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SHIELD® VCF SYSTEM

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IMPORTANT INFORMATION ON THE SHIELD® VCF SYSTEM

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ENGLISH **IMPORTANT INFORMATION ON THE SHIELD® VCF SYSTEM**

DESCRIPTION

The SHIELD® VCF System is a single use, minimally invasive set of instruments and implants to treat Vertebral Compression Fracture (VCF) of the spine in conjunction with PMMA bone cement that is FDA-cleared for vertebral augmentation. The System allows a physician to access a fractured vertebral body through a unipedicular approach, prepare the implant site with a manual cavity creation instrument, and implant a cement controlling device within the prepared cavity in bone. The SHIELD® Implant is designed to receive the initial volume of viscous bone cement from an injector device, and then direct the flow of cement anteriorly into the fractured vertebral body. The SHIELD® Implant is preassembled to a delivery system, which facilitates implantation of the device and injection of cement.

The SHIELD® VCF System includes the SHIELD® Access Kit (including 11g Introducer Needle; K-Wire, Blunt; Trocar; Working Channel, and Cavity Creator), the SHIELD® Delivery Kit, and the SHIELD® Curved Cannula.

INDICATIONS FOR USE

The SHIELD® VCF System is intended to provide control of cement flow during injection of PMMA bone cement that has been cleared for use in vertebral augmentation for the treatment of acute, persistently painful (after a minimum of 6 weeks of conservative care), stable, anterior column osteoporotic compression fractures (wedge or concave) of the vertebrae at levels T4 – L5 in the adult spine.

The SHIELD® Curved Cannula is intended for use in the injection of PMMA bone cement into a prepared cavity within the cancellous bone of an osteoporotic vertebral compression fracture during vertebral augmentation.

MATERIALS

The following materials are used in the SHIELD® Implant: braided NiTi alloy; braided polyethylene terephthalate (PET) filament; polycarbonate urethane polymer.

The following materials are required but not provided:
- PMMA bone cement FDA-cleared for vertebral body augmentation
- Cement Mixer
- Cement Injector

CONTRAINDICATIONS

- Burst fractures or any unstable vertebral body fracture.
- Previously resected or augmented vertebral body
- Uncorrectable coagulation disorder or bleeding disorders of any etiology
- Active systemic or local infection
- Pregnancy
- Multiple myeloma
- Paget's disease
- Bone sclerosis due to osteonecrosis (Kummel's Disease) or osteoradionecrosis
- Blastic or mixed forms of metastatic disease or metabolic bone disease presenting with sclerotic lines or lesions
- Spinal canal compromise
- Any vertebral body fracture geometry having a clearance less than 10mm between the endplates along the projected path of the osteotome cutter, verified with biplanar fluoroscopy during cavity creation. Vertebral bodies with less than adequate space to allow for the creation of a 15 mm long cavity.
- Greater than 3 levels needing treatment
- Inability to intra-operatively visualize anatomy under fluoroscopic guidance

WARNINGS

- Single patient use only. Re-sterilization can cause damage to the system and create an infection control risk.
- The SHIELD® Delivery Kit can be used only on a single level.
- The SHIELD® VCF System in conjunction with PMMA bone cement is indicated to treat vertebral fractures secondary to osteoporosis, not fractures due to other etiologies. It is not intended to prevent future complications associated with osteoporosis.
- The SHIELD® VCF System has not been evaluated in patients with vertebral body fracture of etiology other than osteoporosis.
- Anesthetic, cardiovascular system, myocardial infarction, thrombophlebitis, gastrointestinal, pneumonia, operative site dehiscence, excessive bleeding, hematoma, local or systemic infection, abscess and/or foreign body/allergic reaction, respiratory distress and/or death can occur during any interventional procedure.
- Complications such as bone fracture (transverse process, spinous process, pedicle, sternum, ribs, adjacent vertebrae), nerve root compression, osteomyelitis, necrosis, persistent paresthesia, chronic pain, paralysis and/or other neurological complications can occur during vertebral augmentation procedures.
- The SHIELD® VCF System has not been evaluated in patients presenting with sclerotic bone lesions or abnormal calcification of endplate or trabecular bone.
- The SHIELD® VCF System has not been evaluated in patients younger than 49 years old.
- The SHIELD® Implant should not be deployed if the Cavity Creator fails to create an adequate central cavity within the vertebral body, as may occur when attempting to cut non-osteoporotic bone. In these cases, conversion to traditional vertebroplasty is recommended.
- Inability to deliver the device to the intended site may occur with improper use of the SHIELD® VCF System.
- Patients may present with unanticipated progressive vertebral body collapse not having adequate vertebral body volume for cavity creation with the SHIELD® VCF System. In these cases, conversion to traditional vertebroplasty is recommended.

PRECAUTIONS

- Only physicians thoroughly trained in vertebral augmentation procedures and who have undergone training in the techniques specific to the SHIELD® VCF System should use this device.
- Read the Instructions for Use completely before performing the procedure.
- Do not use after the expiration date printed on the package labels.
- Carefully inspect all system components prior to use. Do not use if the sterile package has been damaged, or if there is any indication that any of the system components are damaged or otherwise inoperable.
- As with any surgical procedure, care should be exercised in treating individuals with pre-existing conditions that may affect the success of the surgical procedure.
- Cement volume used to achieve fracture fixation will change based on individual anatomy and should be determined by the user at the time of procedure.

ADVERSE EFFECTS

Possible adverse effects include but are not limited to:
- Dural injury
- Embolism
- Cement extravasation resulting in neurologic complication
- Vascular injury
- Retreatment
- Refracture
- Incomplete cement fill
- Malpositioned implant
- Pneumothorax or hemothorax
- Infection including deep or superficial wound infection
- Hemorrhage
- Hematoma
- Broken sheath in vertebral body
- Other: See manufacturers labeling for contraindications of the PMMA selected for treatment.

CLINICAL STUDY

Clinical testing consisted of a pilot study and a prospective randomized study using vertebroplasty as the control device. All subjects were diagnosed with osteoporotic compression fractures that had undergone conservative care for a minimum of 6 weeks or had been hospitalized for pain. A total of 69 subjects and 102 levels were treated with the SHIELD® VCF System and 28 subjects and 38 levels were treated with the control device. Pain and functional testing demonstrated equivalent initial improvements and sustained benefits out to one year. The SHIELD® VCF System showed less asymptomatic leaks than the control (vertebroplasty). For the SHIELD® device adverse events included; death, adjacent and distant level fractures, incomplete filling, refracture and retreatment of the treated levels while the control exhibited; death, adjacent and distant level fractures, and, refracture of a treated level.

Overall Demographics and Covariate Information (per-subject)

	Pilot	Randomized		
	SHIELD® VCF SYSTEM	SHIELD® VCF SYSTEM	Control	Overall
Subjects Treated	20	49	28	77
Sex				
N (Data Available)	20	49	28	77
Female	17 (85.0%)	36 (73.5%)	19 (67.9%)	55 (71.4%)
Male	3 (15.0%)	13 (26.5%)	9 (32.1%)	22 (28.5%)
Activity Level				
N (Data Available)	NA	49	28	77
Minimal		6 (12.2%)	4 (14.3%)	10 (13.0%)
Light		16 (32.7%)	8 (28.6%)	24 (31.2%)
Moderate		20 (40.8%)	9 (32.1%)	29 (37.7%)
High		7 (14.3%)	7 (25.0%)	14 (18.2%)
Smoking Status				
N (Data Available)	NA	48	27	75
Never		26 (54.2%)	18 (66.7%)	44 (58.7%)
Prior		11 (22.9%)	5 (18.5%)	16 (21.3%)
Present		11 (22.9%)	4 (14.8%)	15 (20.0%)
Age				
N (Data Available)	20	49	28	77
Mean (Std Dev)	69.1 (8.1)	71.6 (10.3)	73.6 (11.5)	72.3 (10.7)
Median	70.5	73.0	78.0	74.0
Range	(51, 85)	(49, 93)	(51, 89)	(49, 93)
Height				
N (Data Available)	20	49	26	75
Mean (Std Dev)	151.7 (7.6)	165.7 (7.6)	165.2 (10.0)	165.5 (8.5)
Median	150.5	166.0	163.0	165.0
Range	(141, 165)	(150, 182)	(150, 186)	(150, 186)
BMI				
N (Data Available)	20	49	25	74
Mean (Std Dev)	25.6 (4.3)	25.0 (3.4)	24.5 (3.8)	24.9 (3.5)
Median	24.7	25.3	24.1	24.6
Range	(19.2, 35.0)	(17.7, 31.1)	(19.8, 38.9)	(17.7, 38.9)

Overall Demographics and Covariate Information by SHIELD® Implant Size (per-subject)

	Pilot		Randomized		
	Size 15	Size 20	Size 15	Size 20	Size 25
Subjects Treated (Note: Could add up to more than the total number of subjects, since a subject could receive both a 15 and 20)	11	11	21	32	1
Sex					
N (Data Available)	11	11	21	32	1
Female	10 (90.9%)	8 (72.7%)	18 (85.7%)	20 (62.5%)	1 (100.0%)
Male	1 (9.1%)	3 (27.3%)	3 (14.3%)	12 (37.5%)	0 (0.0%)
Activity Level					
N (Data Available)	NA	NA	21	32	1
Minimal			3 (14.3%)	4 (12.5%)	0 (0.0%)
Light			3 (14.3%)	15 (46.9%)	0 (0.0%)
Moderate			11 (52.4%)	9 (28.1%)	1 (100.0%)
High			4 (19.1%)	4 (12.5%)	0 (0.0%)
Smoking Status					
N (Data Available)	NA	NA	20	31	1
Never			8 (40.0%)	17 (54.8%)	1 (100.0%)
Prior			5 (25.0%)	8 (25.8%)	0 (0.0%)
Present			7 (35.0%)	6 (19.4%)	0 (0.0%)
Age					
N (Data Available)	11	11	21	32	1
Mean (Std Dev)	66.7 (8.1)	70.4 (10.3)	70.9 (10.2)	71.9 (10.3)	70.0 (-)
Median	67.0	73	72.0	73.0	70.0
Range	(51, 83)	(51, 85)	(54, 93)	(49, 87)	.
Height					
N (Data Available)	11	11	21	32	1
Mean (Std Dev)	150.9 (7.3)	152.1 (8.5)	166.0 (8.1)	166.5 (7.5)	157.0 (-)
Median	150.0	154	166.0	166.0	157.0
Range	(142, 165)	(141, 164)	(151, 180)	(150, 182)	.
BMI					
N (Data Available)	11	11	21	32	1
Mean (Std Dev)	26.5 (4.6)	24.3 (3.5)	25.2 (3.4)	24.8 (3.2)	25.6 (-)
Median	24.4	23.6	25.6	25.0	25.6
Range	(21.2, 35.0)	(19.2, 29.9)	(18.1, 30.0)	(17.7, 31.1)	.

Overall Treatment Breakdown by Site & Fracture-Type (per-level)

	Pilot	Randomized		
	SHIELD® VCF SYSTEM	SHIELD® VCF SYSTEM	Control	Overall
Levels Treated	37	65	38	103
Fracture Type				
N (Data Available)	36	65	38	103
Concave	20 (55.6%)	48 (73.9%)	28 (73.7%)	76 (73.8%)
Planar	0 (0.0%)	2 (3.1%)	1 (2.6%)	3 (2.9%)
Wedge	16 (44.4%)	15 (23.1%)	9 (23.7%)	24 (23.3%)
Fracture Grade				
N (Data Available)	36	65	38	103
Grade 1	10 (27.8%)	28 (43.1%)	11 (29.0%)	39 (37.9%)
Grade 2	26 (72.2%)	37 (56.9%)	27 (71.1%)	64 (62.1%)
Fracture Type				
N (Data Available)	36	65	38	103
Anterior	36 (100.0%)	64 (98.5%)	38 (100.0%)	102 (99.0%)
A/M	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (1.0%)
Fracture Level				
N (Data Available)	37	65	38	103
T4	2 (5.4%)	1 (1.5%)	0 (0.0%)	1 (1.0%)
T5	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T6	1 (2.7%)	1 (1.5%)	0 (0.0%)	1 (1.0%)
T7	1 (2.7%)	2 (3.1%)	1 (2.6%)	3 (2.9%)
T8	1 (2.7%)	2 (3.1%)	1 (2.6%)	3 (2.9%)
T9	2 (5.4%)	1 (1.5%)	2 (5.3%)	3 (2.9%)
T10	3 (8.1%)	0 (0.0%)	2 (5.3%)	2 (1.9%)
T11	4 (10.8%)	4 (6.2%)	2 (5.3%)	6 (5.8%)
T12	4 (10.8%)	9 (13.9%)	7 (18.4%)	16 (15.5%)
L1	7 (18.9%)	16 (24.6%)	10 (26.3%)	26 (25.2%)
L2	5 (13.5%)	9 (13.9%)	7 (18.4%)	16 (15.5%)
L3	2 (5.4%)	6 (9.2%)	4 (10.5%)	10 (9.7%)
L4	3 (8.1%)	9 (13.9%)	2 (5.3%)	11 (10.7%)
L5	1 (2.7%)	5 (7.7%)	0 (0.0%)	5 (4.9%)

Treatment Breakdown by Site, SHIELD® Implant Size & Fracture Type (per-level)

	Pilot		Randomized		
	Size 15	Size 20	Size 15	Size 20	Size 25
Levels Treated	17	19	26	38	1
Fracture Type					
N (Data Available)	16	19	26	38	1
Concave	9 (56.3%)	11 (57.9%)	19 (73.1%)	28 (73.7%)	1 (100.0%)
Planar	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.3%)	0 (0.0%)
Wedge	7 (43.8%)	8 (42.1%)	7 (26.9%)	8 (21.1%)	0 (0.0%)
Fracture Grade					
N (Data Available)	16	19	26	38	1
Grade 1	6 (37.5%)	4 (21.1%)	6 (23.1%)	22 (57.9%)	0 (0.0%)
Grade 2	10 (62.5%)	15 (79.0%)	20 (76.9%)	16 (42.1%)	1 (100.0%)
Fracture Type					
N (Data Available)	16	19	26	38	1
Anterior	16 (100.0%)	19 (100.0%)	25 (96.1%)	38 (100.0%)	1 (100.0%)
A/M	0 (0.0%)	0 (0.0%)	1 (3.9%)	0 (0.0%)	0 (0.0%)
Fracture Level					
N (Data Available)	17	19	26	38	1
T4	1 (5.9%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)
T5	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T6	1 (5.9%)	0 (0.0%)	1 (3.9%)	0 (0.0%)	0 (0.0%)
T7	1 (5.9%)	0 (0.0%)	2 (7.7%)	0 (0.0%)	0 (0.0%)
T8	0 (0.0%)	1 (5.3%)	2 (7.7%)	0 (0.0%)	0 (0.0%)
T9	2 (11.8%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)
T10	1 (5.9%)	2 (10.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T11	1 (5.9%)	3 (15.8%)	1 (3.9%)	3 (7.9%)	0 (0.0%)
T12	2 (11.8%)	2 (10.5%)	4 (15.4%)	5 (13.2%)	0 (0.0%)
L1	2 (11.8%)	5 (26.3%)	9 (34.6%)	7 (18.4%)	0 (0.0%)
L2	2 (11.8%)	3 (15.8%)	4 (15.4%)	5 (13.2%)	0 (0.0%)
L3	1 (5.9%)	1 (5.3%)	2 (7.7%)	4 (10.5%)	0 (0.0%)
L4	1 (5.9%)	2 (10.5%)	0 (0.0%)	9 (23.7%)	0 (0.0%)
L5	1 (5.9%)	0 (0.0%)	1 (3.9%)	3 (7.9%)	1 (100.0%)

Cement Leakage Data by Site & SHIELD® Implant Size Within 24 Hours After Treatment (per-subject)

	Pilot			Randomized			
	Size 15	Size 20	Combined	Size 15	Size 20	Size 25	Combined
Combined							
N (Data Available)	17	19	37	26	38	1	65
Mean (Std Dev)	0.18 (0.39)	0.32 (0.48)	0.24 (0.43)	0.54 (0.58)	0.74 (0.98)	0.00 (0.00)	0.65 (0.84)
Median	0.00	0.00	0.00	0.50	0.00	0	0.00
Range	(0, 1)	(0, 1)	(0, 1)	(0, 2)	(0, 4)	(0, 0)	(0, 4)
Type B							
N (Data Available)	17	19	37	26	38	1	65
Mean (Std Dev)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.04 (0.20)	0.18 (0.39)	0.0 (0.0)	0.12 (0.33)
Median	0	0	0	0	0	0	0
Range	(0, 0)	(0, 0)	(0, 0)	(0, 1)	(0, 1)	(0, 0)	(0, 1)
Type C							
N (Data Available)	17	19	37	26	38	1	65
Mean (Std Dev)	0.06 (0.24)	0.26 (0.45)	0.16 (0.37)	0.38 (0.57)	0.13 (0.34)	0.00 (0.00)	0.23 (0.46)
Median	0	0	0	0	0	0	0
Range	(0, 1)	(0, 1)	(0, 1)	(0, 2)	(0, 1)	(0, 0)	(0, 2)
Type S							
N (Data Available)	17	19	37	26	38	1	65
Mean (Std Dev)	0.12 (0.33)	0.05 (0.23)	0.08 (0.28)	0.12 (0.33)	0.42 (0.76)	0.00 (0.00)	0.29 (0.63)
Median	0	0	0	0	0	0	0
Range	(0, 1)	(0, 1)	(0.0, 0.0)	(0, 1)	(0, 3)	(0, 0)	(0, 3)

Number of Leaks Within 24 Hours after Treatment – Randomized Study
Concave Fractures only (per-level)

	SHIELD® VCF SYSTEM		Control		p-value
	Mean	95% CI	Mean	95% CI	Wilcoxon Test
Number of Levels Assessed	N=48		N=28		
Number of Leaks Per Level	0.67	(0.41, 0.92)	1.61	(1.09, 2.13)	0.0015
Number of Type B Leaks Per Level	0.10	(0.01, 0.19)	0.29	(0.11, 0.46)	0.0449
Number of Type C Leaks Per Level	0.27	(0.13, 0.41)	0.75	(0.44, 1.06)	0.0032
Number of Type S Leaks Per Level	0.29	(0.10, 0.48)	0.57	(0.27, 0.88)	0.0754

Two-tailed Wilcoxon test with pooled variances assesses whether there is a significant treatment difference

	SHIELD® VCF SYSTEM	Control	Wilcoxon Test p-value
Number of Leaks Per Level			0.0015
N (Data Available)	48	28	
Mean (Std Dev)	0.67 (0.88)	1.61 (1.34)	
Median	0.00	1.00	
Interquartile Range	(0.00, 1.00)	(0.50, 3.00)	
Range	(0, 4)	(0, 4)	
95% Confidence Interval	(0.41, 0.92)	(1.09, 2.13)	

Two-tailed Wilcoxon test with pooled variances assesses whether there is a significant treatment difference.

Number of Leaks Within 24 Hours after Treatment – Randomized Study
Wedge Fractures only (per-level)

	SHIELD® VCF SYSTEM		Control		p-value
	Mean	95% CI	Mean	95% CI	Wilcoxon Test
Number of Levels Assessed	N=15		N=9		
Number of Leaks Per Level	0.67	(0.27, 1.07)	0.89	(0.43, 1.35)	0.3925
Number of Type B Leaks Per Level	0.20	(-0.03, 0.43)	0.44	(0.04, 0.85)	0.2260
Number of Type C Leaks Per Level	0.13	(-0.06, 0.33)	0.11	(-0.15, 0.37)	0.9172
Number of Type S Leaks Per Level	0.33	(-0.01, 0.68)	0.33	(-0.21, 0.88)	0.9060

Two-tailed Wilcoxon test with pooled variances assesses whether there is a significant treatment difference.

	SHIELD® VCF SYSTEM	Control	Wilcoxon Test p-value
Number of Leaks Per Level			0.3925
N (Data Available)	15	9	
Mean (Std Dev)	0.67 (0.72)	0.89 (0.60)	
Median	1.00	1.00	
Interquartile Range	(0.00, 1.00)	(1.00, 1.00)	
Range	(0, 2)	(0, 2)	
95% Confidence Interval	(0.27, 1.07)	(0.43, 1.35)	

Two-tailed Wilcoxon test with pooled variances assesses whether there is a significant treatment difference

VAS Pain Score Data by Site & SHIELD® Implant Size (per-subject)

	Pilot			Randomized			
	Size 15	Size 20	Combined	Size 15	Size 20	Size 25	Combined
Pre-op							
N (Data Available)	12	11	20	21	32	1	49
Mean (Std Dev)	7.8 (1.5)	8.8 (1.0)	8.20 (1.40)	8.4 (1.1)	8.4(1.1)	7.8	8.31 (1.12)
Median	8	9	8	8.0	8.6		8.2
Range	(5, 10)	(7, 10)	(5.0, 10.0)	(6,10)	(5.9,10)		(5.9, 10.0)
Post-op							
N (Data Available)	12	11	20	21	32	1	49
Mean (Std Dev)	2.9 (2.1)	2.5 (2.2)	2.85 (2.13)	1.9 (2.5)	1.5 (1.8)	6	1.77 (2.16)
Median	3	2	3	1.0	0.8		1.3
Range	(0, 6)	(0, 6)	(0.0, 6.0)	(6,10)	(0,6.2)		(0.0, 10.0)
3 Month							
N (Data Available)	11	11	19	16	25	1	37
Mean (Std Dev)	3.0 (2.5)	2.5 (2.1)	3.00 (2.36)	1.2 (2.2)	1.4 (2.1)	8	1.64 (2.41)
Median	3	2	3	0	0.4		0.4
Range	(0, 8)	(0, 6)	(0.0, 8.0)	(0,6.5)	(0,6.7)		(0.0, 8.0)
12 month							
N (Data Available)	10	10	17	14	18		28
Mean (Std Dev)	2.3 (1.4)	2.6 (2.2)	2.53 (1.94)	2.2 (3.1)	1.2 (2.1)		1.84 (2.69)
Median	2	2	2	0.9	0.1		0.4
Range	(0, 5)	(0, 7)	(0.0, 7.0)	(0,8)	(0,7.1)		(0.0, 8.0)

Disability Data by Site & SHIELD® Implant Size (per-subject)

	Pilot			Randomized			
	Size 15	Size 20	Combined	Size 15	Size 20	Size 25	Combined
Function	Roland Morris Questionnaire			Oswestry Disability Index			
Pre-op							
N (Data Available)	12	11	20	21	32		49
Mean (Std Dev)	21.2 (4.3)	22.8 (1.6)	21.8 (3.5)	73.7 (17.2)	79.1 (12.2)	1	76.0 (15.1)
Median	23	24	23	76	81	56	78
Range	(9, 24)	(20, 24)	(9, 24)	(38,96)	(30,96)		(30, 96)
3 Month							
N (Data Available)	11	11	19	16	24	1	36
Mean (Std Dev)	11.6 (6.3)	11.3 (6.0)	12.1 (5.9)	10.6 (16.5)	12.3 (17.4)	88	14.7 (21.3)
Median	10	13	13	2	3		4
Range	(4, 22)	(4, 21)	(4, 22)	(0,50)	(0,62)		(0, 88)
12 month							
N (Data Available)	10	10	17	14	18		28
Mean (Std Dev)	8.1 (4.0)	9.1 (4.1)	9.1 (3.4)	16.0 (20.9)	12.8 (21.2)		15.9 (21.8)
Median	8	10.5	10	5	1		4
Range	(0, 13)	(0, 13)	(0, 13)	(0,56)	(0,62)		(0, 62)

Adverse Event Comparison – Pilot and Randomized studies

	SHIELD® VCF System		Control Procedure
	Pilot	Randomized	Randomized
Subjects Treated (n)	20	49	28
Final Adjudicated Adverse Events (n)	14	62	58
Subjects Involved in at Least 1 AE of Any Kind (n (%))[a]	12 (60.0%)	36 (73.5%)	26 (92.9%)
Asymptomatic Leak-Related AE's (n)	9	38	45
Subjects Involved in at Least 1 Leak AE (n (%))[a]	7 (35.0%)	28 (57.1%)	25 (89.3%)
Non-Leak Related AE's (n)	5	24	13
Subjects Involved in at Least 1 Non-Leak AE (%))[a]	5 (25.0%)	16 (32.7%)	9 (32.1%)
AE's Attributed to Device or Procedure (n)	0 (0.0%)	0 (0.0%)	1 (1.7%)

[a] n =number of AE's; (%) = % of all subjects for the treatment group

Description of All Adjudicated Non-Leak Adverse Events

Adverse Event Description	SHIELD® VCF SYSTEM Adverse Events (n)		Control Adverse Events (n)
	Pilot	Randomized	Randomized
Non Study-Related Medical Conditions	**2**	**10**	**7**
Post-operative hernia	0	1	0
Gluteal fistula / prolonged hospitalization	0	1	0
Prostate biopsy	0	1	0
Bilateral orchidectomy	0	1	0
Gallstones	0	1	0
Cholycystectomy	0	1	0
Esophagitis	0	1	0
Pneumonia	0	1	0
Leukemia	0	1	0
Pt wheelchair-bound due to pre-existing neurological condition affecting the legs	0	1	0
Cardiac valve reconstruction	0	0	1
Osteomyelitis	0	0	1
Superior mesenteric artery occlusion	0	0	2[a]
Apoplexia	0	0	1
Anemia	0	0	1
Intestinal ischemia	0	0	1
Knee pain	1	0	0
Surgical hardware placement to correct pre-existing spinal deformity at distant levels	1	0	0
Death	**3**	**4**	**2**
Prostate Cancer	1	0	0
Cancer – unknown type	1	0	0
Leukemia	1	0	0
Unknown causes	0	3	0
Cardiac disease	0	1	0
Post-procedure heart attack[b]	0	0	1
Death following hip surgery	0	0	1
VB fractures at levels other than the study-treated level(s)	0	5	3
Distant level fractures	0	3	2
Adjacent level fractures	0	2	1
Re-treatment of a study-treated VB	0	3	0
Re-treatment due to re-fractured VB	0	2	0
Re-treatment for insufficient cement fill / malpositioned implant[c]	0	1	NA (no implant)
Re-fracture of a study-treated VB without subsequent retreatment	**0**	**2**	**1**
Total AE's	**5**	**24**	**13**

[a] Two separate events for the same condition applied to 12 subjects
[b] IPA determined that this death was most likely due to overall surgical or general anesthetic stresses on the patient
[c] Implant adjudicated to be positioned correctly by the IPA / film reviewer

STERILITY
All components of the SHIELD® VCF System are provided sterile. The components of this system have been sterilized by ethylene oxide (ETO) sterilization.
- Sterility is guaranteed only if the sterile trays are unopened and not damaged.
- The SHIELD® VCF System must not be re-sterilized.

DIRECTIONS FOR USE

TECHNIQUE PRECAUTIONS:
1. Proper positioning and size selection of the SHIELD® Implant is critical to achieving a stable fracture. The distal tip of the SHIELD® Implant should cross the mid line of vertebral body in both the A/P and lateral views to ensure proper stabilization of the fracture.
2. Proper SHIELD® Implant sizing should be determined intra-operatively while evaluating available space within the cortical confines of the vertebral level being treated.

PROCEDURAL STEPS
Step 1: Patient Preparation and Positioning
- The SHIELD® VCF System is intended for use in a posterior percutaneous surgical procedure by a unilateral approach.
- The pedicles should be large enough to accommodate the Working Channel (WC) which has a 4.2 mm diameter.
- Dependent on the anatomy of the patient's vertebral body, either a transpedicular or extrapedicular approach can be used. The transpedicular approach is typically used from T11 to L5 and the extrapedicular approach is used from T4 to T10. The approach chosen is dependent on both level and anatomy of the vertebral body. Bi-planar imaging is recommended for this procedure.
- Determine correct surgical site by identifying the fractured vertebra with the use of intra-operative imaging in correlation with preoperative imaging studies.
- Proper positioning with pads or other table assisted support mechanisms will maximize the potential for postural reduction of the vertebral body.

Step 2: Initial Procedural Access
1. Using dual C-arm technique, place the 11 gauge Introducer Needle into the vertebral body following a lateral to medial placement while centering the needle parallel to and between the VB endplates (Figure 6.) After needle placement, remove the stylet and replace with the K-wire. Remove needle.
2. Place the WC over the K-wire using the directional markers on the device for proper medial orientation (Figure 7). Using lateral fluoroscopic guidance, tap blue strike surface of WC (Figure 8), with mallet until the distal tip of the cannula portion of the WC is anchored within the vertebral body approximately 3-10 mm beyond the posterior wall. This depth is dependent upon the anatomy of the vertebral body being treated. Remove the K-wire.
3. Check medial arrow on the WC to ensure it is oriented toward the patient sagittal midline (Figure 9). Press blue release button on the end of the WC handle and remove the Trocar leaving the WC in place (Figure 10).

PRECAUTION: Once the Working Channel is at the desired depth, ensure established depth and orientation of the Working Channel is maintained at all times during the procedure. Particular vigilance should be exercised when inserting, locking, or removing components.

Locking Instruction: Advance all system devices into the WC, aligning the key to the slot, and stop when the device locks in place or when an audible click is heard. To unlock the system devices from the WC, press in the blue button on the end of the WC and withdraw the device (Figure 10). Pressing the blue button will always result in the release of the inserted device.

Step 3: Create Cavity and Device Sizing
NOTE: Figure 1 describes the Cavity Creator and its parts.
1. Check Cavity Creator markings to confirm that the slide indicator and knob are in the start positions ("D" for Drill), as shown in (Figure 11).
2. Insert Cavity Creator into the WC:
   a) Disengage tension of Cavity Creator curve by squeezing buttons on side of tool (Figure 12).
   b) Insert Cavity Creator into the WC aligning key with slot and continue advancing until Cavity Creator locks into WC or audible click is heard (Figure 13). Release buttons.

NOTE: The position of the path and cavity created by the Cavity Creator may be adjusted by rotating the WC prior to initiating cutting function. For proper cavity positioning, the degree of rotation will vary with WC depth, anatomy and angle of access (Figure 14).

Warning: Use of the Cavity Creator is not recommended in non-osteoporotic or calcified bone, which may limit the Cavity Creator's ability to drill a pathway and create a central cavity. In this situation a conversion to vertebroplasty is recommended.

3. Secure WC with one hand and rotate Cavity Creator handle clockwise with opposite hand to advance cutting blade. (Figure 15)
   a) Final position should be determined by distal tip proximity to medial portion of contralateral pedicle on A/P, and proximity (less than 5 mm) to anterior VB wall on lateral view. When nearing one of these two landmarks stop at the appropriate size (15 mm, 20 mm and 25 mm) (Table 1) as listed on the numerical scale on the side of the Cavity Creator handle (Figure 16).
4. Once desired depth position is achieved, press white button and dial knob to the desired cavity diameter; 7 mm or 10 mm (Figure 17). This will engage blade for cavity creation:
   a) Adequate space between the device and vertebral body endplates is required on either side of the Cavity Creator for blade deployment. Amount of space available, determined during intra-operative imaging, will dictate the user's selection of cavity diameter.
5. To create the cavity, secure the WC with one hand and rotate handle of Cavity Creator ***counterclockwise***. (Figure 18) An audible clicking should be heard.
   a) Confirm with fluoroscopic imaging that the cutting blade is open during rotation.
   b) Cavity will be created as the open blade rotates and moves back toward the distal tip of the WC.

NOTE: Device prevents clockwise rotation when dial is turned to 7 or 10.
NOTE: Blade may not open to full extent when the device is positioned within high density bone.

PRECAUTION: Proper positioning and fluoroscopic monitoring will confirm that cutting blade is within the cortical margins and endplates during cavity formation. Improper positioning can result in damage to cortical structures.

6. Cavity creation is complete when the slide indicator on the Cavity Creator reaches the top of the triangle marking on the cavity creating diagram. (Figure 19)
7. Dial knob back to position shown in (Figure 20).
8. Continue ***counterclockwise*** rotation of the Cavity Creator handle (Figure 21) until slide indicator has reached the position shown in (Figure 22).

PRECAUTION: Do not make attempts to change orientation of the system while distal tip of the Cavity Creator is exposed beyond the distal tip of the working channel. Failure to maintain rotational orientation may damage the Cavity Creator.

9. Remove Cavity Creator by pressing blue lock button on the WC with one hand while squeezing the buttons on the side of the Cavity Creator (Figure 23) and pulling it out of the WC.

Step 4: SHIELD® Implant Delivery
1. Sheath the SHIELD® Implant:
   a) Hold the base of SHIELD® Delivery Kit handle with one hand and rotate the handle counterclockwise until it comes to a stop (Figure 24).
   b) Remove plastic funnel as shown in (Figure 25).
2. Push top cap until it mates with handle.
3. Insert SHIELD® Delivery Kit into WC:
   a) Secure the WC manually and gently engage 3-5mm of the flexible distal tip of the sheathed SHIELD® Delivery Kit into the WC opening. The SHIELD® Delivery Kit handle axis will be oriented approximately 45 degrees to the WC at this point.
   b) Advance the SHIELD® Delivery Kit down the WC while simultaneously rotating the SHIELD® Delivery Kit vertically to align with the WC.
   c) Align the key of the SHIELD® Delivery Kit with slot of the WC and continue to advance until the SHIELD® Delivery Kit locks into WC.

PRECAUTION: Do not forcibly bend the SHIELD® Delivery Kit sheath before or during insertion, or alter the curve of the flexible tip in any way prior to insertion into the Working Channel, as this may result in damage to the sheath or SHIELD® Implant.

PRECAUTION: The SHIELD® Delivery Kit sheath normally slides easily within the cavity in the vertebral body. The User should be aware that bone fragments or Working Channel misalignment may preclude full advancement of the SHIELD® Delivery Kit. Do not force the distal end of the SHIELD® Delivery Kit into the bone if interference is encountered. Remove the SHIELD® Delivery Kit from the Working Channel, and reinsert the Cavity Creator to recut the cavity.

NOTE: The radiopaque tip at the end of the SHIELD® Implant can be checked to confirm proper implant placement.

NOTE: The anterior direction of the holes of the SHIELD® Implant in vivo is assured by the proper orientation of the WC. In order to maintain proper orientation of the SHIELD® Implant, the SHIELD® Delivery Kit should not be moved once the SHIELD® Implant is located within the vertebral body.

4. Un-sheath SHIELD® Implant by securing WC with one hand and rotating handle of SHIELD® Delivery Kit clockwise until it stops. Ensure blue lines on base of handle match up. (Figure 26).

NOTE: Lateral and AP fluoroscopic views will show the SHIELD® Implant expansion.

5. Remove the top cap (Figure 27).

Step 5: Cement Injection
1. Mix the PMMA following the manufacturer's Instruction for Use.
2. Fill cement into the selected cement injector.
3. When a high viscosity cement is achieved, attach cement injector to the SHIELD® Delivery Kit at the luer lock interface (Figure 28).

NOTE: The bone cement reaches a high viscosity when the proximal end of the cement injector luer portal is held 7.5 cm above the surgical table and upon injection the bone cement forms a continuous string of cement of constant diameter.

PRECAUTION: Follow cement Instructions for Use to determine proper consistency of PMMA for fracture treatment. Environmental factors, such as temperature, may affect the time/viscosity profile of PMMA. The physician should have experience with the approved PMMA selected to understand the effects of these factors intra-operatively. Any PMMA approved for vertebral augmentation may be used with the SHIELD® VCF System.
PRECAUTION: Confirm that the SHIELD® Implant is unsheathed using fluoroscopic imaging prior to starting the injection of the PMMA.

4. Inject cement into the SHIELD® Implant using fluoroscopic guidance until SHIELD® Implant is filled; see (Table 1) for volumes.
5. Inject additional cement while fluoroscopically monitoring flow through the holes and into the anterior aspect of the vertebral body. Continue to inject cement until sufficient fill is achieved as determined by the physician.
6. Remove cement injector from luer lock.
7. If additional cement is desired, the Cement Pusher may be inserted and advanced into the SHIELD® Delivery Kit to clear SHIELD® Delivery Kit chamber which will inject up to an additional 1 mL of cement. (Figure 29)

PRECAUTION: The SHIELD® Implant is intended to direct the flow of cement. It is not designed or intended to fully contain the injected cement.

WARNING: The SHIELD® Implant, once filled with bone cement, must remain implanted. Do not make any attempts to remove the SHIELD® Implant from the vertebral body once filled as this may result in patient injury and/or failure of the device to perform as intended.

Step 6: SHIELD® Implant Release
1. Release the SHIELD® Implant from the SHIELD® Delivery Kit:
   a) Press in blue release buttons and slide proximally until the buttons come to a stop (Figures2-5, 30).
   b) Allow for cement cure, following the manufacturers labeling, before proceeding to next step.
   c) Rotate the entire system 360° and remove from the patient.

Alternate Step 4-6: SHIELD® Curved Cannula Insertion and Cement Injection (if not using SHIELD® Implant)
1. Grasp the curved section of the cannula shaft and insert the distal end of the Curved Cannula into the WC. Advance slowly within the WC. The curved cannula will straighten within the WC tube as it advances.
2. The Curved Cannula has medial markings on the body (Figure 1). Rotate and align the medial markings with the markings on the WC prior to locking to the WC, and advance to lock.

NOTE: Insertion is complete when the medially oriented working channel tab engages the pocket in the device. An audible click will be heard. To unlock the Curved Cannula from the WC, press in the blue button on the lateral side of the WC and withdraw the device. Pressing the blue button will always result in the release of the inserted device.

3. Once locked into the WC, use fluoroscopic visualization and slide the depth adjuster (Figure 1) to position the Curved Cannula towards the distal end of the cavity.
4. Mix selected PMMA bone cement according to the manufacturer's Instructions for Use.
5. When desired consistency of the PMMA has been achieved, attach the cement injector (male luer lock required) to the proximal end of the female luer lock connection.
6. Inject cement into the cavity created using a retrograde fill. The depth adjuster can be moved throughout the procedure to allow for uniform dispersion of PMMA throughout the vertebral body.
7. Fluoroscopic guidance should be used during injection to monitor cement flow.
8. Adequate cement should be injected into the vertebral body to provide fracture stabilization. Final cement volume will be determined by the physician.
9. Remove the Curved Cannula and cement injector from WC.
10. Insert Trocar from Cavity Creator into WC then remove WC from patient.

PRECAUTION: Follow cement Instructions for Use to determine proper consistency of PMMA for treatment.

PRECAUTION: After use, dispose of all instruments according to institutional procedures; failure to do so may result in an infection control risk.

CONTACT INFORMATION
Algea Therapies may be contacted at 1-855-639-6612. A surgical technique manual may be obtained by contacting Algea Therapies.

Storage: This product must be stored in a cool dry place.

This product and /or its use may be protected in whole or in part by the following U.S. patent US7,465,318 B2. Other U.S. patents pending.

KEY TO SYMBOLS USED			
REF	CATALOGUE NUMBER	STERILE EO	ETHYLENE OXIDE STERILIZED
LOT	LOT NUMBER	EC REP	EC REPRESENTATIVE
⚠	ATTENTION, SEE INSTRUCTIONS FOR USE	MR	MR CONDITIONAL
⌛	USE BY	Rx ONLY	CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.
⊘	SINGLE USE DEVICE: DO NOT REUSE	QTY	QUANTITY

MRI Information. The SHIELD® VCF System – SHIELD® Implant was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the SHIELD® VCF System – SHIELD® Implant is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
-Static magnetic field of 3-Tesla or less
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating
In non-clinical testing, the SHIELD® VCF System – SHIELD® Implant produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6°C

Therefore, the MRI-related heating experiments for the SHIELD® VCF System – SHIELD® Implant at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the SHIELD® VCF System – SHIELD® Implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	431-mm²	280-mm²	890-mm²	478-mm²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

FIGURES

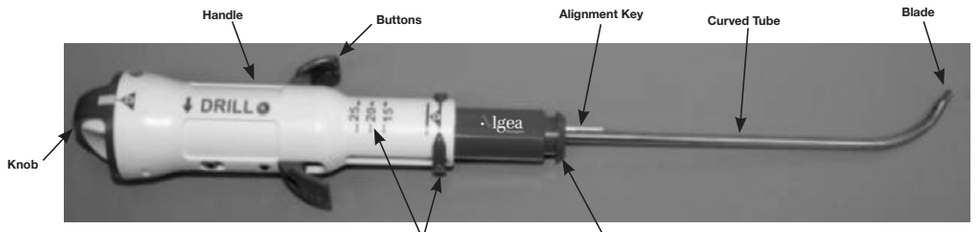


Figure 1: Cavity Creator

Figure 2: Detail of the distal end of the inner and outer hypotubes. The inner hypotube has a flared distal end and slightly reduced outer diameter.

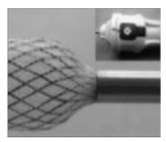


Figure 3: SHIELD® Implant in the locked (mounted) position. The outer hypotube is pressing the Implant against the flared inner tube.

Figure 4: The release button is partially retracted, which begins to uncover the implant tail.

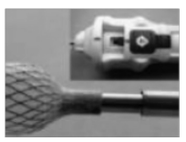


Figure 5: The outer hypotube is fully retracted. The implant tail is no longer captured by the outer hypotube, allowing release of the implant from the Delivery System.

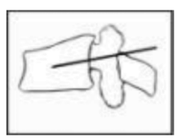


Figure 6

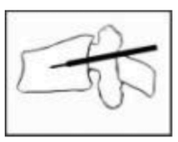


Figure 7

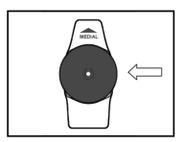


Figure 8

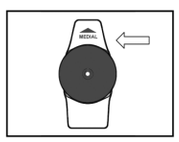


Figure 9

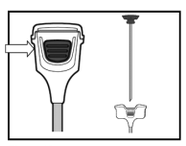


Figure 10

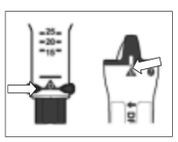


Figure 11

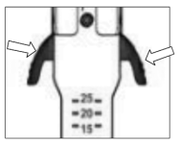


Figure 12

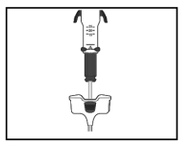


Figure 13

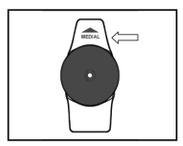
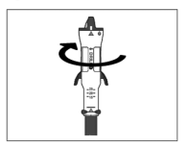


Figure 14



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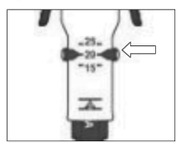

Figure 16

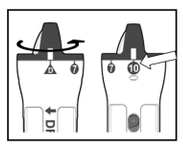

Figure 17

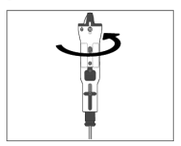

Figure 18

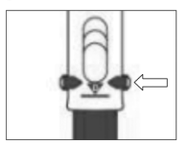

Figure 19

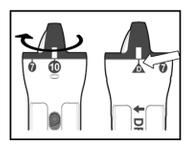

Figure 20

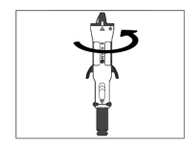

Figure 21

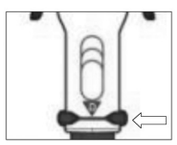

Figure 22

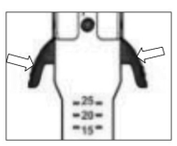

Figure 23

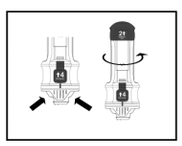

Figure 24

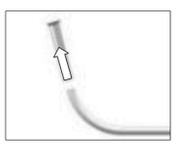

Figure 25

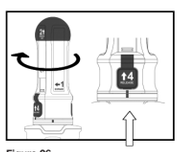

Figure 26

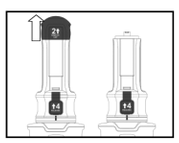

Figure 27

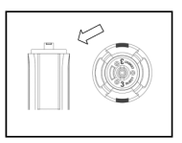

Figure 28

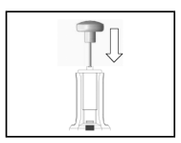

Figure 29

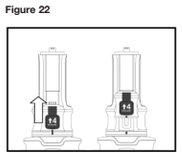

Figure 30

Drill Markings	SHIELD® Implant Size	Volume
15	10 x 15 mm	1.9 mL
20	10 x 20 mm	2.3 mL
25	10 x 25 mm	2.7 mL

Table 1