advantage

● 公司是集医疗器械研发、生产、销售为一体的国家高新技术企业，拥有全智能加工设备生产线。

Beijing Fule is a national high-tech enterprise integrating R&D, production and sales of medical equipment, and has a production line of fully intelligent processing equipment.

● 院士专家工作室成立助力富乐研发能力提升，进一步深入产 - 学 - 研合作；获批博士后科研工作站。

The academician expert studio was established to help Fule improve its research and development capabilities, and further deepen the cooperation of production-academy-research; it was approved as a post-doctoral research station.

● 硬件设施齐全，研发团队精良，与临床专家紧密合作，获得百余项国内外专利。

The hardware facilities are complete, the R&D team is excellent, and the clinical experts work closely with more than one hundred domestic and foreign patents.

● 基于代理商合作模式，建立覆盖全国的销售服务网络，产品供应全国近千家三甲医院，远销 20 余个海外国家。

Based on the agent cooperation model, it has established a nationwide sales and service network, and its products are supplied to nearly a thousand tertiary hospitals across the country and exported to more than 20 overseas countries.



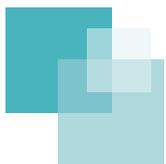
北京市富乐科技开发有限公司

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产品优势 (VSS)

Products Advantage

- 加长臂设计，可视空间大，切口小，微创伤；

Long tail design, large visual space, small incision, and less bleeding

- 双线螺纹设计，适应椎体骨密度分布，把持力更强；

Double thread design, adapt to vertebral bone density distribution, stronger holding power

- 骨水泥孔设计，可用于骨质疏松；

Cannulated bone cement hole, can be used for osteoporosis

- 撑开加压易于实现，操作简单；

Easy to distraction and compression

- 专用置棒器械，置棒精准，操作方便；

Dedicated rod holder, convenient and accurate

- 全面提供 50-260mm 的连接棒；以及 50-200mm 的预弯连接棒。

Include straight rod, 50-260 mm, Bending rod, 50-200 mm



产品优势 (VAS)

Products Advantage



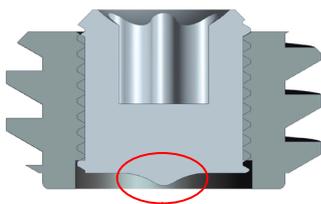
- 双螺塞设计，避免复位丢失

Double screw nut design to avoid loss of reset

使用方式：

- 第一步锁紧钉体（拧紧外螺塞）
- 第二步锁紧连接棒（拧紧内螺塞）

Step:
1. tighten outer nut for screw
2. tighten inner nut for rod



注意：

实现万向钉双螺塞锁紧两步锁紧前提是：内螺塞底部不能露出外螺塞底部。如果露出超过1mm 那就一步就能同时锁死钉体和连接棒。

Note:
Before tightening the double nut, please make sure that the bottom of inner nut must not exceed the outer nut.

产品优势

Product Category



长臂万向单芯椎弓根钉
(双线加长臂球型)

Polyaxial

长臂万向单芯椎弓根钉
(双线加长臂扁型)



Uniplanar



长臂万向单芯椎弓根钉
(双线加长臂柱型)

Monoaxial

使用说明

● 【适应症】 Application

腰椎间盘突出症；腰椎滑脱症；腰椎不稳症；腰椎管狭窄症。

Lumbar disc herniation
Spondylolisthesis
Lumbar Instability
Lumbar spinal stenosis

● 【禁忌症】 Contraindication

严重心肺疾病的老年患者；严重的骨质疏松患者；明显的腰椎或胸腰椎脊柱侧凸患者；
椎弓根发育不良患者；术前定位不明确患者；峡部裂；椎体滑脱 II 度以上等。

Elderly patients with severe cardiopulmonary disease
Patients with severe osteoporosis
Patients with significant scoliosis
Patients with pedicle dysplasia
Patients with spondylolisthesis above degree II

手术步骤

Surgical Technical

【步骤一】

体位准备，体表定位

Step 1. Position preparation, body surface positioning

- 本手术需要在 X 线透视或导航系统的帮助下完成，所以病人要俯卧在一个可透视的手术床上，确保正位和侧位的完全透视（图 1a）。

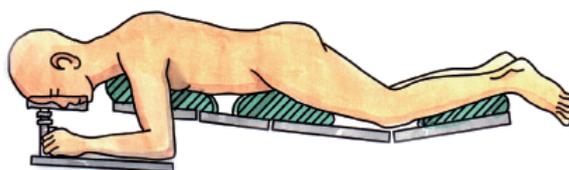


图 1a

- 首先病人麻醉以后可以通过体位的调整来使骨折椎体达到部分或完全的复位。
- 确定穿刺椎弓根体表位置（图 1b）。

This operation needs to be done with the help of X-ray fluoroscopy, so the patient needs to be prone on a fluoroscopy operating table and maintain full fluoroscopy in the front and side positions (1a)



图 1b

After the patient is anesthetized, the fractured vertebral body can be partially or completely reduced by adjusting the position

Determine the body surface position of the punctured pedicle (1b)

手术步骤

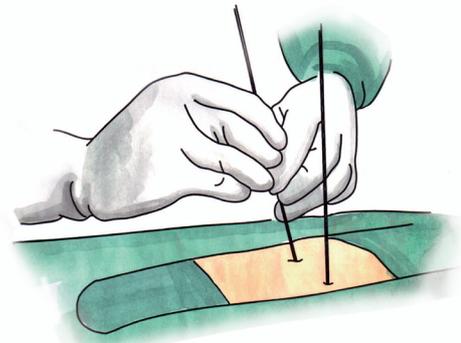
Surgical Technical

【步骤二】

预穿刺

Step 2. Pre-puncture

- 预穿刺确定切口位置，穿刺点位置：椎弓根体表位置点外侧 1-1.5CM，肥胖患者的入路需要再偏向外侧（图 2a）。



- 穿刺示意图。（图 2b）。

Pre-puncture to determine the incision location, the location of the puncture point: 1-1.5cm outside the pedicle body surface position, and the approach of obese patients needs to be deviated to the outside (2a)



图 2a

Puncture diagram (2b)

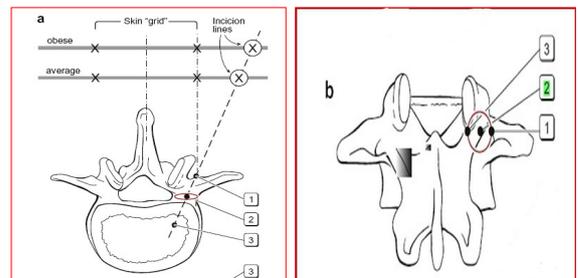


图 2b

手术步骤

Surgical Technical

【步骤三】

切口

Step 3. incision

- 切口部位肾上腺素盐水局部浸润（图 3 a）。
- 取 1.5 CM 切口切开皮肤及筋膜（图 3 b）。

Local infiltration of epinephrine saline at the incision site (3a)

incise the skin and fascia with 1.5 cm incision (3b)

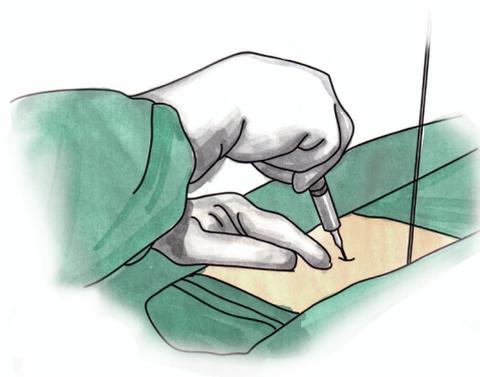


图 3a



图 3b

【步骤四】 定位导向穿刺器放置 Step 4. Puncture needle placement

- 插入定位导向穿刺器，插入过程需通过透视确认定位导向穿刺器插入的位置和方向（图 4a）。
- 前后位 X 线透视引导下，将定位导向穿刺器尖置于椎弓根投影的外缘。（即左侧 9-10 点、右侧 2-3 点处），向内倾斜 10 ~ 15° 平行终板向椎体内穿刺，定位导向穿刺器进入骨质内 6-10mm 后透视定位导向穿刺器尖端在椎弓根投影内未突破内侧皮质（图 4b）。

Insert the positioning guide puncture needle, the insertion process needs to confirm the position and direction of the positioning guide puncture insertion through fluoroscopy (4a).

Under the guidance of anteroposterior X-ray fluoroscopy, place the tip of the positioning guide trocar on the outer edge of the pedicle projection. (I.e. 9-10 points on the left side and 2-3 points on the right side), puncture into the vertebral body with an inwardly inclined 10-15° parallel to the endplate, positioning and guiding the puncture into the bone 6-10mm and fluoroscopic positioning and guiding The tip of the trocar did not break through the medial cortex in the pedicle projection (4b).

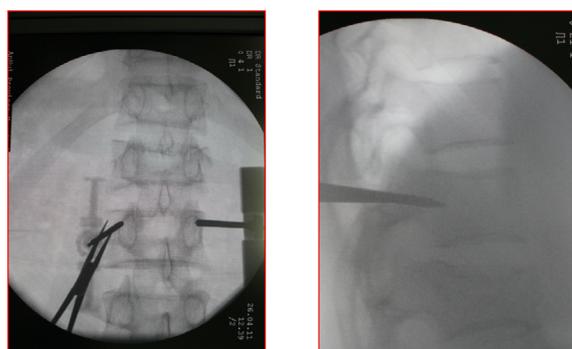


图 4a

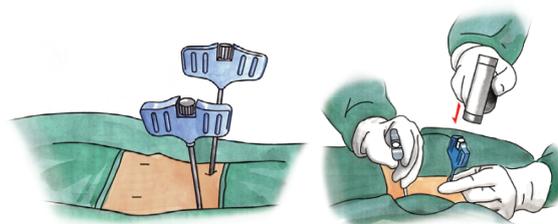


图 4b

【步骤五】

骨定位针放置 Step 5. Pin placement

- 将骨定位针插入穿刺针内。骨定位针应超出穿刺针 35-40mm 已获得骨性固定（图 5a）。骨定位针应比接下来的丝攻（空心）深度要深一些。

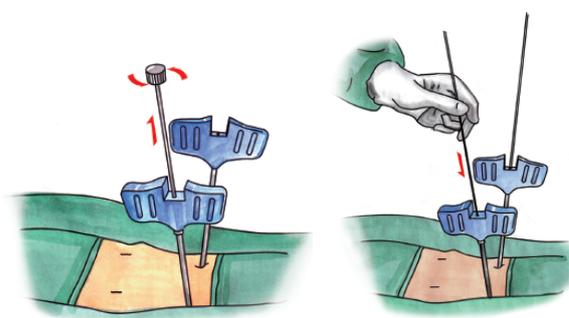


图 5a

- 当骨定位针达到预期的深度以后将定位导向穿刺器移除（图 5 b）。

Insert the pin into the puncture needle. The pin should exceed the puncture needle by 35-40 mm and bone fixation has been obtained (5a). The pin should be deeper than the cannulated tap.

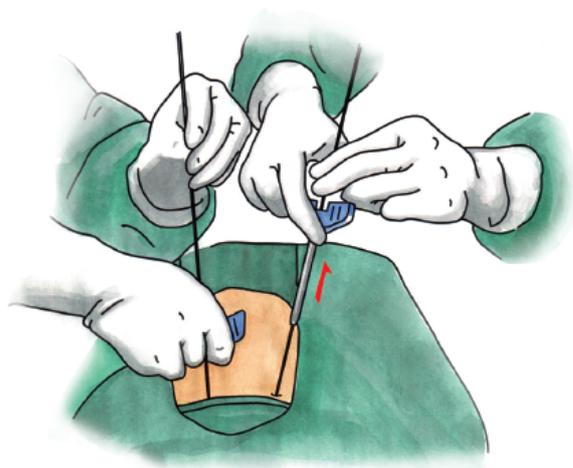


图 5b

When the pin reaches the desired depth, the puncture needle can be removed (5 b).

【步骤六】 椎弓根入路准备 Step 6. Pedicle approach preparation

- 先将护套 (I) 套在骨定位针外面并插入至骨面，再依次套入护套 (II)、护套 (III)、护套。当护套 (II)、护套 (III)、护套位置准备好后，将护套 (I) 移除 (图 6 a)。

- 沿骨定位针插入骨钻 (空心)，在椎弓根钉进钉点的皮质骨处扩口 (图 6 b)。

- 选择合适的丝攻 (空心) 进行丝攻。攻丝时注意深度，不要过度的拧入旋转，并记下攻丝的深度 (图 6 c)。

开路或攻丝时注意骨定位针不能跟丝攻 (空心) 或骨钻 (空心) 往椎体前沿移动。

First put the dilator (small) within pin and insert it into the bone surface, and then insert the larger dilator in sequence. When all the dilators are ready, remove the dilator (small) (6a).

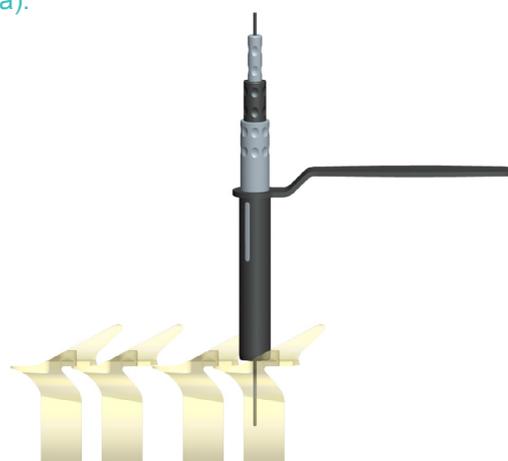


图 6a

Along with the pin, use cannulated drill to bore the cortical bone(6b)

Select the appropriate cannulated tap. Pay attention to the depth when tapping, and note the tapping depth (6c)



图 6b



图 6c

【步骤七】

植入椎弓根钉

Step 7. Pedicle screw implantation

- 取出护套（II），选择相应合适长度和直径的椎弓根钉，通过骨定位针拧入，注意在透视监测下确认椎弓根螺钉到达的位置。
- 螺钉植入后，逆时针旋转持钉钮，卸下椎弓根钉扳手，取出导针。
- 当椎弓根钉的上端与护套的上端平齐时，说明椎弓根钉差不多已经打到位（图 7a）。

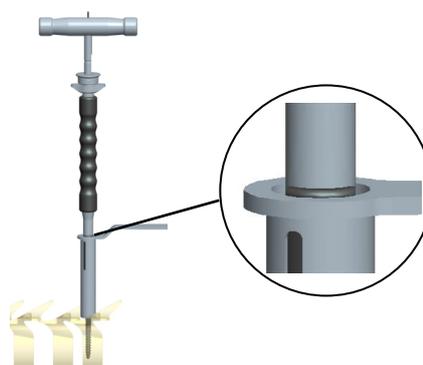


图 7a

注意骨定位针不能跟钉体往椎体前沿移动。

Take out the second dilator, select the pedicle screw of appropriate length and diameter, and implant it in through the pin. Pay attention to confirm the position of the pedicle screw under fluoroscopy monitoring.

After pedicle screw is implanted, remove the pedicle screwdriver, and take out the pin.

When the upper end of the pedicle screw is flush with the upper end of the dilator, it proves that the pedicle screw is implanted correctly (7a).

【步骤八】

棒与夹持器连接

Step 8. holding rod

- 选取合适的棒，将棒尾部插入夹持器小孔中，并使棒尾部的平台朝上（图 8a）。
- 将起子插入夹持器六方孔内，旋转起子直至棒被持紧（图 8b）。

Select a suitable rod, insert the tail of the rod into the small hole of the rod holder, and make the platform of the tail of the rod face up (8a).

Insert and rotate the locker of rod holder until the rod is tightened (8b).

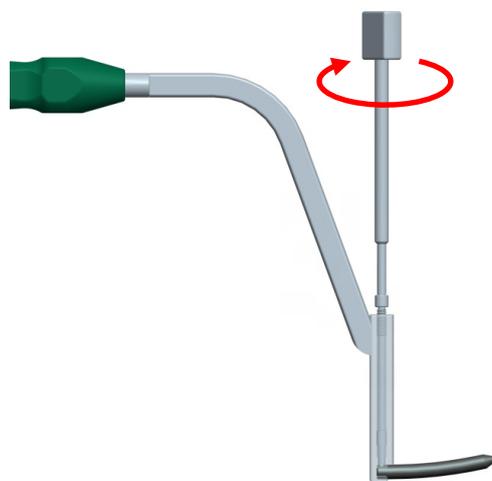


图 8a

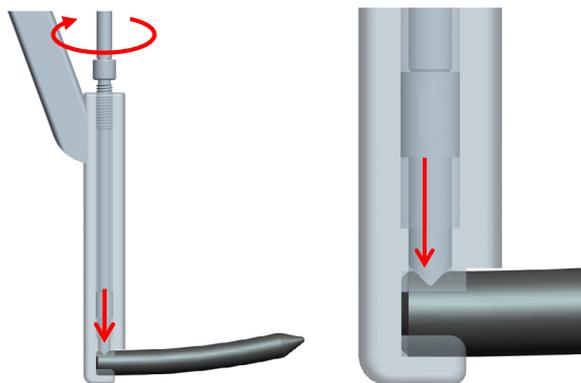


图 8b

手术步骤

Surgical Technical

【步骤九】

置棒

Step 9. rod placement

The rod should be entirely inside the pedicle screw long tail. Slowly lower the rod along the long tail until it touches the end of the screw or until the deepest position that the surrounding tissue can allow it to reach. At least the head of the rod needs to be under the fascia (9a).

- 将连接器的开口对齐，按箭头方向对准连接器。棒应整个在连接器内。慢慢将棒沿连接器往下放直至其触及螺钉的尾部或直至周围组织能允许其能到达的最深的位置。至少棒的头部需要位于筋膜下（图 9a）。

- 将夹持器旋转 90 度。这个步骤将引导棒进入连接器的底部槽口。为了确认棒是否位于连接器的底部槽口内，可以使用术中透视以确认棒的放置位置（图 9b）。

如果棒的弧度不满足预期要求，我们配有专用弯棒器，可保证棒预弯方向与棒的夹持器持取槽的相对位置关系（图 9c）。

Rotate the rod holder with 90 degrees. This step will guide the rod into the bottom of the long tail. To confirm that the rod is located in the bottom of the long tail, intraoperative fluoroscopy can be used to confirm the placement of the rod (9b).

If the arc of the rod does not meet the expected requirements, we can use rod bender to ensure the proper arc of the rod (9c).

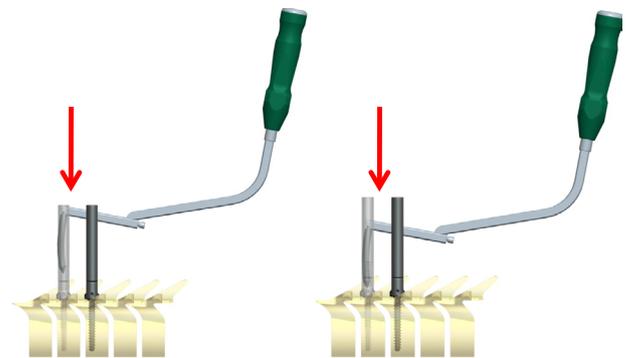


图 9a

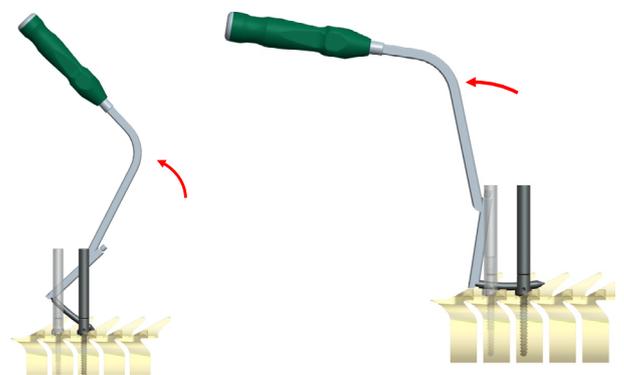


图 9b



图 9c

【步骤十】

预紧固定与钉体的锁紧

Step 10. Pre-locking

- 通过透视或小的微型拉钩确认棒位于螺钉的长尾槽内后，即可用起子（预紧）将螺塞拧入椎弓根钉并将尾端的螺丝拧紧（图 10 a）。
- 为了实现撑开、加压时椎体不出现旋转及高度丢失，需要将所有外螺塞锁死（图 10 b）。

将内螺塞也预紧，除了需要撑开或者加压椎体中任意一个（如使用 VAS 在此步骤加上预紧内螺塞）。

After confirming that the rod is located in the long tail, use nut holder to insert the nut and tighten the nut with distal pedicle screw (10a).

In order to prevent rotation and height loss of the vertebral body during expansion and compression, all distal screw nut need to be tightened (10b).



图 10a



图 10b

【步骤十一】 撑开、加压并最终锁紧 Step 11. distraction, compression, and final tightening

The distractor can realize distraction and compression at the same time. A universal angle can be realized between the two rotating sleeves, which can be well adapted to the expansion and compression of angled pedicle screws.

- 脊柱撑开器能同时实现撑开和加压功能。两个旋转套筒之间能实现万向角度，能很好的适应成角度椎弓根钉的撑开加压。
- 在椎弓根钉上装入套筒，再根据要撑开或加压的椎弓根钉的角度和位置，调整旋转套筒的角度位置，并从套筒上端装入，直至最下端（图 11a）。

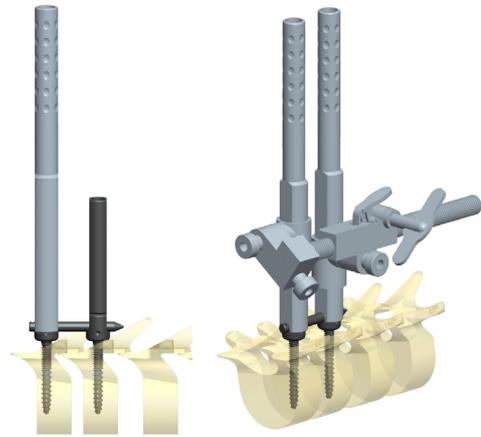


图 11a

- 将椎体撑开器套入套管上端，再用加力扳手插入撑开器旋钮，最后进行撑开复位，然后在撑开状态下，拧紧内螺塞（如使用 VAS 在此步骤加上拧紧内螺塞）（图 11 b）。

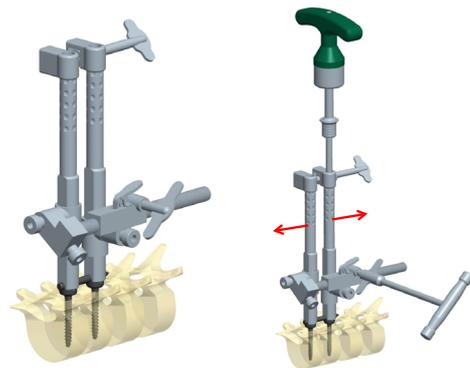


图 11b

- 用扳手将所有内螺塞最终锁紧连接棒（如使用 VAS 在此步骤加上拧紧内螺塞）（图 11 c）。



图 11c

Install extend level on the pedicle screw, and then adjust the angle of extend level according to the angle of pedicle screw to be distracted or compressed (11a).

Use 2 distractors and wrench for distractor to make distraction and compression, and then tighten all nuts in best reset state(11b).

Use 10 N.m Handle and Counter Torque to make sure all nuts are fully tightened (11c).

【步骤十二】

扭断器断臂，缝合

Step 12. remove long tail and suture

- 将扭断器套入钉臂，向外按压，钉臂断裂分离，并将其带出（图 12 a）。
- 所有钉臂折断取出后，将伤口缝合。

Remove all long tails with Break-off wrench(12a).

After all tails are taken out, suture the wound.

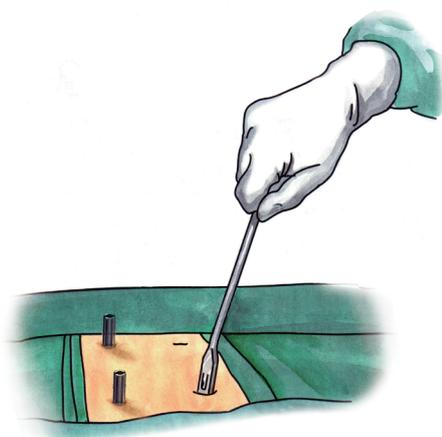


图 12a

产品信息

Products information

Polyaxial Reduction Cannulated Pedicle Screw

- 【长臂万向单芯椎弓根钉 (双线加长臂球型) 】



		螺钉长度 (mm) length					
		30	35	40	45	50	55
螺钉直径 (mm)	5.0		*	*			
	5.5		*	*			
	6.0		*	*	*	*	
	6.5		*	*	*	*	*
	7.0	*	*	*			

Diameter

Polyaxial Reduction Cannulated Pedicle Screw (Uniplanar)

- 【长臂万向单芯椎弓根钉 (双线加长臂扁型) 】



		螺钉长度 (mm) length					
		30	35	40	45	50	55
螺钉直径 (mm)	5.0		*	*			
	5.5		*	*			
	6.0		*	*	*	*	
	6.5		*	*	*	*	*
	7.0	*	*	*			

Diameter

Monoaxial Reduction Cannulated Pedicle Screw

- 【长臂万向单芯椎弓根钉 (双线加长臂柱型) 】



		螺钉长度 (mm) length					
		30	35	40	45	50	55
螺钉直径 (mm)	5.0		*	*			
	5.5		*	*			
	6.0		*	*	*	*	
	6.5		*	*	*	*	*
	7.0	*	*	*			

Diameter

Polyaxial Reduction Cannulated Pedicle Screw (Double Nut)

- 【长臂万向单芯椎弓根钉 (双螺塞) 】

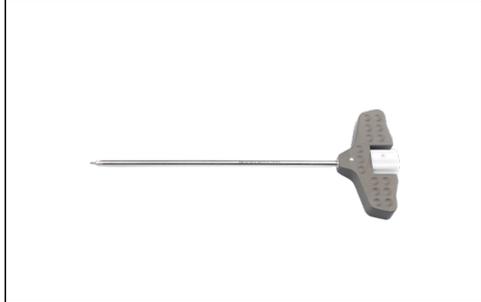


		螺钉长度 (mm) length						颜色 color
		30	35	40	45	50	55	
螺钉直径 (mm)	5.0		*	*				玫瑰紫
	5.5		*	*				浅绿色
	6.0		*	*	*	*		淡蓝色
	6.5		*	*	*	*	*	金黄
	7.0	*	*	*				蓝色

Diameter

器械信息

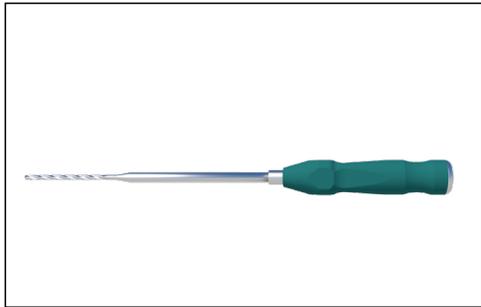
Instruments



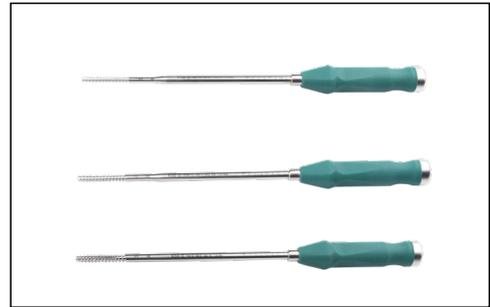
● 110-014
定位导向穿刺器 **puncture needle**



● 110-024
骨定位针 **pin**



● 110-035
骨钻 (空心) **cannulated drill**



● 110-443/444/445
丝攻 (空心) **cannulated tap**



● 110-263
扳手 **VSS screwdriver**



● 110-086
夹持器 **rod holder**



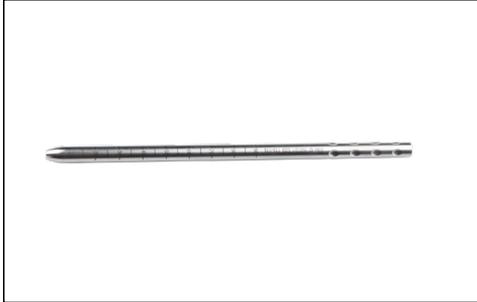
● 110-091
护套 **counter torque**



● 101-512
扭断器 (V) **break-off for long tail**

器械信息

Instruments



● 110-110
护套 (I) dilator



● 110-114
护套 (II) dilator



● 110-115
护套 (III) dilator



● 102-216
起子 outer nut driver



● 110-453
脊柱撑开器 distractor



● 110-455
椎体撑开器 distractor



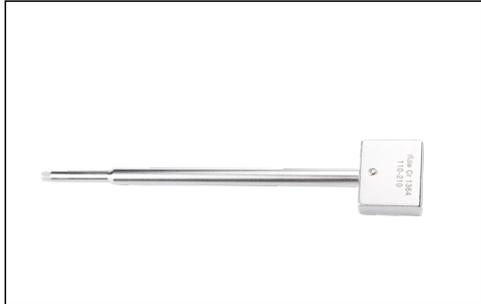
● 110-452
扳手 wrench for distractor



● 110-136
脊柱撑开器 (撑开杆) extend level for distractor

器械信息

Instruments



● 110-210
起子 (锁棒) **locker for rod holder**



● 110-430
起子 (预紧) **double nut holder**



● 110-420
骨锤 **hammer**



● 110-402
弯棒器 **rod bender**



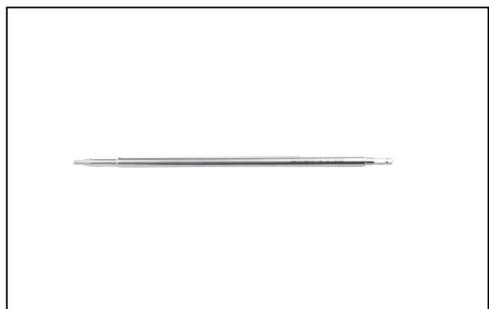
● 102-216
起子 (VAS) **outer nut driver**



● 110-119
护套 (VAS) **dilator**



● 110-382
快装手柄 (VAS) **10 N.m T Handle**



● 110-352
起子 (梅花/VAS) **inner nut driver**