

OVERFIX[®]

SPINE

SURGICAL TECHNIQUE

COALES-XL Interbody Fusion Cage

bioadvance

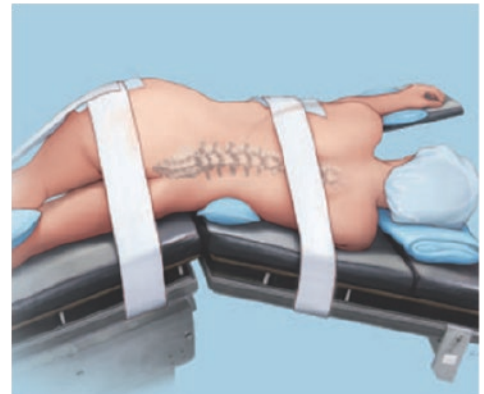
DISPOSITIVOS MÉDICOS



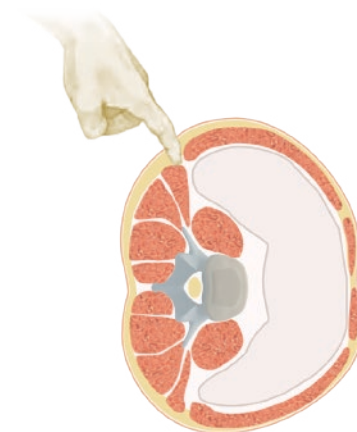
COALES-XL Interbody Fusion Cage

1. PATIENT POSITIONING AND EXPOSURE

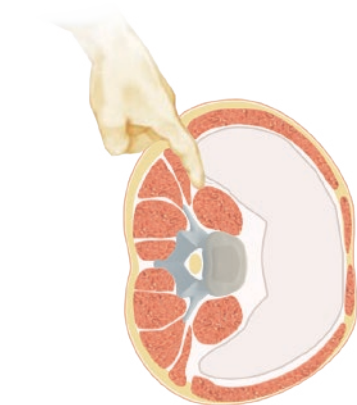
Place the patient in a lateral decubitus position. A bolster placed underneath the hip, to aid in opening the space between the twelfth rib and iliac crest, is recommended. It is also recommended to flex the table, to aid in opening the space between the twelfth rib and iliac crest. Ensure that the rotational alignment is correct. Secure the patient to the table.



Locate the correct operative level and incision with fluoroscopic views. Make a skin incision targeting the anterior third of the intervertebral disc space.



Once the skin incision is made and the subcutaneous tissue is taken down, the oblique muscles of the abdomen should be visible. Separate the muscle fibers with blunt dissection and enter the retroperitoneal space. Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the transverse process. Slide forward to psoas muscle. A minimally invasive approach with neuromonitoring is preferred.



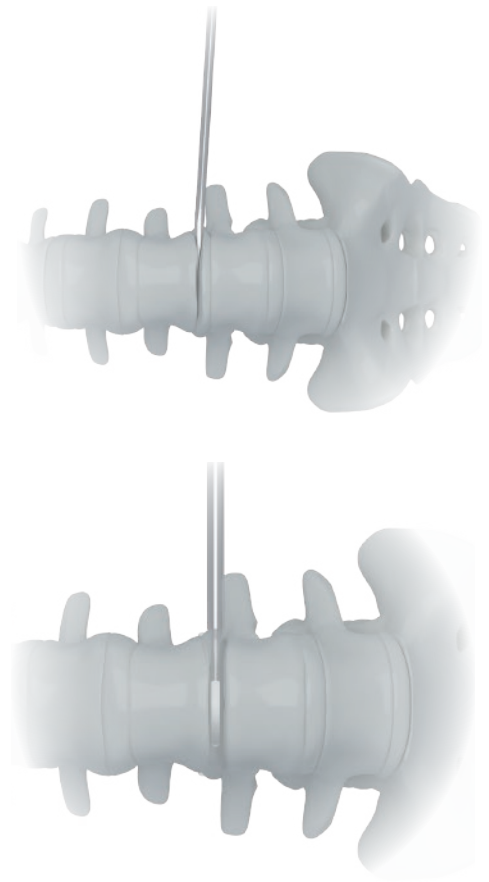
2. DISK PREPARATION

The annulus is then incised and an annulotomy at least 18mm in length is created using the Bayoneted Knife.

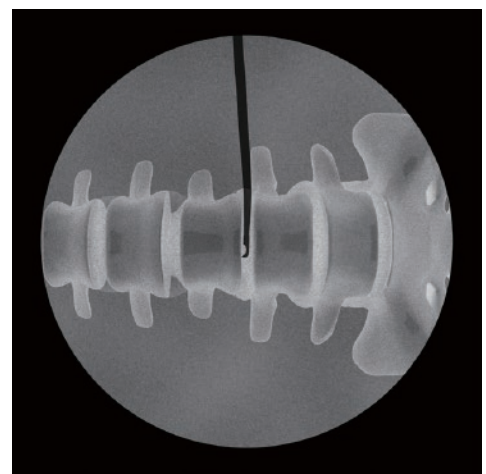
A thorough discectomy is then performed using pituitaries and other disc preparation instruments.

A large Cobb is passed along both end plates to the contralateral annulus. A mallet is then used to gently release both the superior and inferior aspects of the contralateral annulus. This step is critical to ensure that appropriate distraction and coronal alignment can be achieved.

A Paddle Style Shaver is placed into the disc space and rotated several times to clean the end plates. A/P fluoro should be used to center the shaver in the disc before turning. The appropriate sized shavers should be carefully selected to ensure the end plates are not compromised.

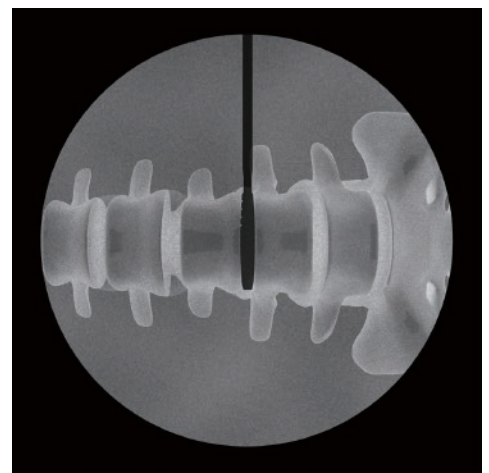
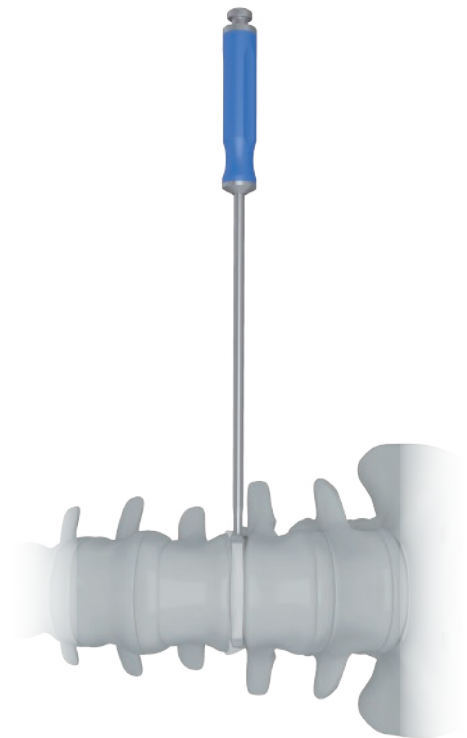


Serrated curettes, a ring curette, combo tools are used to ensure proper end plate preparation. It is extremely important that the end plates be meticulously prepared for fusion by removing the cartilaginous disc without destroying the cortical end plates.



3. TRAILING

The disc space is sequentially distracted with trials until adequate disc space height is obtained and adequate foraminal size is restored. The trial is passed through the retractor and impacted into the disc space. A properly sized trial should be centered with the spinous process and span the ring apophysis in order to reach fully across the vertebral body end plate.

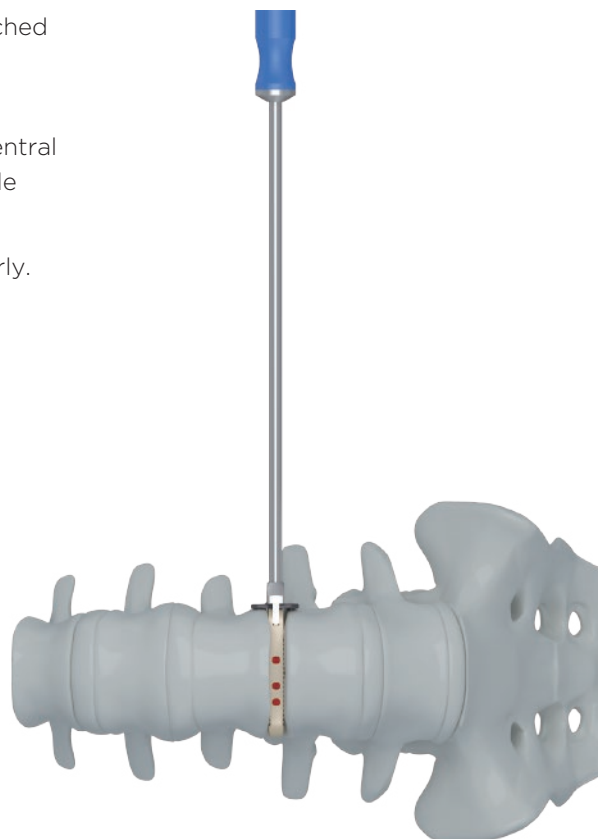


4. IMPLANT PLACEMENT

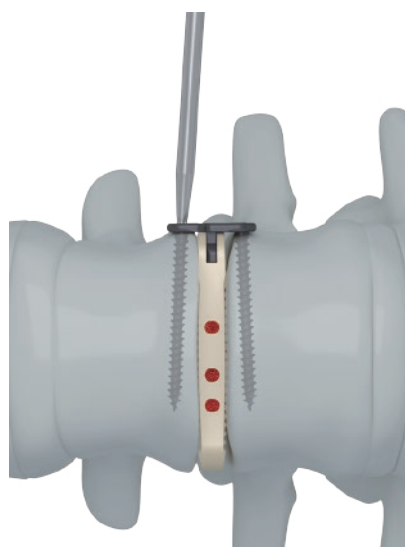
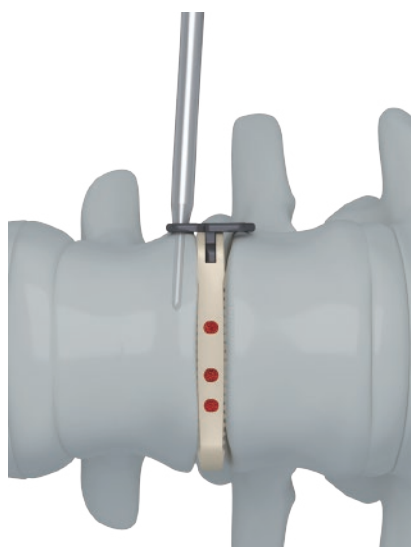
Once trialing is complete, the corresponding cage is attached to the inserter. Take note of the anterior side of the cage, marked "Anterior" before insertion.

Before inserting the cage, place autograft in the cage's central cavity. A mallet is then used to gently insert the cage while monitoring placement under AP fluoroscopy.

Care should be taken to ensure the cage is aligned properly.



After the cage is positioned in the center of the disc space from a medial/lateral perspective, the awl should be used to create the pilot holes, and then insert the screw by using the screwdriver.



The Coales-XL cage includes an attached locking cap mechanism. The same screwdriver used for screw insertion can be used to engage the locking cap mechanism. Insert the tip portion of the screwdriver into the head of the locking cap and rotate until the cap covers screw heads. If the locking cap does not easily rotate and cover screw heads, check to make sure that the screw is fully seated.



5. CLOSURE

The surgical site is irrigated appropriately and the fascia over the external oblique is then closed with interrupted vicryl suture.

Finally, the subcutaneous layers and skin are closed and the skin is sealed with skin adhesive.


6. EXPLANTATION


Should it be necessary to remove or reposition the implant, the removal tool may be used.

To remove the implant, first fit the tips of the removal tool with the divots at the end of the implant. Next, push and rotate the sleeve of the remover to lock onto the implant.

Finally, attach the Handle Extension to the removal tool and gently impact with mallet to facilitate implant removal.



COALES XL	CODE		SPECIFICATION	
	0°	8°	W*L	H
	71590009	71598009	40	9
	71590011	71598011	40	11
	71590013	71598013	40	13
	71590015	71598015	40	15
	71590017	71598017	40	17
	71590109	71598109	45	9
	71590111	71598111	45	11
	71590113	71598113	45	13
	71590115	71598115	45	15
	71590117	71598117	45	17
	71590209	71598209	50	9
	71590211	71598211	50	11
	71590213	71598213	50	13
	71590215	71598215	50	15
	71590217	71598217	50	17
	71590309	71598309	55	9
	71590311	71598311	55	11
	71590313	71598313	55	13
	71590315	71598315	55	15
	71590317	71598317	55	17




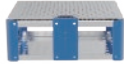
LUMBAR SELF-DRILLING LOCKING SCREW	CODE	D	L
		51584015	Ø4.0
51584020		Ø4.0	20mm
51584025		Ø4.0	25mm
51584030		Ø4.0	30mm

CODE	PARTS DESCRIPTION	PIECES	PICTURE
12024010	Cobb Elevator-L	1	
12024020	Cobb Elevator-S	1	
12024031	7/9 Spreader	1	
12024032	9/11 Spreader	1	
12024033	11/13 Spreader	1	
12011005	Scraper 9mm	1	
12011001	Scraper 11mm	1	
12011001	Scraper 13mm	1	
12011001	Scraper 15mm	1	
12011001	Scraper 17mm	1	
12024050	Curette-Left	1	
12024060	Curette-Right	1	
12024070	Flat Rasp-L	1	
12024080	Flat Rasp-S	1	

CODE	PARTS DESCRIPTION	PIECES	PICTURE
12024090	Convex Rasp	1	
12024101	Trial 0°-9	1	
12024102	Trial 0°-11	1	
12024103	Trial 0°-13	1	
12024104	Trial 0°-15	1	
12024105	Trial 0°-17	1	
12024111	Trial 8°-9	1	
12024112	Trial 8°-11	1	
12024113	Trial 8°-13	1	
12024114	Trial 8°-15	1	
12024115	Trial 8°-17	1	
12011032	Handle Extension	1	
12008005	Hammer	1	
12025010	Insertter	1	
12025020	Awl	1	

COALES-XL Instruments



CODE	PARTS DESCRIPTION	PIECES	PICTURE
12025030	Screw Driver	1	
12025040	Remover	1	
12025991	Instrument Case	1	
12025992	Screw Box	1	

Desde nuestra sede operativa en Estados Unidos, y filiales en México, Argentina, Bolivia y Chile, ofrecemos las gamas más completas para trauma, columna, cadera y rodilla.



Nuestros dispositivos cumplen con las certificaciones de calidad y registros sanitarios vigentes en cada país. Implementamos procedimientos de trazabilidad y tecnovigilancia en las diferentes etapas de almacenamiento y comercialización. Esta rigurosidad en el control nos permite sostener un alto valor de marca, garantizando la mayor seguridad a los pacientes.

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— DISPOSITIVOS MÉDICOS —

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