



Surgical Technique Guide

EPIC[™]

Anterior Thoracolumbar
Plate



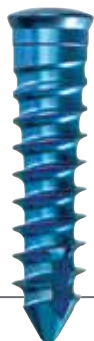
BIOMET
SPINE



With intuitive design and ease of use, the Epic™ Plate provides fixation for use in anterior thoracolumbar fusion procedures.

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those individuals with specialized training and experience in spinal surgery should attempt to use the Epic system. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is required. Detailed preoperative planning is also essential. Refer to the Instructions For Use (IFU) for a complete list of prescribing information.

The **Epic™ Anterior Thoracolumbar Plate System** provides fixation for use in anterior thoracolumbar fusion procedures. Features include the plate's intuitive design and ease of use, including the single-step cover plate for screw back-out prevention. The Epic System offers straightforward, easy-to-use instrumentation that results in minimizing surgical steps.



FEATURES

- Strong, low-profile plate.
 - Lumbar and sacral plate options in a wide range of lengths for optimal anatomic fit.
 - Fixed and variable angle screws.
 - Unique screw thread design provides excellent bone-screw fixation and plate lagging.
 - 18° conical range of screw insertion angles.
 - Single-step cover plate for screw back-out prevention.
 - Simple, intuitive instrumentation.
-

PREOPERATIVE PREPARATION

- Review and inspect all instrumentation and implants prior to sterilization.
- Replace or add any needed components for the planned surgery.
- Primary surgeon must be fully experienced with the required cervical instrumentation techniques.
- Read the Instructions for Use (IFU) for a product description and a list of warnings, cautions, contraindications and risks.

SURGICAL EXPOSURE AND SITE PREPARATION

- Position and drape the patient in the usual fashion (*Figure 1*).
- Expose the affected levels via a standard incision and tissue dissection.
- Perform any necessary bone and tissue removal.
- Prepare vertebral endplates via the use of a combination of curettes, rasps, osteotomes, disc shavers or rongeurs to remove the disc material and cartilage.

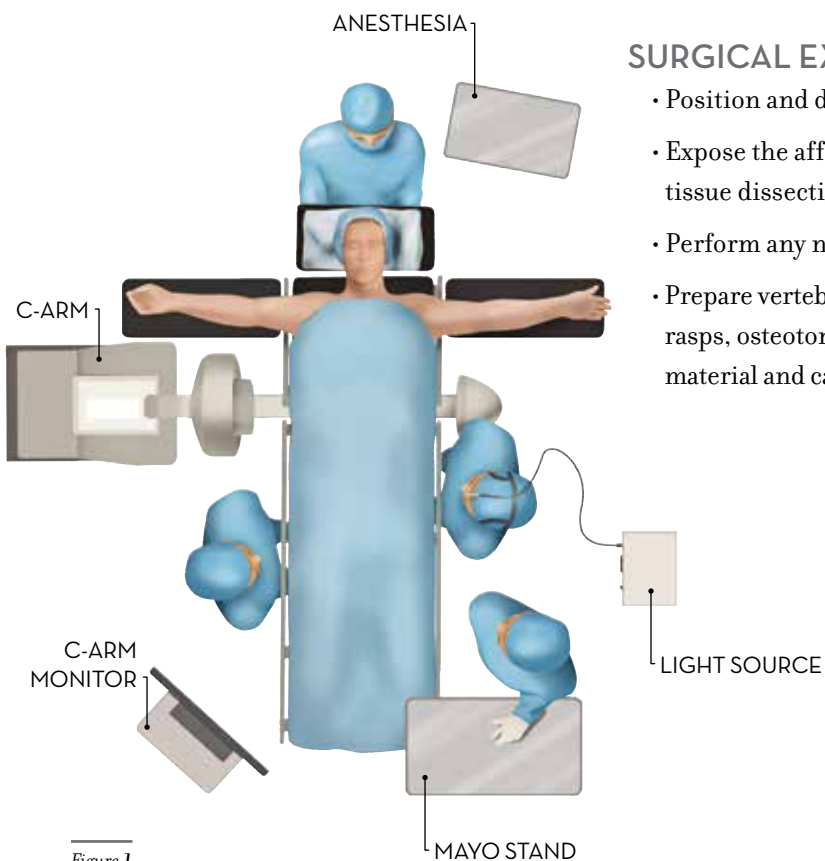


Figure 1

1. PLATE SELECTION

- Plate size and type are determined intraoperatively, ensuring that the screw starting points are properly located over the respective vertebrae and the plate construct adequately conforms to the anatomy.

Note: The distance between the screws is 12 mm less than the length (size) of the plate (Figure 2).

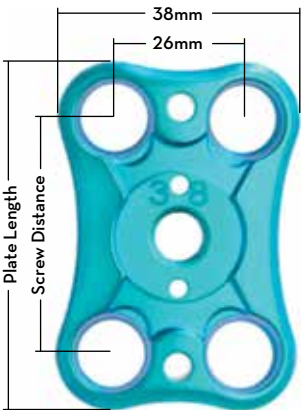


Figure 2

Plate Length	Screw Distance
28mm	16mm
30mm	18mm
32mm	20mm
34mm	22mm
36mm	24mm
38mm	26mm
40mm	28mm
42mm	30mm
44mm	32mm
46mm	34mm
48mm	36mm
50mm	38mm

- Attach the **plate** to the **plate holder** and place at the proper level. Visually confirm appropriate anatomic sizing of the plate (Figure 3).

Note: Intraoperative imaging may be utilized to verify correct anatomic fit.

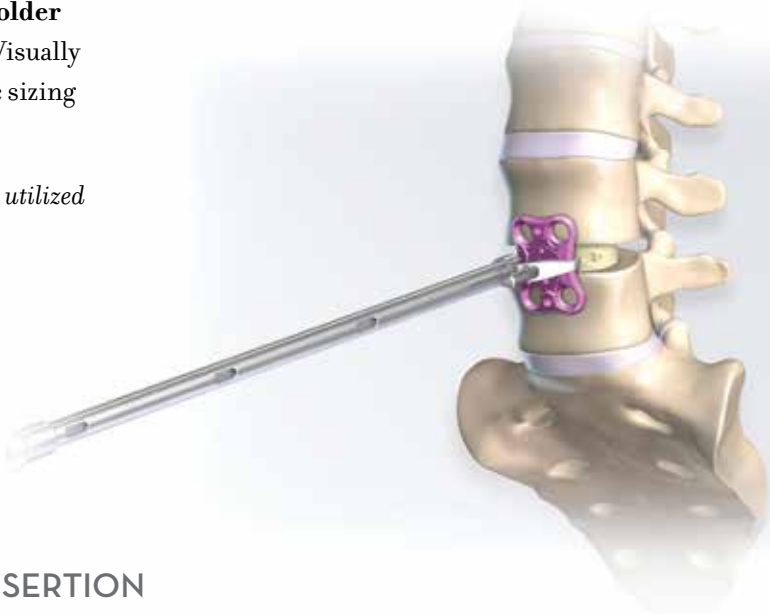


Figure 3

2. TEMPORARY PIN INSERTION

- The plate may be held in place with a **temporary fixation pin** which is introduced with the **temporary pin inserter** (Figure 4a, b).

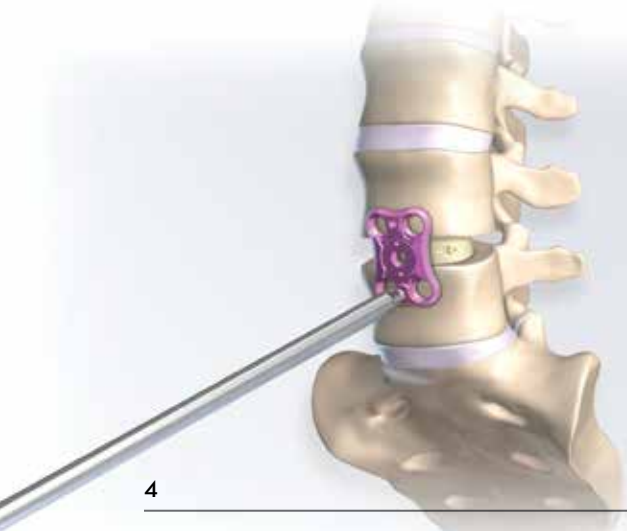


Figure 4a



Figure 4b

3. DRILL/AWL ASSEMBLY



Figure 5

- Select the fixed angle guide to place the screw in the nominal trajectory or variable angle guide to aim the screw in an alternate trajectory.
- Fixed angle screws must be prepared using fixed angle guides. Variable angle screws may be prepared using either fixed angle guides or variable angle guides, which allow for additional angulation (Figure 5).
- Select the **fixed retractable sleeve** or the **variable retractable sleeve**, and insert the **retractable awl** or **retractable drill**, which is assembled to the **ratcheting straight handle** or **ratcheting palm handle** (Figure 6).



Figure 6

4. DRILL/AWL INSERTION

- Insert the tip of the instrument into the screw holes on the plate, and insert the drill or awl into the bone until the stop is reached. This provides 20mm of penetration (Figure 7).

Note: It is recommended to start in the hole opposite the temporary pin and proceed to the opposite corner, followed by the remaining screw holes.



Figure 7

5. SCREW INSERTION

- Assemble the **screw driver** to the **ratcheting straight handle** or **ratcheting palm handle**.
- Insert the screw into the prepared screw hole, leaving the screw slightly proud (Figure 8).

Note: Fixed angle screws can only be used when the bone is prepared using fixed angle guides.



Figure 8

6. FINAL SCREW TIGHTENING

- Once all the screws have been placed, sequentially drive each screw until fully seated in the plate.

COVER PLATE AND INSERTION

7. COVER PLATE ASSEMBLY TO THE INSERTER

- Insert the **cover plate driver** into the **cover plate counter torque sleeve**, and assemble to the **torque limiting T-handle**.
- Load the **cover plate** onto the cover plate driver (Figure 9a,b).



Figure 9a



Figure 9b

8. COVER PLATE INSERTION

- Insert the cover plate set screw into the plate and tighten to the limit of the torque handle (50 in-lb [5.649 Nm]) (Figure 10).



Figure 10

9.

- Inspect the final implant for correct position and assembly (*Figure 11*).

Figure 11



CLOSURE

10.

- Close the fascia and skin incision in the usual manner.

REMOVING THE EPIC™ PLATE (IF NECESSARY)

1. Unscrew the cover plate using the cover plate driver which is assembled on the ratcheting torque handle.
2. Remove all screws using the **split tip screw driver** assembled to the ratcheting straight handle or ratcheting T-handle.
3. Remove the plate.

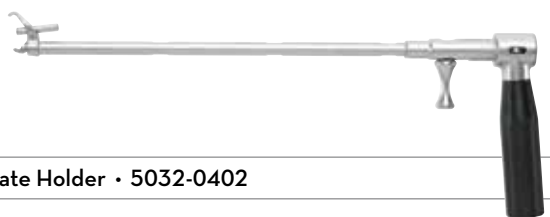


Plate Holder • 5032-0402



Plate Holder Angled* • 5032-0009



Temporary Pin Inserter • 5032-0004



Temporary Pin for Pin Inserter • 5032-0003



Temporary Pin for Screw Driver • 5032-0026



Retractable Awl • 5032-0001



Retractable Drill • 5032-0006



Fixed Retractable Sleeve • 5032-0011



Variable Retractable Sleeve • 5032-0008



Ratcheting Straight Handle • 9801-0003



Double Barreled Guide* • 5032-0005



Awl for Double Barreled Guide • 5032-0007



Drill for Double Barreled Guide • 5032-0023



Tap for Double Barreled Guide • 5032-0022



Screw Driver • 5032-0012



Cover Plate Driver • 5032-0017



Cover Plate Counter Torque Sleeve • 5032-0016



Torque Limiting T-Handle • 5032-0019



Ratcheting Palm Handle • 9801-0004

Plates



Length	Plate	Sacral Plate	Cover Plate	Cover Plate Set Screw**
28mm	5001-0280	5003-0280	5001-1280	5005-0002
30mm	5001-0300	5003-0300	5001-1300	
32mm	5001-0320	5003-0320	5001-1320	
34mm	5001-0340	5003-0340	5001-1340	
36mm	5001-0360	5003-0360	5001-1360	
38mm	5001-0380	5003-0380	5001-1380	
40mm	5001-0400	5003-0400	5001-1400	
42mm	5001-0420	5003-0420	5001-1420	
44mm	5001-0440	5003-0440	5001-1440	
46mm	5001-0460	5003-0460**	5001-1460	
48mm	5001-0480	5003-0480**	5001-1480	
50mm	5001-0500	5003-0500**	5001-1500	

Screws



Self-Tapping Screws

Angle	Length	Standard 6mm	Rescue 7mm
Variable	20mm	5015-6020	—
Variable	24mm	5015-6024	—
Variable	26mm	5015-6026**	—
Variable	28mm	5015-6028	—
Variable	30mm	5015-6030**	—
Variable	32mm	5015-6032	—
Variable	36mm	5015-6036	—
Fixed	20mm	5017-6020	—
Fixed	24mm	5017-6024	5014-7024
Fixed	26mm	5017-6026**	—
Fixed	28mm	5017-6028	5014-7028
Fixed	30mm	5017-6030**	—
Fixed	32mm	5017-6032	5014-7032
Fixed	36mm	5017-6036	5014-7036

Self-Drilling Screws*

Angle	Length	Standard 6mm	Rescue 7mm
Variable	24mm	5011-6024	5010-7024
Variable	28mm	5011-6028	5010-7028

* Ordered Separately

** Pre-assembled to Cover Plate

DEVICE DESCRIPTION

The Epic™ system consists of various plates, screws and associated instruments that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

INDICATIONS FOR USE

The Epic system is intended to provide fixation of the thoracic, lumbar and/or sacral spine (T1-S1) as an adjunct to fusion using autograft or allograft in skeletally mature patients in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spinal stenosis (indicated for L1-S1 only); spondylolisthesis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); trauma (i.e., fracture, dislocation or subluxation); spondylolysis; tumor; pseudarthrosis; and/or failed previous fusion.

The Epic system is indicated for use via the lateral or anterolateral surgical approach for fixation of the thoracic and thoracolumbar spine, or via the anterior surgical approach for fixation of the lumbosacral spine below the bifurcation of the great vessels.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

- Allergy to titanium, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Known or suspected infection/immune system incompetence. Acute or chronic infectious diseases of any etiology or localization.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Morbid Obesity. An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or failure of the device itself.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.

- Open Wounds.
- Pregnancy.
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood cell (WBC) count or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from other manufacturers' systems.
- Any case requiring the mixture of stainless steel with titanium or stainless steel with cobalt chrome implant components.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Previous history of infection.
- Alcoholism or heavy smoking.
- Senility, mental illness or substance abuse, of a severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Any patient unwilling to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, and patients unwilling or unable to cooperate with postoperative care instructions.

POSSIBLE COMPLICATIONS

Possible complications specific to the device may include:

- Early or late implant bending, breakage, failure, loosening or movement/migration.
- Bone fracture.
- Allergic reaction to implant material.
- Other general complications associated with any spinal surgical procedure may include: nonunion or delayed union, pseudarthrosis; pain; additional surgery; bleeding; infection, early and late; tissue or nerve damage, including dural tears or other neurological problems; incisional complications; scar formation; damage to blood vessels and cardiovascular system compromise; neurologic injury; damage to internal organs and connective tissue; complications due to the use of bone grafting, including graft donor site complications; respiratory problems; reactions to anesthesia and/or death.

WARNINGS

If healing is delayed or does not occur, the implant could eventually break due to material fatigue. The patient's weight, activity level and compliance to weight bearing or activity restrictions can have an effect on the stresses to which the implant is subjected. Such stresses may affect the long term survival of the implant. The following warnings do not include all possible adverse effects, but are important considerations particular to spinal fixation devices.

- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
- The Epic system components are not to be connected to the components of devices from another manufacturer.
- Titanium implants should not be mixed with stainless steel implants in the same construct.
- The safety and effectiveness of anterior thoracolumbosacral fixation spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine, DDD, spinal stenosis (indicated for L1-S1 only), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery, where many extenuating circumstances may compromise the results.

PRECAUTIONS

- Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of implants, are important considerations in the successful utilization of the Epic device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results.
- Patients who smoke have been shown to have an increased incidence of nonunions. These patients should be advised of this fact and warned of the consequences. Obese, malnourished and/or alcoholic patients are poor candidates for spinal fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.
- The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. Before beginning the surgical procedure, the surgeon must be acquainted with the specific technique for insertion of the implant, which is available from the manufacturer.
- The Epic system has not been tested for safety and compatibility in the magnetic resonance (MR) environment. The Epic system has not been tested for heating or migration in the MR environment.
- The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important. Use of the cover plate is mandatory for proper use of this device. Failure to use the cover plate may increase the risk of screw back-out.
- Never re-use any implant even if it appears unmarked or undamaged. Any implant implanted and then removed must be discarded. Use only new implants for each case.
- Risks associated with neurosurgery, general surgery, orthopedic surgery and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using implants, as well as alternative treatment methods, are explained to the patient.

This image shows a full page of blank, lined paper. It features approximately 20 evenly spaced horizontal grey lines across the entire width of the page, providing a guide for writing. The background is a solid off-white color. There are no margins, text, or other markings present.



PRODUCT COMPLAINTS – Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to BIOMET SPINE by email: spinecomplaints@biomet.com or phone: **866.956.7579**. When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, surgeon name and the date you became aware of the complaint. Sterilize and return all component(s) to your local BIOMET SPINE representative. Notify BIOMET SPINE immediately of an incident resulting in patient death or serious injury.

If further directions for use of this system are needed, contact BIOMET SPINE Customer Service by email: spinecustomerservice@biomet.com, phone: **866.378.4195** or fax: **303.443.7501**.

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