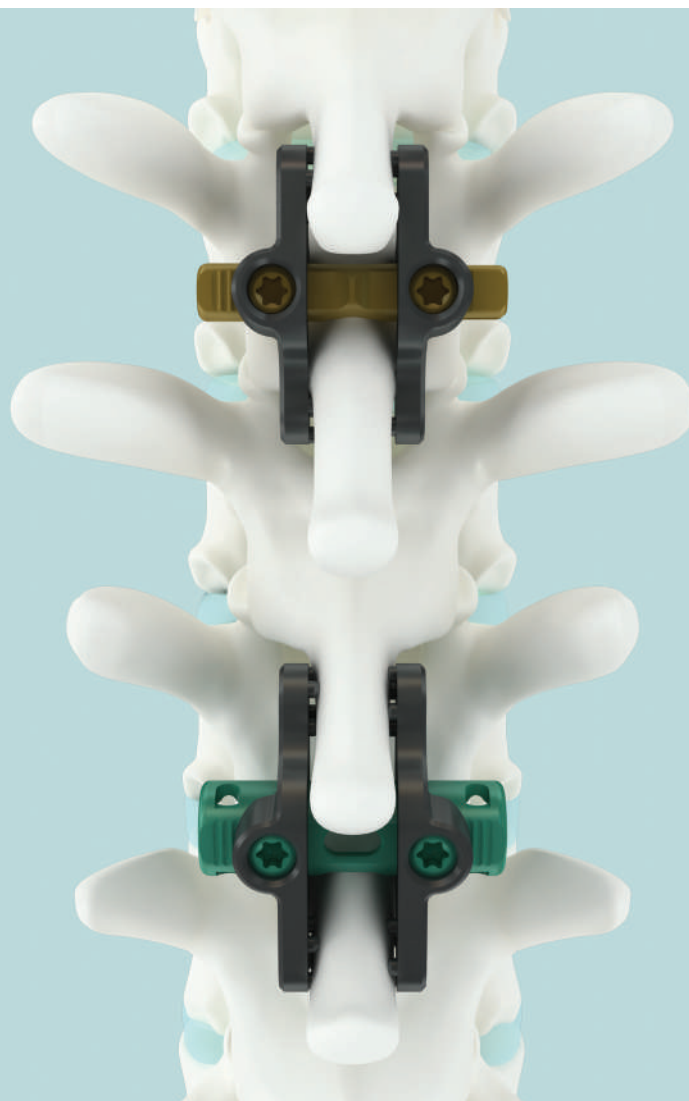
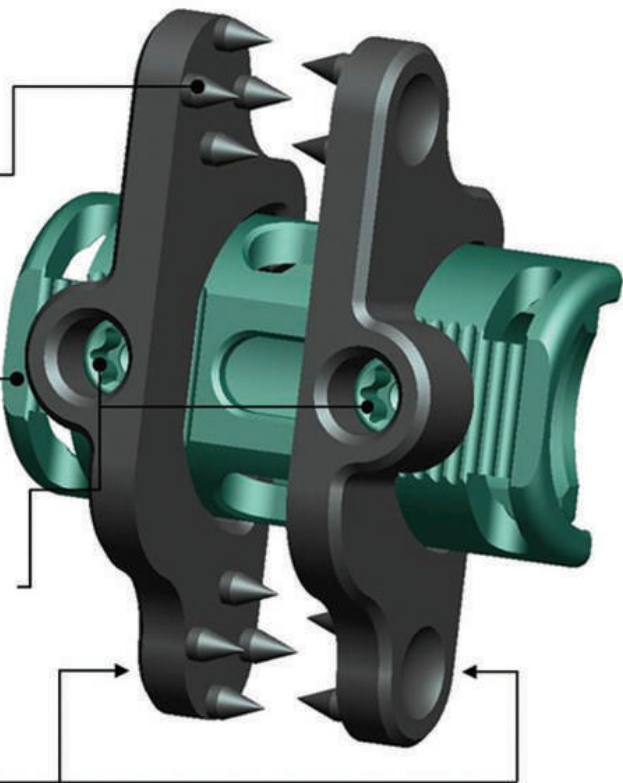


Benefix™

Interspinous Fixation System

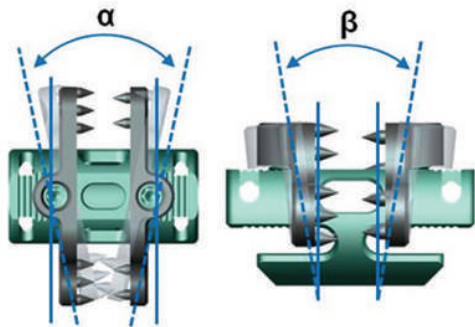


- **Aggressive fixation spikes**
increase stability and security
- **Unique central barrel design**
provides load-sharing support and bone graft containment to facilitate fusion
- **Dual interlocking hub with dual set screws**
provide an exceptionally rigid design
- **Telescoping plates**
provide the ability to compressor distract spinous processes



- **Multiple implant lengths and implant capability**
accommodate a variety of patient anatomies and provide excellent fit and optimal fixation

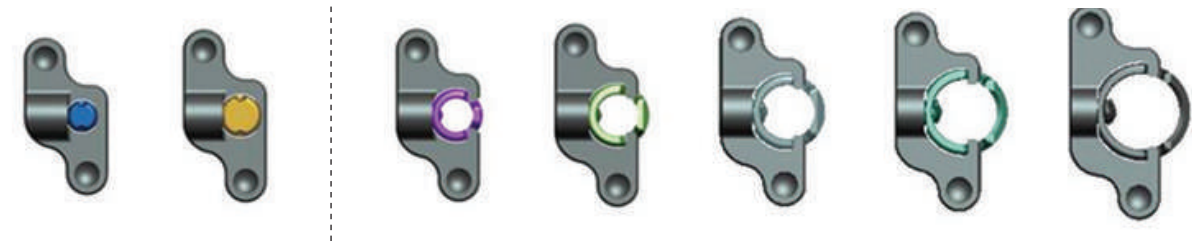
ROM (Range of Motion)		
Barrel Dia.	Frontal(AP) View(α)	Transverse(β)
6mm	19°	22°
8mm	18°	20°
10mm	17°	20°
12mm	17°	20°
14mm	16°	18°
16mm	16°	18°
18mm	15°	17°



- **Color coded barrel for closed and open types**

Closed Type (Barrel : ϕ 6, 8mm)

Open Type (Barrel : ϕ 10, 12, 14, 16, 18mm)



Preparation and Exposure

Position the patient in a prone position for optimal exposure on the operating table. Identify the appropriate spinous processes by using manual palpitation and imaging techniques. Make a midline incision above the spinous processes at the operative level.

Elevate all musculature and adjoining soft tissues from the spinous processes and lamina to be joined.

When fusing through the spinous processes, a burr, rongeur or rasp may be used to remove the interspinous ligament. The interspinous ligament may optionally be incised / dilated without complete removal.

Caution

Care must be taken throughout the procedure that no damage is caused to the dura or spinous process.



Fig. 1

Instrument	
IS5204	Initial Dilator – 4mm
IS5206	Initial Dilator – 6mm
IS6010	Quick Connector Handle

If the interspinous ligament has been left intact, use the **Initial Dilator**, after attached to **Quick Connector Handle** (Fig. 1), to punch a hole through the anterior region of the interspinous ligament. Make sure that the **Initial Dilator** is placed at midpoint between the adjacent spinous processes (Fig. 2).

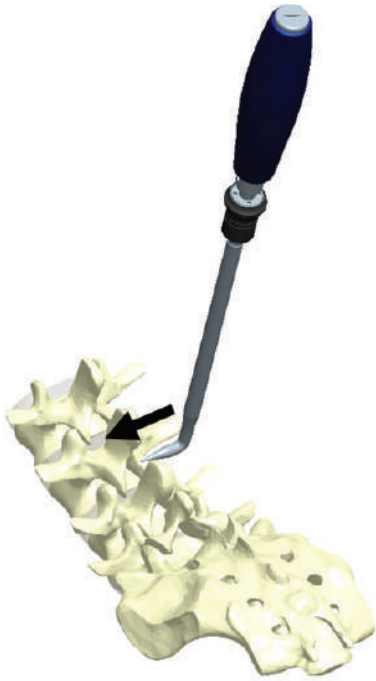


Fig. 2

Distraction and Sizing

Two techniques are available for distraction of the interspinous spaces and measuring the appropriate size of the implants.

Option 1. With Distractor only

Instrument	
IS2010	Distractor

Use the **Distractor** to dilate adjacent spinous processes, with the ratcheting bar up to ensure tactile feedback during distraction (Fig. 3).

After dropping down the racheting bar in the proper tension, read the scale markings on the racheting bar of the **Distractor** to determine appropriate size of implant (Fig. 4).

Caution
Do not overdistract spinous processes. Overdistraction could damage the spinous process.

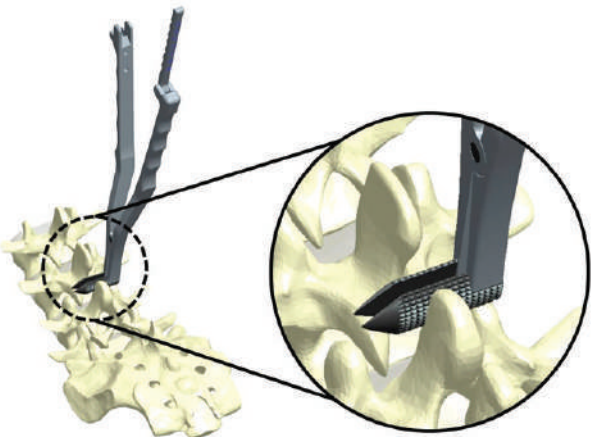


Fig. 3

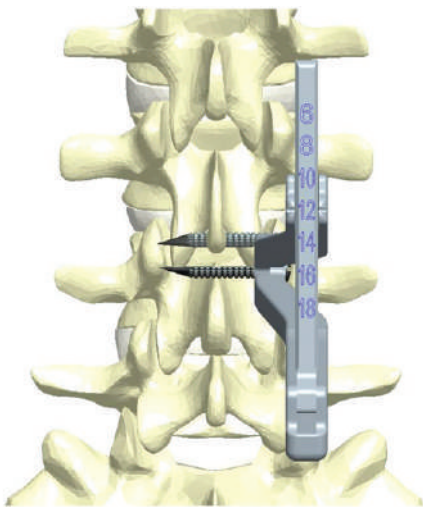
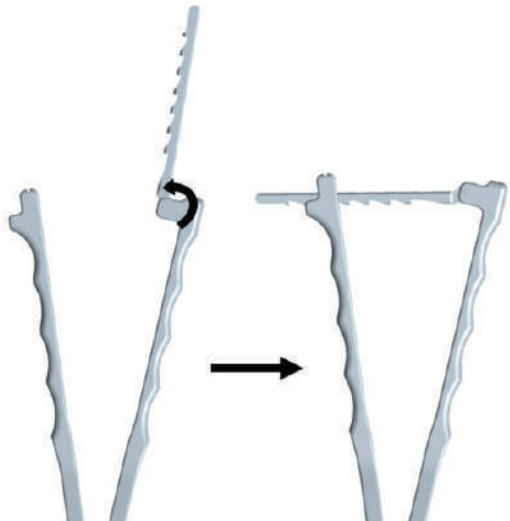


Fig. 4

Option 2. With Dilator and Guide Sleeve

Instrument	
S2010	Distractor
IS5006 ~ IS5018	Dilator, size D6 ~ D18
IS5106 ~ IS5118	Guide Sleeve, size D6 ~ D18
IS6010	Quick Connector Handle

After determining the correct size of **Dilator** by using the **Distractor**, insert the **Dilator** being attached to **Quick Connector Handle** into the interspinous space and rotate the instrument cephalad and caudad to prepare the fusion site (Fig. 5).

Remove the **Dilator** from the interspinous space and slide the instrument into the **Guide Sleeve** (Fig. 6). Insert both instruments into the interspinous space, while holding the **Guide Sleeve** in place (Fig. 7).

Caution
Do not damage the spinous processes.

Remove the **Dilator** only while keeping the **Guide Sleeve** in the interspinous space to create a cannular for easy insertion for the implant (Fig. 8).

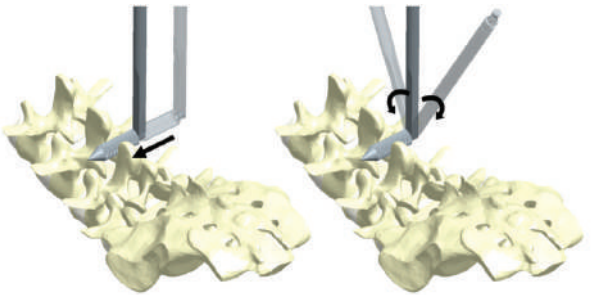


Fig. 5

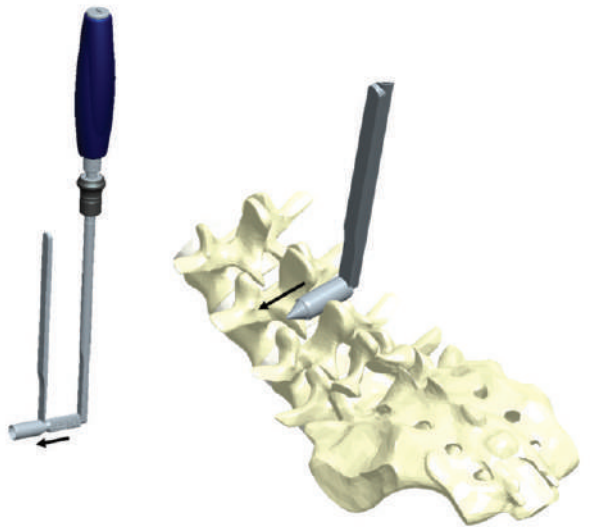


Fig. 6

Fig. 7

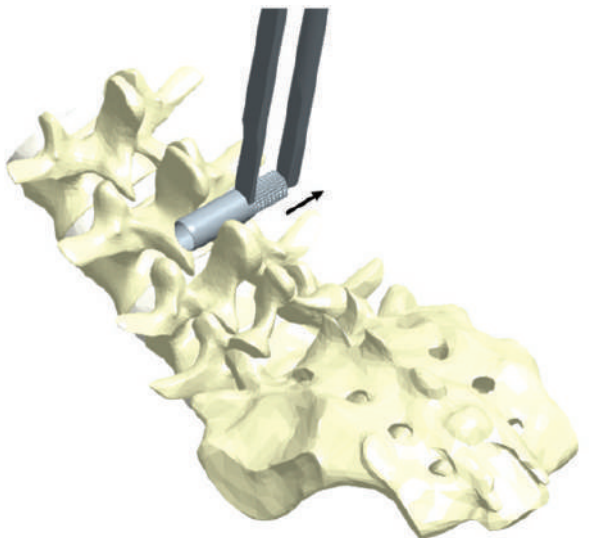


Fig. 8

Implant Attachment

Instrument	
IS1010	Holder for barrel 6~8mm
IS1020	Holder for barrel 10~18mm
IS3010	Set Screw Driver

Insert the barrel to the plate only one side and use the **Set Screw Driver** to loosely tighten the set screw to the top side of the plate (Fig. 9).

Attach the barrel to the corresponding holder as follows :

A. Holder for barrel 6~8mm

Align the protruded portion on the **Holder** tip into the divots on the barrel. Gently squeeze the **Holder** until the implant and instrument are fully engaged (Fig. 10).

B. Holder for barrel 10~18mm

Align the pin on the lower shaft tip into the cannula barrel and slide down the upper shaft by squeezing the **Holder** with ratchet down. Ensure that the pins on the upper shaft tip should be positioned inside the slots on the top aspect of the barrel (Fig. 11).



Fig. 9

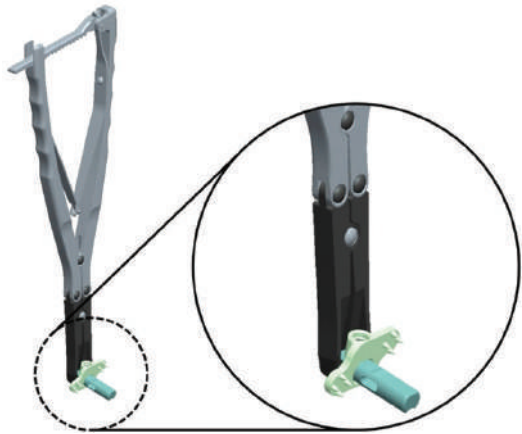


Fig. 10

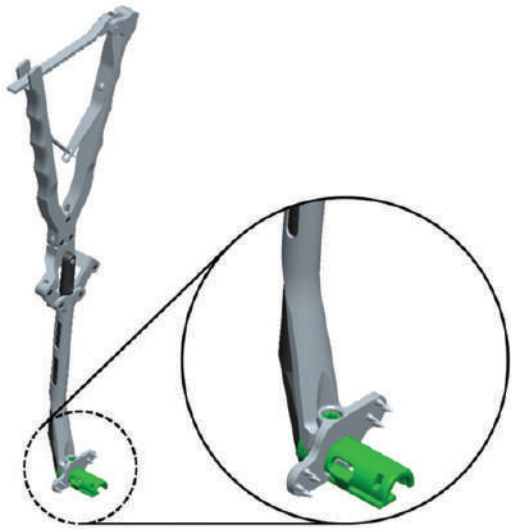


Fig. 11

Implant Insertion

Two techniques are available for placement of the barrel and the plate into the interspinous space.

Option 1. Without Guide Sleeve

Instrument	
IS1010	Holder for barrel 6~8mm
IS1020	Holder for barrel 10~18mm

Begin inserting the plate of the implant rotated approximately 45° to 90° in the sagittal plane (Fig. 12).

In the orientation, the end of barrel, which is not pre-fixed with the plate, can be guided into the space. Rotate the implant back into final position while simultaneously pushing the plate body into the interspinous space.

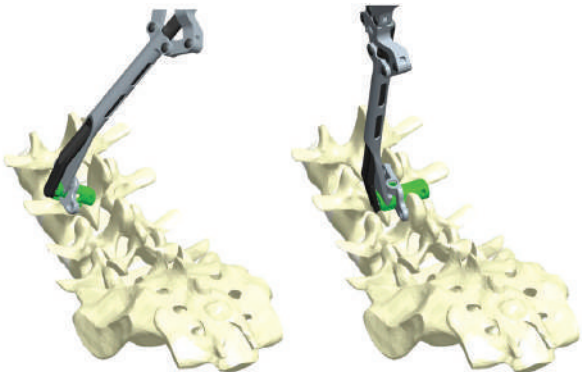


Fig. 12

Option 2. With GUIDE SLEEVE

Instrument	
IS1010	Holder for barrel 6~8mm
IS1020	Holder for barrel 10~18mm
IS5106 ~ IS5118	Guide Sleeve, size D6 ~ D18

From the opposite side of the cannula, introduce the barrel with the plate. Rotate the implant into its final position while simultaneously removing the **Guide Sleeve** from the interspinous space (Fig. 13).

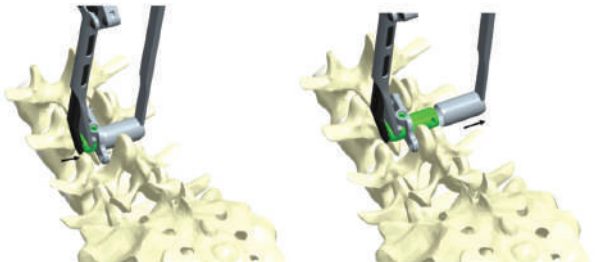


Fig. 13

Final Attachment

Instrument	
IS1030	Plate Holder

Hold the other corresponding plate with the **Plate Holder** by placing the peg side of the holder into the set screw while the curved portion surrounds the set screw housing (Fig. 14).

Slide the implant over the barrel until it comes in contact with the spinous processes (Fig. 15).

Ensure that the set screws on both plates are in the position such that the plates can slide together.

It is important that the implant is placed as far as anteriorly as possible, and that the plate does not protude above the lumbodorsal fascia. Confirm placment with fluoroscopy or visual inspection.

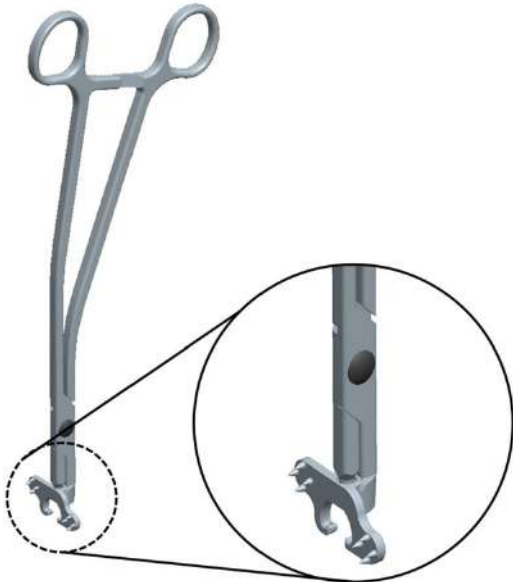


Fig. 14

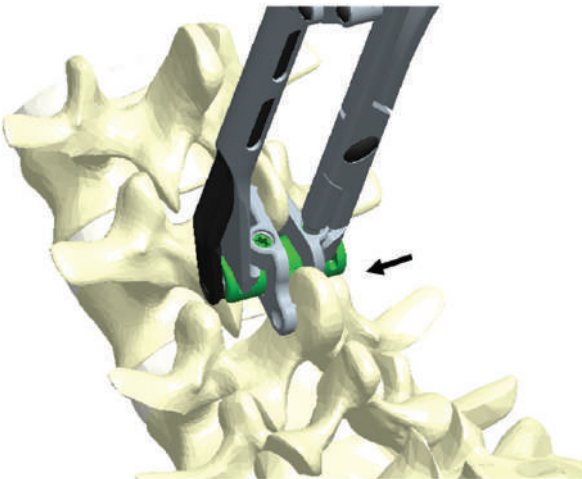


Fig. 15

Compression

Instrument	
IS2020	Compressor

After confirming desired placement, align the hemispherical tips of the **Compressor** into the lateral divots in each plate. Insert the second **Compressor** onto the opposite end of the plate (Fig. 16).

Remove the **Holder** from the plate by releasing the racheting engagement. Also, remove the Plate Holder in the same manner.

Clamp the plates to the spinous processes by squeezing both **Compressors** simultaneously or alternate back and forth. Ensure the spikes of the plates are firmly seated into the bone. Confirm that each grip has engaged the spinous processes by gently attempting to move the implant (Fig. 17).

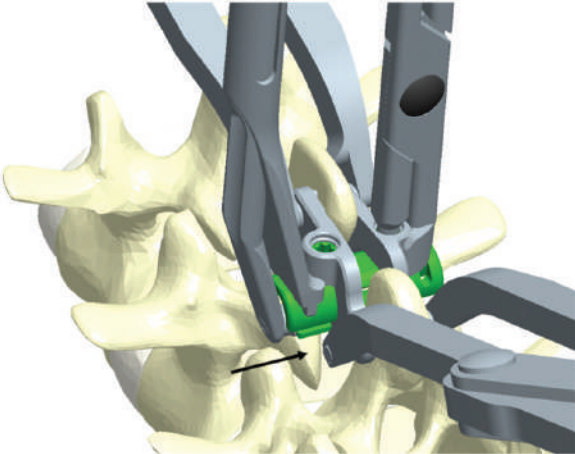


Fig. 16

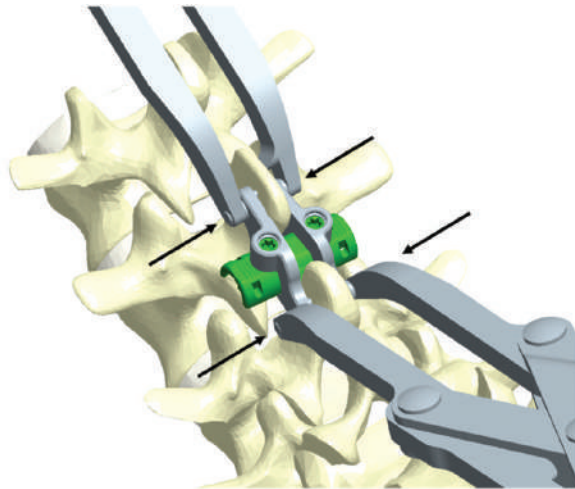


Fig. 17

Final Locking

Instrument	
IS2020	Compressor
IS3010	Set Screw Driver
IS4010	Torque Limiting Driving Handle

Attach the **Set Screw Driver** to the **Torque Limiting Driving Handle** (Fig. 18). While maintaining compression on the plates, insert the **Set Screw Driver** into the set screw. Tighten the set screw until the torque handle clicks twice (Fig. 19).

Caution
While inserting the **Set Screw Driver** into the set screw, keep the **Set Screw Driver** aligned perpendicularly to the set screw. Do not twist or angle the **Set Screw Driver** off axis.

After removing the **Compressors**, manually and visually inspect the plate to confirm secure fixation (Fig. 20).

SUPPLEMENTAL FIXATION

The Benefix™ Interspinous Fixation System is not intended as a stand-alone device and is used with U&i supplemental spinal fixation, e.g. ANAX™ 5.5, OPTIMA™ or PERFIX™ Spinal System.

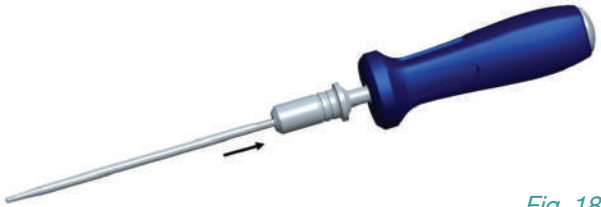


Fig. 18

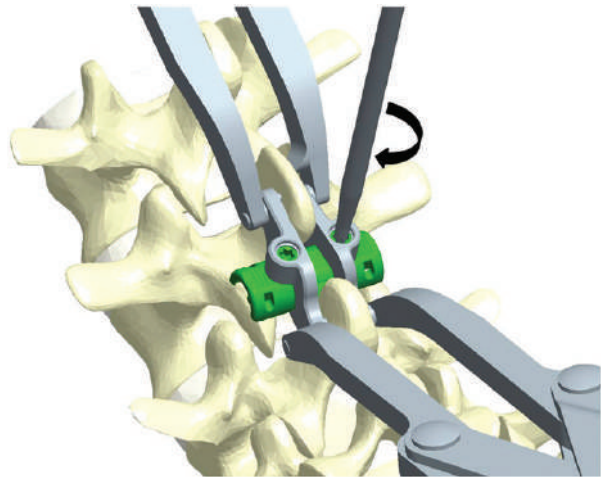


Fig. 19

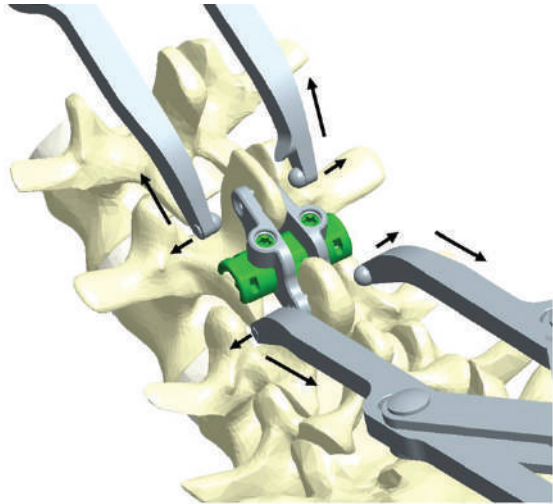


Fig. 20

Implant Removal

Instrument	
IS3010	Set Screw Driver
IS4010	Torque Limiting Driving Handle

Remove any tissue or bone impeding access to the implant. Use the **Set Screw Driver** to loosen the set screw (Fig. 21).

Attach forceps to implant and remove from the spinous processes (Fig. 22).

Note
Explanted surgical implants must never be reused.

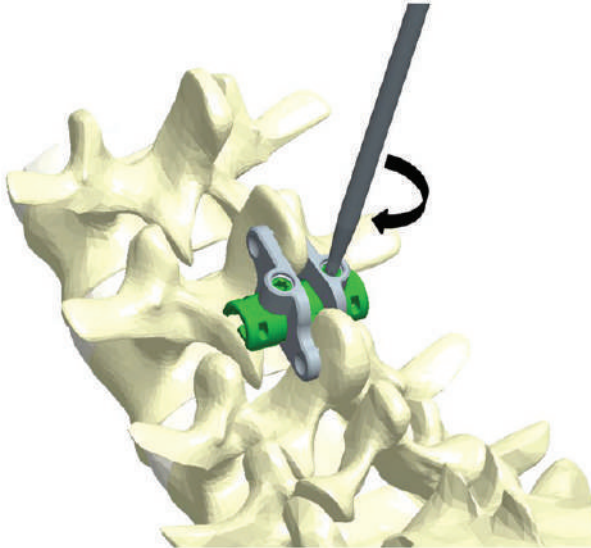


Fig. 21

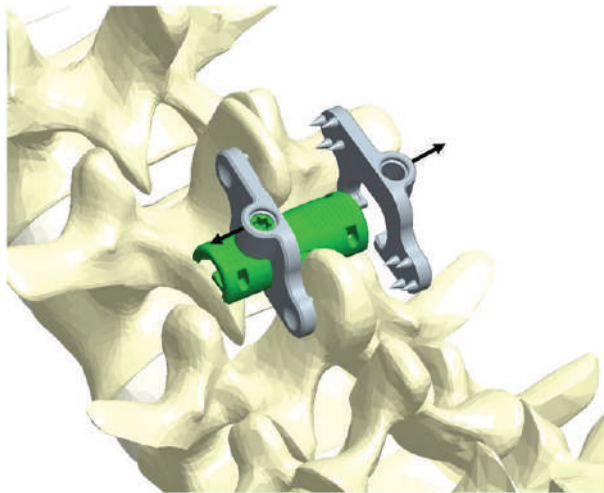


Fig. 22

Ordering Information

Implant (Single Use Only)

Cat. No	Barrel size	
IS10627	Ø6 x L27 mm	
IS10632	Ø6 x L32 mm	
IS10637	Ø6 x L37 mm	
IS10827	Ø8 x L27 mm	
IS10832	Ø8 x L32 mm	
IS10837	Ø8 x L37 mm	
IS11027	Ø10 x L27 mm	
IS11032	Ø10 x L32 mm	
IS11037	Ø10 x L37 mm	
IS11227	Ø12 x L27 mm	
IS11232	Ø12 x L32 mm	
IS11237	Ø12 x L37 mm	
IS11427	Ø14 x L27 mm	
IS11432	Ø14 x L32 mm	
IS11437	Ø14 x L37 mm	
IS11627	Ø16 x L27 mm	
IS11632	Ø16 x L32 mm	
IS11637	Ø16 x L37 mm	
IS11827	Ø18 x L27 mm	
IS11832	Ø18 x L32 mm	
IS11837	Ø18 x L37 mm	

Cat. No	Right Plate size	Cat. No	Left Plate size
IS20630R	Ø6 x 30 mm	IS20630R	Ø6 x 30 mm
IS20635R	Ø6 x 35 mm	IS20635R	Ø6 x 35 mm
IS20640R	Ø6 x 40 mm	IS20640R	Ø6 x 40 mm
IS20833R	Ø8 x 33 mm	IS20833R	Ø8 x 33 mm
IS21033R	Ø10 x 33 mm	IS21033R	Ø10 x 33 mm
IS21235R	Ø12 x 35 mm	IS21235R	Ø12 x 35 mm
IS21435R	Ø14 x 35 mm	IS21435R	Ø14 x 35 mm
IS21637R	Ø16 x 37 mm	IS21637R	Ø16 x 37 mm
IS21840R	Ø18 x 40 mm	IS21840R	Ø18 x 40 mm



Instruments

IS1010 Holder for Barrel 6~8mm



IS1030 Plate Holder



IS2020 Compressor



IS5204 Initial Dilator – 4mm



IS4010 Torque Limiting Driving Handle



IS1020 Holder for Barrel 10~18mm



IS2010 Distractor



IS3010 Set Screw Driver



IS5206 Initial Dilator – 6mm



IS6010 Quick Connector Handle



Instruments

IS5006 Dilator D6



IS5010 Dilator D10



IS5012 Dilator D12



IS5014 Dilator D14



IS5016 Dilator D16



IS5018 Dilator D18



IS5106 Guide Sleeve D6



IS5108 Guide Sleeve D8



IS5110 Guide Sleeve D10



IS5112 Guide Sleeve D12



IS5114 Guide Sleeve D14



IS5116 Guide Sleeve D16



IS5118 Guide Sleeve D18



Important Information on the Benefix™ Interspinous Fixation System

DESCRIPTION
Benefix™ Interspinous Fixation System is an internal fixation device for spinal surgery. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patients. All implants are intended for single use only and should not be reused under any circumstances.

INTENDED USE / INDICATIONS FOR USE
Benefix™ Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for single level use in the non-cervical spine (T1-S1). It is intended for single level plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. Benefix™ Interspinous Fixation System is intended for use with bone graft material, not intended for stand-alone use.

CONTRAINDICATIONS
Contraindications for Benefix™ Interspinous Fixation System are similar to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Incompetent or missing posterior arch (e.g., laminectomy, pars defect, severe osteoporosis).
- Reuse or multiple uses.
- Prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EVENTS

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection
- Dural tears, persistent CSF (Cerebrospinal fluid) leakage, and/or meningitis
- Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
- Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
- Loss of bladder control or other types of urological system compromise
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery
- Non-union (pseudarthrosis), delayed union and/or mal-union
- Cessation of any potential growth of the operated portion of the spine
- Loss or increase in spinal mobility or function.
- Unable to perform daily activities

WARNINGS AND PRECAUTIONS

- Implants and instruments are provided non-sterile and must be cleaned and sterilized before use.
- Validated sterilization cycle parameters are noted in the STERILIZATION section of this insert. A successful result is not always achieved in every surgical case.
- This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization.
- This system is intended for use with bone graft material, not intended for stand-alone use. Use of this product without a bone graft, or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, and/or breakage of the device(s) will occur.
- Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Furthermore, the proper selection and compliance of the patient will greatly affect the results.
- Surgical Technique manual can be obtained by contacting U&I corporation.
- Patients who smoke have been shown to have an increased incidence of non-union.
- Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion. The use of allograft material may not give as good a result as pure autograft.
- Based on the dynamic testing results, the physician should consider the level of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the interspinous fusion device.
- Patients with previous spine surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

CAUTION: For use on or by the order of a physician only.
CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Other preoperative, intraoperative, and postoperative warnings are as follows:

PREOPERATIVE

- Patient who meets the criteria described in the indications only should be selected.
- Patient condition and/or pre dispositions such as those addressed in the contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the device and should personally assemble the device to verify that all parts and necessary instruments are present before surgery begins.
- Components of Benefix™ Interspinous Fixation System should not be combined with components from another manufacturer. Different metal types should never be used together due to a possibility of accelerating corrosion.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage on nerves will cause loss of neurological functions.
- Breakage, slip, or misuse of instruments or implant components may cause injury to patient or operative personnel.
- To ensure fully engaged at the interconnection, barrel is visually confirmed to protrude from the plate surface at least 3 mm (the plate thickness).
- Do not overcompress implants as this may cause fracture/breakage of the spinous process
- Excessive decorticating of the spinous process may cause the bone to fracture or non-union of the implant.
- Be sure not to tear the spinous process ligament during dilation of the spinous process ligament
- Same length of plate should be used for fixation/attachment to the spinous process.
- Before closing soft tissue, all the set screws should be tighten firmly to secure the assembly in its final compressed and implanted state. TORQUE LIMITING DRIVER is provided to ensure the appropriate torque on screw is applied. Rereck the tightness of all mating components and set screws after assembled. Make sure that assembled components are not loosened during tightening of the other set screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE
Physician's postoperative direction and warnings to the patient, and the corresponding patient compliance, are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If the partial weight-bearing is recommended or required prior to firm bone union, then patient must be warned about complications. Bending, loosening and/or breakage of the device(s) may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active or if the patient is debilitated or demented. The patient should be warned to avoid fall or sudden jolt in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgen graphic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures) prophylactic antibiotics may be considered, especially for high-risk patients.
- Benefix™ Interspinous Fixation System of implants is an internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process.
- After spine fusion, these devices serve no functional purpose and may be removed. While the final decision on implant removal is up to the surgeon and patient.
- In most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities.
- If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, refracture, or other complications.

PACKAGING, LABELING AND STORAGE

- Implants removed from a patient of that contact bodily tissues or fluids should never be reused.
- The implants are delivered in packages. These must be intact at the time of receipt. All the legal information required for this type of implant is given in the labeling of each package.
- Implants may be delivered as a complete set, in specially designed trays or in boxes which can be sterilized directly.
- Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the strength and fatigue resistance of the system. This could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants.
- Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if the instruments or implants have been damaged during storage or prior procedures.
- Damaged packages or products should not be used, and should be returned to U&I Corporation.

CLEANING AND DECONTAMINATION
Manual Cleaning Procedure

1. Before starting the cleaning procedure, all dismantable instruments should be disassembled.
2. Use the neutral pH enzyme soaking solution that has been prepared.
3. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes.
4. Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
5. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
6. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
7. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
8. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
9. Thoroughly clean by repeating Steps 5 and 6 with freshly prepared cleaning solution.
10. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
11. Finish the cleaning procedure when the instruments are visually clean. If the instruments are not visually clean, repeat the cleaning procedure until instruments has no visual contamination.

Automated Cleaning Procedure
Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

- **CAUTION:** Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Implants removed from a patient or that contact bodily tissues or fluids should never be reused.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
- Verify that the instruments are in operation condition.

STERILIZATION
Unless noted otherwise on the package labeling, Benefix™ Interspinous Fixation System components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods: Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

- Recommended method to achieve a degree of sterility equal to at least 10⁻⁶.
- Sterilize by the autoclaving procedure regularly used in the hospital.
- All products should be disassembled as Part No. unit before the sterilization.
- Only FDA-cleared wraps should be used when you perform the sterilization.
- Over-killed Method was applied to the steam sterilization.

	Steam Condition	Temperature	Sterilization Time	Drying Time
Method 1	Steam, Gravity Cycle	132 °C	20 min	20 min
Method 2	Steam, Prevacuum Cycle	132 °C	4 min	20 min

• Wrapped method was used for the steam sterilization validation.

- This gravity-displacement cycle, 132 °C, exposure time 20 minute cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle.
- It is the end user's responsibility to use only sterilized and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).
- Do not stack trays during sterilization.

SAFETY AND CONDITIONALITY IN THE MR ENVIRONMENT

- Benefix™ Interspinous Fixation System has not been evaluated for safety and compatibility in the MR environment.
- Benefix™ Interspinous Fixation System has not been tested for heating or migration in the MR environment.

GUARANTEE
The guarantee is only applicable if the device is used in accordance with normal conditions as defined in these instructions and in conformity with the recommended surgical technique.
The use-life of all instruments used with Benefix™ Interspinous Fixation System is 2 years.



Manufactured by U&I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 480-859, Korea
Telephone : +82 31.852.0102 Fax : +82 31.852.0107
E-mail : information@youic.com
Web-site : http://www.youic.com

Represented in the U.S. by RCRI Inc.
Principal Regulatory and Quality Advisor
Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416-1334
Telephone : (650) 746-0080, ext. 234 Direct Fax: (651) 466-0145
Representative in the EU by Obelis S.A.
Bd Grifl Wahis 53, 1030 Brussels, Belgium.
Telephone : +32 2 732 59 54 Fax : +32 2 732 60 63
mail@obelis.net



Headquarter

20, Sandan-ro, 76beon-gil(Rd), Uijeongbu-si,
Gyeonggi-do, Korea 480-859
Tel. + 82 (31) 852 0102
Fax. +82 (31) 852 9025

USA Office

555 W Lambert Road Suite F Brea, CA 92821
Tel. + 1 (714) 280 4955
Fax. +1 (714) 209 7571