



# Dynesys<sup>®</sup> LIS Less Invasive Surgery

As described by:

Reginald J. Davis,  
M.D., F.A.C.S.  
Greater Baltimore  
Medical Center  
Baltimore, MD

James H. Maxwell,  
M.D., F.A.C.S.  
Scottsdale Spine Care  
Scottsdale, AZ



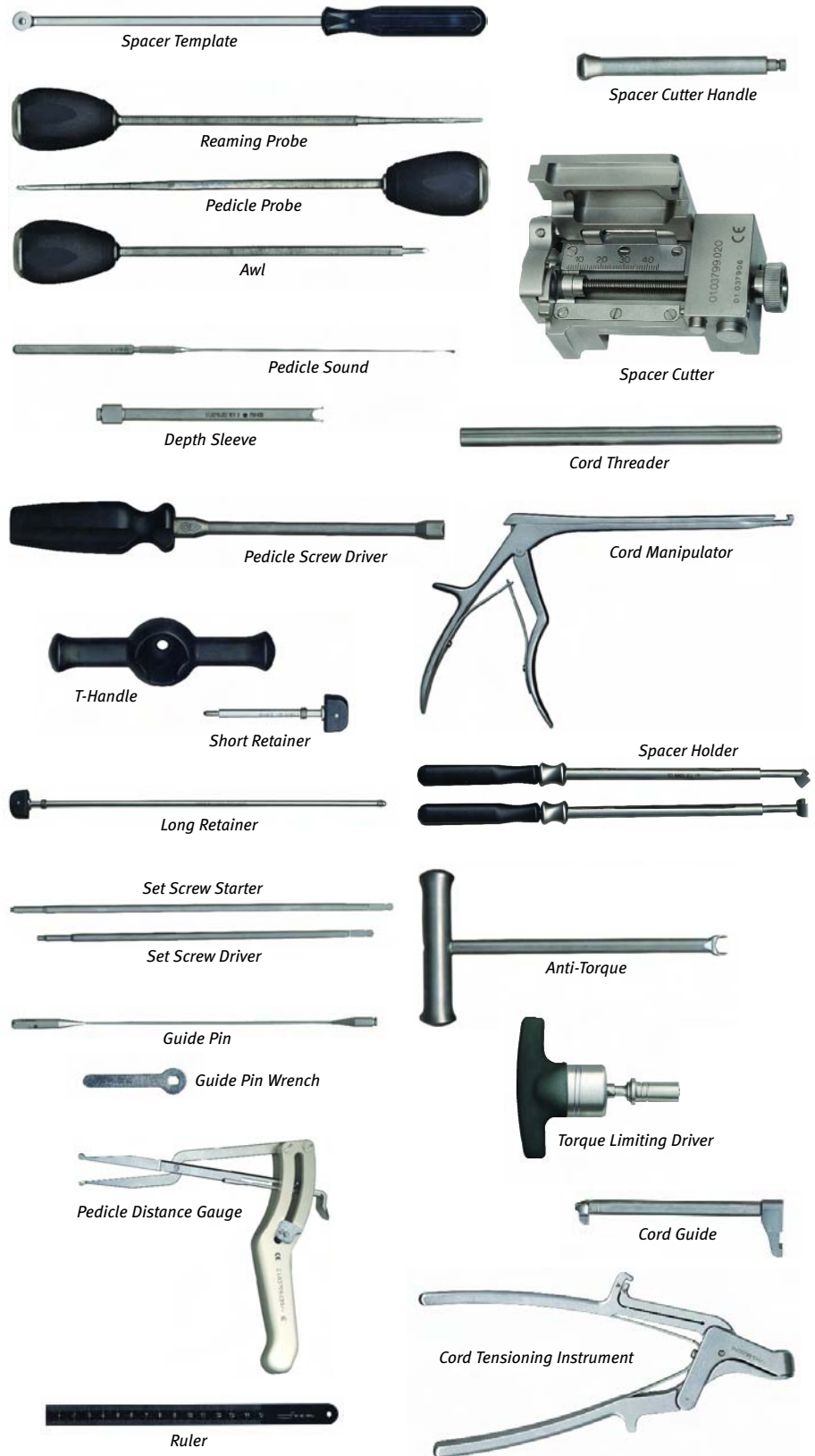
The Dynamic Stabilization System



## The Dynamic Stabilization System

Please refer to the *Dynesys*<sup>®</sup> 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



The *Dynesys* Spinal System is composed of Pedicle Screws, Universal Spacers, and Cords.

**Pedicle Screws:** The screws anchor the *Dynesys* System into the spine.



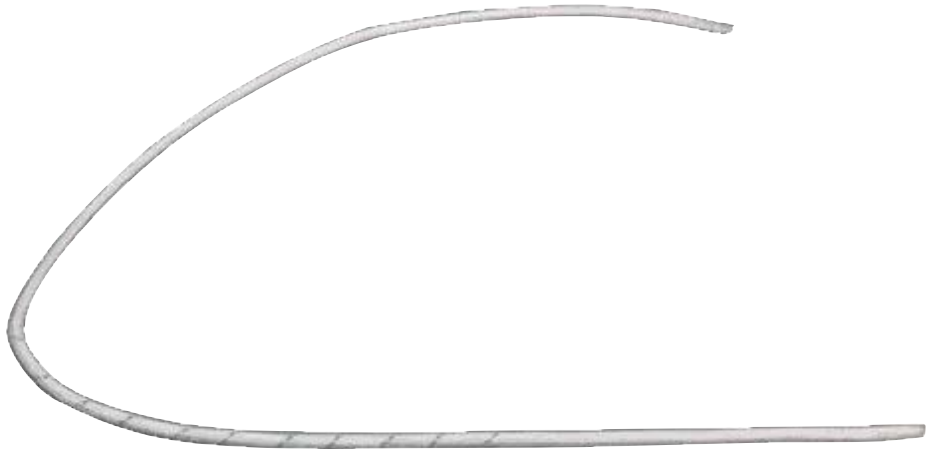
Pedicle Screws:  
PROTASUL<sup>®</sup>-100  
(Titanium alloy)

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



Universal Spacers:  
SULENE<sup>®</sup> PCU  
(Polycarbonate-urethane)

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



Cords:  
SULENE<sup>®</sup> PET  
(Polyethylene-terephthalate)

## 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 is strongly recommended for placement of the screws.

Other valid computer-aided surgical navigational 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).

The musculature should be moved 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:

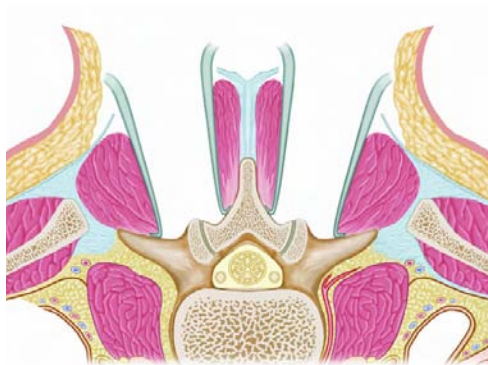
Midline incision over the spinous processes of the vertebrae.

OR

2 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

The screws are placed lateral to the facet joints.

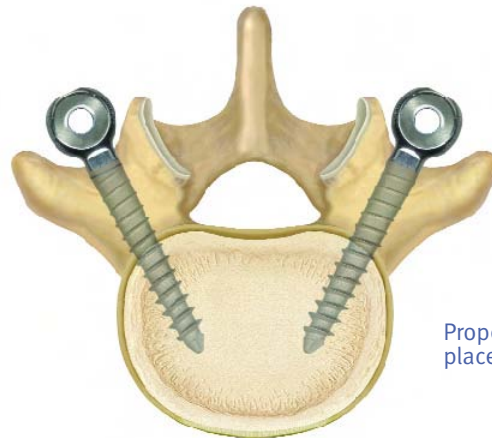
The correct screw placement is absolutely necessary for optimal function of the system and for long term anchorage of the screws.

Note: The facet joints must remain intact.

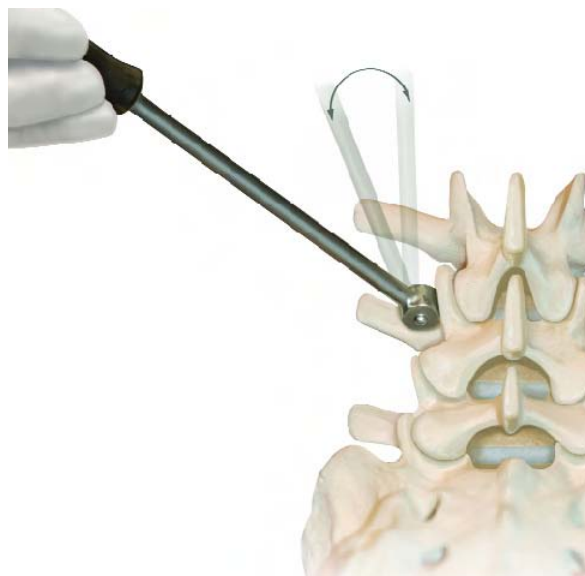
Note: If there is not enough room for the spacer, you can remove bone from the lateral aspect of the articular process, preserving the capsule.

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

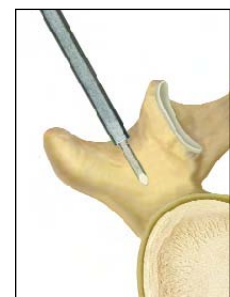
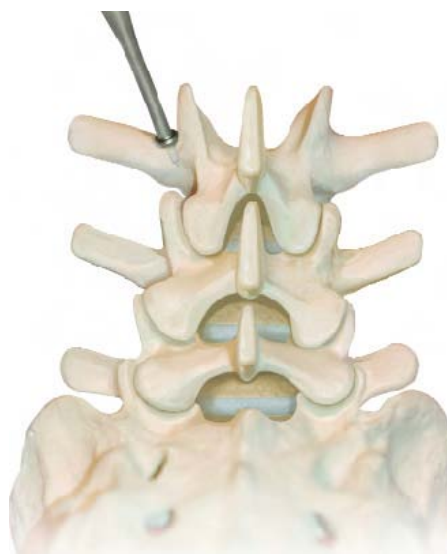
Open the pedicle with the Awl.



Proper lateral screw placement



Spacer Template usage



Proper Awl placement

Use the Pedicle Probe to create the channel for the screw.

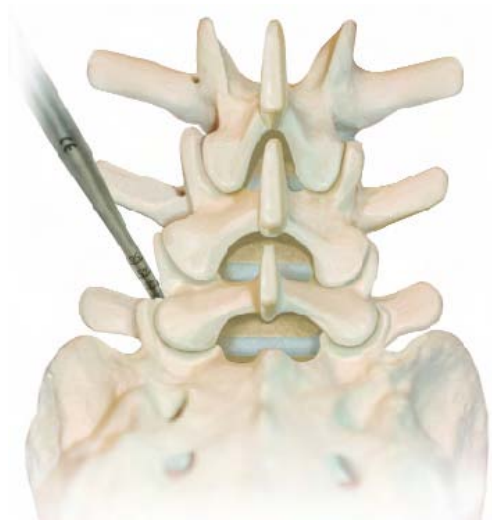
With the Pedicle Probe, the orientation of the screw is determined.

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

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

Note: We do not recommend the use of a curved Pedicle Probe, which may cause widening of the bone channel.

Note: X-ray use is recommended.



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



**OPTIONAL:  
Depth Sleeve**

If you have difficulty seeing the marks on the tip of the Pedicle Probe, use the Depth Gauge and the corresponding marks on the proximal end of the shaft.

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



## Pedicle Screws

20 screw sizes are available:

5.2 mm Diameter	6.0 mm Diameter	6.4 mm Diameter	7.2 mm Diameter	8.0 mm Diameter
5.2 x 35 mm	6.0 x 35 mm	6.4 x 35 mm	7.2 x 35 mm	8.0 x 35 mm
	6.0 x 40 mm	6.4 x 40 mm	7.2 x 40 mm	8.0 x 40 mm
	6.0 x 45 mm	6.4 x 45 mm	7.2 x 45 mm	8.0 x 45 mm
	6.0 x 50 mm	6.4 x 50 mm	7.2 x 50 mm	8.0 x 50 mm
		6.4 x 55 mm	7.2 x 55 mm	8.0 x 55 mm

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

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



Pedicle Screw

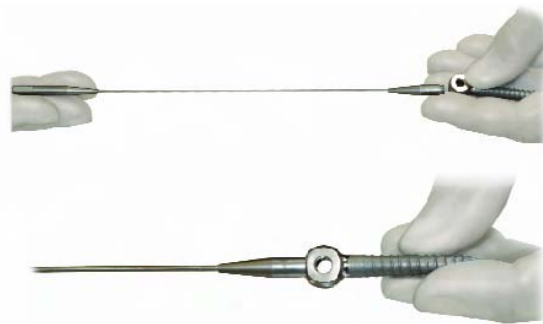
## Set Up of the Guide Pin and Pedicle Screw



Fix the screw on the Guide Pin (with your hand).

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

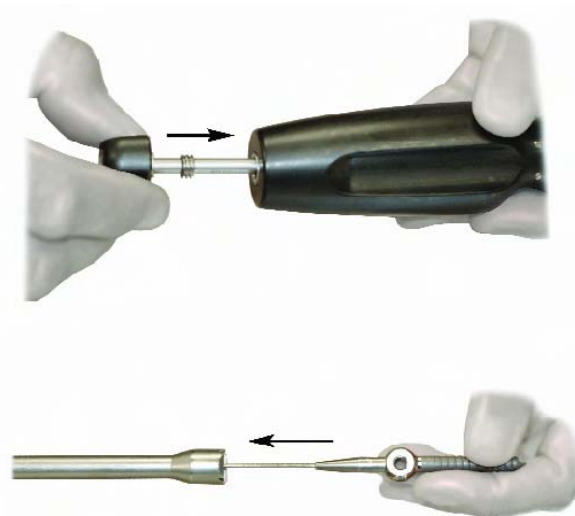
Do not over tighten the Guide Pin, otherwise it could be difficult to loosen.



Screw the Short Retainer in 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 on the direction of the screw head).



By the tightening of 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.

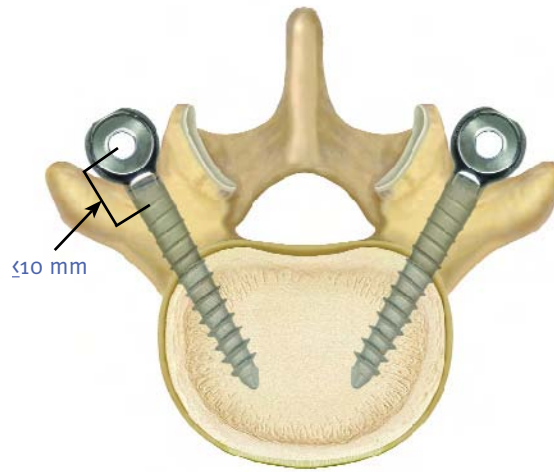
Advance the screw until the head or the polished portion of the screw is in contact with the bone.

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

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

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

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



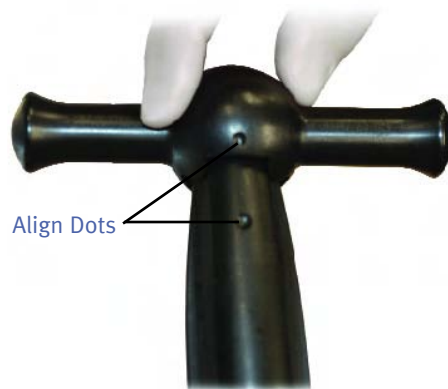
Marks are located on the Pedicle Screw Driver to indicate the position of the screw head.

### 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 the dot on the T-Handle to the dot on the Pedicle Screw Driver.



Remove the Short Retainer by turning the handle counter clockwise.

Remove the Pedicle Screw Driver.

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 insure adequate room for the spacer.



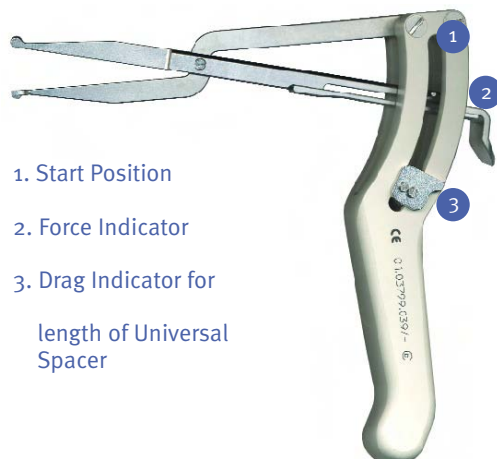
Place all screws. Align them as shown in the picture to the right.

Check the screw placement with fluoroscopy, x-ray or other valid computer-aided surgical navigational techniques.



## Universal Spacer

Verify that the Drag Indicator is in the start position.



1. Start Position
2. Force Indicator
3. Drag Indicator for length of Universal Spacer



Universal Spacer

To measure the appropriate spacer length, place the Pedicle Distance Gauge between the screw heads in the center of the holes.

Assess the movement in the facets in distraction and compression.

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

Possible guidelines are:  
 Distract to create parallel endplates  
 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 (under consideration of 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.



Top View of Pedicle Distance Gauge



Proper placement of Pedicle Distance Gauge

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 6mm to 45mm.

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 19 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.



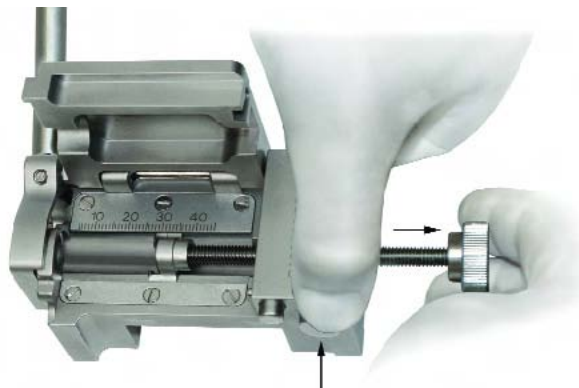
Remove the Lever from the tray.

Put the Lever into the Blade Holder.

Open the Cover while pressing the Unlock Button.

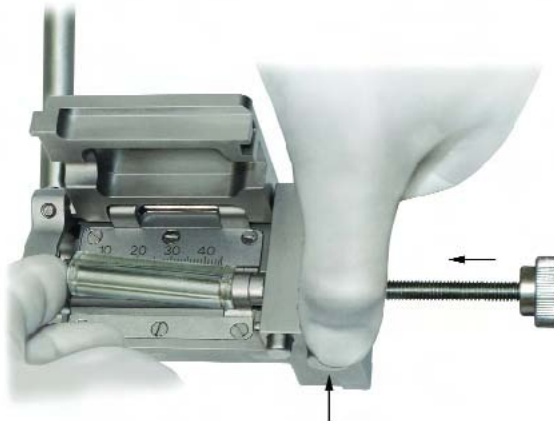
Note: The Lever must be in the starting position, otherwise it is not possible to open the Cover.

By pressing the Fast Shift Button, while pulling the Adjustable Screw to the right (as far as it will go), the channel for the spacer is opened.

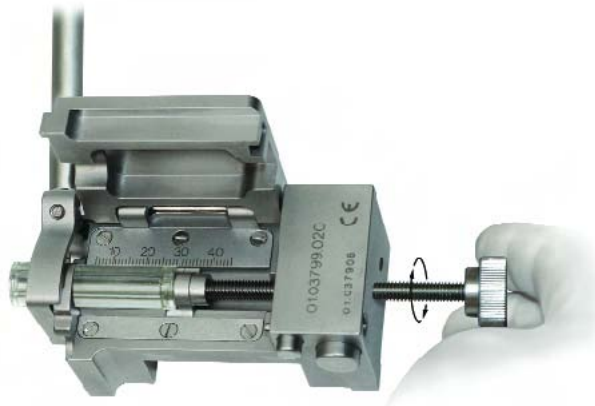


Place the spacer groove into the slot provided on the Adjustable Screw.

For an initial adjustment, push the Fast Shift Button while pushing the Adjustable Screw to the left.



Turn the Adjustable Screw to obtain the desired length.



Alignment of the markers shows the actual size being cut. Here we can see the spacer length is 23 mm.



Close the Cover while pressing the Unlock Button.

Hold the Spacer Cutter with the right hand and with the other hand, using your thumb as a fulcrum, pull the Lever forward 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.



## Cord

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

Note: Use the 100 mm length for 1 level or 2 levels.  
Use the 200 mm length for 2 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 is used to facilitate the introduction of the  
cord into the screws heads.

Note: The Working Zone is wrapped in green thread.  
And can be used to facilitate cord tensioning.

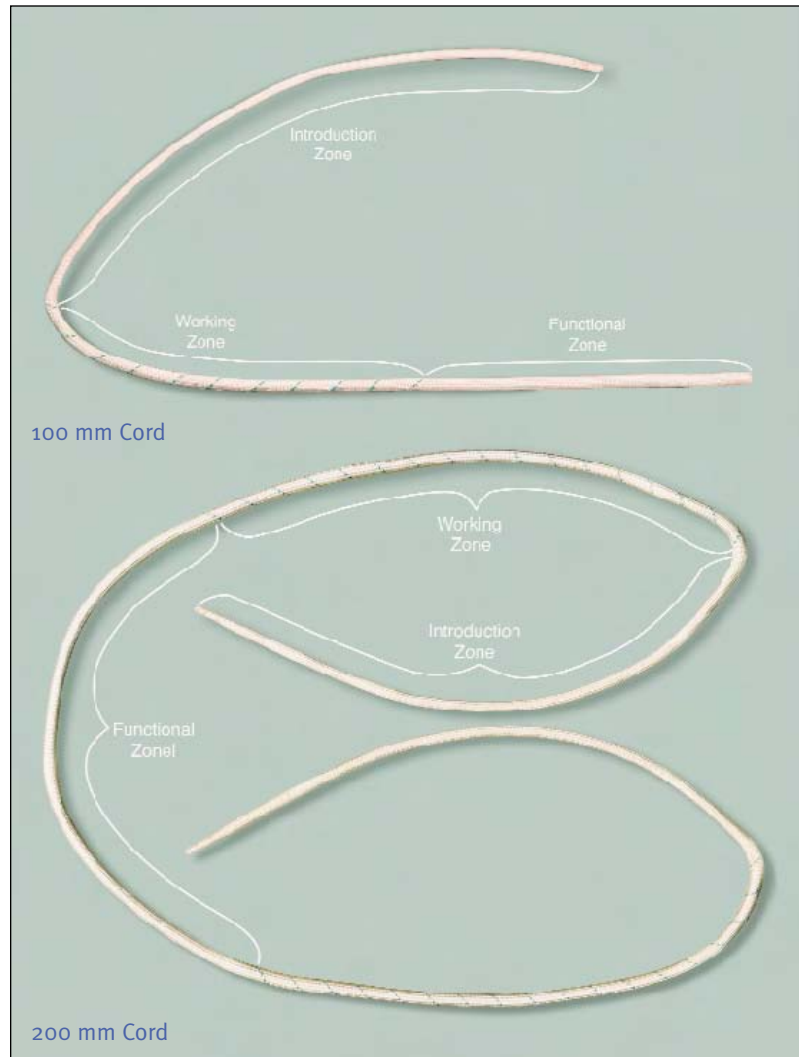
Note: With the Cord Tensioning Instrument, only work  
in the Working Zone.

Note: The Functional Zone is the part implanted in  
the patient.

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

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).



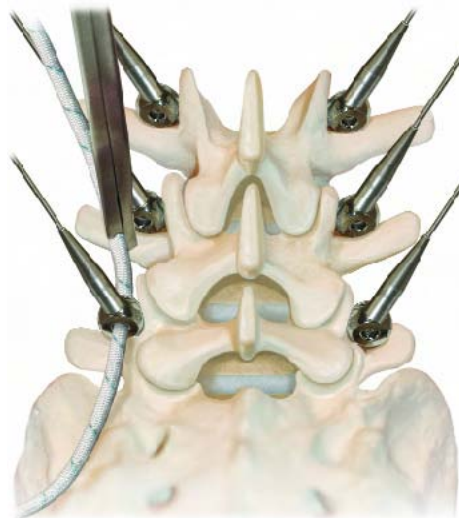
## Construct Assembly

Insert 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.



**OPTIONAL:**  
Use the Cord Threader to guide the cord tip into the screw.

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

Remove the Guide Pin.

The pressure of the tissue on the Anti-Torque could bind the Guide Pin. In order to remove it, compensate the pressure on the Anti-Torque Handle and loosening of the Guide Pin will be easier.

Remove the Guide Pin, only if the Anti-Torque Handle or the Cord Guide are in place.

If necessary, remove the Guide Pin with the Guide Pin Wrench. Turn 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.



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 appropriate 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 tensioning in the Introduction Zone of the cord.

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

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



With the Cord Guide in place, remove the Guide Pin.

Tissue on the Cord Guide could bind the Guide Pin. When you remove the Guide Pin, compensate 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.



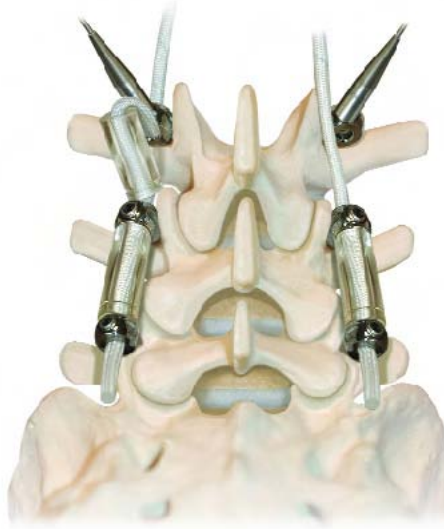
Tension the cord against the Cord Guide.

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.

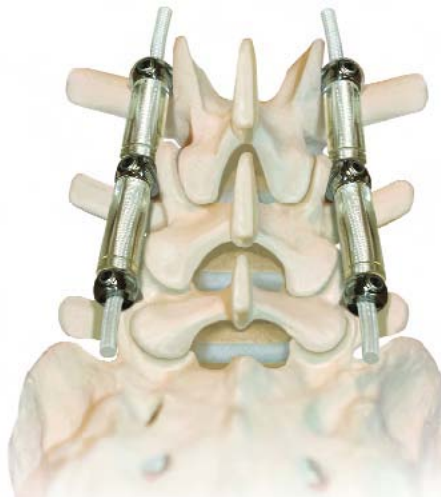
Note: No Working Zone or Introduction Zone remains in the body.

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



Implanted two-level *Dynesys* system.

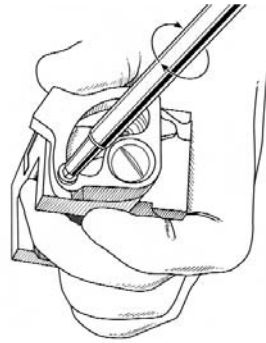
Decorticate the posterior elements as necessary. Place bone graft to achieve the desired fusion.



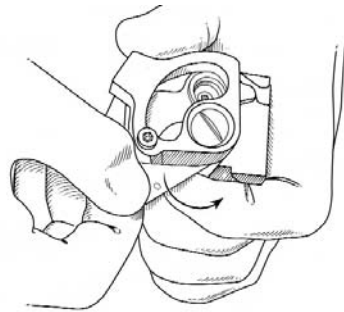
## APPENDIX A

### Changing the Cutter Blade

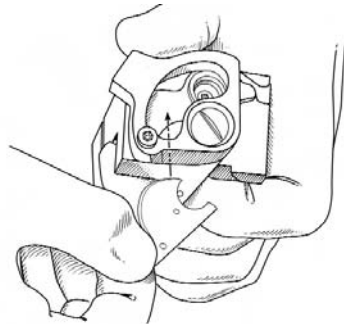
Loosen the screw on the Blade Holder one turn using the Set Screw Driver.



Turn the Replacement Blade counter-clockwise and pull it down, removing it from the Spacer Cutter.



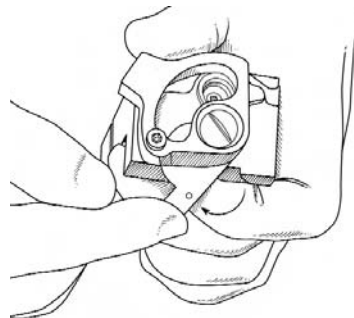
Take the new Replacement Blade and insert it into the Spacer Cutter as far as it will go.



Rotate the Replacement Blade (clockwise), as far as it will go.

Tighten the screw with the Set Screw Driver.

Note: Do not over-tighten the Blade Cutter Screw.



## Postoperative Treatment

Analgesics

Possible antibiotic prophylaxis against infection

Possible prophylaxis against thromboembolism

Early physiotherapy

Limited activity is recommended for approximately 6 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

## 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 (pseudoarthrosis). The *Dynesys* Spinal System is comprised of a variety 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. The tensioning cords are manufactured from Sulene-PET (polyethylene-terephthalate). The longitudinal spacers are manufactured from Sulene-PCU (polycarbonate-urethane). Before using the *Dynesys* Spinal System 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, and may be implanted only using original instruments also belonging to the same system.

- 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 or used with instruments supplied by other companies, unless these are instruments that are in general use in the operating theatre and/or are described in the surgical technique. No liability is accepted for products of third parties that are used by the purchaser or the user.
- Spinal implants must not be machined or altered in any way, unless this is expressly envisaged in the design and 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.

## 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 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, prosthetic replacements are only indicated for patients whose skeleton is fully developed.

## 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 (pseudoarthrosis). 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.

## CONTRAINDICATIONS

Contraindications of the *Dynesys* Spinal System 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.

## 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; 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.

## WARNINGS

The safety and effectiveness of the *Dynesys* Spinal System has not been established for spinal indications beyond those stated in the Indications section. The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

## PRECAUTIONS

Only experienced spinal surgeons with specific training in the use of the *Dynesys* Spinal System should perform the implantation of the system. This is due to the technically demanding procedure presenting a risk of serious injury to the patient. This system should only be used with instrumentation specifically designed for this system. Components of other spinal fixation systems than those from Zimmer companies should not be used with components of the *Dynesys* Spinal System. No component of the *Dynesys* Spinal System should be reused or re-sterilized. The *Dynesys* Spinal System is 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.

Contact your Zimmer Spine representative or visit us at [www.zimmerspine.com](http://www.zimmerspine.com)



[www.zimmerspine.com](http://www.zimmerspine.com)

Zimmer Spine, Inc.  
7375 Bush Lake Road  
Minneapolis, MN 55439-2027  
U.S.A.

Telephone 952.832.5600  
or 800.655.2614  
Fax 952.832.5620