



CONSTRUX® Mini

PEEK Spacer System

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION

The CONSTRUX Mini PEEK Spacer System offers two footprints of small and large to address the cervical interbody fusion or partial vertebrectomy solution. The implants are available in both parallel and lordotic angles with heights of 5mm-14mm in one-millimeter increments. CONSTRUX Mini is equipped with aggressive anti-migration ribs on the superior and inferior endplates along with large graft windows to enhance the potential for fusion.



Fig. 1a

1. PATIENT POSITIONING

Preoperative planning is critical in the preparation for spinal surgery. A complete radiographic evaluation (A/P and lateral films) is recommended for proper diagnosis prior to surgery. Carefully place the patient in the supine position on the operating table ensuring all bony prominences are padded and the cervical spine in neutral to a slightly extended position following the induction of anesthesia.



Fig. 2a

2. EXPOSURE/DISCECTOMY

The affected disc space is exposed using the appropriate anterior approach. The disc material is excised and both the superior and inferior endplates are prepared. **(Fig. 2a)**

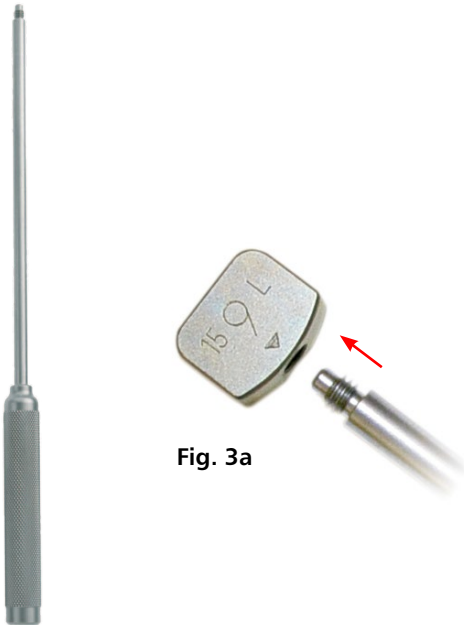


Fig. 3a

3. IMPLANT SIZING

Selection of the proper implant is essential. Attach the trial inserter into the allotted screw hole in the trial. **(Fig. 3a)** Place the trials, in sequential order, into the disc space to determine the proper implant size (height and footprint).

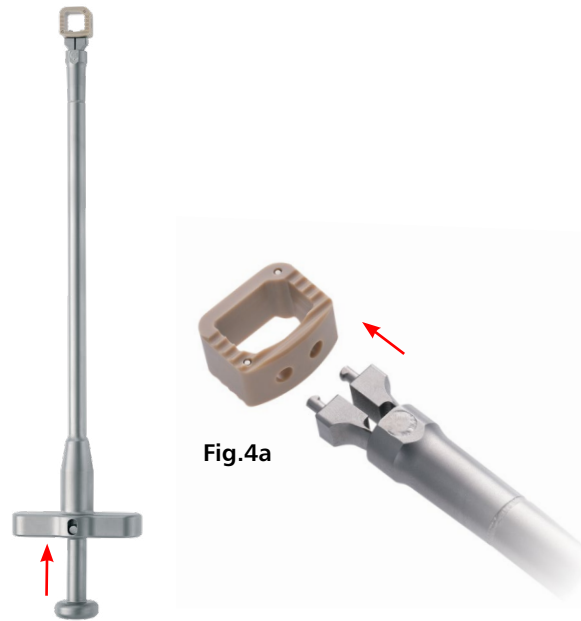
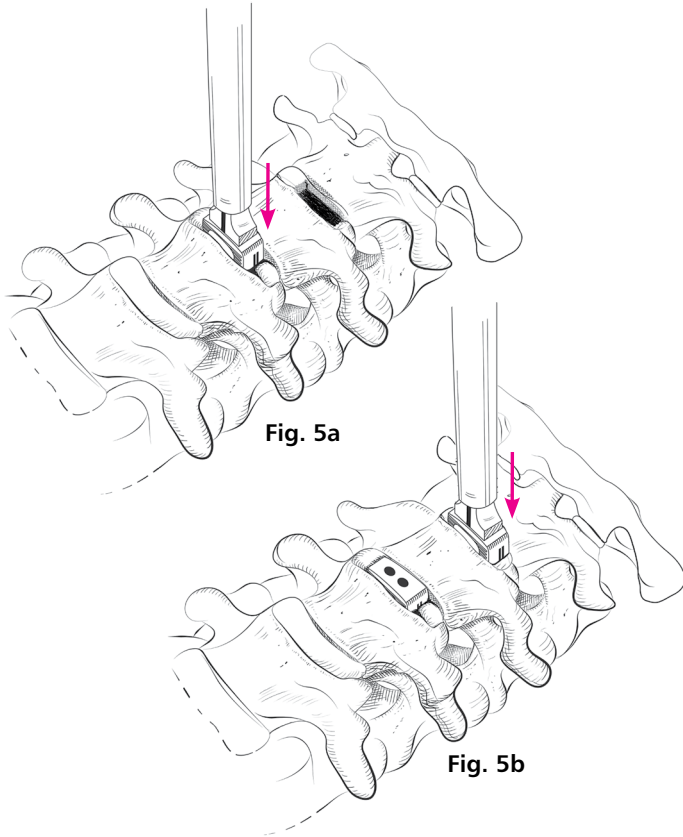


Fig.4a

4. LOADING THE IMPLANT

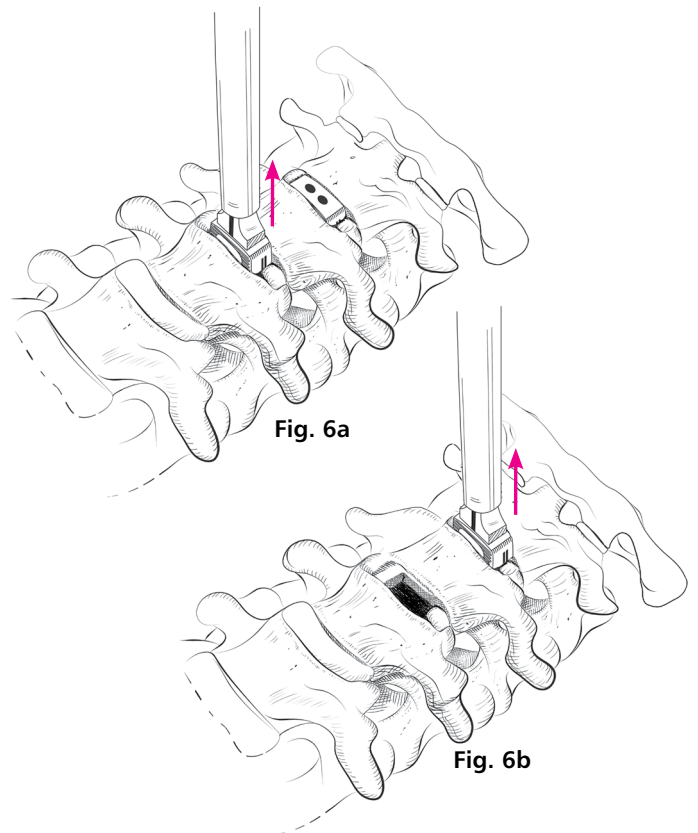
Once the proper implant size has been determined, attach the implant to the inserter. This is achieved by pressing the back of the inserter forward while sliding the implant onto the prongs on the inserter. **(Fig. 4a)** Release the back of the inserter to secure the implant. Autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft may be placed in the window of the implant to help promote fusion.



5. IMPLANT INSERTION

Insert the implant into the disc space. (**Fig. 5a**)
Under guidance of fluoroscopy, the orientation of the implant can be assessed. If repositioning is needed, use the implant tamp.

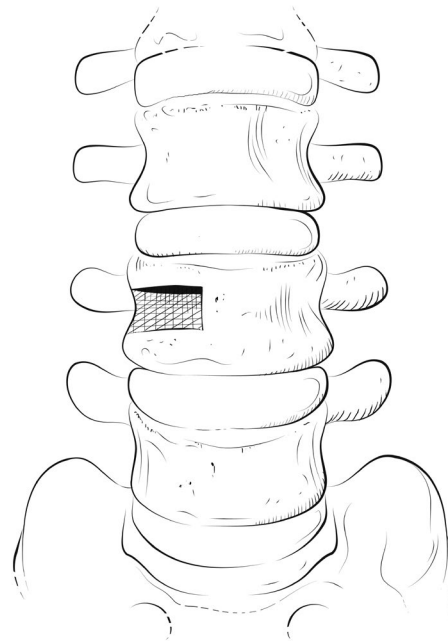
Repeat steps 2-5 for adjacent level implant (**Fig. 5b**)



6. IMPLANT REMOVAL AND REVISION

If removal of the implant is required use the implant inserter to re-engage the implant and pull the implant out of the intervertebral space. If necessary, distract the vertebrae inferior and superior to the implant for removal. (**Fig. 6a**)

Repeat step 6a to remove adjacent level implant (**Fig. 6b**)

**Fig. 1b****Fig. 2b**

1. PREOPERATIVE PLANNING AND PATIENT POSITIONING

Preoperative planning is critical in the preparation for spinal surgery. A complete radiographic evaluation (A/P and lateral films) measuring the vertebral body dimension is recommended for proper diagnosis prior to surgery.

Carefully place the patient in the supine position on the operating table with all bony prominences padded and the lumbar spine in neutral to slight extension following induction of anesthesia. **(Fig. 1b)** Once the patient is placed on the table, use a lateral C-Arm fluoroscopy to visualize the lumbar spine.

2. PARTIAL VERTEBRAL BODY REMOVAL

The traumatized or diseased vertebral body is exposed through the appropriate anterior approach. The affected partial vertebral body and disc material is excised and the both superior and inferior surfaces are prepared. **(Fig. 2b)**

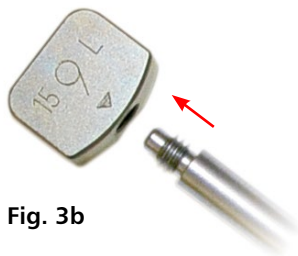


Fig. 3b

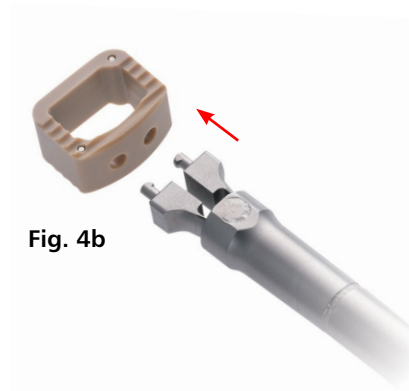


Fig. 4b

3. IMPLANT SIZING

Selection of the proper implant is essential. Attach the trial inserter into the allotted screw hole in the trial. **(Fig. 3b)** Place the trials, in sequential order, into the affected space to determine the proper implant size (height and footprint).

Note: When used as a partial VBR device, the CONSTRUX Mini PEEK Spacer System is intended for use in affected vertebral body segments that are equal to or smaller than the size of the device. For larger affected vertebral body segments, a larger device indicated for partial or full VBR is recommended.

4. LOADING THE IMPLANT

Once the proper implant size has been determined, attach the implant to the inserter. This is achieved by pressing the back of the inserter forward while sliding the implant onto the prongs on the inserter. **(Fig. 4b)** Release the back of the inserter to secure the implant. Autograft and/ or allograft bone graft may be placed in the window of the implant to help promote fusion.

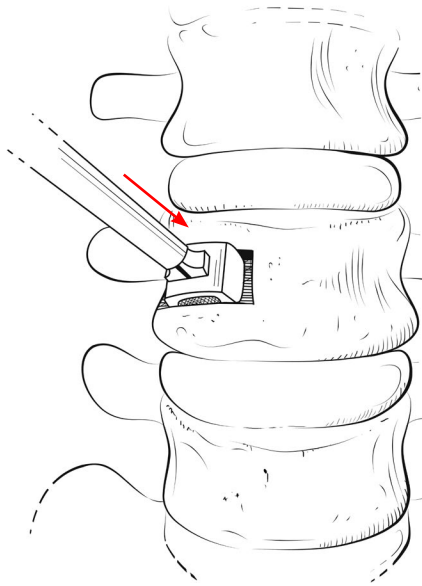


Fig. 5b

5. IMPLANT INSERTION

Insert the implant into the affected space. **(Fig. 5b)**
Under guidance of fluoroscopy, the orientation of the implant can be assessed. If repositioning is needed, use the implant tamp.

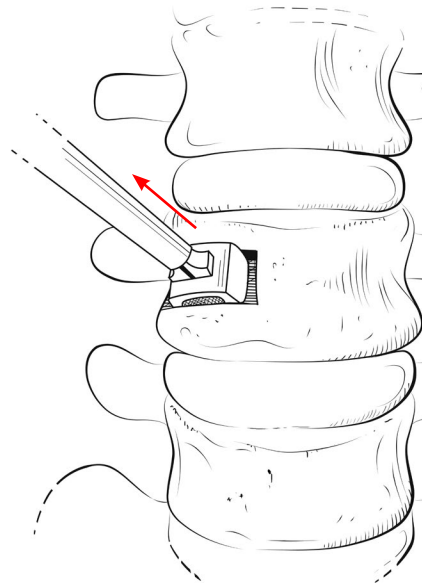


Fig. 6b

6. IMPLANT REMOVAL AND REVISION

If removal of the implant is required use the implant inserter to re-engage the implant and pull the implant out of the affected space. **(Fig. 6b)**
If necessary, distract inferior and superior to the implant for removal.

12MM x 12MM LORDOTIC

Implant#	Trial#	Description	Graft Volume (cc)
47-3005C	47-1005	12mm W x 12mm L, 5° Lordotic - 5mm H	0.28
47-3006C	47-1006	12mm W x 12mm L, 5° Lordotic - 6mm H	0.34
47-3007C	47-1007	12mm W x 12mm L, 5° Lordotic - 7mm H	0.40
47-3008C	47-1008	12mm W x 12mm L, 5° Lordotic - 8mm H	0.46
47-3009C	47-1009	12mm W x 12mm L, 5° Lordotic - 9mm H	0.52
47-3010C	47-1010	12mm W x 12mm L, 5° Lordotic - 10mm H	0.58
47-3011C	47-1011	12mm W x 12mm L, 5° Lordotic - 11mm H	0.64
47-3012C	47-1012	12mm W x 12mm L, 5° Lordotic - 12mm H	0.70
47-3013C	47-1013	12mm W x 12mm L, 5° Lordotic - 13mm H	0.76
47-3014C	47-1014	12mm W x 12mm L, 5° Lordotic - 14mm H	0.82

12MM x 12MM PARALLEL

Implant#	Trial#	Description	Graft Volume (cc)
47-3105C	47-1105	12mm W x 12mm L, Parallel - 5mm H	0.31
47-3106C	47-1106	12mm W x 12mm L, Parallel - 6mm H	0.37
47-3107C	47-1107	12mm W x 12mm L, Parallel - 7mm H	0.43
47-3108C	47-1108	12mm W x 12mm L, Parallel - 8mm H	0.49
47-3109C	47-1109	12mm W x 12mm L, Parallel - 9mm H	0.55
47-3110C	47-1110	12mm W x 12mm L, Parallel - 10mm H	0.61
47-3111C	47-1111	12mm W x 12mm L, Parallel - 11mm H	0.67
47-3112C	47-1112	12mm W x 12mm L, Parallel - 12mm H	0.73
47-3113C	47-1113	12mm W x 12mm L, Parallel - 13mm H	0.79
47-3114C	47-1114	12mm W x 12mm L, Parallel - 14mm H	0.85

Items in blue available upon request only.

INSTRUMENTS

PART#	DESCRIPTION
30-1030	Impactor
47-0090	System Case, CONSTRUX Mini
47-1020	Trial Handle, CONSTRUX Mini
47-1030	Mini Inserter, CONSTRUX Mini
47-1050	Packing Tool, CONSTRUX Mini
47-0010	Complete Set

15MM x 12MM TIC

Implant#	Trial#	Description	Graft Volume (cc)
47-4005C	47-2005	15mm W x 12mm L, 5° Lordotic - 5mm H	0.38
47-4006C	47-2006	15mm W x 12mm L, 5° Lordotic - 6mm H	0.47
47-4007C	47-2007	15mm W x 12mm L, 5° Lordotic - 7mm H	0.55
47-4008C	47-2008	15mm W x 12mm L, 5° Lordotic - 8mm H	0.63
47-4009C	47-2009	15mm W x 12mm L, 5° Lordotic - 9mm H	0.71
47-4010C	47-2010	15mm W x 12mm L, 5° Lordotic - 10mm H	0.79
47-4011C	47-2011	15mm W x 12mm L, 5° Lordotic - 11mm H	0.88
47-4012C	47-2012	15mm W x 12mm L, 5° Lordotic - 12mm H	0.96
47-4013C	47-2013	15mm W x 12mm L, 5° Lordotic - 13mm H	1.04
47-4014C	47-2014	15mm W x 12mm L, 5° Lordotic - 14mm H	1.12

15MM x 12MM PARALLEL

Implant#	Trial#	Description	Graft Volume (cc)
47-4105C	47-2105	15mm W x 12mm L, Parallel - 5mm H	0.43
47-4106C	47-2106	15mm W x 12mm L, Parallel - 6mm H	0.51
47-4107C	47-2107	15mm W x 12mm L, Parallel - 7mm H	0.59
47-4108C	47-2108	15mm W x 12mm L, Parallel - 8mm H	0.67
47-4109C	47-2109	15mm W x 12mm L, Parallel - 9mm H	0.76
47-4110C	47-2110	15mm W x 12mm L, Parallel - 10mm H	0.84
47-4111C	47-2111	15mm W x 12mm L, Parallel - 11mm H	0.92
47-4112C	47-2112	15mm W x 12mm L, Parallel - 12mm H	1.00
47-4113C	47-2113	15mm W x 12mm L, Parallel - 13mm H	1.08
47-4114C	47-2114	15mm W x 12mm L, Parallel - 14mm H	1.17

Description: The CONSTRUX Mini PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone), as described by ASTM F-2026, with titanium markers as described by ASTM F-67. The implants are available in two footprint sizes, a small and a large. The implants are available in various heights, in one-millimeter increments. The superior and inferior surfaces of the implant have a pattern of ripples to provide increased stability and help prevent anterior/posterior movement of the device.

The CONSTRUX Mini PEEK Spacer System is not intended to be used as a stand-alone device. The CONSTRUX Mini PEEK Spacer System must be used with supplemental fixation. The CONSTRUX Mini PEEK Spacer System device is used singly and is implanted using an anterior approach. The CONSTRUX Mini PEEK Spacer System is provided non-sterile and requires sterilization prior to use.

Indications for Use: When used as a cervical intervertebral body fusion device, the CONSTRUX Mini PEEK Spacer System is indicated for spinal fusion procedures at one or two contiguous levels in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The CONSTRUX Mini PEEK Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation (i.e. anterior cervical plate such as the Orthofix ACP or Hallmark® System).

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PEEK Spacer System in the cervical spine.

When used as a Partial Vertebral Body Replacement (VBR) System, the CONSTRUX Mini PEEK Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The CONSTRUX Mini PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The CONSTRUX Mini PEEK Spacer 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 of time. The Partial VBR device is intended to be used with autograft or allograft.

The CONSTRUX Mini PEEK Spacer System is intended for use with supplemental fixation. The supplemental fixation system that may be used with the CONSTRUX Mini PEEK Spacer System is the Orthofix Spinal Fixation System (SFS) or the Firebird Spinal Fixation System.

Contraindications: The CONSTRUX Mini PEEK Spacer System, as with other orthopedic implants, is contraindicated for use in patients:

1. With active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection.
2. With rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation.
3. With conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. With prior fusion at the level to be treated.

Potential Adverse Effects: Potential adverse effects include, but are not limited to:

1. Failure of the device to provide adequate mechanical stability
2. Loss of fixation of the implant
3. Device component failure
4. Migration or bending of the device
5. Loss of bony alignment
6. Non-union
7. Fracture of bony structures
8. Resorption without incorporation of any bone graft utilized
9. Immunogenic response to the implant materials

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.


Note: When used as a partial VBR device, the CONSTRUX Mini PEEK Spacer System is intended for use in affected vertebral body segments that are equal to or smaller than the size of the device. For larger affected vertebral body segments, a larger device indicated for partial or full VBR is recommended.

Warnings and Precautions:

The surgeon should be aware of the following when using implants:

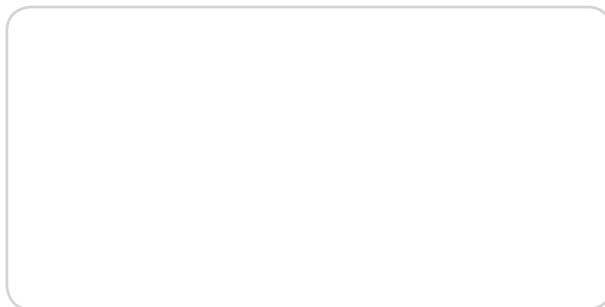
1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The correct handling of the implant is extremely important. Implants should not be bent, notched or scratched. These operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.
3. Single use only. No surgical implants should be reused. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure.
4. Non-sterile; the CONSTRUX Mini PEEK Spacer implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
5. Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
6. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not re-sterilize single-use implants that come in contact with body fluids.
7. The CONSTRUX MINI PEEK Spacer System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. The CONSTRUX Mini PEEK Spacer System components have not been tested for heating or migration in the MR environment.

Instructions for Use: See actual package insert for Instructions for Use.

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 0086 **RX Only**

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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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