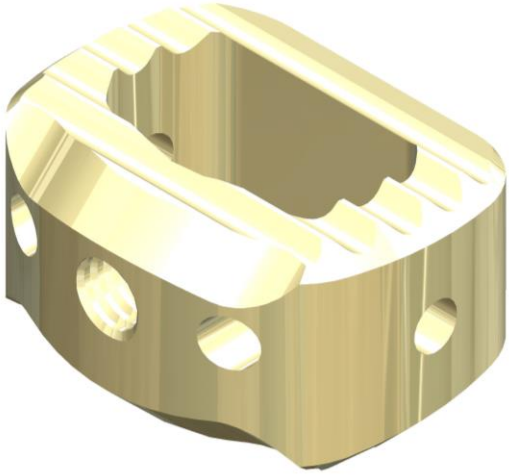
ROIMD

Royal Oak Cervical IBFD System

Surgical Technique



Indications and Features

Indications:
The Cervical Implant is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The Cervical Implant is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device is to be used in patients who have had six weeks of non-operative treatment. The Cervical Implant is intended to be used with a supplemental internal fixation system.

Features:

RANGE OF SIZES

The Cervical Implant is available in heights of 6, 7, 8, 9, and 10mm and widths of 12 and 15mm. All Implants are lordosed 7º. Specific dimensions (mm) are shown in Figure 1.

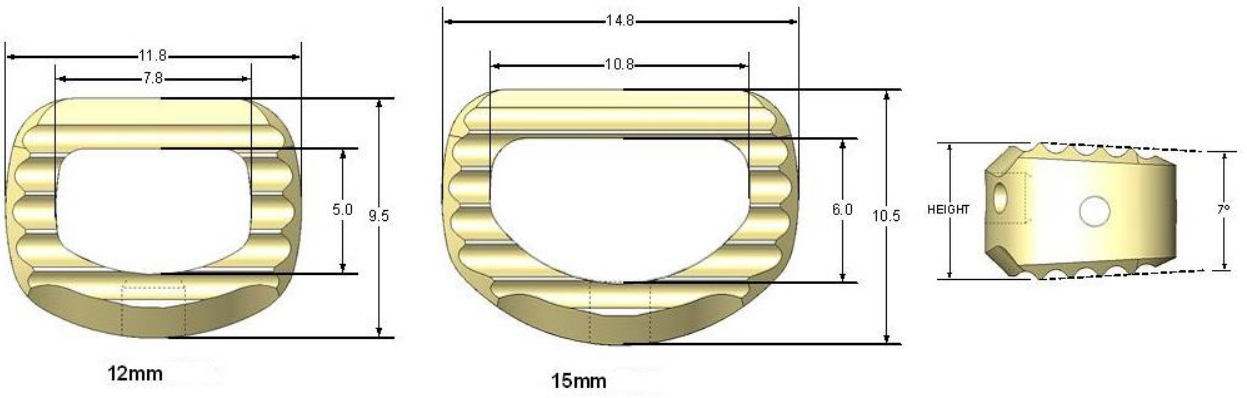


Figure 1.

GRAFT VOLUME

The interior of the Cervical Implant accommodates a large volume of autograft material.

Height	6mm	7mm	8mm	9mm	10mm
12mm	210	245	280	315	350
15mm	324	378	432	486	540

Autograft Volume (mm^3)

PERIPHERAL SUPPORT

The Cervical Implant is designed to seat around the perimeter of the endplate facilitating load transfer through the cortical shell.

PEEK OPTIMA POLYMER

The Cervical Implant is constructed of PEEK polymer to facilitate fusion visualization. A radiodense tantalum marker rod is embedded in the posterior wall of the implant.

EASE OF USE

The set is easy to use with very few instruments required for implantation. The set includes *Sizers*, which help insure correct implant fit. The set also includes an *Inserter* for removing the spacer from the caddy and implanting it between the vertebrae. The set is compact and lightweight.

Surgical Approach

Use the appropriate surgical approach for anterior cervical interbody fusion. Direct anterior access must be provided. Make provision for the distraction method of choice.

Surgical Technique

Surface Preparation:

The disc should be opened to provide full access to the disc space. Curettes and rongeurs are then used to remove the disc and cartilaginous cephalad and caudal endplates. Anterior osteophytes may need to be removed to improve visualization and access. Distraction may be adjusted during discectomy and decompression. The endplates should be flattened to maximize the implant contact area.

It is important that the discectomy extend far enough laterally. In order to achieve fusion the cartilaginous endplates must be removed and contact between the implant and endplates must be maximized. Gaps between the endplates and the implant and central spacer graft chamber must be eliminated.

Implant Selection:

Using the sizers, first determine the width required. Then sequentially increase the sizer height until a snug fit is achieved. The *Sizer* should fit snuggly, but not tightly. **Only gentle impaction should be required to insert the *Sizer*.** In the medial-lateral direction, the width of the implant should fit within the available exposure. Fluoroscopy can be used to evaluate fit and position.

Implantation:

The implant is docked to the Inserter by rotating the knob at the end of the handle clockwise (Figure 2). Two pins prevent rotation of the *Inserter* relative to the implant (inset).

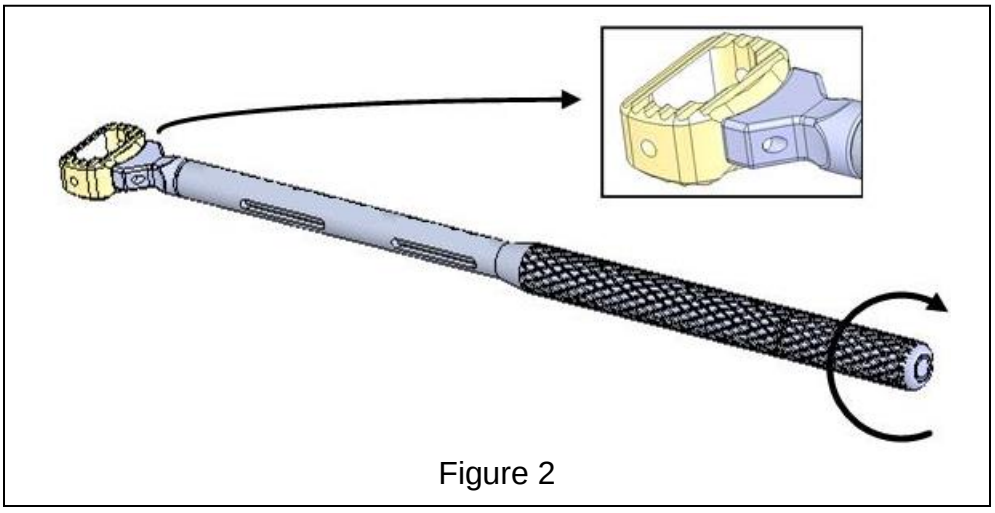


Figure 2

Pack the interior chamber of the implant with autograft. The autograft material should extend beyond the implant by no more than 1mm.

Do not release distraction until after the implant has been inserted. Only gentle impaction should be required to insert the implant. NEVER use the implant attached to the *Inserter* as a

sizer, distractor, or to pry apart or otherwise spread the vertebrae. Only apply force along the axis of the inserter. Check the implant for damage after insertion.

Confirming Proper Installation:

An x-ray or fluoroscopy should be used to confirm that the implant is in the desired location. If misalignment is apparent, consideration should be given to repositioning the implant.

Refer to the package insert for a complete list of warnings, precautions, indications, and contraindications.

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