Dynesys Dynamic Stabilization System
LIS Surgical Technique

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The Dynamic Stabilization System

Please refer to the Dynesys® Spinal System package insert for the Instructions for Use/indications, device description, contraindications, precautions, warnings and potential risks associated with the Dynesys System.

Dynesys Instruments

- Spacer Template
- Reaming Probe
- Pedicle Probe
- Awl
- Pedicle Sound
- Depth Sleeve
- Pedicle Screw Driver
- T-Handle
- Short Retainer
- Long Retainer
- Set Screw Starter
- Set Screw Driver
- Guide Pin
- Guide Pin Wrench
- Guide Pin Wrench/ Set Screw Limiter
- Ratcheting Handle
- Ruler
- Pedicle Distance Gauge
- Screw Driver with Retaining Clip
- Cord Tensioning Instrument
- Cord Threader
- Cord Manipulator
- Spacer Holder
- Anti-Torque
- Torque Limiting Driver
- Spacer Cutter
- Spacer Cutter Handle
The *Dynesys* Spinal System is composed of pedicle screws, universal spacers and cords.

**Pedicle Screws:** The screws anchor the *Dynesys* System into the spine. Hydroxyapatite (HA) and standard screws are provided.

*Note: The HA-coated screw threads have a white appearance.*

**Universal Spacers:** The spacers are used to hold the segments in a more natural anatomical position and to control the spine in extension.

**Cords:** The cord controls forward flexion movements.

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**Pedicle Screw:**

PROTASUL®-100 (Titanium alloy)

**HA-Coated Pedicle Screw:**

PROTASUL®-100

**Universal Spacers:**

SULENE® PCU
(Polycarbonate-urethane)

**Cords:**

SULENE® PET
(Polyethylene-terephthalate)
Patient Positioning

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

The use of fluoroscopy for placement of the screws is strongly recommended.

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

Incision

Two Options:

Midline Approach:
Make a lumbar median incision over the spinous processes of the vertebrae.

Make the incision one segment longer (proximal and distal) than the planned operative level(s).

Move the musculature aside from the spinous process.

Paraspinal Approach:
The Paraspinal Intermuscular Approach is the preferred minimally invasive technique to be used (without bone decompression indication).

Incision Choices:
Use a midline incision over the spinous processes of the vertebrae.

OR

Make two cuts 3.5 cm lateral from the spinous processes of the vertebrae.

Open the dorsal fascia.

Split up the muscles (L1-L3 between Multifidus and Longissimus L4-S1 between Iliocostalis and Longissimus).
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.
Use the Pedicle Probe to create the channel for 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 with the Pedicle Sound whether the pedicle wall is intact.

*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.*
Pedicle Screws

Twenty screw sizes are available:

<table>
<thead>
<tr>
<th>Diameter</th>
<th>5.2 mm</th>
<th>6.0 mm</th>
<th>6.4 mm</th>
<th>7.2 mm</th>
<th>8.0 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td>5.2 x 35 mm</td>
<td>6.0 x 35 mm</td>
<td>6.4 x 35 mm</td>
<td>7.2 x 35 mm</td>
<td>8.0 x 35 mm</td>
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<td></td>
<td>6.0 x 40 mm</td>
<td>6.4 x 40 mm</td>
<td>7.2 x 40 mm</td>
<td>8.0 x 40 mm</td>
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<td>6.0 x 45 mm</td>
<td>6.4 x 45 mm</td>
<td>7.2 x 45 mm</td>
<td>8.0 x 45 mm</td>
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<td></td>
<td>6.0 x 50 mm</td>
<td>6.4 x 50 mm</td>
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<td></td>
<td>6.4 x 55 mm</td>
<td>7.2 x 55 mm</td>
<td>8.0 x 55 mm</td>
<td></td>
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</tr>
</tbody>
</table>

Note: A screw with a diameter greater than 6.0 mm is recommended for good anchorage in the sacrum.

Note: 8.0 mm screws should be used for revisions only.

Use the largest diameter and longest length screw possible according to the patient's anatomy. Consider the individual patient's case when selecting a screw.

In case of sclerotic bone, a standard screw is recommended.
Set Up of the Guide Pin and Pedicle Screw

Optional placement of pedicle screws with Screw Driver with Retaining Clip is available in Appendix B.

Note: Use the Long Retainer to secure the screw to the Pedicle Screw Driver when not using the optional Guide Pin.

Fix the screw on the Guide Pin.

Caution: Avoid contact between glove and screw threads to ensure aseptic conditions.

The Guide Pin improves the orientation possibilities and makes instrument positioning easier.

Do not over tighten the Guide Pin; it could be difficult to loosen.

Screw the Short Retainer into the Pedicle Screw Driver handle. This ensures that the Short Retainer won’t fall out of the handle.

Insert the screw and attached Guide Pin into the bore of the Pedicle Screw Driver (take care with the direction of the screw head).

By tightening the Short Retainer, the Guide Pin and the screw are fixed to the Pedicle Screw Driver.

Caution: Do not over tighten.
Placement of the Guide Pins and Pedicle Screws

Insert the screws. It is important to place the screws lateral to the facets.

Advance the screw until the head or the polished portion of the screw is in contact with the bone.

**Caution:** Upon insertion of the screw, do not reverse the screw to back it up.

The distance between the bone and the middle of the screw head must be less than 10 mm.

Align them so the through-holes will allow passage of the cord.

**Caution:** A torque and/or bending load that is too high can fracture the pedicle.

OPTIONAL:
After fitting the screw, a T-Handle can be placed on top of the Pedicle Screw Driver to facilitate the insertion of the screw.

*Note:* Use of the T-Handle is only recommended during the final tightening steps to avoid wobbling of the screw.

When placing the T-Handle, align the dot on the T-Handle to the dot on the Pedicle Screw Driver.
Remove the Short Retainer by turning the handle counterclockwise.

Remove the Pedicle Screw Driver.

The Guide Pin remains on the screw head.

After the first screw has been placed, use the Spacer Template to visualize the exact placement and orientation of the second screw head and to ensure adequate room for the spacer.

Place all screws. Align them as shown in the picture to the right.

Check the screw placement with fluoroscopy, x-ray or other valid computer-aided surgical navigation techniques.
Verify that the Drag Indicator is in the start position.

Place the Pedicle Distance Gauge between the screw heads in the center of the holes to measure the appropriate spacer length.

Assess the movement in the facets in distraction and compression.

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

Possible guidelines: Distract to create parallel endplates or distract to create neutral facet joint position.

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

*Note:* Fluoroscopy usage is highly recommended while measuring the spacer length.

Determine the spacer length according to the specific indication in a light distraction or compression for each side separately (considering the patient position).

Record the measured spacer length for all levels. Spacer length measurement must be done on both sides before cord and spacer are implanted.

*Note:* Reset the Drag Indicator after each measurement. Not resetting may lead to incorrect spacer measurement.
Use the Spacer Cutter to cut the spacer.

The spacer can only be cut once and is used only on one vertebral segment side.

Spacer lengths can be cut from 6 mm to 45 mm.

The Cutter Blade must be replaced if the cutting edge has deteriorated (nicks on the cutting surface of the spacer). Refer to Appendix A on page 21 for instructions.

*Note: For cleaning and sterilization, please refer to the instrument inserts.*

**Spacer Cutter Assembly:**
1. Cover
2. Unlock Button
3. Fast Shift Button
4. Adjustable Screw
5. Lever
6. Blade Holder

*Note: Lever is located in the bottom of the Instrument Tray and must be placed in the slot over the cutting blade.*

Remove the Lever from the tray.

Put the Lever into the Blade Holder.

Open the Cover while pressing the Unlock Button.

*Note: The Lever must be in the starting position, otherwise it is not possible to open the Cover.*
To open the channel for the spacer, press the Fast Shift Button and move the Adjustable Screw as far to the right as it will go.

Place the spacer groove into the slot provided on the Adjustable Screw.

Hold down the Fast Shift Button and push the Adjustable Screw to the left for the initial adjustment.

Turn the Adjustable Screw to set the final desired length.
Alignment of the markers shows the actual size being cut. Here we can see that the spacer length is 23 mm.

Close the Cover while pressing the Unlock Button.

Hold the Spacer Cutter with one hand and, using your thumb as a fulcrum, pull the Lever forward with the other hand until it stops.

*Note: It is not possible to turn the Lever if the Cover is not closed properly.*

Move the Lever back to the starting position. Open the Cover while pressing the Unlock Button.

*Note: The Lever must be in the starting position, otherwise it is not possible to open the Cover.*

Remove the cut spacer from the Spacer Cutter. The remaining part of the spacer is removed and must be discarded.

*Note: The spacer with the groove is implanted.*

The Spacer Organizer (P/N 07.01174.001) is an optional item that can be ordered as a means to organize the cut spacers by placing them on a peg that corresponds to the correct level and side.
Cord

The cord is available in two sizes: 100 mm and 200 mm.

*Note: Use the 100 mm length for one level or two levels. Use the 200 mm length for two or more levels.*

The cord is made up of three segments: the Introduction Zone, the Working Zone and the Functional Zone.

*Note: The Introduction Zone is the thin part of the cord and it is used to introduce the cord into the screw’s heads.*

*Note: The Working Zone is wrapped in green thread and is intended to facilitate cord tensioning.*

*Note: With the Cord Tensioning Instrument, only work in the Working Zone.*

*Note: The Functional Zone is the part implanted into the patient.*

Do not work with the Cord Tensioning Instrument in the Functional Zone.

The 100 mm cord has one Introduction Zone, one Working Zone and one Functional Zone.

The 200 mm cord has two Introduction Zones (one on each end), two Working Zones (next to the Introduction Zones) and one Functional Zone (in the middle of the cord).

*Note: Handle the cord carefully to ensure aseptic conditions.*
Construct Assembly

Thread the cord through the first screw.

*Note: The end of the Introduction Zone can be bent to facilitate introduction of the cord.*

Insert the cord almost completely; at least 10 mm of the Functional Zone remains outside of the screw head.

*Note: Always start the instruments from the most caudal screw.*

Place the Anti-Torque over the Guide Pin onto the screw head.

Remove the Guide Pin.

Tissue pressure on the Anti-Torque could bind the Guide Pin. In order to remove it, compensate for the pressure on the Anti-Torque Handle. The Guide Pin will be easier to loosen.

Only remove the Guide Pin if the Anti-Torque Handle or the Cord Guide is in place.

If necessary, remove the Guide Pin with the Guide Pin Wrench. Turn it up to a maximum of 90°, otherwise it could damage the Guide Pin.

Attach the set screw to the Set Screw Starter.

Insert the Set Screw Starter into the tube of the Anti-Torque (tip first).

Engage the set screw into the screw by rotating the Set Screw Starter 360°.

Remove the Set Screw Starter from the Anti-Torque.

*Note: Proper alignment is necessary to ensure set screw is properly engaged. Never force the set screw. Thread stripping may result.*
Attach the Set Screw Driver to the Torque Limiting Driver.

Engage the Set Screw Driver with the set screw. Tighten the set screw until the Torque Limiting Driver snaps.

Push the cord through the appropriately sized spacer and place the spacer against the first screw head.
Insert the cord through the second screw.

*Note: Use caution to avoid twisting the cord.*

Put the Cord Guide on the Guide Pin and screw.

Hold the free end of the cord with one hand.

Place the Cord Tensioning Instrument on top of the Cord Guide.

Work in the Working Zone of the cord with the Cord Tensioning Instrument.

**Optional:**
The Spacer Holder may be used to guide the spacer into position.
Use caution to keep the cord, spacer and screws in alignment.

*Note: The cord, screws and spacer must be placed as shown.*

Use the Cord Tensioning Instrument to pull the spacer carefully into position.

Avoid tension in the Introduction Zone of the cord.

Repeat the same procedure for the contralateral side (insert cord, set screws and spacer).

*Caution: Tensioning the first side too early may complicate setting up the cord and spacer on the opposite side. Ensure that spacers are in place on both sides before tensioning any of the levels, otherwise it could be difficult to achieve the required distraction.*

Remove the Guide Pin with the cord in place.

Tissue pressure on the Cord Guide could bind the Guide Pin. When you remove the Guide Pin, compensate for the pressure of the tissues on the Cord Guide.

Remove the Guide Pin only if the Cord Guide is in place.

Attach the set screw to the Set Screw Starter.

Insert the set screw into the Cord Guide using the Set Screw Starter.

Engage the set screw to the screw by rotating the Set Screw Starter 360°. Remove the Set Screw Starter.

Attach the Set Screw Driver to the Torque Limiting Driver.

Engage the Set Screw Driver with the set screw.
Engage the Cord Tensioning Instrument with the cord.

The marks for the appropriate cord tension are visible on both sides of the Cord Tensioning Instrument. The system is appropriately loaded when the two marks on the Cord Tensioning Instrument are in line.

Tension the cord against the Cord Guide.

While maintaining tension on the cord, verify alignment of the marks, then tighten the set screw until the Torque Limiting Driver snaps.

Repeat the same procedure for the contralateral side.
Repeat the same procedure for the adjacent segment(s) if needed.

When the system is fully tensioned, cut the cords leaving at least 10 mm of cord out of the screw heads and remove the cut ends.

*Note: No Working Zone or Introduction Zone remains in the body.*

*Caution: Only implant the Functional Zone of the cord. Implantation of the Working or Introduction Zones in the patient could lead to cord failure.*

The image to the right is an implanted two-level Dynesys system.

Decorticate the posterior elements as necessary. Place bone graft to achieve the desired fusion.
Postoperative Treatment

- 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 six weeks.

APPENDIX A
Hardware Removal / Revision Instructions

Note: It may be necessary to use general surgical instrumentation to remove the implants.

Set Screw Removal

Use the 3.0mm Set Screw Driver to remove the set screw. The Anti-Torque Instrument can be positioned over the screw head to help guide the Set Screw Driver into the set screw and provide counter-torque.

Spacer and Cord Removal

Use the Cord Tensioner to pull the cord through the screw heads; use forceps or a coker to remove the spacers.

Pedicle Screw Removal

Assemble the Screw Driver with Retaining Clip to the Ratcheting Handle. Attach the Pedicle Screw Driver to the screw head. Turn the Screw Driver counter-clockwise until the screw is removed.
APPENDIX B
Changing the Cutter Blade

Loosen the screw on the Blade Holder one rotation using the Set Screw Driver.

Turn the Replacement Blade counterclockwise and pull it down, removing it from the Spacer Cutter.

Take the new Replacement Blade and insert it into the Spacer Cutter as far as it will go.

Rotate the Replacement Blade clockwise as far as it will go. Verify that the hole of the blade is properly aligned with the screw.

Tighten the screw with the Set Screw Driver.

*Note: Do not over-tighten the Blade Cutter Screw.*
APPENDIX C
Inserting the Set Screw into the Pedicle Screw

Note: Use of the Dynesys Screw Driver with Retaining Clip to insert pedicle screws and set screws together will preclude Guide Pin use during the procedure.

Insert Guide Pin Wrench/Set Screw Limiter into the cord hole of the pedicle screw until the shoulder contacts face of the pedicle screw.

Using Set Screw Inserter, thread set screw into pedicle screw until it comes into contact with the shaft of the Guide Pin Wrench/ Set Screw Limiter.

Unthread set screw one half turn (180°) to ensure that cord can pass through screw.

Remove Set Screw Inserter.

Remove Guide Pin Wrench/ Set Screw Limiter.

Assemble the Ratcheting Handle to the Screw Driver with the Retaining Clip.

Insert the screw head into the assembled Screw Driver aligning tangs with pedicle screw slots until the screw head stops (screw head recessed about 50%).

Flush hole (A) and flats (B) are located on the Screw Driver with the Retaining Clip to indicate the position of the screw head.
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. 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 rod-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 as 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.

2.0 INDICATIONS, CONTRAINDICATIONS AND POTENTIAL ADVERSE EVENTS

• 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 functionality 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, prosthesis 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 skeletally 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-rod 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 of 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 must 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 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 postoperative 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.
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.