Surgical Technique

Pedestal™

Fenestrated Tap System

Foundation

The Art & Science of Spine Surgery

Abbott Spine


Pedestal Tap fenestrations

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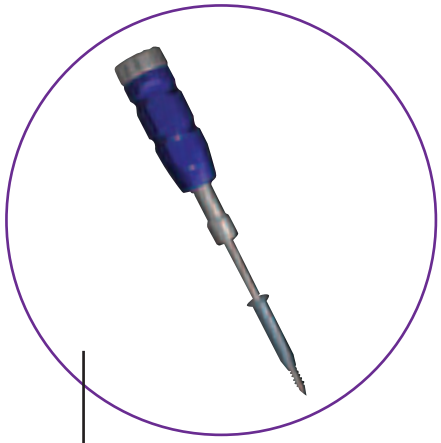
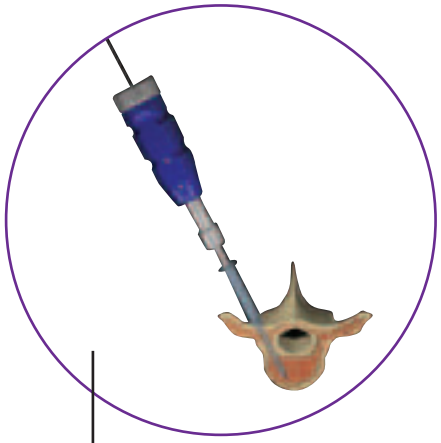


The Pedestal system provides minimally invasive access to the vertebral body



Sleek method for vertebral body bone biopsy and the delivery of cement cleared for use in the spine into the vertebral body

Introduction

The Pedestal System provides surgeons with a new, safe and efficient means to access the vertebral body through dilation and unique fenestrations for the purpose of:

- Bone biopsy: bone marrow aspiration
- Cement delivery: vertebral body augmentation

Product Features

- 4.5, 5.5 and 6.5 mm diameter Taps
- Tap threads **prevent backflow** of cement out of the pedicle column
- Radiolucent Flanged Dilators feature tapered distal tip and proximal circumferential ring for **safe, stable, and easy placement** and removal
- Not self-tapping; allows bone displacement rather than bone cutting. If very hard cancellous bone is encountered, a bone awl may be necessary

Indications

Indications

- The Abbott Spine Pedestal System is intended for use as a stand alone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using an aspiration technique while maintaining access to the same surgical site.

- When used as a cement dispenser, the Pedestal System is intended to dispense cement cleared for use in the spine into a vertebral body for vertebral body augmentation using a vertebroplasty procedure.

Contraindications

- Contraindications to biopsy are hemophilia, active systemic infection, and/or localized infection at the biopsy site.

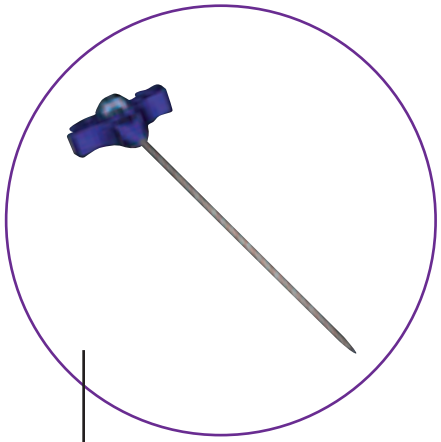
- Contraindications to vertebroplasty are hemophilia, active systemic infection and/or localized infection at the injection site, unstable fracture due to posterior element involvement, lack of a definable level of vertebral collapse, spinal stenosis (>20% by retropulsed fragments), and vertebral plana (collapse >90%), and non-pathological, acute traumatic fractures of the vertebra. Relative contraindications include patient inability to lie prone for the expected procedure duration (1-2 h) and the presence of neurological signs and symptoms caused by vertebral body collapse or tumor extension.

- Known patient sensitivity to device materials (stainless steel, Radel, acetal copolymer).

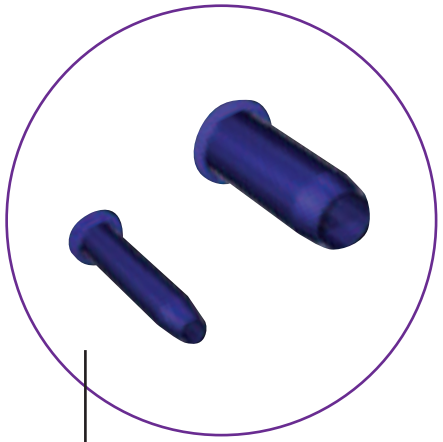
- When dispensing cement with the Pedestal System, consult the package insert that accompanies the cement for product specific indications, contraindications and instructions for use.

CEMENT DISPENSATION: Consult the package insert that accompanies cement for product specific indications, contraindications and instructions for use.

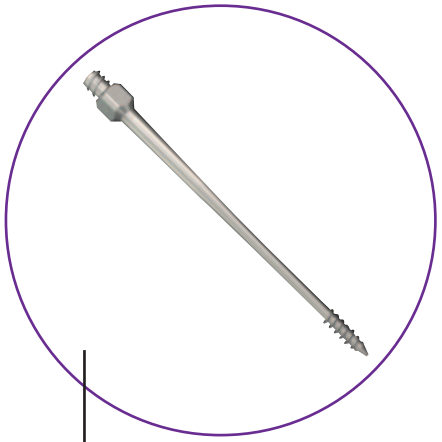
Key Instruments



Targeting Needle with Luer Lock



Small and Large Flanged Dilators



Fenestrated Tap; 4.5, 5.5 and 6.5 mm diameters

Targeting Needle with Luer Lock

After removal of center stylette, use K-wire with trocar tip as a guide.

Use one single-use Targeting Needle and one K-wire per pedicle.

Flanged Dilators

Used for final dilation and Tap working port.

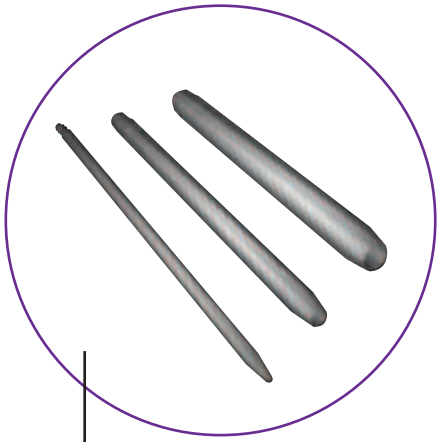
Tapered distal tip aids in advancement through tissue.

Reusable on same patient only. Small for 4.5 and 5.5 mm Taps, large for 6.5 mm Tap.

Fenestrated Tap

Used for biopsy or cement delivery. Proximal end interfaces with syringe.

Single use only. Use only one tap per pedicle.

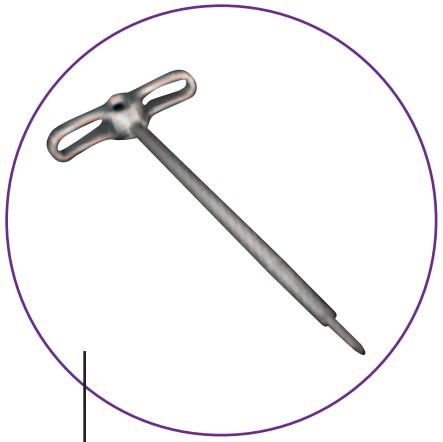


Tissue Dilators #1, #2 and #3

Tissue Dilator

Sequential Dilators fit over K-wire.

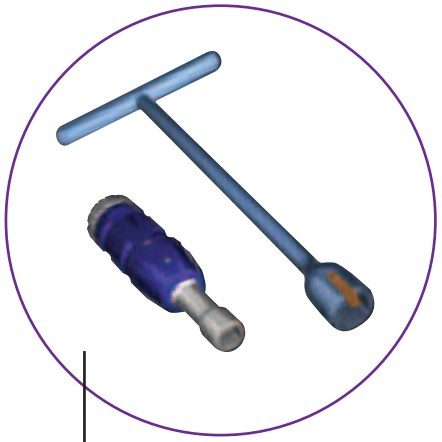
Use Dilator #1 for 4.5 and 5.5 mm Taps
Use Dilator #2 and #3 for 6.5 mm Tap



Cannulated T-handle Bone Awl

Bone Awl

Prepares pedicle entry point to accept Fenestrated Tap, if necessary for very hard bone.



Fenestrated Tap Straight Handle
Fenestrated Tap T-handle

Straight Handle or T-handle

Cannulated for advancement over K-wire. Both options used for Tap insertion and removal.

Surgical Technique

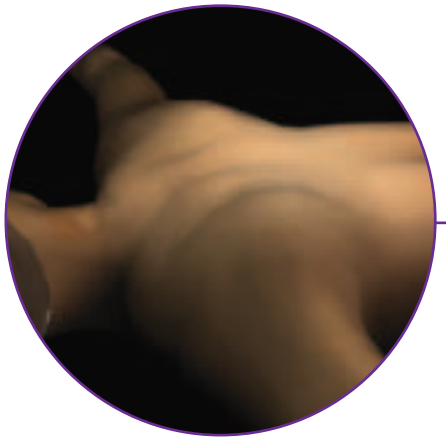


Figure 1

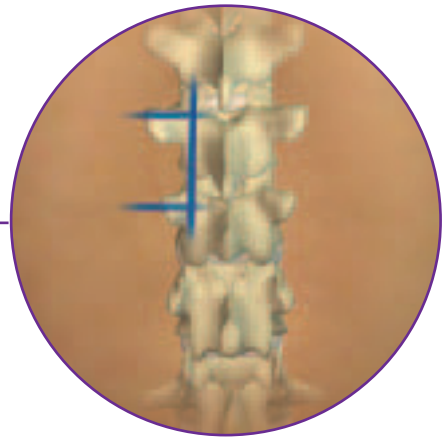


Figure 2

Patient Positioning

Position on radiolucent table with adequate clearance for fluoroscopic C-arm (for A/P, lateral and oblique images of pedicle and vertebral body). All other hardware utilized for patient positioning should be checked for radiolucency.

Pedicle Marking

There are several pedicle targeting techniques. Obtain A/P image of vertebral body, endplates parallel. Pedicles on left side of spine should be entered at the 10 o'clock position, and right sided pedicles at the 2 o'clock position.

Alternatively, fluoroscopically locate pedicle's lateral border. With sterile pen, mark vertical line on skin. Mark horizontal line over pedicle with slightly superior bias. The lines' intersection marks optimal pedicle entry.

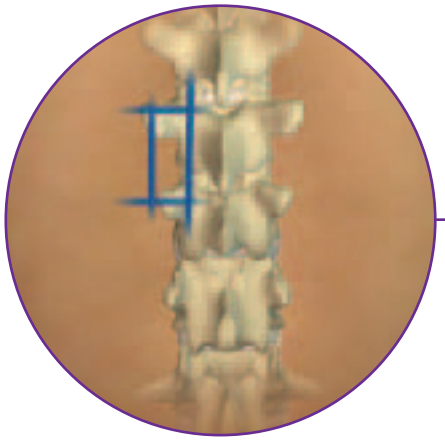


Figure 3

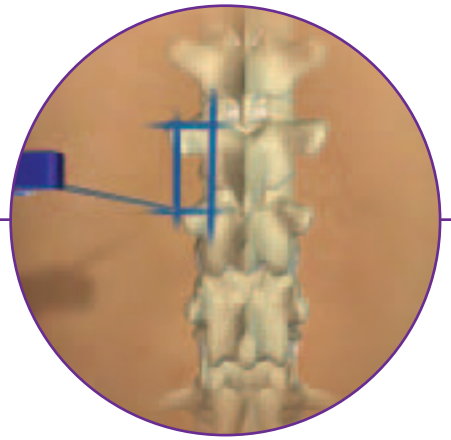


Figure 4

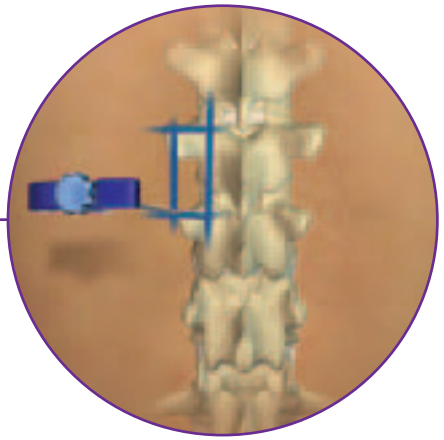


Figure 5

Pedicle Marking

Make second vertical line lateral to first, referencing skin entry point. Lateral distance depends on tissue depth; greater obesity requires greater lateral distance.

Position Targeting Needle

Insert Targeting Needle into skin at intersection of second vertical and horizontal lines. Pass Targeting Needle toward pedicle's bony entry point at the 10 o'clock position on the left and at the 2 o'clock position on the right.

Confirm Targeting Needle Position

Reference A/P image, confirming Needle's position at pedicle's lateral, superior margin.

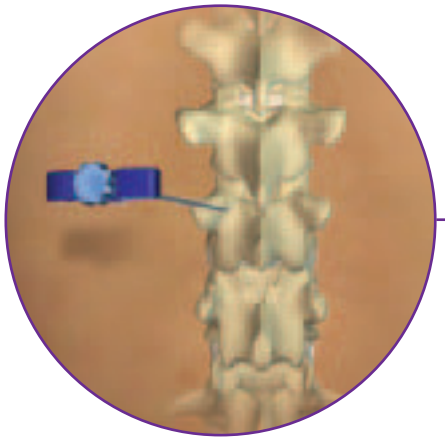


Figure 6

Figure 7

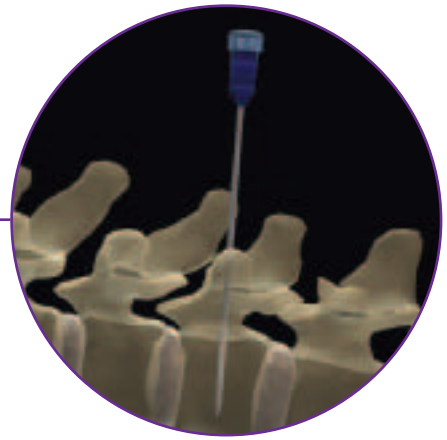


Figure 8

Advance Targeting Needle

Tap lightly with mallet to advance Targeting Needle into pedicle. On an A/P image, it should approach middle of the pedicle cylinder.

Confirm Targeting Needle Position

Reference lateral and A/P images, confirming Targeting Needle placement. A direct lateral image will ensure that Targeting Needle's trajectory matches pedicular anatomy.

Final Positioning

An A/P image is necessary before entering vertebral body, confirming medial pedicle wall integrity.

Advance Targeting Needle 2/3 into vertebral body.

Figure 9

Figure 10

K-wire Advancement/Positioning

With Targeting Needle docked in bone, remove the sharp center stylet and insert K-wire with trocar tip. Gently tap K-wire's proximal end during lateral fluoroscopy, securing into bony anatomy.

Advance K-wire 2/3 into vertebral body. When docked and secure, remove Targeting Needle.

K-wire Management

Caution is vital throughout this procedure to prevent inadvertent removal or dangerous advancement of K-wire.

Figure 11

Figure 12

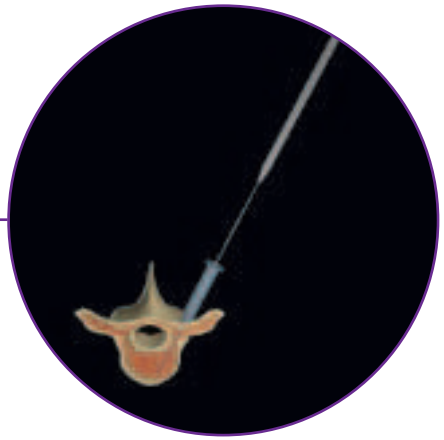


Figure 13

Tissue Dilation

Place Tissue Dilator #1 over positioned K-wire; dock on targeted pedicle entry point.

Sequential Dilation

For 4.5 or 5.5 mm Taps, place small Flanged Dilator over Tissue Dilator #1 and dock on pedicle entry point.

For 6.5 mm Tap, insert Tissue Dilators #2 and #3, followed by large Flanged Dilator.

During soft tissue dilation, it may be necessary to make a small incision with #11 scalpel, for increased dilation.

Dilator Removal

Remove inner Dilators, leaving Flanged Dilator in place for subsequent surgical steps.

Figure 14

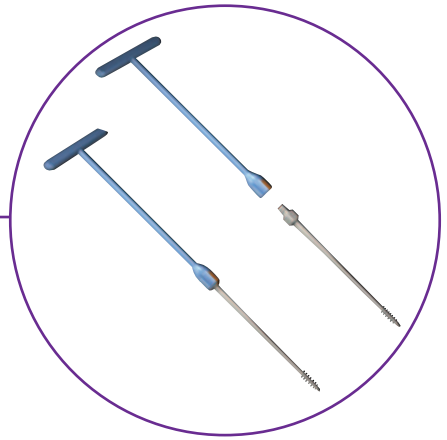


Figure 15

Option A: Attach Straight Handle

Place Tap's proximal end into Straight Handle. Turn capture knob clockwise to secure the connection.

Option B: Attach T-Handle

Push Tap's proximal end into T-Handle. Tab on T-Handle's distal end will securely hold Tap.

Simply pull apart for removal.

Figure 16

Figure 17

Figure 18

Tap Insertion

Pass assembled Tap over K-wire with fluoroscopy. Advance into pedicle, rotating clockwise until Tap tip is positioned in anterior 1/3 of vertebral body.

Small Flanged Dilator will only accommodate 4.5 and 5.5 mm Taps. Use large Flanged Dilator with 6.5 mm Tap.

Tap Insertion, option 2

If very hard bone prevents Tap advancement, remove Tap assembly and insert cannulated Bone Awl over K-wire. Prepare cortical bone of pedicle entry point.

Handle and K-wire Removal

Straight Handle: While stabilizing K-wire, turn Handle knob counterclockwise and pull from Tap. Remove K-wire.

T-Handle: While stabilizing K-wire, carefully pull handle directly from Tap. Remove K-wire.

Large flanged dilator accommodates use of bone awl.

Option 1: Biopsy

For vertebroplasty, skip to page 15.

Figure 19

Figure 20

Figure 21

Syringe Attachment

With clockwise turn, thread compressed Luer Lock syringe (5 - 15 cc's) onto Tap's proximal fitting.

Aspiration

Circumferential biopsy is obtained. Staggered Tap fenestrations allow multiple biopsy sites within vertebral body. Able to advance or withdraw tap to biopsy different vertebral body depths. If performing vertebroplasty after biopsy, leave tap in place, flush with 2 cc saline into vertebral body and proceed to figure 24.

Instrument Removal

Remove syringe while stabilizing Tap. Reattach Handle to Tap, then turn counterclockwise, removing Tap from pedicle. Grasp small Flanged Dilator by lip at skin surface. Gently pull until Dilator is removed. Hold pressure at site and suture skin if necessary.

Option 2: Vertebroplasty

For biopsy, refer to page 14.

Figure 22

Figure 23

Figure 24

Tissue Dilation

Use of 4.5 mm Fenestrated Tap and Small Flanged Dilator allows for minimal tissue dilation while providing appropriate access to vertebral body.

Cement Preparation

Follow manufacturer's recommendations for cement preparation. Fill 5 - 15 cc Luer Lock syringe with prepared cement. Thread onto Tap's proximal connection.

Cement Injection

Under continuous lateral fluoroscopy, inject cement into vertebral body while watching for posterior cement migration. Monitor fill, adjusting Tap depth if necessary. Optimal fill is 2 - 6 cc's for osteoporosis and hemangioma, and 1.5 - 2.5 cc's for tumor.

CAUTION: Immediately discontinue cement delivery upon evidence of leakage or backflow into posterior 1/3 of vertebral body or venuous plexi.

If transitioning from biopsy procedure, flush tap with two cc's sterile saline into vertebral body prior to cement injection.

Figure 25

Figure 26

Syringe Removal

When optimal fill achieved, remove syringe with counterclockwise turn. Check cement fill with A/P image. If cement has not proliferated bilaterally in vertebral body, use bilateral approach accessing both pedicles.

Tap and Flanged Dilator Removal

Reattach preferred Handle to Tap; turn counter-clockwise to remove from pedicle. Grasp Flanged Dilator by lip at skin surface. Gently pull until removed from soft tissue. Hold pressure at site and suture skin if necessary.

Surgeon preference indicates whether to target multiple pedicles simultaneously.

Kit Contents

Sellables

Part Number	Description	Standard Quantity
1001-18	K-wire, Trocar Tip, .054 X 18.0	12
1913-010	Targeting Needle with Luer Lock	4
9266-002	Flanged Dilator #2-Sterile (small)	4
9266-004	Flanged Dilator #4-Sterile (large)	4
9265-0245	Fenestrated Bone Tap, 4.5mm-Sterile	6
9265-0255	Fenestrated Bone Tap, 5.5mm-Sterile	6
9265-0265	Fenestrated Bone Tap, 6.5mm-Sterile	6
1911-19-1140	Radiolucent Dilator	1

Instruments

Part Number	Description	Standard Quantity
1011-18	K-wire Dispenser (18”)	1
1155-2	Cannulated T-handle Bone Awl II	1
1904-010	Tissue Dilator #1	1
1904-020	Tissue Dilator #2	1
1904-030	Tissue Dilator #3	1
9259-001	Fenestrated Bone Tap Handle	1
9259-002	Fenestrated Tap Handle-Straight	1