

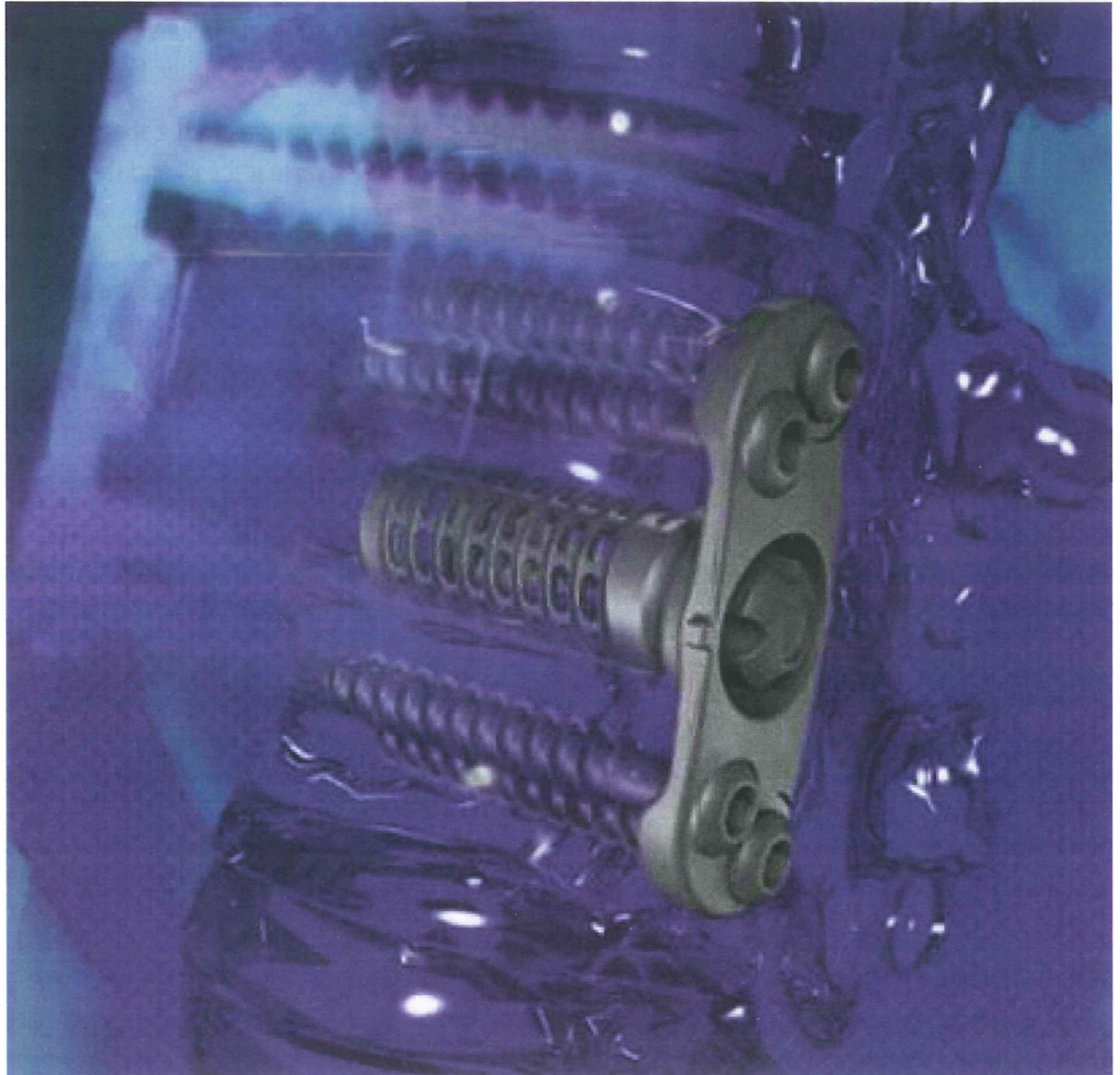


**Medtronic**  
SOFAMOR DANEK



# BUTTERFLY

Fusion System



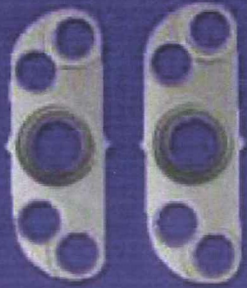
## *Surgical Technique*

MSD 1123  
IPR2013-00506  
IPR2013-00508

DRAFT COPY  
*for internal use only*

# BUTTERFLY

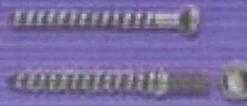
## ANTERIOR LATERAL FIXATION SYSTEM



**Standard Plates**  
Length: 48mm and 49.5mm



**Standard Cages**  
Diameter: 14mm or 16mm  
Length: 30mm, 35mm, or 40mm



**Screw or Bolt Option**  
Diameter: 6.5mm  
Length: 30mm, 35mm, 40mm and 45mm.

The BUTTERFLY system has been designed to answer the growing need for an anterior lateral plate and offers advanced product features:

- Provides significant supplementary fixation to an interbody construct
- Low profile lumbar anterior lateral plate for L4-5 and higher levels
- Anatomical fit between the concavity of the vertebral wall and the BUTTERFLY plate
- Mini-open or endoscopic approach
- Option of using a threaded cage which can be attached to the BUTTERFLY plate
- Option of using the BUTTERFLY plate in conjunction with an anterior lateral impacted cage.

### Case 1

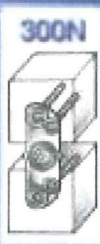


**Pre-op**  
51 year old female, painful discopathy with intermittent radicular pain, bulging disc on MRI.

**Post-op**  
Post-op L4-5 anterior lateral arthrodesis with UNION interbody cage and BUTTERFLY plate. Complete restoration of the foramen height.

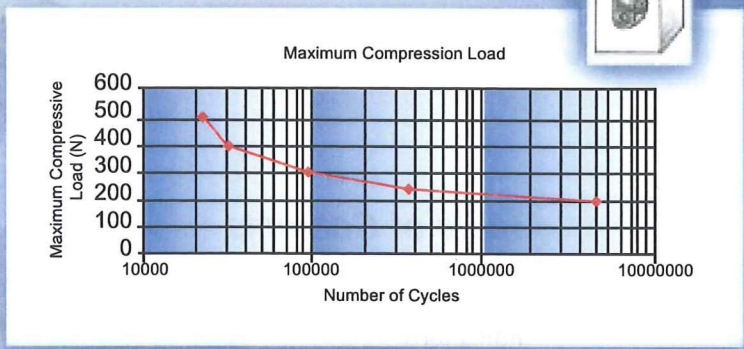


*Used in conjunction with a Union-L Cage*



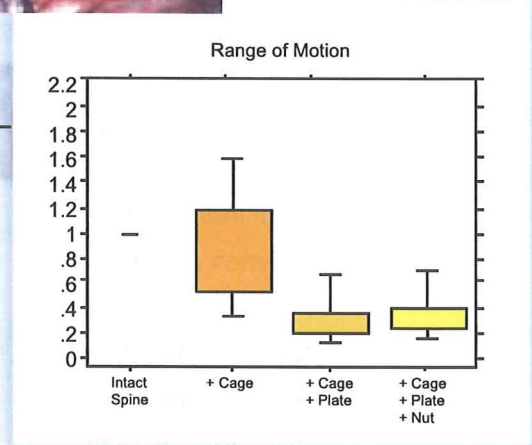
## Mechanical Test

The Butterfly Plate went under the static fatigue compression tests under ASTM F1717 corpectomy model. It showed that the Butterfly Plate presents a high level of mechanical strength.

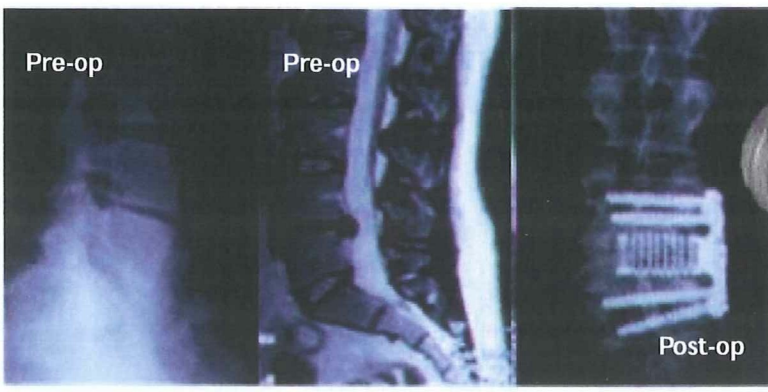


## Biomechanical Test

The Butterfly Plate went through biomechanical tests on human cadaver models. It showed that the Butterfly Plate provided significant supplementary stabilization to the spine.

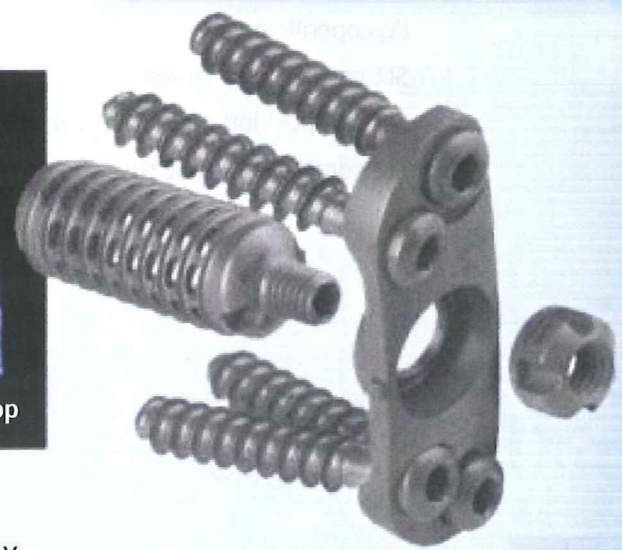


## Case 2



**Pre-op**  
Male, L4-5 foraminal stenosis with painful discopathy and loss of disc height.

**Post-op**  
L4-5 anterior lateral approach for interbody arthrodesis using BUTTERFLY cage and plate.



Attached with a Butterfly Cage

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## **INDICATIONS**

Generally indicated for lumbar and lumbosacral pathologies indicated for segmental arthrodesis including:

- Degenerative discopathy:
  - Primary surgery for advanced discopathies or extensive destabilizing decompressions
  - Revision surgery for failed disc surgery, (recurrent disc herniation, post-operative instability)
- Lumbar pseudarthrosis
- Certain lumbar stenosis

## **CONTRAINDICATIONS**

This device is not intended for cervical spine use. Contraindications include, but are not limited to:

Infection, local to the operative site

Signs of local inflammation

Fever or leukocytosis

Morbid obesity

Pregnancy

Mental illness

Rapid joint disease, bone absorption, osteopenia, osteoporosis

Suspected or documented allergy or intolerance to composite materials

Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery

These devices should not be used for pediatric cases, nor where the patient still has skeletal growth

Spondylolisthesis unable to be reduced to Grade 1

Any cases where the implant components selected for use would be too large or too small to achieve a successful result

Any case that requires the mixing of metals from two different components or systems

Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality

Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance

### ***PATIENT POSITIONING AND SURGICAL EXPOSURE***

The following selection describes the procedure using the Lateral Approach.

The patient is placed in a right decubitus lateral position on the operating table. An oblique skin incision is made above the center of the targeted disc space. Exposure to the lateral aspect of the spine is obtained by a retroperitoneal approach. Psoas muscle is retracted posteriorly and held in place with the help of a retractor. Confirm the fusion level by means of lateral fluoroscopic control.

A mini-ALIF approach can be made with the help of the Medtronic Sofamor Danek ENDORING retractor system.

### ***DISCECTOMY***

Perform about a 2.5mm wide lateral block discectomy. Using a Disc Rongeur to remove the disc material.

Endplate preparation is carried out using surgical chisels and curettes. Remove the cartilage from the endplates to obtain a large flat surface on subchondral bone and a bleeding area in the center of the endplate.

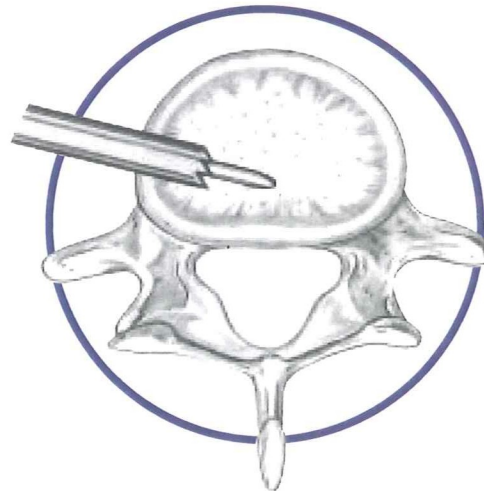
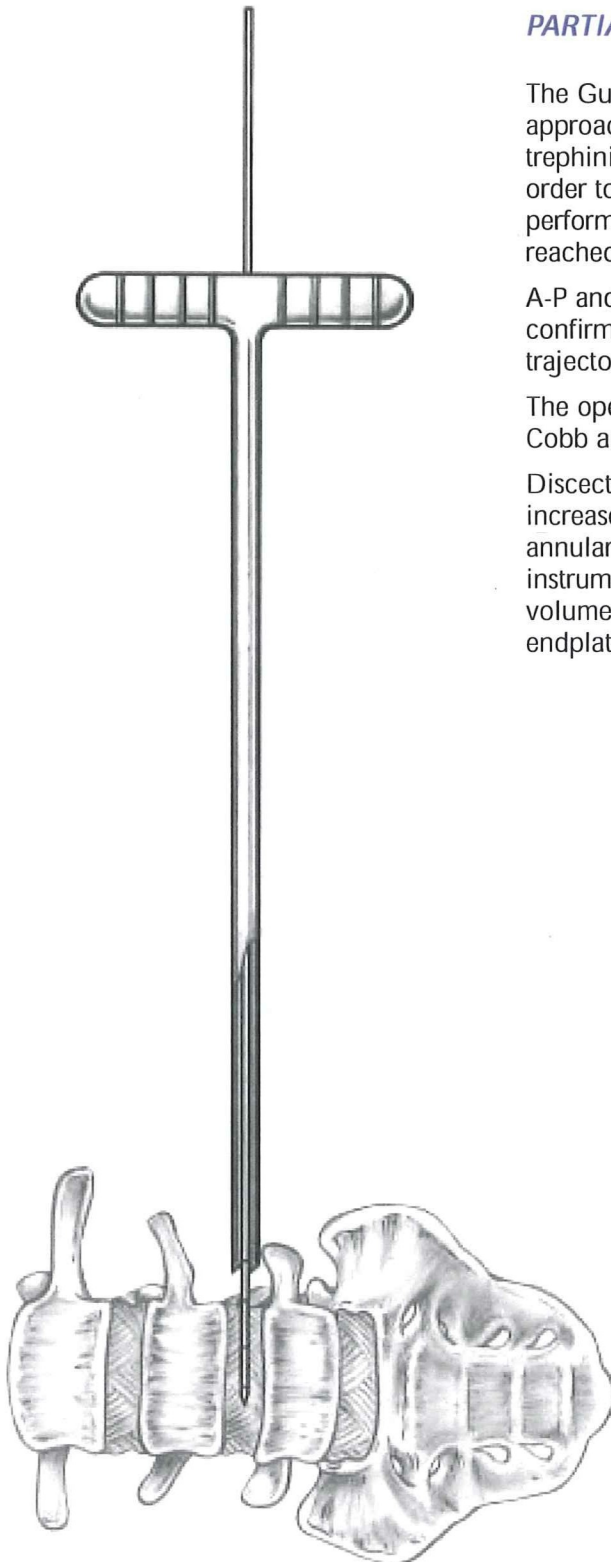
### *PARTIAL DISCECTOMY*

The Guide Wire is placed into the Trepphine and then approached to the entrance point on the disc. Before trephining, slightly impact the Guide Wire into the disc in order to avoid any slippage. A pre-perforation of the disc is performed with the Trepphine until the stop level is reached.

A-P and lateral fluoroscopic checks are recommended to confirm the targeted lumbar level and to ensure the safe trajectory of the trephine.

The opening on the disc is enlarged with the help of the Cobb and the Kerrison in the set.

Discectomy is performed, but the annulus is preserved to increased mechanical stability by tensioning the remaining annular and ligamental structures of the disc. The instrumentation will simultaneously remove the required volume of the disc and prepare the adjacent vertebral endplates for the fusion implant.

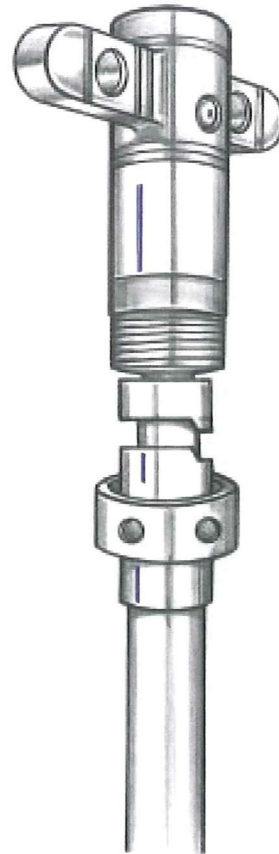
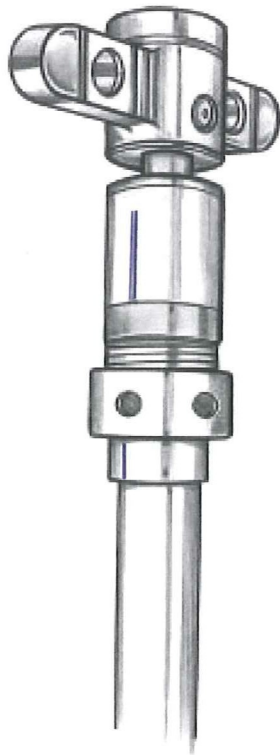


## GUIDE SLEEVE DISTRACTOR ASSEMBLY

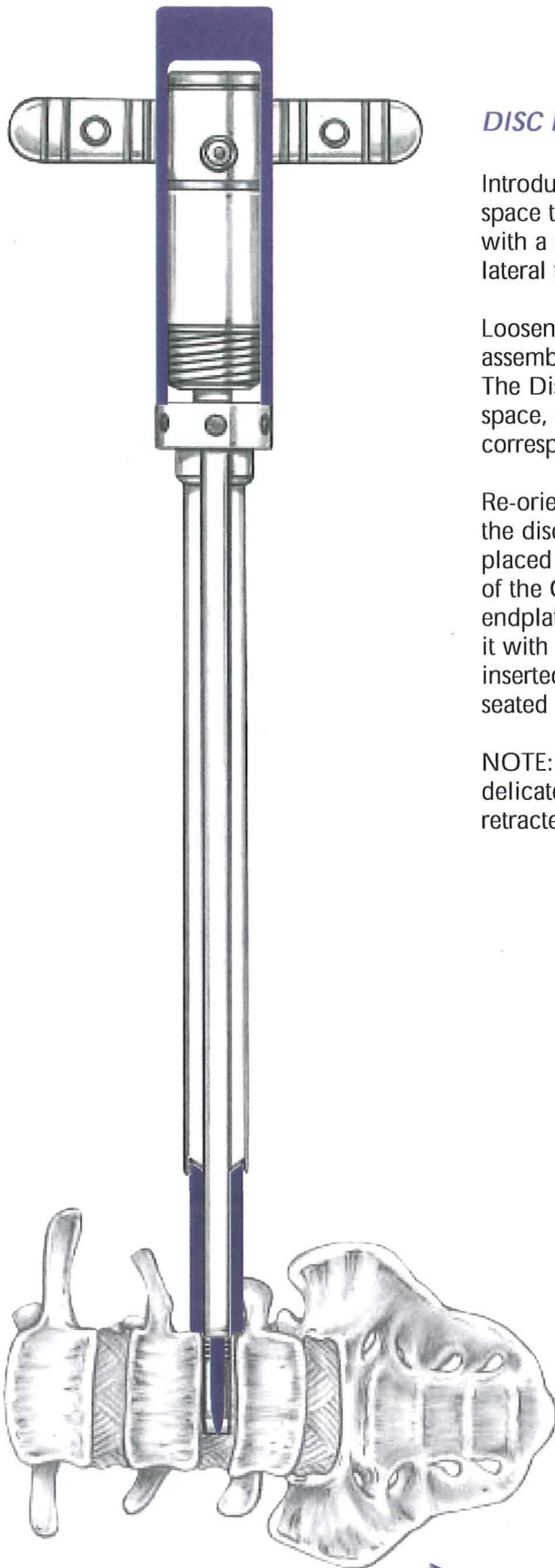
Attach the Distractor head to the Implant Inserter. The number marked on the Distractor head indicates the distraction height in mm.

Choose the corresponding Guide Sleeve, the first number marked on the sleeve should match that of the Distractor Head. Assemble the Guide Sleeve with the Implant Inserter and the Switching Sleeve in the following manner:

1. Hold the Implant Inserter and keep pushing the sliding bloc,
2. Slide the Switching Sleeve on the Implant Inserter and turn it to find the indexed position,
3. Slide the Guide Sleeve onto the Switching Sleeve and find the indexed position,
4. Turn the slack collar on the Protection Sleeve for connecting.







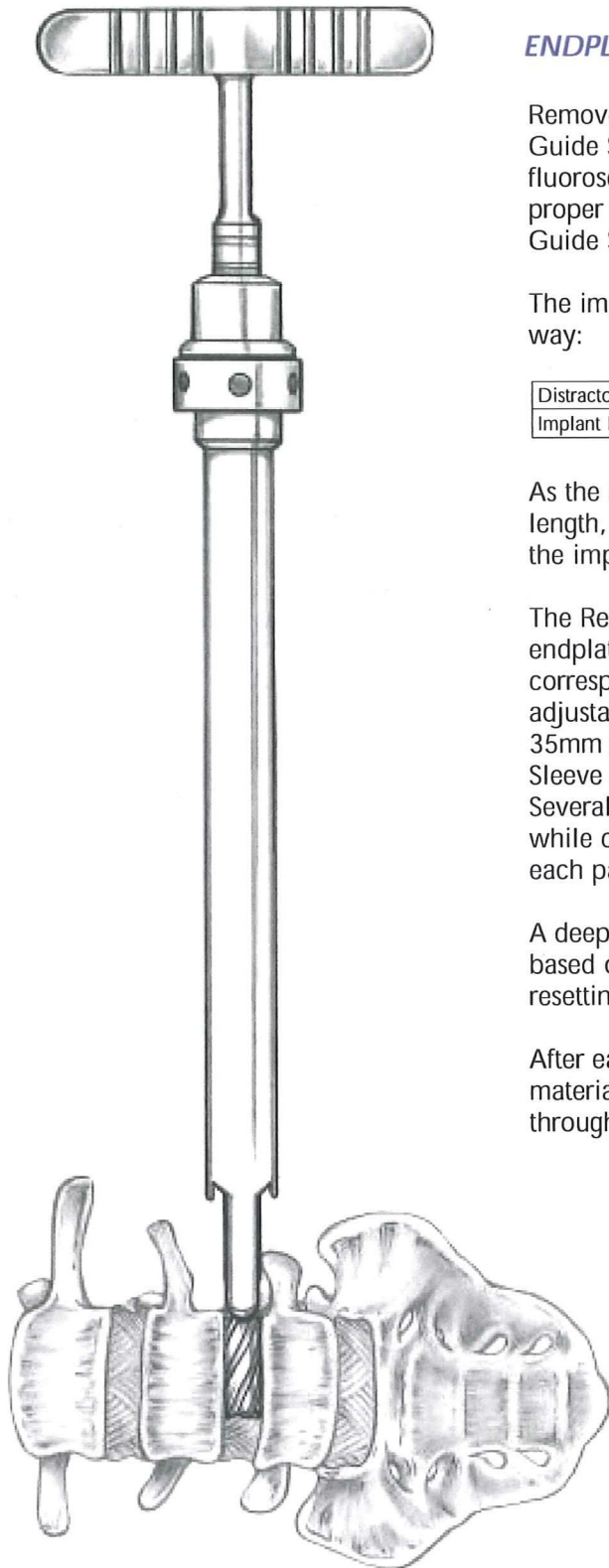
### *DISC DISTRACTION AND GUIDE SLEEVE SEATING*

Introduce the assembly (long blade anterior) into the disc space through the prepared opening and impact it slightly with a mallet until it is firmly seated into the disc space. A lateral fluoroscopic control is recommended at this stage.

Loosen completely the slack collar to disconnect the assembly. Turn the T-Handle 90° to open the disc space. The Distractor Head should be firmly held into the disc space, otherwise choose a larger Distractor Head and the corresponding Guide Sleeve, (go back to Step 2).

Re-orientate the extension blades on the Guide Sleeve to the disc space. Be sure that the longer extension blade is placed to the anterior side of the spine and the curved end of the Guide Sleeve matched the border of the vertebral endplates. Place the Impactor on the Guide Sleeve. Impact it with a mallet until both extension blades are completely inserted into the disc space and the Guide Sleeve firmly seated against the vertebral bodies.

**NOTE:** Prior to impacting, make sure that all surrounding delicate soft tissues are clearly identified and adequately retracted.



**ENDPLATE REAMING**

Remove the Distractor and the Switching Sleeve from the Guide Sleeve. At this stage of the surgery, A-P and lateral fluoroscopic controls are recommended to confirm the proper disc distraction and the correct placement of the Guide Sleeve.

The implant can be precisely determined in the following way:

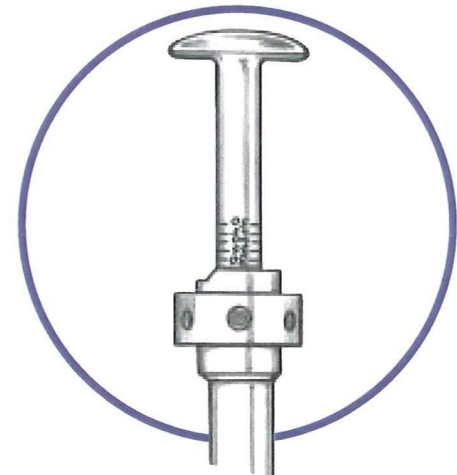
Distractor Size	8mm	10mm	12mm	14mm
Implant Diameter	14 or 16mm	16mm	18 or 20mm	20mm

As the anterior extension blade is measured 30mm in length, the A-P fluoroscopic image can help to determine the implant length.

The Reamer is used to complete the discectomy and endplate preparation. The number marked on the Reamer corresponds to the diameter of the cage to be used. Set the adjustable stop to the first line which corresponds to a 35mm reaming depth. Place the Reamer into the Guide Sleeve and turn it clockwise until the stop level is reached. Several passes of reaming process need to be performed while cleaning the disc debris attached to the reamer after each pass.

A deeper reaming depth can be adjusted every 3mm, based on fluoroscopic check, by loosening the collet and resetting.

After each reaming process, any remaining loose disc material should be removed by using the IVD Rongeur through the protection Sleeve.



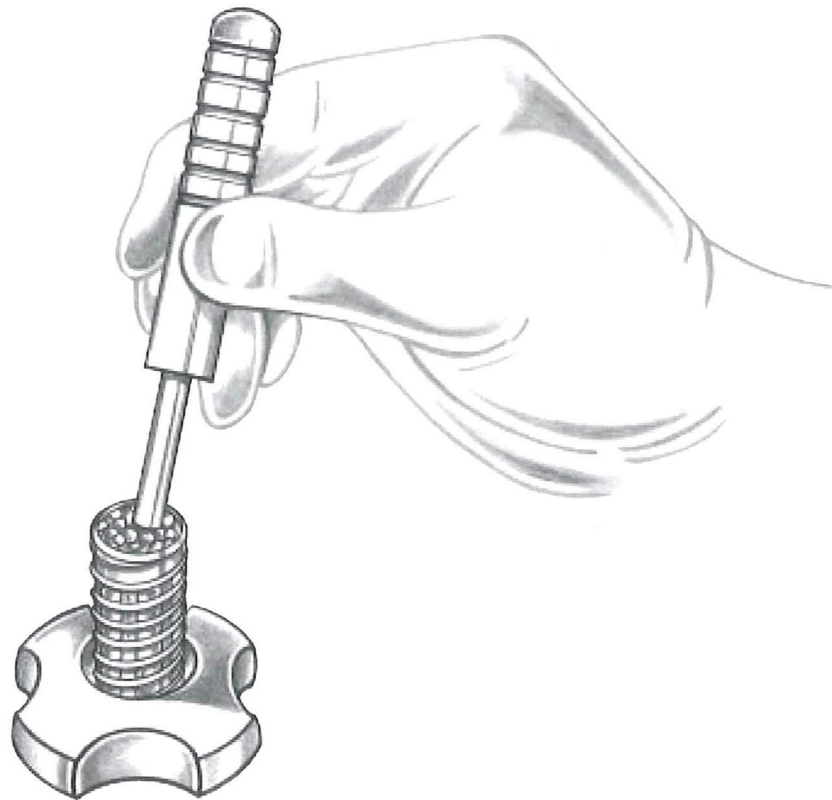
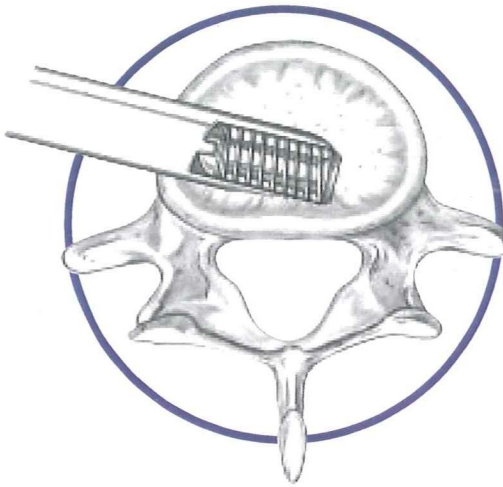
### **CAGE PACKING AND IMPLANTATION**

The Implant is placed on the Implant Support in an upright position and the cap is removed. The Graft Impactor is used to gently compact the morsalized fragments into the Implant to ensure the Implant is completely filled. The cap is placed on the Implant.

Attach the Butterfly Implant to the Implant Inserter. Place the Implant Inserter into the Guide Sleeve and begin screwing the Implant into the prepared disc space until the predetermined depth indication reaches the border of the Guide Sleeve. The cage should be positioned about 2-3mm countersink to the lateral wall.

Detach the Implant Inserter after the cage position is confirmed by A-P and lateral fluoroscopic check. Connect the Wrench to the Guide Sleeve. Remove the Protection Sleeve with the help of the Fork Hammer.

**NOTE:** We recommend to use a cage of 5mm shorter than the measured depth in order to place cancellous bone in the disc space before cage insertion.



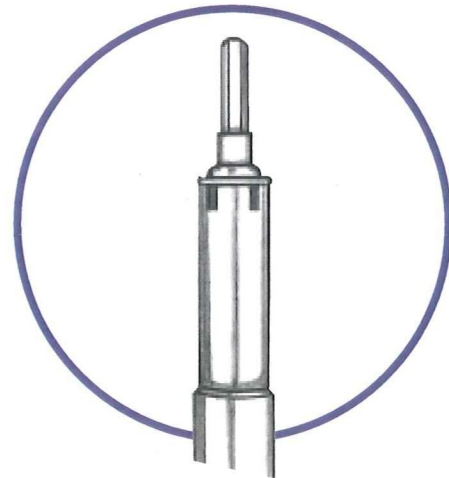
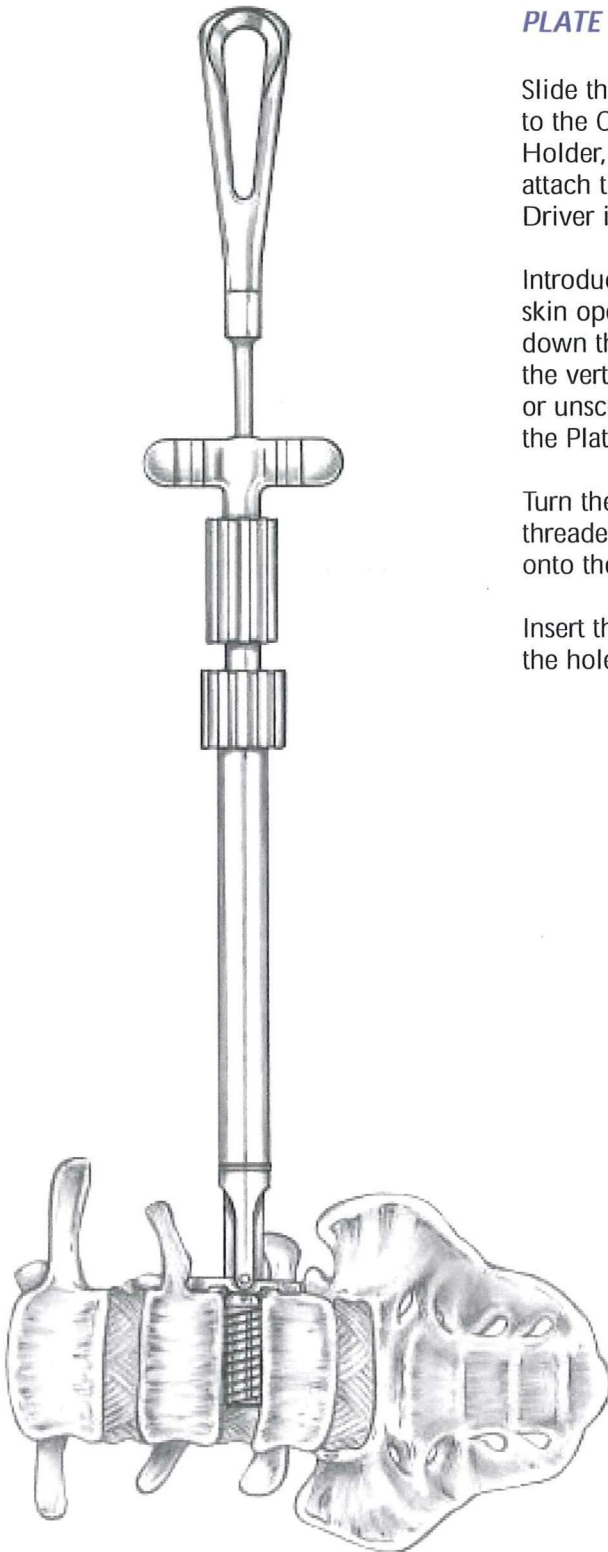
### **PLATE INSTALLATION**

Slide the Cage Adjuster into the Nut Driver. Attach the Nut to the Cage Adjuster. Take the Butterfly Plate with the Plate Holder, turning the outer sleeve down in order to firmly attach the Plate. Slide both the Cage Adjusters and the Nut Driver into the Plate Holder.

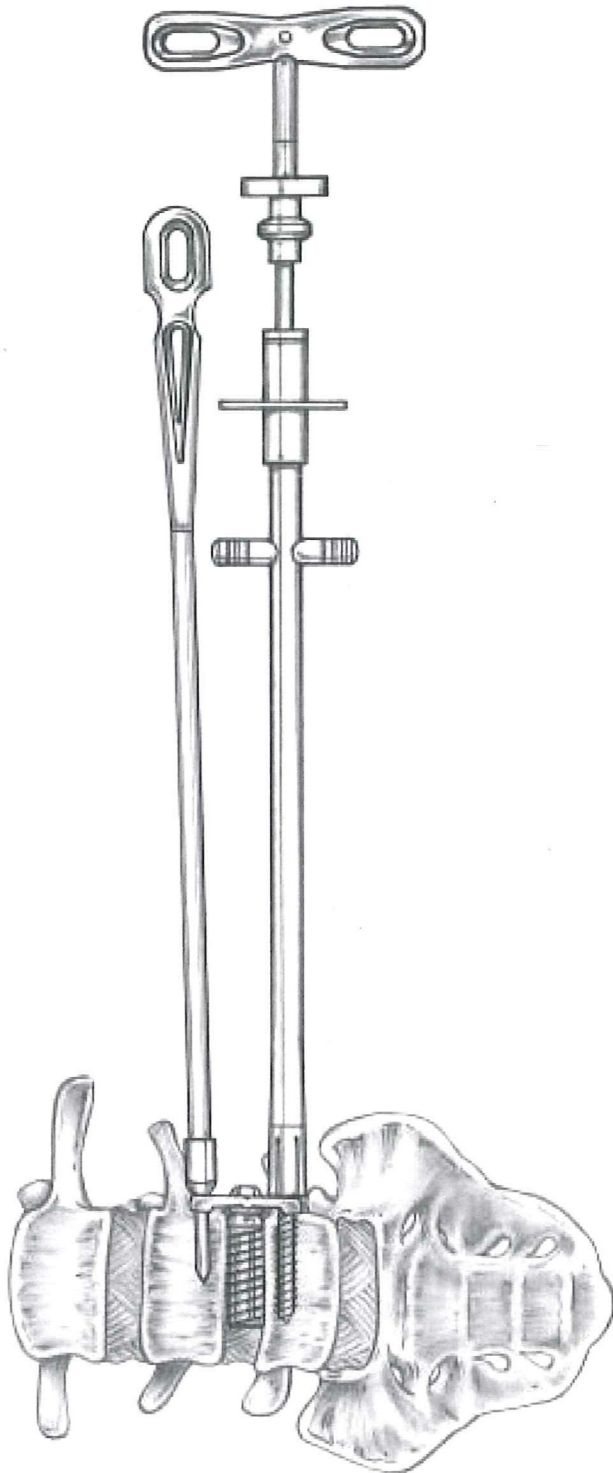
Introduce the assembly into the operation field through the skin opening. Attach the cage Adjuster to the Cage. Slide down the Plate Holder and push the Plate firmly against the vertebral bodies. Adjust the cage position by screwing or unscrewing in order for the cage to be in contact with the Plate.

Turn the Nut Driver to release the Nut and bring it to the threaded end of the cage. Tighten the Nut to fix the Plate onto the cage.

Insert the Z-Plate screws in to the vertebral bodies through the holes of the Plate.



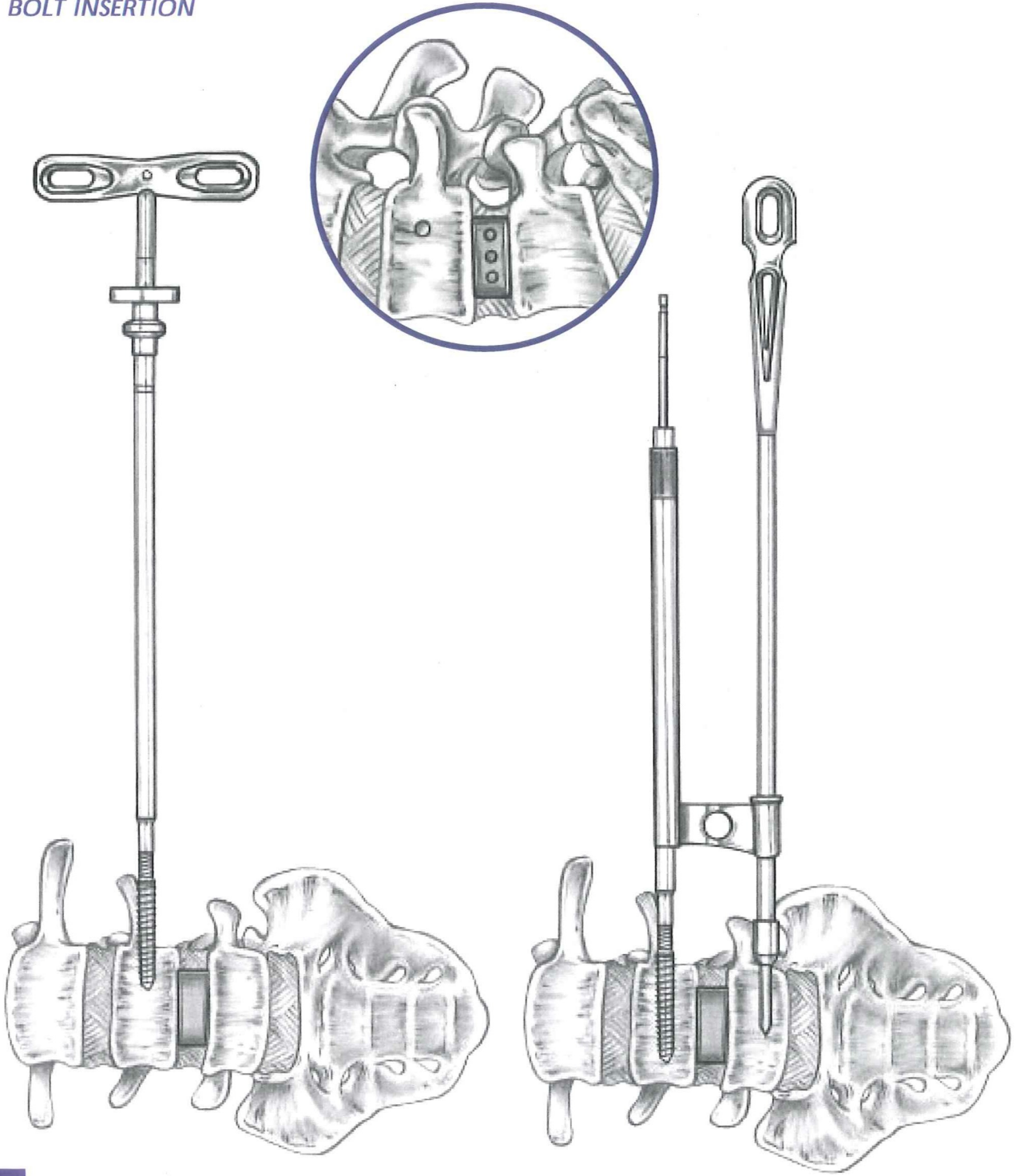
*INSERTION OF SCREWS*



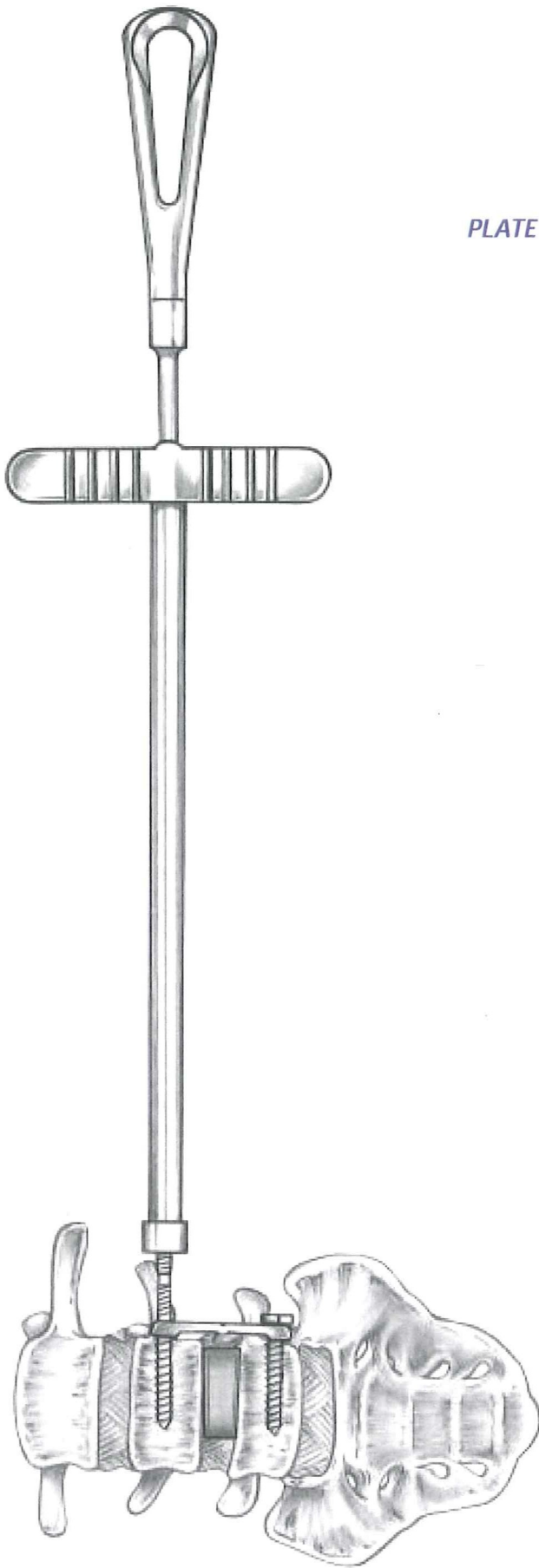
*Option with the Union-L™ cage*

Insertion of the cage - refer to Union-L™ Surgical Technique

**BOLT INSERTION**



*PLATE INSERTION WITH UNION CAGE*



***POST-OPERATIVE CARE***

Wound closure is carried out in a routine manner.  
Ambulation begins when tolerated, usually the following day.  
Keep patient calm for first 3 days.



**SET COMPOSTION UNION-L™**

**UNION™ & UNION-L™ INSTRUMENTS**

**GENERAL INSTRUMENTS UNION**

175106	Guide Tip 6
175108	Guide Tip 8
175110	Trial 10/26
175112	Trial 12/26
1750114	Trial 14/26
1750116	Trial 16/26
175210	Trial 10/31
175212	Trial 12/31
1750214	Trial 14/31
1750216	Trail 16/31
175120	Rail Cutter 10/26
175122	Rail Cutter 12/26
1750124	Rail Cutter 14/26
1750126	Rail Cutter 16/26
175220	Rail Cutter 10/31
175222	Rail Cutter 12/31
1750224	Rail Cutter 14/31
1750226	Rail Cutter 16/31
175126	Protection Tube 6/26
175128	Protection Tube 8/26
175136	Protection Tube 6/31
175138	Protection Tube 8/31
175426	Handle 26
175431	Handle 31
175502	Impactor Cap
175503	Fork Hammer
175506	Graft Impactor
895-IDR00	Disc Rongeur
175109	Connection Pin

**GENERAL INSTRUMENTS UNION-L**

1750300	Lateral Distractor Tip
1750310	Lateral Trial M10
1750312	Lateral Trial M12
1750314	Lateral Trial M14
1750316	Lateral Trial M16
1750130	Lateral Rail Cutter M10
1750132	Lateral Rail Cutter M12
1750134	Lateral Rail Cutter M14
1750136	Lateral Rail Cutter M16
1750230	Lateral Guide 10
1750232	Lateral Guide 12
1750234	Lateral Guide 14
1750236	Lateral Guide 16

**SET COMPOSITION INTERFIX-LATERAL**

**INTERFIX-LATERAL INSTRUMENTS**

**GENERAL INSTRUMENTS**

- 894.093 Guide Wire
- 896.103 Wrench
- 896.104 Fork Hammer
- 896.105 Trepine 8
- 896.106 Trepine 10
- 950.940 IVD Rongeur
- 950.931 Kerrinson 5mm
- 896.101 Bone Graft Impactor
- 950.902 Cobb
- 896.102 Impactor

**14/16mm Instruments**

- 896.508 Distractor Head 8
- 896.510 Distractor Head 10
- 896.346 Implant Inserter 14/16
- 896.414 Protection Sleeve 8/14,16
- 896.416 Protection Sleeve 10/16
- 896.646 Switching Sleeve 14/16
- 896.746 Adapter Sleeve 14/16
- 895-IBF00 Adjustable Reamer Stop
- 896.214 Reamer 14
- 896.216 Reamer 16

**SET COMPOSITION BUTTERFLY**

**BUTTERFLY IMPLANTS & INSTRUMENTS**

**IMPLANTS**

8965001 Butterfly Nut  
8966430 Butterfly Cage 14/30  
8966435 Butterfly Cage 14/35  
8966440 Butterfly Cage 14/40  
8966630 Butterfly Cage 16/30  
8966635 Butterfly Cage 16/35  
8966640 Butterfly Cage 16/40

**Plates**

8968848 Plate 48mm  
8968849 Plate 49.5mm

**Bolts**

8962630 Butterfly Bolt D6.5 L30  
8962635 Butterfly Bolt D6.5 L35  
8962640 Butterfly Bolt D6.5 L40  
8962645 Butterfly Bolt D6.5 L45  
843-160 Nut Bolt

**Bone Screw (Z-Plate Screws)**

822-230 Bone Screw D6.5 L30  
822-235 Bone Screw D6.5 L35  
822-240 Bone Screw D6.5 L40  
822-245 Bone Screw D6.5 L45

**INSTRUMENTS**

8961010 Butterfly Plate Holder  
8961030 Butterfly Cage Holder  
8961020 Butterfly Nut Holder  
8961040 Butterfly Cage Support  
8961050 Butterfly Gauge  
8963048 Butterfly Bolt Gauge 48  
8963049 Butterfly Bolt Gauge 49.5  
8963010 Butterfly Bolt Holder 1  
8963020 Butterfly Bolt Holder 2  
8963060 Butterfly Awl  
8963070 Butterfly Bolt Nut Holder  
8963080 Butterfly Screw Holder  
8963090 Butterfly Std Handle

**BOX**

8969100 Butterfly Container/Base Tray  
8969110 Butterfly Insert Tray  
8969200 Butterfly Lid

**MEDTRONIC SOFAMOR DANEK EUROPEAN SPINE CENTER**

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SOFAMOR SNC  
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