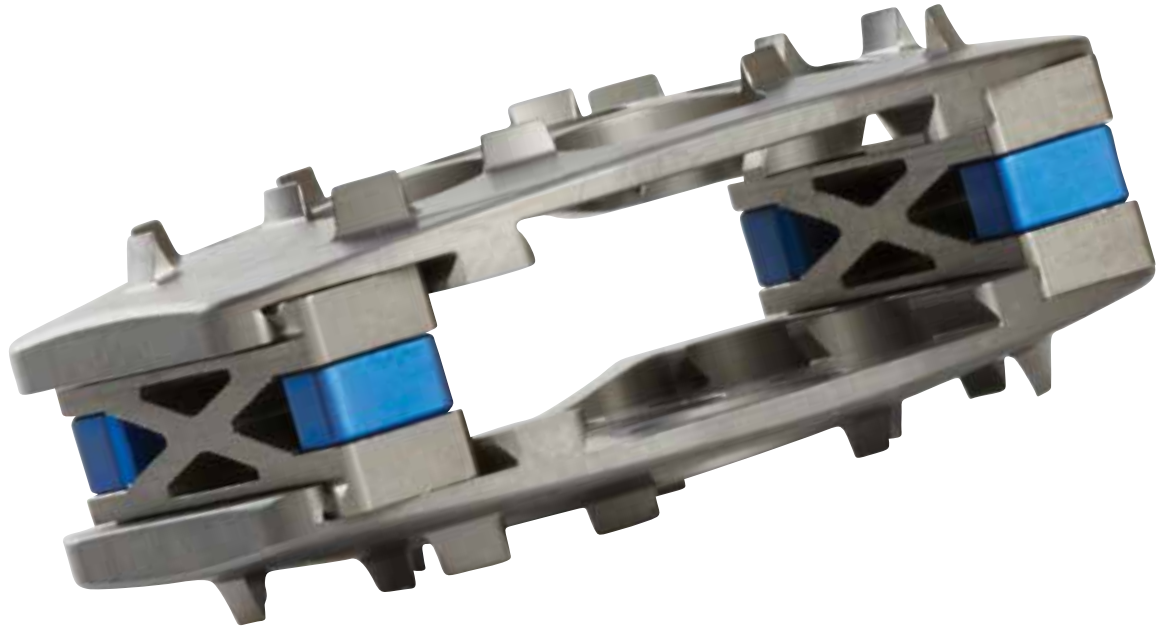




ZIMMER BIOMET

Your progress. Our promise.®



InFix®

Anterior Lumbar Device

Surgical Technique Guide



InFix Anterior Lumbar System's modular design is intended to restore lordosis, disc height and sagittal balance. Its unique in situ assembly was designed to avoid tissue disruption.

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

DISCECTOMY



Figure 1



Figure 2

ENDPLATE PREPARATION



Figure 3

STEP 1

After the patient has been properly positioned for an anterior lumbar interbody fusion and the operative level(s) has been exposed, perform a discectomy. Begin the box discectomy by incising the annulus with a scalpel. The “box” should be centered around the midline and of sufficient width to accommodate the desired implant. Begin by making a transverse incision between the inferior annulus and the vertebra as well as the superior annulus and the vertebra. Then, complete the box incision by making perpendicular incisions at the end of the superior and inferior incisions (Figure 1).

Pituitary rongeurs and curettes can be used to perform the discectomy (Figure 2). Continue to remove disc material until the posterior longitudinal ligament (PLL) is exposed. If necessary, incise the PLL to obtain additional distraction or to facilitate removal of herniated disc material from the spinal canal.

Note: *If using the device as a vertebral body replacement device, resect the disc directly adjacent to the affected segment and the damaged or diseased portion of the vertebral body (partial vertebrectomy). Rongeurs and curettes can be used to perform the discectomy and resection.*

Caution: *Care should be taken to ensure that all exposed blood vessels are properly retracted prior to discectomy to avoid unintended contact with the curettes and rongeurs.*

STEP 2

Use a curette to clean the disc space. Scrape the cartilaginous endplates without perforating the bony endplates. Move the curette from side to side to avoid slipping out of the disc space and causing damage to vessels or intra-abdominal structures. Make certain the endplates are well cleaned and bleeding bone has been exposed laterally, posteriorly and on the anterior lip (Figure 3).

Instruments

ENDPLATE SIZING



Figure 4



Figure 5

STEP 3

Endplate trials correspond with endplate sizes (small, medium, and large). To size the disc space, place the endplate trial into the prepared space, centered around the midline on the adjacent vertebral bodies (Figure 4). Select the largest trial possible to resist subsidence.

A lateral radiographic image can then be taken to confirm sizing and vertebral endplate coverage (Figure 5).

Note: The small trial is 24 mm x 29 mm; the medium trial is 26.5 mm x 32 mm; the large trial is 29 mm x 35 mm.

Instruments



Endplate Trial Handle

1850-0100 Small
1850-0300 Medium
1850-0500 Large

ANTERIOR AND POSTERIOR HEIGHT SIZING



Figure 6



Figure 7



Figure 8

STEP 4

Select the appropriate trial caliper based off of the endplate size selected. Ensure the trial caliper is in its fully collapsed position by pulling the release lever at the proximal end of the instrument and ensuring the lordosis tabs are in the 0 degree position. (Figure 6 Inset) place the trial caliper into the disc space, centered around the midline until it is completely recessed in the disc space (Figure 6). **In the case of a very collapsed disc space**, light malleting may be necessary. Please note that excessive malleting should not be necessary and can lead to damage of the instrumentation or bony anatomy.

Warning: Avoid inserting the distal tip of the trial caliper past the posterior edge of the vertebral body to avoid patient injury.

Distract the disc space until you reach the desired posterior and anterior height, taking care not to over-distract. The anterior and posterior heights can be increased by squeezing the handle, while the anterior height can be further increased by sliding the lordosis tabs forward. Use fluoroscopy to ensure proper positioning and height of the device. If difficulty advancing the lordosis tabs is encountered, they can be advanced prior to squeezing the handle to distract (Figure 7).

Take note of the size selected and return the trial caliper back to its fully collapsed position before removing it from the disc space. The slaphammer may be connected to the trial caliper to aid with removal if necessary.

To collapse the trial caliper, use the thumb tabs to return the selected lordosis to the zero degree position. Then, press the release trigger to return the trial caliper to its original height. If the handles do not return to the original height, pull the release bar on the proximal end of the trial caliper (Figure 8).

Caution: For maximum implant stability, care should be taken during the trialing step to ensure a properly sized implant is selected for the patient anatomy.

Instruments



Trial Caliper
1850-1100 Small
1850-1300 Medium
1850-1500 Large



Slaphammer
1850-5000

ENDPLATE ASSEMBLY



Figure 9



Figure 10



Figure 11

STEP 5

Select the endplate inserter, labeled with a ① for identification. Ensure the endplate inserter arms are in the start position by confirming an “unlocked symbol” can be seen in the window of the slide arm (Figure 9).

Select the appropriately sized endplates. Position the endplates onto the distal tip of the endplate inserter by mating the endplate holes onto the corresponding endplate inserter bosses (Figure 10).

Slide the endplate inserter arm forward until it is completely engaged. This can be confirmed by visualizing a “locked symbol” in the window of the slide arm (Figure 11).

Warning: Take caution to ensure the endplate inserter arms are fully engaged during the entirety of the procedure until implant locking has taken place.

Instruments



Endplate Inserter

1850-2100 Small

1850-2300 Medium

1850-2500 Large

ENDPLATE INSERTION



Figure 12



Figure 13

STEP 6

Place the endplate inserter into the disc space. If necessary, the disc space may be distracted to create room for the insertion and/or the endplate inserter may be gently malleted into position. If malleting, place the impaction cap on the proximal end of the endplate guide (Figure 12). Please note that excessive malleting should not be necessary and can lead to damage of the instrumentation or bony anatomy.

Warning: Malleting the endplate inserter directly without the impaction cap can result in damage to the instrument.

With a lateral radiograph, verify adequate vertebral endplate coverage and position. The endplates should be positioned on the ring apophysis to reduce the risk of subsidence (Figure 13).

Warning: Care should be taken to ensure the endplates are not placed anterior or posterior to the edge of the vertebral bodies to prevent injury to the patient.

DISTRACTOR ASSEMBLY AND STRUT LOADING



Figure 14

STEP 7

Select the appropriately sized distractor body (labeled with ②A) and distractor shaft (labeled with ②B) that correspond with the trialed footprint and height. Press the button on the distractor body and slide the distractor shaft into the distractor body until the two pieces are engaged (Figure 14). Verify that the distractor shaft is fully locked into the distractor body by lightly pulling on the distractor shaft while holding the distractor body.

Instruments



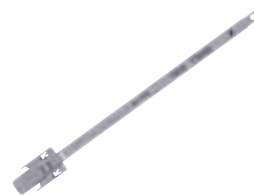
Impaction Cap
1850-2000



Mallet
07.01237.001



Distractor Body
1850-3010 Small
1850-3030 Medium
1850-3050 Large



Distractor Shaft
8 mm, 10 mm, 12 mm, 14 mm
1850-3108-1850-3114 Small
1850-3308-1850-3314 Medium
1850-3508-1850-3514 Large

DISTRACTOR AND STRUT INSERTION



Figure 15

Next, select the appropriately sized struts. Preload the distractor with the struts by inserting the struts into the distractor with their narrow end toward the distal tip of the distractor (Figure 15).

Note: If the struts do not fit in the insertion holes, verify the correct size and orientation.



Figure 16

STEP 8

If the impaction cap was used in the previous step, remove it from the endplate inserter.

Slide the distractor into the opening on the proximal end of the endplate inserter (Figure 16) until it is fully seated as pictured (Figure 17).



Figure 17

If malleting is necessary, engage the impaction cap with the proximal end of the distractor (Figure 17). Please note that excessive malleting should not be necessary and can lead to damage of the instrumentation or boney anatomy.

Warning: Malleting the distractor directly without the impaction cap can result in damage to the instrument.

Instruments



Impaction Cap
1850-2000



Mallet
07.01237.001

RADIOGRAPHIC CONFIRMATION



Figure 18

Once fully seated, remove the impactation cap by pressing the buttons on the distractor and select the strut inserter, identified with a ③. Mate the strut inserter with the proximal end of the distractor (Figure 18).

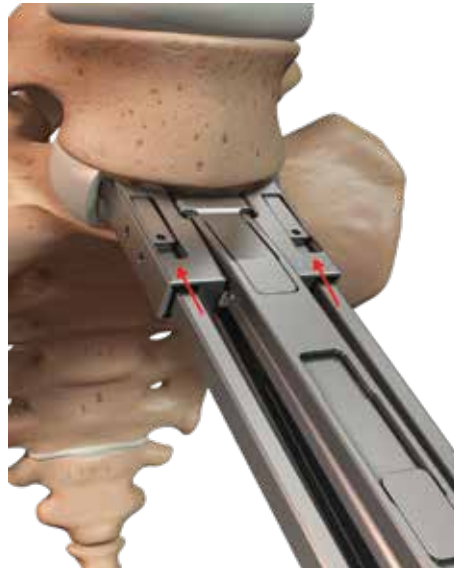


Figure 19

Advance the strut inserter (Figure 19) until it is fully seated into the distractor so the struts are fully advanced into the endplates. The strut inserter will snap-in and be retained when it is fully seated.



Figure 20

STEP 9

Remove the distractor from the endplate inserter by pressing the buttons on the endplate inserter identified with a black dot and pulling it until it has been completely removed (Figure 20). Please note that the ability to confirm strut placement before locking will be limited if the distractor tip is not removed from the distal end of the endplate inserter.

Instruments



Strut Inserter
1850-4000

IMPLANT DISASSEMBLY (OPTIONAL)



Figure 21

Use fluoroscopy to assess implant position and size (Figure 21). Once complete, return the distractor to the fully seated position in the endplate inserter and remove the strut inserter by pressing the buttons on the distractor.



Figure 22

STEP 10

If upon radiographic evaluation an adjustment to the implant is necessary, the implant may be disassembled prior to locking using the strut remover. Remove all instrumentation from the disc space until only the implant remains.

Select the strut remover, T-handle and the appropriately sized strut remover tip. Attach the T-handle to the strut remover. Attach the tip to the strut remover by advancing the center shaft until the strut remover tip can be mated to the shaft (Figure 22).



Figure 23

Return the strut remover to the start position. The start position can be confirmed by ensuring you can no longer see the black laser-marked line on the center shaft (Figure 23).

Instruments



Strut Remover
1850-5100



Strut Remover Tip
8 mm, 10 mm, 12 mm, 14 mm
1850-5108 – 1850-5114 S
1850-5308 – 1850-5314 M
1850-5508 – 1850-5514 L



T-handle
1850-5600

IMPLANT LOCKING



Figure 24

Position the strut remover in the disc space until it is fully seated. The “hooks” on the distal end of the strut remover should be placed posterior to the implant struts (Figure 24).



Figure 25

Begin rotating the T-handle clockwise until the struts are completely removed from the device (Figure 25). Next, use forceps to remove the endplates.



Figure 26

STEP 11

Select the locker, identified with a ④, and insert it into the proximal end of the distractor. Ensure the locker is fully seated. It will snap-in and be retained when this has occurred (Figure 26).

Instruments



Locker
1850-4200



Figure 27



Figure 28



Pull down on the locker tab until it does not return to its original position when released. Begin squeezing the handles of the locker. If necessary, release the locker to change grip location and continue squeezing (Figure 27).

The implant is locked once the handles return to the open position. If the locker's handles do not return to the open position, the implant is not locked; keep squeezing. This is an indication that the implant is not fully locked (Figure 28).

Once locked, remove the distractor by pressing the buttons on the endplate inserter marked with a black dot. Next, press the buttons on the endplate inserter slide arms and pull up on the slide arm until it is in the unlocked position, and remove it from the disc space.

Caution: Do not disengage the endplate inserter from the endplates until after final locking to ensure that the implant is completely locked.

Warning: Failure to exercise adequate care while removing the endplate inserter can result in vascular damage.

IMPLANT REMOVAL (OPTIONAL)



Figure 29



Figure 30

STEP 12

If the implant must be removed after final locking, whether intraoperatively, immediately post-operative, or in a later revision surgery, the strut remover can be used to remove the entire construct.

Select the strut remover, T-handle and the appropriately sized strut remover tip. Attach the T-handle to the strut remover. Attach the tip to the strut remover by advancing the center shaft until the strut remover tip can be mated to the shaft (Figure 29).

Return the strut remover to the start position. The start position can be confirmed by ensuring you can no longer see the black laser-marked line on the center shaft.

Position the strut remover in the disc space until it is fully seated. The “hooks” on the distal end of the strut remover should be placed posterior to the implant struts. Begin rotating the T-handle clockwise until significant resistance is met.

Remove the T-handle and connect the slaphammer to the strut remover. Distract the disc space if desired and use the slaphammer connection of the strut remover to remove the locked construct from the disc space (Figure 30).

Note: The strut remover will not function to remove the struts in a locked construct, but it will remove the entire construct.

Instruments



Strut Remover
1850-4200



Strut Remover Tip
8 mm, 10 mm, 12 mm, 14 mm
1850-5108 – 1850-5114 S
1850-5308 – 1850-5314 M
1850-5508 – 1850-5514 L



T-handle
1850-5600



Slaphammer
1850-5000

PREPARATION FOR GRAFT MATERIAL (OPTIONAL)



Figure 31

STEP 13

Insert the bone awl into the implant assembly and score the vertebral endplates by passing the tip of the bone awl through each endplate fenestration on both the inferior and superior endplates (Figure 31).

ENDCAP PLACEMENT (OPTIONAL)



Figure 32

STEP 14

Insert the endcap inserter rod into the endcap inserter as shown (Figure 32). Press the inserter rod into the endcap inserter and rotate clockwise until it is retained.



Figure 33

Select the endcap size corresponding to the strut size used. If large endplates were used, the endcaps can be inserted without any manipulation (Figure 33). If medium endplates were used, scissors should be used to cut along the first perforation on each lateral side of the endcap. If small endplates were used, scissors should be used to cut along the second perforation on each lateral side of the endcap.

Warning: Use of an endcap size smaller than the strut size may allow the endcap to be pushed through the construct during insertion.

Instruments



Bone Awl
1850-0600



Endcap Inserter Rod
1850-0750



Endcap Inserter
1850-0700

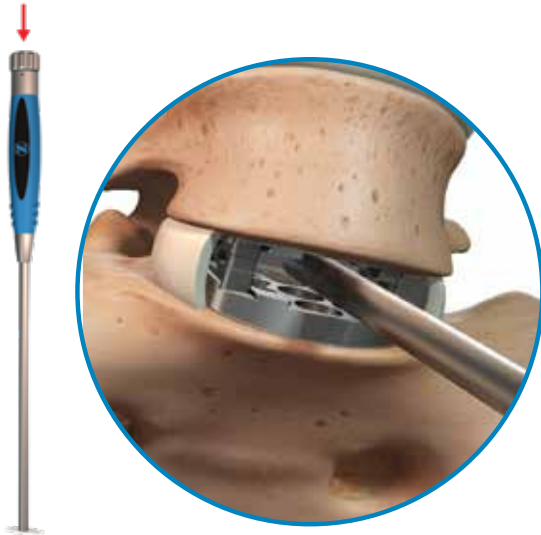


Figure 34

Place the endcap inserter's tip into the center hole of the endcap. Orient the endcap with the ridges facing the instrument's handle and insert the endcap into the center channel of the device. Position the endcap at the posterior aspect of the endplates and apply slight downward pressure until it is retained by the construct. Release the endcap from the endcap inserter by rotating the endcap inserter rod counterclockwise (Figure 34).

Warning: Do not mallet the endcap inserter. Excessive force during use of the endcap inserter can force the endcap out of the construct.

GRAFT PACKING

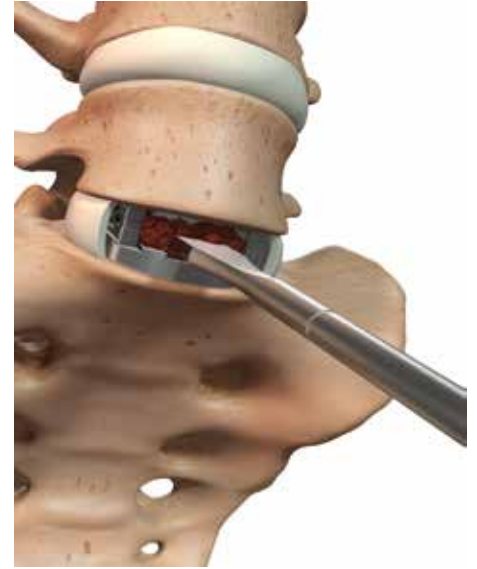


Figure 35

STEP 15

Place autograft into the cavity of the implant using the graft packing tool (Figure 35).

Warning: Excessive force during use of the graft packing tool can force the endcap or graft material out of the construct.

Instruments



Graft Packing Tool
1850-0800

RADIOGRAPHIC ASSESSMENT

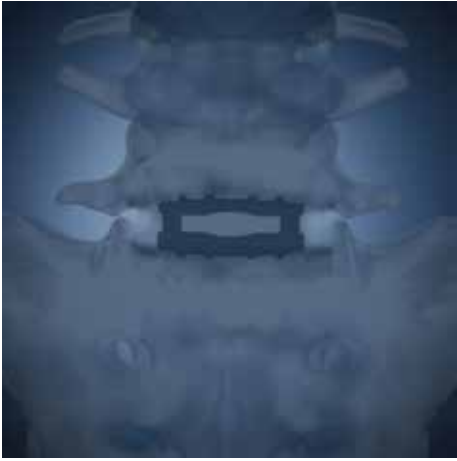


Figure 36

STEP 16

After graft placement, make a final confirmation of the implant's position with A/P and lateral radiographs (Figure 36). Wound closure can now be performed in the usual manner.

SUPPLEMENTAL FIXATION

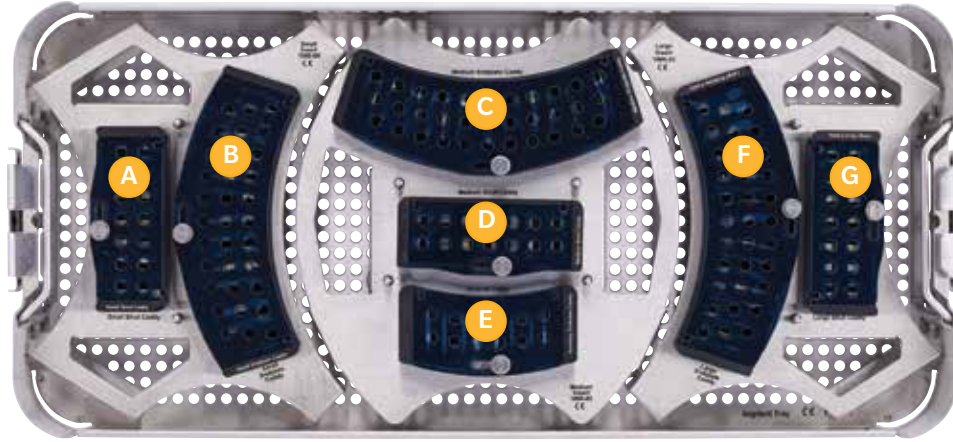
STEP 17

If used as an interbody fusion device, the use of supplemental fixation is required.

TRAY LAYOUTS

InFix System Implant Kit

07.01966.401



InFix System Endcap Kit

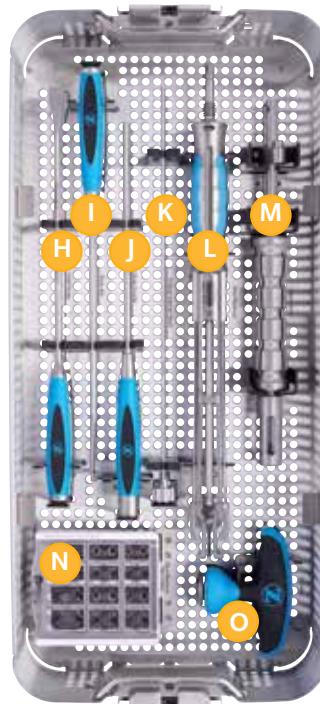
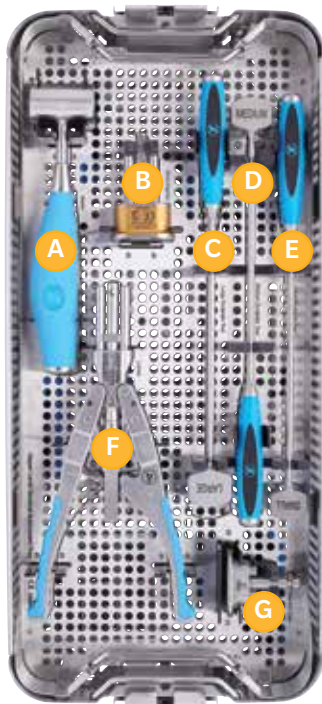
07.01966.403

Part Number	Description	Kit Quantity	Reference
1801-100	Endplate - S, 0°	3	B
1801-103	Endplate - S, 3°	5	B
1801-106	Endplate - S, 6°	5	B
1801-109	Endplate - S, 9°	3	B
1801-300	Endplate - M, 0°	3	C
1801-303	Endplate - M, 3°	5	C
1801-306	Endplate - M, 6°	5	C
1801-309	Endplate - M, 9°	3	C
1801-500	Endplate - L, 0°	3	F
1801-503	Endplate - L, 3°	5	F
1801-506	Endplate - L, 6°	5	F
1801-509	Endplate - L, 9°	3	F
1804-108	Strut - S, 8 mm	6	A
1804-110	Strut - S, 10 mm	6	A
1804-112	Strut - S, 12 mm	4	A
1804-114	Strut - S, 14 mm	4	A
1804-308	Strut - M, 8 mm	6	D
1804-310	Strut - M, 10 mm	6	D
1804-312	Strut - M, 12 mm	4	D
1804-314	Strut - M, 14 mm	4	D
1804-508	Strut - L, 8 mm	6	G
1804-510	Strut - L, 10 mm	6	G
1804-512	Strut - L, 12 mm	4	G
1804-514	Strut - L, 14 mm	4	G

Part Number	Description	Kit Quantity	Reference
1803-08	InFix Endcap, 8 mm	2	E
1803-10	InFix Endcap, 10 mm	2	E
1803-12	InFix Endcap, 12 mm	2	E
1803-14	InFix Endcap, 14 mm	2	E

InFix System General Instrument Kit

07.01966.421



Part Number	Description	Quantity	Reference
07.01237.001	Mallet	1	A
1850-0300	Trial Handle - M	1	D
1850-0500	Trial Handle - L	1	C
1850-0600	Bone Awl	1	I
1850-0700	Endcap Inserter	1	J
1850-0750	Endcap Inserter Rod	1	K
1850-0800	Graft Packer	1	H
1850-0100	Trial Handle - S	1	E
1850-2000	Impaction Cap	1	G
1850-4000	Strut Inserter	1	B
1850-4200	Locker	1	F
1850-5000	Slaphammer	1	M
1850-5100	Strut Remover	1	L

Part Number	Description	Quantity	Reference
1850-5108	Strut Remover Tip - S, 8 mm	1	N
1850-5110	Strut Remover Tip - S, 10 mm	1	N
1850-5112	Strut Remover Tip - S, 12 mm	1	N
1850-5114	Strut Remover Tip - S, 14 mm	1	N
1850-5308	Strut Remover Tip - M, 8 mm	1	N
1850-5310	Strut Remover Tip - M, 10 mm	1	N
1850-5312	Strut Remover Tip - M, 12 mm	1	N
1850-5314	Strut Remover Tip - M, 14 mm	1	N
1850-5508	Strut Remover Tip - L, 8 mm	1	N
1850-5510	Strut Remover Tip - L, 10 mm	1	N
1850-5512	Strut Remover Tip - L, 12 mm	1	N
1850-5514	Strut Remover Tip - L, 14 mm	1	N
1850-5600	T-handle	1	O

TRAY LAYOUTS *(continued)*

InFix System Small Instrument Kit

07.01966.422

Part Number	Description	Kit Quantity
1850-1100	Trial Caliper - S	1
1850-2100	Endplate Inserter - S	1
1850-3010	Distractor Body - S	1
1850-3108	Distractor Shaft - S,8 mm	1
1850-3110	Distractor Shaft - S,10 mm	1
1850-3112	Distractor Shaft - S,12 mm	1
1850-3114	Distractor Shaft - S,14 mm	1

InFix System Large Instrument Kit

07.01966.424

Part Number	Description	Kit Quantity
1850-1500	Trial Caliper - L	1
1850-2500	Endplate Inserter - L	1
1850-3050	Distractor Body - L	1
1850-3508	Distractor Shaft - L,8 mm	1
1850-3510	Distractor Shaft - L,10 mm	1
1850-3512	Distractor Shaft - L,12 mm	1
1850-3514	Distractor Shaft - L,14 mm	1

InFix System Medium Instrument Kit

07.01966.423

Part Number	Description	Kit Quantity
1850-1300	Trial Caliper - M	1
1850-2300	Endplate Inserter - M	1
1850-3030	Distractor Body - M	1
1850-3308	Distractor Shaft - M,8 mm	1
1850-3310	Distractor Shaft - M,10 mm	1
1850-3312	Distractor Shaft - M,12 mm	1
1850-3314	Distractor Shaft - M,14 mm	1

INSTRUMENT VISUAL GUIDE



Endplate Trial Handles	PART NUMBER
Small	1850-0100
Medium	1850-0300
Large	1850-0500



Trial Caliper	PART NUMBER
Small	1850-1100
Medium	1850-1300
Large	1850-1500



Slaphammer	PART NUMBER
	1850-5000



Endplate Inserters	PART NUMBER
Small	1850-2100
Medium	1850-2300
Large	1850-2500



Impact Cap	PART NUMBER
	1850-2000



Mallet	PART NUMBER
	07.01237.001



Strut Inserter	PART NUMBER
	1850-4000



Strut Remover	PART NUMBER
	1850-5100

INSTRUMENT VISUAL GUIDE (continued)



Distractor Body	PART NUMBER
Small	1850-3010
Medium	1850-3030
Large	1850-3050



Distractor Shaft	PART NUMBER
Small, 8 mm	1850-3108
Medium, 8 mm	1850-3308
Large, 8 mm	1850-3508
Small, 10 mm	1850-3110
Medium, 10 mm	1850-3310
Large, 10 mm	1850-3510
Small, 12 mm	1850-3112
Medium, 12 mm	1850-3312
Large, 12 mm	1850-3512
Small, 14 mm	1850-3114
Medium, 14 mm	1850-3314
Large, 14 mm	1850-3514



Locker	PART NUMBER
	1850-4200



Strut Remover Tip	PART NUMBER
Small, 8 mm	1850-5108
Medium, 8 mm	1850-5308
Large, 8 mm	1850-5508
Small, 10 mm	1850-5110
Medium, 10 mm	1850-5310
Large, 10 mm	1850-5510
Small, 12 mm	1850-5112
Medium, 12 mm	1850-5312
Large, 12 mm	1850-5512
Small, 14 mm	1850-5114
Medium, 14 mm	1850-5314
Large, 14 mm	1850-5514



T-handle	PART NUMBER
	1850-5600



Bone Awl PART NUMBER
1850-0600



Endcap Inserter PART NUMBER
1850-0700



Endcap Inserter Rod PART NUMBER
1850-0750



Graft Packing Tool PART NUMBER
1850-0800

IMPORTANT INFORMATION ON THE INFIX ANTERIOR LUMBAR DEVICE

DESCRIPTION

The InFix implant is manufactured from implantable grade Ti-6Al-4V alloy that conforms to ASTM F136. The implant is comprised of two opposing Endplates (provided in 0°, 3°, 6° and 9° angles) supported by two vertical Struts available in a range of heights, allowing the surgeon to fix the vertebrae in proper anatomical alignment and lordosis. Each of the Struts includes a load-sharing mechanism that allows a limited amount of strain across the fusion mass while supporting the load bearing surfaces. An Ultra High Molecular Weight Polyethylene (UHMWPE) Endcap may be placed inside the implant prior to packing it with bone graft. The Endcap serves as an optional block of the posterior opening in the implant construct to assist in containing the material inside. Holes in the Endplates provide space for bone in-growth while angled spikes penetrate the vertebral endplates and provide resistance to rotation and migration.

INDICATIONS

When used as a vertebral body replacement device, the InFix System is intended for use in the thoracic and/or lumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The InFix System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The InFix implant is intended to be used with bone graft.

When used as an intervertebral body fusion device, the InFix System is indicated for use with autogenous bone graft at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. When used as an intervertebral body fusion device, the InFix implant is intended to be used with supplemental fixation.

For both of the indications listed above, the InFix implant is intended to be implanted via an open anterior approach.

CONTRAINDICATIONS

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.
4. Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication.
5. Obesity
6. Pregnancy
7. Certain degenerative diseases of the spine that does not require a spinal fusion.
8. Foreign body sensitivity; known patient sensitivity to device materials (titanium alloy Ti-6Al-4V; Ultra High Molecular Weight Polyethylene UHMWPE).
9. The patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.
10. Metabolic disorders that may impair bone formation.
11. Inadequate bone stock to support the device.
12. Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).
13. When used without posterior fixation as a vertebral body replacement, the device should only be used for Grade 1 or less spondylolisthesis or retrolisthesis.
14. Where attempted correction exceeds the limits of physiological conditions.
15. Any condition not described in the indications for use.
16. Prior fusion at the level(s) to be treated.

MATERIALS

The InFix implants are manufactured from Titanium alloy (Ti-6Al-4V) per ASTM F136.

The InFix Endcaps are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM F648.

The InFix instrumentation is made from surgical grade stainless steel.

The InFix implant should not be implanted with any implants made of stainless steel as titanium alloy and stainless steel are not compatible. Specifications are controlled for optimization of metallurgical properties and corrosion resistance, and are based on the strength and rigidity requirements of the individual component.

To achieve the best results, **do not use any of the InFix components with the components from any other system** or company unless otherwise stated in this document. As with other orthopedic implant, none of the InFix implant components should be reused or re-implanted under any circumstances.

WARNINGS

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic interbody fusion devices. General surgical risk should be explained to the patients prior to surgery.

It is strongly recommended that the patient be informed of the risks associated with surgical procedures and components.

1. THE SAFETY AND EFFECTIVENESS OF INTERBODY FUSION HAS BEEN ESTABLISHED ONLY FOR SPINAL CONDITIONS WITH SIGNIFICANT MECHANICAL INSTABILITY OR DEFORMITY REQUIRING FUSION WITH INSTRUMENTATION. These conditions are significant mechanical instability secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions is unknown.
2. Potential risks identified with the use of this device system, which may require additional surgery, include:
 - a. Device component fracture
 - b. Loss of fixation
 - c. Non-union
 - d. Fracture of the vertebra
 - e. Neurological injury
 - f. Vascular or visceral injury
3. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Implant height should be determined such that adequate decompression and stability are imparted to the instrumentation segment.
4. When used as a vertebral body replacement device, the need for supplemental fixation must be determined by the surgeon based upon the amount of instability imparted by the surgery, as well as the pathology itself.
5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
6. Patient selection shall consider the following factors which are important to the success of the procedure and the performance of the device.
 - a. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to a loss of interbody height or failure of the device and/or the operation.
 - b. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause loss of disc height and/or failure of the device.
 - c. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
 - d. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary relief.
 - e. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
 - f. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
7. Do not use damaged product; implants and instruments should be inspected for damage prior to use.
8. Do not use this product for other than labeled indications (off-label use).
9. Do not use components and/or instruments from competitive anterior spinal systems with the InFix device(s) during implant and/or explant.
10. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
11. These warnings do not include all adverse effects that can occur with surgery in general. General surgical risks should be explained to the patients prior to surgery.
12. Maintain proper standard aseptic technique throughout the procedure to avoid infection.
13. When inserting the implant, care should be taken to avoid using excessive force which has the potential to cause damage to the implant or surrounding tissue.
14. When preparing the disc space, care should be taken to ensure an appropriate amount of bone is removed; excessive removal of bone has the potential to cause subsidence while failing to remove enough bone has the potential to cause poor fusion.
15. During distraction of the disc space, care should be taken to prevent over-distraction or under-distraction which has the potential to cause irreversible damage to the patient or an unstable implant construct.
16. If an existing implant(s) is present, compatibility between the InFix implant and the existing implant(s) should be verified prior to use.
17. Do not mallet the endcap inserter. Malleting or excessive force during use of the Endcap Inserter has the potential to force the Endcap out of the posterior end of the construct and cause permanent injury to the patient.

PRECAUTIONS

1. **THE INFIX ANTERIOR LUMBAR SYSTEM SHOULD ONLY BE USED AFTER THE SPINE SURGEON HAS HAD TRAINING IN THIS METHOD OF FIXATION AND IS THOROUGHLY KNOWLEDGEABLE ABOUT THE SPINAL ANATOMY AND BIOMECHANICS. A SURGICAL TECHNIQUE IS PROVIDED FOR EACH INSTRUMENT SET. THE SURGICAL TECHNIQUE IS NOT A SUBSTITUTE FOR TRAINING AND IS FOR INFORMATIONAL PURPOSES ONLY.**
2. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be re-implanted. Even though the device appears undamaged; it may have small defects and internal stress patterns that may lead to early breakage. A Reuse of a single use device that has contacted blood, bone, tissue or other body fluids may lead to patient or user injury. Additional risks associated with re-use of single use devices include:
 - Mechanical malfunction
 - Transmission of infectious agents
3. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the device. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
5. Patient access shall utilize an anterior approach in accordance with InFix Surgical Technique Guides.
6. Carefully read all instructions and be familiar with the InFix System Surgical Technique Guides prior to use.

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.



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