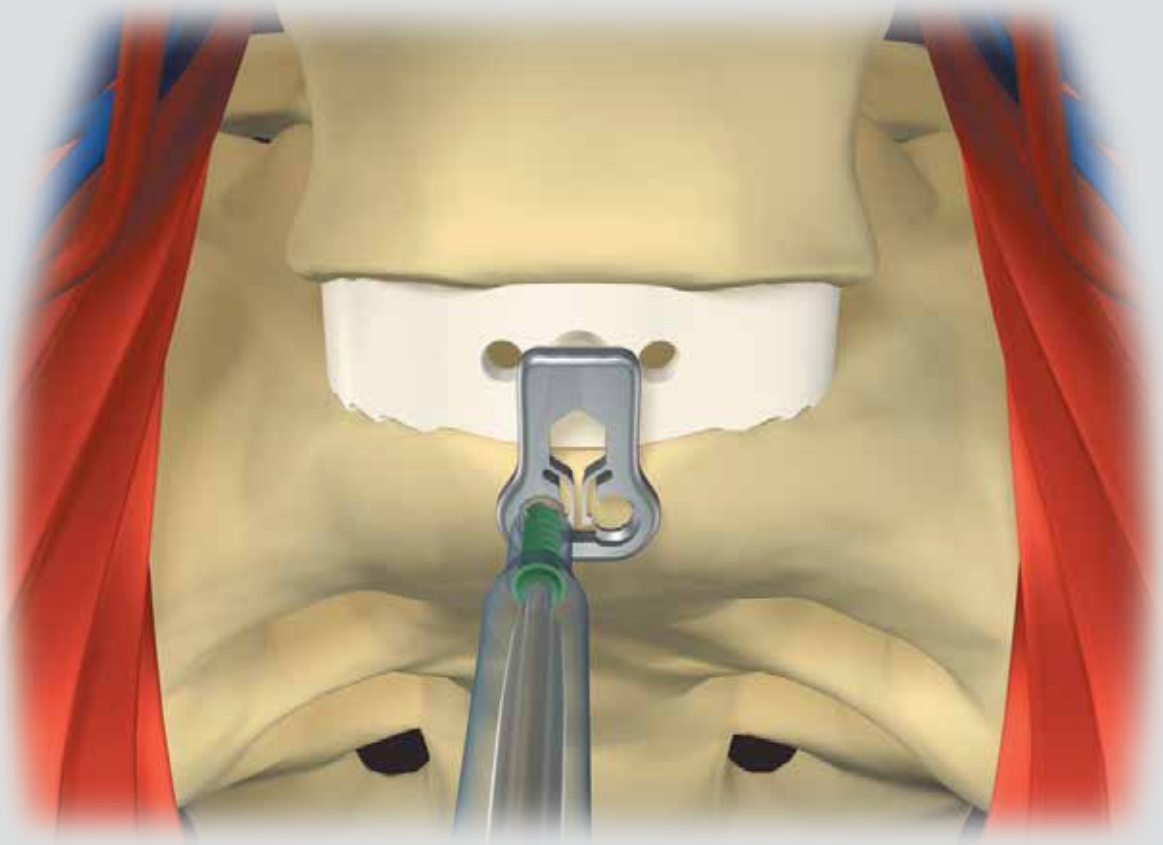
Zimmer® Anterior Buttress Plate System

Surgical Technique



zimmer

Personal Fit. Renewed Life.™

Zimmer Anterior Buttress Plate System
Surgical Technique

Description, Indications & Contraindications

DESCRIPTION

The *Zimmer* Anterior Buttress Plate System is intended for anterior screw fixation to the L1 to S1 spine. The *Zimmer* Anterior Buttress Plate System consists of a variety of shapes and sizes of bone plates and screws. The components are manufactured from titanium alloy (Ti 6Al 4V ELI) as described by ASTM F136. Components of the *Zimmer* Anterior Buttress Plate System should not be used with components from any other system or manufacturer. The *Zimmer* Anterior Buttress Plate System components are provided non-sterile. The products need to be steam sterilized by the hospital prior to use.

INDICATIONS FOR USE

The *Zimmer* Anterior Buttress Plate System is intended for anterior intravertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease (DDD). DDD is defined as follows: back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

CONTRAINDICATIONS

Contraindications for the *Zimmer* Anterior Buttress Plate System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity.
3. Pregnancy.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.
8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.

Surgical Technique

Approach

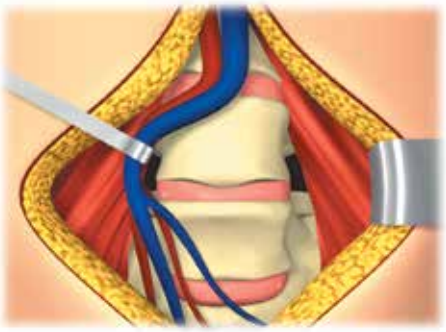


Fig. 1 ▲

Step 1

The anterior lumbar spine is approached via a standard exposure of the retroperitoneal space.

The great vessel bifurcation should be identified and appropriate retraction performed so that there is adequate exposure of the disc space to be fused and the adjacent vertebral bodies. (Fig. 1)

Discectomy

Fig. 2 ▲

Step 2

Once adequate exposure of the disc space is obtained and the correct level confirmed by radiography, an anterior discectomy is performed. (Fig. 2)

Allograft Placement

Fig. 3 ▲

Step 3

An appropriately sized allograft spacer is placed into the disc space. A load bearing cortical allograft, such as a femoral ring allograft (FRA), is placed into the disc space. (Fig. 3)

Allograft Position Confirmation

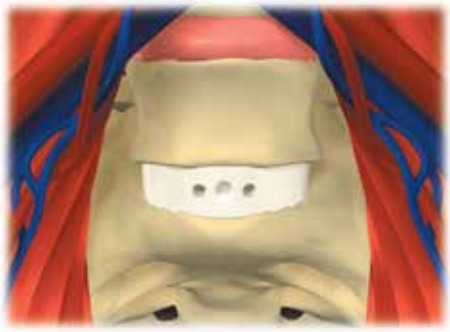


Fig. 4 ▲

Step 4

The position of the allograft should be confirmed, as well as the adequate exposure of the anterior vertebral bodies. The great vessels and iliac vessels should be retracted in preparation for the *Zimmer* Anterior Buttress Plate. The plate must be placed caudal to the great vessel bifurcation. (Fig. 4)

Plate Sizing

Fig. 5 ▲

Step 5

The appropriate sized plate should be selected with the plate holes directly anterior to the midpoint of the vertebrae caudal to the fused level. (Fig. 5) Plates are provided in 22mm and 26mm lengths.

WARNING: *The plate must be placed such that the tip of the plate does not impinge upon the adjacent vertebral body. Such placement may result in abnormal plate loading and device loosening or failure.*

NOTE: *Fixation Pins may be inserted with the Fixation Pin Inserter to provisionally stabilize the plate.*

Instruments

Plate Holder
07.02220.014
(X023-0100)

Fixation Pin Inserter
07.02220.003
(N60001054)

Fixation Pins (single use)
07.02220.001
(N60000158)

Drill Guide

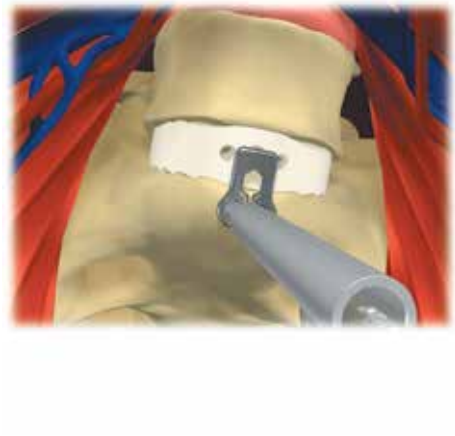


Fig. 6 ▲

Step 6

Single and Double Barrel Drill Guides are provided for the placement of screws. The Drill Guide should engage the plate. 20, 22 and 24mm drill bits are provided to drill pilot holes. A quick-connect Handle may be connected to the Drill bits for drilling. (Fig. 6)

Drilling

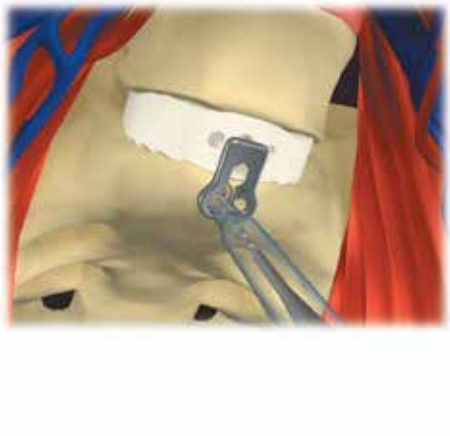


Fig. 7 ▲

Step 7

The Drill bit should be driven until it stops at the upper portion of the Drill Guide. (Fig. 7)

Thread Tapping

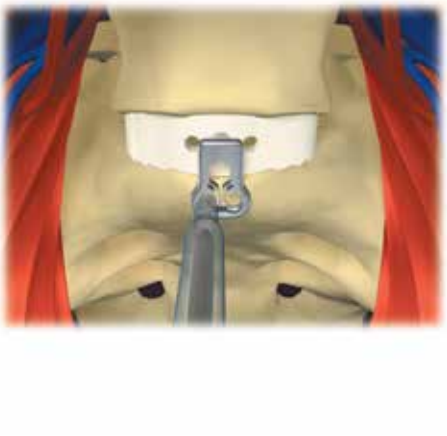


Fig. 8 ▲

Step 8

A 4.3mm thread Tap is provided to place threads into the pilot hole. (Fig. 8)

Instruments

Drill Guides
07.02220.013 Single Barrel
(X023-0070)
07.02220.008 Double Barrel
(X023-0040)

Drill Handle
07.02220.002
(N60000178)

Drills (20,22,24mm)
07.02220.005 – 07.02220.007
(X023-0031 – X023-0033)

4.3mm Tap
07.02220.009
(X023-0045)

Screw Placement

Fig. 9 ▲

Step 9

After pilot hole tapping, a screw can be placed, using the provided self-retaining hex Screwdriver. (Fig. 9)

Screws are provided in the following sizes:

4.3mm Fixed Screw	20mm
4.3mm Fixed Screw	22mm
4.3mm Fixed Screw	24mm
4.5mm Fixed Screw	20mm
4.5mm Fixed Screw	22mm
4.5mm Fixed Screw	24mm

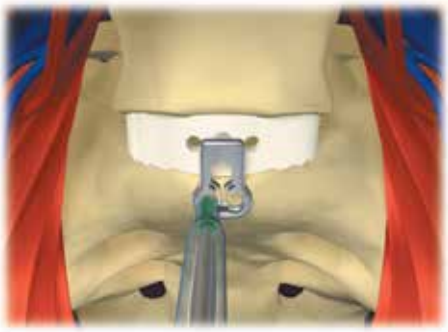


Fig. 10 ▲

Note that the screws are to be placed centrally on the ventral surface of the vertebral body. Screws should be placed within the spinal midline and centrally in the craniocaudal axis of the ventral vertebral body. (Fig. 10) This minimizes the risk of screw placement into the weaker vertebral endplate.

Final Position Confirmation

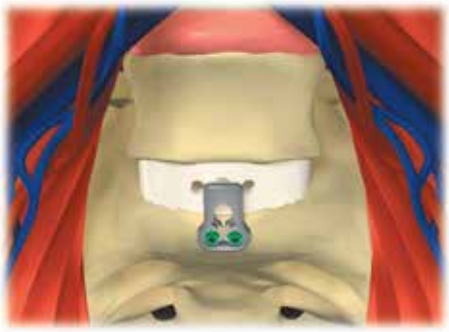


Fig. 11 ▲

Step 10

The plate incorporates resilient locking arms with tabs which seat on a corresponding locking surface of the placed bone screw head. After placement of the screw, the resilient arm should be visualized with the locking tab positioned over the medial portion of the screw head. (Fig. 11)

Instruments

Screwdriver
07.02220.010
(X023-0050)

Posterior Fixation

Fig. 12 ▲

Step 11

The *Zimmer* Anterior Buttress Plate System is only intended to be used in the presence of supplemental posterior fixation, such as pedicle screw fixation.

After placement of the intervertebral graft and plate, normal closure of the anterior approach should be performed. The patient should then be repositioned and a posterior fixation construct performed. Failure to utilize the *Zimmer* Anterior Buttress Plate System with supplemental posterior fixation may result in abnormal loading and product failure. See an example of a rod and pedicle screw based posterior fixation system above. (Fig. 12)

Plate Removal (if required)

Fig. 13 ▲

Step 12

The Screw Removal Instrument is placed into the plate slots adjacent to the screw sockets. This flexes the locking arms inward and allows for screws to be removed using the Screwdriver. Please note that the contoured side of the removal tool should be oriented in the cranial direction. (Fig. 13)

NOTE: *Locking mechanism should only undergo three locking cycles. If three locking cycles are exceeded, it is recommended to replace the plate.*

Instruments

Screw Removal Instrument
07.02220.011
(X023-0055)

Screwdriver
07.02220.010
(X023-0050)

Tray Layouts

Zimmer Anterior Buttress Plate System Implants and Instruments

07.00219.400

Catalog Number	Description	Kit Quantity
07.02219.001	Plate, 22mm	3
07.02219.002	Plate, 26mm	3
07.02219.003	4.3mm Fixed Screw,20mm	6
07.02219.004	4.3mm Fixed Screw,22mm	6
07.02219.005	4.3mm Fixed Screw,24mm	6
07.02219.006	4.5mm Fixed Screw,20mm	6
07.02219.007	4.5mm Fixed Screw,22mm	6
07.02219.008	4.5mm Fixed Screw,24mm	6
07.02220.018	Plate/Screw Caddy	1

Catalog Number	Description	Kit Quantity
07.02220.001	Fixation Pins (single use)	2
07.02220.002	Mini 3-Sided Drill Handle	1
07.02220.003	Fixation Pin Inserter	1
07.02220.005	20mm Drill	2
07.02220.006	22mm Drill	2
07.02220.007	24mm Drill	2
07.02220.008	Double Barrel Drill Guide	1
07.02220.009	4.3mm Tap	1
07.02220.010	Screwdriver	2
07.02220.011	Screw Removal Instrument	1
07.02220.012	Awl	1
07.02220.013	Single Barrel Drill Guide	1
07.02220.014	Plate Holder	1
07.02220.015	Sterilization Case	1
07.02220.017	Instructions for Use	1

Instrument Visual Guide

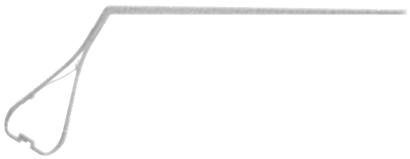


Plate Holder
07.02220.014
(X023-0100)

Awl
07.02220.012
(X023-0060)

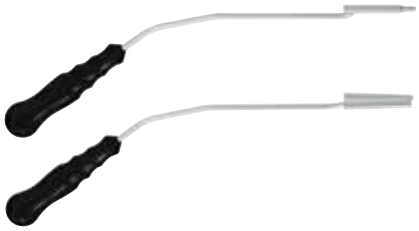
Fixation Pin Inserter
07.02220.003
(N60001054)

Drill Handle
07.02220.002
(N60000178)

Drills
07.02220.005 20mm
(X023-0031)

07.02220.006 22mm
(X023-0032)

07.02220.007 24mm
(X023-0033)



Drill Guides
07.02220.013 Single Barrel
(X023-0070)

07.02220.008 Double Barrel
(X023-0040)

Tap
07.02220.009
(X023-0045)

Screwdriver
07.02220.010
(X023-0050)

Screw Removal Instrument
07.02220.011
(X023-0055)

Warnings and Precautions

WARNINGS

1. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct. The *Zimmer* Anterior Buttress Plate System should not be used with components from any other system or manufacturer. As with all orthopedic implants, the *Zimmer* Anterior Buttress Plate System should not be reused after use as an implant or prior to sterilization.
3. To avoid the risk of vascular injury, the plate MUST be placed caudal to the bifurcation of the great vessels.

PRECAUTIONS

Implants and instruments are provided non-sterile and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of the Instructions for Use.

The *Zimmer* Anterior Buttress Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

The *Zimmer* Anterior Buttress Plate System is only a temporary implant used for the anterior buttressing of a lumbar intervertebral bone graft. This device system is not intended to be used as a means of spinal support or fixation. Bone grafting must be part of the spinal fusion procedure in which the *Zimmer* Anterior Buttress Plate System is utilized. Use of this product without a bone graft or in cases that develop into a nonunion will not be successful. The spinal implant cannot stand body loads. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

After the spine is fused, these devices serve no functional purpose and should be removed. 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/or 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, and (7) bone loss due to stress shielding. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant.

As with all orthopedic and neurosurgical implants, none of the *Zimmer* Anterior Buttress Plate System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The *Zimmer* Anterior Buttress Plate System has not been evaluated for safety and compatibility in the MR environment. The *Zimmer* Anterior Buttress Plate System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and *Zimmer* Spine cannot make any claims regarding the safety of *Zimmer* Spine implants and devices with any specific MR system.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

Disclaimer:

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

Printed in U.S.A. Subject to change without notice.

zimmer

Personal Fit. Renewed Life.™

Contact your Zimmer Spine representative or visit us at www.zimmerspine.com

Manufactured by:

X-spine Systems, Inc.
452 Alexandersville Road
Miamisburg, OH 45342
800.903.0640

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31.70.345.8570
Fax: +31.70.346.7299

CE 0086

Distributed by:

Zimmer Spine
7375 Bush Lake Road
Minneapolis, MN 55439
800.655.2614

zimmerspine.com

L1644 Rev. B (2016-07)
(851S-1001-00)