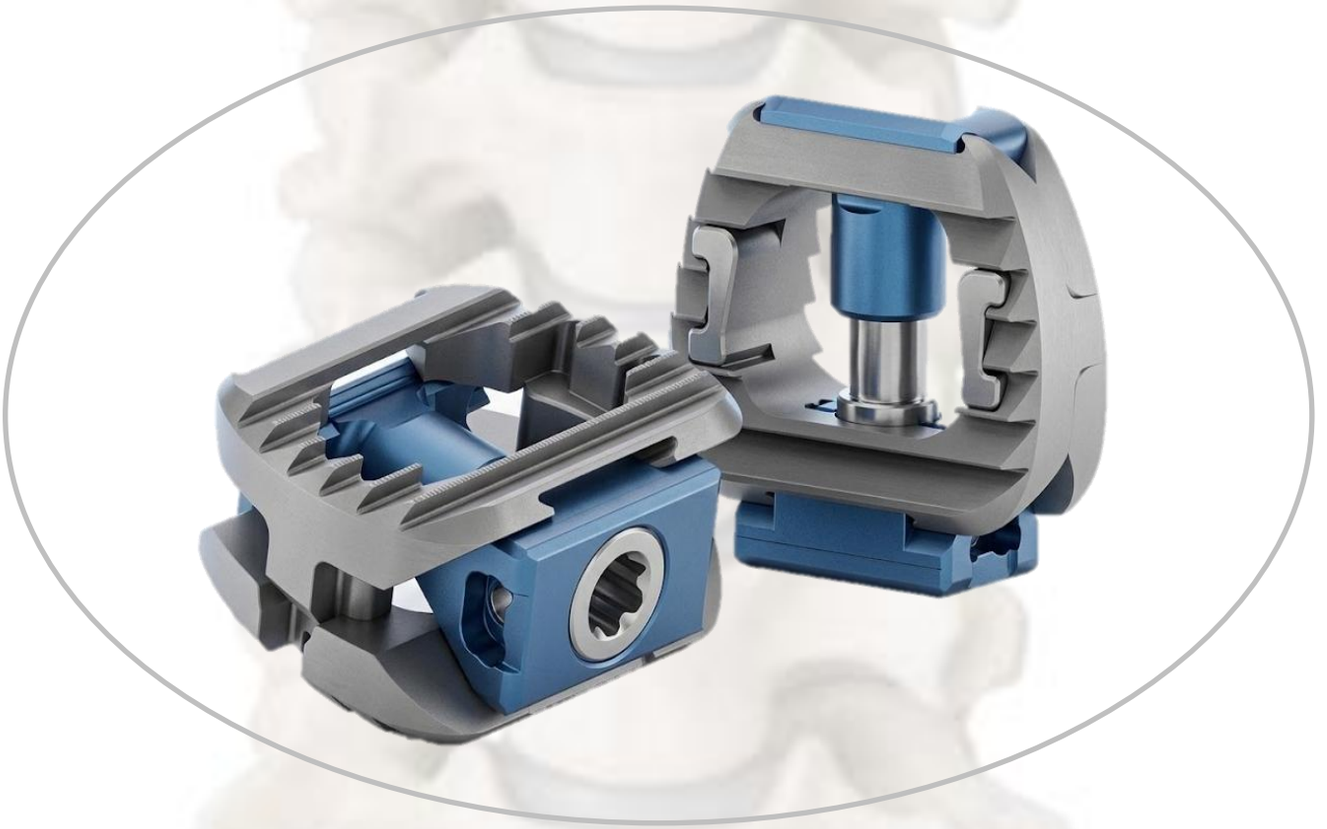
BluEX-C

CastleLoc Cervical Expandable Cage System

Anterior Cervical Interbody Fusion Cage System



LEARNING & KNOWLEDGE BIOMED

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TAP OF CONTENT

General Information

Surgical Technique

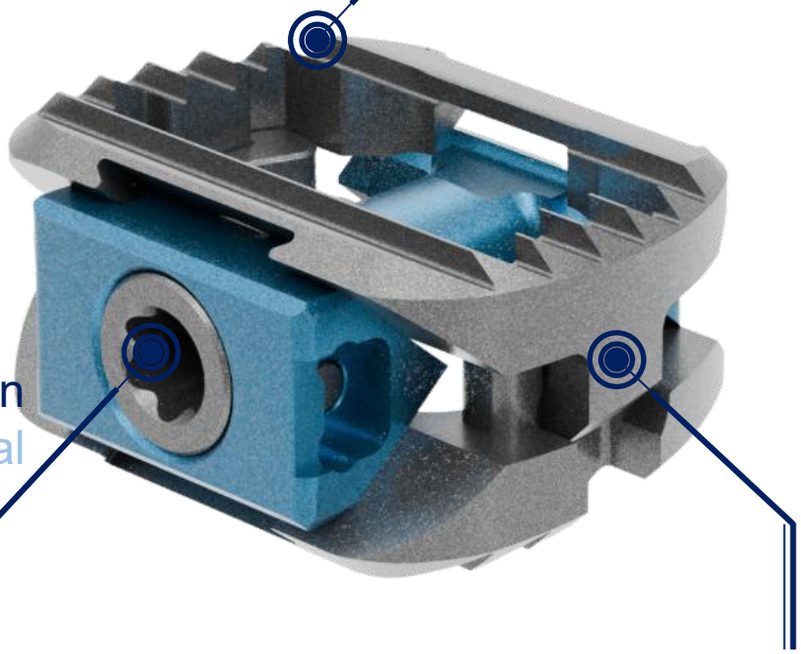
INTRODUCTION

The BluEX Cervical Expandable Cage System is an expandable intervertebral body fusion device intended for use in the cervical spine to facilitate fusion between adjacent vertebral bodies following discectomy. The device is designed to be inserted into the intervertebral disc space in a collapsed configuration and subsequently expanded in situ to restore disc height and provide structural support during the fusion process.

MATERIALS
The material is titanium alloy (Ti-6Al-4V) conforming to ASTM F136 approved for medical use.

INDICATIONS
The BluEX Cervical Expandable Cage System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The BluEX Cervical Expandable Cage System is intended for use in anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), resulting in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The BluEX Cervical Expandable Cage System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion. The BluEX Cervical Expandable Cage System is intended to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Core of L&K expandable technology is in its Mechanical Structure.
The Structure of L&K Expandable Cage family is designed for safe and long-lasting Load Distribution.



ORDER INFORMATION - IMPLANT

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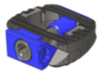
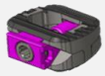
1214-0407S	4~6mm	Blue	14mm	12mm	7°	
1214-0607S	6~8mm	Purple	14mm	12mm	7°	
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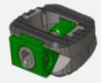
1214-1007S*	10~12mm	Green	14mm	12mm	7°	
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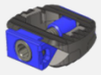
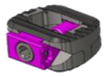
1417-0407S	4~6mm	Blue	17mm	14mm	7°	
1417-0607S	6~8mm	Purple	17mm	14mm	7°	
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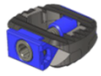
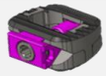
1214-0400S*	4~6mm	Blue	14mm	12mm	0°	
1214-0600S*	6~8mm	Purple	14mm	12mm	0°	
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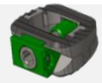
1214-1000S*	10~12mm	Green	14mm	12mm	0°	
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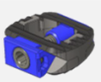
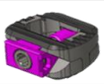
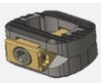
1417-0400S*	4~6mm	Blue	17mm	14mm	0°	
1417-0600S*	6~8mm	Purple	17mm	14mm	0°	
1417-0800S*	8~10mm	Gold	17mm	14mm	0°	
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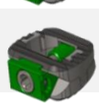
1417-1300S*	13~15mm	Green	17mm	14mm	0°	

INSTRUMENTS DETAIL – Cage Placement System

Image	Cat. No.	Name	QTY.
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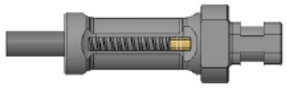
	CC10-0002	BluEX-C Height Adjustable Driver	2
	CC10-0004	BluEX-C Indicator Module	2
	CC10-0008	Torque Limiting I-Handle 1.1Nm	2

INSTRUMENTS DETAIL – Trial System

Image	Cat. No.	Name	QTY.
	CC02-4705	TRIAL 7º SMALL 5mm	1
	CC02-4706	TRIAL 7º SMALL 6mm	1
	CC02-4707	TRIAL 7º SMALL 7mm	1
	CC02-4708	TRIAL 7º SMALL 8mm	1
	CC02-4709	TRIAL 7º SMALL 9mm	1
	CC02-4710	TRIAL 7º SMALL 10mm	1
	CC02-5705	TRIAL 7º LARGE 5mm	1
	CC02-5706	TRIAL 7º LARGE 6mm	1
	CC02-5707	TRIAL 7º LARGE 7mm	1
	CC02-5708	TRIAL 7º LARGE 8mm	1
	CC02-5709	TRIAL 7º LARGE 9mm	1
	CC02-5710	TRIAL 7º LARGE 10mm	1

INSTRUMENTS DETAIL – Container

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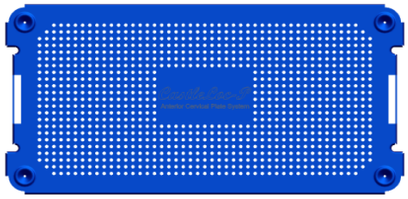
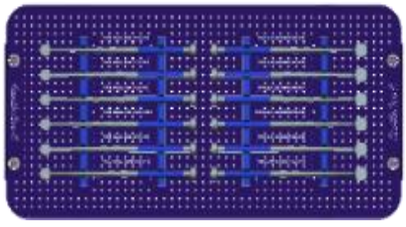
	CC02-0001	CONTAINER COVER	1
	CC02-0002	CONTAINER BASE	1
	CC02-0005	TRAY	1

Preparation

Carefully review and inspect all instruments and implants before sterilization to ensure that they are intact, functional, and free from defects.

- Verify that all required components are available, and replace or add any necessary items as needed to align with the planned surgical procedure.
- Confirm that all instruments are properly assembled and in optimal condition for use.
- The surgeon must have extensive experience with spinal fusion techniques, as well as a thorough understanding of implant selection, positioning, and surgical approach to ensure optimal patient outcomes.

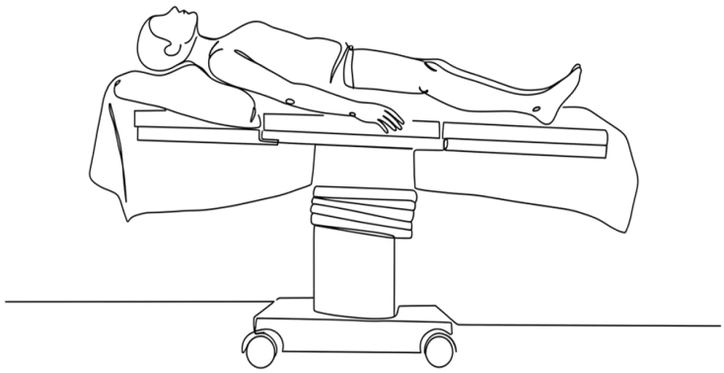


Figure 1

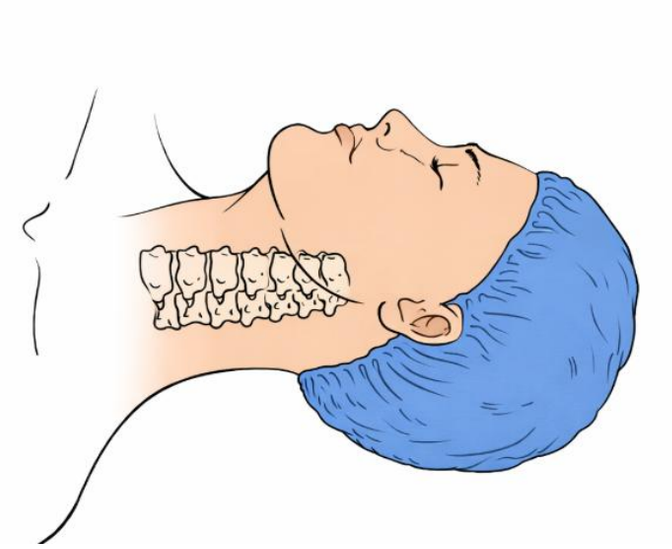


Figure 2

Patient Positioning

The patient is positioned supine with the head slightly extended, ensuring proper support for the posterior cervical spine to maintain its natural lordotic curve (Figure 1)

The surgeon must determine whether to proceed with a right- or left-sided approach to access the cervical vertebral column. Once the approach is selected, the head may be rotated as needed to optimize visibility and access to the upper cervical spine. (Figure 2)

Exposure

The anterior portions of the vertebral bodies above and below the affected segment are carefully exposed to provide adequate visualization and access for the procedure. (Figure 3)

Once the anterior vertebral column is fully exposed, the longus colli muscles are carefully elevated, and the medial and lateral self-retaining retractor blades are securely positioned beneath them (Figure 4).

If an anterior osteophyte obstructs proper placement, a slotted blade may be used for better positioning.

Subsequently, the longitudinal self-retaining retractor is placed to ensure optimal visualization of the surgical field.

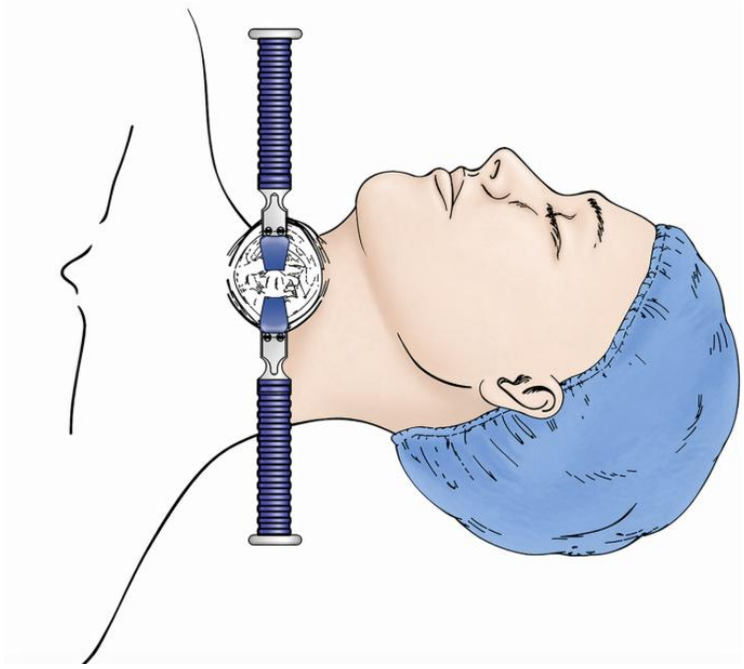


Figure 3

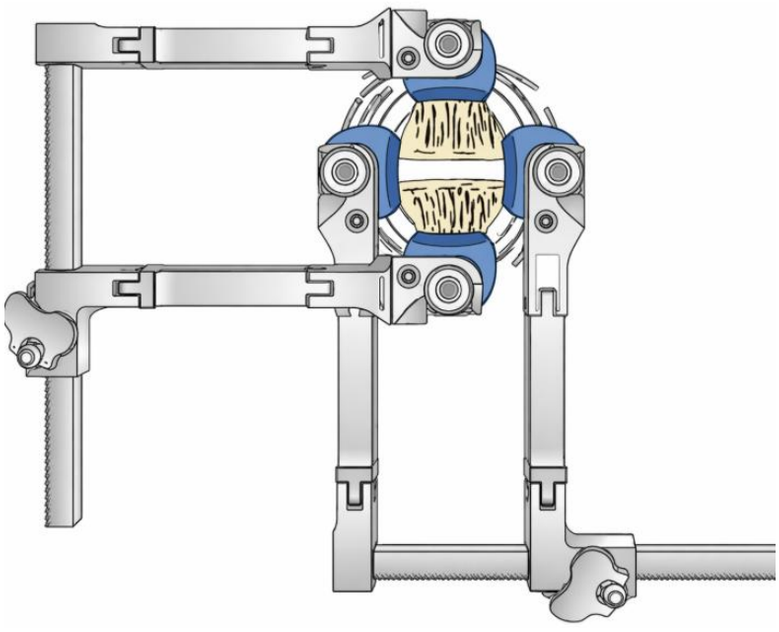


Figure 4

Discectomy

Discectomy is performed at the targeted disc level, ensuring thorough removal of disc material. A small ring curette is primarily used for this process, while pituitary forceps and Kerrison punches are used to assist in removing disc material and cartilage. This step is performed carefully to expose the posterior longitudinal ligament and allow optimal surgical access.

Discectomy should be performed with consideration of angle 7°.

After decompression is completed, the next step is endplate preparation. This involves carefully shaping the endplates to create a precisely matched mortise for the cage, ensuring optimal fit and stability for implantation.

INSTRUMENTS IN USE

CC02-4705 Trial 7º Small 5mm

CC02-4706 Trial 7º Small 6mm

CC02-4707 Trial 7º Small 7mm

CC02-4708 Trial 7º Small 8mm

CC02-4708 Trial 7º Small 9mm

CC02-4708 Trial 7º Small 10mm

Discectomy should be performed with consideration of angle 7°.

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Trial Implant

The appropriate cage size can be determined using trial implants, which help identify the best fit for the disc space. Like the implants, the trials also feature a superior surface with either a convex or wedge-shaped profile to accommodate different anatomical needs (Figure 5).

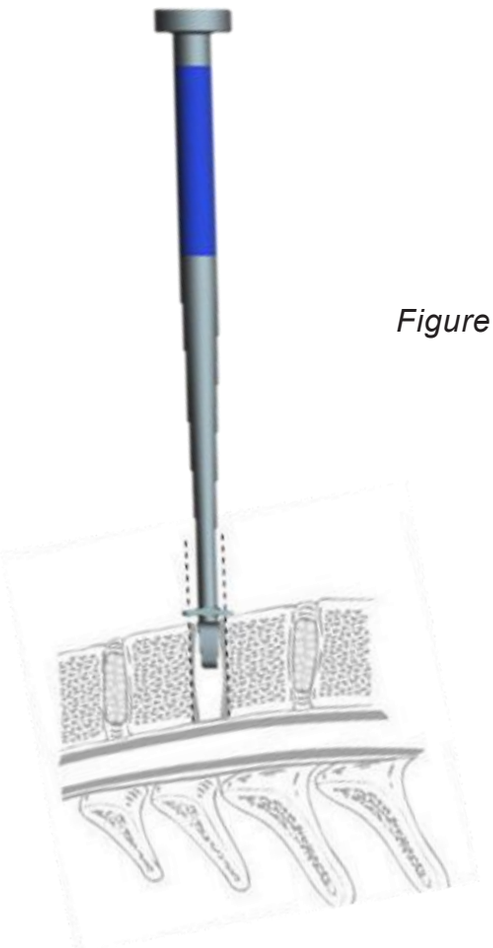


Figure 5

INSTRUMENTS IN USE

CC10-0001 BluEX-C Expandable Cage Inserter

Cage Preparation

Ensure that the Expandable Cage Inserter is in the “Open” position (the arms of the inserter are fully protruded from the inserter and in a wide position) by fully turning the knob of the Expandable Cage Inserter counterclockwise.

Align the non-bulleted end of the cage with the arms of the inserter (the notches on the arms should match the grooves on the cage). Once aligned, while holding the assembly in place, turn the knob on the Expandable Cage Inserter clockwise until the cage is fully engaged and locked to the holder and the arms have retracted back into the holder (the knob should no longer turn clockwise). (Figure 6)

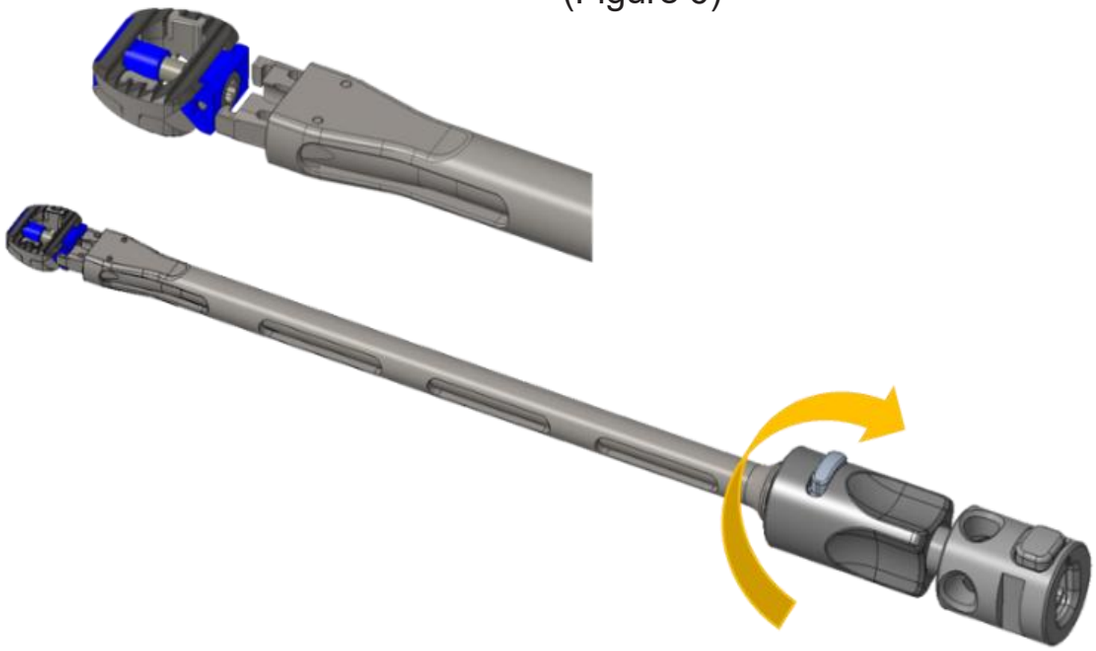
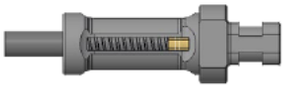


Figure 6

INSTRUMENTS IN USE

CC10-0001 BluEX-C Expandable Cage Inserter

CC10-0002 BluEX-C Height Adjustable Driver



CC10-0004 BluEX-C Indicator Module

CC10-0008 Torque Limiting I-Handle 1.1Nm

Cage Insertion

Carefully insert the implant into the prepared disc space. Use fluoroscopy to verify accurate implant placement. The implant should be centered within the disc space, ensuring full coverage of the apophyseal ring for optimal stability and fusion support (Figure 7).

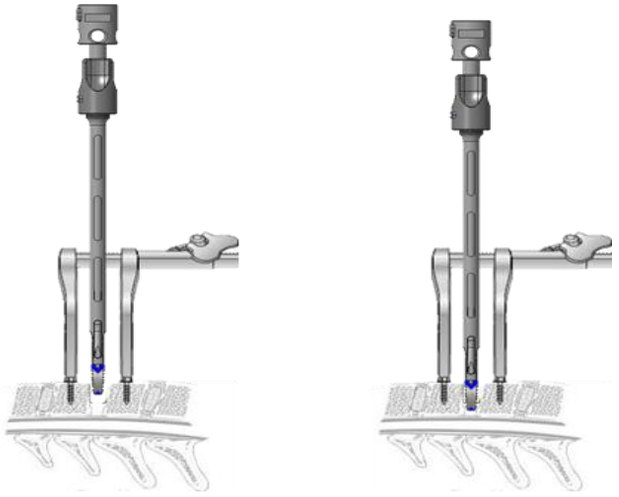


Figure 7

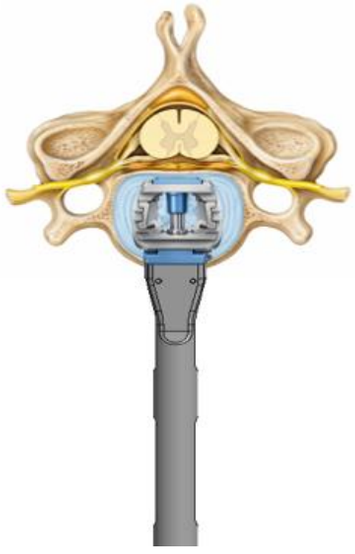


Figure 8

INSTRUMENTS IN USE

CC10-0001 BluEX-C Expandable Cage Inserter

CC10-0002 BluEX-C Height Adjustable Driver

CC10-0004 BluEX-C Indicator Module

CC10-0008 Torque Limiting I-Handle 1.1Nm

Figure 11

Cage Expansion

Attach the Height Adjustable Driver to the Torque Limiting I-Handle (Figure 9).

With the cage and Expandable Cage Inserter still fully engaged, insert the Height Adjustable Driver/Torque Limiting I-Handle assembly through the proximal opening of the Expandable Cage Inserter until it is fully seated. (Figure 10)

Figure 9

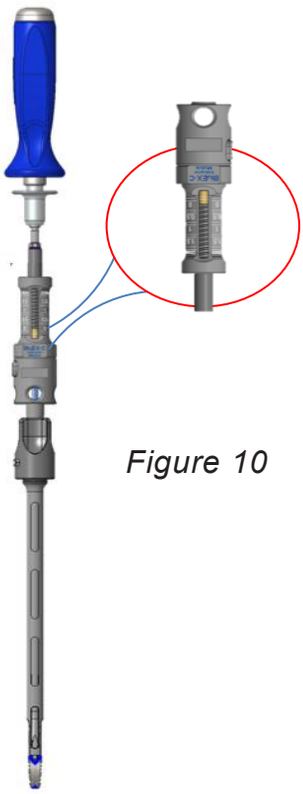


Figure 10

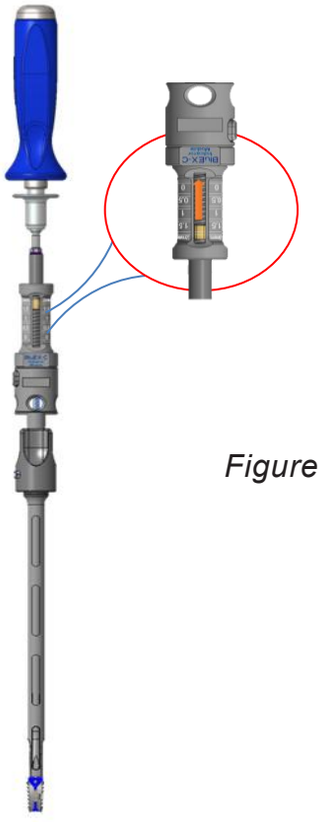


Figure 12

Tip: Make sure that the expansion indicator on the Expandable Cage Inserter is at the initial position of 0 mm. If it is not at the 0 mm position, disengage the cage from the Expandable Cage Inserter, then insert the Height Adjustable Driver into the Expandable Cage Inserter and rotate it counterclockwise to return it to 0 mm. (Figure 11)

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