

BAK INTERBODY FUSION SYSTEM PATIENT INFORMATION BROCHURE

Introduction

This Patient Information Brochure is to help you make an informed decision about your back surgery, specifically with the BAK Interbody Fusion System.

What is the BAK System

The BAK Interbody Fusion System consists of implants and optional endcaps. The implants are made from titanium alloy and the endcaps from polyethylene. Both of these materials are compatible with the human body. The implants are similar to large, hollow screws with holes in them and are usually implanted in pairs in the disc space (cushion between the vertebrae of the spine). The implants are filled with bone taken from the patient's hip.

Which Patients Might Benefit From the BAK System

In your lower back there are five vertebrae (bones). Between each of the vertebra is a disc which is a cushion-like material. Motion occurs through the disc. Your disc can wear down and cause pain.

Based on your examination, your doctor has asked you to consider a spinal fusion procedure with the BAK Interbody Fusion System because you have a condition called "degenerative disc disease" (DDD). This results in pain coming from the disc. The purpose of this surgery is to stabilize and fuse one or two disc spaces of your spine and relieve your back pain.

Although your doctor is planning to use the BAK Interbody Fusion System for your condition, you should be aware that there are alternative treatments to this type of device. If you want information on these options, please discuss them with your doctor.

As a note, the BAK Interbody Fusion System is

approved for patients with degenerative disc disease. The BAK implant is filled with bone from your hip and may be implanted from the second lumbar disc (L2) down to the sacrum. Only one or two disc spaces are to be fused. These patients with DDD may also have limited slippage of one vertebra over the vertebra below it (Grade I spondylolisthesis). Patients should be skeletally mature and should have had six month of non-operative treatment.

Above describes which patients should receive the BAK Interbody Fusion System. You should also be aware that the BAK Interbody Fusion System should not be used in patients with severe infection.

In addition, you should be aware that there was little data or no data for patients with gross obesity, symptomatic cardiac disease, pregnancy, three or more levels to be fused, excessive forward or backward vertebral slippage, major illness, significant loss of quantity or quality of vertebral bone, condition requiring steroid use, active drug abuse, or had a previous fusion attempt at the same disc space. If you have any of these conditions, please discuss the issue with your doctor.

The BAK Surgery

Portions of the disc and bone are drilled out and the BAK implants are screwed into the holes. Bone graft is placed inside and between the BAK implants so that the bone may grow through the implants, fusing the disc space. The BAK Interbody Fusion System is implanted from the front (anterior) or back (posterior) surgical approach. Your doctor will make this decision depending on your condition.

After Surgery

You will be expected to be seen by your doctor several times after surgery to evaluate your pain and function. X-rays will be taken to check the BAK implants. You should ask your doctor about



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his/her postoperative rehabilitation program and follow-up plan. It is important to follow your doctor's instructions carefully in order to recover from your surgery as quickly as possible.

Possible Complications

Complications related to spinal implant surgery include, but are not limited to, the following: tear in the outer lining of the spinal cord (dura), spinal fluid leak, nerve complications, infection, slow movement of the intestines (ileus), implant migration, blood vessel damage/bleeding, leg pain, bruise (hematoma), pneumonia, retrograde ejaculation into bladder, fractured sacrum, blood clots, wound closure problems and bladder problems.

Information on rates of specific complications may be discussed with your doctor. Your doctor may refer to the package insert that was provided to him/her for a list of complication rates observed in the clinical study discussed below.

Clinical Results

A clinical study of the BAK System was conducted at a number of hospitals. There were a total of 283 patients with available data at two years. The success rates are shown below for overall success and for each major individual measure of success. The patients who were an overall success had successful results in all four of the major measurements (fusion, pain, function and muscle strength). As you can see, the results were separated by the type of surgical approach and number of disc spaces fused.

	Anterior		Posterior	
	<u>1</u>	<u>2</u>	<u>1</u>	<u>2</u>
Overall Success	81%	59%	78%	50%
Fusion Rate	98%	80%	94%	71%
Pain Improvement	84%	86%	87%	81%
Function Maintained or Improved	95%	94%	92%	95%
Strength Maintained or Improved	94%	94%	94%	100%

Note that the number of patients used to calculate the success rates were slightly different for each of the measurements above due to unavailable data. Please talk to your doctor if you have questions regarding this clinical information or about the statements in the following section.

Based on this clinical study, the following statements may be made about the BAK system.

- The two year data indicates that the likelihood of needing additional supplemental fixation increases over time in patients who were not fused or showed no improvement in pain.
- For both the anterior and posterior approaches, patients with one disc space fused had lower overall complication rates than patients with two disc spaces fused.
- Patients implanted with a BAK device from the posterior approach had higher rates of operative complications and early postoperative surgical interventions than patients implanted from the anterior approach.
- Patients implanted from the anterior approach had a higher overall rate of early postoperative complications than patients implanted from the posterior approach.
- For both the anterior and posterior approaches, patients who had higher preoperative pain scores showed better pain improvement throughout the study than patients with lower preoperative pain scores.

Your doctor's experience may be similar to or different than the findings listed above. It is your choice to have a spinal fusion using the BAK implants. Please ask your doctor any questions you have so that you will make a decision that is best for you.



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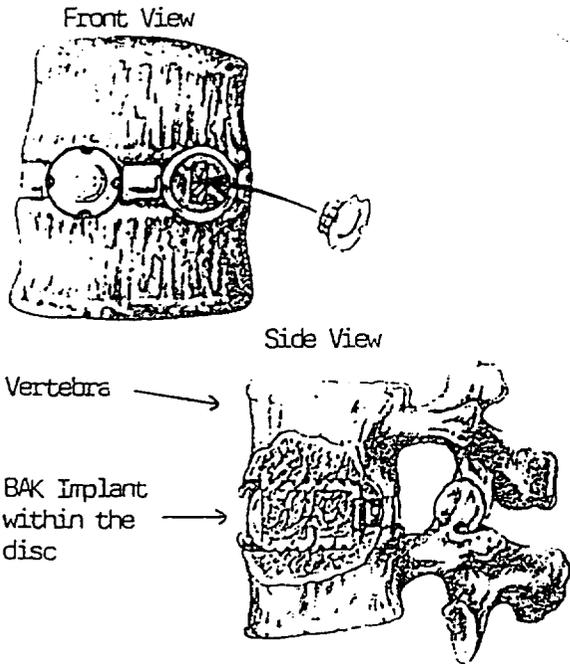
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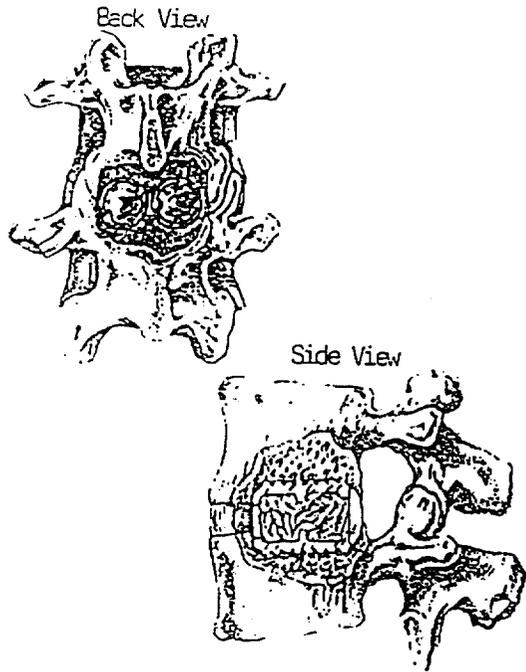
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Questions

If you have any questions or need additional information, please contact your doctor.



BAK Implants shown using the anterior (front) approach



BAK Implants shown using the posterior (back) approach



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BAK INTERBODY FUSION SYSTEM

Description

The BAK Interbody Fusion System consists of BAK Interbody implants and BAK endcaps. The BAK implant is available in five sizes (diameter x length): 13mm x 20mm, 15mm x 20mm, 15mm x 24mm, 17mm x 24mm and 17mm x 28mm. The BAK implant may be used with an optional endcap which is available in corresponding diameters of 13mm, 15mm and 17mm.

The BAK implants are made from titanium alloy (Ti-6Al-4V), conforming to ASTM F136. The endcaps are made from ultra-high molecular weight polyethylene (UHMWPE), conforming to ASTM F648. Instruments designed for implantation of the BAK device are made from stainless steel, conforming to ASTM F899. These instruments are identified in the Surgical Technique Manual.

Indications

The BAK device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK devices are to be implanted via an open anterior or

posterior approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Contraindications

BAK devices should not be implanted in patients with an active infection at the operative site.

Precautions

The surgeon should only implant the BAK device after adequate training and familiarity with the surgical technique manual.

Safety and effectiveness have not been established in patients with the following conditions: gross obesity, three or more levels to be fused, symptomatic cardiac disease, pregnancy, previous fusion attempts at the involved level(s), spondylolisthesis or retrolisthesis of Grade II or greater, systemic or terminal illness, significant loss of quantity or quality of vertebral bone stock usually due to osteoporosis or osteomalacia, a condition requiring steroid use or active drug abuse.

Two devices should be implanted at each surgical level whenever possible. One device may be used if patient anatomy or surgical exposure does not allow for placement of two devices.

The BAK implant and endcap are supplied sterile and should be handled in a manner to avoid contamination. In the event of damage to the sterile packaging or inadvertent contamination, implants may be steam sterilized using a gravity cycle of 270 degrees F for 3 minutes. The endcaps should not be re-sterilized if contaminated.

No implant or endcap should be re-used if it has come in contact with human tissue or bodily fluid.

Instruments for implantation of the BAK device are provided non-sterile and must be sterilized prior to use. They may be sterilized using gravity steam at 270 degrees F for 10 minutes or 250 degrees F for 15 minutes.

Adverse Effects

The following adverse effects were reported during a multi-center clinical study of 947 patients implanted with the BAK device. These adverse effects were recorded and classified as operative and postoperative. The rates presented are the number of patients with a particular complication divided by the total number of patients with available data at a given time period. Anterior and posterior complications are combined.

Complications Over Time

	Operative % N=947	Post-Op % N=947	3 Month % N=847	6 Month % N=770	12 Month % N=661	24 Month % N=283	Total % Complication Incidence
<i>Complications not requiring surgical intervention:</i>							
Dura Related	3.1	-	-	-	0.2*	-	3.3
Neurologic	1.9	0.2	0.4	0.4*	-	-	2.9
Infection	-	2.1	0.2	-	0.1*	-	2.4
Implant Migration (no reoperation)	-	0.3	0.9	0.4	-	-	1.6
Ileus (post-op)	0.4	1.1	-	-	-	-	1.5
Vessel Damage, Bleeding	1.5	-	-	-	-	-	1.5
Atelectasis, Pneumonia	-	1.2	0.1	-	-	-	1.3
Hematoma, Seroma	0.1	1.0	0.1	0.1	-	-	1.3
Retorsade Ejaculation	0.2	0.1	0.7	0.3	-	-	1.3
Other**	0.1	0.7	-	0.1	0.1	0.3	1.3
Urologic, Swollen Testicle, Prostatitis, Epididymitis	0.2	0.6	0.1	-	-	-	0.9
Wound Dehiscence, Incisional Hemia	-	0.4	0.1	0.1	0.1	-	0.7
Thrombophlebitis, Embolism	-	0.5	0.2	-	-	-	0.7
Leg Pain	0.1	0.1	0.1	-	-	0.3*	0.6
<i>Complications requiring surgical intervention:***</i>							
Additional Stabilization	-	0.2	0.3	0.6	1.5	2.1	4.7
Additional Level Fusion	-	-	0.1	0.1	0.8	0.7	1.7
Implant Migration with Reoperation	-	0.6	0.5	0.1	-	-	1.2
Leg Pain with Decompression	-	0.4	0.1	0.1	0.3	0.3	1.2
Dura Related Comp with Repair	0.5	-	0.1	-	-	-	0.6
Reposition of Implants	-	0.3	-	0.1	-	-	0.4
Other Decompression	-	0.1	-	0.1	-	-	0.2
Penetration of Anterior Ligament	0.1	-	-	-	-	-	0.1
Fractured Sacrum with Instability	-	0.1	-	-	-	-	0.1

* Due to Secondary Surgical Intervention
 ** Other = anemia, colitis, GI bleed, wound drainage without infection, undisplaced sacral fracture, unrelated S1 joint infection, chronic subdural hematoma, umbilical hernia (unrelated to surgery), loose implant postoperatively, occipital infarction, possible pre-existing disc space infection
 *** Complications requiring surgical intervention include 9 revisions, 7 removals, 27 reoperations and 26 supplemental fixations

Clinical Results

The following are clinical results of the same multi-center clinical study presented above. Two year data was available for 283 patients. The data are stratified by surgical approach and one versus two levels. The success rates are shown below for each criteria as well as overall success based on all four criteria.

The success rates are shown below for overall success as well as for each of the four criteria. Overall success was defined as fusion at the involved level(s), improvement in pain, maintenance or improvement in function and maintenance or improvement in muscle strength. Note that the number of patients with available data differ slightly due to unavailable data.

	Anterior	
	One Level	Two Level
Overall Success	81% (85/105)	59% (39/66)
Fusion Rate	98% (106/108)	80% (56/70)
Pain Improvement	84% (93/111)	86% (62/72)
Function Maintenance or Improvement	95% (105/111)	94% (68/72)
Strength Maintenance or Improvement	94% (102/109)	94% (64/68)

	Posterior	
	One Level	Two Level
Overall Success	78% (52/67)	50% (8/16)
Fusion Rate	94% (68/72)	71% (12/17)
Pain Improvement	87% (66/76)	81% (17/21)
Function Maintenance or Improvement	92% (70/76)	95% (20/21)
Strength Maintenance or Improvement	94% (67/71)	100% (20/20)

From the clinical data, the following statistical differences were observed among the subgroups up to or at the two year time period:

- The two year postoperative data indicates that the likelihood of needing additional supplemental fixation increases over time in patients who were not fused or showed no improvement in pain.
- For both the anterior and posterior approaches, patients with one level fusion had lower overall complication rates than patients with two level fusions.
- Patients implanted with the BAK device from the posterior approach had higher rates of intraoperative complications and early postoperative surgical interventions than patients implanted from the anterior approach.
- Patients implanted from the anterior approach had a higher overall rate of early postoperative complications than patients implanted

- For both the anterior and posterior approaches, patients who had higher preoperative baseline pain scores showed better pain improvement throughout the study than patients with lower baseline pain scores.

Device Retrieval Efforts

Should it be necessary to remove a BAK, please call Spine-Tech's Regulatory Affairs Department at 800/655-2614 for instructions regarding implant preparation, shipment and data collection.

CAUTION: United States (federal) law restricts this device to sale by or on the order of a physician with appropriate training or experience.



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 B-5001 Namur
 Belgium



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13mm D X 20mm L

BAK Interbody Implant
 Qty: 1

REF 3000-1320-00 **STERILE EO** 

LOT P950050  2000-11 

SHELF BOX LABEL

SPINETECH 

BAK Interbody Implant, 13mm D X 20mm L,
 REF 3000-1320-00 **STERILE EO**

LOT P950050 Qty: 1  2000-11 

OUTER TYVEK POUCH LABEL

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 REF 3000-1320-00 **LOT** P950050

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PATIENT LABELS

62


SPINETECH
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13mm 

BAK™ Endcap, 13mm
U.S. Patent 5,499,308
 Qty: 1

REF 3000-13PE-00 **STERILE EO**  0044

BAK™ ENDCAP SIZE: 13mm

SHELF BOX LABEL


SPINETECH

BAK™ Endcap, 13mm
 REF 3000-13PE-00

STERILE EO 

 Qty: 1  

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 REF 3000-13PE-00 


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BAK™ Endcap, 13mm
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BAK™ Endcap, 13mm
 REF 3000-13PE-00 

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13mm D X 20mm L

BAK Interbody Implant
U.S. Patent 4,961,267, 5,033,247
 Qty: 1

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1/2


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13mm 

BAK™ Endcap, 13mm
U.S. Patent 5499308
 Qty: 1

REF 3000-13PE-00 **STERILE EO**  0044

LOT  

BAK™ ENDCAP SIZE: 13mm

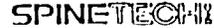
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BAK™ Endcap, 13mm
 REF 3000-13PE-00 **STERILE EO**

LOT Qty: 1  

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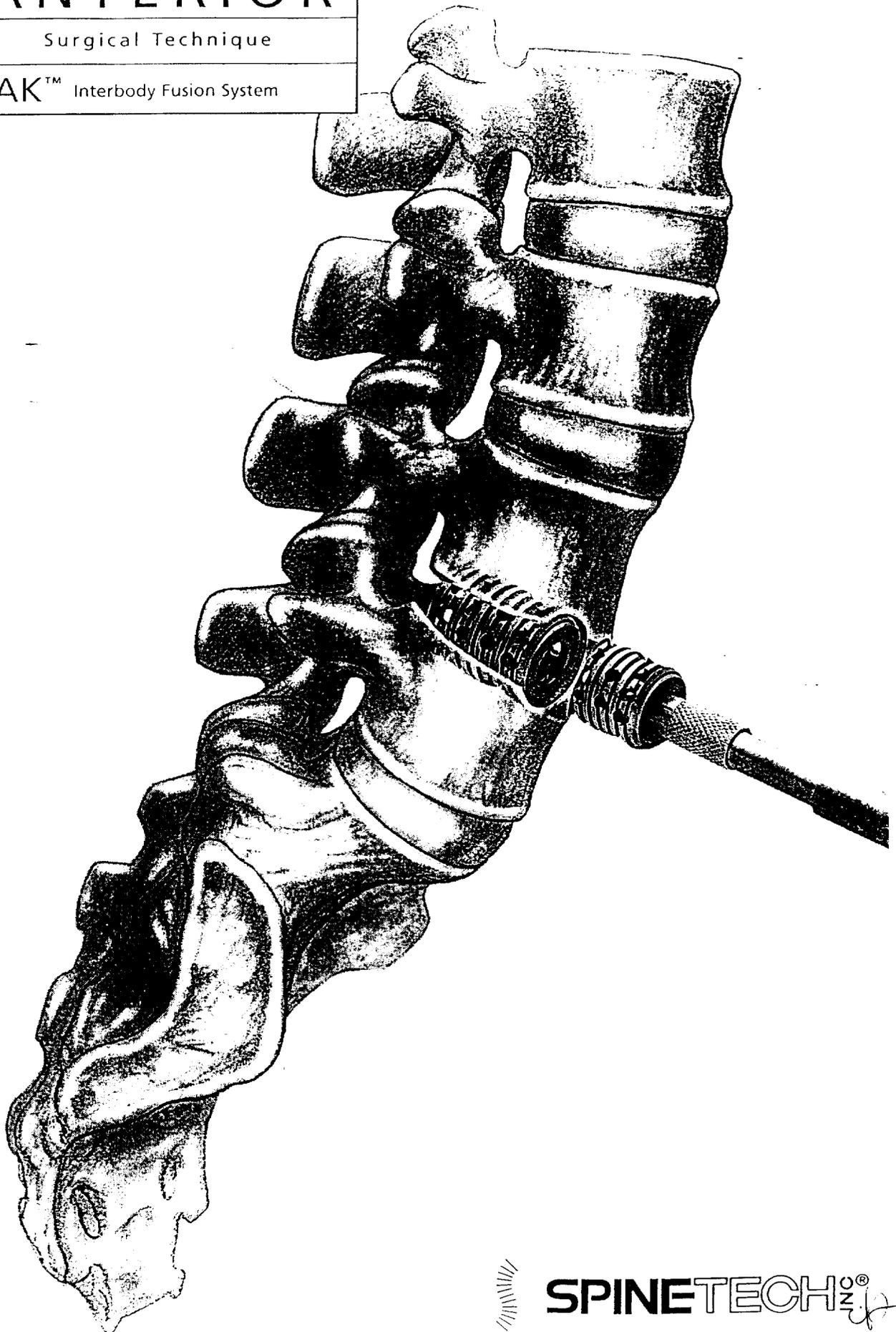
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ANTERIOR

Surgical Technique

BAK™ Interbody Fusion System



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INTRODUCTION

Anterior Surgical Technique

The Spine-Tech BAK implant is a fenestrated, threaded, cylindrical, titanium alloy device to be inserted within the intervertebral disc space. The implant is coupled with instruments designed to reproducibly prepare the bone bed, protect surrounding tissues and safely position the implants. The system is designed to provide an immediately stable motion segment to allow fusion and relief of symptoms.

Design features of the BAK implant include:

- Vertebral distraction evenly tenses the remaining annulus creating a tension band around the implants
- Threads engage the vertebral body to enhance resistance to shear forces
- "Keystone" effect resists rotational forces
- Internal ribbing to enhance fatigue strength
- Lordosis maintained through vertebral body support
- Foraminal volume and area are increased through distraction providing decompression

Design features of the BAK instruments include:

- Drill tubes aid in retraction and protection of vital structures during implantation
- Positive stops prevent overdrilling
- Drill Tube teeth ease tube docking and prevent instrument migration
- Alignment Guides facilitate accurate implant insertion and spacing

Indications, contraindications, potential adverse effects and precautions are referenced in the package insert.

RADIOGRAPHIC TEMPLATING

Anterior Surgical Technique

Radiographic templating assists with selecting appropriate implant and Distraction Plug sizes which maximize implant endplate coverage and create proper vertebral distraction and annular tension. Selection of the proper size BAK implants is critical for optimum results.

Radiographic templates (Figure 1) are available in 15% magnification for use with plain x-rays and 50% to 80% reductions for MRI and CT scans. Templates include the following information:

- Implant size and distraction plug size chart
- Lateral BAK implant and associated drilling representations
- Lateral distraction plug representations
- Anterior/Posterior implant representations
- Magnification or reduction scale

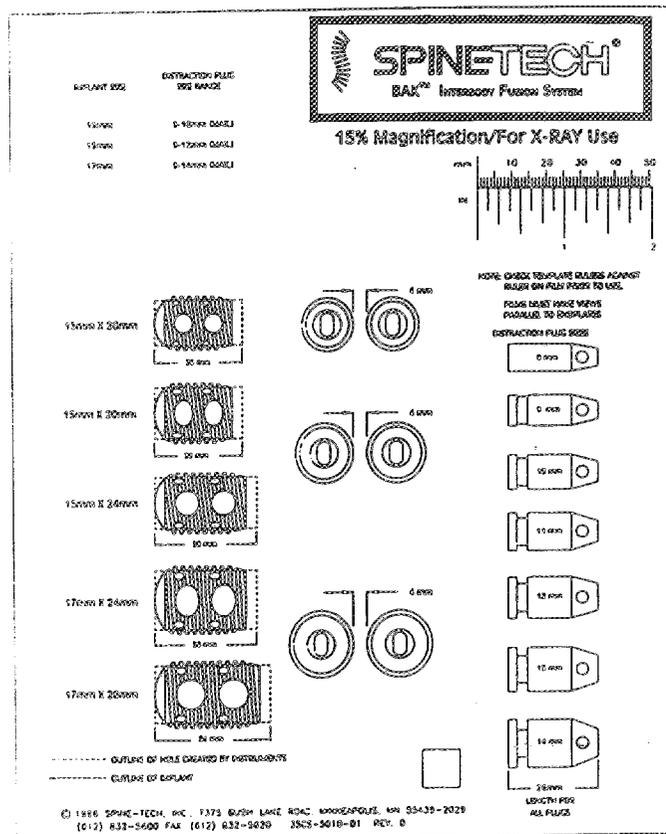


Figure 1

Step 1

The proper implant length is assessed with a lateral x-ray. The red dotted lines, representing the final reaming depths, and lateral implant representations are overlaid on the affected disc (Figure 2). Select the maximum reaming depth and implant size which is safely contained within the anterior and posterior vertebral margins.

This assessment will typically reduce the implant selections to one length and two diameters.

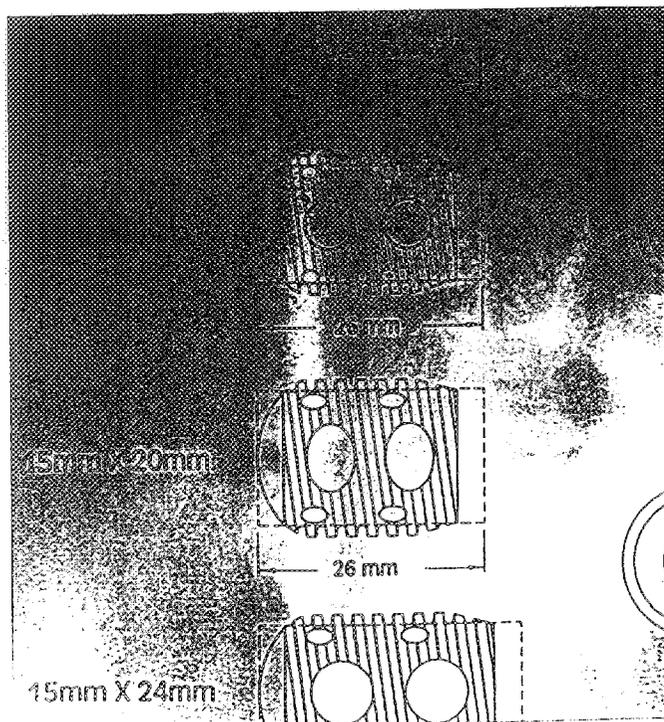


Figure 2

RADIOGRAPHIC TEMPLATING CONTINUED

Anterior Surgical Technique

Step 2

On the same lateral x-ray, overlay the Distraction Plug outline on an adjacent healthy disc (Figure 3). The Distraction Plug which bridges the space is an indication of the potential distraction of the affected motion segment.

Step 3

Compare the implant diameters indicated in Step 1 with the Distraction Plug size indicated in Step 2 using the Implant Size/Distraction Plug Size Range chart in the upper left hand corner of the template.

If the Distraction Plug size indicated in Step 2 is not within the range listed for the smaller implant diameter, the larger implant diameter is selected. If it is, the A/P x-ray is used to further assess the correct implant size.

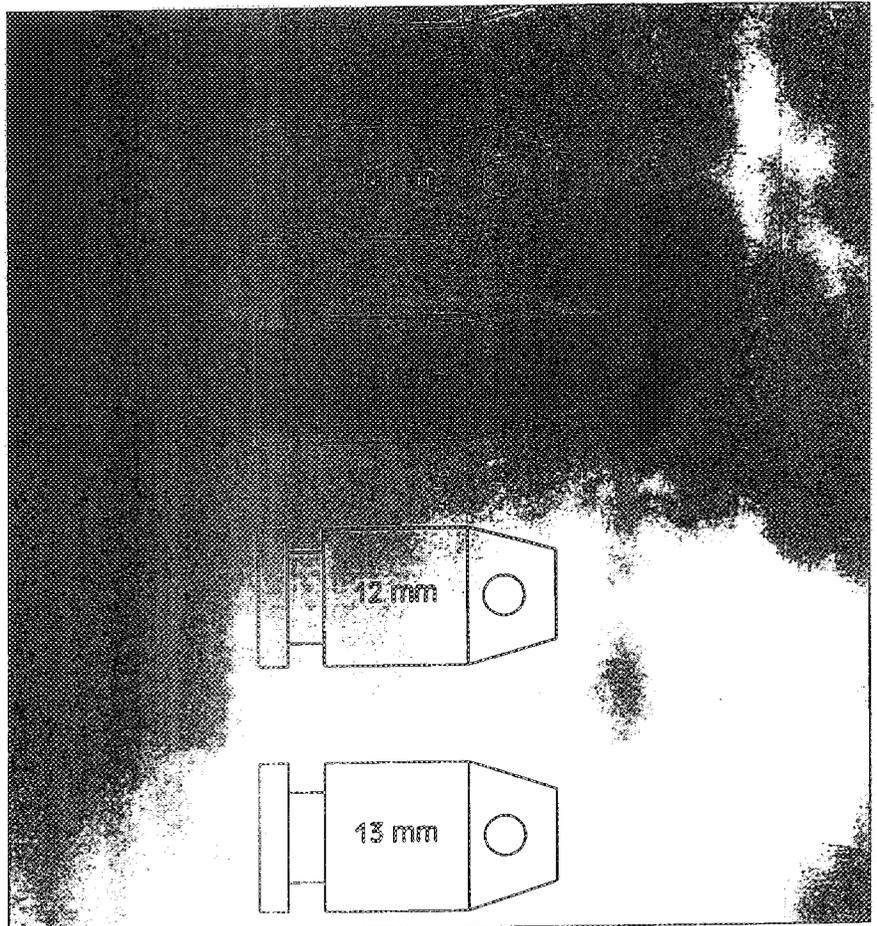


Figure 3

The Implant Size/Distraction Plug Size Range chart is recreated below.

Implant Size	Distraction Plug Size Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used.

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RADIOGRAPHIC TEMPLATING CONTINUED

Anterior Surgical Technique

Step 4

The appropriate implant diameter is further assessed or confirmed by overlaying the A/P BAK outlines of the implant diameters determined in Steps 1 and 2, over the A/P x-ray. Center the images over the superior most vertebral body to be fused (Figure 4). The largest implant representations which fit within the lateral margins indicate the implant size to be used.

An MRI/CT axial cut reflecting the smallest endplate of the affected disc can help determine implant size. To select the proper BAK MRI/CT template, match the scale on the template to that of the scan (Figure 5). Use the bilateral axial template images to assess the largest outlines which are safely contained within the disc margins (Figure 6).

Caution: When using the MRI/CT templates, it is critical that the transverse vertebral representations are parallel to the endplates. If they are not, the images will be oversized and may lead to selection of an implant and associated drilling depth which is too long.

Note: Templating provides an estimate of implant and distraction plug size. Final sizes will be determined intraoperatively.

After implant size selection is complete, the common instruments and the instruments specific to the selected implant size are removed from the instrument trays.

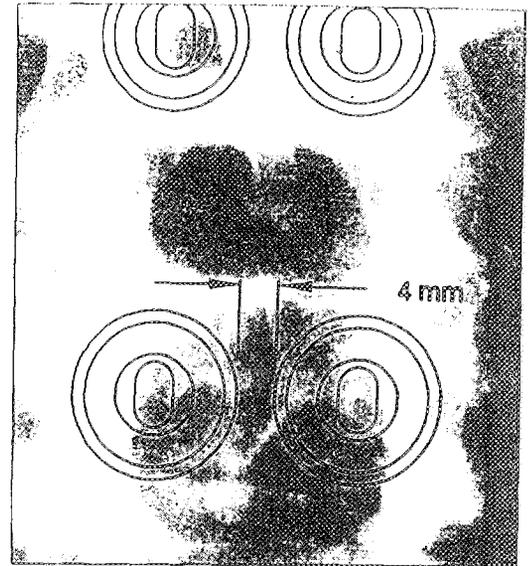


Figure 4

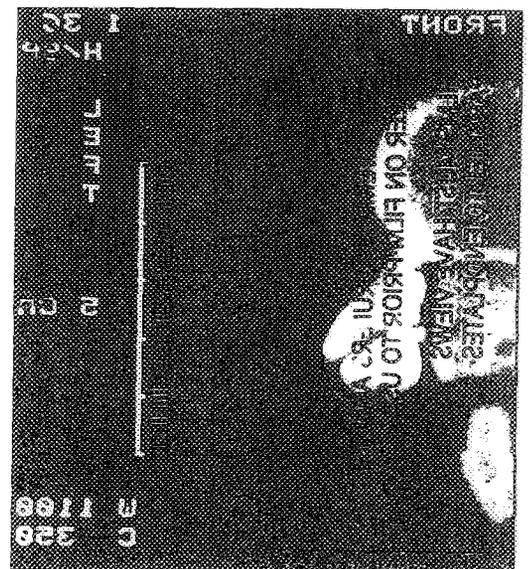


Figure 5

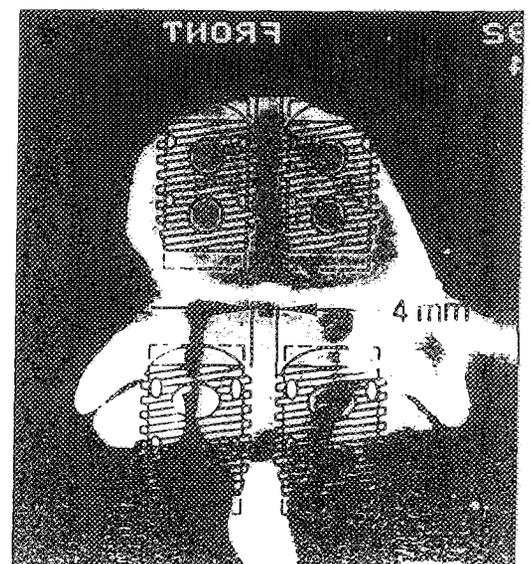


Figure 6

SURGICAL POSITIONING AND EXPOSURE

Anterior Surgical Technique

The patient is placed in the supine position and general anesthesia is administered. A pad is placed under the lumbar spine to maintain lordosis (Figure 7) and the arms are positioned 90 degrees to the torso on boards to better facilitate radiographic imaging (Figure 8). A vascular or general surgeon usually provides the exposure while the spine surgeon assists and then performs the implantation. The lumbar spine is exposed through a low transverse or paramedian incision, and a retroperitoneal plane is developed.

The anterior rectus sheath is split longitudinally about 3 to 4cm left of the midline anterior to the level(s) to be fused. Since the BAK implantation will be accomplished in a direct anterior-posterior plane, the retroperitoneal plane must be developed from an anterior rather than lateral direction. This is most easily accomplished by retracting the left rectus abdominus muscle laterally to the left. In addition to providing a more direct anterior to posterior plane, the retraction tension on the left rectus is reduced and the blood flow to the muscle is improved. This exposes the peritoneum below the arcuate line and the posterior rectus sheath above it. The peritoneum is stripped from the undersurface of the posterior rectus sheath, and the rectus sheath is divided near its insertion on the lateral wall, from inferior to superior, until sufficient exposure is achieved. The left psoas, great vessels, left ureter, and left sympathetic trunk are identified and protected from injury.

Caution: Electro-cautery of any kind must be used very sparingly, if at all, in the tissues around and between the great vessels and the anterior surface of the spine in order to minimize risk of injury to the autonomic nerve plexus. This plexus is thought to be involved with the complication of retrograde ejaculation.

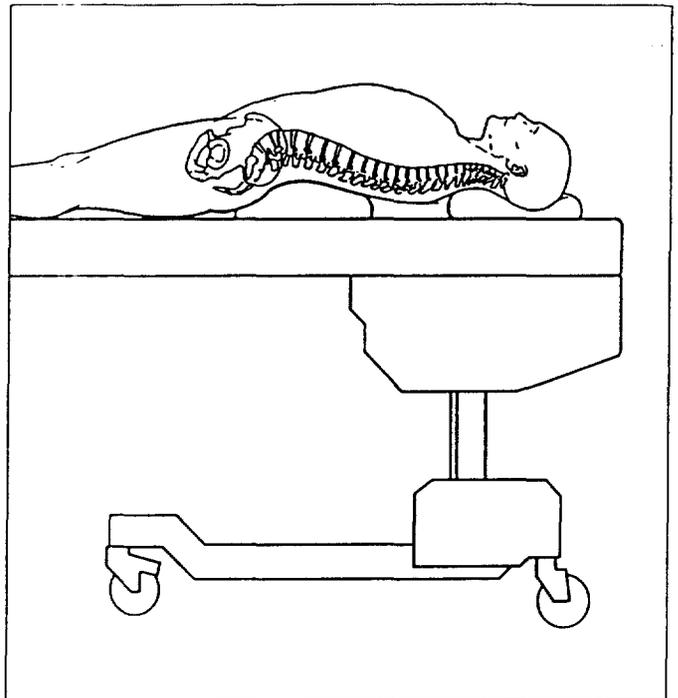


Figure 7

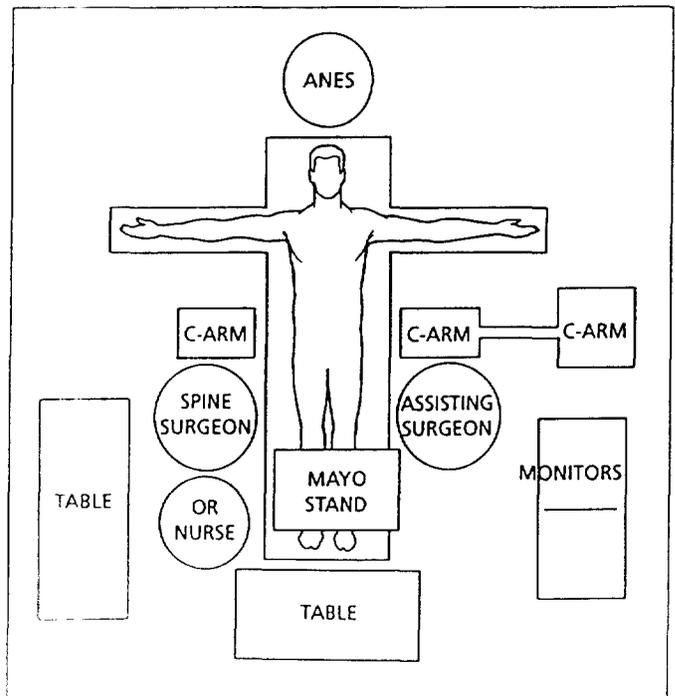


Figure 8

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SURGICAL POSITIONING AND EXPOSURE CONTINUED

Anterior Surgical Technique

Normally, the L5-S1 disc level can be exposed below the bifurcation of the great vessels (Figure 9), while the exposure of the L4-5 level and above requires the left iliac vein and/or vena cava be mobilized to the right lateral margin of the spine (Figure 10). The middle sacral vessels, segmental vessels above the disc to be fused and the ascending lumbar vein may need to be identified, ligated and sectioned to provide adequate exposure without excessive traction on the great vessels. The Buckwalter Frame and Wiley Renal Vein Retractors greatly facilitate the operation.

Following complete exposure of the anterior aspect of the spine, a pin or needle is inserted approximately in the midline. An anterior-posterior radiograph is taken to verify the location of the midline. Identification and radiographic confirmation of this landmark is critical to ensure accurate bilateral implant placement.

If iliac crest graft is to be used within the implants, sufficient bone graft can be harvested from the anterior iliac crest in cases of one level-fusion. However, a preliminary posterior iliac graft harvest may be necessary for two-level fusions. About five to seven cubic centimeters of compacted cancellous graft is necessary for each implant.

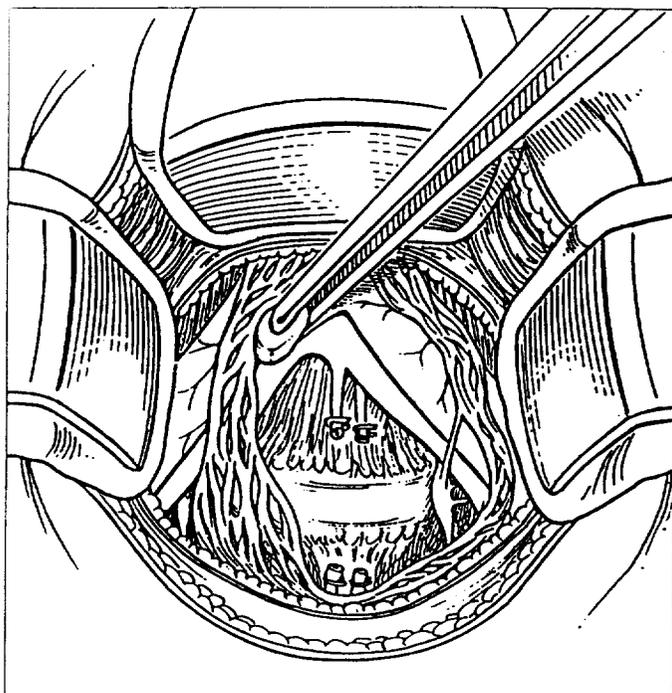


Figure 9

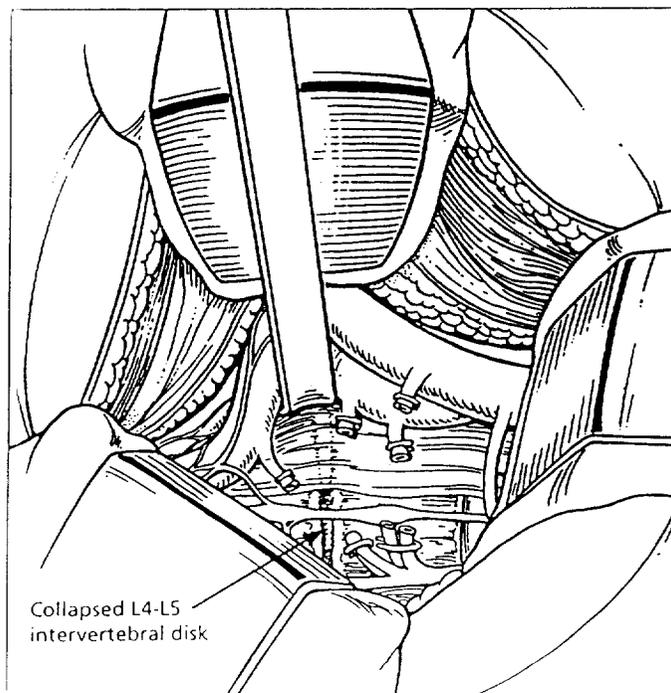


Figure 10

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STEP 1 IMPLANT ALIGNMENT

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Anterior Alignment Guide 8mm Drill

The Anterior Alignment Guide is used to establish the proper position of two BAK implants parallel within the intervertebral space and to initiate the discectomy procedure. It is designed to place the implants 4mm apart.

Cut a small vertical slit in the previously established midline of the involved disc with a size 15 scalpel blade. Insert the guide peg of the Anterior Alignment Guide into the slit (Figure 11). Using a mallet, secure the spikes into the vertebral bodies with the guide holes centered over the disc. Slit the annulus visible through the lower guide hole with the scalpel blade. Insert the 8mm Drill through the Alignment Guide and drill until the positive stop on the drill contacts the top of the Alignment Guide (Figure 12).

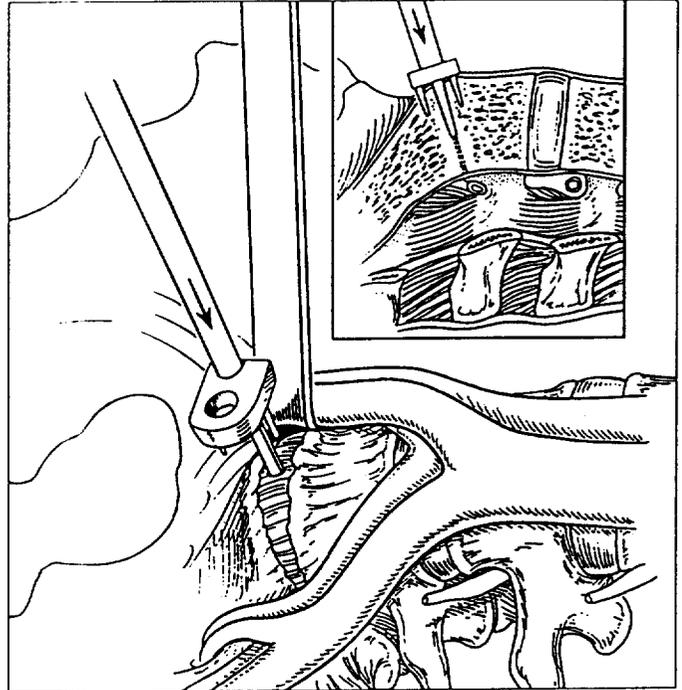


Figure 11

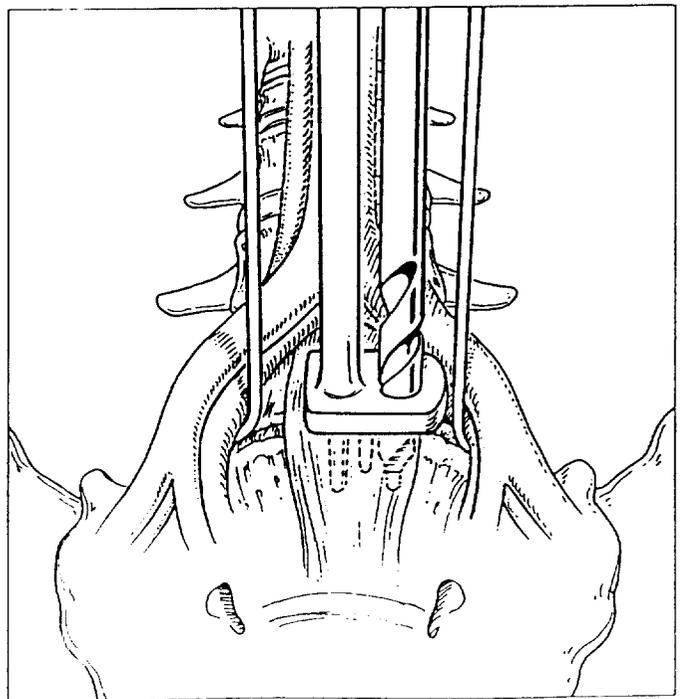


Figure 12

STEP 1 IMPLANT ALIGNMENT CONTINUED

Anterior Surgical Technique

Disengage the spikes and rotate the Alignment Guide in the central hole 180°. Resecure the Alignment Guide and prepare the disc space for the second implant using the 8mm Drill as described previously.

Note: Using a pituitary rongeur and/or small curette, nucleus material can be removed through the drill holes (Figure 13). Additional annulus may also be removed, but care should be taken to remove an equal amount around the original 8mm holes. Avoid elongation of the holes and decortication of the endplate as it may affect Distraction Plug or Guide Pin placement and subsequent alignment.

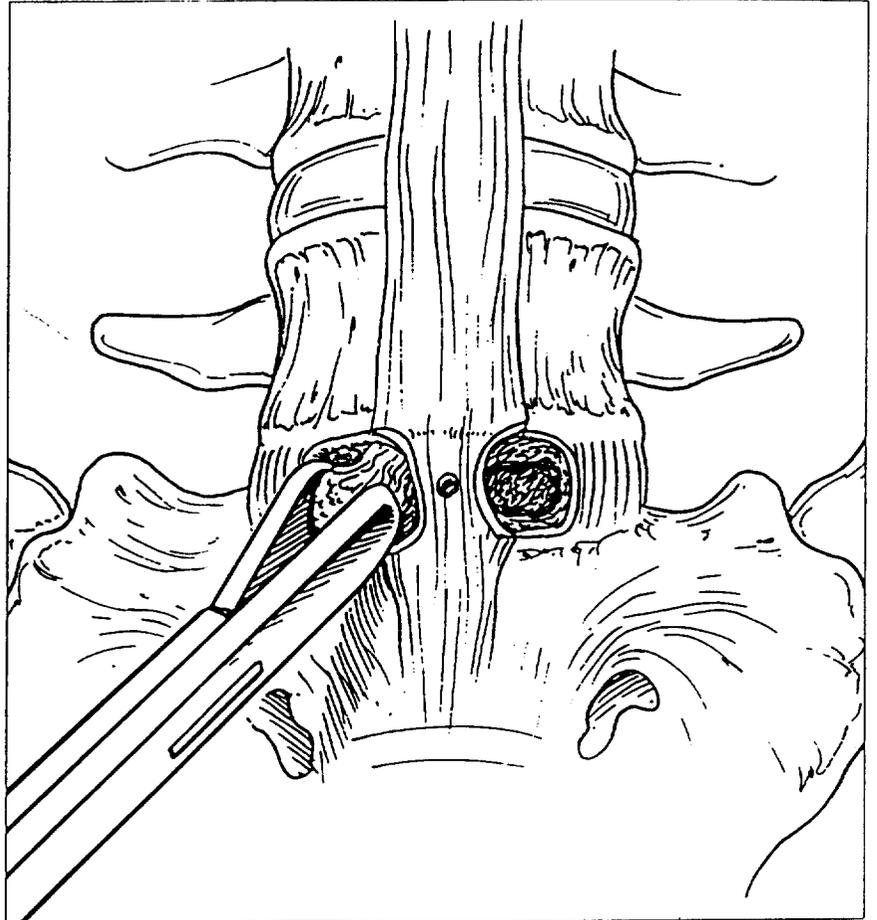


Figure 13

STEP 2 VERTEBRAL DISTRACTION AND ANNULAR TENSING

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Distraction Plug Inserter Distraction Plugs

Distraction Plugs are used to distract the vertebral bodies and apply tension to the annulus prior to vertebral reaming.

Attach a relatively small Distraction Plug onto the Distraction Plug Inserter. Retract the vessels with a vein retractor and impact the Distraction Plug into one of the 8mm drill holes (Figure 14). The Distraction Plug is impacted until the back edge of the plug is slightly recessed below the anterior margin of the disc. Check the annular tension by pulling straight up on the Distraction Plug Inserter. If the Distraction Plug pulls out easily, repeat this procedure using incrementally larger Distraction Plugs until the annulus is sufficiently taut. This is indicated when significant resistance is met during Distraction Plug removal.

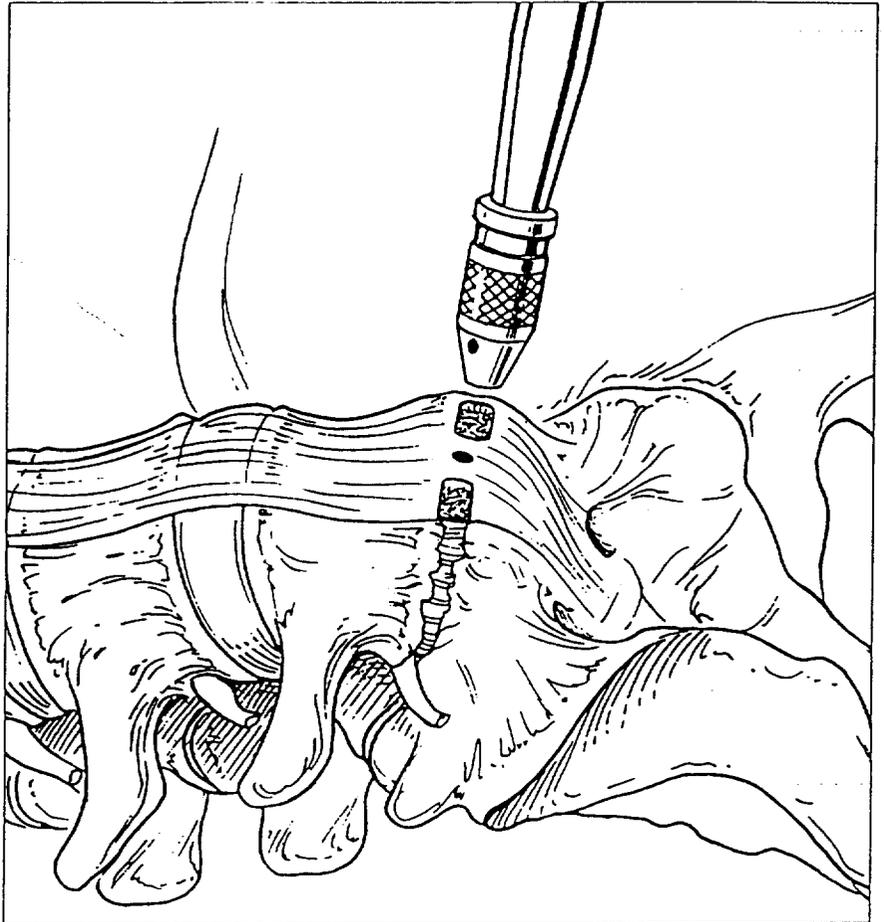


Figure 14

STEP 2 VERTEBRAL DISTRACTION AND ANNULAR TENSING CONTINUED

Anterior Surgical Technique

Once the correct Distraction Plug is identified, assess the disc space angle by noting the angle of the Distraction Plug Handle (Figure 15). This angle is critical as all future drilling, tapping and implantation steps need to be performed at this angle. Remove the handle, leaving the Distraction Plug in place.

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used. See chart below.

Implant Size	Distraction Plug Size Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

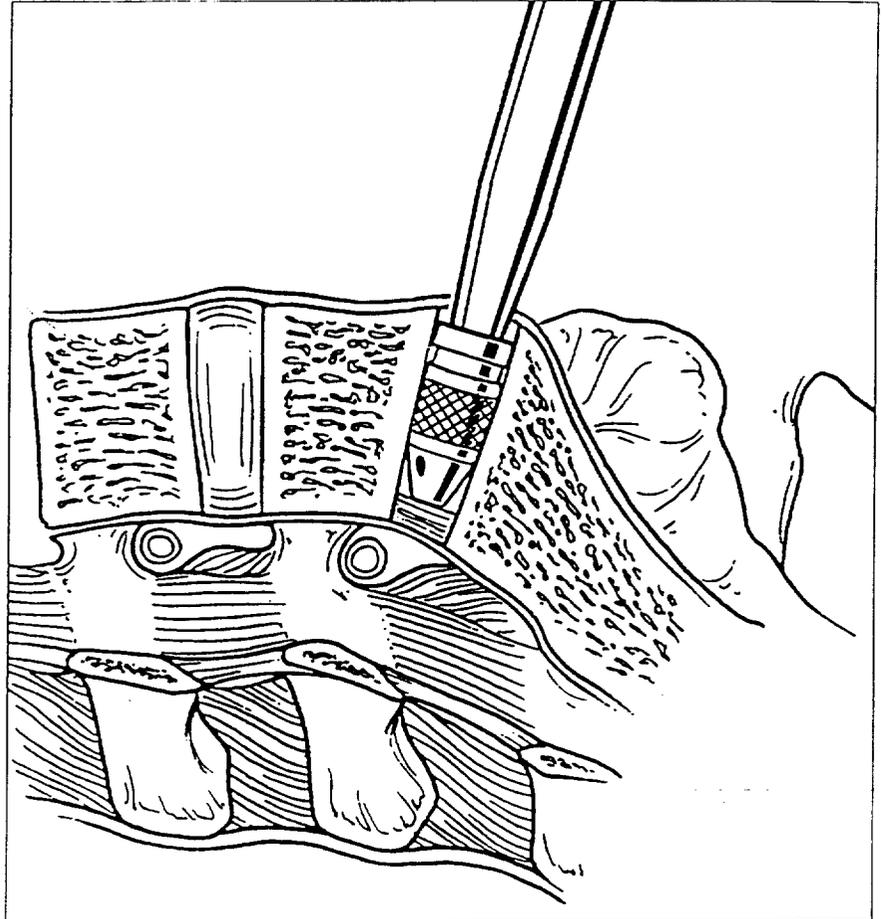


Figure 15

STEP 3 DRILL TUBE PLACEMENT

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Drill Tube Guide	Drill Tube
Guide Pin	Drill Tube Sheath
Slap Hammer	Alignment Guide Handle

Thread a Guide Pin equivalent in size to the inserted Distraction Plug onto the Drill Tube Guide.

Impact the Drill Tube Guide and Guide Pin into the 8mm drill hole opposite the Distraction Plug (Figure 16). This will center the Drill Tube Guide over the disc.

Slide the protective Drill Tube Sheath onto the Drill Tube with the curved end of the Drill Tube Sheath placed distally and covering the anchoring teeth (Figure 17). Slide the Drill Tube and Sheath over the Drill Tube Guide.

Caution: Prior to anchoring the Drill Tube, great care must be taken to identify and retract all soft tissue.

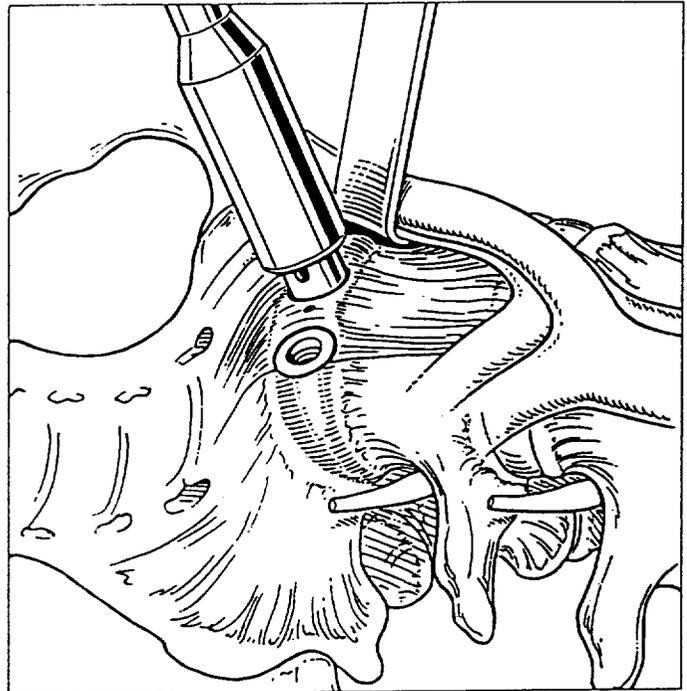


Figure 16

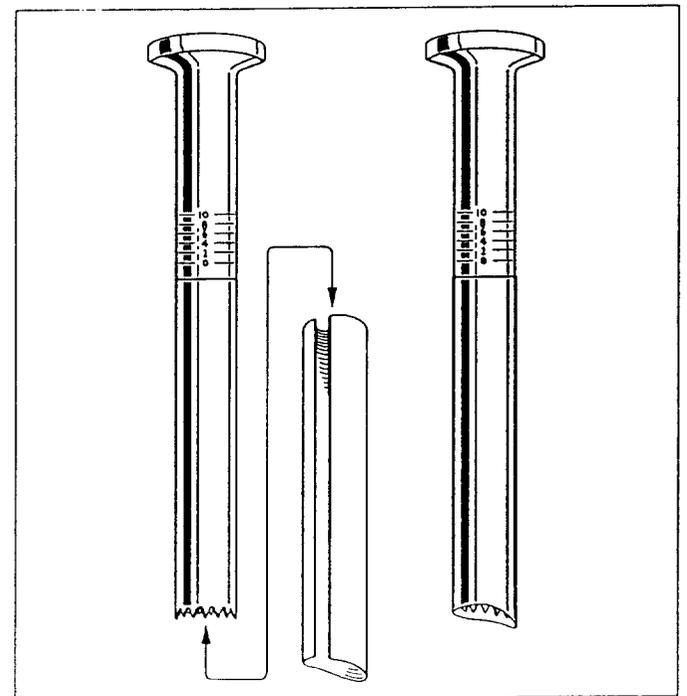


Figure 17

STEP 3 DRILL TUBE PLACEMENT CONTINUED

Anterior Surgical Technique

Using lateral radiographic imaging, ensure the superior and inferior sides of the Drill Tube are aligned parallel to the vertebral endplates. Additionally, visually inspect and ensure the Drill Tube is perpendicular to the coronal plane of the disc. If a convergent angle is placed on the Drill Tube, it may cause the implants to contact one another. Conversely, a divergent angle may cause the implants to break out of the disc laterally, disrupting the annular tension band.

Place the Slap Hammer over the Drill Tube Guide and Drill Tube. Secure the anchoring teeth of the Drill Tube into the vertebral bodies by impacting the Slap Hammer until the inner surface of the Drill Tube Guide and Slap Hammer meet (Figure 18).

Once the Drill Tube is secure and alignment is verified, remove the Drill Tube Guide and Guide Pin by rotating the Drill Tube Guide clockwise and pulling straight up while applying downward pressure to the Drill Tube.

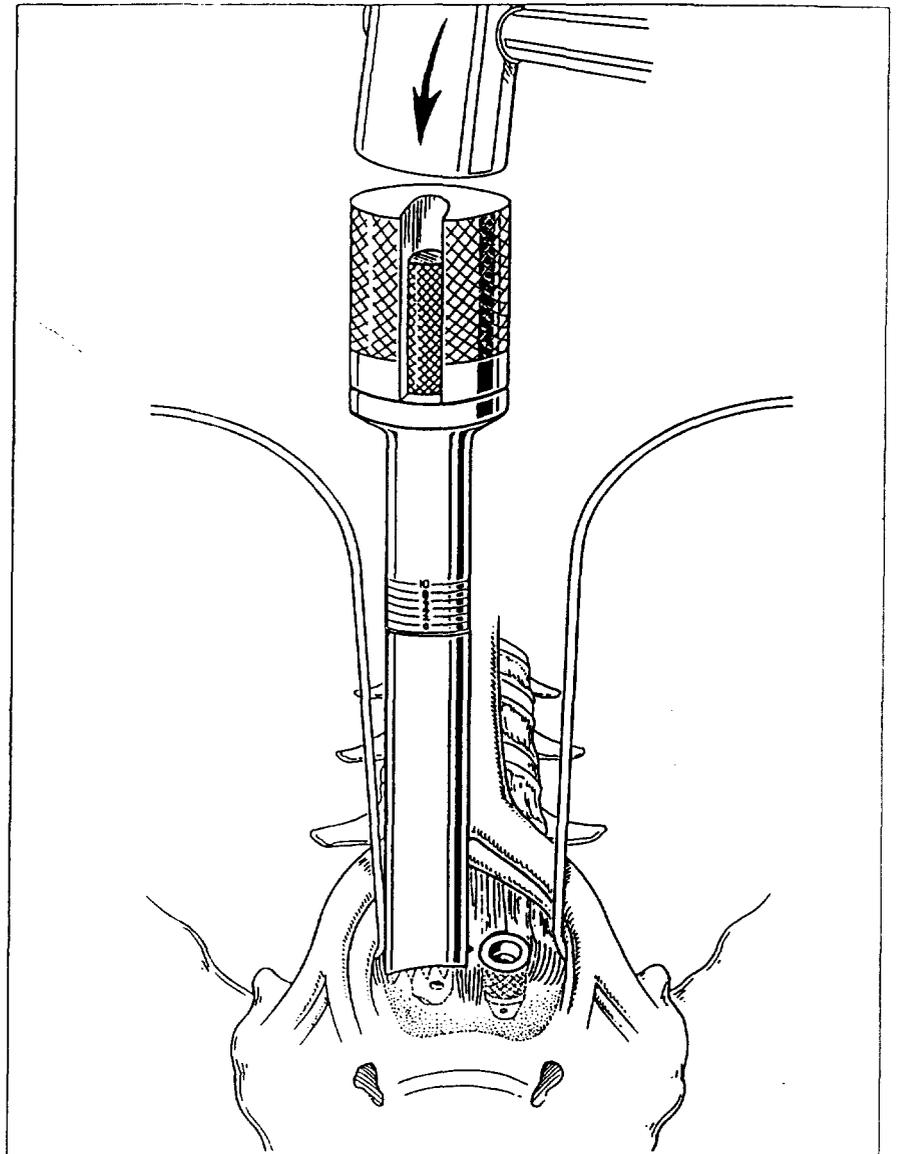


Figure 18

If extreme difficulty is experienced while removing the Drill Tube Guide and Guide Pin, screw the Alignment Guide Handle into the top of the Drill Tube Guide and use the Slap Hammer to vertically impact the bottom of the knob on the Alignment Guide Handle while applying downward pressure to the Drill Tube.

STEP 4 DRILL TUBE ADJUSTMENT FOR 15x20 AND 17x24 IMPLANTS

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Short Series Spacer

If size 15 x 20 or 17 x 24 BAK implants are to be used, it is necessary to reduce the drilling, tapping and implanting depths. This is accomplished by increasing the length of the Drill Tube.

Slide the Short Series Spacer onto the top of the Drill Tube prior to reaming (Figure 19). This spacer lengthens the Drill Tube and shortens the reaming, tapping and implantation depths by 4mm.

Implant	Reaming Depth
15 x 20	26mm
17 x 24	30mm

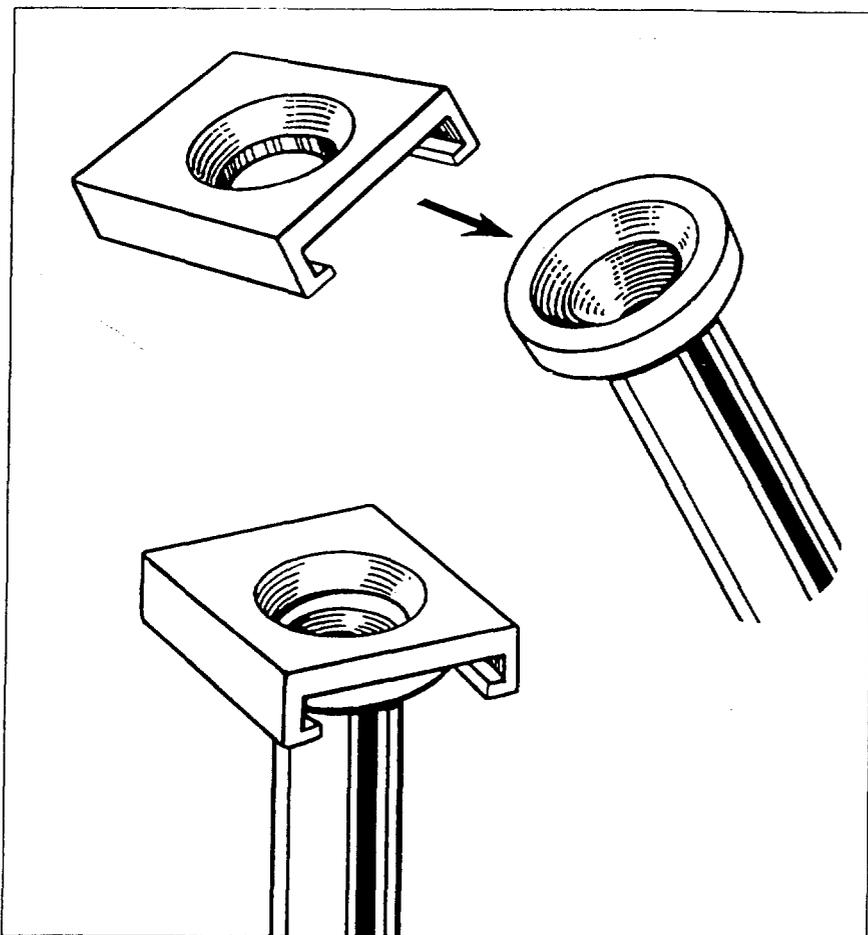


Figure 19

STEP 5 VERTEBRAL REAMING

Anterior Surgical Technique

NECESSARY INSTRUMENTS

T-Handle	Guide Pin
Starter Reamer	Pituitary Rongeur
Final Reamer	Drill Tube Sheath
Drill Tube Sleeve	

Slide the Drill Tube Sleeve into the Drill Tube (Figure 20).

Thread a Guide Pin the same size as the Distraction Plug onto the Starter Reamer.

While maintaining appropriate Drill Tube alignment and downward pressure, advance the Starter Reamer until the positive stop makes contact with the top of the Drill Tube (Figure 21). Remove the Starter Reamer while continuing to rotate it clockwise. This will prevent the Guide Pin from unthreading and ensure that debris is trapped within the reamer flutes.

Note: Lateral radiographic images may be taken during reaming to assess depth and endplate purchase.

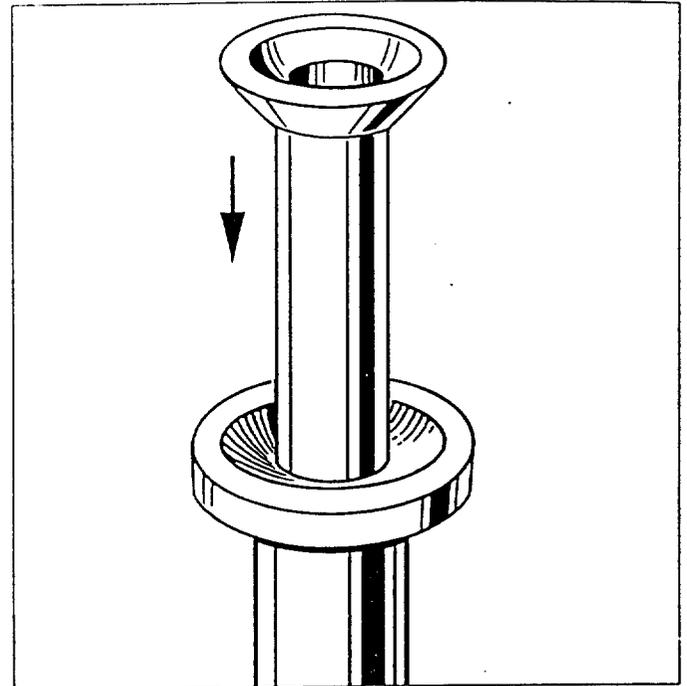


Figure 20

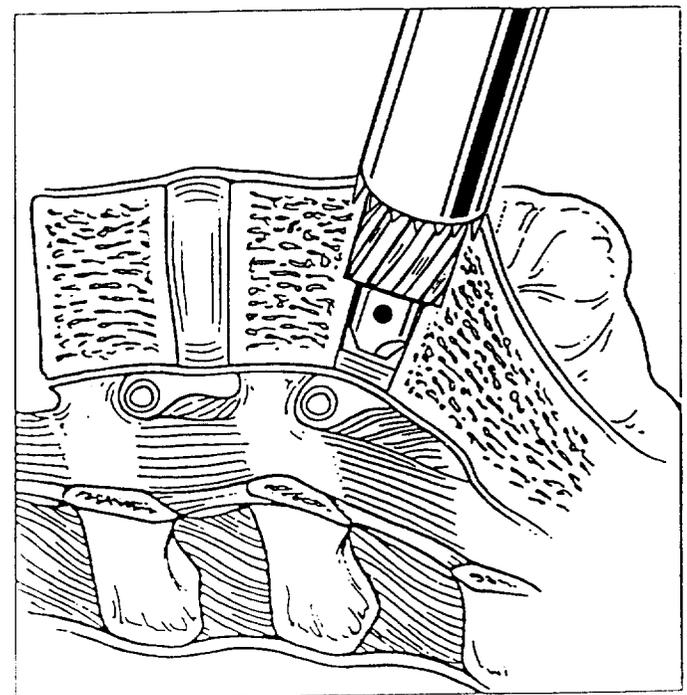


Figure 21

STEP 5 VERTEBRAL REAMING CONTINUED

Anterior Surgical Technique

Insert the Final Reamer into the Drill Tube and advance until the positive stop makes contact with the top of the Drill Tube (Figure 22). Final reaming depth is noted radiographically and saved to aid in final placement of the implant. Reaming depth should show penetration into the posterior third of the disc space. Remove the Final Reamer while rotating it clockwise.

Note: If additional reaming depth is desired, it is necessary to advance the Drill Tube further. To control the additional depth of reaming, an impaction ruling is etched onto the Drill Tube. As the Drill Tube is impacted directly, it will move relative to the Drill Tube Sheath. By noting the ruling etched onto the Drill Tube, an indication of the millimeters advanced can be assessed. If this step is deemed necessary, additional depth should be achieved in multiple small incremental advances and caution should be exercised to prevent overreaming.

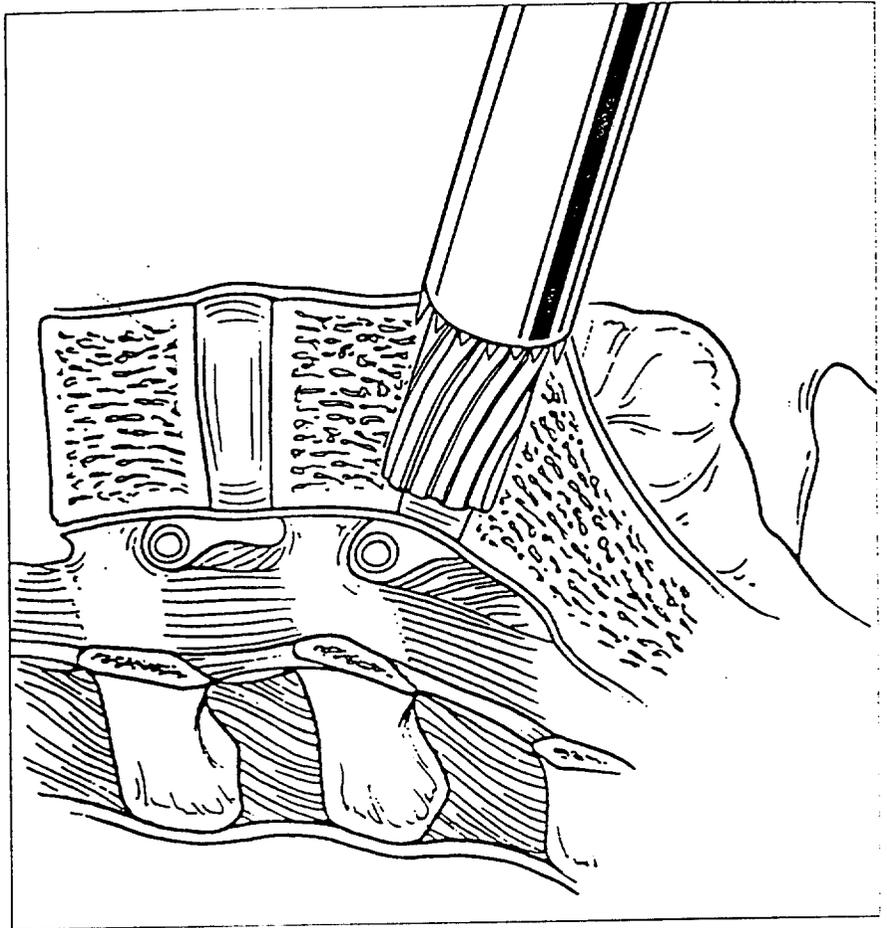


Figure 22

Remove the Drill Tube Sleeve.

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STEP 5 VERTEBRAL REAMING CONTINUED

Anterior Surgical Technique

To prevent disc material from retropulsing, remove any remaining disc material using the long Pituitary Rongeur. This can be accomplished by passing the Pituitary Rongeur through the Drill Tube and grasping the remaining fragments that may be at the bottom of the hole (Figure 23).

Caution: Care should be taken to ensure the posterior annulus is not penetrated with the Pituitary Rongeur. To control the depth of the Pituitary Rongeur, insertion etchings have been placed on the shaft of the instrument corresponding to the implant diameters. Prior to grasping material, note the locations of the etchings in relation to the top of the Drill Tube and palpate the bottom of the hole with the Pituitary Rongeur closed to ensure the annulus is intact.

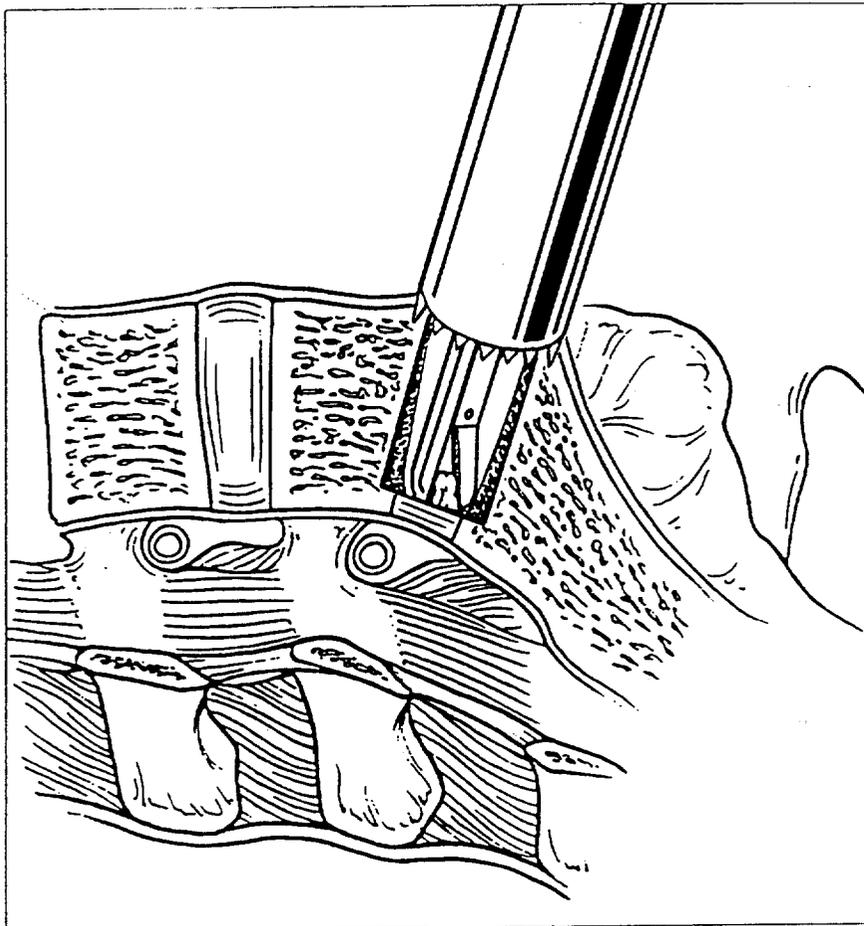


Figure 23

STEP 6 TRIAL IMPLANT PLACEMENT (OPTIONAL)

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Trial Implant Distraction Plug Inserter

Trial Implants are available to assess final drilling depth and implant location.

Thread the appropriate Trial Implant onto the Distraction Plug Inserter. Insert the Trial Implant through the Drill Tube and into the prepared hole (Figure 24). A lateral radiographic image is taken to verify reaming depth and implant position. The Trial Implant should be recessed 3-4mm below the anterior margin of the vertebral bodies and show placement into the posterior third of the disc space.

Remove the Trial Implant.

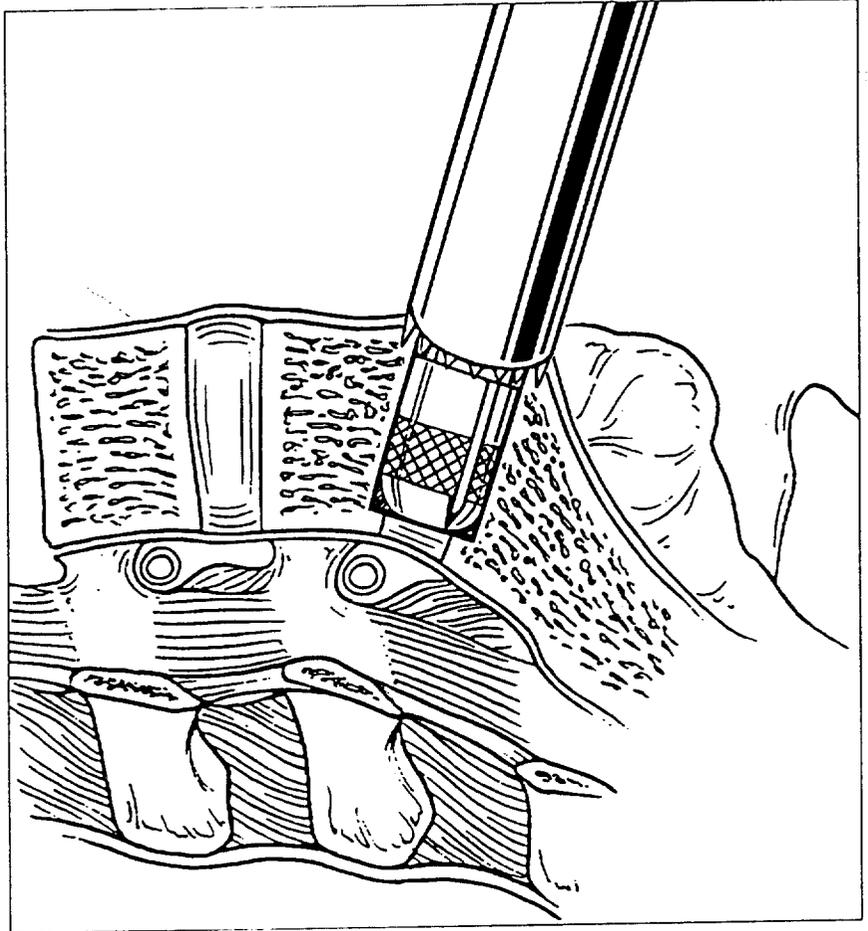


Figure 24

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STEP 7 BONE TAPPING

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Bone Tap

While maintaining proper alignment, advance the Bone Tap through the Drill Tube and place the leading edge of the Tap within the hole. Apply a small amount of downward pressure to the Tap and rotate clockwise until the positive stop on the Tap contacts the top of the Drill Tube (Figure 25).

Unthread the Tap by rotating it counter-clockwise and remove it.

Caution: Do not attempt to advance the Tap beyond the point of contact with the Drill Tube. Further clockwise rotation of the Tap after contacting the stop will result in stripped bone threads.

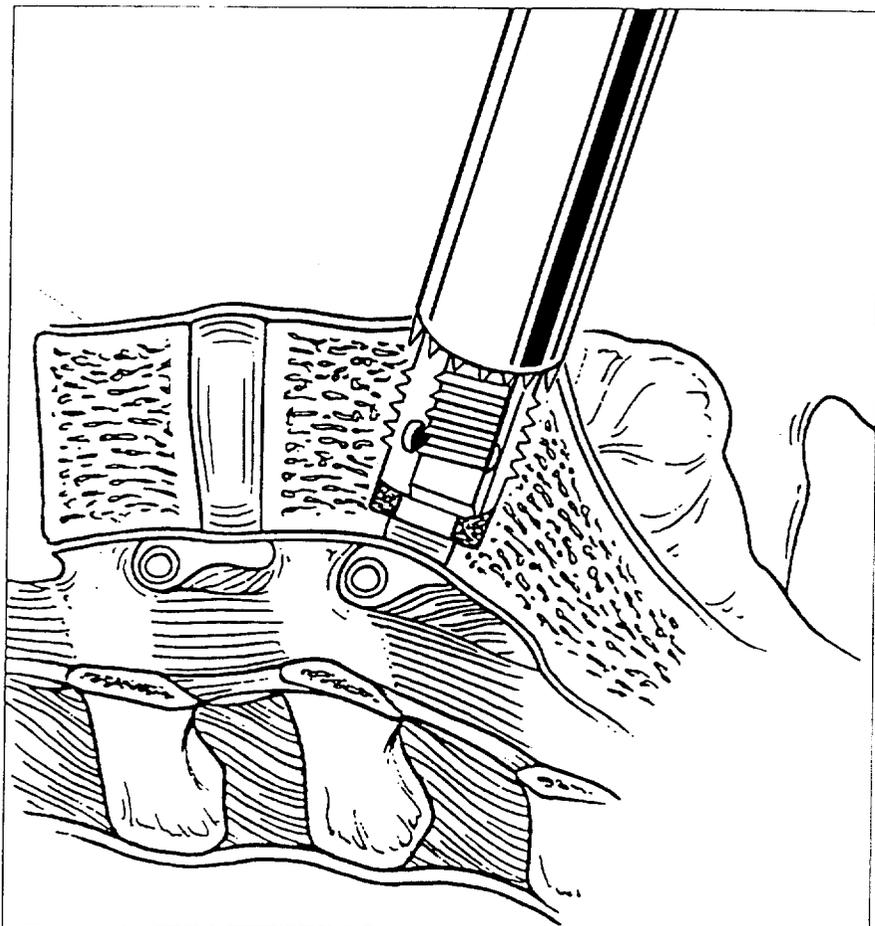


Figure 25

STEP 8 IMPLANTING THE BAK

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Implant Driver

Position the BAK implant onto the Implant Driver with the implant etching facing the handle. Secure the implant to the Implant Driver by advancing the press fit collet into the trailing chamber of the implant (Figure 26). Pack the leading chamber and large holes with morselized autograft bone. (Figure 27).

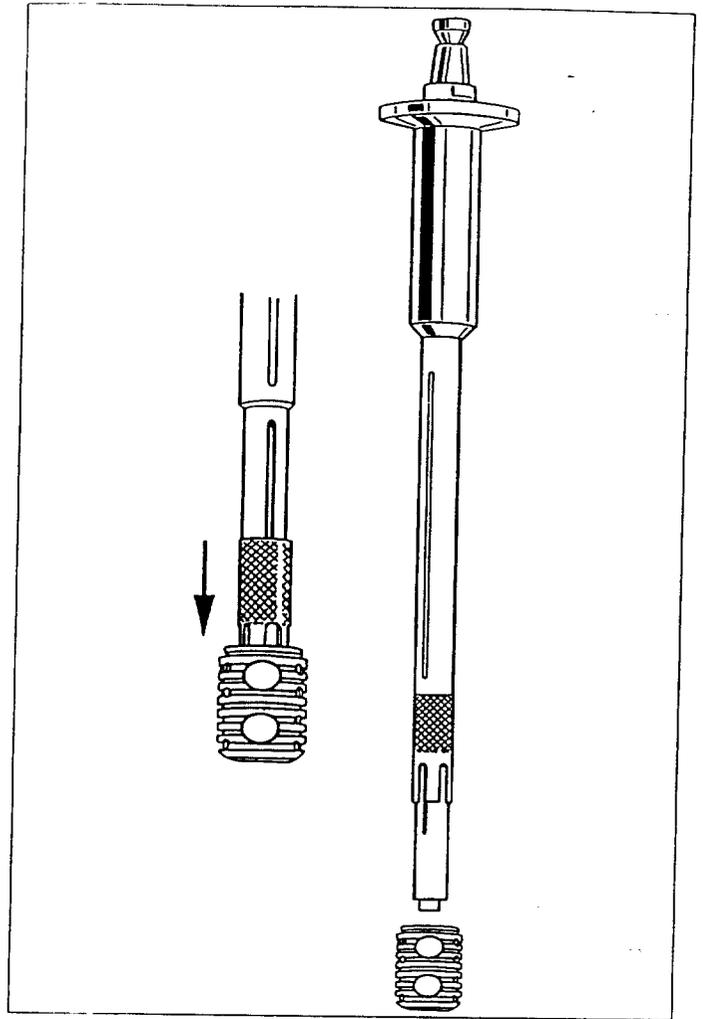


Figure 26

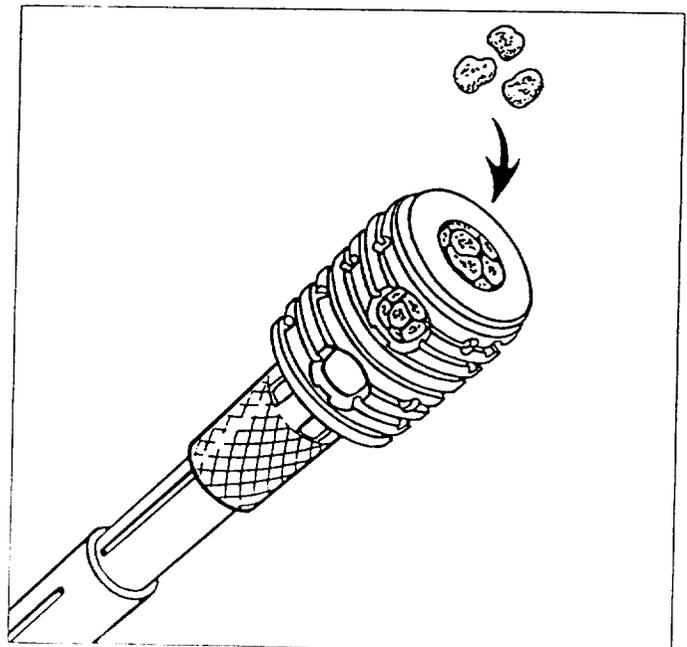


Figure 27

STEP 8 IMPLANTING THE BAK CONTINUED

Anterior Surgical Technique

While maintaining the alignment angles utilized during drilling and tapping, insert the implant through the Drill Tube. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant and Implant Driver until the positive stop on the Implant Driver contacts the top of the Drill Tube (Figure 28).

Proper implant orientation is achieved when the large holes are placed in a cephalad-caudal direction. This is attained when the Implant Driver T-handle is aligned parallel to the disc space.

Remove the Implant Driver by pulling straight up on the handle. This will cause the Implant Driver collet to release automatically. Remove the Drill Tube. Final implant placement is verified with a lateral radiograph. Implant placement should be recessed 3-4mm below the anterior margin of the vertebral bodies and show placement into the posterior third of the disc space

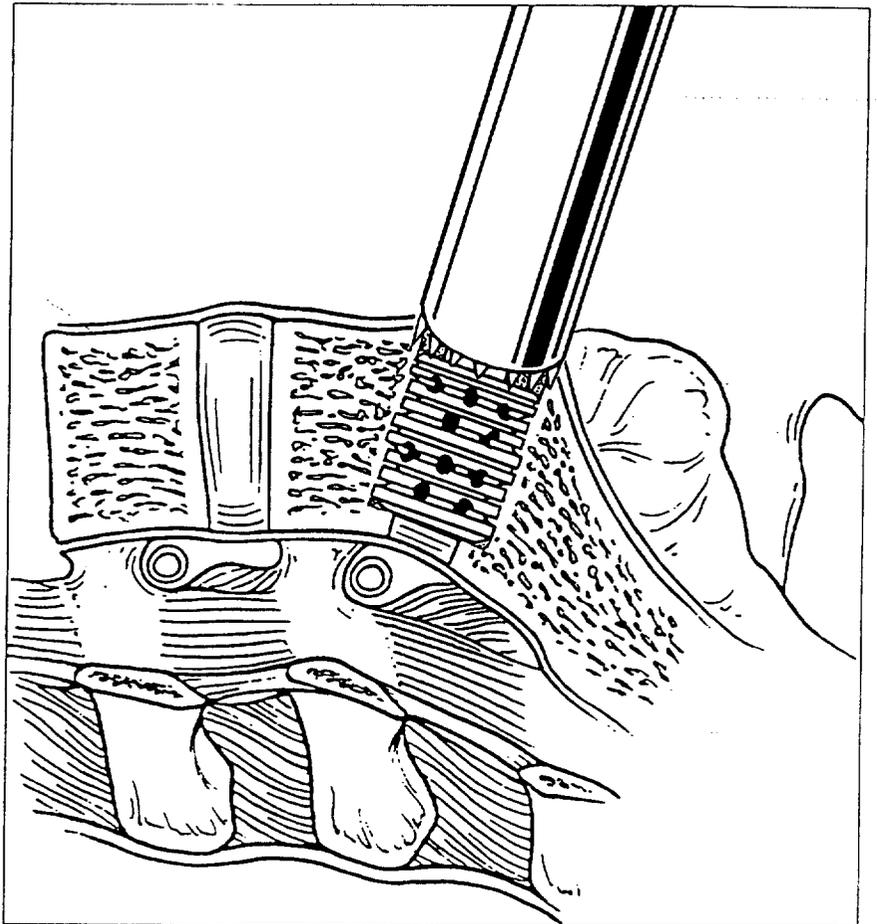


Figure 28

Caution: When the positive stop on the Implant Driver reaches the top of the Drill Tube, the implant should be properly placed. If additional advancement is desired, it can be accomplished provided space is still available at the bottom of the hole. After removing the Drill Tube, place the Implant Driver directly into the slot in the implant. Proceed to rotate the implant clockwise, with caution, under direct vision and/or radiographic imaging. It is critical that if additional insertion is attempted, the implant must always be advancing when rotated clockwise. Once the Implant contacts the bottom of the hole, continued clockwise rotation of the Implant Driver will result in stripped bone threads.

STEP 9 PLACEMENT OF SECOND IMPLANT

Anterior Surgical Technique

Assess the distance between the initial implant and the Distraction Plug to ensure medial shifting of the Drill Tube did not occur and adequate space for the second implant is still available.

Position the vein retractors appropriately. Thread the Distraction Plug Inserter into the Distraction Plug. Remove the Distraction Plug by rotating clockwise while pulling straight up (Figure 29). If this proves difficult, the Slap Hammer will fit on the Distraction Plug Inserter and can be used to impact upward and remove the Distraction Plug. Additional discectomy can be accomplished at this time.

The preparation of the remaining side is identical to that described in Steps 3-8.

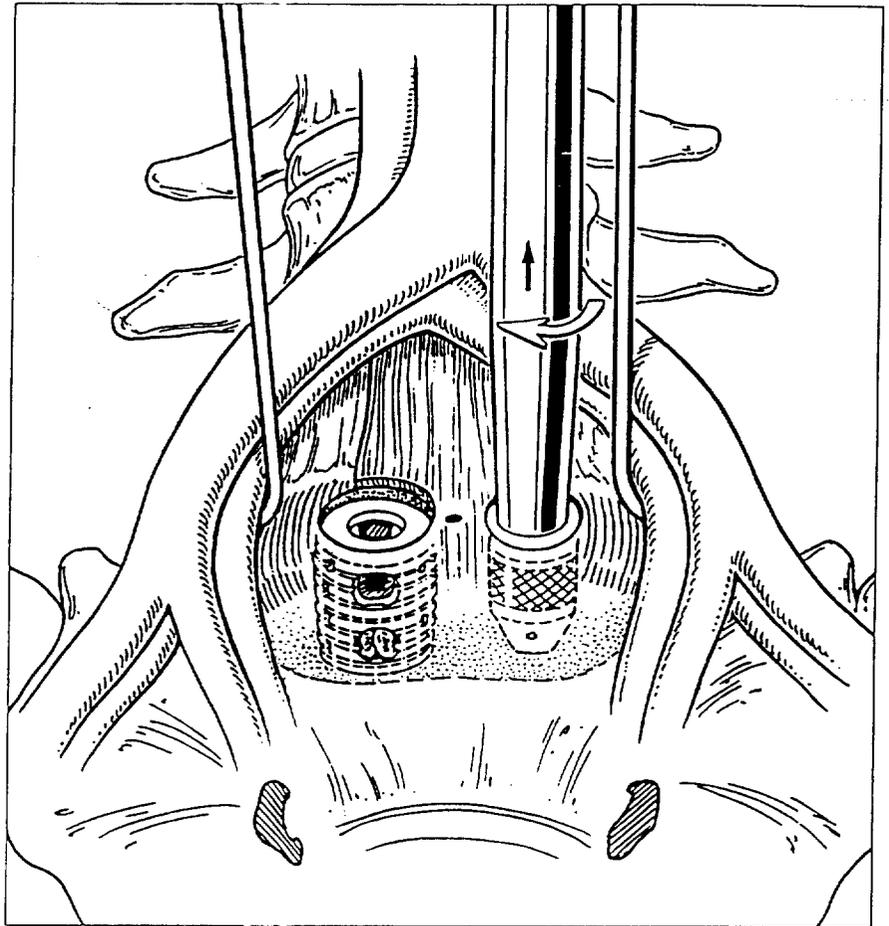


Figure 29

Note: If desired, additional bone can be packed between the implants. This is accomplished by placing bone into the second hole following tapping, packing it against the first implant, and then inserting the second implant.

Radiographic imaging will verify implant positioning within the intervertebral space.

STEP 9 PLACEMENT OF SECOND IMPLANT CONTINUED

Anterior Surgical Technique

Following confirmation of proper implant positioning and orientation (see note), the trailing chamber of both implants is packed with bone (Figure 30).

Note: Implants should be recessed 3-4 mm below the anterior cortical margin and have the leading edge penetrating into the posterior third of the motion segment. Additionally, the implant orientation is correct when the large holes are positioned in cephalad and caudal directions. This is indicated when on visual inspection it is noted that either the Quick Disconnect T-Handle orientation is parallel to the disc space or the long axis of the oval hole in the central web of an implant is parallel to the midline.

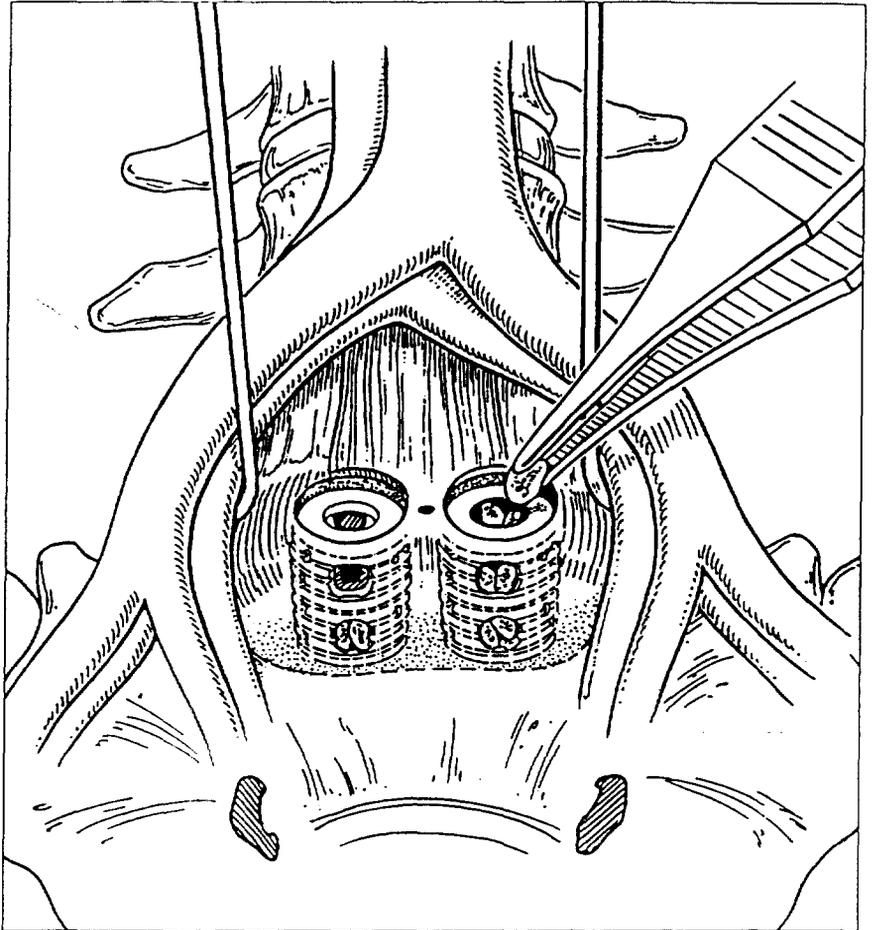


Figure 30

STEP 10 ENDCAP PLACEMENT (OPTIONAL)

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Endcap Inserter

Endcap placement is optional. The endcaps are designed to close off the trailing end of the implants and provide a smooth barrier to prevent the adhesion of soft tissues to the implant. In an anterior procedure, endcaps are utilized if an implant is not fully recessed and a smooth barrier is necessary to prevent vessel irritation.

Attach the appropriate size endcap onto the Endcap Inserter by pressing the domed end of the endcap into the bottom of the instrument. The endcap attaches to the Endcap Inserter with a loose press fit. Following packing of the trailing chamber of the implants with bone, clear all tissue from the rim of the implant. The endcap is centered over the implant and lightly impacted into the implant (Figure 31). Proper positioning is achieved when the endcap spins freely but remains intact.

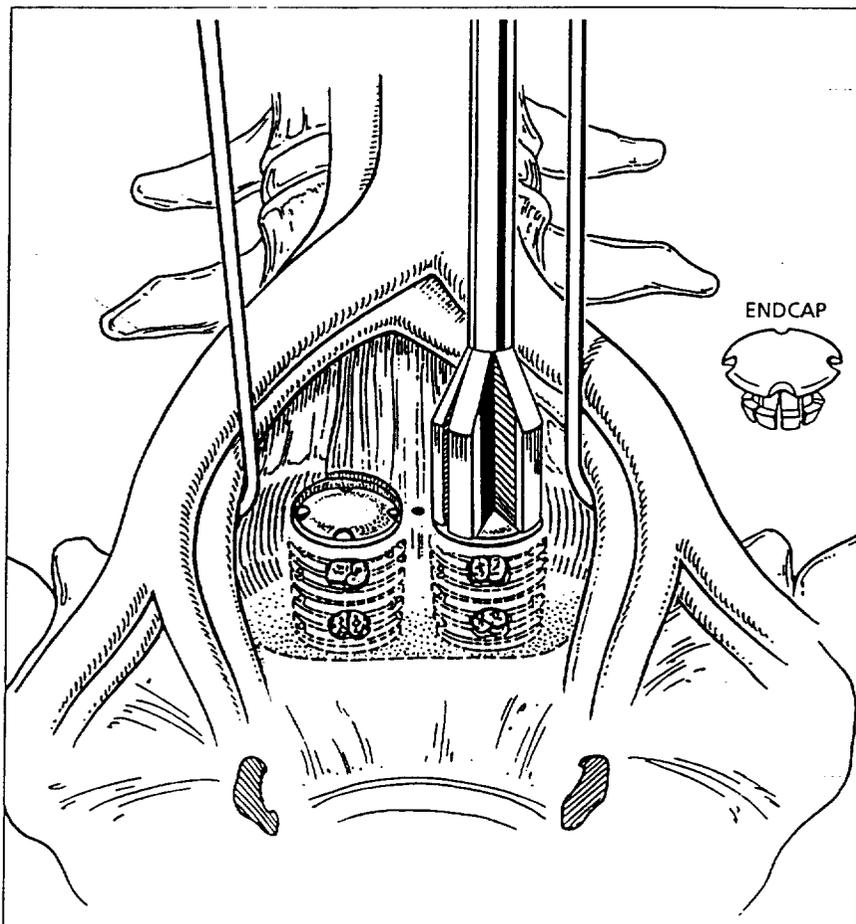


Figure 31

The retractors are removed and the incision is closed in the usual manner.

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APPENDIX I ALTERNATIVE TAPPING AND IMPLANTING TECHNIQUE

Anterior Surgical Technique

If minimal discectomy is performed throughout the procedure, it may be desirable to more closely inspect the hole following reaming. To accomplish this, the Drill Tube is removed at the end of Step 5 and the following technique is followed in place of Steps 6-8 of the regular technique.

Step 6: Trial Implant Placement

In this instance Step 6 is no longer an optional step.

Following reaming, additional disc fragments are removed (Figure 32) and the Trial Implant is inserted into the hole (Figure 33). A visual reference point is selected corresponding to the trailing edge of the Trial Implant. Since the implant and Trial Implant are the same length this reference point indicates the depth to which the implant may be screwed in without jeopardizing bone thread integrity.

Remove the Trial Implant.

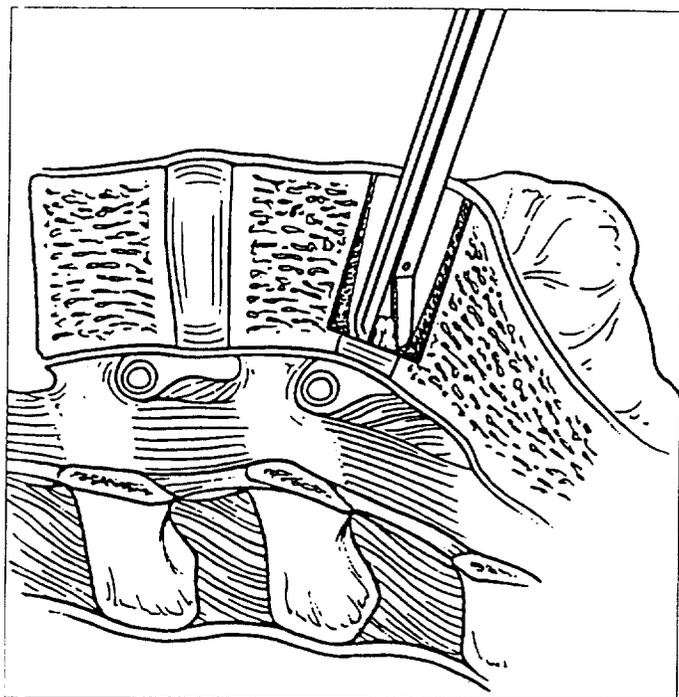


Figure 32

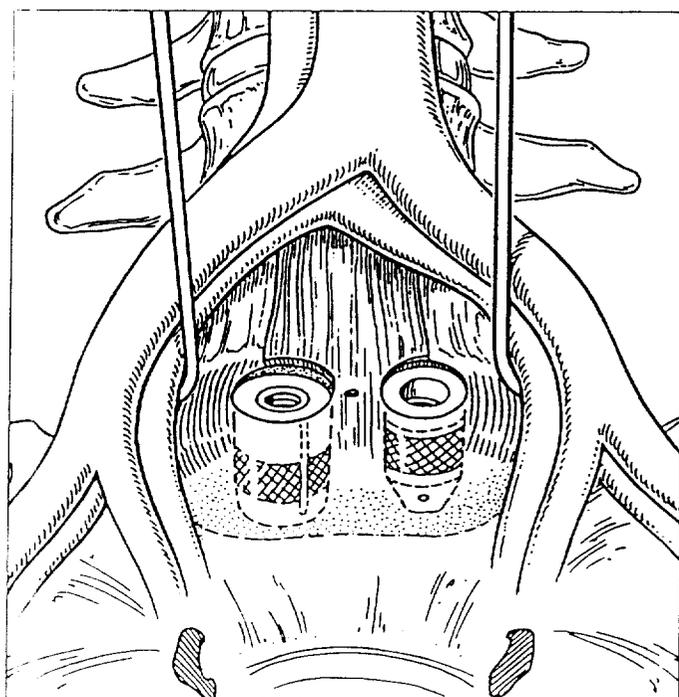


Figure 33

APPENDIX I ALTERNATIVE TAPPING & IMPLANTING TECHNIQUE CONTINUED

Anterior Surgical Technique

Step 7: Bone Tapping

Place the leading edge of the Bone Tap directly into the hole and position the instrument shaft at the angles previously used to perform the drilling. Rotate the Tap clockwise to cut the first few threads into the bone (Figure 34). Unthread and remove the Tap.

Step 8: Implanting the BAK

Place the implant on the Implant Driver and pack it appropriately with bone. Insert the implant directly into the tapped hole. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant until the trailing edge reaches the reference point predetermined by the Trial (Figure 35).

Note: If desired, additional bone can be packed between the implants. This is accomplished by placing bone into the second hole following tapping, packing it against the first implant, and then inserting the second implant.

Insert the second implant and pack the trailing chamber with bone.

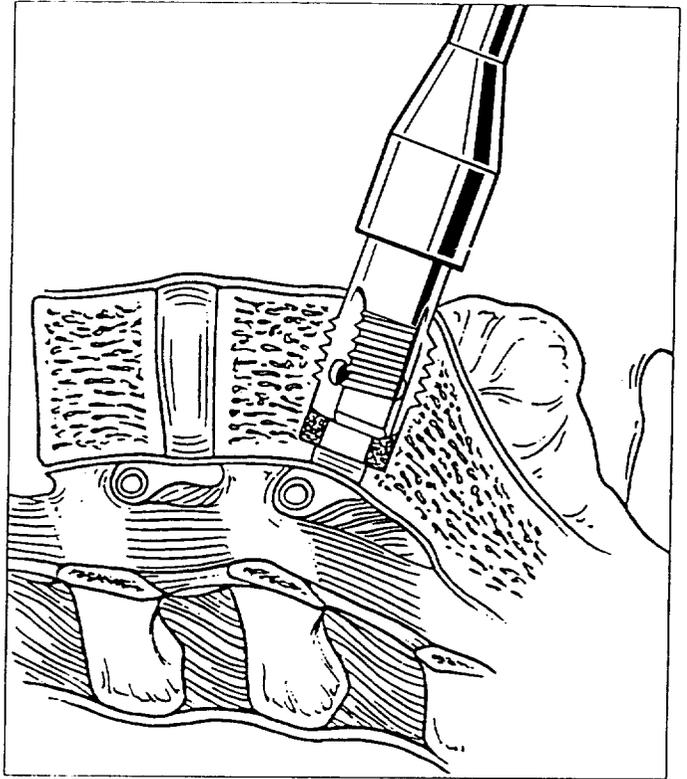


Figure 34

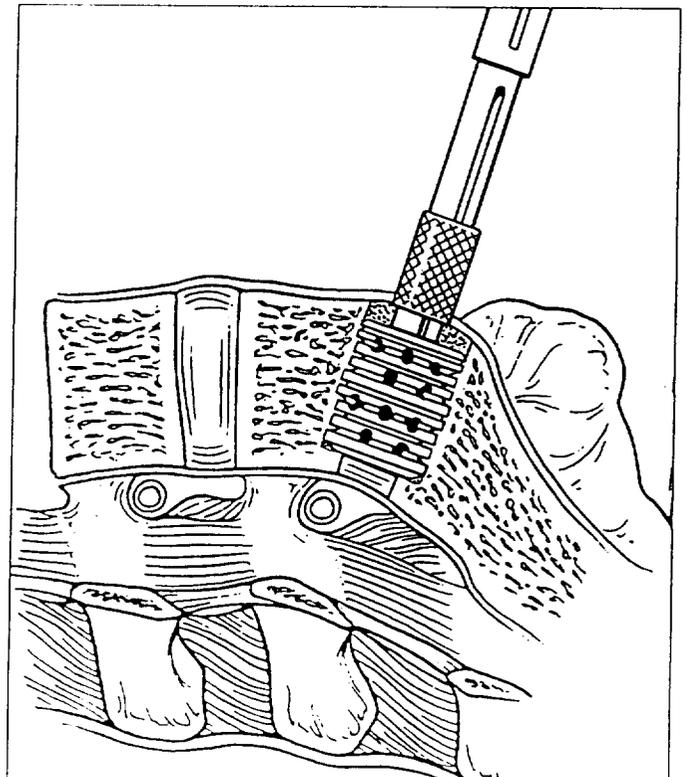


Figure 35

APPENDIX II DIFFICULT SURGICAL SCENARIOS

Anterior Surgical Technique

Concave Endplates:

It is not uncommon for patients with exaggerated concave endplates to present for surgery. This patient population requires a minor modification to the BAK procedure to ensure that proper implant alignment, vertebral purchase and lumbar lordosis are achieved and maintained.

Prior to placement of the Distraction Plugs, it is necessary to remove the large marginal osteophytes at the location of the 8mm drilling sites. This can be easily accomplished with a 1/4 inch osteotome or Kerrison rongeur.

This step is necessary to achieve an accurate representation of the disc height which needs to be bridged by the implant.

APPENDIX II DIFFICULT SURGICAL SCENARIOS CONTINUED

Anterior Surgical Technique

Spondylolisthesis:

It is not uncommon for patients with Grade I spondylolisthesis or retrolisthesis to present for surgery. This population requires a minor modification to the BAK procedure to ensure proper implant alignment and vertebral purchase are achieved.

If the slip is mobile, correction of the spondylolisthesis can many times be affected by distracting the motion segment incrementally on one side and then the other until the proper Distraction Plug is identified. If this is possible and complete reduction is achieved, proceed with the implantation in the usual fashion.

If the spondylolisthesis does not fully reduce, the Drill Tube and Drill Tube Sheath may not sit evenly over the anterior margin of the disc space. Rather, they will angle such that drilling would cut much more out of one vertebra than the other.

To correct this situation, following impaction of the Drill Tube, use lateral radiographs to modify the angle of the Drill Tube to be parallel with the endplates of the disc. After realignment, gently strike the top of the tube to firmly reseal the teeth.

APPENDIX II DIFFICULT SURGICAL SCENARIOS CONTINUED

Anterior Surgical Technique

Inadequate Vessel Mobilization:

A scenario which may arise at the L4-5 level is inadequate great vessel mobilization to place the right side implant. In these instances a single implant may be placed in the midline. When a single implant must be used, select the largest size which will fit within the anterior/posterior dimension. This is typically a 17x24 or 17x28.

Step 1

Following exposure of the anterior aspect of the spine, a pin or needle is inserted approximately in the midline. An anterior-posterior radiograph is taken to verify the location of the midline. A size 15 scalpel blade is used to slit the annulus at the indicated spot on the disc. Development of this landmark is critical to ensure accurate midline implant placement.

Step 2

The 8mm Drill is placed into the 8mm Drill Tube. This protects soft tissue while drilling and provides a positive stop. Taking care to retract the vessels appropriately, insert the drill tip into the slit and drill until the positive stop on the drill meets the top of the Drill Tube.

Note: Using a pituitary rongeur and/or small curette, nucleus material can be removed through the drill hole. Additional annulus may also be removed, but care should be taken to remove it equally around the original 8mm hole. Avoid elongation of the hole and decortication of the endplate as it may affect Distraction Plug or Guide Pin placement and subsequent alignment.

Step 3

A small Distraction Plug is impacted into the hole and tested. If it pulls out easily, incrementally larger plugs are used until significant resistance is met while extracting the plug.

After identifying the correct Distraction Plug size, Remove the Distraction Plug.

APPENDIX II DIFFICULT SURGICAL SCENARIOS CONTINUED

Anterior Surgical Technique

Step 4

Thread a Guide Pin equivalent in size to the Distraction Plug onto the Drill Tube Guide.

Impact the Drill Tube Guide and Guide Pin into the 8mm drill hole. This will center the Drill Tube Guide over the disc.

Assemble the Drill Tube Sheath onto the Drill Tube and slide the assembly over the Drill Tube Guide. Use lateral radiographic imaging and visual inspection to ensure the Drill Tube is properly aligned. Secure the anchoring teeth of the Drill Tube into the vertebral bodies and remove the Drill Tube Guide.

To prevent disc material from retropulsing, pass the Pituitary Rongeur through the Drill Tube and grasp any remaining disc fragments that may be at the bottom of the hole. Care should be taken to ensure the posterior annulus is not penetrated with the Pituitary Rongeur.

Step 5

If a 15 x 20 or 17 x 24 BAK implant is to be used, slide the Short Series Spacer onto the top of the Drill Tube prior to reaming, tapping and implanting.

Step 6 (Optional)

Thread the appropriate Trial Implant onto the Distraction Plug Inserter. Insert the Trial Implant through the Drill Tube and into the prepared hole. A lateral radiographic image is taken to verify reaming depth and implant position. The Trial Implant should be recessed 3-4mm below the anterior margin of the vertebral bodies and show placement into the posterior third of the disc space.

Remove the Trial Implant.

APPENDIX II DIFFICULT SURGICAL SCENARIOS CONTINUED

Anterior Surgical Technique

Step 7

Advance the Bone Tap through the Drill Tube until the positive stop on the Tap meets the top of the Drill Tube.

Caution: Do not attempt to advance the Tap beyond this point. Further clockwise rotation of the Tap after contacting the stop will result in stripped bone threads.

Step 8

Place the implant on the Implant Driver and pack the leading chamber appropriately with bone. Insert the implant through the Drill Tube. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant and Implant Driver until the positive stop on the Implant Driver contacts the top of the Drill Tube. Align the implant in the usual fashion and pack the trailing chamber with bone.

Note: Inadequate vessel mobilization is the primary reason for utilizing a single implant. If other anatomical or pathological abnormalities arise which preclude use of bilateral implants, this same technique is followed.

APPENDIX II DIFFICULT
SURGICAL SCENARIOS CONTINUED

Anterior Surgical Technique

Implant Contact:

If alignment has been compromised, the threads on the implants may mesh together during insertion. If this occurs, there is a possibility that as the second implant is screwed in, it will unscrew the first implant.

If this occurs, position the first implant appropriately and hold it stationary by inserting a small osteotome in the central slot. This will prevent the first implant from unscrewing as the second implant is screwed in.

APPENDIX II DIFFICULT SURGICAL SCENARIOS CONTINUED

Anterior Surgical Technique

Bone Thread Stripping:

The BAK implants require thread purchase within the vertebral bodies to achieve optimal stability. As previously stated, great care should be taken not to damage the bone threads during implantation.

If damage should occur and the implant is deemed unstable, corrective action to regain a stable condition is recommended. The BAK implant sizing has been established with incremental increases of 2.0mm from one size to the next.

If the bone threads become stripped, the action which caused the stripping will create a hole equivalent in size to the minor diameter of the next larger diameter implant.

In this instance, the reaming depth is inspected with a Trial Implant to ensure the larger implant can be positioned behind the anterior cortical margin. If it does not fit, careful retraction of the vessels is accomplished. The Final Reamer is then directly introduced and carefully advanced under radiographic control until the Trial Implant fits.

Following Trial Implant inspection and subsequent additional reaming, where necessary, the larger Tap is advanced directly into the hole to cut the first few threads. The larger implant is then assembled onto the Implant Driver, packed with bone, and threaded into the hole.

In situations where the 17mm implants were used and stripping occurred, a bone dowel of 20mm in diameter is necessary to fill the hole as the 17mm diameter is the largest BAK implant available.

The following table illustrates the implants necessary to re-establish stability following bone thread stripping:

Implant Stripped	Recovery Device
13 x 20mm	15 x 20mm
15 x 20mm	17 x 24mm
15 x 24mm	17 x 24mm
17 x 24mm	20mm bone dowel
17 x 28mm	20mm bone dowel

APPENDIX III POSTOPERATIVE CARE

Anterior Surgical Technique

Immediate postoperative care includes:

- Routine monitoring of vital signs and neurological status.
- Administration of appropriate pain medication.
- If nasogastric tubes and/or Foley catheters are utilized, discontinue within 24 hours post-op.
- The patient is encouraged to ambulate as tolerated the day of surgery. The use of a brace is at the discretion of the surgeon.
- Diet is restricted to small amounts of liquids until bowel sounds are heard. Diet is then advanced as tolerated.
- Patients should be instructed to restrict activity until advised by their surgeon.

APPENDIX V DRILL TUBE COMBINATIONS

Anterior Surgical Technique

The BAK system utilizes slight variations in drill tube combinations when implants are inserted from an anterior vs. posterior approach.

These variations are necessary to minimize the retraction of neural structures during posterior implantation of the BAK.

Posterior

Implant size	Drill Tube	Drill Tube Guide	Sheath
13mm	4010-1425	4010-1424	4010-1350
15mm	4010-1625	4010-1624	4010-1550
17mm	4010-1825	4010-1824	4010-1750

Anterior

Implant size	Drill Tube	Drill Tube Guide	Sheath	Drill Tube Sleeve
13mm	4010-1625	4010-1624	4010-1351	4010-1326
15mm	4010-1825	4010-1824	4010-1551	4010-1526
17mm	4010-2025	4010-2024	4010-1751	4010-1726



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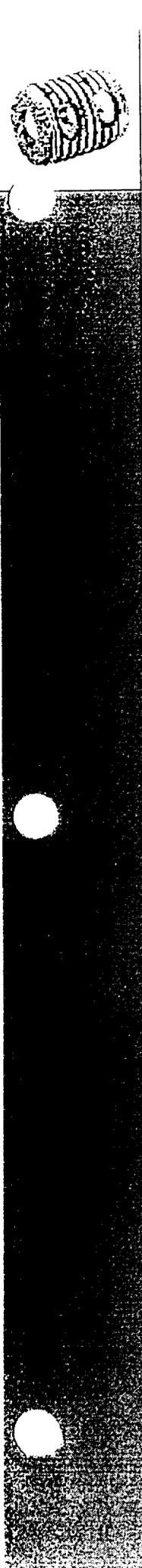
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POSTERIOR

Surgical Technique

BAK™ Interbody Fusion System

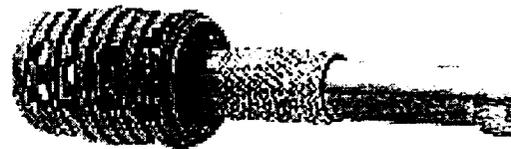


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INTRODUCTION

Posterior Surgical Technique

The Spine-Tech BAK implant is a fenestrated, threaded, cylindrical, titanium alloy device to be inserted within the intervertebral disc space. The implant is coupled with instruments designed to reproducibly prepare the bone bed, protect surrounding tissues and safely position the implants. The system is designed to provide an immediately stable motion segment to allow fusion and relief of symptoms.

Design features of the BAK implant include:

- Vertebral distraction evenly tenses the remaining annulus creating a tension band around the implants
- Threads engage the vertebral body to enhance resistance to shear forces
- "Keystone" effect resists rotational forces
- Internal ribbing to enhance fatigue strength
- Lordosis maintained through vertebral body support
- Foraminal volume and area are increased through distraction providing decompression

Design features of the BAK instruments include:

- Drill tubes aid in retraction and protection of vital structures during implantation
- Positive stops prevent overdrilling
- Drill Tube teeth ease tube docking and prevent instrument migration
- Alignment Guides facilitate accurate implant insertion and spacing

Indications, contraindications, potential adverse effects and precautions are referenced in the package insert.

RADIOGRAPHIC TEMPLATING

Posterior Surgical Technique

Radiographic templating assists with selecting appropriate implant and Distraction Plug sizes which maximize implant endplate coverage and create proper vertebral distraction and annular tension. Selection of the proper size BAK implants is critical for optimum results.

Radiographic templates (Figure 1) are available in 15% magnification for use with plain x-rays and 50% to 80% reductions for MRI and CT scans. Templates include the following information:

- Implant size and distraction plug size chart
- Lateral BAK implant and associated drilling representations
- Lateral distraction plug representations
- Anterior/Posterior implant representations
- Magnification or reduction scale

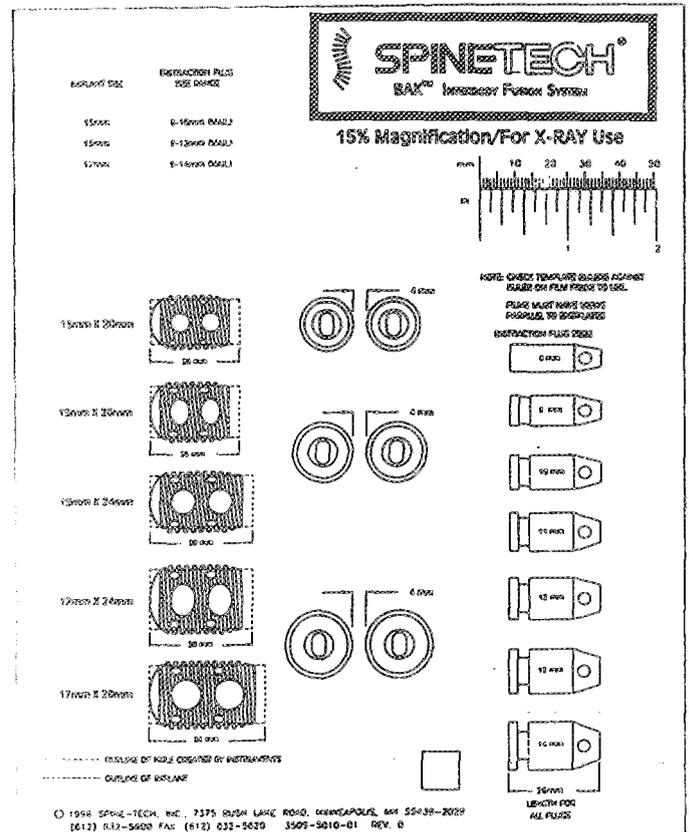
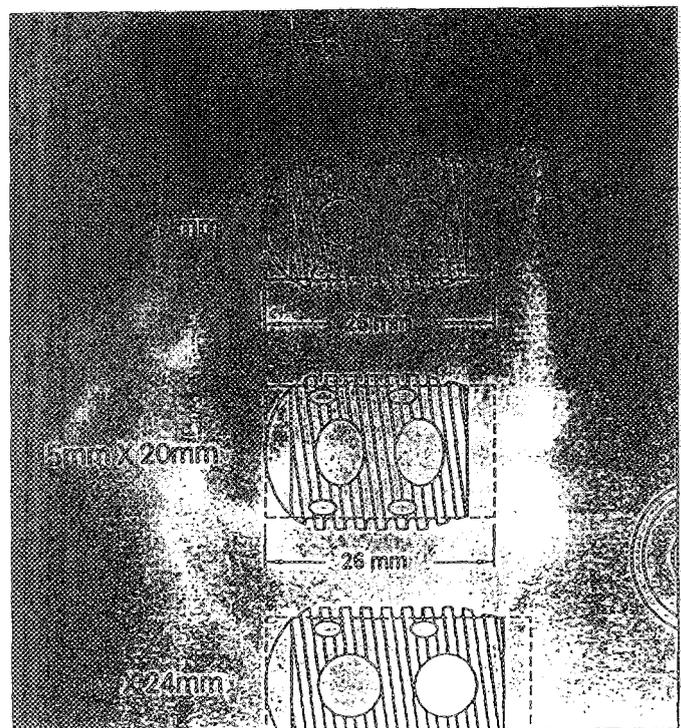


Figure 1

Step 1

The proper implant length is assessed with a lateral x-ray. The red dotted lines, representing the final reaming depths, and lateral implant representations are overlaid on the affected disc (Figure 2). Select the maximum reaming depth and implant size which is safely contained within the anterior and posterior vertebral margins.

This assessment will typically reduce the implant selections to one length and two diameters.



RADIOGRAPHIC TEMPLATING CONTINUED

Posterior Surgical Technique

Step 2

On the same lateral x-ray, overlay the Distraction Plug outline on an adjacent healthy disc (Figure 3). The Distraction Plug which bridges the space is an indication of the potential distraction of the affected motion segment.

Step 3

Compare the implant diameters indicated in Step 1 with the Distraction Plug size indicated in Step 2 using the Implant Size/Distraction Plug Size Range chart in the upper left hand corner of the template.

If the Distraction Plug size indicated in Step 2 is not within the range listed for the smaller implant diameter, the larger implant diameter is selected. If it is, the A/P x-ray is used to further assess the correct implant size.

The Implant Size/Distraction Plug Size Range chart is recreated below.

Implant Size	Distraction Plug Size Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used.

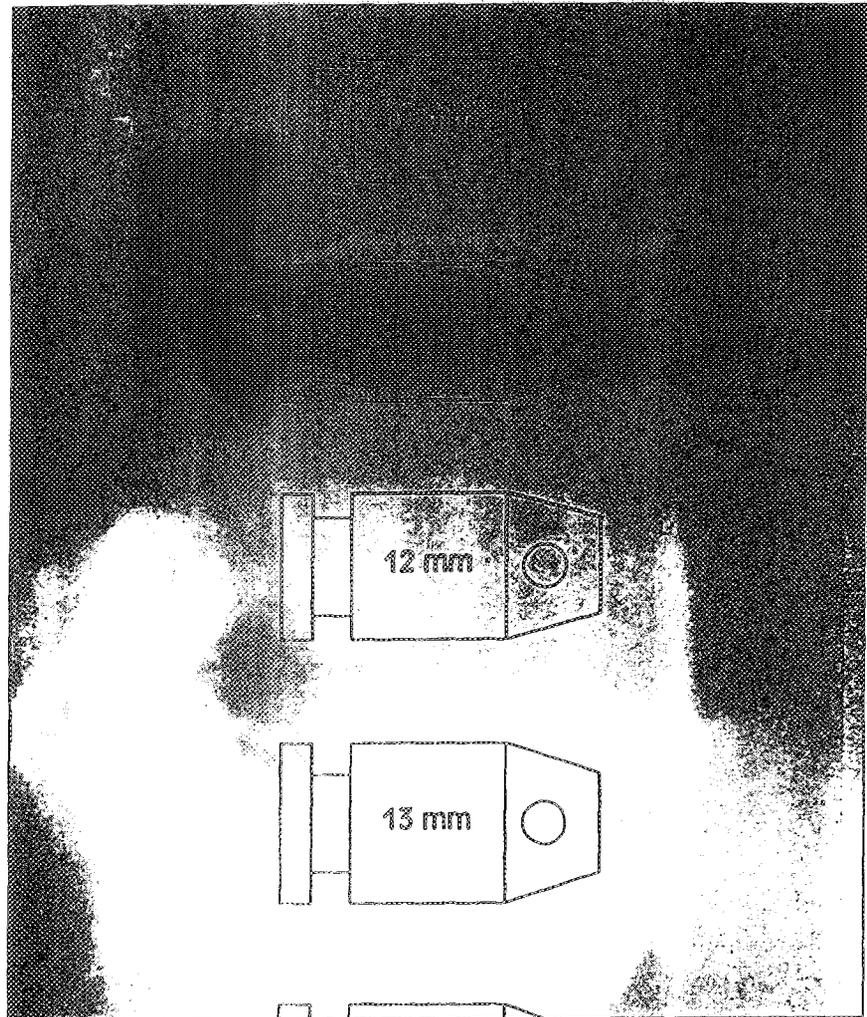


Figure 3

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RADIOGRAPHIC TEMPLATING CONTINUED

Posterior Surgical Technique

Step 4

The appropriate implant diameter is further assessed or confirmed by overlaying the A/P BAK outlines of the implant diameters determined in Steps 1 and 2 over the A/P x-ray. Center the images over the superior most vertebral body to be fused (Figure 4). The largest implant representations which fit within the lateral margins indicate the implant size to be used.

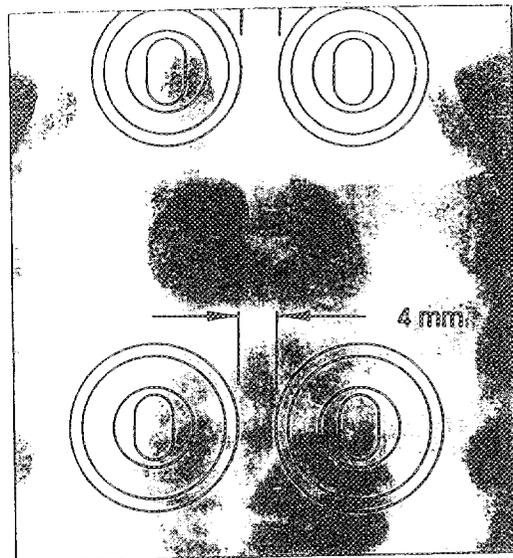


Figure 4

An MRI/CT axial cut reflecting the smallest endplate of the affected disc can help determine implant size. To select the proper BAK MRI/CT template, match the scale on the template to that of the scan (Figure 5). Use the bilateral axial template images to assess the largest outlines which are safely contained within the disc margins (Figure 6).

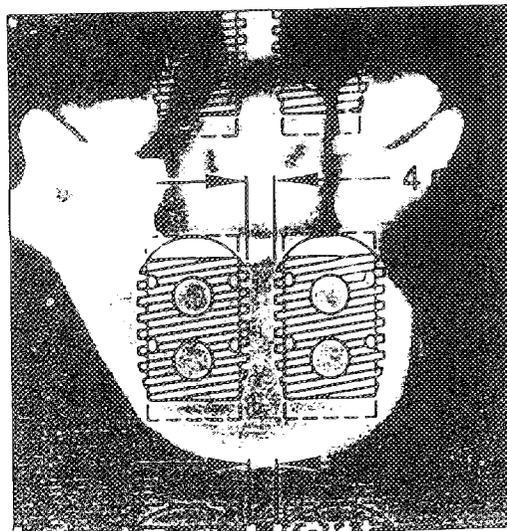


Figure 5

Caution: When using the MRI/CT templates, it is critical that the transverse vertebral representations are parallel to the endplates. If they are not, the images will be oversized and may lead to selection of an implant and associated drilling depth which is too long.

Note: Templating provides an estimate of implant and distraction plug size. Final sizes will be determined intraoperatively.

After implant size selection is complete, the common instruments and the instruments specific to the selected implant size are removed from the instrument trays.



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SURGICAL POSITIONING AND EXPOSURE

Posterior Surgical Technique

The patient is placed in a 90 degree kneeling-sitting position on an Andrews or similar frame to maintain lumbar lordosis and affect abdominal decompression to reduce epidural and venous pressure (Figures 7 and 8). Spinal, general or progressive local anesthesia is administered. The skin is incised in the midline above the level(s) to be fused. The paravertebral muscles are then split and retracted laterally to the outer edge of the facet joints. A laminotomy of sufficient size and/or partial or total facetectomy is performed to accommodate the implants and instruments. The bone is retained and morselized to increase the volume of the bone graft available to pack the implants. When necessary, additional decompression is performed.

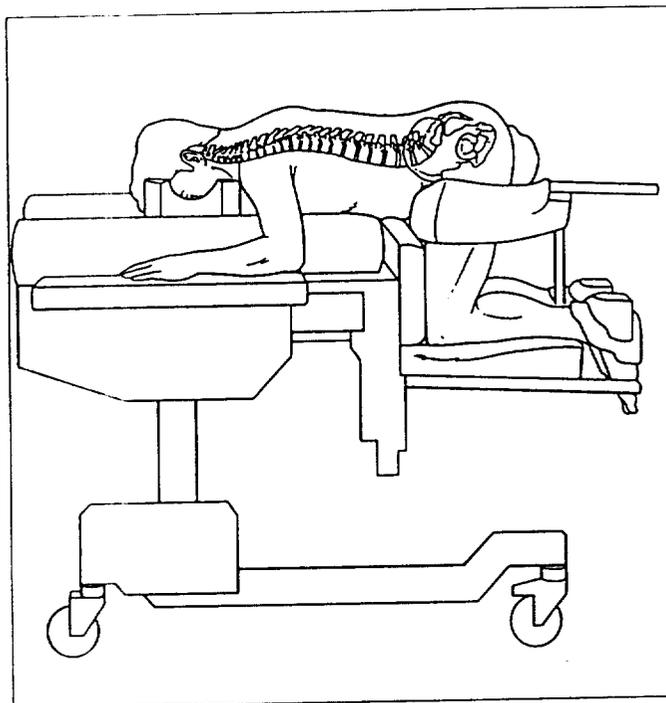


Figure 7

The epidural veins are identified, cauterized with bipolar electro-cautery and divided and/or packed away prior to full mobilization of the dura to the midline. As with any PLIF operation, the dura and nerve roots above and below must be identified, mobilized and protected from injury during the drilling and instrumentation. Use of the operating microscope or loops greatly facilitates the safety of the exposure.

If bone graft is to be obtained from the iliac crest, it should be harvested prior to nerve retraction to minimize the duration of retraction placed on the nerve roots and dura. About five to seven cc's of compacted cancellous graft is necessary for each implant.

Note: The presence of conjoined nerve roots or other anomalies and pathologies may render the posterior interbody fusion impossible by this or any other PLIF method.

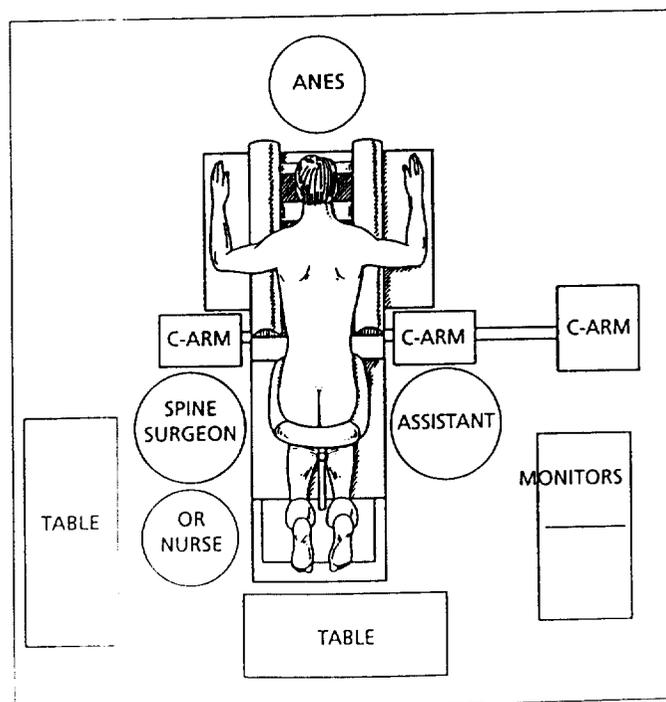


Figure 8

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STEP 1 IMPLANT ALIGNMENT

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Starter Alignment Guide Alignment Guide Handle

The Starter Alignment Guide is used to establish drilling locations and spacing for the BAK implants within the intervertebral space. It is designed to place the implants 4mm apart.

Initially, place the plastic portion of the Starter Alignment Guide on the handle with the prongs pointing towards the handle. The flat surface acts as a template indicating the exposure necessary to place the size specific instruments and implants (Figure 9). Any bone dissected from the lamina, facets and spinous process to create access can be preserved for use as bone graft.

The handle of the Starter Alignment Guide is then secured to the guide with the prongs pointing away from the handle. The prongs are placed on either side of the cauda equina such that they are at mid-disc height and equidistant from the midline. Mark the points by cutting a small slit in the disc with a size 15 scalpel blade (Figure 10). These marks indicate the locations for implant insertion.

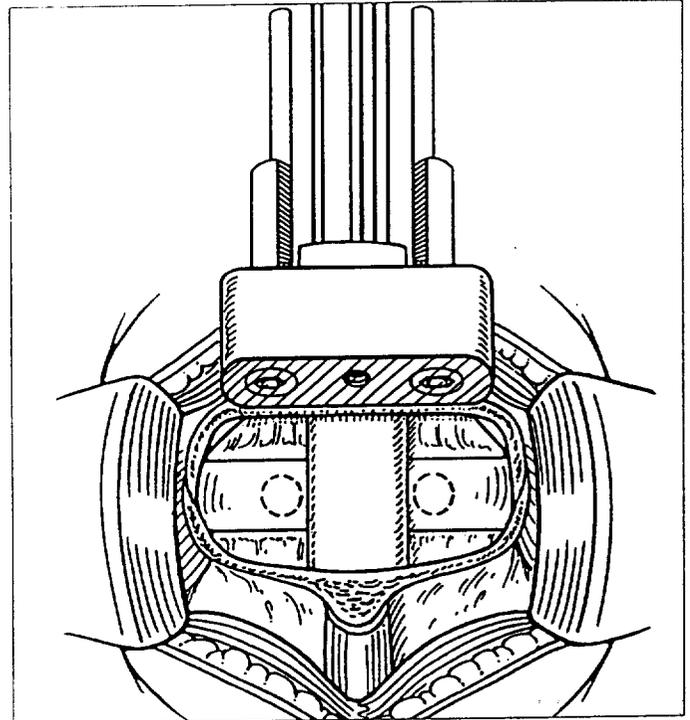


Figure 9

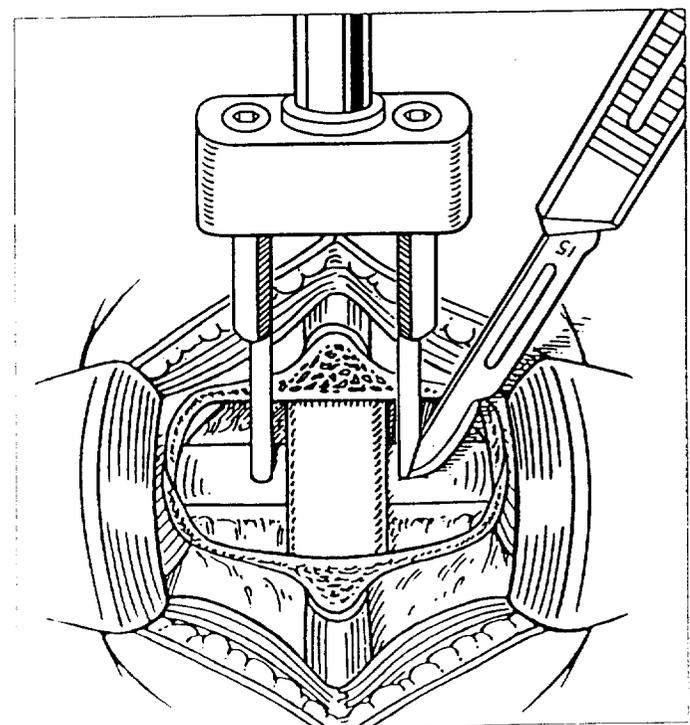


Figure 10

STEP 1 IMPLANT ALIGNMENT CONTINUED

Posterior Surgical Technique

The Starter Alignment Guide may be pressed ventrally into the disc until the positive stops on the prongs contact the disc. With radiographic assessment, the Starter Alignment Guide prongs can be used to assess final reaming depth and angle (Figure 11). See the chart below for prong lengths and the corresponding maximum reaming depths:

Guide Size	Prong Length	Final Maximum Reaming
13	26 mm	26 mm
15	30 mm	30 mm
17	34 mm	34 mm

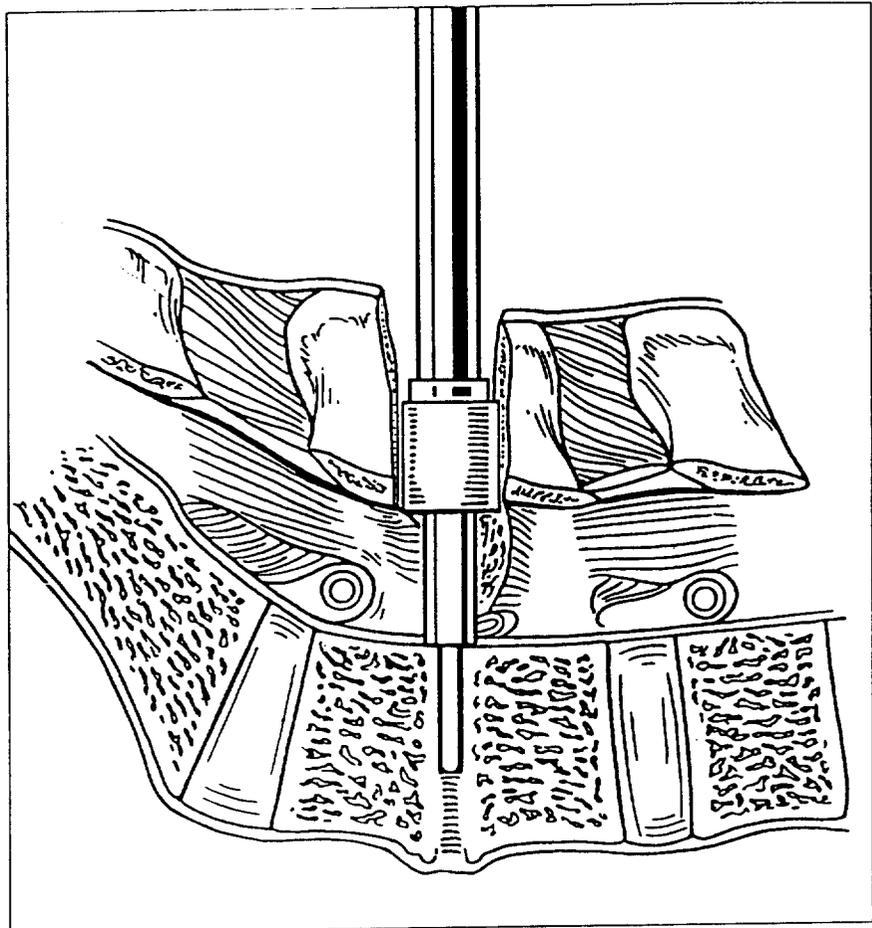


Figure 11

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STEP 2 DISCECTOMY

Posterior Surgical Technique

NECESSARY INSTRUMENTS

8mm Drill

8mm Drill Tube

The 8mm Drill is used to increase the size of the small slits created by the scalpel blade and begin the discectomy required to place the implants.

The 8mm Drill is placed into the 8mm Drill Tube. This protects soft tissue while drilling and provides a positive stop. Taking care to retract the nerves appropriately, insert the drill tip into the slit and drill until the positive stop on the drill meets the top of the Drill Tube. Repeat this on the opposite side (Figure 12).

Note: Using a pituitary rongeur and/or small curette, nucleus material can be removed through the drill holes (Figure 13). Additional annulus may also be removed, but care should be taken to remove an equal amount around the original 8mm holes. Avoid elongation of the holes and decortication of the endplate as it may affect Distraction Plug or Guide Pin placement and subsequent alignment.

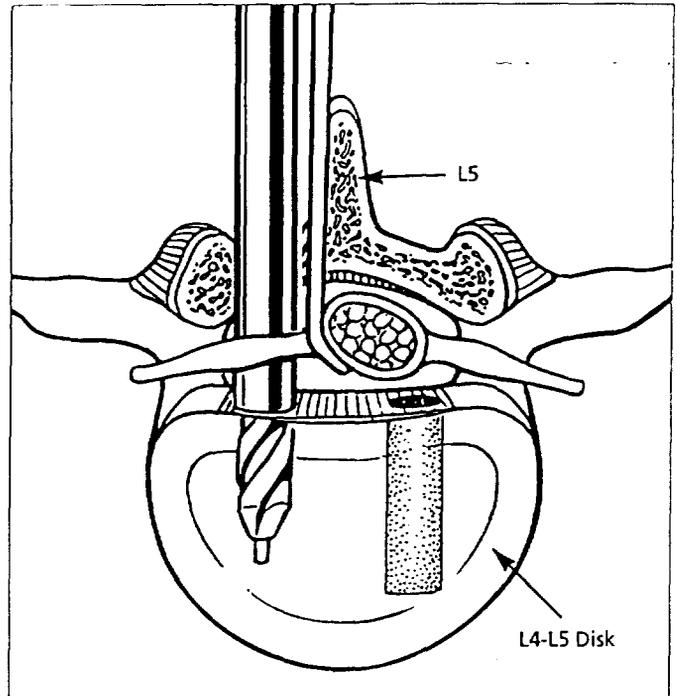


Figure 12

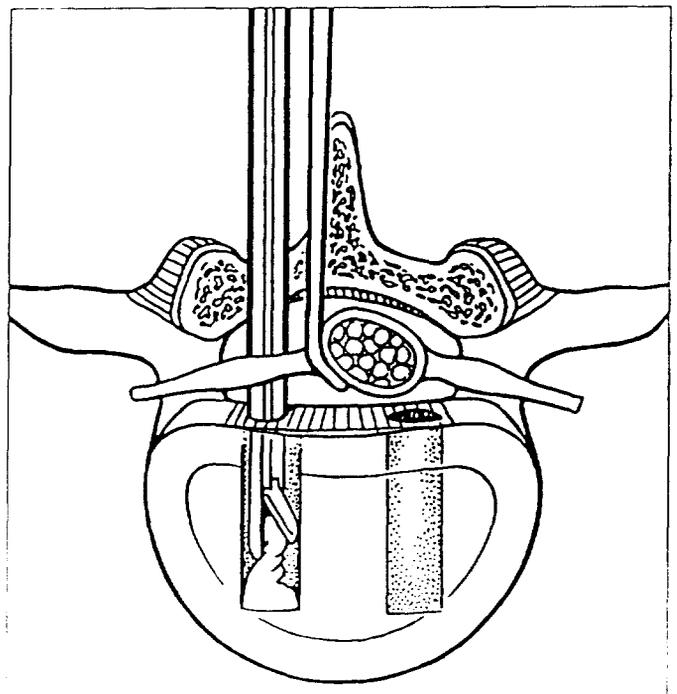


Figure 13

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STEP 3 VERTEBRAL DISTRACTION AND ANNULAR TENSING

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Distraction Plug Inserter Distraction Plugs

Distraction Plugs are used to distract the vertebral bodies and apply tension to the annulus prior to vertebral reaming.

Attach a relatively small Distraction Plug onto the Distraction Plug Inserter. Retract the nerve root and dura with thin dural retractors and impact the Distraction Plug into one of the 8mm drill holes (Figure 14). The Distraction Plug is impacted until the back edge of the plug is slightly recessed below the posterior margin of the disc (Figure 15). Check the annular tension by pulling straight up on the Distraction Plug Inserter. If the Distraction Plug pulls out easily, repeat this procedure using incrementally larger Distraction Plugs until the annulus is sufficiently taut. This is indicated when significant resistance is met during Distraction Plug removal.

Once the correct Distraction Plug is identified, assess the disc space angle by noting the angle of the Distraction Plug Handle. This angle is critical as all future drilling, tapping and implantation steps need to be performed at this angle. Remove the handle, leaving the Distraction Plug in place.

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used. See chart below.

Implant Size	Distraction Plug Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

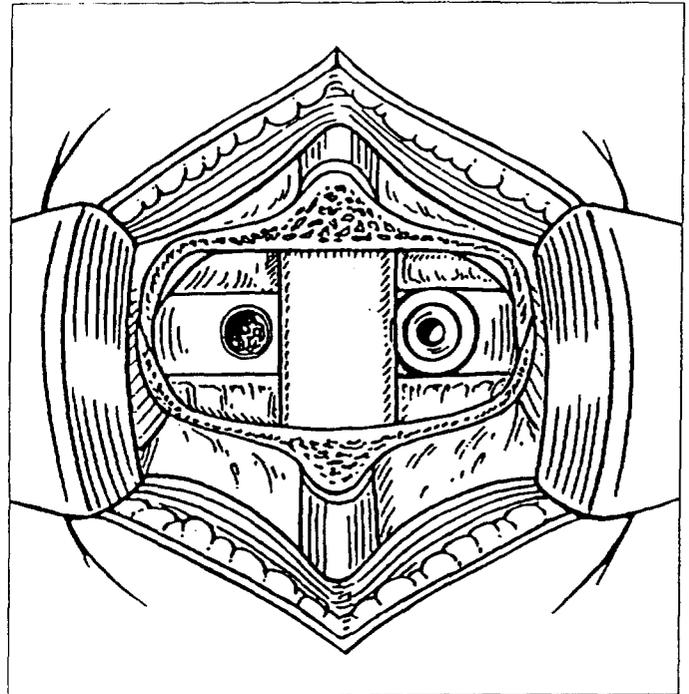


Figure 14

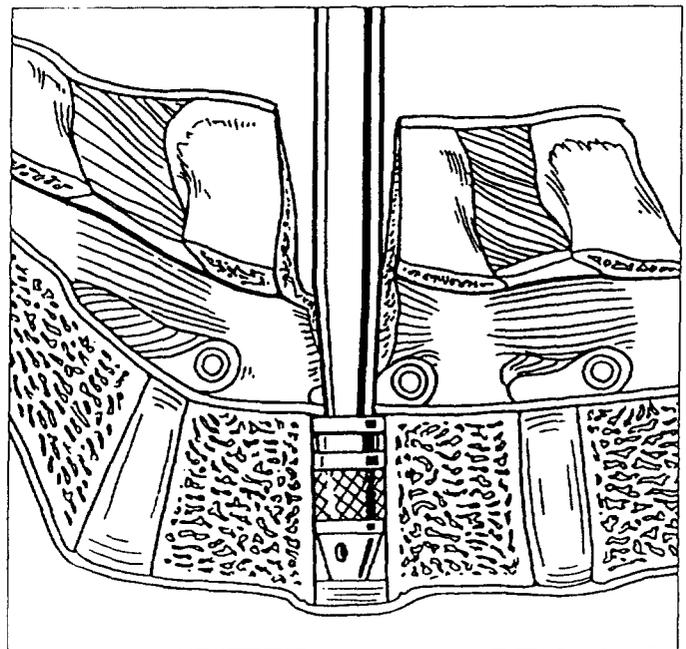


Figure 15

STEP 4 DRILL TUBE PLACEMENT

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Drill Tube Guide
Drill Tube
Guide Pin
Posterior Drill Tube Sheath
Distraction Plug Inserter
Alignment Guide Handle
Slap Hammer

On the side opposite to the Distraction Plug, carefully insert the Posterior Drill Tube Sheath under the axilla of the nerve root using thin dural retractors (Figure 16). Center the sheath over the 8mm drill hole with the sheath's lip under the nerves. The Distraction Plug Inserter is screwed into the side of the Drill Tube Sheath to aid in stabilization of the instruments.

Note: A visual inspection down the sheath is made to ensure the nerve root and dura are retracted. Once the inspection is complete and the nerves are cleared, remove the retractors, if possible, to prevent excessive tension upon the dura.

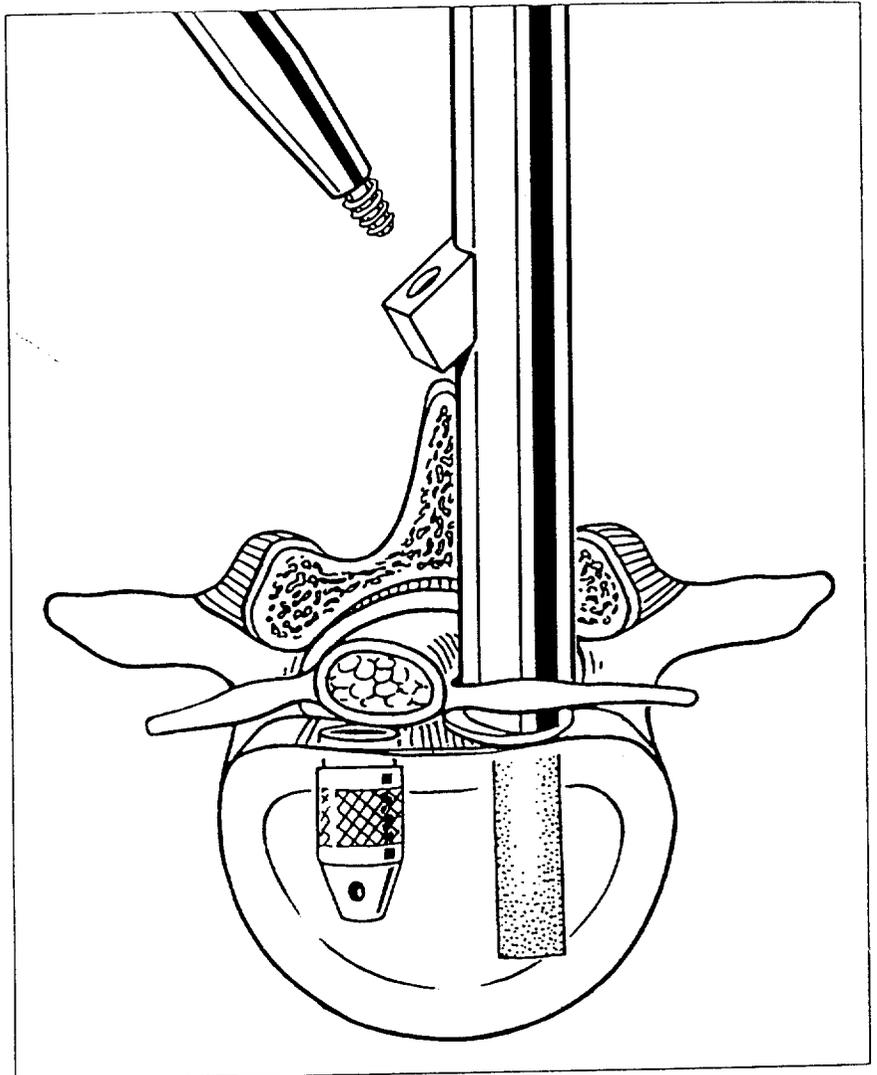


Figure 16

STEP 4 DRILL TUBE PLACEMENT CONTINUED

Posterior Surgical Technique

Thread a Guide Pin, equivalent in size to the Distraction Plug onto the Drill Tube Guide. Insert the Drill Tube Guide through the Sheath and place the Guide Pin into the 8mm hole (Figure 17).

The Drill Tube is then inserted over the Drill Tube Guide and into the Drill Tube Sheath.

Using lateral radiographic imaging, ensure the superior and inferior sides of the Drill Tube are aligned parallel to the vertebral endplates. Additionally, visually inspect to ensure the Drill Tube is perpendicular to the coronal plane of the disc. If a convergent angle is placed on the Drill Tube, it may cause the implants to contact one another. Conversely, a divergent angle may cause the implants to break out of the disc laterally, disrupting the annular tension band.

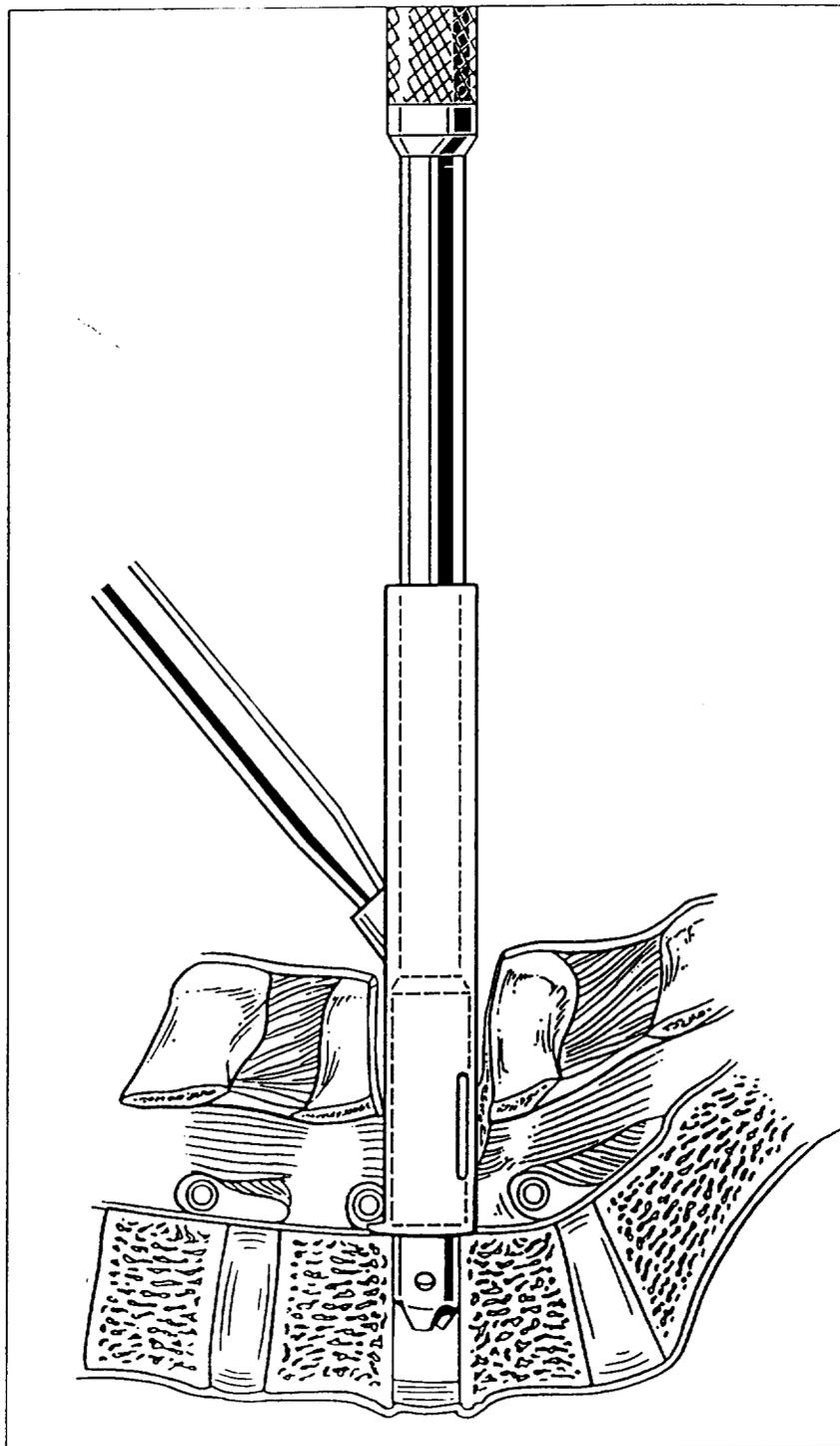


Figure 17

STEP 4 DRILL TUBE PLACEMENT CONTINUED

Posterior Surgical Technique

Place the Slap Hammer over the Drill Tube Guide and Drill Tube. Secure the anchoring teeth of the Drill Tube into the vertebral bodies by impacting the Slap Hammer until the inner surface of the Drill Tube Guide and Slap Hammer meet (Figure 18).

Once the Drill Tube is secure and alignment is verified, remove the Drill Tube Guide and Guide Pin by rotating the Drill Tube Guide clockwise and pulling straight up while applying downward pressure to the Drill Tube.

If extreme difficulty is experienced while removing the Drill Tube Guide and Guide Pin, screw the Alignment Guide Handle into the top of the Drill Tube Guide and use the Slap Hammer to vertically impact the bottom of the knob on the Alignment Guide Handle while applying downward pressure to the Drill Tube.

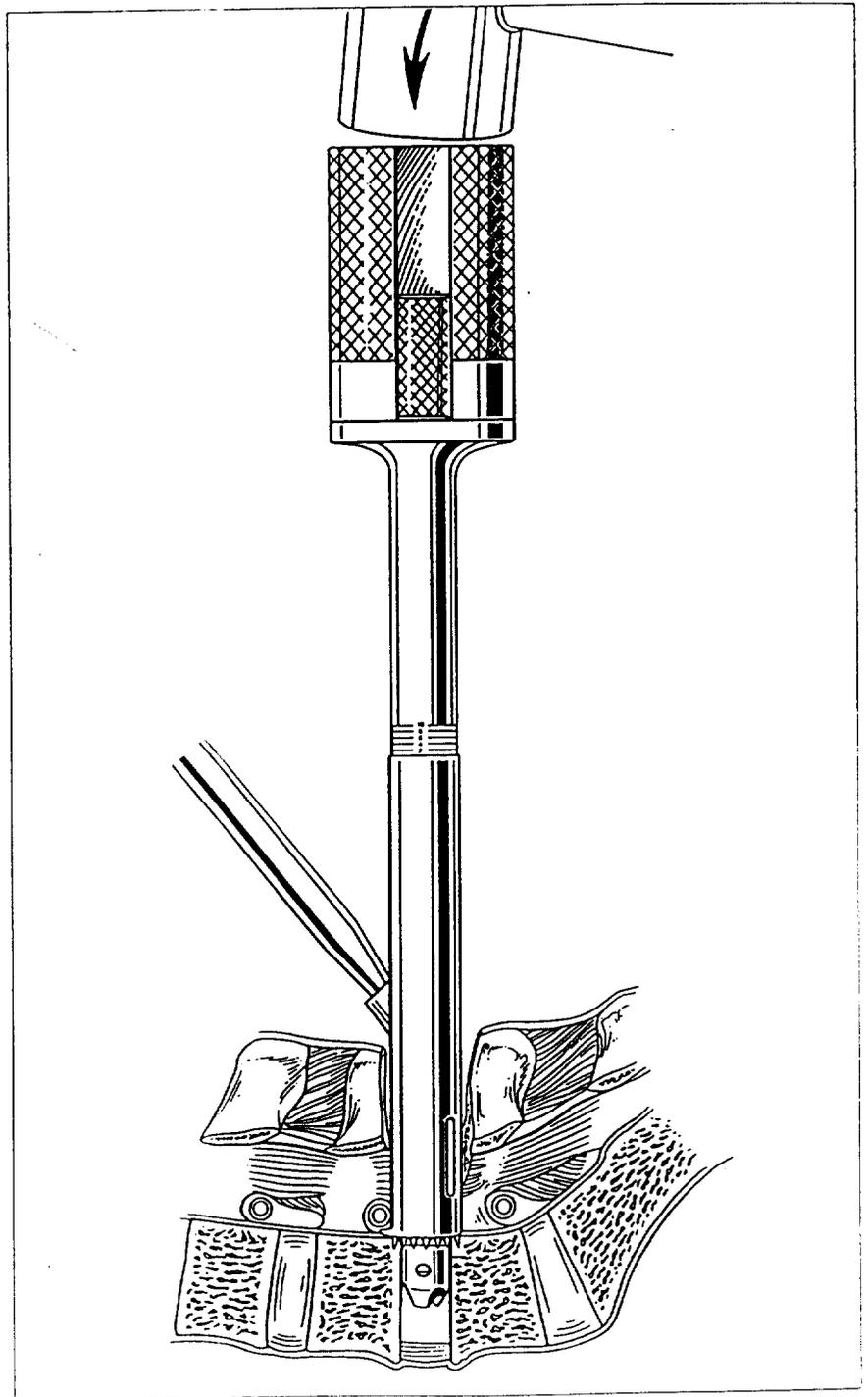


Figure 18

STEP 5 DRILL TUBE ADJUSTMENT FOR 15x20 & 17x24 IMPLANTS

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Short Series Spacer

If size 15 x 20 or 17 x 24 BAK implants are to be used, it is necessary to reduce the drilling, tapping and implanting depths. This is accomplished by increasing the length of the Drill Tube.

Slide the Short Series Spacer onto the top of the Drill Tube prior to reaming. This spacer lengthens the Drill Tube and shortens the reaming, tapping and implantation depths by 4mm (Figure 19).

Implant	Reaming Depth
15 x 20	26mm
17 x 24	30mm

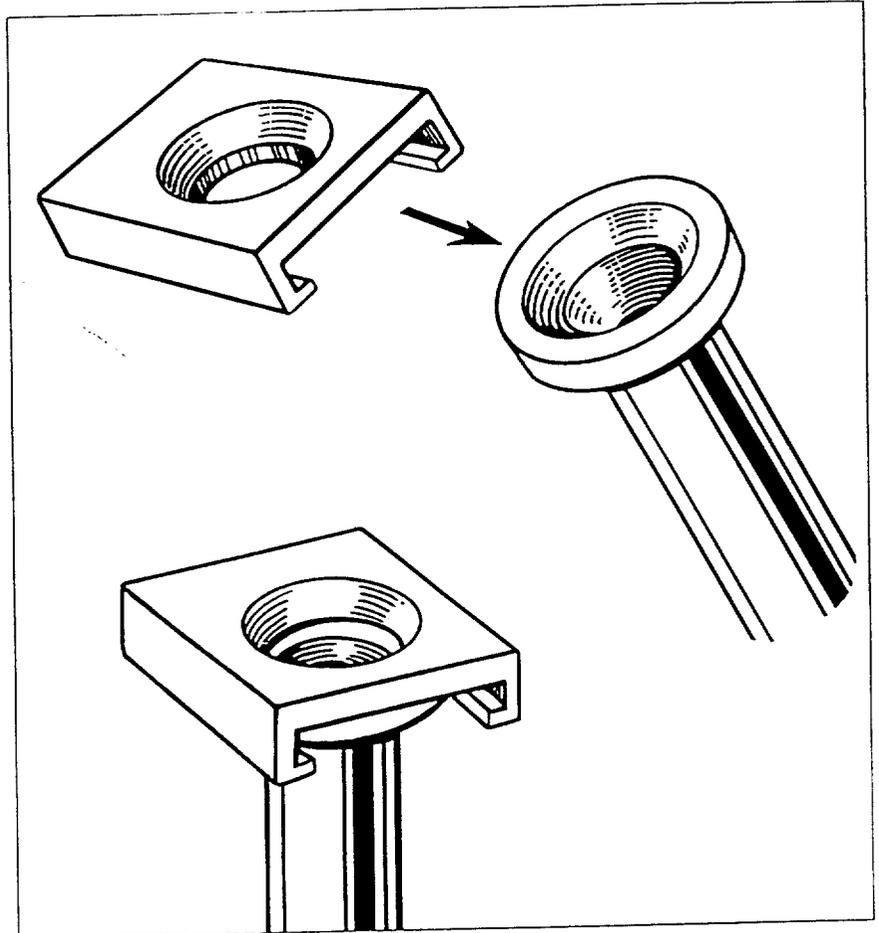


Figure 19

Handwritten signature or initials.

STEP 6 VERTEBRAL REAMING

Posterior Surgical Technique

NECESSARY INSTRUMENTS

T-Handle
Starter Reamer
Guide Pin

Final Reamer
Pituitary Rongeur

Thread a Guide Pin the same size as the Distraction Plug onto the Starter Reamer.

While maintaining appropriate Drill Tube alignment and downward pressure, advance the Starter Reamer until the positive stop makes contact with the top of the Drill Tube. Remove the Starter Reamer while continuing to rotate it clockwise. This will prevent the Guide Pin from unthreading and ensure that debris is trapped within the reamer flutes (Figure 20).

Note: Lateral radiographic images may be taken during reaming to assess depth and endplate purchase.

Insert the Final Reamer into the Drill Tube and advance until the positive stop makes contact with the top of the Drill Tube (Figure 21). Final reaming depth is noted radiographically, and saved to aid in final placement of the implant. Reaming depth should show penetration into the anterior third of the disc space. Remove the Final Reamer while rotating it clockwise.

Note: If additional reaming depth is desired, it is necessary to advance the Drill Tube further. To control the additional depth of reaming, an impaction ruling is etched onto the Drill Tube. As the Drill Tube is impacted directly, it will move relative to the Drill Tube Sheath. By noting the ruling etched onto the Drill Tube, an indication of the millimeters advanced can be assessed. If this step is deemed necessary, additional depth should be achieved in multiple small incremental advances and caution should be exercised to prevent overreaming.

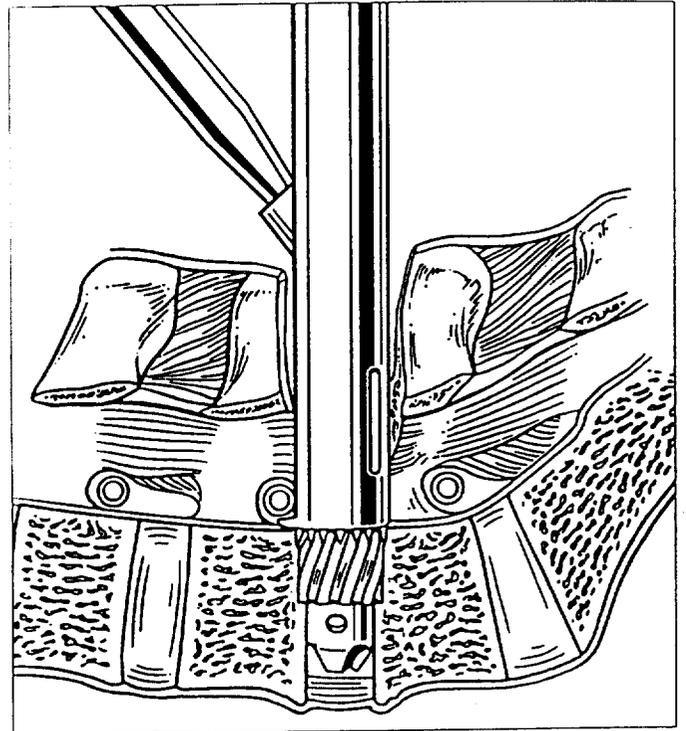


Figure 20

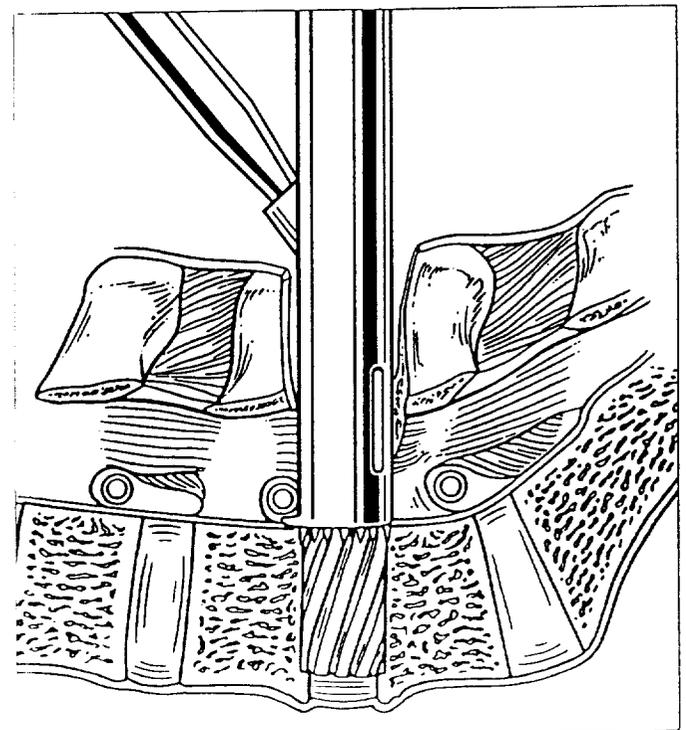


Figure 21

STEP 6 VERTEBRAL REAMING CONTINUED

Posterior Surgical Technique

Once the desired final reaming depth is achieved, the Final Reamer and Drill Tube are removed and any remaining disc fragments are removed through the Drill Tube Sheath with a Pituitary Rongeur (Figure 22).

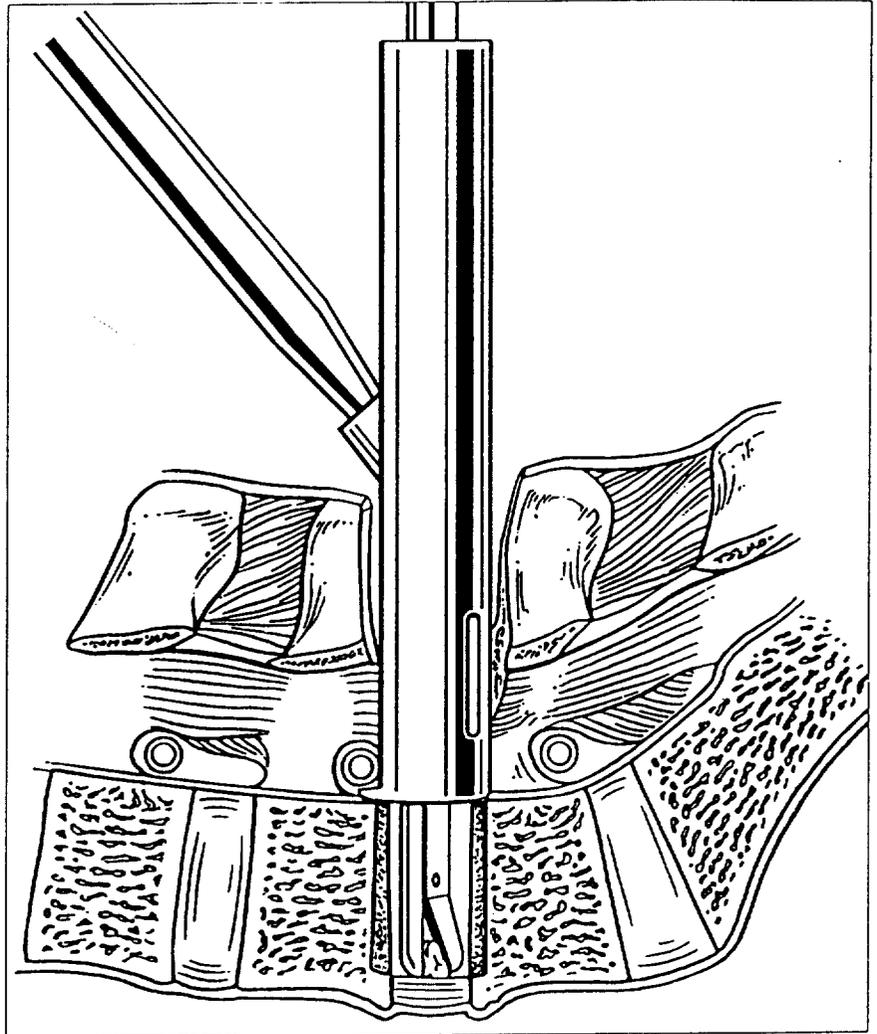


Figure 22

STEP 7 TRIAL IMPLANT PLACEMENT (OPTIONAL)

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Trial Implant Distraction Plug Inserter

Trial Implants are available to assess final drilling depth and implant location.

Thread the appropriate Trial Implant onto the Distraction Plug Inserter. Insert the Trial Implant into the prepared hole (Figure 23). A lateral radiographic image is taken to verify reaming depth and implant position. The Trial Implant should be recessed 3-4mm below the posterior margin of the vertebral bodies and show placement into the anterior third of the disc space.

Remove the Trial Implant.

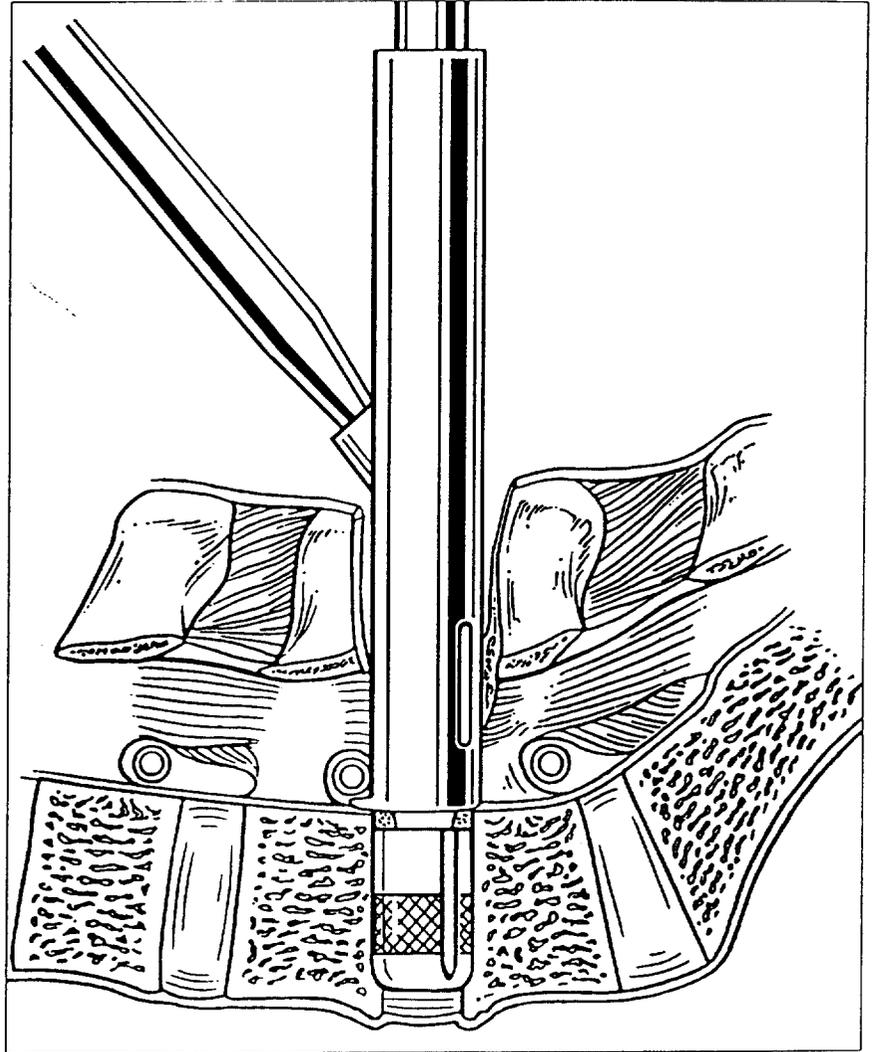


Figure 23

STEP 8 BONE TAPPING

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Bone Tap

While maintaining proper alignment, advance the Bone Tap through the Drill Tube Sheath and place the leading edge of the Tap within the hole. Apply a small amount of downward pressure to the Tap and rotate clockwise until the etch mark on the shaft of the Tap is even with the top of the Drill Tube Sheath (Figure 24).

Unthread the Tap by rotating it counter-clockwise and remove it.

Caution: Do not tap beyond the etch mark as attempting to advance beyond this point will result in stripping the bone threads.

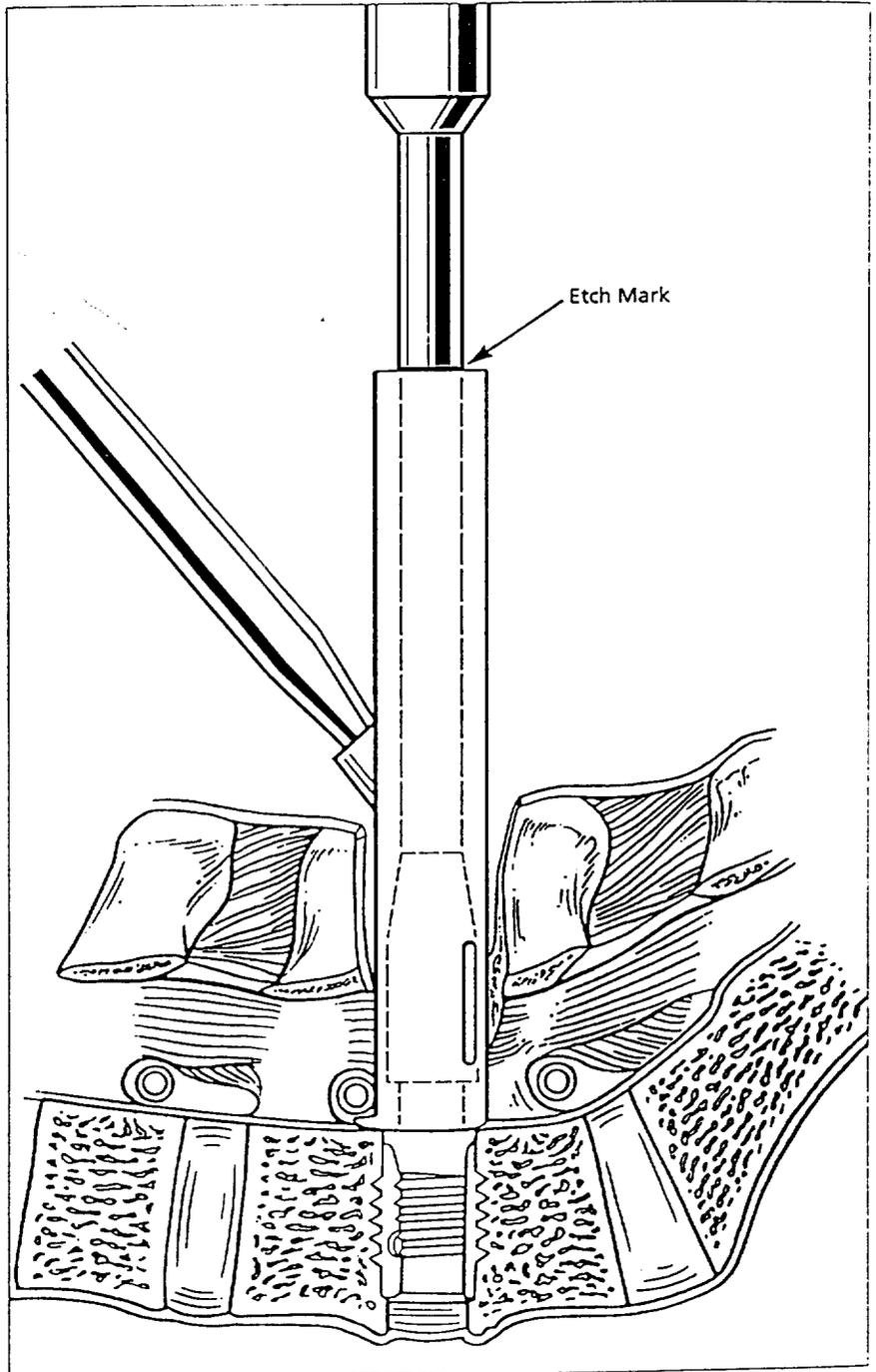


Figure 24

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STEP 9 IMPLANTING THE BAK

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Implant Driver

Position the BAK implant onto the Implant Driver with the implant etching facing the handle. Secure the implant to the Implant Driver by advancing the press fit collet into the trailing chamber of the implant (Figure 25). Pack the leading chamber and large holes with morselized autograft bone. (Figure 26).

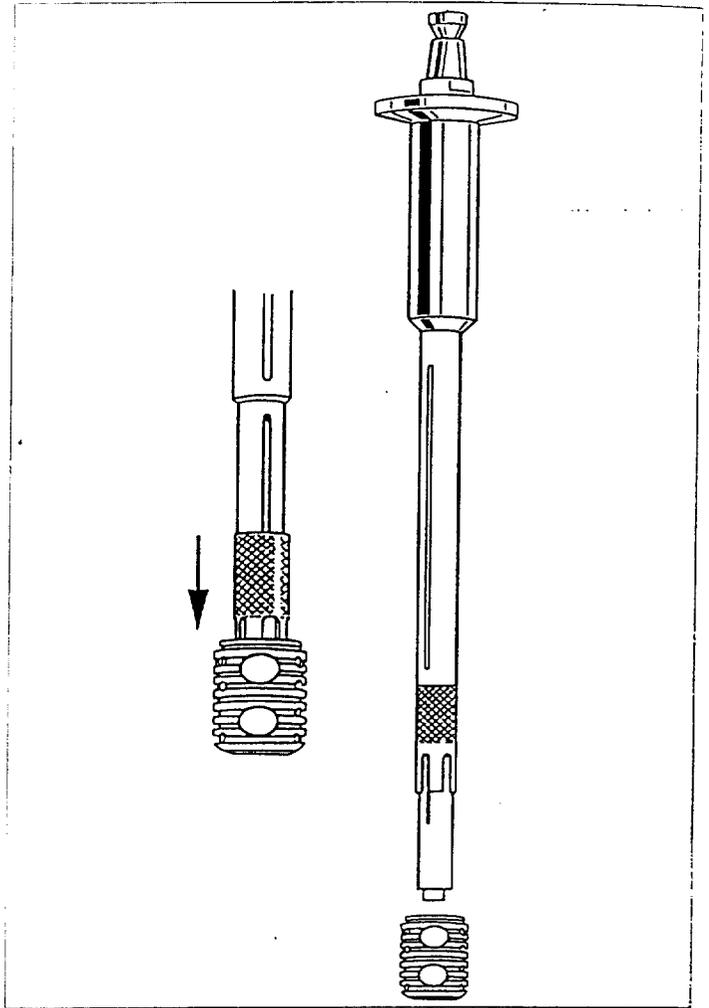


Figure 25

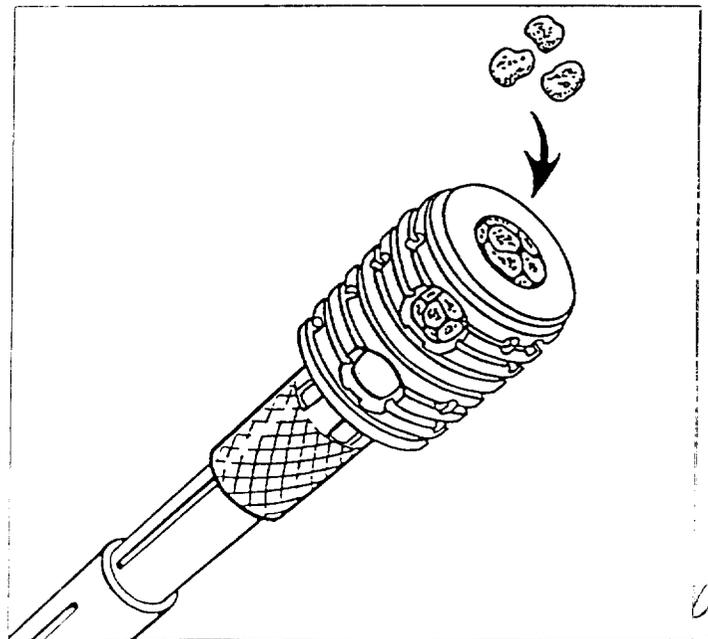


Figure 26

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STEP 9 IMPLANTING THE BAK CONTINUED

Posterior Surgical Technique

While maintaining the alignment angles utilized during drilling and tapping, insert the implant through the Drill Tube Sheath. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant and Implant Driver until the etch mark on the Implant Driver shaft is even with the top of the Drill Tube Sheath (Figure 27).

Proper implant orientation is achieved when the large holes are placed in a cephalad-caudal direction. This is attained when the Implant Driver T-handle is aligned parallel to the disc space.

Remove the Implant Driver by pulling straight up on the handle. This will cause the Implant Driver collet to release automatically. Remove the Drill Tube Sheath. Final implant placement is verified with a lateral radiograph. Implant placement should be recessed 3-4mm below the posterior margin of the vertebral bodies and show placement into the anterior third of the disc space.

Caution: When the etch mark is even with the top of the Drill Tube Sheath, the implant should be properly placed. If additional advancement is desired, it can be accomplished

provided space is still available at the bottom of the hole. This can be assessed by comparing the reaming depth on the saved final reaming depth radiographic image to a radiographic image indicating the location of the leading edge of the implant. After removing the Drill Tube Sheath, place the Implant Driver directly into the slot in the implant. Proceed to rotate the implant clockwise, with caution, under direct vision and/or radiographic imaging. It is critical that if additional insertion is attempted, the implant must always be advancing when rotated clockwise. Once the Implant contacts the bottom of the hole, continued clockwise rotation of the Implant Driver will result in stripped bone threads.

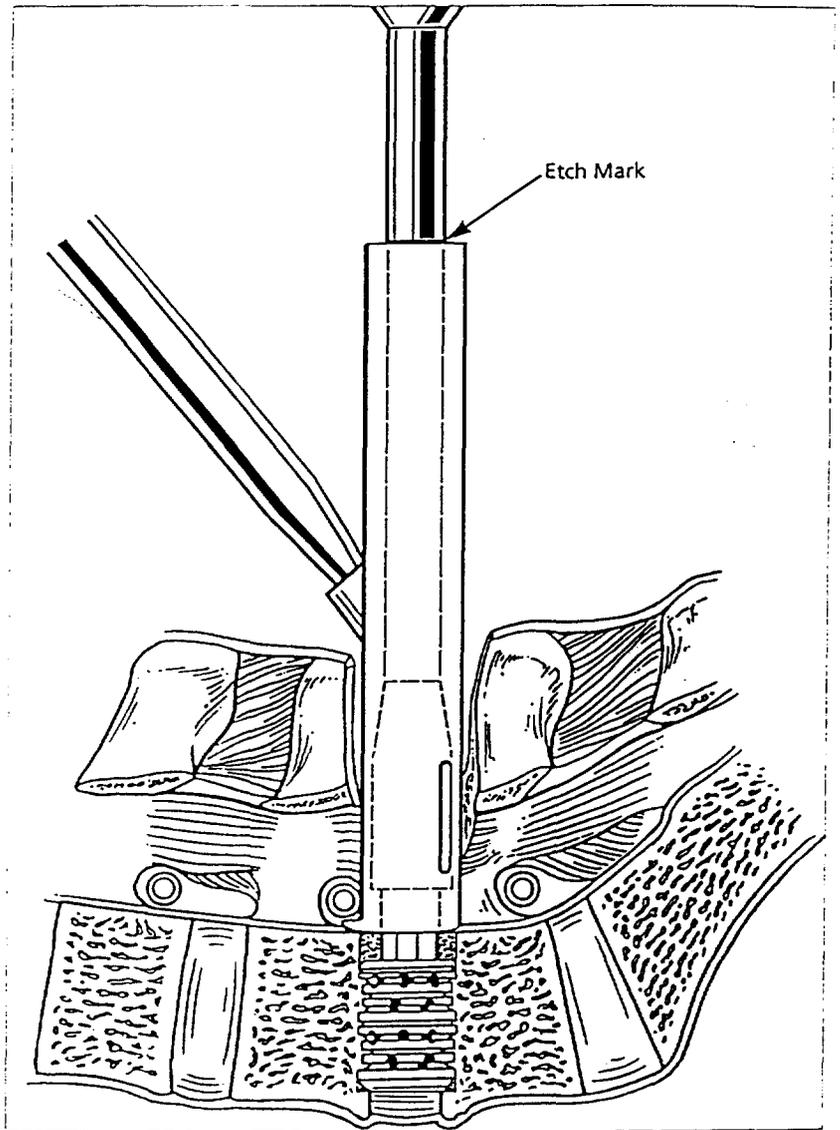


Figure 27

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STEP 10 PLACEMENT OF SECOND IMPLANT

Posterior Surgical Technique

Assess the distance between the initial implant and the Distraction Plug with the Starter Alignment Guide to ensure that medial shifting of the Drill Tube did not occur and adequate space for the second implant is still available.

Position the nerve root and dural retractors appropriately. Thread the Distraction Plug Inserter into the Dis-traction Plug. Remove the Distraction Plug by rotating clockwise while pulling straight up. If this proves difficult, the Slap Hammer will fit on the Distraction Plug Inserter and can be used to impact upward and remove the Distraction Plug.

Additional discectomy can be accomplished at this time.

The preparation of the remaining side is identical to that described in Steps 4-9.

Note: If desired, additional bone can be packed between the implants. This is accomplished by placing bone into the second hole following tapping, packing it against the first implant, and then inserting the second implant.

Radiographic imaging will verify implant positioning within the inter-vertebral space.

Following confirmation of proper implant positioning and orientation (see note), the trailing chamber of both implants is packed with bone (Figure 28).

Note: Implants should be recessed 3-4 mm below the posterior cortical margin and have the leading edge penetrating into the anterior third of the motion segment. Additionally, implant orientation is correct when the large holes are positioned in cephalad and caudal directions. This is indicated when on visual inspection it is noted that either the Quick Disconnect T-Handle orientation is parallel to the disc space, or the long axis of the oval hole in the central web of an implant is parallel to the midline.

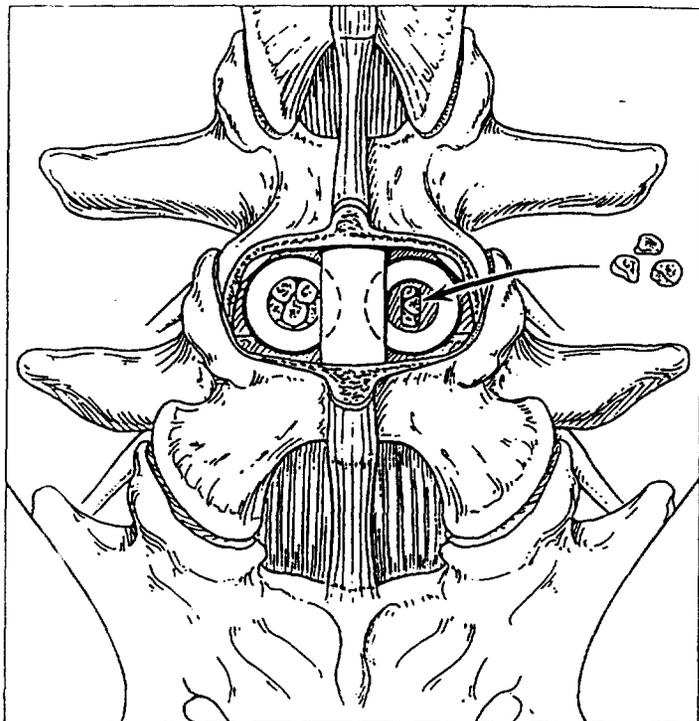


Figure 28

STEP 11 ENDCAP PLACEMENT (OPTIONAL)

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Endcap Inserter

Endcap placement is optional. The endcaps are designed to close off the trailing end of the implants and provide a smooth barrier to prevent the adhesion of soft tissues to the implant. In a posterior procedure, endcaps are utilized if an implant is not well recessed and a smooth barrier is desired to prevent dural adhesion to the implant. Inspection of the nerve root should be performed following endcap placement to ensure adequate freedom of the nerve root is maintained.

Attach the appropriate size endcap onto the Endcap Inserter by pressing the domed end of the endcap into the bottom of the instrument. The endcap attaches to the Endcap Inserter with a loose press fit. Following packing of the trailing chamber of the implants with bone, clear all tissue from the rim of the implant. The endcap is centered over the implant and lightly impacted into the implant (Figure 29). Proper positioning is achieved when the endcap spins freely but remains intact.

The dura is inspected for leaks and a thin layer of fat may be placed around the dura to reduce postoperative adhesions. A drain is placed if required. The retractors are removed and the wound is closed in the usual manner.

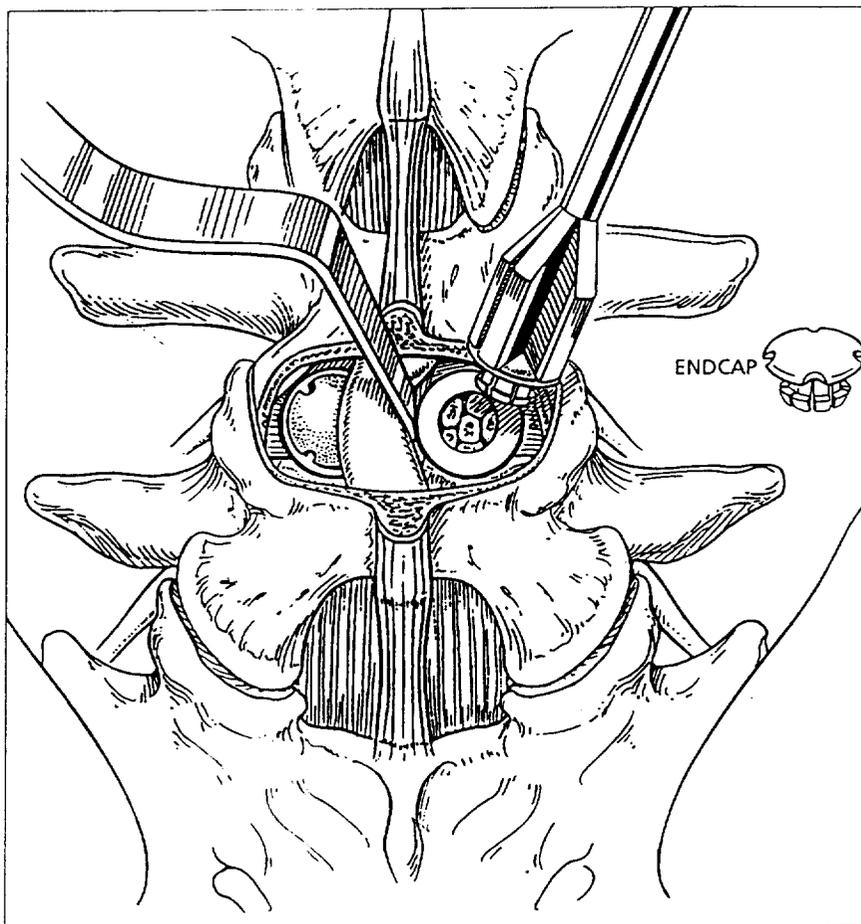


Figure 29

APPENDIX I DIFFICULT SURGICAL SCENARIOS

Posterior Surgical Technique

Concave Endplates:

It is not uncommon for patients with exaggerated concave endplates to present for surgery. This patient population requires a minor modification to the BAK procedure to ensure proper implant alignment, vertebral purchase and lumbar lordosis are achieved and maintained.

Prior to placement of the Distraction Plugs, it is necessary to remove the large marginal osteophytes at the location of the 8mm drilling sites. This can be easily accomplished with a 1/4 inch osteotome or Kerrison rongeur.

This step is necessary to achieve an accurate representation of the disc height which needs to be bridged by the implant and to prevent the motion segment from being "tipped" into local kyphosis.

APPENDIX I DIFFICULT
SURGICAL SCENARIOS CONTINUED

Posterior Surgical Technique

Spondylolisthesis:

It is not uncommon for patients with low Grade I spondylolisthesis or retrolisthesis to present for surgery. This population requires a minor modification to the BAK procedure to ensure proper implant alignment and vertebral purchase are achieved.

If the slip is mobile, correction of the spondylolisthesis can many times be affected by distracting the motion segment incrementally on one side and then the other until the proper Distraction Plug is identified. If this is possible and complete reduction is achieved, proceed with the implantation in the usual fashion.

If the spondylolisthesis does not fully reduce, the Drill Tube and Drill Tube Sheath may not sit evenly over the posterior margin of the disc space. Rather, they will angle such that drilling would cut much more out of one vertebra than the other.

To correct this situation, following impaction of the Drill Tube, use lateral radiographs to modify the angle of the Drill Tube to be parallel with the endplates of the disc. After realignment, gently strike the top of the tube to firmly reseat the teeth.

APPENDIX I DIFFICULT
SURGICAL SCENARIOS CONTINUED

Posterior Surgical Technique

Implant Contact:

If alignment has been compromised, the threads on the implants may mesh together during insertion. If this occurs, there is a possibility that as the second implant is screwed in, it will unscrew the first implant.

If this occurs, position the first implant appropriately and hold it stationary by inserting a small osteotome in the central slot. This will prevent the first implant from unscrewing as the second implant is screwed in.

APPENDIX I DIFFICULT SURGICAL SCENARIOS CONTINUED

Posterior Surgical Technique

Bone Thread Stripping:

The BAK implants require thread purchase within the vertebral bodies to achieve optimal stability. As previously stated, great care should be taken not to damage the bone threads during implantation.

If damage should occur and the implant is deemed unstable, corrective action to regain a stable condition should be taken. The BAK implant sizing has been established with incremental increases of 2.0mm from one size to the next.

If the bone threads become stripped, the action which caused the stripping will create a hole equivalent in size to the minor diameter of the next larger diameter implant.

In this instance, the reaming depth is inspected with a Trial Implant to ensure the larger implant can be positioned behind the posterior cortical margin. If it does not fit, careful retraction of the dura and nerve root is accomplished. The Final Reamer is then directly introduced and carefully advanced under radiographic control until the Trial Implant fits.

Following Trial Implant inspection and subsequent additional reaming where necessary, the larger Tap is advanced directly into the hole to cut the first few threads. The larger implant is then assembled onto the Implant Driver, packed with bone, and threaded into the hole.

In situations where the 17mm implants were used and stripping occurred, a bone dowel of 20mm in diameter is necessary to fill the hole as the 17mm diameter is the largest BAK implant available.

The following table illustrates the implants necessary to re-establish stability following bone thread stripping:

Implant Stripped	Recovery Device
13 x 20 mm	15 x 20mm
15 x 20 mm	17 x 24mm
15 x 24mm	17 x 24mm
17 x 24mm	20mm bone dowel
17 x 28mm	20mm bone dowel

APPENDIX II POSTOPERATIVE CARE

Posterior Surgical Technique

Immediate postoperative care includes:

- Routine monitoring of vital signs and neurological status.
- Administration of appropriate pain medication.
- If nasogastric tubes and/or Foley catheters are utilized, discontinue within 24 hours post-op.
- The patient is encouraged to ambulate as tolerated the day of surgery. The use of a brace is at the discretion of the surgeon.
- Diet is advanced as tolerated.
- Patients should be instructed to restrict activity until advised by their surgeon.

APPENDIX III BAK IMPLANTS

Posterior Surgical Technique

The BAK implants are constructed of 6Al-4V titanium alloy and available in the following dimensions.

Part Number	Size	Minor Dia. (mm)	Major Dia. (mm)	Length (mm)	Drilling Depth (mm)	Implant Volume (cc)*
3000-1320-00	13 x 20	13	15.5	20	26	2.5
3000-1520-00	15 x 20	15	17.5	20	26	3
3000-1524-00	15 x 24	15	17.5	24	30	3.5
3000-1724-00	17 x 24	17	19.5	24	30	4
3000-1728-00	17 x 28	17	19.5	28	34	5

Endcaps are optional with the BAK system. They are designed to enclose the graft within the device. Endcaps are constructed from ultra high molecular weight polyethylene. Sizes correspond to the implants:

Sizes

13mm

15mm

17mm

* Refers to air volume of an individual implant. More bone graft will be required to tightly pack implants and spaces around the implants.

APPENDIX IV DRILL TUBE COMBINATIONS

Posterior Surgical Technique

The BAK system utilizes slight variations in drill tube combinations when implants are inserted from an anterior vs. posterior approach.

These variations are necessary to minimize the retraction of neural structures during posterior implantation of the BAK.

Posterior

Implant size	Drill Tube	Drill Tube Guide	Sheath
13mm	4010-1425	4010-1424	4010-1350
15mm	4010-1625	4010-1624	4010-1550
17mm	4010-1825	4010-1824	4010-1750

Anterior

Implant size	Drill Tube	Drill Tube Guide	Sheath	Drill Tube Sleeve
13mm	4010-1625	4010-1624	4010-1351	4010-1326
15mm	4010-1825	4010-1824	4010-1551	4010-1526
17mm	4010-2025	4010-2024	4010-1751	4010-1726



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