MADISON ORTHO

MINERVA™

Variable Angle ACIF Cage System

Surgical Technique

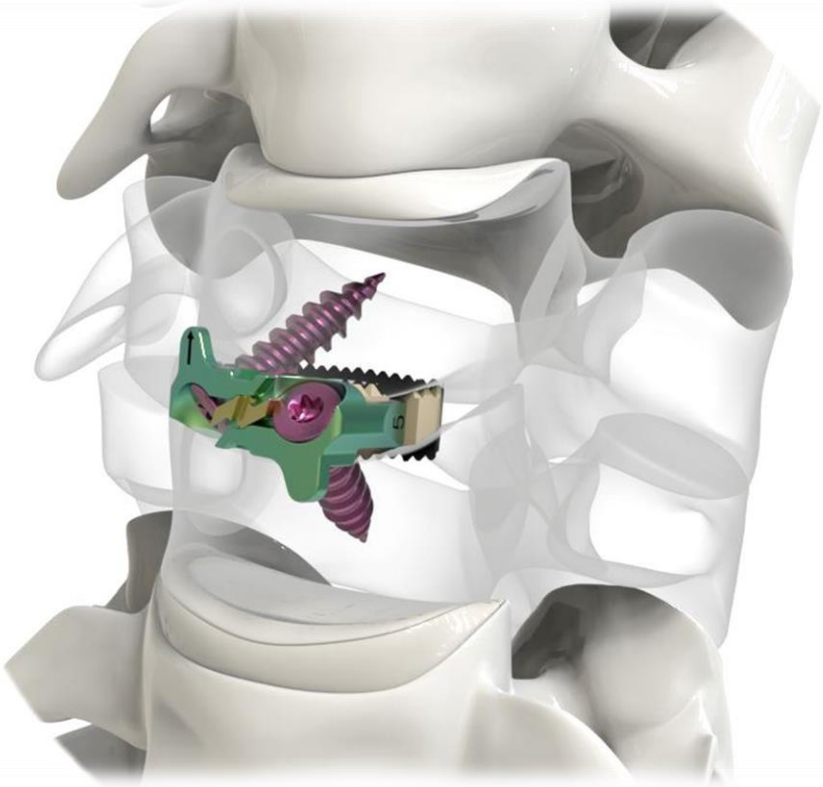


Table of Contents

Warning
The contents of this manual are intended to be only a guide and are not intended to set a standard of care. Instruction by a surgeon experienced in handling these instruments is highly recommended.

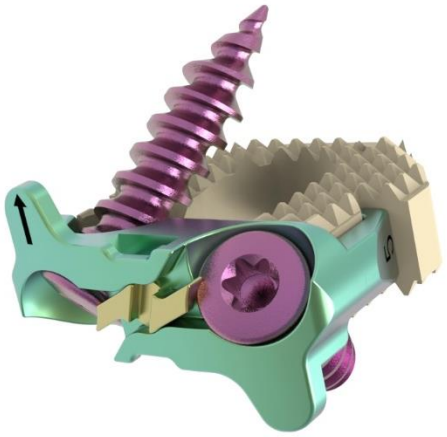
INTRODUCTION

The MINERVA™ Variable Angle ACIF Cage is a stand-alone interbody fusion device with internal screw fixation and is intended to be used in anterior cervical discectomy and fusion procedures, which combines the functionality of a cervical interbody spacer and benefits of an anterior cervical plate.

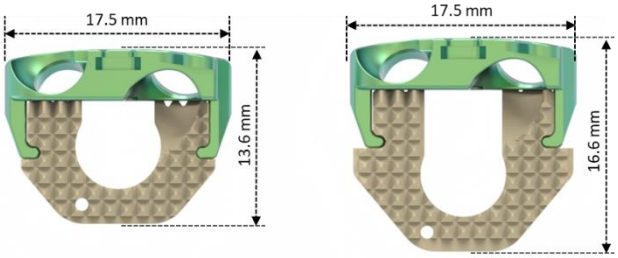
This system integrates a hollow PEEK spacer with a titanium screw locking mechanism and is designed to aid in cervical interbody fusion. A titanium marker is embedded into the cage to help visually confirm the posterior position under fluoroscopy. The interbody plate with stops is pre-attached to the PEEK spacer, the interbody plate with stops is automatically aligned upon implant insertion. The integrated design allows for rigid screw fixation without any added anterior profile.

The interbody device is offered in a variety of lengths, heights and lordotic angles.

Implant Features



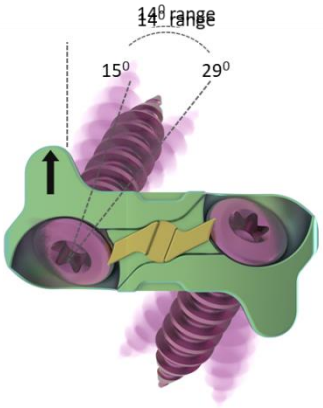
- **Zero-profile midline designed to minimize the risk of contact with vessels and adjacent soft tissues**
- **Prevents adjacent level ossification**
- **Easy of use**
  - Variable angle screws, designed with a wide range of allowable screw trajectories, potentially facilitate screw insertion.
  - An easy and secure locking mechanism allows quick reconstruction and retains the screw to prevent backout.
  - Small incision sizes are possible in comparison to plate and spacer usage.
- **Interbody Spacer**
  - Spacer component is made of a biocompatible radiolucent polymer (PEEK) which allows visualization and assessment of the bones to be fused.
  - Teeth on the implant surface provide initial stability.
  - Radiopaque marker for posterior visualization during imaging.

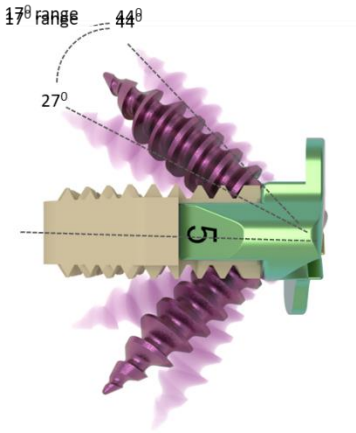


- **Interbody plate with stops**
  - Titanium alloy interbody plate provides a stable fixation with screws.
  - Stresses in the interbody plate with stops are decoupled from the spacer through an innovative interface.
  - Contralateral safety stops designed to prevent over insertion and align with the anterior surface of the vertebral bodies.

Variable angle screws

- Self-drilling and self-tapping screws.
- Screws can be inserted 27°–44° (17° range) in cranial-caudal direction and 15°–29° (14° range) in medial-lateral direction.
- Designed to help prevent graft expulsion.
- Screws are allowed to toggle postoperatively within vertebral bodies, which may potentially prevent load shielding of the graft in the event of graft subsidence.

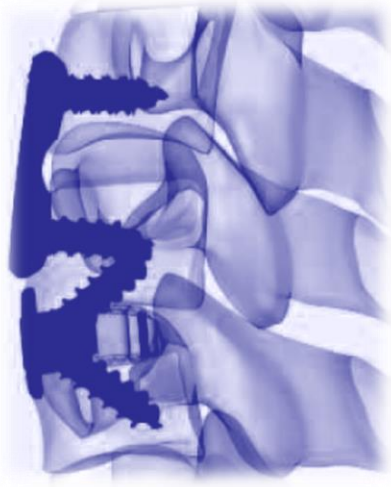




Indications

The MINERVA™ VA ACIF system is intended for use following anterior cervical discectomy for reduction and stabilization of the cervical spine (C2– C7).

- Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spinal stenosis
- Failed previous fusions
- Pseudoarthrosis



Contra-indications

- Spinal fracture
- Spinal tumor
- Severe osteoporosis
- Spinal infection

Note for long spans or poor bone quality: The surgeon is urged to consider the nature of such cases. The treatment may require the use of screws longer than 18 mm, and/or posterior fixation for this kind of inherently unstable case.

SURGICAL TECHNIQUE

1
Patient Positioning

Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagittally neutral position and supported by a cushion. The posterior cervical spine is supported to establish and maintain normal cervical lordosis (Figure 1). When treating C6–C7 make sure that the shoulders do not limit the x-ray monitoring. For all cases, both vertebrae should be completely visible.

Figure 1

2
Anterior Approach

Locate the correct operative level under radiographic control and incise.

Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine. After exposing the cervical spine, the self-retaining retractor is placed to provide optimal visualization (Figure 2). Careful positioning of the retractor is required to avoid soft tissue damage.

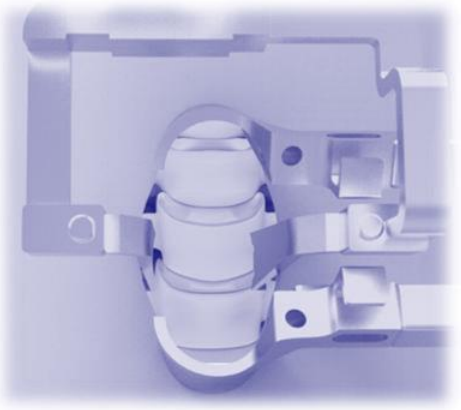


Figure 2

3
Discectomy / Endplate Preparation

Distraction of the segment is essential for restoring disc height and for providing good access to the inter-vertebral space.

Open the cortex with an Awl. The **Distraction Rods** (MOI 2201007) are then positioned midline in the vertebral bodies adjacent to the level to be treated (Figure 3).

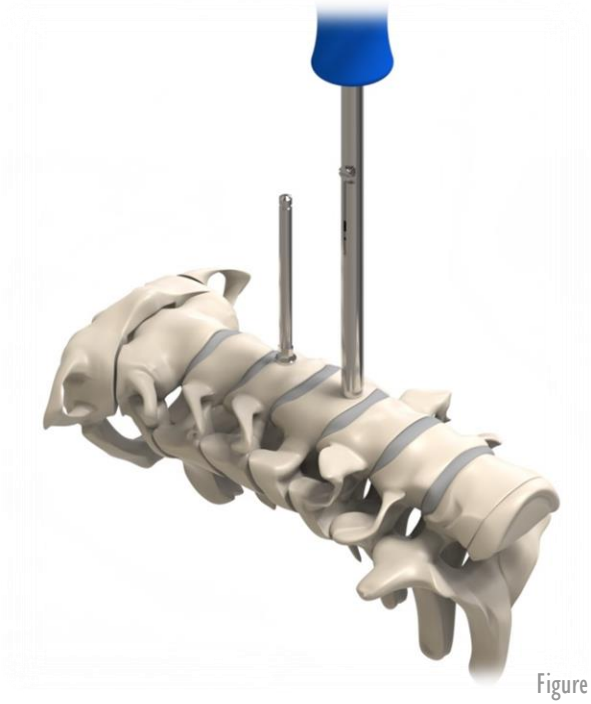


Figure 3

In-Line Round Awl (MOI 2201005)

Distraction Rods (MOI 1900007)

Holders for Distraction Rods (MOI 1900014)

3
Discectomy / Endplate Preparation (Continued)

Use **Distractor** (MOI 2201024) to perform segmental distraction. The distractor is placed over the shafts and the appropriate amount of distraction is applied (Figure 4).

Prepare the fusion site following the appropriate technique for the given indication (Figure 5).

Remove the disc through the window until only the lateral and posterior annuli remain intact. The **Curettes** (MOI 2201003 or MOI 2201009) facilitate removal of the disc material.

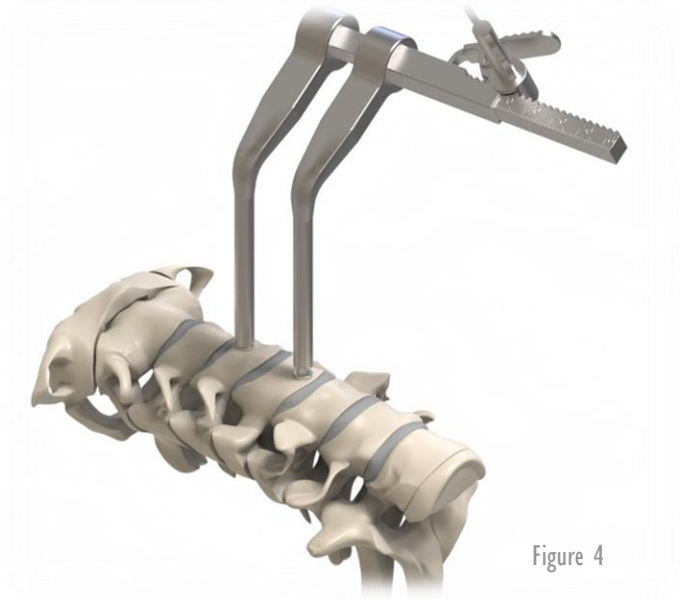


Figure 4

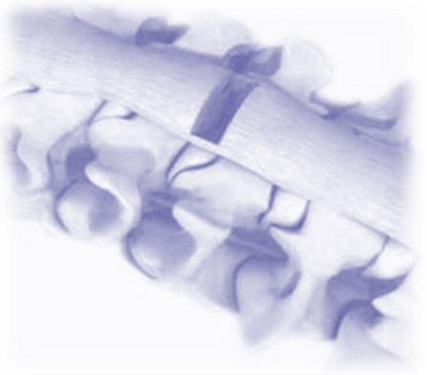


Figure 5

4
Determine Appropriate Implant

Choose a parallel, lordotic or convex **Trial Spacer** of the appropriate height and depth. Selection of the Trial Spacer depends on the height and depth of the intervertebral space, the preparation technique, and patient anatomy.

Attached the corresponding **Shaft** to the Trial Spacer. Position the Trial Spacer in the correct cranial/caudal alignment and carefully insert it into the disc space (Figure 6).

The **Hammer** (MOI 2201012) can be used to help insert and/or remove the Trial Spacer.

Shafts for trial spacers have depth stops corresponding to the depth stops of the MINERVA™ VA implant.

Although the trial spacers have depth stops, use of an image intensifier is recommended to check the position during insertion. With the segment fully distracted, the trial spacer must fit tightly and accurately between the end plates.

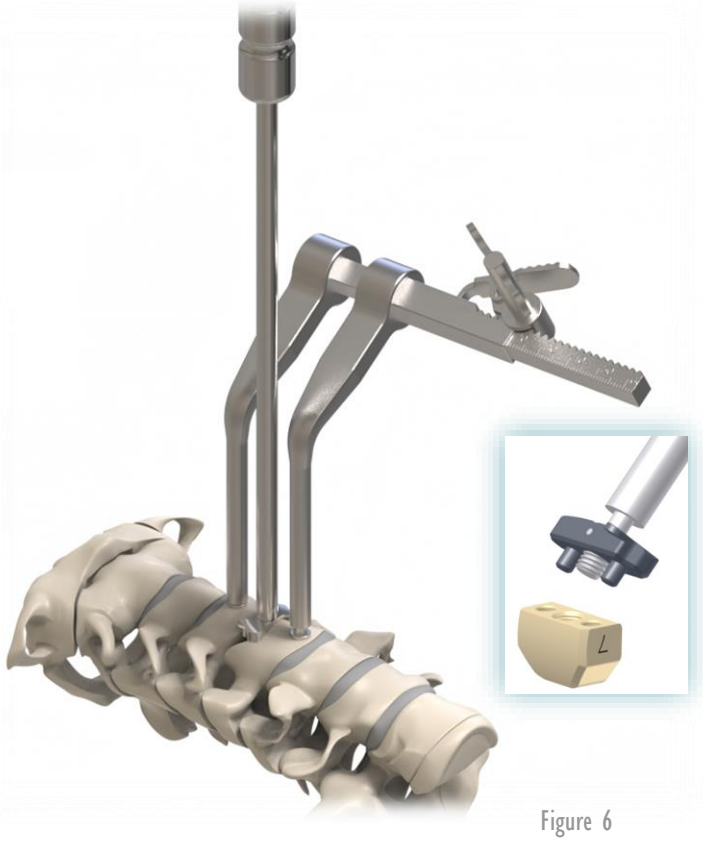


Figure 6

Distractor (MOI 2201024)

Curettes (MOI 2201003 / MOI 2201009)

Shaft for Trial Spacers (MOI 2201016 – MOI 2201019)

Hammer (MOI 2201012)

NOTES:

- It is recommended to remove interfering anterior osteophytes before implant insertion.

- To minimize potential risk of injuring the patient, it is recommended to trial with smaller height trial spacers before trialing with taller height trial spacers.

- Trial spacers are not for implantation and must be removed before insertion of the MINERVA™ VA implant.

5
Select the Implant

Attach the **Insertion Device** (MOI 2201021) to the implant by aligning the recessed grooves located midline on the anterior face of the implant with the pronged tabs of the device tip. Squeeze the insertion device handles to secure the implant; the thumb nut on the insertion device may then be advanced clockwise to affix the implant to the insertion device (Figure 7).

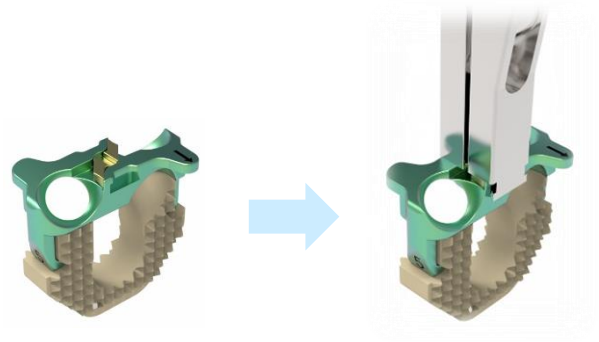


Figure 7

6
Pack Implant with Bone Graft

Place the MINIVER™ VA implant into the **Packing Block** (MOI 2201022).

Use the **Cancellous Bone Impactor** (MOI 2201001) to firmly pack the graft material into the implant cavity (Figure 8).

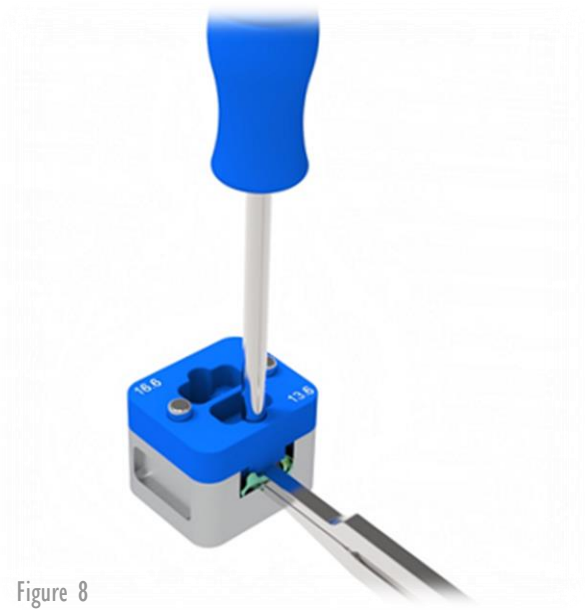


Figure 8

Insertion Device (MOI 2201021)

Packing Block (MOI 2201022)

Cancellous Bone Impactor (MOI 2201001)

7
Implant Insertion

Carefully insert the implant into the distracted segment. Advance the implant until the implant stops rest on the anterior surface of the vertebral body. The implant should fit tightly and accurately between the endplates (Figure 9).

If necessary, the top of the insertion device can be tapped with a hammer to advance the implant into the disc space. If distraction has been applied, release the distractor, leaving the insertion device attached to the implant.

Important:
Verify final implant position relative to the vertebral bodies in the AP and lateral directions with the help of an intra operative x-ray. A posterior x-ray marker incorporated in the PEEK spacer enables accurate intraoperative radiographic assessment of implant position.

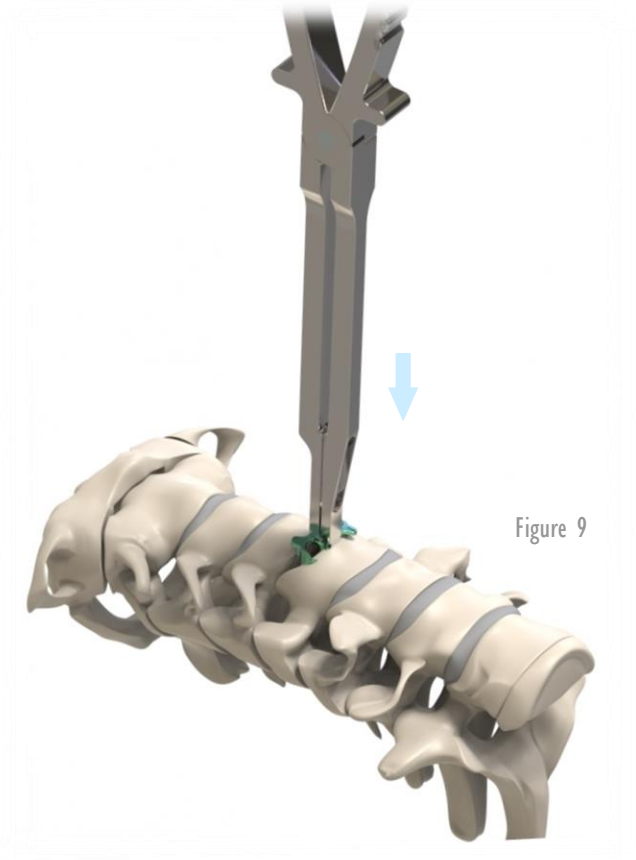


Figure 9

8
Create First Pilot Hole for Screw

Determine the entry point and trajectory for the first screw. The correct angulations for the screws range between 27°–44° cranial / caudal and 15°–29° medial / lateral (Figure 10).

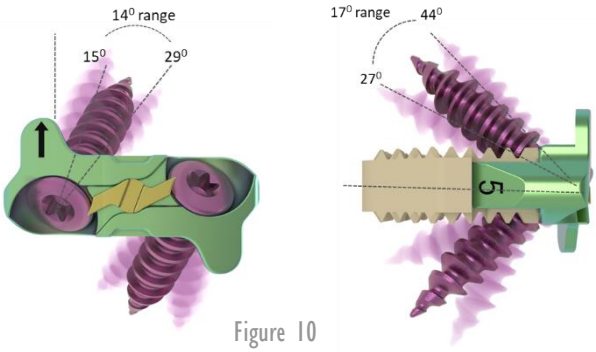


Figure 10

Option A: Awl and Self-drilling Screws

It is recommended to create the first hole for the caudally aimed screw.

Insert the **In-Line Round Awl** (MOI 2201005) into the first screw hole of the interbody plate. Intraoperative imaging should be used to verify awl position. Once the correct trajectory is confirmed, push down on the ball handle of the awl while simultaneously twisting the handle to advance the awl (Figure 11).

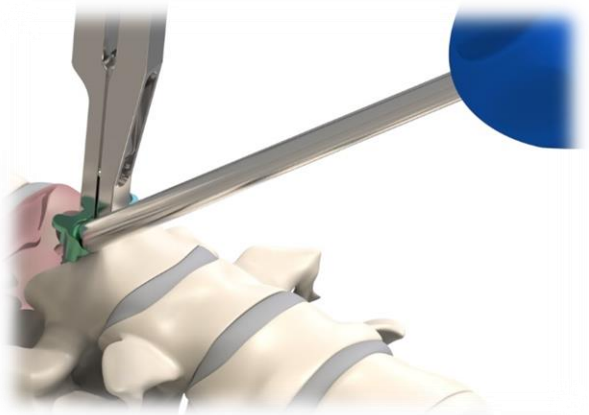


Figure 11

In-Line Round Awl (MOI 2201005)

When screws holes are difficult to prepare due to interfering anatomy, the angled **Awl** (MOI 2201006) may be used (Figure 12).

When using the awl, the Insertion Device should be used to minimize implant movement.

Remove the awl while maintaining alignment of the hole and implant.

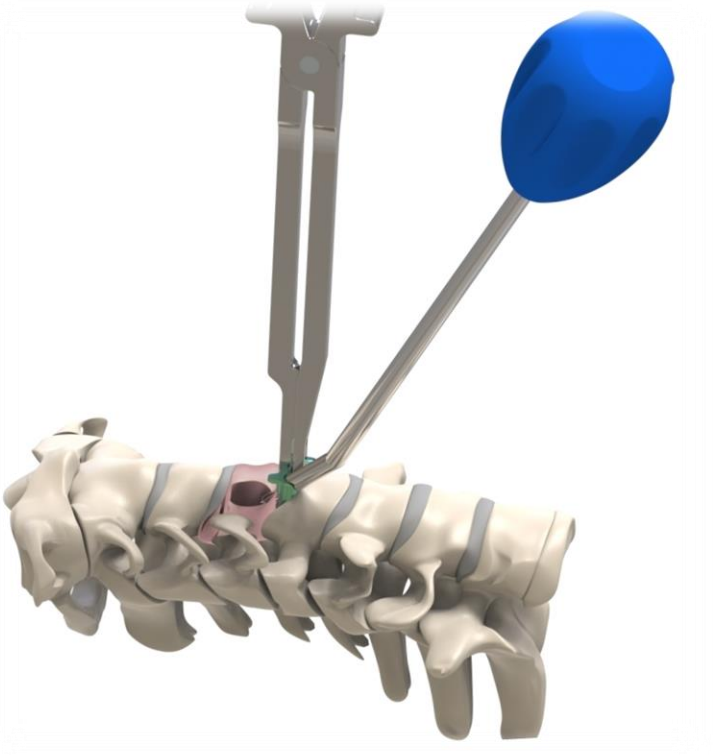


Figure 12

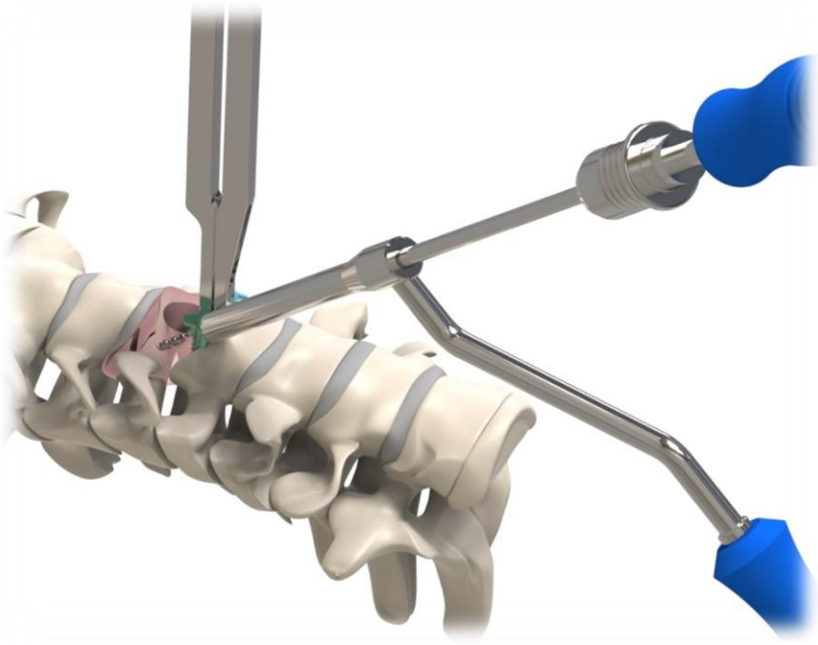


Figure 13

Option B: Drill Guide

Select a **Drill Bit 2.0 mm** of appropriate length and assemble the drill bit to the **Quick Coupling Handle** (MOI 2201011).

Insert the **Drill Guide** (MOI 2201025) into the screw hole of the interbody plate. To ensure proper angle of the pilot hole, fully seat the tip of the drill guide into the interbody plate and confirm correct trajectory. Insert the drill bit into the guide and drill until the stop of the drill contacts the guide (Figure 13). When drilling, make sure to drill on-axis, in the same trajectory as the drill guide. Intraoperative imaging should be used to verify drill bit position.

Remove the drill bit and drill guide.

Angled Awl (MOI 2201006)

Drill Bit 2.0 mm (MOI 2201013 – MOI 2201015)

Drill Guide (MOI 2201025)

Quick Coupling Handle (MOI 2201011)

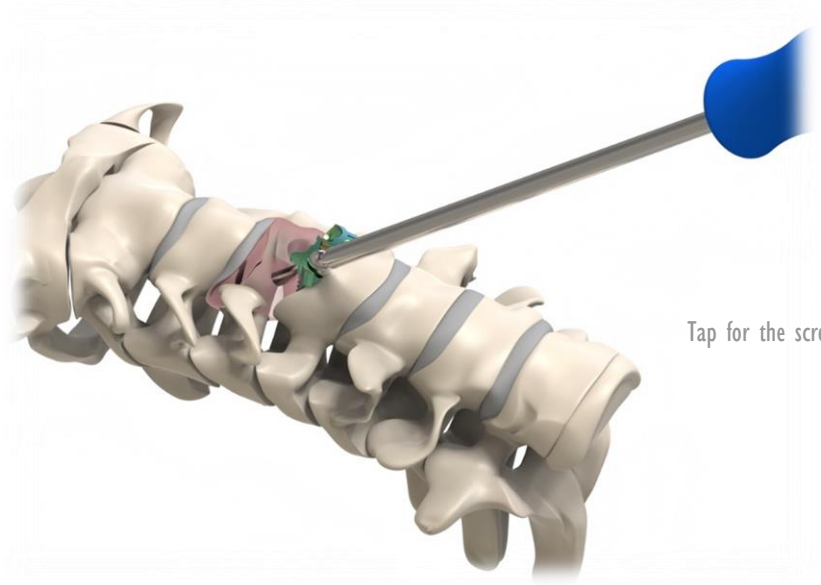


Figure 14

Tap for the screw if necessary (Figure 14).

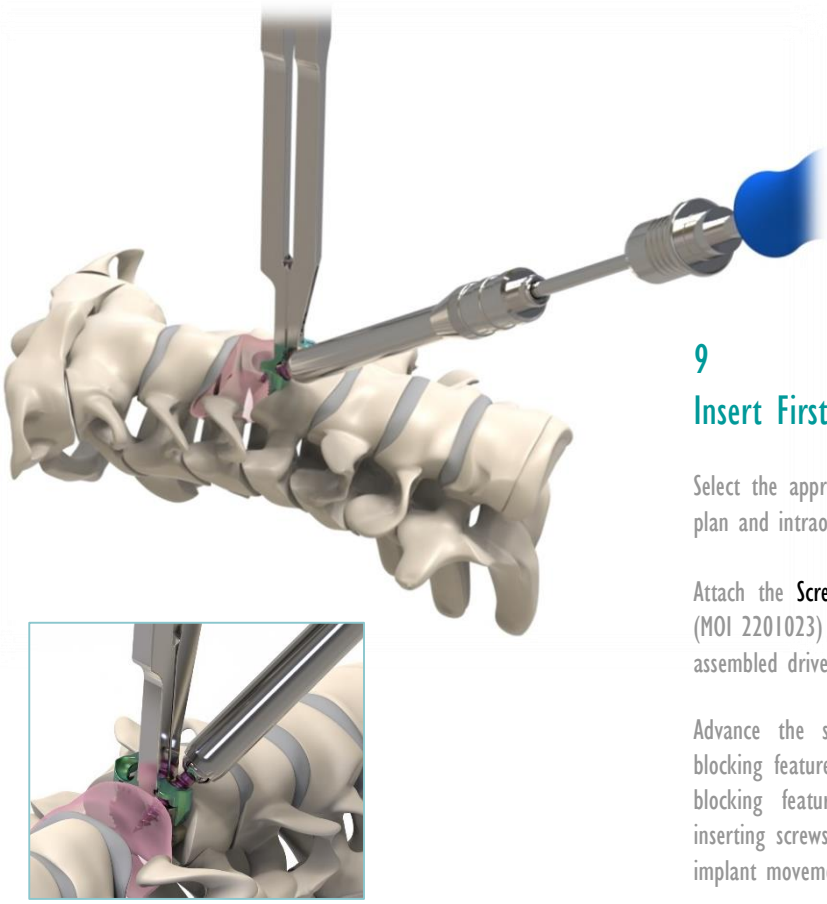


Figure 15

9
Insert First Screw

Select the appropriate screw length according to the preoperative plan and intraoperative findings.

Attach the **Screwdriver Shaft** (MOI 2201020) with **Holding Sleeve** (MOI 2201023) to the handle, then load the selected screw to the assembled driver.

Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head (Figure 15). When inserting screws, the Insertion Device should be used to minimize implant movement.

Intraoperative imaging should be used to verify screw position and to verify the screw follows the trajectory of the pilot hole created by the awl or the drill.

Tap 3.7 mm, for Fixation Screw 3.7 mm (MOI 2201082)

Screwdriver Shaft Stardrive (MOI 2201020)

Holding Sleeve (MOI 2201023)

When screws difficult to insert due to interfering anatomy, the **Angled Screwdriver** (MOI 2201008) may be used (Figure 16).

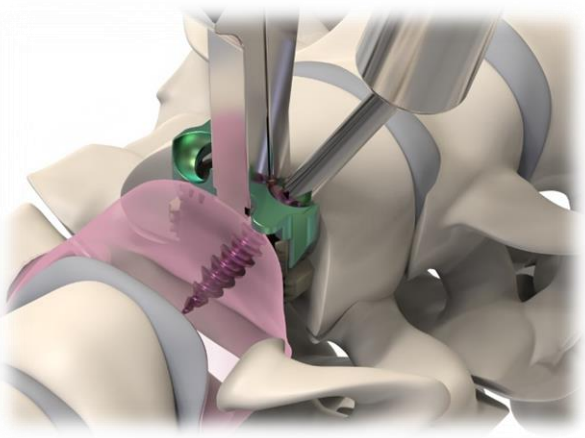


Figure 16

10
Insert Second Screw

Repeat the above steps for the second screw (Figure 17).

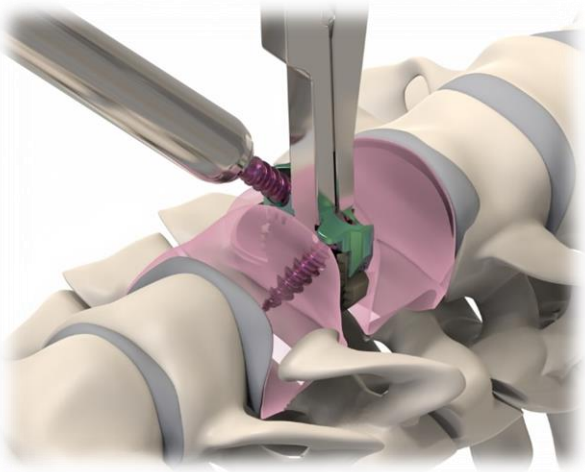


Figure 17

11
Lock the Screws

Remove the Implant Insertion Assembly from the Implant Construct.

Rotate the Retention Rivet with the **Locking Cap Tightener** (MOI 2201081) clockwise to lock the screws into the implant assembly (Figure 18).

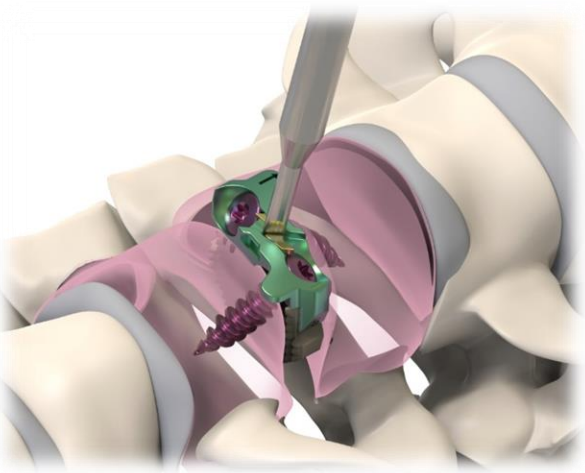


Figure 18

Angled Screwdriver (MOI 2201008)

Locking Cap Tightener (MOI 2201081)

IMPLANT REMOVAL

If a MINERVA™ VA implant must be removed, the following technique is recommended.

1
Remove Screws

Unlock the Retention Rivet by rotating the Rivet counter-clockwise, until the screws are no longer retained. Attach the handle to the screwdriver shaft, then engage the assembled driver into the first screw to be removed. While pressing the blocking mechanism toward the midline with the removal blade, turn the assembled driver counterclockwise to remove the screw (Figure 18).

Repeat this step with the other screw.

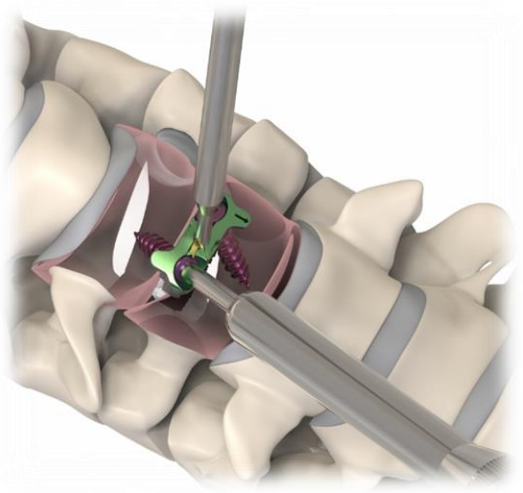


Figure 18

2
Extract Implant

Once the screws are removed, remove the MINERVA™ VA implant using the Insertion Device. Engage the insertion device to the implant by first aligning the recessed grooves located midline on the anterior face of the implant with the pronged tabs of the device tip (Figure 19).

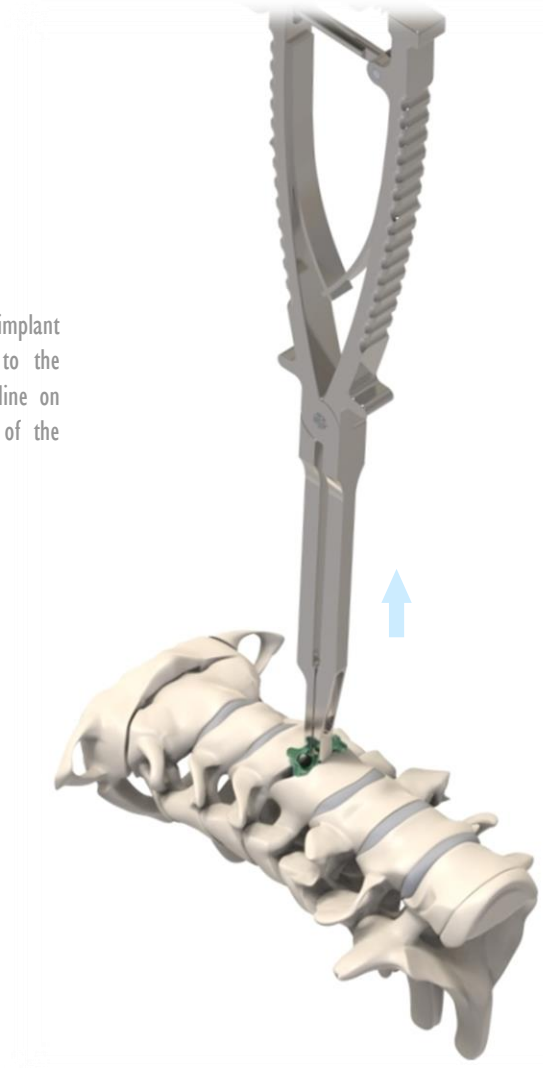
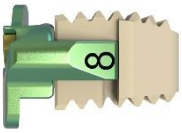


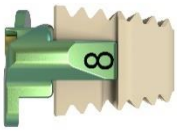
Figure 19

IMPLANT INFORMATION



Standard MINERVA™ VA ACIF Cage Convex

HEIGHT	REF
5 mm	MOI 47201005
6 mm	MOI 47201006
7 mm	MOI 47201007
8 mm	MOI 47201008
9 mm	MOI 47201009
10 mm	MOI 47201010
11 mm	MOI 47201011
12 mm	MOI 47201012



Standard MINERVA™ VA ACIF Cage Lordotic

HEIGHT	REF
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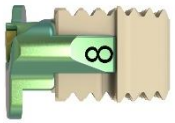
6 mm	MOI 47202006
7 mm	MOI 47202007
8 mm	MOI 47202008
9 mm	MOI 47202009
10 mm	MOI 47202010
11 mm	MOI 47202011
12 mm	MOI 47202012



Standard MINERVA™ VA ACIF Cage Parallel

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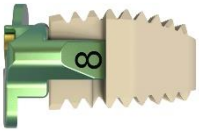
6 mm	MOI 47203006
7 mm	MOI 47203007
8 mm	MOI 47203008
9 mm	MOI 47203009
10 mm	MOI 47203010
11 mm	MOI 47203011
12 mm	MOI 47203012



Large MINERVA™ VA ACIF Cage Convex

HEIGHT	REF
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6 mm	MOI 47204006
7 mm	MOI 47204007
8 mm	MOI 47204008
9 mm	MOI 47204009
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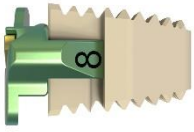
11 mm	MOI 47204011
12 mm	MOI 47204012



Large MINERVA™ VA ACIF Cage Lordotic

HEIGHT	REF
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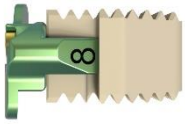
7 mm	MOI 47205007
8 mm	MOI 47205008
9 mm	MOI 47205009
10 mm	MOI 47205010
11 mm	MOI 47205011
12 mm	MOI 47205012



Large MINERVA™ VA ACIF Cage Parallel

HEIGHT	REF
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6 mm	MOI 47206006
7 mm	MOI 47206007
8 mm	MOI 47206008
9 mm	MOI 47206009
10 mm	MOI 47206010
11 mm	MOI 47206011
12 mm	MOI 47206012

Fixation Screw 3.7 mm Self-drilling

LENGTH	REF (TIT)
14 mm	MOI 37207014

Fixation Screw 3 7 mm Self-drilling

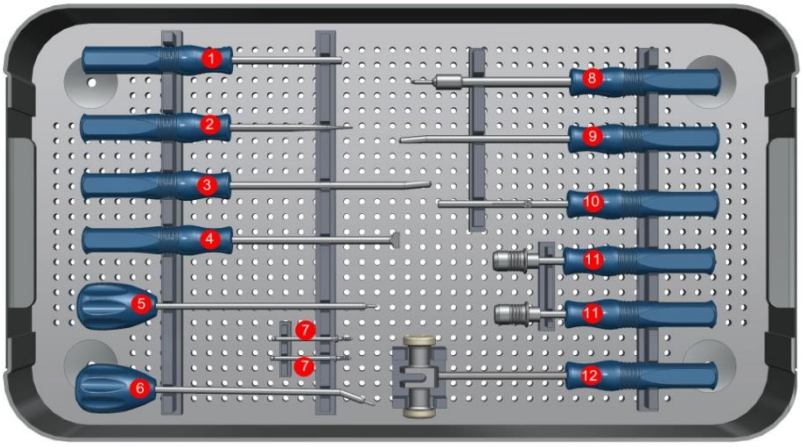
LENGTH	REF (TIT)
16 mm	MOI 37208016

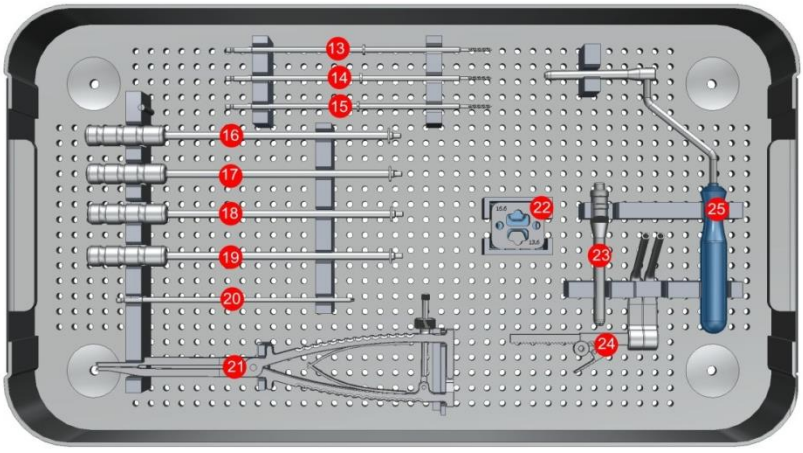
Fixation Screw 3.7 mm Self-tapping

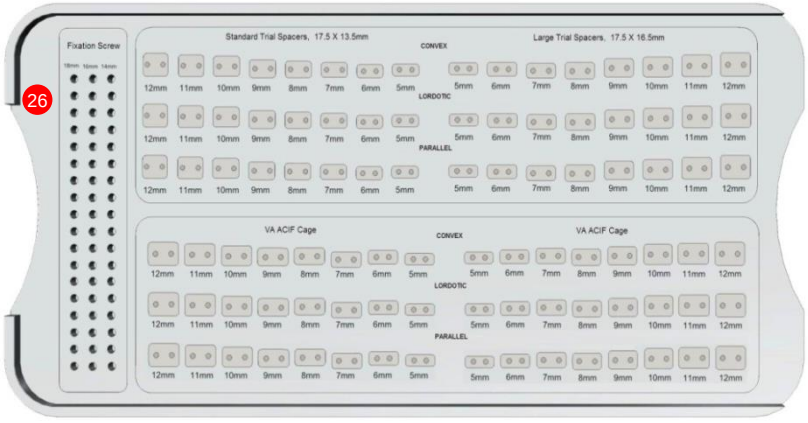
LENGTH	REF (TIT)
18 mm	MOI 37209018

INSTRUMENTS INFORMATION

MINERVA™ Variable Angle ACIF Cage Basic Instrument Set (MOI-MINERVA-01R)







MOI 2201082 Tap 3.7 mm, for Fixation Screw 3.7 mm

MOI 2201081 Locking Cap Tightener

	REF	DESCRIPTION	UNITS
1	MOI 2201001	Cancellous Bone Impactor	1
2	MOI 2201002	Screw Removal Blade	1
3	MOI 2201003	Curette 5°	1
4	MOI 2201004	Impactor, flat	1
5	MOI 2201005	In-Line Round Awl	1
6	MOI 2201006	Awl, angled	1
7	MOI 2201007	Distraction Rod	2
8	MOI 2201008	Angled Screwdriver Stardrive, self-holding	1
9	MOI 2201009	Curette 15°	1
10	MOI 2201010	Holder for Distraction Rod	1
11	MOI 2201011	Quick Coupling Handle	2
12	MOI 2201012	Hammer	1
13	MOI 2201013	Drill Bit 2.0 mm, drilling depth 12 mm	1
14	MOI 2201014	Drill Bit 2.0 mm, drilling depth 14 mm	1
15	MOI 2201015	Drill Bit 2.0 mm, drilling depth 16 mm	1
16	MOI 2201016	Shaft for Trial Spacers 5 / 6 mm	1
17	MOI 2201017	Shaft for Trial Spacers 7 / 8 mm	1
18	MOI 2201018	Shaft for Trial Spacers 9 / 10 mm	1
19	MOI 2201019	Shaft for Trial Spacers 11 / 12 mm	1
20	MOI 2201020	Screwdriver Shaft Stardrive, Self-Holding	1
21	MOI 2201021	Insertion Device for VA ACIF Fusion Cage	1
22	MOI 2201022	Packing Block	1
23	MOI 2201023	Holding Sleeve for Screws	1
24	MOI 2201024	Distractor	1
25	MOI 2201025	Drill Guide	1
26	MOI 2201026	Rack for Screws and Trial Spacers	1
	MOI 2201027 - MOI 2201034	Standard Trial Spacers, Convex	8
	MOI 2201035 - MOI 2201042	Standard Trial Spacers, Lordotic	8
	MOI 2201043 - MOI 2201050	Standard Trial Spacers, Parallel	8
	MOI 2201051 - MOI 2201058	Large Trial Spacers, Convex	8
	MOI 2201059 - MOI 2201066	Large Trial Spacers, Lordotic	8
	MOI 2201067 - MOI 2201074	Large Trial Spacers, Parallel	8
*	MOI 472000C	Trays and Container	1

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