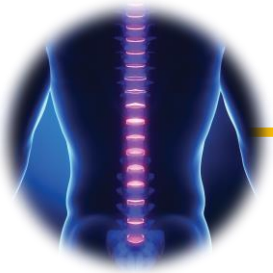

# SURGICAL TECHNIQUE

PRECISION SPINE

# FACET

## SCREW SYSTEM

PRECISION SPINE®

*Discover the Difference*

Made in the USA

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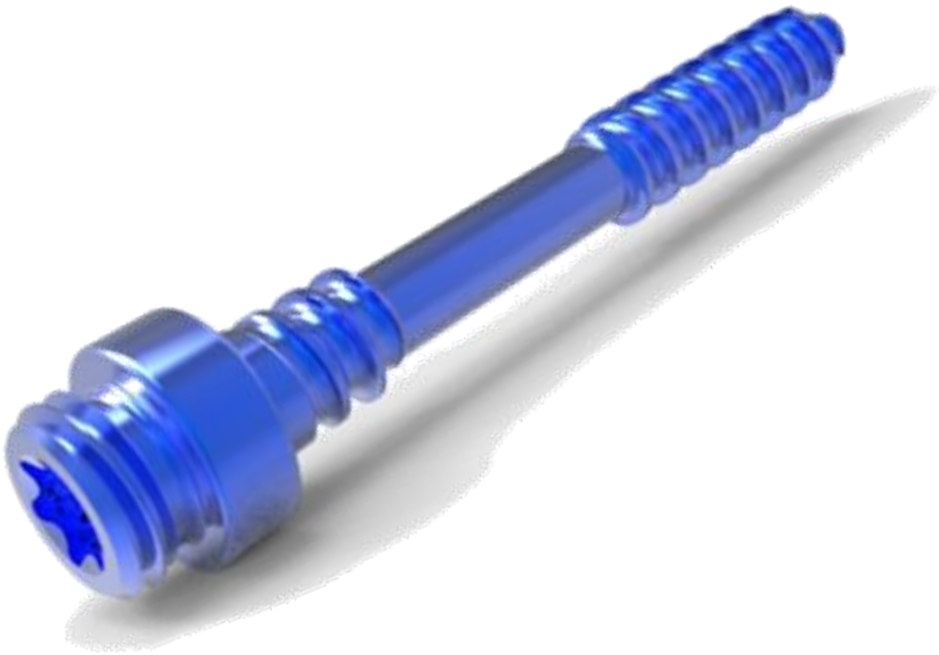
# FACET SCREW SYSTEM OVERVIEW

## DESCRIPTION

The Facet Screw System is composed of Facet Screws in 2 diameter sizes and 6 lengths. The implant with the associated instruments, is used to provide stabilization to the spine with minimal invasion; and offered as an alternative to pedicle screw fixation. All components are made from medical grade titanium or titanium alloy described by standard ASTM F 136. The products are supplied clean and 'Non-Sterile'.



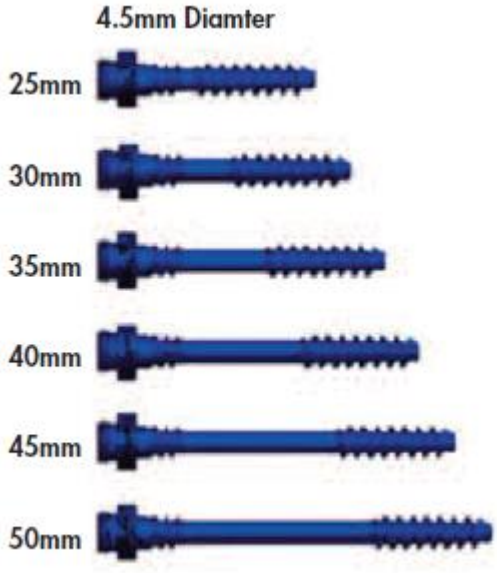
## INDICATIONS

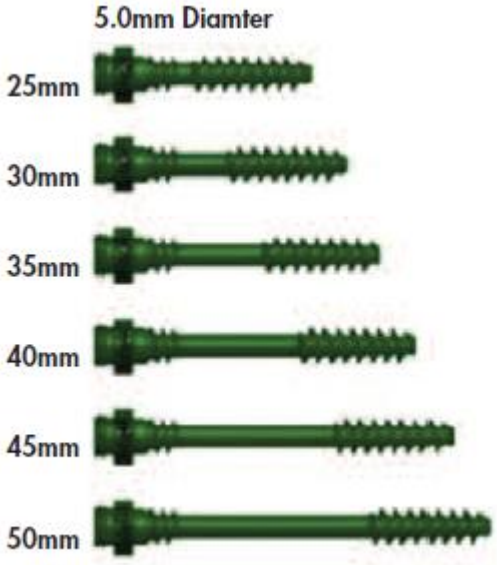
The Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment, with or without bone graft, at single or multiple spinal levels, of any or all of the following spinal levels L1 to S1 (inclusive), of Spondylolisthesis; Spondylolysis; Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD), as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies, and/or degenerative disease of the facets with instability, Fracture.

Please refer to package insert (LBL-IFU-012) for complete system description, indications and warnings.

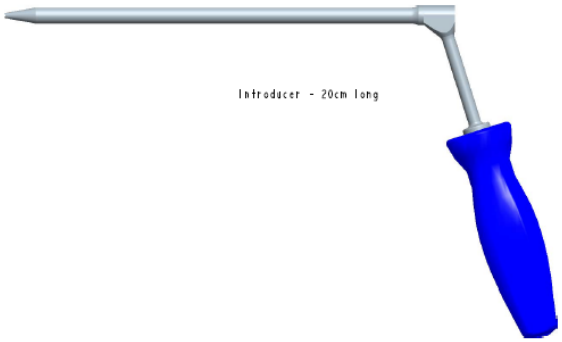
## SPECIFICATIONS

- 4.5mm & 5mm Diameters
- 25, 30, 35, 40, 45 and 50mm Lengths
- Cannulated & Non Cannulated options

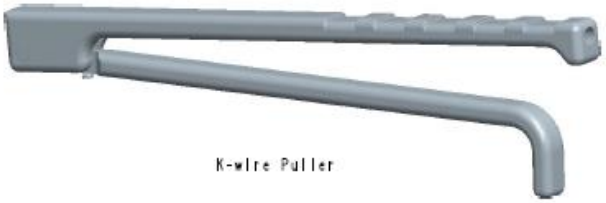


# INSTRUMENTS

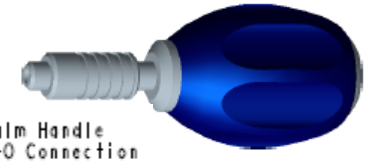














| PART NUMBER | DESCRIPTION |
|---|---|
| 35-9007 | K-Wire, 1.4mm diameter x 23.5" long, trocar tip |
| 35-9011 | K-Wire, 1.4mm diameter x 23.5" long, partially threaded tip |
| 35-9012 | Introducer with handle |
| 35-9013 | Handle, Palm, Cannulated, AO connection |
| 35-9014-8 | 8mm Dilator |
| 35-9014-12 | 12mm Dilator |
| 35-9015 | Drill, AO connection |
| 35-9016 | Tap, AO connection |
| 35-9017 | Screw Inserter, AO connection |
| 09-9027 | K-Wire Puller |

# FACET SCREW SIZES

| PART NUMBER | DESCRIPTION |
|---|---|
| 35-S4525-K | 4.5mm x 25mm Long Cannulated Screw |
| 35-S4530-K | 4.5mm x 30mm Long Cannulated Screw |
| 35-S4535-K | 4.5mm x 35mm Long Cannulated Screw |
| 35-S4540-K | 4.5mm x 40mm Long Cannulated Screw |
| 35-S4545-K | 4.5mm x 45mm Long Cannulated Screw |
| 35-S4550-K | 4.5mm x 50mm Long Cannulated Screw |
| 35-S5025-K | 5.0mm x 25mm Long Cannulated Screw |
| 35-S5030-K | 5.0mm x 30mm Long Cannulated Screw |
| 35-S5035-K | 5.0mm x 35mm Long Cannulated Screw |
| 35-S5040-K | 5.0mm x 40mm Long Cannulated Screw |
| 35-S5045-K | 5.0mm x 45mm Long Cannulated Screw |
| 35-S5050-K | 5.0mm x 50mm Long Cannulated Screw |
| 35-S4525-X | 4.5mm x 25mm Long Non-Cannulated Screw |
| 35-S4530-X | 4.5mm x 30mm Long Non-Cannulated Screw |
| 35-S4535-X | 4.5mm x 35mm Long Non-Cannulated Screw |
| 35-S4540-X | 4.5mm x 40mm Long Non-Cannulated Screw |
| 35-S4545-X | 4.5mm x 45mm Long Non-Cannulated Screw |
| 35-S4550-X | 4.5mm x 50mm Long Non-Cannulated Screw |
| 35-S5025-X | 5.0mm x 25mm Long Non-Cannulated Screw |
| 35-S5030-X | 5.0mm x 30mm Long Non-Cannulated Screw |
| 35-S5035-X | 5.0mm x 35mm Long Non-Cannulated Screw |
| 35-S5040-X | 5.0mm x 40mm Long Non-Cannulated Screw |
| 35-S5045-X | 5.0mm x 45mm Long Non-Cannulated Screw |
| 35-S5050-X | 5.0mm x 50mm Long Non-Cannulated Screw |

# SURGICAL TECHNIQUE

## 1 INSERTION OF INTRODUCER & K-WIRE

The Cannulated Introducer (35-9012) is inserted into the facet to be instrumented (Fig. 1). The trocar tip K-Wire (35-9007) or the partially threaded tip (35-9011) is then inserted into the Cannulated Introducer (Fig. 2). The K-Wire has depth markings for screw lengths of 25-50mm with the wire extending 10mm past the end of screw. When the first mark on the K-Wire is flush with the face of the introducer the depth of the K-Wire is 35mm into the facet (25mm screw length + 10mm extending past the tip of the screw). The additional 10mm depth is needed in order to retain wire contact with bone during drilling and tapping otherwise the wire may not be retained and become unattached.

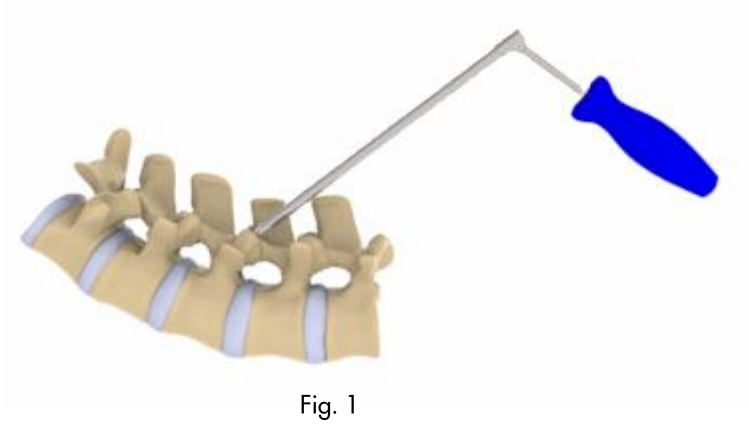


Fig. 1

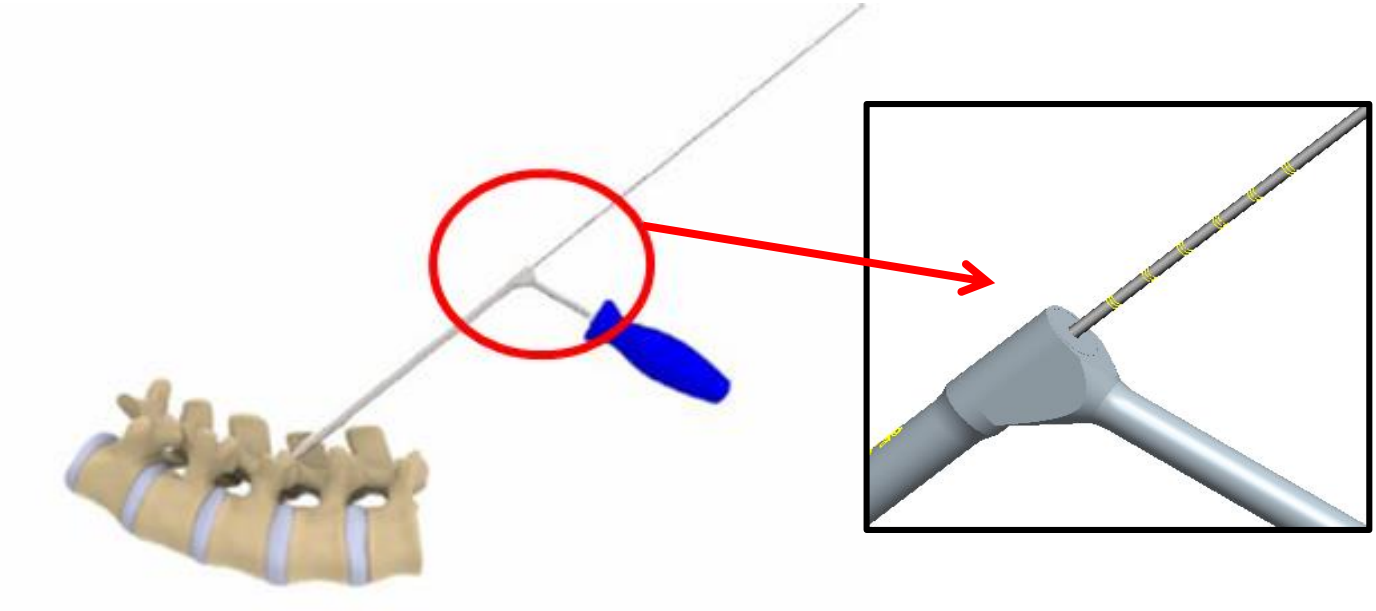


Fig. 2

## 2 K-WIRE POSITIONING

Once the K-Wire has been securely placed, the Cannulated Introducer can be removed, leaving the K-Wire in place (Fig. 3). The K-Wire is used to guide the instrumentation and implant.

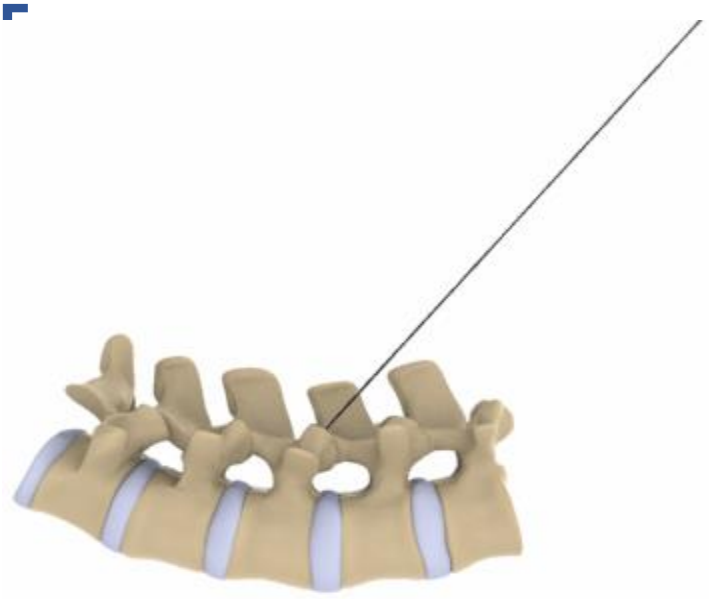


Fig. 3

## 3 DILATOR POSITIONING

The 8mm Dilator (35-9014-8) is placed over the K-Wire and advanced until it interfaces with the Facet (Fig. 4). The 12mm Dilator (35-9014-12) is then placed over the 8mm Dilator (Fig. 5). Once the 12mm Dilator is in place, the 8mm Dilator can be removed.

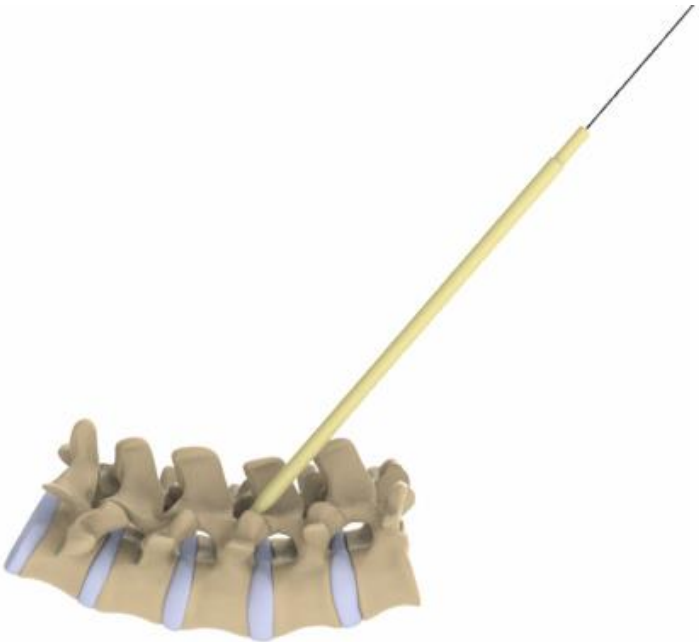


Fig. 4

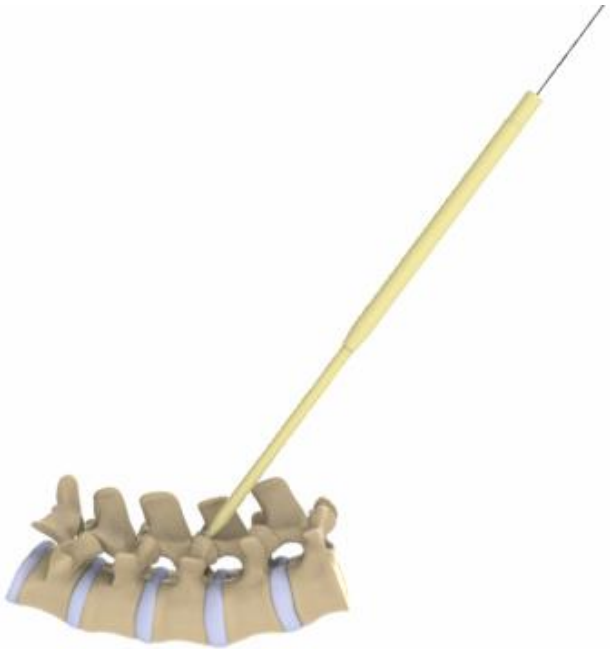


Fig. 5

# SURGICAL TECHNIQUE

## 4 FACET PREPARATION

Attach the Palm Ratcheting Handle (35-9013) onto the Drill (35-9015). The Drill is then advanced into the facet to the desired depth which corresponds to the length of the Bone Screw that will be introduced (Fig. 6). Remove the Drill.

Attach the Palm Ratcheting Handle (35-9013) onto the Tap (35-9016). The Tap (35-9016) is then advanced into the facet to the desired depth (Fig. 7). Remove the Tap.

Fig. 6

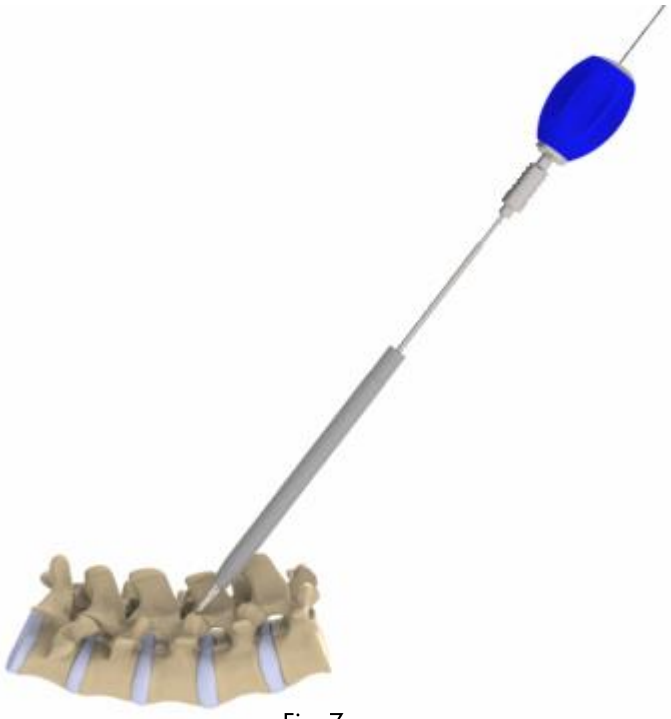


Fig. 7

# SURGICAL TECHNIQUE

## 5 SCREW INSERTION

Attach the Palm Ratcheting Handle (35-9013) onto the Facet Screw Inserter (35-9017). Load the selected cannulated or non-cannulated Facet Screw onto the inserter. The Cannulated Facet Screw is then advanced into the facet to the desired depth (Fig. 8). (If the Non-Cannulated Facet Screw is being inserted, remove the K-Wire first and then advance the screw.) Detach the Facet Screw Inserter and remove. Remove the K-Wire with the K-Wire Puller (09-9027).

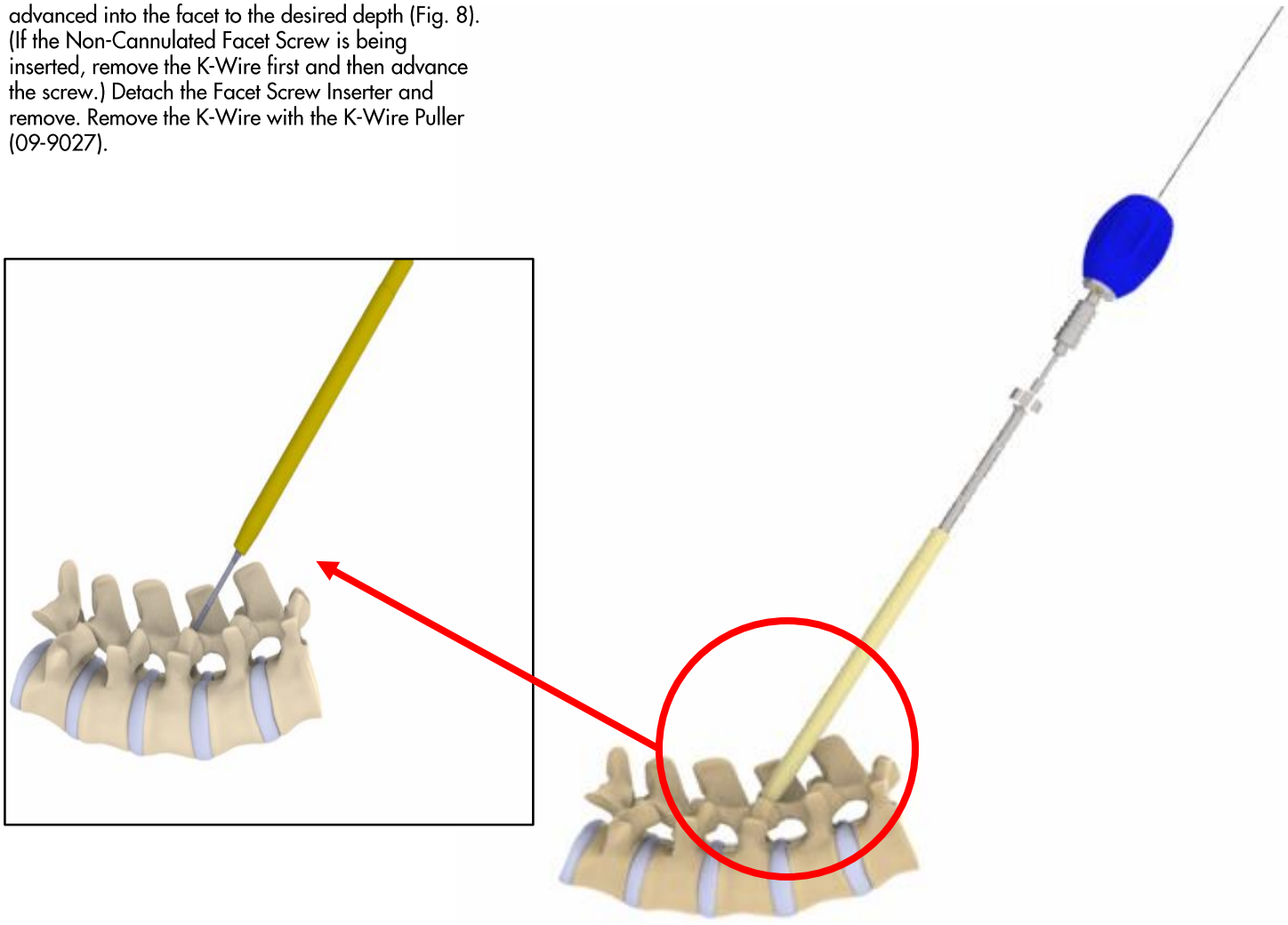
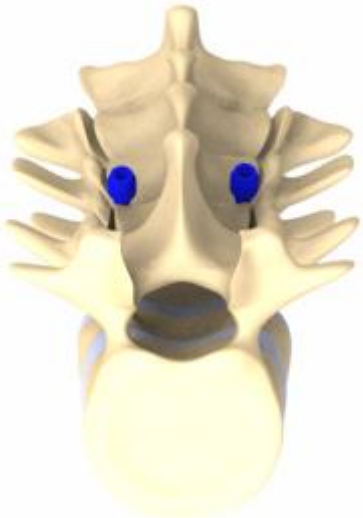


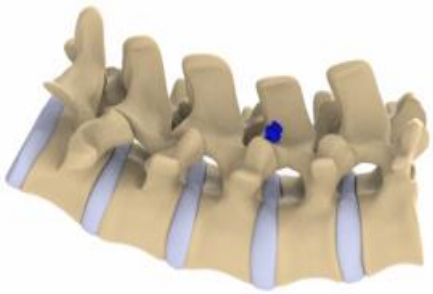
Fig. 8

## 6 FACET SCREW POSITIONING

Verify the final Facet Screw position in the A/P and Lateral directions with the help of an intraoperative x-ray.



A/P



Lateral

## 7 FACET SCREW REMOVAL

If the removal of the Facet Screw is desired, the Facet Screw should be exposed and prepared for removal. Attach the Palm Ratcheting Handle (35-9013) onto the Facet Screw Inserter (35-9017). Engage the Facet Screw Inserter with the Facet Screw (Fig. 9). Position the Inserter dial in the counter clockwise setting and remove the Facet Screw.

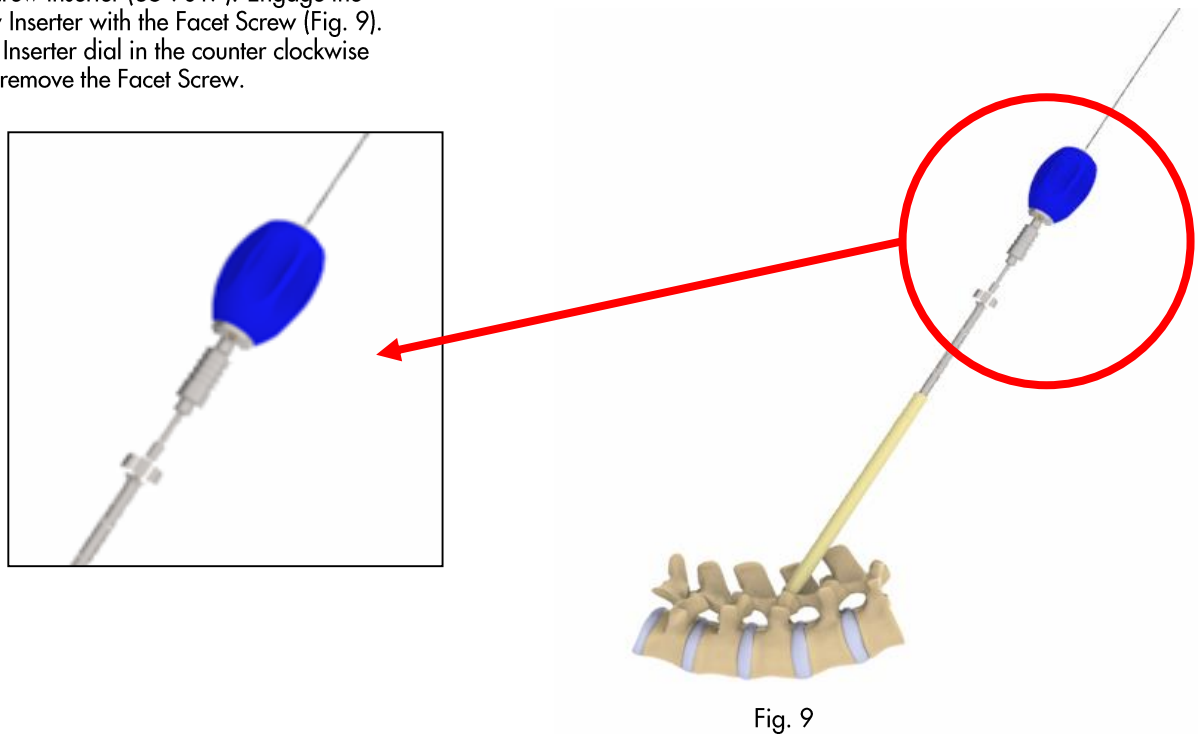


Fig. 9

# INDICATIONS

## CONTRAINDICATIONS

The Facet Screw System contraindications include, but are not limited to:

1. Sepsis, local or systemic
2. Osteomyelitis at the surgical site
3. Absence or destruction of any portion of the facet joint, or procedures which will require removal of any portion of the facet joint
4. Known or suspected sensitivity to implant materials
5. Significant metabolic bone disease (e.g. osteoporosis or osteomalacia) to a degree that posterior spinal instrumentation is contraindicated
6. Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

## POTENTIAL ADVERSE EFFECTS

The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects.

The following are potential adverse effects, but not limited to:

1. Infection of soft tissue and/or bone (osteomyelitis); fever
2. Implant loosening
3. Bending or breakage of the device
4. Incomplete relief of symptoms
5. Incomplete fusion, delayed union or non-union
6. Fracture of the pedicle or bone of the facet joint
7. Soft tissue injury
8. Edema
9. Skin irritation, wound dehiscence
10. Dural injury, with or without CSF leakage
11. Neurologic injury, transient or permanent
12. Pain and loss of function
13. Hemorrhage, hematoma
14. Device migration

## WARNINGS

The following are warnings for this device.

1. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
2. Single use only.
3. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. AN IMPLANT SHOULD NEVER BE RE-USED. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
4. Non-sterile; the screws and instruments are sold non-sterile, and therefore must be sterilized before use.
5. The components of this system should not be used with components of any other system or manufacturer.
6. Titanium components should not be used with stainless steel components within the same system.

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