



Dynesys® Dynamic Stabilization System

Surgical Technique



Dynesys – The non-fusion System with LIS
(Less Invasive Surgery)

Disclaimer

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Surgical Technique Dynesys® LIS Less Invasive Surgery

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Dynesys® and Dynamic Neutralization® are trademark of Zimmer GmbH. Dynesys® is developed in partnership with Mr. Dubois, MD (France)

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The Dynamic Stabilization System

Dynesys is a Dynamic Stabilization (Neutralization) System for the lumbar spine (L1-S1).

The goal of the *Dynesys* system is to realign and restabilize dynamically unstable segments.

The system supports a controlled range of motion by suppressing discovertebral diskynesia (instability).

General Information

The operation handling requires high aseptic standards, in order to minimise the risk of infection.

The implants must be used directly from the sterile package.

The *Dynesys* LIS instruments should only be used in conjunction with the *Dynesys* Spinal Implant System. Liability claims regarding damage caused by the misuse of *Dynesys* LIS instruments will be rejected.

For further information regarding indications, warnings, precautions, adverse events and other important medical information, please read the instruction leaflet.

Dynesys LIS Instruments



Pedicle Distance Gauge
01.03799.001



Spacer Cutter
01.03799.020



Guide Wire
01.03799.033



Guide Wrench
01.03799.034



Torsion Torque Driver
01.03799.040



Screw Driver
01.03799.030



Pedicle Distance Gauge Novo
01.03799.039



Counter Torque Handle
01.03799.037



Awl
01.03799.043



Pedicle Probe
01.03799.044



Coupling Screw
01.03799.031



T-Handle
01.03799.023



Spacer Positioner
01.03799.041



Hexagonal Screw Driver
01.03799.036



Holding Sleeve
109.01.060



Coupling Screw (Short)
01.03799.032



Spacer Trial
01.03799.042



Cord Guide
01.03799.038



Ruler
7323



Test Hook
01.03799.035



Cord Tensioning Instrument
01.03799.104



Cord Introduction Aid
01.03799.049

Dynesys Implants

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

Pedicle Screws

The screws anchor the *Dynesys* System into the spine. HA (Hydroxyapatite) coated and uncoated screws are provided.

Note: The HA-coated screws have a white thread.



HA-coated Pedicle Screws:
Protasul®-100
(Titanium alloy)



Standard Pedicle Screws:
Protasul®-100
(Titanium alloy)



Universal Spacers:
Sulene® PCU
(Polycarbonate-urethane)

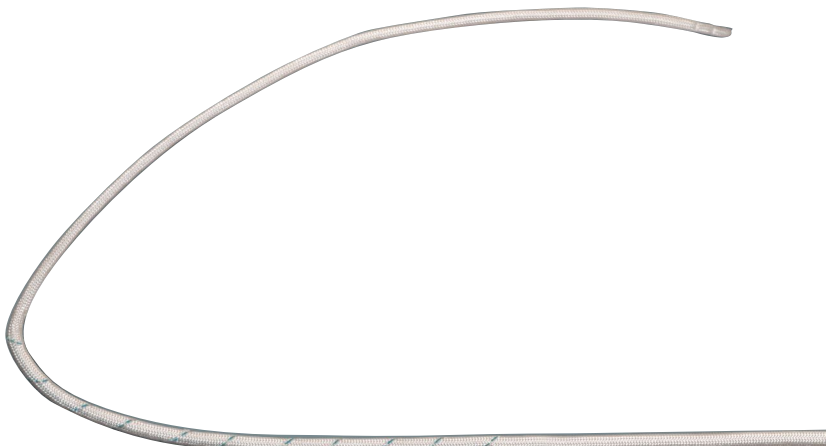
Universal Spacers

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

Cords

The cord controls the forward flexion movements.

Materials of the spacer and cord meet the international standard ISO 10993 (biocompatibility). The material of the pedicle screws meets the international standard ISO 5832-11 and 13779. The *Dynesys* implants have been CE marked since 1998.

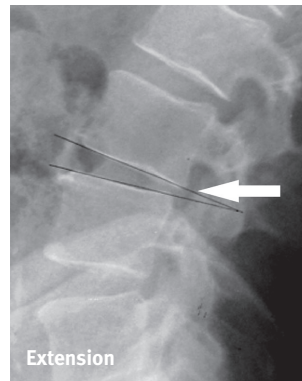


Cords:
Sulene® PET
(Polyethylene-terephthalate)

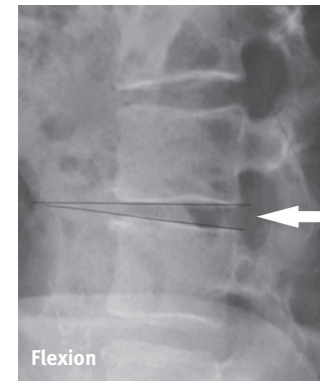
Indications

Primary spondylosis (discopathy) –
spondylarthrosis

- Instability



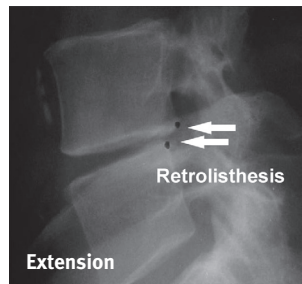
Dr. G. Dubois, Toulouse, F



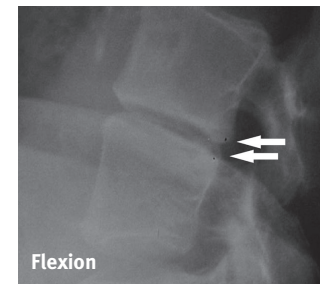
Primary spondylosis (discopathy)/
spondylarthrosis

Posterior vertebrae (hypomobile
status) – Retrolisthesis
(up to Grade 1)

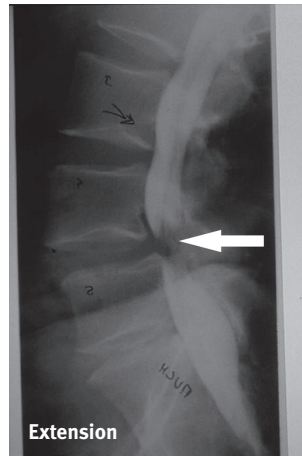
- Recurrent disc herniation
- Dynamic stenosis
- Post nucleolysis



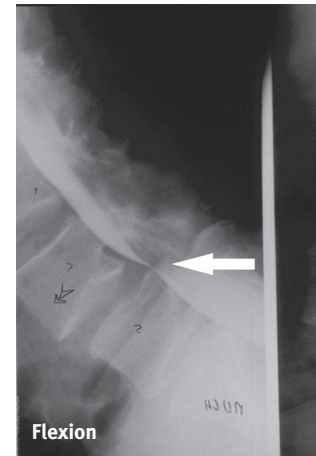
Dr. G. Dubois, Toulouse, F



Primary spondylosis (discopathy) and spondylarthrosis are combined with dynamic stenosis



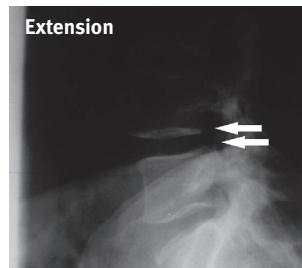
Dr.G.Dubois, Toulouse, FR



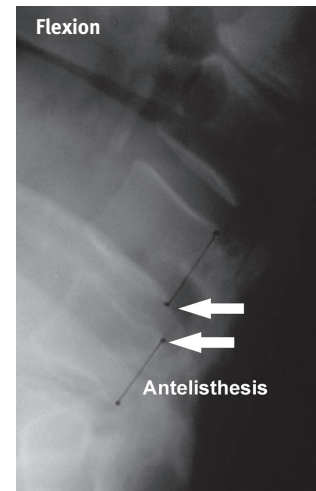
Primary spondylosis (discopathy)/ spondylarthrosis

Anterior slipped vertebrae (hypermobile status) – antelisting (up to Grade 1)

- Degenerative spondylolisthesis and Stenosis



Dr.G.Dubois, Toulouse, FR



Pre- and Intraoperative Treatment

If no contraindication exists:

- prophylaxis against thromboembolism
- prophylaxis against infection

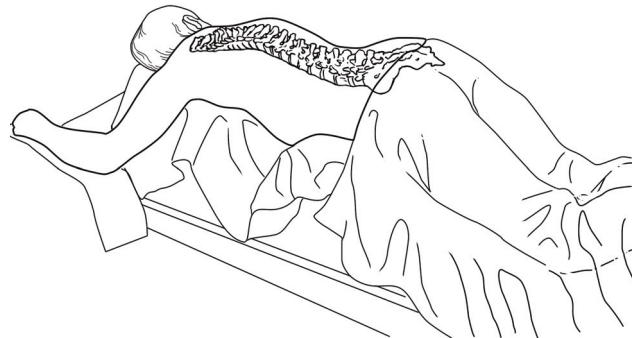
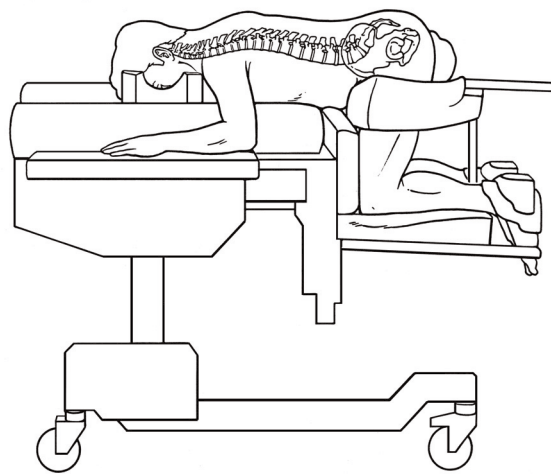
according to the prophylaxis standards.

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.



Incision

The midline approach or paraspinal intermuscular approach are possible.

Two Options

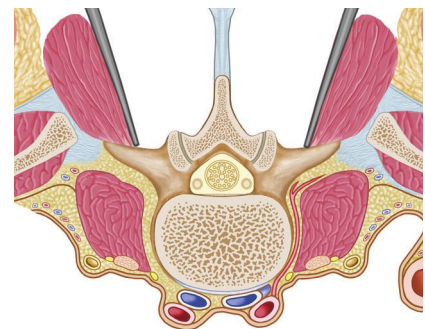
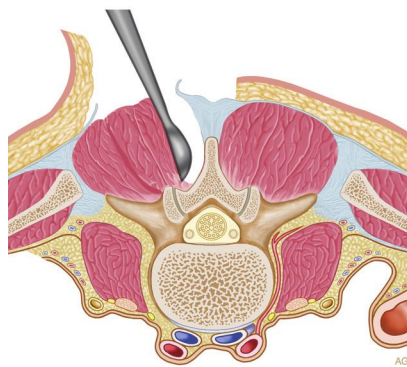
Midline Approach

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.

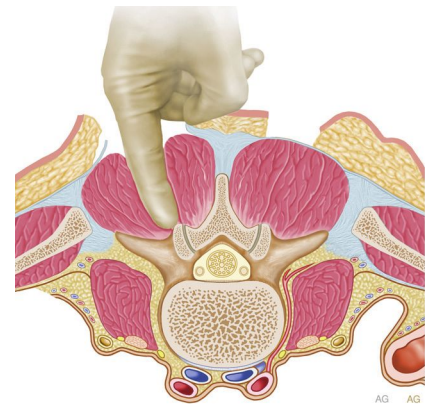
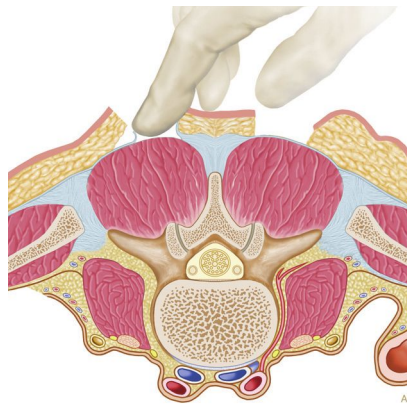
Midline Approach



Paraspinal Approach

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

Paraspinal Approach



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).

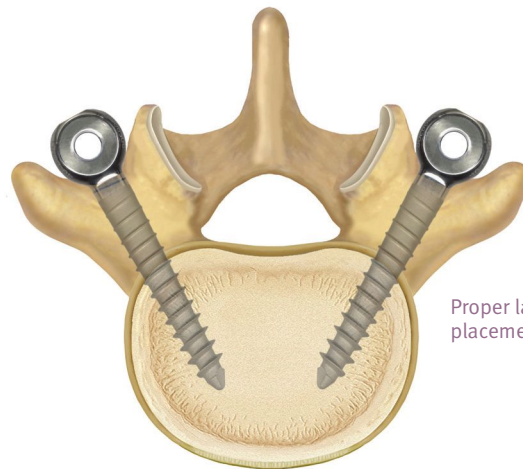
Preparation for Placement of Pedicle Screws

The screws are placed lateral to the facet joints.

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

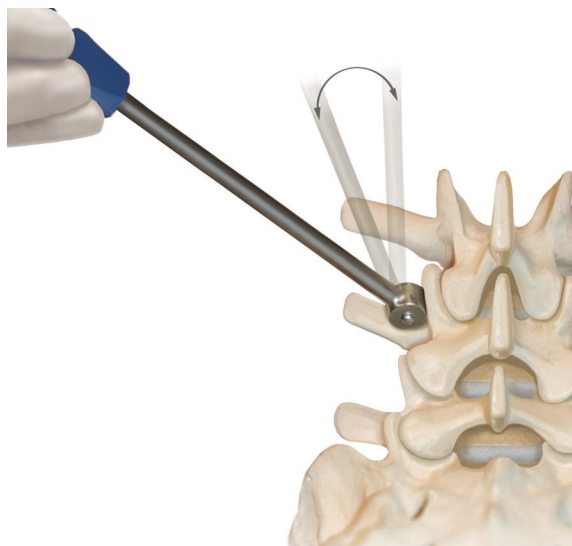
Note: The facet joints must remain intact.

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.



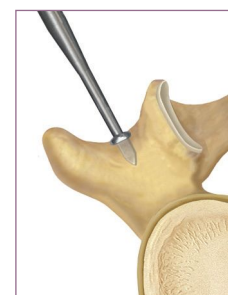
Proper lateral screw placement

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



Spacer Trial usage

Open the pedicle with the Awl.



Proper Awl placement

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

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: X-ray use is recommended, both AP and lateral views.

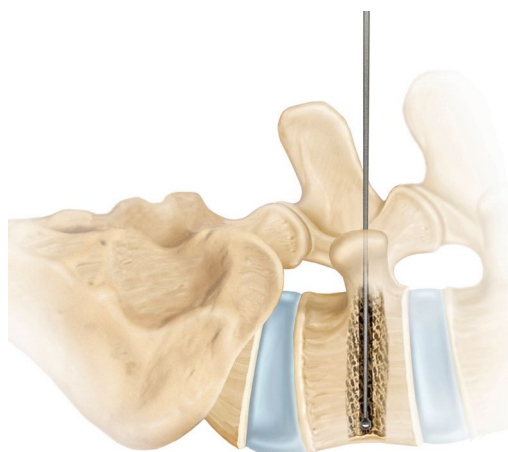
Note: The pedicle preparation is crucial for a good insertion of the screw.



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

Check the integrity of the pedicle wall with the Test Hook.

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



Pedicle Screws

Standard screws and HA coated screws are provided for all the screw sizes.
In each product line, 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

Notes:

For good anchorage in the sacrum, a screw with a diameter greater than (>) 6.0 mm is recommended.

8.0 mm screws should be used only for revisions.

Use the largest and longest pedicle screw (length and diameter) possible according to the anatomy.

In case of sclerotic bone, a standard screw is recommended.

HA coated screws may be more difficult to revise.¹

HA coated screws may accelerate bone ongrowth and increase the strength of the bone screw interface.¹

Combination of HA coated and standard screws is possible.

The surgeon selects the type of screw according to the patient's case.



Standard Pedicle Screw



HA-coated Pedicle Screw

HA-coated Screws can be recommended for S1

1. Reference from the literature:

- David, A., Pommer, A., Eitenmuller, J., and Muhr, G.: The effect of hydroxylapatite coating of AO/ ASIF screws on bonding strength in bones. *Unfallchirurg.* 96:12-17, 1993
- M. Wong, J:eulenberger, R. Schenk and E. Hunziker, Effect of surface topology of the osteointegration of implant materials in trabecular bone, 5 *J. Biomed Matter Res*, vol 29, no. 12, pp. 1567-1575, Report: (Dec, 1995)
- L. Sun, CC. Berndt, K.A. Gross, and A. Kucuk, Material fundamentals and clinical performance of plasma-sprayed hydroxyapatite coatings: a review *J Biomed Mater Res* 58. 570-592 (2001)
- A. Moroni, C. Faldini, M. Rocca, S. Stea, and S. Giannini, Improvement of the bone-screw interface strength with hydroxyapatite-coated and titanium-coated AO/ ASIF cortical screws. *J Orthop Trauma*, vol 16, no. 4, pp 257-263, Report: (Apr, 2002)
- Sanden, B., Olerud, C., Petren-Mallmin, M. and Larsson, S. : Hydroxyapatite coating improves fixation of pedicle screws. A clinical study *J Bone Joint Surg Br*, vol 84. no.3, pp 387-391 (Apr, 2002)

Set Up of the Guide Wire and Pedicle Screw

Fix the pedicle screw to the Guide Wire .

Caution: Avoid any contact of the gloves with the screw thread in order to guarantee aseptic conditions.

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

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

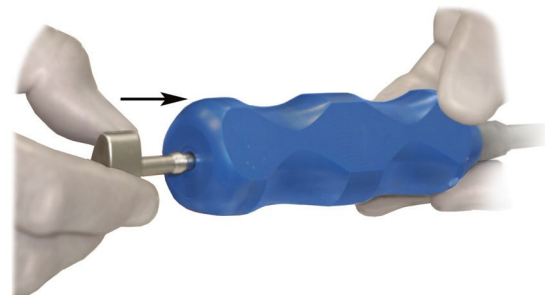
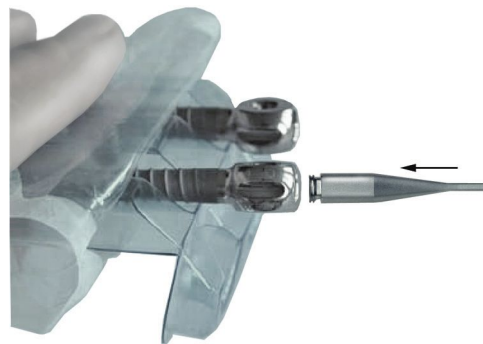
Screw the Short Coupling Screw in the Screw Driver handle.

This ensures that the Short Coupling Screw will not fall out of the handle.

Insert the pedicle screw and attached Guide Wire into the bore of the Screw Driver. Pay attention to screw head orientation.

By tightening the Short Coupling Screw, the Guide Wire and the pedicle screw are correctly located into the Screw Driver.

Caution: Do not over tighten.



Placement of the Guide Wire and Pedicle Screws

Insert the pedicle screws.

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

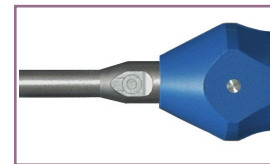
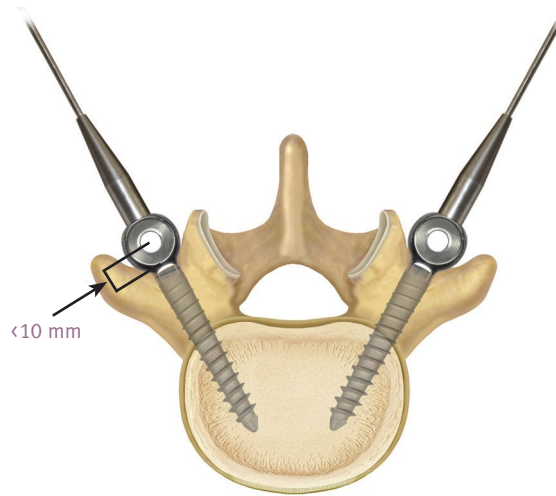
Advance the pedicle screw until the head or the polished portion of the screw is in contact with the bone.

Caution: Upon insertion of the pedicle screw, do not reverse the screw to back it up. This could lead to a bad screw fixation due to the conical core of the screw.

Advance the pedicle screw as deep as possible. 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 for the passage of the cord.

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

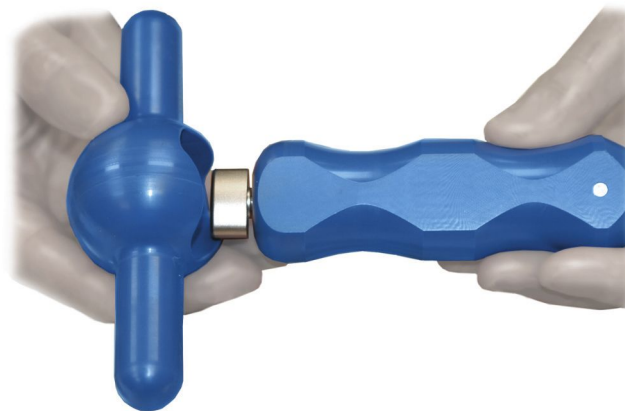


Marks are located on the Screw Driver to indicate the position of the screw head.

Optional

After fitting the pedicle screw, a T-handle can be placed on top of the Screw Driver to facilitate the insertion of the pedicle screw.

Note: Use of the T-Handle is only recommended during the final tightening steps to avoid wobbling of the screw, and/or incorrect alignment.

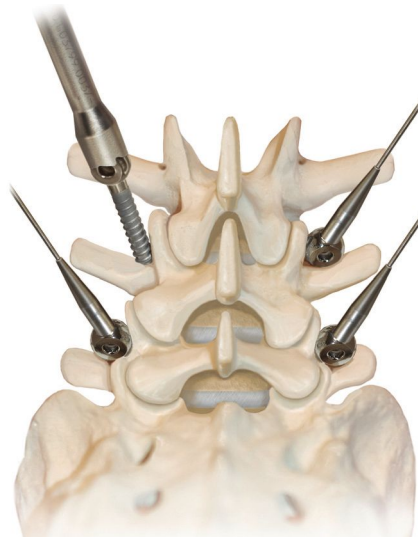


Remove the Short Coupling Screw by turning the handle counter clockwise.

Remove the Screw Driver.

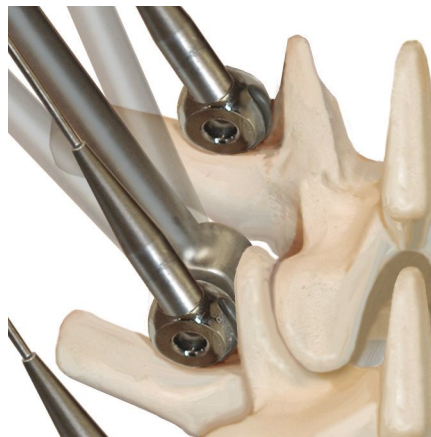
Guide Wire remains on the screw head.

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



Place all pedicle screws.

Ensure the alignment of the pedicle screws as shown in the picture on the right.



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



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.

The Working Zone is wrapped in green thread. Only work in the working zone with the Cord Tensioning Instrument (if possible in case of the 200 mm cord).

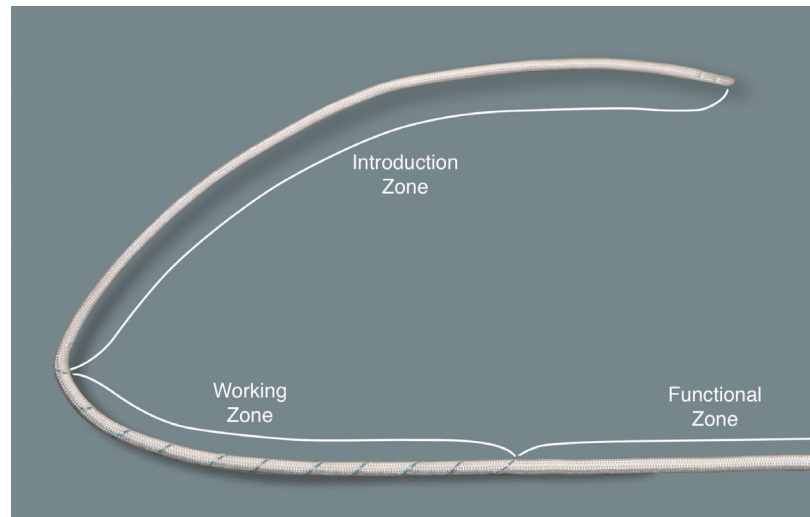
The Functional Zone is the part implanted in the patient.

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

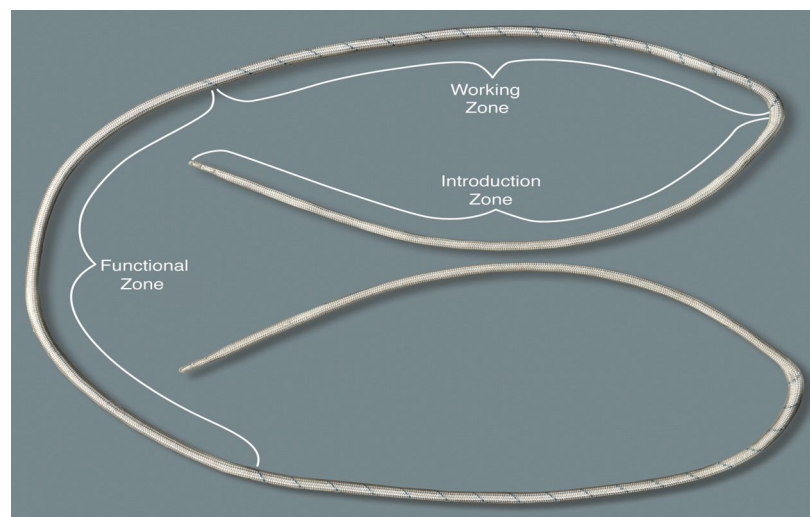
The 100 mm cord has one Introduction Zone, one Working Zone and one Functional Zone.

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).

Note: Carefully handle the cord to allow for aseptic handling conditions.



100 mm Cord



200 mm Cord

Construct Assembly

Insert the cord through the first pedicle screw.

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

Note: The Cord Insertion Aid instrument can help to insert the cord more easily.

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

Note: Always start the insertion procedure from the most caudal pedicle screw.

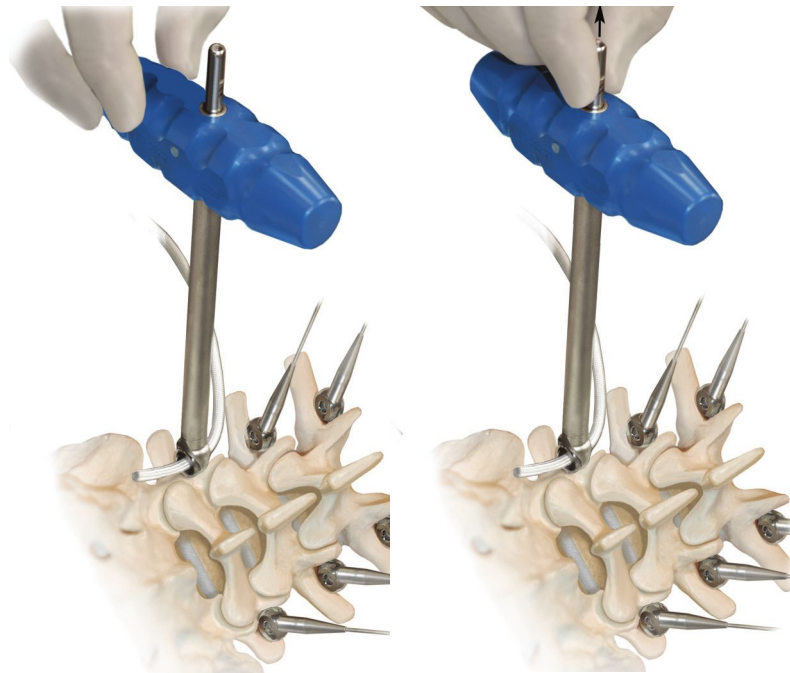


Optional:
Use the Cord Introduction Aid to guide the cord tip into the screw.

Place the Counter Torque Handle over the Guide Wire onto the screw head.

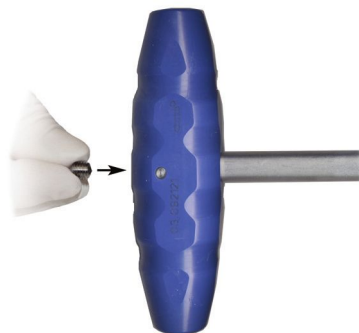
Remove the Guide Wire.

Should the alignment between the Counter Torque Driver and Guide Wire no longer be correct due to the pressure from the tissues, compensate the tissue pressure on the Counter Torque Driver to bring the Guide Wire back into alignment. This will ease its removal.



Remove the Guide Wire, only if the Counter Torque Handle or the Cord Guide are in place.

If necessary, remove the Guide Wire with the Guide Wrench. Do not exceed a turn of more than 90°, otherwise it could damage the Guide Wire.



Insert the set screw into the tube of the Counter Torque Handle (tip first).

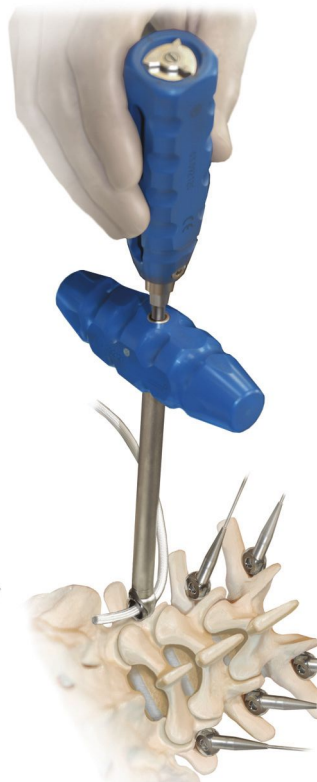
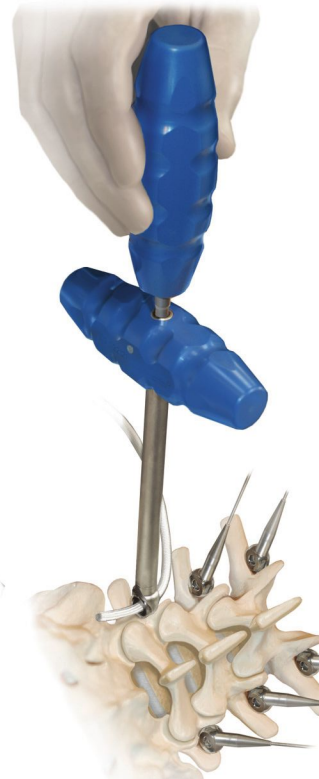
Insert the Hexagonal Screw Driver into the Counter Torque Handle. Tighten the set screw (4 Nm). Remove the Hexagonal Screw Driver from the Counter Torque Handle.

Optional

Use the Torsion Torque Driver (4 Nm)

Note: if the set screw is cross-threaded or slanted, turn it back slightly.

Note: If the tissue pressure slants the Counter Torque Handle, push it back to compensate tissue pressure and avoid cross-threading the set screw.



Dynesys Torsion Torque Driver is designed to tighten the set screws to a torque of 4 Nm.

The Torsion Torque Driver must be cleaned in a specific manner (see the paragraph sterilization process).



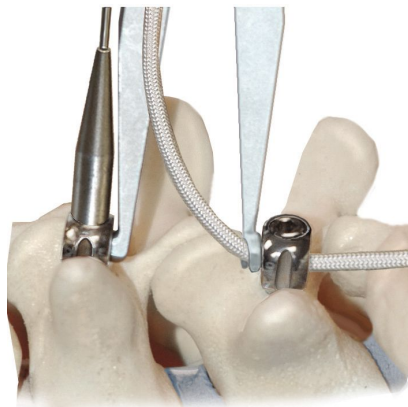
The neutral position (C-mark between the two lines) indicates that the Torsion Torque Driver has the right calibration.

The other marks show when a torque of 4Nm is reached.

Place the pedicle distance gauge between the pedicle screw heads.

The forked end is placed on the cord. Assess the movement in the facets in distraction and compression. Measure the distance (spacer length) with a slight distraction force.

Possible guidelines are: parallel endplates, neutral facet joint position (in hyperflexion according to page 9).



Universal Spacer

Caution: Do not induce a kyphosis or scoliosis.

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).

Instruction for use of the Pedicle Distance Gauge Novo:

Verify that the Drag Indicator is in the start position.

To measure the appropriate spacer length, place the Pedicle Distance Gauge between the screw heads. Reset the Drag Indicator after each measurement. Not resetting the Drag Indicator may lead to incorrect spacer measurement. The Drag Indicator stores the maximum length of the spacer.

Recommendation:

Tighten the set screw of the first segment, only after the assembly of the system is complete on both sides, otherwise compression or distraction of the first side could sidestep the measurement of the opposite side.



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



Top View of Pedicle Distance Gauge

Use the Spacer Cutter to cut the spacer.

Spacer Cutter Assembly:

1. Cover
2. Unlock Button
3. Fast Shift Button
4. Adjustable Screw
5. Lever
6. Blade Holder

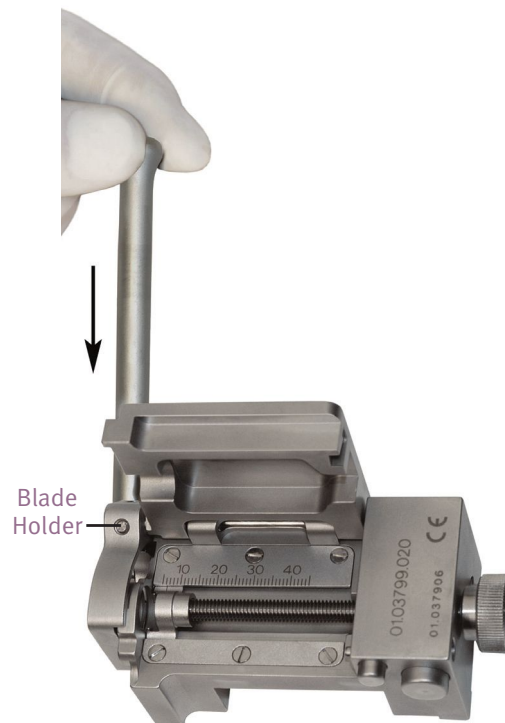
The spacer can only be cut once and is used only on one vertebral segment side.

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 for instructions.

Note: For cleaning and sterilization, please refer to the *Dynesys* cleaning leaflet and IFU for instruments.

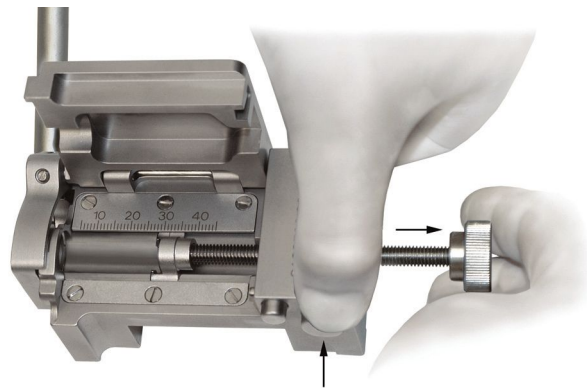


Put the Lever into the Blade Holder.

Open the Cover while pressing the Unlock Button.

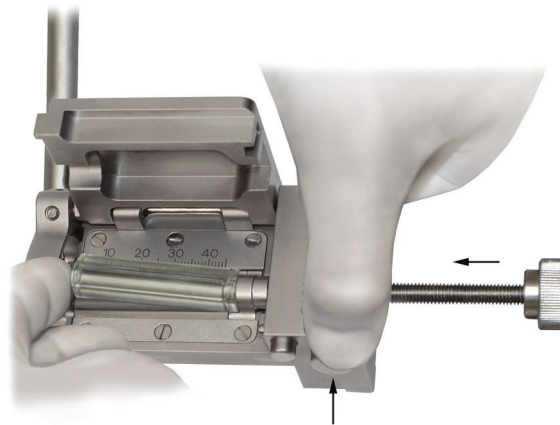
Note: The Lever must be in the starting position, otherwise it is not possible to open the Cover.

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.

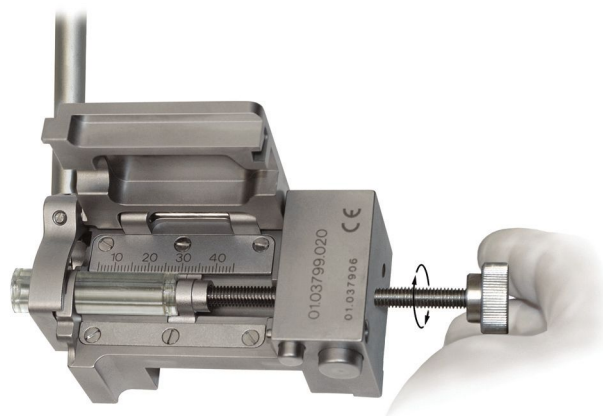


Place the spacer groove into the slot provided on the Adjustable Screw.

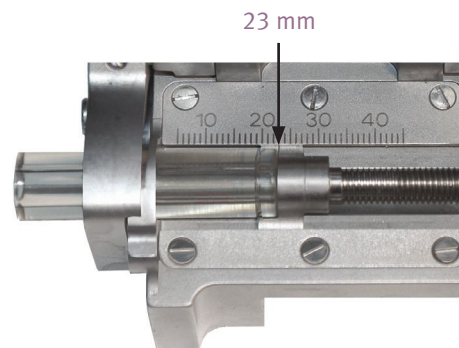
For an initial adjustment, push the Fast Shift Button while pushing the Adjustable Screw to the left.



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.

Caution: Applying high forces on the lever while the cover is not closed properly may lead to severe damage of the space cutter.

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

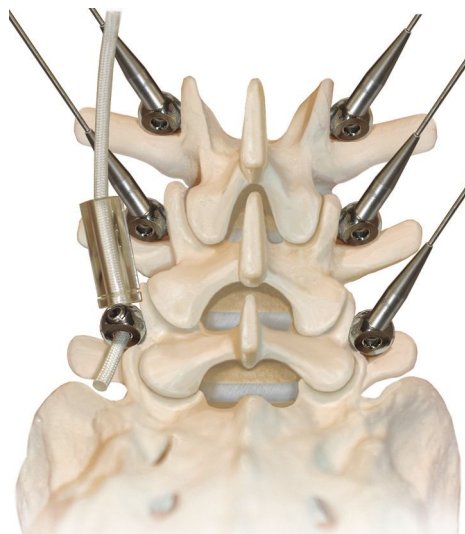
Note: the Lever must be in the starting position; otherwise it is not possible to open the Cover.

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

Caution: A remaining part of the previously cut spacer can lead to severe damages during the cut of the next spacer.



Insert the cord through the spacer.



Insert the cord through the second pedicle screw.

Note: Use caution to avoid twisting and looping of the cord.

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



Place the Cord Guide on the Guide Wire and screw head.

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

Only work in the Working Zone of the cord with the Cord Tensioning Instrument.

Hold the free end of the cord with one hand.

Use caution to keep the cord, spacer and screws in alignment.



Snap in the spacer with the Cord Tensioning Instrument.

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

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



Remove the Guide Wire.

Should the alignment between the Counter Torque Driver and Guide Wire no longer be correct due to the pressure from the tissues, compensate the tissue pressure on the Counter Torque Driver to bring the Guide Wire back into alignment. This will ease its removal.

Note: Remove the Guide Wire only if the Cord Guide is in place.

Insert the set screw into the Cord Guide (tip first).



Insert the Hexagonal Screw Driver into the Cord Guide and tighten the set screw.

Optional

Tighten with the Torsion Torque Driver (4 Nm).



The system is pre-loaded with 300N when the two marks on the Cord Tensioning Instrument are in line.

Note: Verify the alignment of the marks.



Tension the cord against the Cord Guide.

Repeat the same procedure for the contra-lateral side.

Tighten the set screw to a torque of at least 4Nm while tensioning the cord.

Note: When the tension load is correct, a slight bulging of the spacer is observed.

Note: Use the Counter Torque Handle or the Cord Guide to avoid turning the pedicle screw.

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.

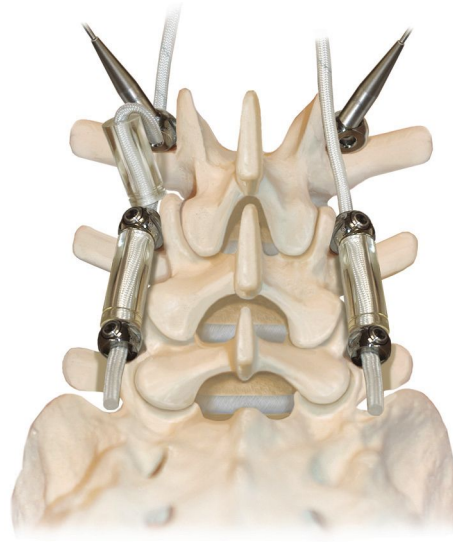


Repeat the same procedure for the adjacent segment, if needed.

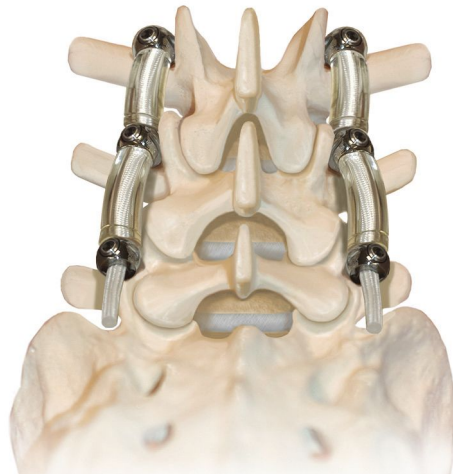
Caution: Only implant the Functional Zone of the cord. Implantation of the Working or Introduction Zones in the patient could lead to cord failure.

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

Note: No Working Zone or Introduction Zone must remain in the patient's body.



Implanted two-level *Dynesys* system.



Wound Closing

If no contraindication exists, irrigate well and drain according to the prophylaxis standards.

Postoperative Treatment

If no contraindication exists:

- Prophylaxis against thromboembolism
- Prophylaxis against infection
- Early mobilisation of the patient according to the prophylaxis standards.

Use of a brace is recommended if some doubt regarding the primary fixation exists on the part of the surgeon.

Sterilization Processes for Instruments

Sterilization according to EN 285.

Only steam sterilization is allowed.

For further information, please consult:

- the instruction leaflet (implants D011400216 and instruments D011400192) and
- instrument cleaning leaflet (Lit-No: 06.01206.012)

Appendix A

Changing the Cutter Blade

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

Note: For cleaning, dismantle the blade.

Caution: Further dismantling is not recommended.

Caution: The moving parts (e.g. Blade Holder) must be treated with a suitable maintenance oil before sterilization.

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

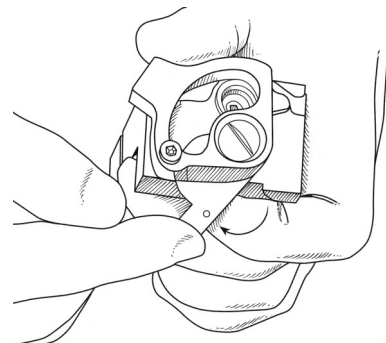
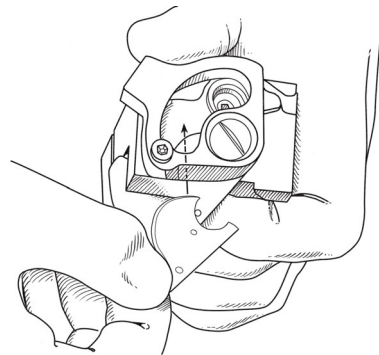
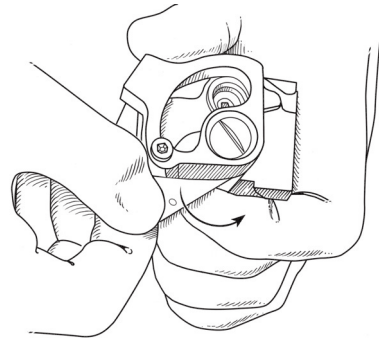
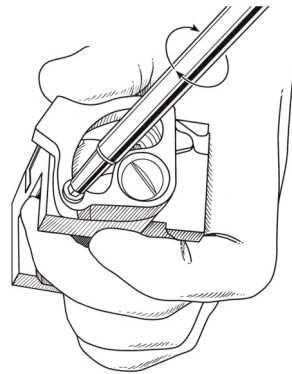
Take the new Replacement Blade and insert it into the Spacer Cutter as far as it will go.

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

Tighten the screw with the Set Screw Driver.

Caution: Verify that the hole of the blade is properly aligned with the screw.

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



Appendix B

Clamp screw driver 01.03799.050

With this Clamp Screw Driver, it is possible to insert the pedicle screw together with the set screw already engaged at the same time. The assembly (insertion of the cord and spacer) can then be done consecutively.

This avoids any slanting of the set screw during the tightening of the set-screw during the final assembly.

Caution: This technique implies the mandatory use of the Cord Guide during any tensioning activities on the cord in order to let the spacer snap in.

Insert the set screw on the pedicle screw.

Note: Check that the set screw is inserted at least one turn in the pedicle screw thread.

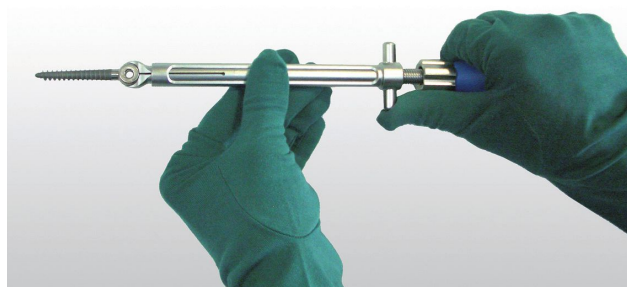
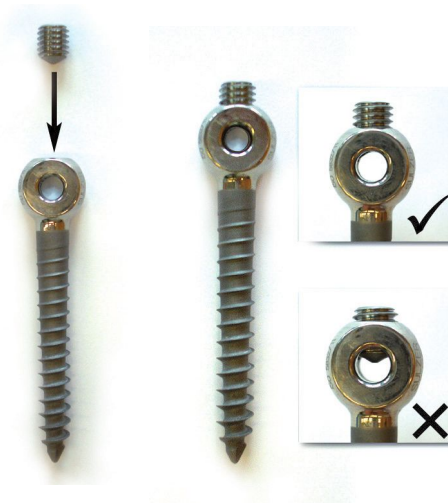
Caution: Check that the set screw is not inserted too deep into the pedicle screw; otherwise it will not be possible to thread the cord through the pedicle screw head. The cord may also be damaged by the tip of the set screw during the insertion of the cord through the eye of the pedicle screw.

Caution: If the set screw is not engaged enough in the screw, it could create a risk of losing it in the patient.

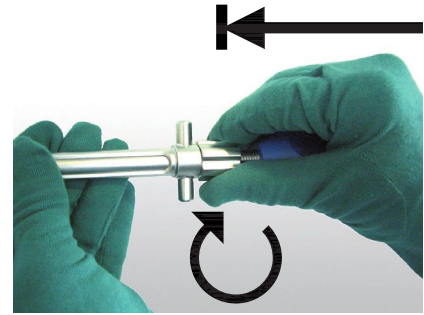
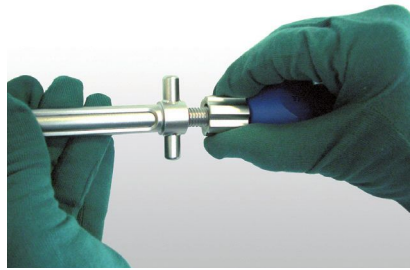
Recommendation: Check visually the set screw positioning before inserting the screw.

Clamp the pedicle screw on the clamp screw driver.

Firmly fix the pedicle screw by sliding the T-sleeve



Slide the Locking Nut to the T-sleeve and turn it clockwise to lock the system.



Now the pedicle screw is locked in the screwdriver and is ready to be used.



Insert the pedicle screw in the pedicle.

Caution: Turn the pedicle screw slowly into the pedicle and avoid turning the Locking Nut as this would unlock the pedicle screw.

Caution: Respect the positioning and inserting technique of the screw as explained in the surgical technique.

Note: do not impinge or damage the muscles with the instrument.

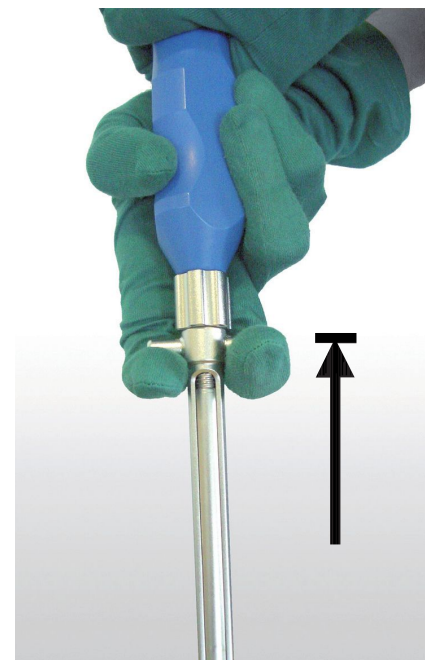
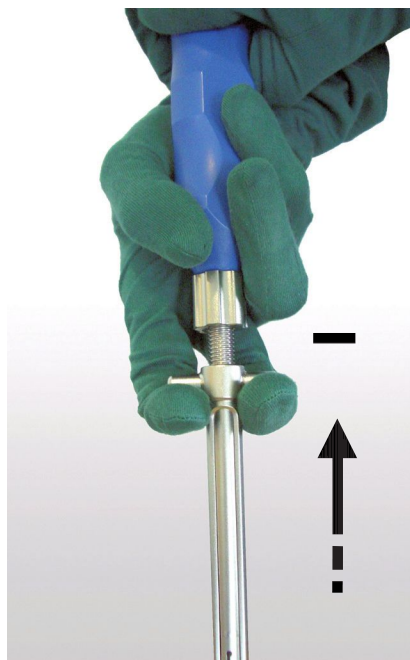


Release the system by unscrewing the Locking Nut Counter-Clockwise. Slide the Locking Nut against the blue handle and fix its position by turning the Locking nut again Counter-Clockwise.



Remove the Clamp Screw Driver by pulling the T-Sleeve backward, releasing the pedicle screw.

Caution: Place the Cord Guide on the screw head before tensioning the cord and snapping in the spacer in order to avoid any contact between the thread of the set screw, the spacer and the cord.



Appendix C

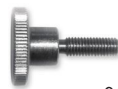
Dynesys LIS Cord Tensioner Set ZS01.03799.065

In order to ease the cord tensioning step during the *Dynesys* surgery, two instruments, the Cord Tensioner and the Cord Guide, have been combined. The result is the LIS Cord Tensioner Set. This instrument is compatible with the standard LIS instrumentation (Hexagonal Screw Driver, Torsion Torque Driver and LIS Guides).

The LIS Cord Tensioner can be coupled to the right or left of the LIS Cord Guide according to surgeon preference. This avoids collision with the patient's body.



ZS01.03799.065
Dynesys LIS Cord Tensioner Set
(optional instrument)



01.03799.051
Dynesys Locking Screw



01.03799.052
Dynesys LIS Cord Tensioner



01.03799.053
Dynesys LIS Cord Guide

In order to assemble the LIS Cord Tensioner with the LIS Cord Guide, carefully tighten the Locking Screw by hand.

Caution: Do not overtighten the Locking Screw.

In order to change the side of the instrument's assembly, loosen the Locking Screw, remove the *Dynesys* LIS Cord Tensioner and fix it to the other side by locking the screw.

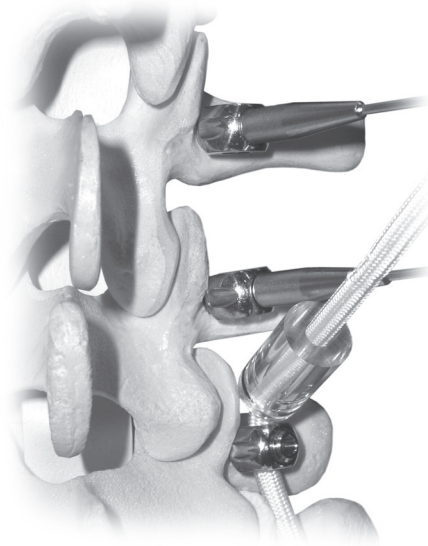
Caution: Be careful not to fully disengage the Locking Screw from the instrument.

Caution: Only use these instruments in combination. The LIS Cord Tensioner is not adapted to be used as stand alone in order to tension the cord inside the wound.

Insert the cord through the spacer.

Insert the cord through the second pedicle screw.

Place the LIS Cord Tensioner Set over the Guide Wire on top of the screw head.

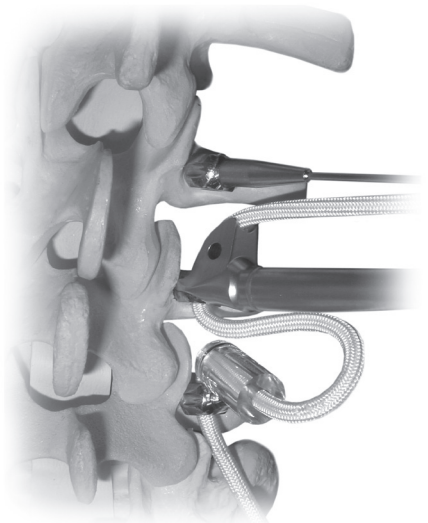


Pass the cord through the LIS Cord Tensioner.

Caution: Use caution to avoid twisting and looping of the cord. To ensure that the spacer can be snapped into space easily, arrange spacer and cord as shown in the picture.

Only work in the Working Zone of the cord with the LIS Cord Tensioner.

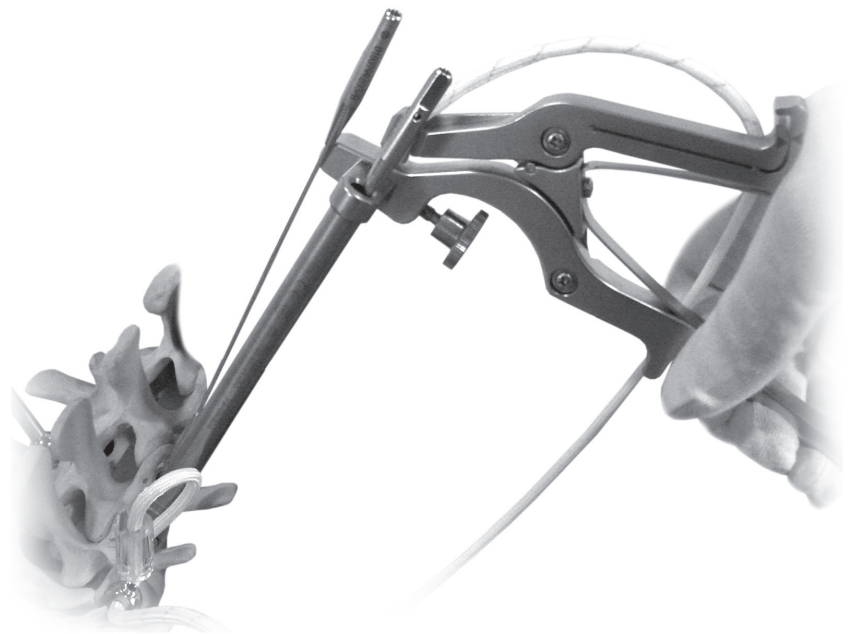
Use caution to keep the cord, spacer and screws in alignment.



Snap the spacer with the LIS Cord Tensioner Set.

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

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

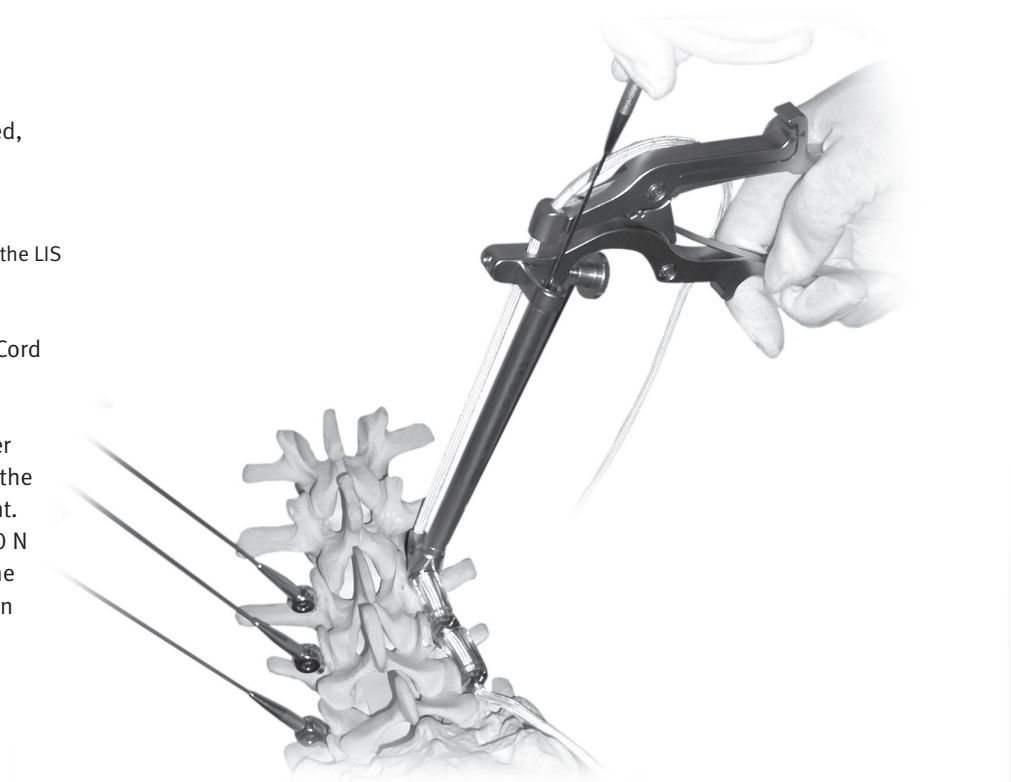


Remove the Guide Wire (if needed, slightly compensate the muscle pressure on the instruments).

Note: Remove the Guide Wire only if the LIS Cord Tensioner Set is in place.

Insert the set screw into the LIS Cord Tensioner Set (tip first).

Insert the Hexagonal Screw Driver or the Torsion Torque Driver into the LIS Cord Tensioner Set instrument. Simultaneously preload with 300 N and tighten the set screw with the Hexagonal Screw Driver or Torsion Torque Driver.



Note: Tighten the set screw with the Torsion Torque Driver (4 Nm).

Note: Avoid turning the screw head. You can balance the torque from tightening the set screw by applying counter torque with the LIS Cord Tensioner.

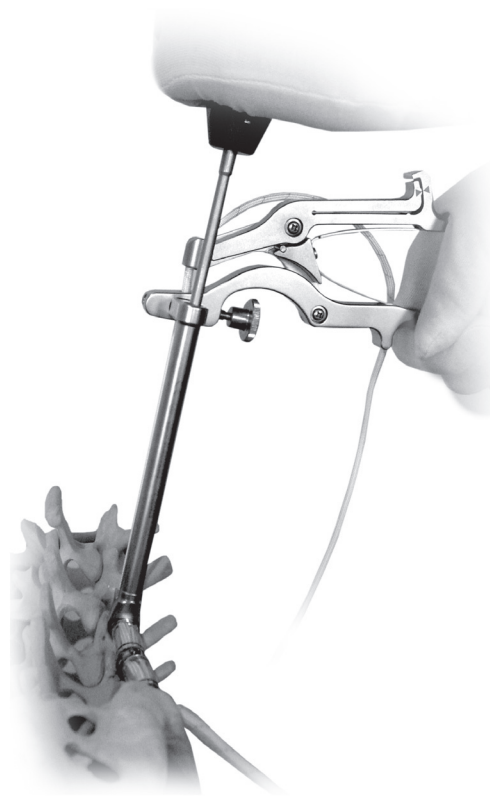
Note: The system is pre-loaded with 300 N when the two marks on the LIS Cord Tensioner are in line.

Note: When the tension load is correct, a slight bulging of the spacer is observed.

Note: Remove first the Hexagonal Screw Driver or Torsion Torque Driver before removing the LIS Cord Tensioner Set. Otherwise the hexagonal tip can be damaged.

Caution: Do not remove the Hexagonal Screw Driver or Torsion Torque Driver with the help of the LIS Cord Tensioner (Slap Hammer) because this may lead to a damaged hexagonal tip.

Repeat the same procedure for the contra-lateral side.



Caution: Investigational device, limited by the United States law to investigational use. This device is not available in the United States for the use described above.

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