

ACE Spinal Fixation System Instructions for Use (IFU)

* **Product Name** : Spinal Fixation System[B030160.01]
 * **Product Approval No.** : Manufacturing License No.18-156
 * **Model Name** : Refer to Appendix 1

* **Manufacturer License No.** : 6102
 * **Packaging Unit** : 1EA/ 1 Pack
 * **This product is a "Single-Use Medical Device"**

1. Intended Use

The ACE Spinal Fixation System is a non-cervical spinal fixation device intended for posterior, pedicle and non-pedicle fixation for the following indications: degenerative disc disease(DDD), spondyloisthesis, trauma, spinal stenosis, curvatures (such as scoliosis, kyphosis, or lordosis), tumor, pseudoarthrosis, and failed previous fusion. It is composed of screws, rods, cross-links, and set screws used for the fixation, support, or alignment correction of the thoracic and lumbar spine.

2. Directions for Use

(1) Pre-operative Preparation

- 1) Inspect the packaging for any signs of damage or compromise.
- 2) This product is supplied NON-STERILE. It must be sterilized using a steam autoclave (ISO 17665) prior to use. (Sterilization conditions: Temperature $\geq 132^{\circ}\text{C}$, 2 atm pressure for at least 4 minutes). Use with a sterilization indicator to verify the status.
- 3) Surgeons must be fully proficient in the surgical techniques, indications, and contraindications associated with the specific instruments and this system.
- 4) Verify that no biological or biomechanical factors exist that could adversely affect the surgical outcome.
- 5) Read the Instructions for Use thoroughly before use.

(2) Surgical Procedure

- 1) Make an incision at the surgical site and carefully dissect soft tissues to gain safe access.
- 2) Secure the entry point using a guide pin while confirming via C-ARM.
- 3) Remove the guide pin and create a hole in the pedicle using an awl.
- 4) Remove the awl and determine the appropriate screw size using a probe.
- 5) Verify the hole depth, internal wall integrity, vertebral body penetration, and angle using a sound tester.
- 6) Insert the screw, ensuring no excessive force is applied.
- 7) After all screws are inserted, verify the alignment of the screw heads.
- 8) Determine the rod length; use a pre-curved rod or adjust the rod angle using a rod bender to match the alignment.
- 9) Position the rod into the screw head using a rod holder and rod pusher.
- 10) Maintain the vertebral spacing using a compressor and distractor, then securely tighten the set screws.
- 11) If using reduction screws, remove the extended arm portion of the head using the authorized manual bone surgery instrument (A67050.01(1)).
- 12) If transverse fixation is required, connect and secure the cross-links between the left and right rods.
- 13) Remove all surgical instruments and suture the surgical site.

(3) Post-operative Storage and Maintenance

- 1) This device is for SINGLE USE ONLY. Do not reuse.
- 2) Store unused products in accordance with the specified storage conditions.

3. Precautions

(1) Contraindications

- 1) Do not use in patients with active infection.
- 2) Contraindicated in patients with osteoporosis, bone or soft tissue defects, sepsis, mental or physical conditions that preclude post-operative care, or hypersensitivity to the device raw materials.
- 3) Do not use for fixation of spinal regions other than the thoracic and lumbar spine.
- 4) Obesity or heavyweight patients may cause excessive loading on the system, leading to device failure or fixation loss.

(2) Adverse Effects

- 1) Reduced bone growth rate, non-union, or pseudoarthrosis.
- 2) Implant breakage due to excessive activity, pressure, or incomplete healing.
- 3) Allergic reactions to titanium alloys.
- 4) Breakage of fixation screws due to implant migration or loosening.
- 5) Nerve damage resulting from surgical trauma.
- 6) Bone/tissue necrosis, bone resorption, or incomplete healing.

(3) Warnings and Precautions

- 1) Use caution in patients with poor healing capacity, such as the elderly, patients with mental disorders, or alcohol addiction.
- 2) Do not use for any surgical procedures other than the stated intended use.
- 3) Titanium alloys contain metals that may trigger allergic reactions; perform appropriate testing if hypersensitivity is suspected.
- 4) Do not use any damaged or mishandled products.
- 5) Surgery must be performed by a qualified orthopedic surgeon.
- 6) Use extreme caution during thoracic procedures as the pedicle is adjacent to the spinal cord.
- 7) Thoracic pedicles are narrower than lumbar pedicles; ensure precise screw placement.
- 8) Oversized screws in the thoracic spine may cause pedicle fracture; undersized screws may lead to implant breakage.
- 9) Inform the patient about potential implant loosening, migration, or failure due to excessive activity or pressure.
- 10) Warn the patient that failure to follow post-operative instructions may lead to implant failure.
- 11) MR Safety: This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts. Scanning a patient with this implant may result in patient injury.

(4) Storage Conditions

- 1) Store at room temperature ($1\sim 30^{\circ}\text{C}$).
- 2) Store in a place where no physical damage or impairment to the appearance occurs.
- 3) Avoid chemical storage areas or locations where gas is generated.
- 4) Avoid chemical storage areas or locations where gas is generated.

(5) Adverse Event Reporting: National Institute of Medical Device Safety Information (NIDS) (080-080-4183)

Manufactured for : ACE Mediacorp Co., Ltd
 Address : #1014, C-dong,10, Munhwa-ro,
 Uijeongbu-si, Gyeonggi-do, Republic of Korea
 TEL : 031) 837-5001
 FAX : 031) 5171-3597
 Control No.: ACE-IFU-013

Appendix 1 Model name

BF.MS.45XX, BF.MS.50XX, BF.MS.55XX, BF.MS.60XX, BF.MS.65XX,
 BF.MS.70XX, BF.MS.75XX, BF.MS.80XX
 BS.MS.45XX, BS.MS.50XX, BS.MS.55XX, BS.MS.60XX, BS.MS.65XX,
 BS.MS.70XX, BS.MS.75XX, BS.MS.80XX
 BF.MD.45XX, BF.MD.55XX, BF.MD.55XX, BF.MD.60XX BF.MD.65XX,
 BF.MD.70XX, BF.MD.75XX, BF.MD.80XX
 BS.MD.45XX, BS.MD.55XX, BS.MD.55XX, BS.MD.60XX BS.MD.65XX,
 BS.MD.70XX, BS.MD.75XX, BS.MD.80XX
 BF.PS.45XX, BF.PS.50XX, BF.PS.55XX, BF.PS.60XX, BF.PS.65XX,
 BF.PS.70XX, BF.PS.75XX, BF.PS.80XX, BF.PS.85XX
 BS.PS.45XX, BS.PS.50XX, BS.PS.55XX, BS.PS.60XX, BS.PS.65XX,
 BS.PS.70XX, BS.PS.75XX, BS.PS.80XX, BS.PS.85XX
 BT.PS.45XX, BT.PS.50XX, BT.PS.55XX, BT.PS.60XX, BT.PS.65XX,
 BT.PS.70XX, BT.PS.75XX, BT.PS.80XX, BT.PS.85XX
 BF.PD.45XX, BF.PD.50XX, BF.PD.55XX, BF.PD.60XX, BF.PD.65XX,
 BF.PD.70XX, BF.PD.75XX, BF.PD.80XX, BF.PD.85XX
 BS.PD.45XX, BS.PD.50XX, BS.PD.55XX, BS.PD.60XX, BS.PD.65XX,
 BS.PD.70XX, BS.PD.75XX, BS.PD.80XX, BS.PD.85XX
 BT.PD.45XX, BT.PD.50XX, BT.PD.55XX, BT.PD.60XX, BT.PD.65XX,
 BT.PD.70XX, BT.PD.75XX, BT.PD.80XX, BT.PD.85XX
 BF.CS.55XX, BF.CS.60XX, BF.CS.65XX, BF.CS.70XX, BF.CS.75XX,
 BF.CS.80XX
 BS.CS.55XX, BS.CS.60XX, BS.CS.65XX, BS.CS.70XX, BS.CS.75XX,
 BS.CS.80XX
 BF.RC.55XX, BF.RC.60XX, BF.RC.65XX, BF.RC.70XX, BF.RC.75XX,
 BF.RS.80XX
 BS.RC.55XX, BS.RC.60XX, BS.RC.65XX, BS.RC.70XX, BS.RC.75XX,
 BS.RC.80XX
 BF.LR.55XX, BF.LR.60XX, BF.LR.65XX, BF.LR.70XX, BF.LR.75XX,
 BF.LR.80XX
 BS.LR.55XX, BS.LR.60XX, BS.LR.65XX, BS.LR.70XX, BS.LR.75XX,
 BS.LR.80XX
 BF.MR.55XX, BF.MR.60XX, BF.MR.65XX, BF.MR.70XX, BF.MR.75XX,
 BF.MR.80XX
 BS.MR.55XX, BS.MR.60XX, BS.MR.65XX, BS.MR.70XX, BS.MR.75XX,
 BS.MR.80XX
 AF.CS.55XX, AF.CS.60XX, AF.CS.65XX, AF.CS.70XX, AF.CS.75XX,
 AF.CS.80XX
 AS.CS.55XX, AS.CS.60XX, AS.CS.65XX, AS.CS.70XX, AS.CS.75XX,
 AS.CS.80XX
 CF.CS.55XX, CF.CS.60XX, CF.CS.65XX, CF.CS.70XX, CF.CS.75XX,
 CF.CS.80XX
 CS.CS.55XX, CS.CS.60XX, CS.CS.65XX, CS.CS.70XX, CS.CS.75XX,
 CS.CS.80XX
 AF.RC.55XX, AF.RC.60XX, AF.RC.65XX, AF.RC.70XX, AF.RC.75XX,
 AF.RC.80XX
 AS.RC.55XX, AS.RC.60XX, AS.RC.65XX, AS.RC.70XX, AS.RC.75XX,
 AS.RC.80XX,
 AF.LR.55XX, AF.LR.60XX, AF.LR.65XX, AF.LR.70XX, AF.LR.75XX,
 AF.LR.80XX
 AS.LR.55XX, AS.LR.60XX, AS.LR.65XX, AS.LR.70XX, AS.LR.75XX,
 AS.LR.80XX
 AF.MR.55XX, AF.MR.60XX, AF.MR.65XX, AF.MR.70XX, AF.MR.75XX,
 AF.MR.80XX,
 AS.MR.55XX, AS.MR.60XX, AS.MR.65XX, AS.MR.70XX, AS.MR.75XX,
 AS.MR.80XX,
 CF.RC.55XX, CF.RC.60XX, CF.RC.65XX, CF.RC.70XX, CF.RC.75XX,
 CF.RC.80XX
 CF.LR.55XX, CF.LR.60XX, CF.LR.65XX, CF.LR.70XX, CF.LR.75XX,
 CF.LR.80XX
 CS.LR.55XX, CS.LR.60XX, CS.LR.65XX, CS.LR.70XX, CS.LR.75XX,
 CS.LR.80XX
 RS.55XXX, RS60XXX, RS.63XXX
 RC.55XXX, RC60XXX
 TR.55XXX, TR.60XXX, TR.55XXXH, TR.60XXXH
 ZR54XXX, ZR55XXX, ZR57XXX, ZR64XXX, ZR65XXX, ZR67XXX
 RM.55XXX, RM.60XXX
 SS.1039
 CLA.551XXX, CLA.601XXX, CLA.631XXX
 LTR5555X, LTR6060X
 RTR55XX, RTR60XX
 SRTR HRTR

Surgical Instruments

OPERATION INSTRUCTIONS

Important Note

The users acknowledge that they have read and agreed on the conditions in this surgical technique brochure, which are to be considered as contractual.

Basic Structure

ACE Medicorp's Surgical Instruments are composed of various forms and sizes so that adaptations can always be made to take into account the pathology and individual patient.

Materials

The raw material of this item is consisted of SUS303, SUS304, SUS431, SUS455, SUS630, this material which complies with JIS G 4316, ASME SA213, JIS G 4303, ASTM A564. The raw material composition covered by this regulation has been employed successfully in each instrument.

Indication

ACE Medicorp's Surgical Instruments are indicated to be used with implants for temporary or permanent correction or stabilization of the vertebral column and with the aim of helping consolidation of bone fusion. They are indicated for:

General Conditions of Use

- Prior to use, the instruments should be cleaned and sterilized as per instructions described below.
- It is recommended to inspect the instruments prior to use for any signs of defects.
- The Instruments must be used only by physicians having undergone the necessary training in surgery. Their use in instruments must be decided upon in accordance with the surgical and medical indications and procedure.
- It is recommended that ACE Medicorp's Surgical Instruments should only be used together with ACE Medicorp's implants. If any problem occur by using the instruments with implants from a different source, a different manufacturer, or made from a different material, then ACE Medicorp declines all responsibility.
- Immediately after each surgical procedure, all instruments should be thoroughly cleaned.

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the ACE Medicorp's Surgical Instruments require detailed knowledge of surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such surgery. Knowledge of surgical techniques, proper reduction, selection, placement, and basic management of instruments are considerations essential to a successful surgical outcome.
- Appropriate selection, placement and fixation of the instruments are critical factors which affect surgical procedure and success.

- Note: While proper Instrument selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the Instruments.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual damage of instruments.

Warning

- Deviation from cleaning method may result in damage to the instruments. Should you try alternate cleaning and disinfecting procedures, ACE Medicorp is not responsible for any adverse consequences that may occur.
- Discard all damaged or mishandled Instruments.
- Before reused of the instruments, assure that they had been processed a strict cleaning screening. Deviation from cleaning may cause unexpected problems.
- Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, ACE Medicorp's Surgical Instruments should not be used in conjunction with implant components from any other manufacturer's implant system. Any such use will negate the responsibility of ACE Medicorp Co., Ltd. for the performance of the resulting mixed component implant.

Packaging, Labeling and Storage

- The instruments are supplied non-sterile. They must be cleaned and sterilized (see below)
- The instruments are delivered in packages; these must be intact at the time of receipt. All the legal information required for this type of instruments is given on the label of each package.
- The instruments may be delivered as a complete set : instrumentations are set out on specially designed trays or in boxes which can be sterilized directly.
- Use care in handling and storage of instruments. Cutting, sharply bending, or scratching the surface can significantly reduce the characteristic of the instruments. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to damage of tissue, nerves, etc while performing the surgery. 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 instruments have been damaged during storage or prior procedures.

Sterilization Procedures

A. Pre-cleaning (Instruments only)

1. Pre wash

Remove contaminants using a nylon brush after soaking for 20 minutes in Enzymatic Detergent.

2. 1st rinsing

Rinse using the water for 3 minutes to remove Enzymatic Detergent of product.

3. Detergent wash

Wash using the Enzymatic Detergent in the ultrasound cleaner at 45~55°C for 10 minutes.

Rinse 3 times using the water for 30 seconds

4. Purified water rinse

Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 45~55°C.

5. Alcohol disinfection

Wipe using dustabsorbent after the product soaked in alcohol(70%) for 30 seconds.

6. Dry

Dry using the heating device at 100°C (±10°C) for 50 minutes.

B. Sterilization (Implants and Instruments)

Autoclave : recommended method to achieve a degree of sterility equal to at least 10⁻⁶

Sterilize by the autoclaving procedure regularly used in the hospital,

Suggested method : Steam, Wrapped Pre-vacuum cycle at 132°C(270°F) for 4 minutes.

Any other procedure is the sole responsibility of the user and ACE Medicorp Co., Ltd. declines all responsibility.

Detailed information concerning these procedures will be supplied by ACE Medicorp Co., Ltd. on the specific request of the user.

※ The number of Instruments re-sterilization : ACE Medicorp guarantee a number of re-sterilization number for surgical instrument within 200 cycles. If user wants to do the more sterilization additionally, the appearance of products or its performance should be considered.

Guarantee

The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in this instructions and in conformity with the recommended surgical technique.

