Because different stages of spinal degeneration require a different solution.
<table>
<thead>
<tr>
<th>TABLE OF CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
</tr>
<tr>
<td>General information</td>
</tr>
<tr>
<td><strong>Zimmer DTO Implant</strong></td>
</tr>
<tr>
<td><strong>OPTIMA ZS Transition Screw</strong></td>
</tr>
<tr>
<td><strong>Zimmer DTO Instruments</strong></td>
</tr>
<tr>
<td><strong>Surgical Technique</strong></td>
</tr>
<tr>
<td>Patient Positioning</td>
</tr>
<tr>
<td>Approach</td>
</tr>
<tr>
<td>Preparation Before the Placement of the Pedicle Screws</td>
</tr>
<tr>
<td>Dynesys Screw Pedicle Preparation</td>
</tr>
<tr>
<td>Dynesys Screw Placement</td>
</tr>
<tr>
<td>OPTIMA ZS Screw Pedicle Preparation</td>
</tr>
<tr>
<td>OPTIMA ZS Transition Screw Placement</td>
</tr>
<tr>
<td>OPTIMA ZS Screw Placement</td>
</tr>
<tr>
<td>DTO Implant Selection</td>
</tr>
<tr>
<td>DTO Implant – Final Preparation Before Insertion</td>
</tr>
<tr>
<td>DTO Implant Assembly</td>
</tr>
<tr>
<td>Compression / Distraction</td>
</tr>
<tr>
<td>Final Set Screw Tightening of OPTIMA ZS Transition Screws</td>
</tr>
<tr>
<td>Final Set Screw Tightening of OPTIMA ZS Screws</td>
</tr>
<tr>
<td>Dynesys Assembly</td>
</tr>
<tr>
<td>Final Construct</td>
</tr>
<tr>
<td><strong>Hardware Removal/Revision Instructions</strong></td>
</tr>
<tr>
<td><strong>Postoperative Treatment</strong></td>
</tr>
<tr>
<td><strong>Cleaning Instructions</strong></td>
</tr>
<tr>
<td><strong>Appendix 1: The Hand-Press</strong></td>
</tr>
<tr>
<td><strong>Appendix 2: Aseptic handling of the DTO Implant</strong></td>
</tr>
<tr>
<td><strong>Warnings and Precautions</strong></td>
</tr>
</tbody>
</table>
Foreword

- This document describes the surgical technique to implant the Zimmer® DTO® Implant and the OPTIMA™ ZS Transition Screw in combination with the Dynesys® and OPTIMA ZS Spinal Systems.

- For implant selection and the complete respective surgical techniques of the Dynesys and OPTIMA ZS systems, please refer to:

  - Dynesys LIS Less Invasive Surgery, L1301
  - Dynesys Top-Loading System, L1388
  - OPTIMA ZS Spinal Fixation System, L1264

- When the Dynesys and OPTIMA ZS systems are used on contiguous levels, they must be used with the Zimmer DTO implant, rod-cord combination implant, and the OPTIMA ZS transition screw. The indication for use for each level is as specified for each system.

General information

- The Dynesys LIS or the Dynesys Top-Loading instruments should only be used with the Dynesys Spinal System. OPTIMA ZS instruments should only be used with OPTIMA ZS screws. The Zimmer DTO implant and OPTIMA ZS transition screw should be used with Zimmer DTO instruments, Dynesys LIS or Top-Loading instruments, and OPTIMA ZS instruments according to the instructions for use described in this brochure.

- For further information regarding indications, warnings, precautions, adverse events and other important medical information, please read the respective Instructions for Use leaflets for the systems.
Zimmer DTO Implant

DTO Implant

The DTO implant and OPTIMA ZS transition screw are designed to allow the Dynesys and OPTIMA ZS systems to be implanted at contiguous levels of the lumbar spine.

The DTO implant is made of a combined 100 mm PET (Polyethylene-Terephthalate) Dynesys cord and a titanium alloy 6 mm rod. The rod is pre-bent.

The DTO implant is delivered partially assembled (cord inserted in the rod and maintained in position by means of a small needle).

The assembly must be finalized intra-operatively by pressing the pre-assembled pin with the DTO Hand Press or the optional DTO Pin Press.

The Dynesys cord must be carefully handled in order to maintain aseptic conditions during the assembly.

The DTO implant is available in six pre-contoured rod lengths:
- 40 mm
- 50 mm
- 60 mm
- 70 mm (optional)
- 80 mm
- 90 mm (optional)
- 100 mm (optional)

The DTO implant is delivered sterile.

The Dynesys system is placed cranially from the OPTIMA ZS system.

The DTO implant is intended only for index surgery.
OPTIMA ZS Transition Screw

The polyaxial OPTIMA ZS transition screw is specially designed to be used with the DTO implant.

Available sizes:

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0 mm</td>
<td>7.0 mm</td>
</tr>
<tr>
<td>6.0 x 35 mm</td>
<td>7.0 x 35 mm</td>
</tr>
<tr>
<td>6.0 x 40 mm</td>
<td>7.0 x 40 mm</td>
</tr>
<tr>
<td>6.0 x 45 mm</td>
<td>7.0 x 45 mm</td>
</tr>
<tr>
<td>6.0 x 50 mm</td>
<td>7.0 x 50 mm</td>
</tr>
</tbody>
</table>

The OPTIMA ZS transition screw is delivered nonsterile.

Caution: The DTO implant can only be used in connection with the OPTIMA ZS transition screw.

Zimmer DTO Instruments

Four DTO instruments are available:

The specific instruments for Dynesys LIS, Dynesys Top-Loading, and OPTIMA ZS systems are described in their respective surgical techniques.
Patient Positioning

Prone or Knee-Chest positions are acceptable, provided that care is taken to preserve the natural lordosis in the lumbar spine as well as to avoid any pressure on the abdominal cavity that might result in excessive bleeding.

The use of fluoroscopy or X-ray (AP and lateral view) is strongly recommended for placement of the screws.

Other valid computer-aided surgical navigational techniques may also be used.

Approach

The spine is approached through a standard posterior midline incision or a paraspinal approach. Muscles are retracted until the facet joints are visible.

Caution: Do not damage the posterior ligaments or the facet joint capsules.

Preparation Before the Placement of the Pedicle Screws

Place the screws lateral to the facet joints.

Correct screw placement is absolutely necessary for optimal functioning of the system and for long term anchorage of the screws.

Note: The facet joints must remain intact.

Note: If there is not enough room for the spacer, you can remove bone from the lateral aspect of the articular process, preserving the capsule.

Use the Spacer Template to determine the correct position of the screws.

Open the pedicle with the Awl.
Dynesys Screw Pedicle Preparation

The assembly is started at the most cranial level with the placement of the Dynesys pedicle screws.

Using the Dynesys Awl and the Pedicle Probe, prepare the pedicle for insertion of the screw.

The marks on the Pedicle Probe help determine the appropriate screw lengths (35, 40, 45, 50, or 55 mm).

Note: Do not open the pedicle deeper than length of the intended screw (maximum screw length is 55 mm). Screw length depends on patient morphology.

Note: We do not recommend using a curved Pedicle Probe, which may widen the bone channel.

Note: X-ray use is recommended.

Check the integrity of the pedicle wall with the Pedicle Sound.

Note: Dynesys screws do not require tapping. Use of the Dynesys Bone Tap System is optional.

Caution: X-ray use is recommended when using Bone Taps. Always select the Bone Tap diameter that corresponds to the pedicle screw size to be implanted. Do not tap beyond the length of the pedicle screw to be implanted. Inspect cannulated Bone Taps prior to use to ensure the cannula is not occluded.

OPTIONAL: Depth Sleeve
If you have difficulty seeing the marks on the tip of the Pedicle Probe, use the Depth Sleeve and the corresponding marks on the proximal end of the shaft.
**Dynesys Screw Placement**

Place *Dynesys* screws as described in the following sections of the *Dynesys* LIS Surgical Technique Manual, L1301, or the *Dynesys* Top-Loading Surgical Technique, L1388:

- Pedicle Screws
- Set Up of the Guide Pin and Pedicle Screw
- Placement of the Guide Pins and Pedicle Screws

**OPTIMA ZS Screw Pedicle Preparation**

Using the *OPTIMA ZS* Awl and Probe, prepare the pedicles of the vertebrae below the *Dynesys* screw for insertion of the *OPTIMA ZS* transition screw and *OPTIMA ZS* screw(s).

Screw insertion should follow the angle of the pedicle canal.
Guide Pins may be placed to identify the appropriate screw trajectory (OPTIMA ZS screws and OPTIMA ZS transition screw only) via a lateral X-Ray view.

Check the integrity of the pedicle wall with the OPTIMA ZS Tester.

**OPTIMA ZS Transition Screw Placement**

The OPTIMA ZS transition screw is placed lateral to the facet joint (see Pedicle Screw Preparation).

Select the appropriate size OPTIMA ZS transition screw.

Using the OPTIMA ZS Small Poly Screw Driver, insert the OPTIMA ZS transition screw.

*Note: Insert the OPTIMA ZS transition screw as deep as possible.*

Insert the OPTIMA ZS transition screw into the desired pedicle.

*Note: Ensure that the Driver is fully engaged with the screw prior to inserting. The tip of the screw will not toggle when the driver is fully engaged.*

**Caution:** While implanting the OPTIMA ZS transition screw, do not damage the facet joint capsule.

*Note: In order to facilitate the assembly of the screws, the optional Dynesys Guide Pin can be removed.*
OPTIMA ZS Screw Placement

Place the OPTIMA ZS screws as described in the following sections of the OPTIMA ZS Surgical Technique, L1264:

• Pedicle Preparation

• Polyaxial Screw Insertion

Note: Select only OPTIMA ZS polyaxial screws for a proper alignment with the OPTIMA ZS transition polyaxial screw.

Note: Check that the standard OPTIMA ZS screw is placed lateral to the facet joint like the cranial Dynesys screws.

Repeat the same procedure for all pedicle screws on the contra-lateral side.

DTO Implant Selection

Once screws have been placed, determine the appropriate rod length of the DTO implant.

The rod should extend approximately 5 mm beyond the most distal edge of the inferior screw polybody.
**DTO Implant – Final Preparation Before Insertion**

*Caution: Use new gloves when handling the DTO implant and Hand Press.*

Carefully remove the DTO implant from its sterile packaging (Refer to Appendix 2).

The DTO implant is delivered partially assembled. A small needle ensures that the cord maintains its position in the rod.

*Caution: The DTO implant cord must be handled carefully during assembly to maintain aseptic conditions. It is delivered in a protective bag to maintain aseptic conditions prior to assembly.*

In order to complete the assembly of the implant, the pin must be fully pressed using the Hand Press. Final insertion ensures sufficient connection strength between the cord and the rod.

Keep the cord in its protective bag during handling.

*Caution: Do not implant the DTO without fully pressing the pin.*

Open the Hand Press.

*Note: The Blue handle is placed on the top.*

*Note: Refer to Appendix 1 for more information regarding the Hand Press.*
Place the DTO implant into the Hand Press and position according to the 'cord' and 'rod' markings on the instrument.

Once the DTO implant is correctly placed in the Hand Press, close the Hand Press.

*Note: The Hand Press can only be closed in one direction.*

Ensure the Power Screw is at its highest position prior to closing the Hand Press. The Hand Press cannot be closed if the Power Screw is partially advanced.

*Caution: Do not use excessive force to close the instrument; otherwise, it may be damaged.*
Turn the handle of the Hand Press in a clockwise direction until there is no further rotation.

Ensure the line on the ram is past the line on the Hand Press body.
Release the Power Screw by turning the handle counterclockwise until the Hand Press opens.

Carefully remove the DTO implant from the Hand Press.

*Note: Hold the cord by its protective bag to ensure aseptic handling.*

Caution: Visually check that the pin has been fully inserted/pressed into the DTO implant prior to implantation.

Check that the pin surface is flush with the DTO implant.

If the pin is not fully inserted, repeat the preparation with the Hand Press.

Caution: Remove the protective bag before continuing the assembly.
**DTO Implant Assembly**

The *DTO* rod is delivered pre-bent.

**Caution:** Rod is supplied pre-bent and must not be further contoured.

First place the connecting part of the *DTO* implant into the *OPTIMA ZS* transition screw.

**Caution:** The *OPTIMA ZS* Persuader cannot be used with the *OPTIMA ZS* transition screw.

In the cranio-caudal direction, placement of the *DTO* implant is guided by the two flanges on each side of the connecting part.

**Caution:** Carefully handle the cord during the assembly in order to ensure aseptic conditions.

**Caution:** The surface containing the pin of the connecting part must be facing upwards from the exposure.

The *DTO* rod is placed in the *OPTIMA ZS* screw head using the Rod Holder.

The Rod Pusher may be used to seat the *DTO* rod while inserting set screws with the Set Screw Inserter.
Note: Use a set screw from the OPTIMA ZS Set for the OPTIMA ZS transition screw.

Caution: Only use a small set screw for the OPTIMA ZS transition screw.

Insert the set screw of the OPTIMA ZS transition screw using the OPTIMA ZS Set Screw Driver Guide.

Note: The DTO implant must be adequately seated prior to set screw insertion.

The set screw starts easily when properly aligned. If incorrectly aligned, the set screw will exhibit noticeable resistance during the initial threading. If this occurs, back the set screw completely off the screw and check that it is properly seated on the Set Screw Driver Guide.

Advance the set screw as far as possible, but:

- Do not attempt to final tighten the system using the Set Screw Driver Guide.
- Over-tightening of the set screw could damage the OPTIMA ZS transition screw thread.

Repeat the same procedure for the OPTIMA ZS screws.
Caution: Select the appropriate set screw for the OPTIMA ZS screw. Two set screws are available.

Select and place the DTO implant for the contra-lateral side.

Insert the set screws.

**Compression / Distraction**

Provisionally tighten the set screw on the side of the segment being translated, while leaving the set screw on the contra-lateral side loose.

Perform compression or distraction against the provisionally tightened assembly.

In case of a compression, a special DTO Compressor with Protective Adapters has been designed to protect the polished surface of the DTO implant.

**Caution:** Only use the DTO Compressor for compression.

**Caution:** Excessive compression force can result in damage of anatomical structures or compromise the implant/bone interface.

**Caution:** Do not use any Compressor on the Dynesys screw.

**Caution:** Complete any compression/distraction before the implanting of the Dynesys spacer.

- 5.0 mm, 6.0 mm and 7.0 mm polyaxial screws utilize the Small Set Screw
- 7.5 mm and 8.0 mm polyaxial screws utilize the Large Set Screw
**Final Set Screw Tightening of OPTIMA ZS Transition Screws**

After achieving the desired amount of correction, perform final tightening of the set screw.

Place the DTO Anti-Torque on the OPTIMA ZS transition screw and use the OPTIMA ZS Axial Torque Wrench to tighten the set screw(s).

*Caution: The DTO Anti-Torque is intended for use on the OPTIMA ZS transition screw only.*

Tighten the set screw until the line and arrow on the Torque Wrench Handle (106 in-lbs./12 Nm) align.

![Initial torque position](image1)

![Final torque position (106 in-lbs.)](image2)
Final Set Screw Tightening of OPTIMA ZS Screws

Position the OPTIMA ZS Anti-Torque over the polybody of the OPTIMA ZS screws to be tightened.

Insert the Axial Torque Wrench through the cannulated Anti-Torque Device into the set screw.

Tighten the set screw until the line and arrow on the Torque Wrench Handle (106 in-lbs./12 Nm) align.

Repeat the process until the remaining set screws are tightened.

Alternative Tightening Technique for OPTIMA ZS Screws and OPTIMA ZS Transition Screws:
Assemble the 4 mm OPTIMA ZS Hex Driver and the Torque Limiting T-handle.

Insert the 4 mm Hex Driver through the cannulated Anti-Torque into the OPTIMA ZS set screw.

Caution: Only use this optional instrument with the OPTIMA ZS screws and not with the OPTIMA ZS transition screw.
Tighten the set screw until the Torque Limiting T-handle breaks over/clicks at 106 in-lbs./12 Nm.

*Note:* The Axial Torque Wrench or 4 mm Hex Driver and Torque Limiting T-Handle used in conjunction with the Anti-Torque are the only instruments acceptable for final set screw tightening.

**Caution:** Do not place the transverse link against the connecting part of the *DTO* implant.

Optional: Transverse links may be used to connect rod segments.

*For more information, please review the OPTIMA ZS Spinal System surgical technique.*
**Dynesys Assembly**

Re-insert the optional Dynesys Guide Pins on the Dynesys screws heads to assist in docking instrumentation.

Select the appropriate Pedicle Distance Gauge for the Dynesys screw being used. Using the appropriate Dynesys Pedicle Distance Gauge, measure the spacer length between the Dynesys pedicle screw and the OPTIMA ZS transition screw.

Verify that the Drag Indicator is in the start position.

Assess the movement in the facets in distraction and compression.

Measure the distance (spacer length) with a slight distraction force.

**Caution: Do not induce kyphosis or scoliosis.**

Record the measured spacer length for the levels. Spacer length measurements must be taken for both sides before the cord and spacers are implanted.

Cut the Dynesys spacer with the Dynesys Spacer Cutter according to the previously determined measurement.

Thread the appropriately sized spacer onto the DTO cord and place against the OPTIMA ZS transition screw head.

Using a clamp, insert the DTO cord through the Dynesys pedicle screw head.

*Note: The end of the introduction zone of the cord can be bent to facilitate the introduction of the cord into the screw head.*

*Note: Avoid twisting and looping of the cord.*
For *Dynesys* LIS Instrumentation:

Complete the *Dynesys* construct assembly and cord tensioning according to the *Dynesys* LIS Surgical Technique, L1301:

• Construct Assembly

For *Dynesys* Top-Loading Instrumentation:

Complete the *Dynesys* construct assembly and cord tensioning according to the *Dynesys* Top-Loading Surgical Technique, L1388:

• *Dynesys* Glide Instrumentation: Adjacent Level
Final Construct

After segment by segment work, a two-level assembly is completed.

Decorticate the posterior elements as necessary. Place bone graft to achieve the desired fusion.
Hardware Removal/Revision Instructions

Set Screw Removal

Position the appropriate Anti-Torque Device over the pedicle screw body of the set screw to be removed. Insert the matching Torque Wrench through the Anti-Torque Device and into the set screw. Turn the Torque Wrench counterclockwise until the set screw is loose but not completely disengaged. Remove the Torque Wrench and Anti-Torque Device. Carefully remove the OPTIMA ZS set screws with the Set Screw Driver Guide and the Dynesys set screws with the Set Screw Starter. Repeat for all set screws.

DTO Implant Removal

Place the OPTIMA ZS Rod Holder onto the rod component of the DTO implant near the connecting portion and remove from the OPTIMA ZS pedicle and transition screws. Once the DTO Implant connecting portion has been removed from the OPTIMA ZS transition screw, carefully remove the DTO cord and Dynesys spacer assembly. It may be necessary to cut the cord adjacent to the spacer with a scalpel blade to facilitate removal. Remove all components of the DTO implant. Repeat on the contralateral side.

Dynesys Pedicle Screw Removal

For the Dynesys LIS Screw:

Insert the Long Retainer into the Pedicle Screw Driver handle and turn clockwise to engage. Place the Pedicle Screw Driver onto the Dynesys screw head using the marks located on the Pedicle Screw Driver to ensure proper orientation. Turn the Long Retainer clockwise and secure the Dynesys screw to the Pedicle Screw Driver. Caution: Do not overtighten the Long Retainer.

Once the pedicle screw is fully engaged on the driver, carefully turn the Screw Driver counterclockwise until the Dynesys screw is removed. Repeat for all Dynesys pedicle screws.

Carefully examine the operative site to ensure all hardware has been removed.

For the Dynesys Top-Loading Screw:

Reference the Dynesys Top-Loading System Surgical Technique, L1388.

• Hardware Removal / Revision Instructions

OPTIMA ZS Transition and Pedicle Screw Removal

Insert the tip of the OPTIMA ZS Small Poly Screw Driver into the polybody, positioning the tangs of the attached T-Handled Screwdriver Sleeve into the slots on the screw body. Turn the Ratchet handle clockwise while holding the Screwdriver Sleeve. Once the pedicle screw is fully engaged on the driver, carefully turn the screwdriver counterclockwise until the OPTIMA ZS screw is removed. Repeat for all OPTIMA ZS transition and pedicle screws.
Postoperative Treatment

It is the responsibility of the surgeon to assess the adequate postoperative treatment depending on the patient’s condition.

Analgesics
Possible antibiotic prophylaxis against infection
Possible prophylaxis against thromboembolism
Early physiotherapy
Limited activity is recommended for approximately six weeks

A non-rigid brace should be considered during the period of limited activity

A gradual resumption of activities can begin after approximately 6 weeks

Cleaning Instructions

For information on cleaning and sterilization refer to:

• OPTIMA ZS Instruction for Use leaflet, IFU-SD01

• Dynesys Spinal System and the Zimmer DTO Implant Instructions for Use leaflet, D011500217

Caution: Pedicle screws should not be put back in the tray for resterilization if they have been in contact with bodily fluids. They should be treated as a biohazard and disposed of accordingly.

Please consult the following documents for additional information on the instrumentation:

• Dynesys LIS Instruments Instructions for Use 07.00996.001

• Dynesys Top-Loading System Instruments Instructions for Use 07.01408.001

• Zimmer DTO Instruments Cleaning Leaflet, 07.01352.001

• Instructions for Use for Surgical Instruments, D011500192

Warning: Do not sterilize the OPTIMA ZS transition screw tray with the Zimmer DTO instrument tray. The effectiveness of the sterilization of these two trays together has not been established. Refer to the sterilization instructions for each system in their respective Instructions for Use leaflets.
Appendix 1

The Hand-Press

- Handle (top)
- Power Screw Housing
- Ball and Spring Plunger
- Handle (bottom)
- Power Screw
- Ram
- Implant Housing
- Hinge Screw
Appendix 2

Aseptic handling of the DTO Implant

Remove the DTO implant from its innermost pouch but leave the cord in its protective bag to allow aseptic handling of the implant during the assembly.

Caution: The protective bag must be removed before the final assembly of the implant inside the patient.
OPTIMA® ZS Spinal System & OPTIMA® ZS Transition Screw
Instructions for Use

Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Warning: The safety and effectiveness of pedicle screw 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 secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion, (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown. The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

Important Note: The users of the OPTIMA® ZS Spinal System acknowledge that they have read and agreed to the conditions in this insert, which are considered to be contractual. When using the Zimmer GmbH Zimmer® DTO® Implant, the users of the OPTIMA® ZS Spinal System should also study carefully instruction for Use and Surgical Technique Manual of the Zimmer GmbH Dynesys® Spinal System as well as the product-specific information. In addition, it should be noted that the Dynesys® Spinal System and the Zimmer® DTO® Implant are only indicated for use in the posterior lumbar spine. For additional details regarding the indications for use, precautions, warnings, contraindications and other product specific information for the Dynesys® Spinal System and the Zimmer® DTO® Implant refer to the Instructions for Use for these devices.

Basic Structure: The OPTIMA® ZS Spinal System is an internal fixation device for spinal surgery comprising pedicle screws, connectors, rods, housings and transverse link assemblies. Various forms and sizes of these implants are available, so that adaptations can be made to take into account the pathology and individual patient.

Material: All components of the OPTIMA® ZS Spinal System and the OPTIMA® ZS Transition Screw are made of Ti6Al4V ELI, a titanium-based alloy which complies with ASTM F136.

Indications for Use: The OPTIMA® ZS Spinal System is a posterior pedicle screw fixation system indicated for the treatment of severe spondylolisthesis, (Grade 3 and 4), of the L5-S1 vertebra in skeletally-mature patients receiving fusion due to congenital bone graft having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion. In addition, The OPTIMA® ZS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:
• Degenerative spondylolisthesis with objective evidence of neurological impairment
• Fracture of the vertebral body
• Dislocation
• Scoliosis
• Kyphosis
• Spinal tumor
• Failed previous fusion (Pseudarthrosis).

When the Zimmer GmbH Dynesys® Spinal System and the OPTIMA® ZS Spinal System are used on contiguous levels, they must be used with the Zimmer GmbH Zimmer® DTO® Implant, rod-cord combination implant, and the OPTIMA® ZS Transition Screw. The indications for use for each level is as specified for each system.

Note: The OPTIMA® ZS Spinal System’s Surgical Technique Manual should be followed carefully. Important information on the proper usage of implants and instruments is included. When using the Zimmer® DTO® Implant, the users of the OPTIMA® ZS Spinal System should also study carefully Instruction for Use and Surgical Technique Manual of the Dynesys® Spinal System as well as the product-specific information.

Levels of Fixation: Levels of fixation are for the thoracic, lumbar and sacral spine.

General Conditions of Use:
• The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with surgical and medical indications, the potential risks and limitations related to this type of surgery, the contraindications, side effects and precautions. The surgeon should also possess knowledge of the metallurgical and biological characteristics of the implants.
• The OPTIMA® ZS Spinal System implants and implants parts should never be combined with parts from other companies, unless otherwise indicated in the Instruction for Use and/or Surgical Technique Manual. General use operating room instruments and/or other instruments described in the surgical technique are permitted for use. In addition, when using the Zimmer GmbH Zimmer® DTO® Implant it is permitted to combine the Zimmer GmbH Dynesys® Spinal System with the OPTIMA® ZS Spinal System. Each system must be implanted using the appropriate instruments and surgical technique as defined in the respective Surgical Technique Manuals. The instruments for the different systems must not be commingled or used interchangeably. If this should occur, U&I Corporation declines all responsibility.
• Under no circumstances may the implants be re-used after previous implantation or patient contact. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.

Contraindications:
• Any active or suspected latent infection in or about the spine.
• Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
• Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the implant.
• Obesity, an overweight or obese patient can produce loads on the spinal system which can lead to failure of the implant, the device or to failure of the device itself.
• Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
• Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the implant.
• Obesity, an overweight or obese patient can produce loads on the spinal system which can lead to failure of the implant, the device or to failure of the device itself.

Recent infection, fever or leukocytosis
• Bony abnormalities preventing safe screw fixation
• Open wounds
• Metal sensitivity, documented or suspected
• Bone absorption, osteopenia and/or osteoporosis
• Patients having inadequate tissue coverage over the operative site
• Pregnancy
• Excessive local inflammation
• Use in the cervical spine
• Alcohol or drug abuse
• Patient unwilling or unable to follow postoperative instructions
• Sensitivities/allergy to polymers, polyethylene, polycarbonate, urethane and polyethylene terephthalate when using the Zimmer GmbH Dynesys® Spinal System and the Zimmer® DTO® Implant
• Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count, (WBC) or marked left shift in the WBC differential count.

Side Effects:
• Late bone grafting or no visible fusion mass and pseudarthrosis
• Neurosensory complication, paralysis, soft tissue lesions, pain, wound complication, paresthesia and cerebral spinal fluid leakage due to the surgical procedure, breakage deformation and or migration of the implant
• Pedicle failure while preparing and inserting the pedicle screw
• Superficial or deep-set infection and inflammatory phenomena
• Allergic reaction to the implant material
• Reduction in bone density due to different distribution of mechanical stresses
• Pain and abnormal sensations due to hardware bulkiness
• Neurological and spinal dura mater lesions from surgical trauma
• Bursitis
• Presence of micro-particles around the implants
• Growth of the fused vertebrae is altered
• Partial loss of the degree of correction achieved during surgery
• Modification of spinal curvature and stiffness of the vertebral column
• Loosening, disassembly, bending or breakage of components
• Non-union or delayed union
• Fracture of vertebrae
• Foreign body reaction (allergic) to components or debris
• Loss of fixation
• Vascular or visceral injury
• Gastrointestinal, urological and/or reproductive system compromise
• Loss of bone or fracture of bone above or below the level of surgery
• Bone graft donor site pain, fracture, and/or delayed wound healing
• Restriction of activities
• Lack of effective treatment of symptoms for which surgery was intended
• Death
• The above list of side effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

28 Zimmer® DTO® Implant and OPTIMA™ ZS Transition Screw with Dynesys® System Instruments
Precautions:
- The surgeon should consider the level of implantation, the weight of the patient, the patient’s activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the appliance. In such cases, orthopedic devices may be considered only as a delaying technique to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation system. This device is recommended for use only by surgeons familiar with pre-operative and surgical techniques, cautions and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape and strength of the implants.)
- 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 breakage of the implant.

Warning:
- The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.
- The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spine.
- Potential risks associated with the use of this system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
- Discard all damaged or mishandled implants.
- Never reuse an implant after patient contact even though it may appear undamaged.
- Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
- Corroding or bending of a screw or hook may reduce its fatigue strength and cause failure under load. If spinal screws or hooks are bent or otherwise damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
- The Zimmer GmbH Zimmer® DTO® Implant rods are supplied pre-bent and should not be further contoured.
- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants and the amount of metal compounds released into the body system may also increase. Internal fixation devices such as rods, connectors, screws, hooks, etc., which come into contact with other metal objects must be made from like or compatible metals.
- Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically.
- Any decision by a surgeon to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Implant removal should be followed by adequate postoperative management to avoid fracture.

Packaging, Labeling and Storage:
- Individual OPTIMA™ ZS Spinal System 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 also 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 implant system. This, in turn, 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 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.

Sterilization Procedures:
The OPTIMA™ ZS implants are provided clean and non-sterile, and must be sterilized prior to use using one of the following recommended sterilization cycles.
- CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Implant removed from a patient or that contact bodily tissues or fluids should never be reused.
- Sterilization: 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 (1): Steam, Wrapped Gravity Cycle at 132° C (270° F) for 20 minutes.
  ° Suggested method (2): Steam, Prevacuum Cycle at 132° C (270° F) for 4 minutes.

Warning:
The Zimmer GmbH Dynesys® Spinal System Implants and the Zimmer® DTO® Implants are delivered sterile and cannot be re-sterilized. Do not sterilize the OPTIMA™ ZS Transition Screw tray inside the Zimmer® DTO® Instrument Tray. The effectiveness of the sterilization of these two trays together has not been established.
Dynesys® Spinal System and the Zimmer® DTO® Implant

Instructions for Use

1.0 DESCRIPTION

When used as a pedicle screw fixation system, the Dynesys Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudarthrosis). The Dynesys Spinal System is comprised of a variety of pedicle screws sizes, tensioning cords and longitudinal spacers that are uniquely fitted for each individual case. All the pedicle screws are manufactured from medical grade titanium alloy conforming to ISO 5832-11. They are provided with or without hydroxyapatite coating conforming to ISO 13779-2. The tensioning cords are manufactured from Sulene-PET (polyethylene-terephthalate). The longitudinal spacers are manufactured from Sulene-PCU (polycarbonate-urethane).

The Zimmer DTO Implant is a cord-rod combination implant that is assembled intraoperatively by the final tightening of the fastening pin. The U & I Corporation Optima™ ZS Transition Screw is a transition pedicle screw that is part of the Optima ZS Spinal System. The Zimmer DTO Implant is used an interface device when the Dynesys Spinal System and the Optima ZS Spinal System are implanted at adjacent levels. The tensioning cords are manufactured from Sulene-PET. The rod and pin are manufactured from Ti-6Al-4V conforming to ISO 5832-3. For information on the intended use, device description and materials for the Optima ZS Spinal System and the Optima ZS Transition Screw refer to the U & I Corporation’s Instructions for Use for the Optima ZS Spinal System.

Before using the Dynesys Spinal System alone or in combination with the Zimmer DTO Implant the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information.

Any complications or other effects that may occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, sepsis, etc., fall within the responsibility of the operating surgeon; the manufacturer, the importers or the suppliers of Zimmer products cannot be held liable for same.

Zimmer products should be implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical technique.

Implants are always components of a system. They should only be combined with other components belonging to the same system as defined in the surgical technique, and may be implanted only using original instruments also belonging to the same system unless otherwise indicated.

- Occasional exceptions to the above rules are pointed out in the description of the surgical technique or in the product description.
- Zimmer Companies Implants and implant parts should never be combined with parts from other companies, unless otherwise indicated in the Instructions for Use and/or the Surgical Technical Manual. General use operating room instruments and/or other instruments described in the surgical technique are permitted for use. In addition, when using the Zimmer DTO Implant it is permitted to combine the Dynesys Spinal System with the Optima ZS Spinal System. Each system must be implanted using the appropriate instruments and surgical technique as defined in the respective Surgical Technique Manuals. The instruments for the different systems must not be commingled or used interchangeably.
- Spinal implants must not be machined or altered in any way, unless instructed to do so in the surgical technique.
- Implants or implant-parts that are contaminated, not sterile, damaged, scratched or have been improperly handled or altered without authorization may not be implanted under any circumstances.

2.0 INDICATIONS, CONTRAINDICATIONS AND POTENTIAL ADVERSE EVENTS

- An implant should only be considered if all other therapeutic possibilities have been carefully considered and found unsuitable or inappropriate.
- Any implant is subject to unavoidable wear and aging. In the course of time, an implant initially implanted in a stable manner can loosen or its functiona-ility can become impaired. Wear, aging, loosening and so on can lead to the need for re-operation.
- The selection of patients depends to a great extent on the age of the patient, his/her general state of health, the condition of the existing bone, previous operations and anticipated further surgery. Normally speaking, pros-thetic replacements are only indicated for patients whose skeleton is fully developed.
- For the indications, contra-indications and potential adverse events of the Optima ZS Spinal System refer to the Instructions for Use for that system.

2.1 Indications

When used as a pedicle screw fixation system in skele-tally mature patients, the Dynesys Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the Dynesys Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

When the Dynesys Spinal System and the Optima ZS Spinal System are used on contiguous levels, they must be used with the Zimmer DTO Implant, rod-cord combination implant, and the U & I Corporation Optima ZS Transition Screw. The intended use for each level is as specified for each system.

2.2 Contraindications

Contraindications of the Dynesys Spinal System and the Zimmer DTO Implant are similar to other commercially available posterior spinal fixation systems. Contraindications include but are not limited to the following:

- Use in the cervical spine;
- Active systemic or local infection;
- Obesity;
- Pregnancy;
- Mental illness;
- Severe osteoporosis or osteopenia;
- Sensitivities/allergy to metals, polymers, polyethylene, polycarbonate urethane and polyethylene terephthalate;
- Alcohol or drug abuse;
- Patient unwilling or unable to follow postoperative instructions;
- Soft tissue deficit not allowing sound closure;
- Any medical or physical condition that would preclude the potential benefit of spinal implant surgery;
- Congenital abnormalities, tumors or other conditions that would prevent secure component fixation that has the potential to decrease the useful life of the device;
- Any medical or mental condition which would exclude the patient at high risk from surgery of this severity;
- For pedicle screw cases, inadequate pedicles of the thoracic, lumbar, and sacral vertebrae.

2.3 Complications and Possible Adverse Events

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential for additional surgery to correct these effects:

- Loosening, disassembly, bending or breakage of components;
- Tissue sensitivity to implant material;
- Potential for skin breakdown and/or wound complications;
- Non-union or delayed union;
- Infection;
- Nerve damage, including loss of neurologic function, dural tears, paralysis, paresthesia, and cerebral spinal fluid leakage;
- Fracture of vertebrae;
- Foreign body reaction (allergic) to components or debris;
- Loss of fixation;
- Vascular or visceral injury;
- Change of normal spinal curvature;
- Gastrointestinal, urological and/or reproductive system compromise;
- Pain or discomfort;
- Bursitis;
- Decrease in bone density due to stress shielding;
- Loss of bone or fracture of bone above or below the level of surgery;
- High removal torques may be encountered with the use of the hydroxyapatite coated screw;
- Bone graft donor site pain, fracture, and/or delayed wound healing;
- Restriction of activities;
- Lack of effective treatment for symptoms for which surgery was intended;
- Death.

3.0 WARNINGS

The safety and effectiveness of the Dynesys Spinal System and the Zimmer DTO Implant have not been established for spinal indications beyond those stated in the Indications section.

The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with bone graft is being performed at all instrumented levels.

For a complete list of Warnings and Precautions for the Optima ZS Spinal System, including the Optima ZS Transition Screw, refer to the Instructions for Use for that system.

3.1 Precautions

Only experienced spinal surgeons with specific training in the use of the Dynesys Spinal System, the Zimmer DTO Implant and the Optima ZS Spinal system should perform the implantation of these systems. This is due to the technically demanding procedure presenting a risk of serious injury to the patient. These systems should only be used with instrumentation specifically designed for each system. Refer to the respective surgical techniques to determine which instruments should be used for each step of the surgical procedure.

Unless the Zimmer DTO Implant is being used, components of spinal fixation systems other than Zimmer Companies should not be used with the components of the Dynesys Spinal System. Only the Optima ZS Spinal System, including the Optima ZS Transition Screw, may be used in combination with the Zimmer DTO Implant.

No component of the Dynesys Spinal System and the Zimmer DTO Implant should be reused or re-sterilized.

The Dynesys Spinal System and the Zimmer DTO Implant are intended to be used with bone graft, which is required to provide additional spinal support. A successful result is not always achieved in every surgical case.

The patients should be made aware that a successful result, as defined by reduced pain, increased function and the establishment of solid fusion, is not always achieved in every surgical case. Proper patient selection will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be informed of this increased risk and counselled to discontinue tobacco use prior to and immediately after surgery. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spinal fusion. Patients with poor muscle tone and bone quality, and/or nerve paralysis are also poor candidates for spinal fusion. The use of autogenous bone graft has been shown to provide superior results compared to the use of allograft bone graft material.

In addition to the above specified warnings and precautions, general surgical risks should be explained to the patient prior to surgery.

3.2 Preoperative

- Only patients that meet the criteria described in Indications section and that do not have any conditions included in the Contraindications section of this package insert should be selected for surgery.
- Implants of this system must be handled and stored to avoid damage. Implants should be protected from damage including scratches, nicks and corrosive environments.
- The surgeon should be instructed on the proper use of instruments and implants.
- The doctor must explain the risks of a spinal implant to the patient, including the possible impact of the factors mentioned under Section 2.3 on the success of the operation and the possible side effects. The patient should also be informed as to what steps he/she can take in order to reduce the possible effects of these factors.

Note: The Dynesys Spinal System, the Zimmer DTO Implant and the Optima ZS Spinal System Surgical Technique Manuals should be followed carefully. Important information on the proper usage of implants and instrument are included.

3.3 Intraoperative

- The surgeon must follow the instructions provided in the surgical technique manual for the Dynesys Spinal System, the Zimmer DTO Implant and/or the Optima ZS Spinal System. Extreme caution must be used around the spinal cord and nerve root, especially during insertion of screws.
- A correct choice of the implant is extremely important. The appropriate type and size of an implant for the individual patient must be selected, taking anatomical and biomechanical factors into account.
- Aseptic handling is to be observed during the implantation. Implants removed from a patient should never be re-sterilized or reused.
- The Zimmer DTO Implant requires specific assembly; refer to the respective Surgical Technique Manual for the assembly instructions.
- When using the Zimmer DTO Implant, surgeon must be cautious about verifying that no component of the implant has become loose in the packaging, if the Zimmer DTO Implant components have become loose in the packaging please return the implant to Zimmer.
- Verify that the Zimmer DTO Implant is fully assembled prior to implantation.
- Remove any protective devices prior to implantation (i.e. protective caps or bags).
- The Zimmer DTO is supplied pre-bent and must not be further contoured.

3.4 Postoperative

- Implant removal should be considered after fusion has occurred. The risk and benefit of a second surgical procedure must be evaluated carefully. The surgeon is expected to supply post-operative care and management instructions to the patient. The patient should be advised that non-compliance with post-operative instructions could lead to poor results, including implant failure.
- The patient must be adequately instructed regarding the risks and limitations of this implant system. Additional surgeries may be required if fusion does not occur and implant failure occurs.
- Patient must be instructed on the physical limitations that are required to avoid placing excessive stress on the implant causing implant failure or delays in recovery.
- The patient must be informed that the risks of multiple complications do exist.
- Components of this system are only intended to support the spine during the period required to achieve solid spinal fusion.
- Regular X-ray checks are recommended in order to detect any changes in the position of the implant and signs of loosening or breakage of components.
- The patient should be urged to inform his doctor immediately of any unusual changes to the operated area.
- The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.
- An implant-bearer’s card should also be made out for the patient
The Dynesys Spinal System and Zimmer DTO Implant are manufactured by:
Zimmer GmbH
Sulzer Allee/ P.O. Box
CH-8404 Winterthur
Switzerland
Tel: 41 (0)52 262 60 70
Fax: 41 (0)52 262 01 39

The OPTIMA ZS Spinal System and OPTIMA ZS Transition Screw are:
Manufactured by U&i Corporation
529-1, Yonghyun-dong, Euijangbu, Kyunggi-do, Korea, 480-050
Telephone: +82.31.852.0102
Fax: +82.31.852.0107
Email: information@youic.com
www.youic.com

U&i Corporation is:
Represented in the EU by Obelis S.A
Av.de Tervuren 34, bte 44, B-1040 Brussels, Belgium
Telephone: +32.2.732.59.54
Fax: +32.2.732.60.03
Email: mail@obelis.net or miguel@obelis.net

Zimmer is the exclusive, worldwide distributor of OPTIMA™ ZS Spinal System (except in Belgium, Luxembourg, Turkey and South Korea). Zimmer has the exclusive, worldwide distribution rights for the OPTIMA™ ZS Transition Screw.

OPTIMA™ is a trademark of the U&i Corporation, Korea. All other names, trademarks, service marks and logos referenced to within this brochure are the property of Zimmer GmbH and/or their respective subsidiaries.

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.