BIOMET SPINE

C-THRU™
Anterior Spinal System

Surgical Technique

Manufactured From

PEEK-OPTIMA®

Contents

Introduction

The **C-THRU** Anterior Spinal System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column while the fusion process is occurring.

Product Overview

The open design of the **C-THRU** Spacer, coupled with subsidence resistance and anti-expulsion features[1], accommodates fusions and can restore sagittal plane alignment. The **C-THRU** Spacer is a trapezoidal-shaped implant constructed of PEEK-OPTIMA® polymer (Polyetheretherketone), a radiolucent material. The **C-THRU** Spacer has a large opening for maximal bone graft packing volume. The superior and inferior toothed surfaces provide multi-directional expulsion resistance. Tantalum markers are located in three locations to facilitate desired implant positioning.

The **C-THRU** Spacer offers three endplate contour options (Lordotic, Parallel, and Convex) for a better anatomical fit. Each design is coupled with an instrument set that is unique to that implant's endplate design. The lordotic option is flat on the inferior surface, with a 9° lordotic superior surface, as is experienced in spinal anatomy. The footprint of all three endplate designs measures 14mm wide x 12mm deep.

The **C-THRU** spacer footprint utilizes a gently curving anterior surface and parallel lateral walls which taper to a narrower width posteriorly.

The **C-THRU** Spacers are available in a variety of height options, ranging 5mm-12mm in 1mm increments.

The **C-THRU** Spacers are indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The **C-THRU** Spacers are also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The **C-THRU** Spacers are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

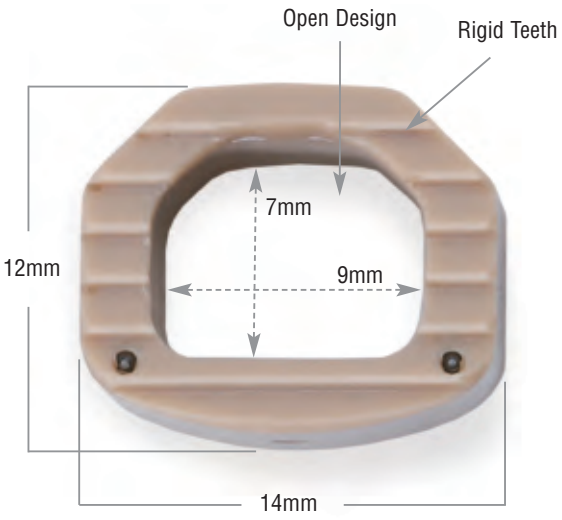
Design Features

PEEK-OPTIMA

- Radiolucent material allows for accurate visualization and assessment of the fusion
- Provides excellent modulus of elasticity and load sharing attributes

Open Design

- Large single chamber design accommodates the fusion process by providing a large core for packing graft material
- Subsidence resistance



Rigid Teeth

- Provides stability by engaging bony endplate

Available In A Wide Range Of Sizes

- Implant heights available from 5mm - 12mm in 1mm increments
- Multiple endplate designs to better accommodate the anatomy
  - Lordotic
  - Parallel
  - Convex

Size	Core Volume (cc)
14 x 12 x 5	0.23
14 x 12 x 6	0.28
14 x 12 x 7	0.34
14 x 12 x 8	0.40
14 x 12 x 9	0.45
14 x 12 x 10	0.51
14 x 12 x 11	0.56
14 x 12 x 12	0.62

Lordotic Parallel Convex

Instruments

Various instruments are available with the **C-THRU** Anterior Spinal System for use by the surgeon to facilitate implantation of the device.

Lordotic Trial

Lordotic Rasp Trial

Single Sided Rasp

Inserter

Tamp

Distraction

1. Obtain anterior exposure per surgeon preference.

2. Expose the midline of the intervertebral disc above and below the vertebrectomy site and remove the appropriate amount of disc and vertebral body. If performing a partial vertebrectomy, remove the disc and portion of the adjacent vertebral body or bodies according to surgeon preference.

3. If the implant site ends at the inferior or superior endplates of the vertebral body adjacent to the replacement site, remove the superficial layers of the cartilaginous endplates to expose bleeding bone. This can be done with a variety of instruments such as osteotomes, scrapers, curettes and rasps. Adequate preparation of the endplates is important to enhance vascular supply to the fusion site.

CAUTION: Aggressive cleaning of the endplate may remove excess bone and weaken the endplate.

Curette And Bone Rasps (Figure 1 And Figure 2).

Figure 1

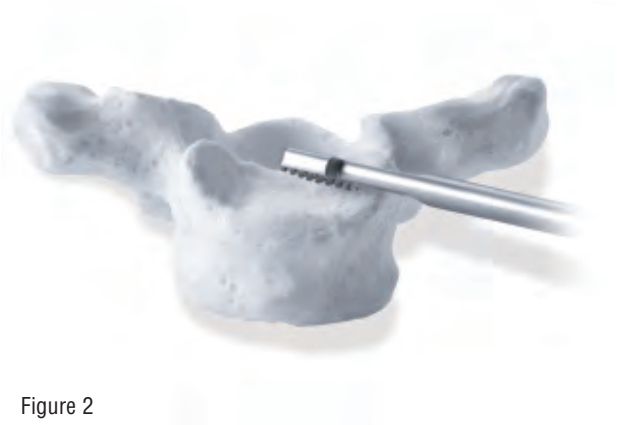


Figure 2

Trialing

4. After the endplates are prepared, Trials are used to approximate the appropriate size of the implant to be inserted. Trials also provide the surgeon with tactile feedback as it relates to the distraction of the vertebral space. After the appropriate size Trial has been determined, the comparable size implant is selected. (Figure 3)

Figure 3

Implant Insertion

5. Load the **C-THRU** Spacer onto the Inserter by placing it between the tines and manipulating the instrument to fully engage the implant. (Figure 4)

6. Introduce the implant into the vertebral disc space using the Inserter. The implant should be the same height or slightly larger than the size determined by the Trial and should be seated securely within the disc space.

Figure 4

Surgical Technique (Continued)

7. Tap the distal tip of the inserter with a mallet to gently seat the implant. The implant may be inserted flush with the anterior rim of the adjacent vertebral bodies or may be countersunk past the anterior rim at the physician's discretion. (Figure 5)

8. Disengage the Implant from the Inserter and remove the instrument. The Tamp may be utilized to further advance the implant in the disc space. (Figure 6)

9. Final positioning of all implant(s) should be confirmed using fluoroscopy. Additional autogenous bone material may be placed beside the implants at the surgeon's discretion.

10. Repeat steps to insert additional PEEK **C-THRU** Spacers.

Figure 5

Figure 6

Product Information

Catalog #	Implants
Lordotic	
14-531145	5mm Spacer
14-531146	6mm Spacer
14-531147	7mm Spacer
14-531148	8mm Spacer
14-531149	9mm Spacer
14-531150	10mm Spacer
14-531151	11mm Spacer
14-531152	12mm Spacer
Parallel	
14-531165	5mm Spacer
14-531166	6mm Spacer
14-531167	7mm Spacer
14-531168	8mm Spacer
14-531169	9mm Spacer
14-531170	10mm Spacer
14-531171	11mm Spacer
14-531172	12mm Spacer
Convex	
14-531185	5mm Spacer
14-531186	6mm Spacer
14-531187	7mm Spacer
14-531188	8mm Spacer
14-531189	9mm Spacer
14-531190	10mm Spacer
14-531191	11mm Spacer
14-531192	12mm Spacer

Catalog #	Instruments
55001914	14mm Inserter
55002195	Single Sided Rasp
55002198	11mm Tamp
Lordotic	
55002115	5mm Trial
55002116	6mm Trial
55002117	7mm Trial
55002118	8mm Trial
55002119	9mm Trial
55002120	10mm Trial
55002121	11mm Trial
55002122	12mm Trial
55002215	5mm Rasp Trial
55002216	6mm Rasp Trial
55002217	7mm Rasp Trial
55002218	8mm Rasp Trial
55002219	9mm Rasp Trial
55002220	10mm Rasp Trial
55002221	11mm Rasp Trial
55002222	12mm Rasp Trial

Product Information (Continued)

Catalog #	Instruments
Parallel	
55002145	5mm Trial
55002146	6mm Trial
55002147	7mm Trial
55002148	8mm Trial
55002149	9mm Trial
55002150	10mm Trial
55002151	11mm Trial
55002152	12mm Trial
55002245	5mm Rasp Trial
55002246	6mm Rasp Trial
55002247	7mm Rasp Trial
55002248	8mm Rasp Trial
55002249	9mm Rasp Trial
55002250	10mm Rasp Trial
55002251	11mm Rasp Trial
55002252	12mm Rasp Trial
Convex	
55002175	5mm Trial
55002176	6mm Trial
55002177	7mm Trial
55002178	8mm Trial
55002179	9mm Trial
55002180	10mm Trial
55002181	11mm Trial
55002182	12mm Trial

Closure And Postoperative Care

- The operative site should be closed per hospital protocol and the surgeon's discretion. Prior to adequate fusion, the physician may prescribe additional external support to accommodate full load bearing
- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient
- Pain Medication
- NG tubes and/or Foley catheters are discontinued within 24-48 hours
- Diet is restricted to small amounts of liquids until return of bowel function in completed
- The patient is encouraged to ambulate as soon as possible. The individual surgeon determines activity level
- Braces are to be used as per each surgeon's discretion

Indications For Use

The **C-THRU** Spacers are indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The **C-THRU** Spacers are also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The **C-THRU** Spacers are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

Warnings

C-THRU Spacer devices should not be implanted in patients with an active infection at the operative site.

Precautions

- **C-THRU** Spacer device is to be implanted using an open anterior approach
- The surgeon should only implant the **C-THRU** Spacer device after adequate training and familiarity with the information provided in the Surgical Technique Manual

The surgeon should be aware of the following:

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 spine presents 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 surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

3. All instruments must be cleaned and sterilized prior to surgery.

4. As with all orthopaedic implants, the **C-THRU** Anterior Spinal System should never be reused under any circumstances.

5. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

6. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

See the Adverse Events section of the package insert for a complete list of potential risks.

Further Information

For further information on:

- INDICATIONS FOR USE
- CONTRAINDICATIONS
- PRECAUTIONS
- STERILIZATION

Please refer to the **C-THRU** Anterior Spinal System package insert.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

The **C-THRU** Spine System Surgical Technique is presented to demonstrate the surgical technique utilized by Paul S. Lin, M.D., Sun Orthopedics, Lewisburg, PA. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

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References:

1. Data on file. See MTP #074 and addendum and MTP #075.

Notes:

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