

# Surgical technique 操作手册

## FAST 微型锁定钢板 FAST Mini LOC Plate



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## 前言 INTRODUCTION

本文只是对于产品的一般描述，不能仅仅以此为参考选择型号，或者进行手术操作。详情请参照完整标签。

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

## 适应症（接骨板系统） INDICATIONS (Fragment Plating System)

接骨板系统主要用于对非承重新鲜骨折碎片的稳定及固定术，也用于修复，关节融合术，手足，腕关节，踝关节，肱骨，肩胛骨，指掌骨，趾骨，骨盆，颌面骨等小骨重建手术。

The Fragment Plate System is intended for essentially non-load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis and craniomaxillofacial skeleton.

## 禁忌症 CONTRAINDICATIONS

如果出现以下症状，植入手术前必须进行测试。感染或潜在感染，败血症，骨 / 软组织量不足或骨 / 软组织质量不好。材料过敏，患者不愿意或者不能够遵从术后护理。

If any of the following are suspected, tests are to be performed prior to implantation. Active or latent infection. Sepsis. Insufficient quantity or quality of bone and/or soft tissue. Material sensitivity. Patients who are unwilling or incapable of following post operative care instructions.

## 警告和注意事项 WARNING AND PRECAUTIONS

尽管医生对于产品公司以及患者都很了解，但还是要向患者阐述本文所述的产品重要信息。患者必须了解植入物的使用方法，限制，可能发生的不良反应。医生必须警告患者，如果术后不遵从医嘱，可能会导致植入或治疗失败。

Although the surgeon is the learned intermediary between the company and the patient, the important information conveyed in this document should be conveyed to the patient. The patient must be cautioned about the use, limitations and possible adverse effects of these implants. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.

植入物必须是未使用过的。前期的压力可能会导致植入不成功。禁止划伤植入物表面或进行敲击。这些压力集中在一起会导致手术失败。

An implant must never be reused. Previous stresses may have created imperfections that can potentially lead to device failure. Protect implant appliances against scratching or nicking. Such stress concentration can lead to failure.

骨科手术器械没有固定的使用寿命，所有反复使用的器械都要反复承受来自各种压力，包括骨接触，撞击，常规清洁，消毒等。在使用前必须自己检查，以保证其性能完好。划痕或凹痕会导致断裂。刀刃变钝会导致功能减退。一旦发现器械损坏要立即更换，防止潜在的危险发生，比如金属碎片遗落在手术部位。在清理碎屑，组织以及骨碎片的时候要非常小心，因为他们很容易粘附到器械上。一般器械包括：衬垫 / 托盘以及容器。大部分器械都是为特定的植入物设计的，因此医生和其他医护人员充分了解各种植入物相对应的手术器械及操作技术就显得尤为重要。

Orthopaedic instrumentation does not have an indefinite functional life. All re-usable instruments are subjected to repeated stresses related to bone contact, impaction, routine cleaning and sterilization processes. Instruments should be carefully inspected before each use to ensure that they are fully functional. Scratches or dents can result in breakage. Dullness of cutting edges can result in poor functionality. Damaged instruments should be replaced to prevent potential patient injury such as release of metal fragments into the surgical site. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. Most instrument systems include inserts/trays and a container(s). Many instruments are intended for use with a specific implant system. It is essential that the surgeon and operating theatre staff are fully familiar with the appropriate surgical technique for the instruments and associated implant

## 不良反应

### ADVERSE EFFECTS

以下就是植入物可能发生的不良反应：由于松动可能导致的植入失败，以及 / 或者松板，压力过大，过度运动，超重负荷尤其是持续承受超重负荷引起的延迟愈合，骨不连，或者不完全愈合。

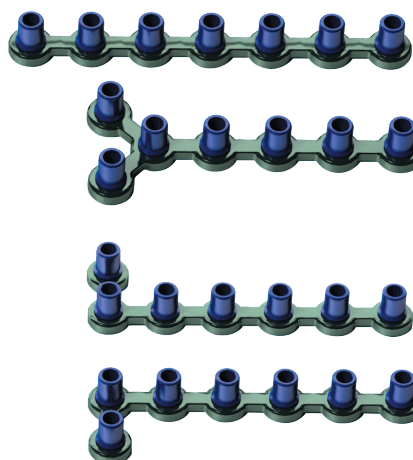
The following are possible adverse effects of these implants: potential for these devices failing as a result of loose fixation and/or loosening, stress, excessive activity, load bearing particularly when the implants experience increased loads due to a delayed union, nonunion, or incomplete healing.

## 植入物

### IMPLANTS



FAST 微型锁定接骨板（高强度型）  
FAST Mini LOC plate (High-strength)



FAST 微型锁定接骨板（柔韧型）  
FAST Mini LOC plate (High-flexibility)

### 高柔韧型 High Flex Plates:

三维折弯（矢状位，轴向以及冠状位），可适应各种复杂的骨骼面。

3-dimensional contouring (Sagittal, Axial, and Coronal) designed to help match the most complex bone surfaces.

专属的 FAST 导向器技术可以缩短手术时间，且在折弯的时候保护锁定孔。

High Flex Plates: 3-dimensional contouring (Sagittal, Axial, and Coronal) designed to help match the most complex bone surfaces.

锁定螺钉是结构稳定牢固的保障

Locking screw technology provides a strong and stable construct

当然也可以选择非锁定螺钉

Non-locking screw options also available

### 高强度型 High Strength Plates:

可以二维折弯（轴向和冠状位），强度比高柔韧型的大。

2-dimensional contouring (Axial and Coronal) provide increased plate stiffness over the High Flex Plates.

#### Fully Threaded Screws (Locking)



10, 12, 14, 16, 18, 20, 22, 24, 26, 28 and 30 mm

#### Fully Threaded Screws (Non-Locking)



10, 12, 14, 16, 18, 20, 22, 24, 26, 28 and 30 mm

## 工具 INSTRUMENTS



15057-101  
骨钻 (Ø2.0)  
Drill (Ø2.0)



15069-001  
导向器  
Drill Sleeve



15069-002  
钢板把持器  
Plate Holding Forceps



15069-003/103  
钢板折弯器 (左 / 右)  
Plate Bending Wrench (L / R)



15007-107  
微型骨撬  
Mini Retractor



15007-006  
微型测深尺  
Mini Depth Gauge



15007-020/203  
快换手柄 / 四方起子  
Screw Driver (Square)



15069-000  
微型锁定器械盒  
Instrument Case



## 操作技术 OPERATIVE TECHNIQUE

After making the incision and dissecting the surgical site, debride the fracture as needed. A K-wire can be used for temporary fixation of the fracture. Hold the plate firmly and drill through one of the holes using the 2.0 mm drill bit (Figure 1).

Measure the depth using the F.A.S.T. Bone Depth Gauge (FBDG) (Figure 2).

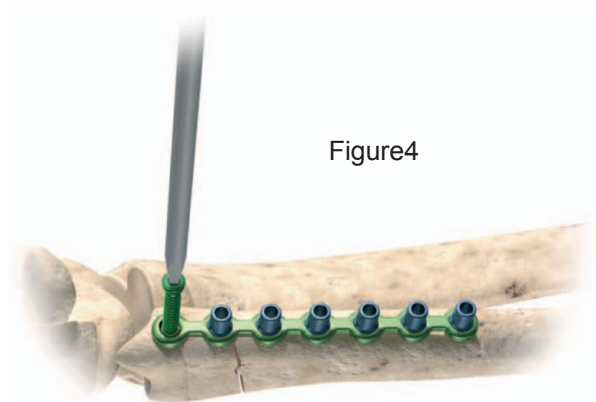
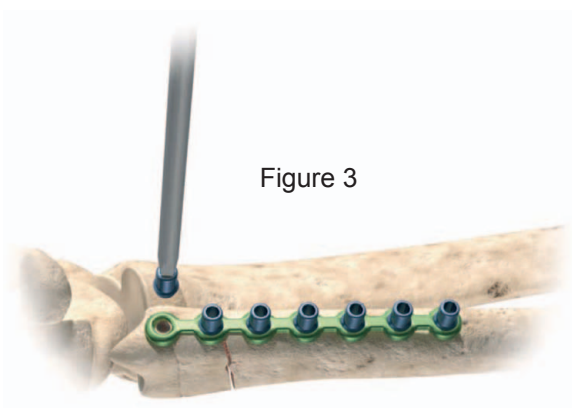
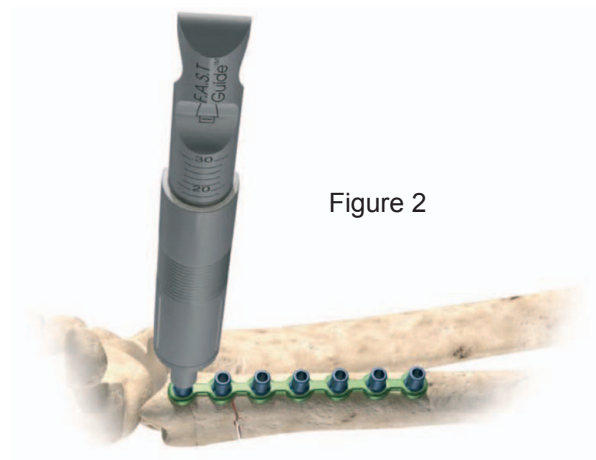
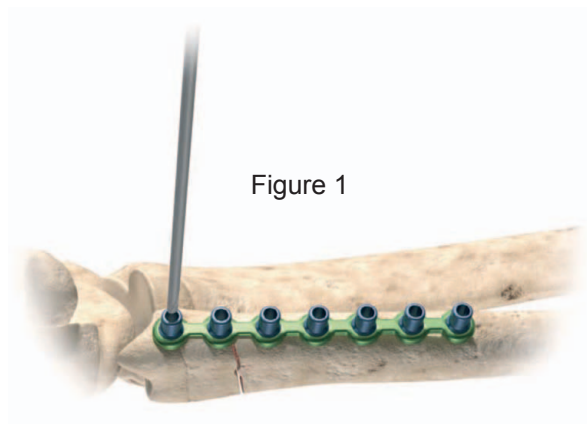
Remove the F.A.S.T. Guide with the F.A.S.T. Peg Driver and discard (Figure 3).

Using the F.A.S.T. Peg Driver, apply the appropriate length locking (FP series) or non-locking (SP series) screws to secure the plate to the bone. Reduce the fracture (Figure 4).

Once the plate is initially fastened to the bone, the plate may be contoured using the benders.

Note: The plate may be pre-bent initially to allow insertion into a concavity.

It is important not to drill through more than one F.A.S.T. Guide before attaching the screw in the plate. Drill one hole, remove the F.A.S.T. Guide and apply the appropriate screw before moving to the next hole. This will help guarantee that each screw locks or seats firmly in the plate.





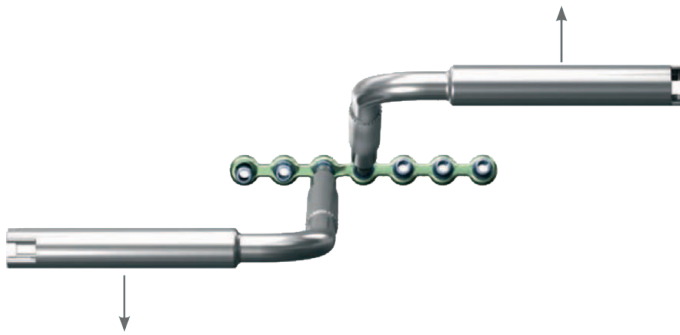


Figure 5

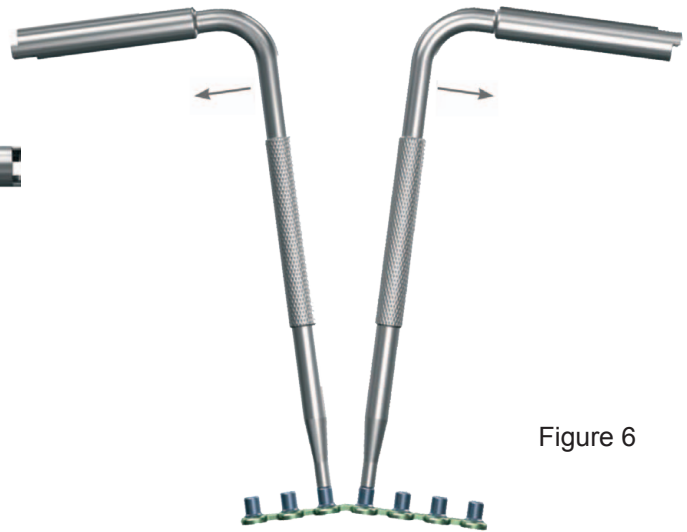


Figure 6

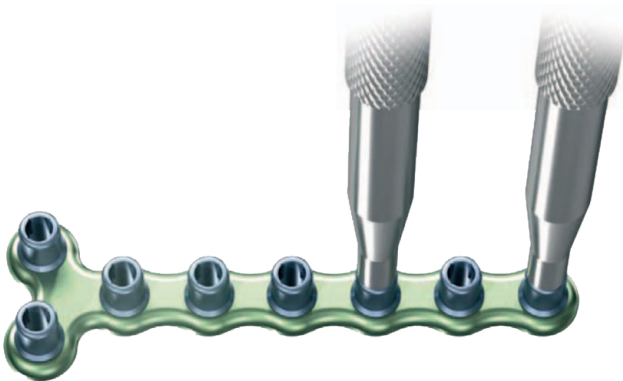


Figure 7



Figure 8

### Axial and Coronal Bends

Insert the pin end of each of the benders into the F.A.S.T. Guide. Apply force to the benders in opposite directions (Figures 5 and 6). **Care should be taken not to over-bend the plate.**

For the High Strength Plates, it is recommended to leave one node free between bender locations (Figure 7).

**Sagittal / Planar Bends (High Flex Plates only)** For sagittal bends, place the cylindrical end of the benders over the F.A.S.T. Guide ensuring the handles are pointed in opposite directions and are parallel with the plate. Pull the handles inward (Figure 8).

Drill through the F.A.S.T. Guide, remove the F.A.S.T. Guide and insert the appropriate length screw.

Figure 9

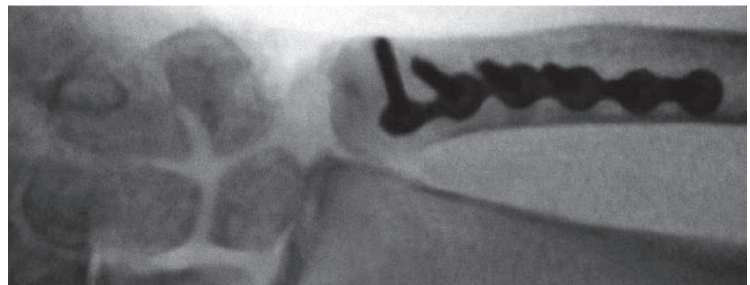
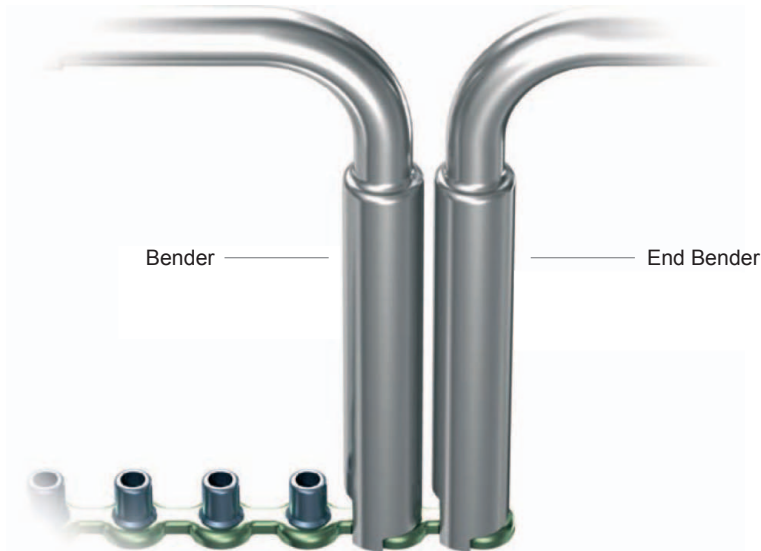


Figure 10

When bending the end node of plate, the End Bender must be placed over the F.A.S.T. Guide in the end hole (Figure 9).

Use fluoroscopy to confirm reduction and placement. Close the wound with standard technique (Figure 10).

**Trimming of Fragment Plates High Strength Plates**, a pair of cutters is necessary and should be used before implantation.

**High Flex Plates**, a pair of cutters may be used, however, the benders can be used to bend the node back and forth until it breaks. The cut edges should be smoothed with a bone rasp to avoid soft tissue irritation.

## 产品信息 PRODUCT ORDERING INFORMATION

### 工具 INSTRUMENTS

器械编号 Product No.	器械名称	Product Name	数量 Qty
15057-101	骨钻 (Ø2.0)	Drill (Ø2.0)	2
15069-001	导向器	Drill Sleeve	1
15069-002	钢板把持器	Plate Holding Forceps	1
15069-003/103	钢板折弯器 (左 / 右)	Plate Bending Wrench (L/ R)	各 1
15007-107	微型骨撬	Mini Retractor	1
15007-006	微型测深尺	Mini Depth Gauge	1
15007-203	四方起子	Screw Driver (Square)	2
15007-020	快换手柄	Quick Coupling	1
15069-000	器械盒	Instrument Case	1



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