

VBOSS®

Surgical Technique

• Vertebral Body Support System



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NOTE

Refer to the packaging insert and Instructions for Use for information related to the intended uses and indications, device description, contraindications, precautions, warnings and potential risks associated with the Stryker Spine VBOSS cages and instruments.

REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the Stryker Spine VBOSS System is not intended to be removed unless the management of a complication or adverse event requires the removal.

Standard instruments will be used to hold and disengage the device from the vertebrae.

Any decision by a physician to remove the device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

1. System Description

1.1 Implants

The Stryker Spine Vertebral Body Support System (VBOSS) is intended for use as an aid in spinal fusion and stabilization and consists of a hollow cylindrical tube. The sides of the cylinder are perforated by equally spaced round holes. The cylinder is segmented and the grooves can be used as cutting lines. The VBOSS implants are available in a variety of diameters from Ø12mm to 25mm and lengths from 8mm to 120mm.

The end caps snap into each end of the VBOSS cage. The exterior side of the end cap features evenly spaced round spikes providing fixation. The end cap is available in round, oval, round angled

and oval angled shapes depending on the diameter of the system. It is also offered in different heights.

The cage body is available in 5 diameters and 8 heights (see following table). The grooves, designed to make the cutting step easier, are distant of 5mm.

The evenly staggered holes allow optimal porosity for maximum fusion.

The cage body and end caps are composed of commercially pure titanium alloy.

A color coding for each cage body and end cap diameter allows for easy identification.

The end caps are modular and available in 5 diameters and 10 different configurations :

2 shapes:	round and oval
3 angles:	0°, 5° and 10°
2 different heights:	small and large

The small and large end caps are respectively 1.65mm and 3.3mm high. The construct of the VBOSS (cage body and end caps) matches the spinal anatomy, by offering an increment of 1.65mm.

Cage body references

Diameter of the body (Ø External) [mm]

		Ø12	Ø14	Ø16	Ø20	Ø25
Height of body (mm)	8	336612008	336614008			
	9	336612009	336614009			
	10	336612010	336614010			
	11	336612011	336614011			
	12	336612012	336614012			
	40	336612040	336614040	336616040	336620040	336625040
	80	336612080	336614080	336616080	336620080	336625080
	120				336620120	336625120

End cap references

Diameter of the body [mm]

		Angle	Height	Ø12	Ø14	Ø16	Ø20	Ø25
Shape	Round Shape	0°	Small	33661200SR	33661400SR	33661600SR	33662000SR	33662500SR
			Large	33661200MR	33661400MR	33661600MR	33662000MR	33662500MR
		5°	Small	33661205SR	33661405SR	33661605SR	33662005SR	33662505SR
			Large	33661205MR	33661405MR	33661605MR	33662005MR	33662505MR
	Oval Shape	0°	Small				33662000SO	33662500SO
			Large				33662000MO	33662500MO
		5°	Small				33662005SO	33662505SO
			Large				33662005MO	33662505MO
		10°	Small				33662010SO	33662510SO
			Large				33662010MO	33662510MO

1.2 Instruments

Caliper 33660050



This instrument indicates the height corresponding to the minimum space between two or more vertebral bodies. Combined with the Cage Cutter, the caliper determines the length of the cage body to cut and the combination of end caps to use. The combination – cage body and end caps corresponds to the indicated intervertebral space. The forceps provide easy memorization of the measurement and a reliable return to its original position with the correct distance. The rectangular tips are inserted into notches, either on the Cage Cutter, or on the container in order to define the right end cap combination.



Cage Cutter 33660100

This instrument is for cutting the implant cage bodies and for determining the combination of endplates to be assembled, with the help of the Caliper. It consists of a frame and a cutting block. The cutting block is a system composed of several parts aimed at maintaining and moving the cutting blade in the axial and transverse direction of the implant. The frame is composed of 4 rods and 2 plates, provided with guiding clevis for the mandrels.



Cutting Blade Shaft 33660111

The shaft acts as an interface between the Cutting Blade and the Cage Cutter. It is intended for use up to a maximum of 5 cutting cycles until which point mechanical performances are optimal and repeatable. Then the part should be discarded. A silicone pin in the tray will help track the number of shaft uses.



Cutting Blade 33660112

The blade rotates freely around the shaft. **For optimal cutting performance, it is highly recommended to use a new blade for each procedure.** Then the old part must be discarded immediately.



- Mandrel Ø12 33660212**
- Mandrel Ø14 33660214**
- Mandrel Ø16 33660216**
- Mandrel Ø20 33660220**
- Mandrel Ø25 33660225**

These instruments hold the cage bodies during the cutting and deburring steps.

They consist of a cylindrical body that lodges itself in the clevis of the Cage Cutter and an insert pin which holds the cage in position. The various sizes of mandrel correspond to each cage diameter.

All mandrels come in the trays already fitted with insert pins. Spare parts can be ordered as separate references whenever applicable.



Cage Deburring Tool 33660250

This instrument removes the burrs created on the cage bodies after cutting. With a cylindrical protective sleeve and a conical cutting tool, it fits all cage diameters.



Small Graft Impactor 33660450 **Graft Impactor 33660460**

These instruments, available in two sizes, are provided to assist in filling the cage with grafting material, out of the operative field.

They both have a molded silicone handle.

The cylindrical body ends with a rod whose contact surface with the bone graft is knurled.



- Endplate Tip Small 33660310**
- Endplate Tip Medium 33660320**
- Endplate Tip Large 33660330**
- Endplate Tip Finger 33660340**
- Endplate Tip Offset 33660350**

These elements, coupled with the Parallel Distractor, enable a parallel distraction load on vertebral endplates.

Provided with two ramps with teeth, they make it possible to insert the implant through a notch to position it in the middle of the vertebrae.

The various sizes are adapted to all diameters and shapes of end caps.



Parallel Distractor 33660300

The Parallel Distractor is a forceps with a ratchet and a threaded rod that maintains the load applied on the vertebrae. The arms with a cross pin allow parallel motion and distraction. On each tip of the distractor, a clipping system is designed to hold the various end tips.



Insert Pin Ø12 33660412

Insert Pin Ø14 33660414

Insert Pin Ø16 33660416

Insert Pin Ø20 33660420

Insert Pin Ø25 33660425

These parts are sub-components of the mandrels.

Inserted through the cage body and mandrel holes, they maintain the implant during the cutting and deburring steps.

Cylindrical with a knurled head, the rounded tip gives a simple and quick fastening.



Ratcheting Handle 33660800

This L-shaped handle connected to a non-return system rotates the various mandrels of the Cage Cutter.



Standard Cage Inserter 33660500

With this instrument, the surgeon inserts the implant into the patient. With its molded silicone handle, it has a cylindrical body which includes a knob and ends with two pins. These two pins are introduced into the openings of the external shape of the cage body and maintain it after a clockwise rotation of the knob. It provides a tight grasp of the cage through two of the cage perforations. The disassembly of the instrument and the implant is performed by turning the knob in the reverse direction.



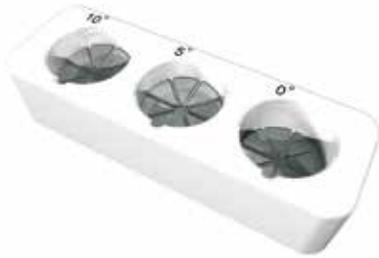
Small Cage Inserter 33660700

With the same design and features as the Standard Cage Inserter, this instrument has an 8mm diameter shaft, a truly low profile for insertion of smaller size cages. Unlike the larger version, the pins of the Small Cage Inserter are designed to grasp the cage horizontally, in a plane that is perpendicular to the axis of the cage itself.



Cage Impactor 33660600

This instrument is made for a progressive final impaction and placement of the cage. With its molded silicone handle, this instrument has a cylindrical body which ends with a V shape rod, for the external shape of the cage bodies. The Cage Impactor has a pin at the tip which is intended to engage the perforations of the cage and to prevent accidental slippage.



Base End Cap Impactor 33660650

This instrument is a base on which the cage body and the end caps are assembled in order to obtain the final construct. It is a PTFE block with 3 holes able to receive the 3 impacting bases of 0°, 5° and 10°. This base permits the final alignment of angled and / or oval end caps with each other.



End Cap Impactor 5° 33660652

Used with the Base End Cap Impactor and a mallet, this instrument permits the assembly of the cage body and the end caps for construct assembly. With its cylindrical shape, the surface, in contact with the implant, features grooves adapted to the end cap spikes. It is angled at 5° in order to fit all end cap angle combinations.

2. Indications

The Stryker Spine VBOSS implant is a device intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra due to tumor or trauma (i.e., fracture). For both corpectomy and vertebrectomy procedures, the Stryker Spine VBOSS system is intended to be used with supplemental internal fixation systems. The use of bone graft is optional.



3. Patient Position

The patient should be placed on the operating table in a lateral decubitus position.

A left anterolateral approach is usually used.

4. Surgical Approach

Through a retroperitoneal or combined thoracolumbar approach, the lateral aspect of the spine column is exposed. Confirm the appropriate level radiographically.

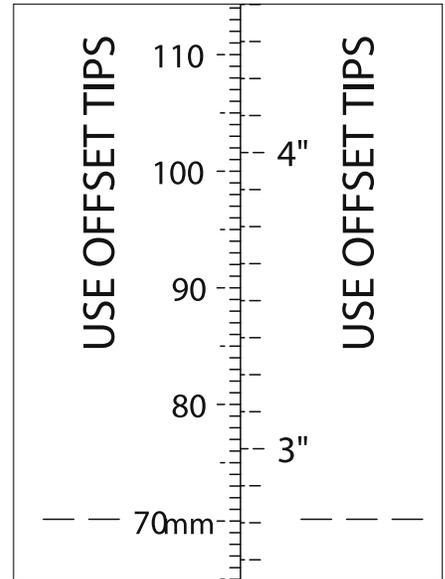
X-ray or fluoroscopy should be used to localize the correct level of the spine.

Perform the corpectomy or vertebrectomy procedure as needed and prepare bone endplates using standard instruments.

4.1 Choice of adequate Parallel Distractor Tips

4.1.1.

Use the Caliper to determine the length of the construct and then refer to the ruler of the implant tray to make a choice between Offset or Non Offset Tips.



4.1.2.

Select the adequate pair of tips (small, medium, large, finger or offset) depending on the level to address and connect them to the Parallel Distractor.



Construct Height 5mm to 70mm	Construct Height 70mm to 120mm
Non Offset Tips	Offset Tip
 <p data-bbox="194 598 292 630">Finger</p> <p data-bbox="470 598 552 630">Large</p> <p data-bbox="730 598 828 630">Medium</p> <p data-bbox="1006 598 1088 630">Small</p>	 <p data-bbox="1282 598 1364 630">Offset</p>

4.2 Correction of the adjacent vertebral bodies and implant sizing

4.2.1. Reinsert the Caliper to determine the correct length of the construct to be implanted.

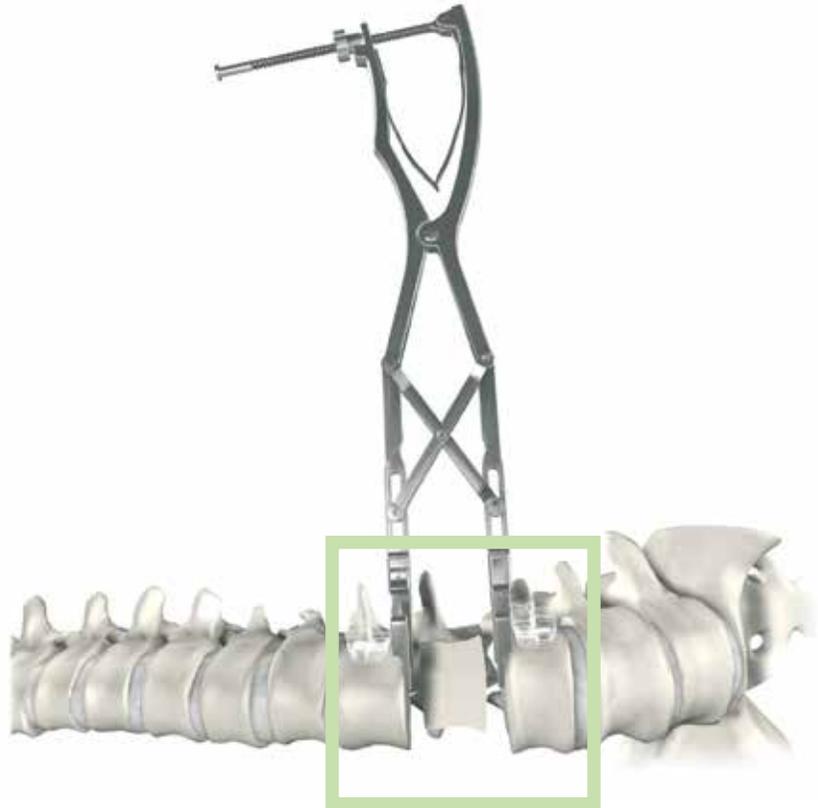
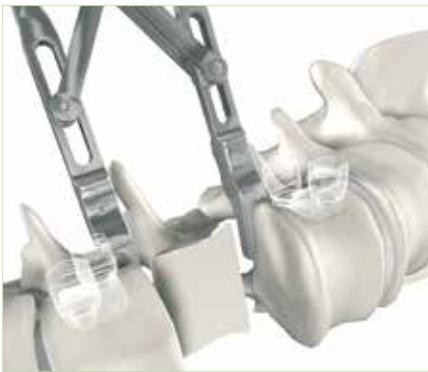
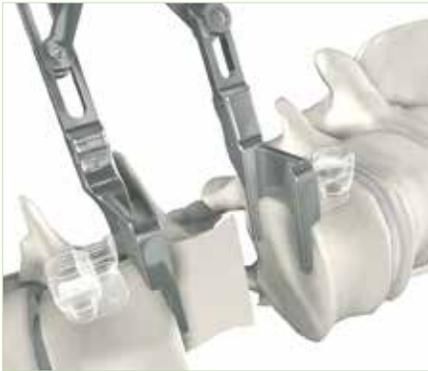
Lock the Caliper in position after having chosen the **narrowest gap between adjacent vertebral bodies**.

Insert the monoaxial screws of the anterior fixation system.



4.2.2.

Distract the vertebrae and secure the locking mechanism of the instrument. **Reinsert the Caliper to determine the correct length of the construct to be implanted.**



4.2.3.

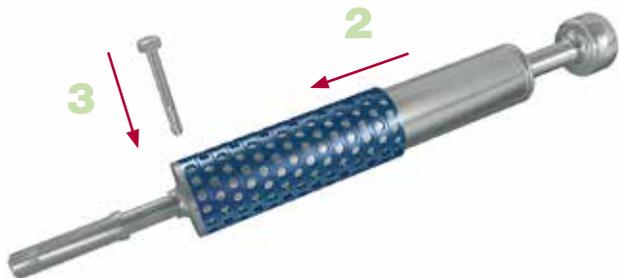
After determining the appropriate diameter of the VBOSS cage to be implanted, select the appropriate size mandrel (identified with the laser marking of the diameter).

Remove the pin from the mandrel and slide the cage onto the mandrel until it reaches the mechanical stop (for diameters 14mm, 16mm, 20mm and 25mm).

Place the pin through the cage into the mandrel.

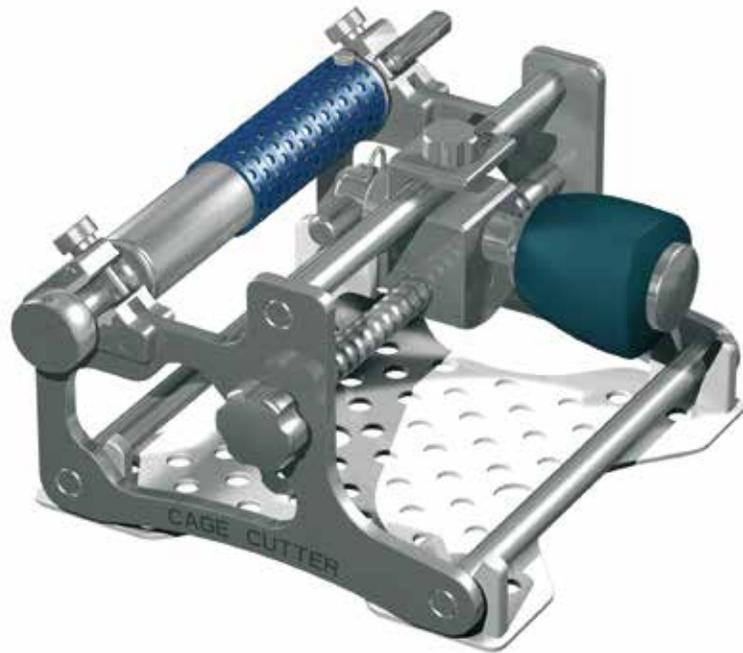
TIPS & TRICKS

On the Ø12mm mandrel, there is no mechanical stop. The secure pins must always be inserted in one of the FIRST row holes. In any case, **DO NOT FORCE** the pin while inserting. If the insertion is difficult, remove the cage from its mandrel and load it on the other side. Pin insertion should then be easier.



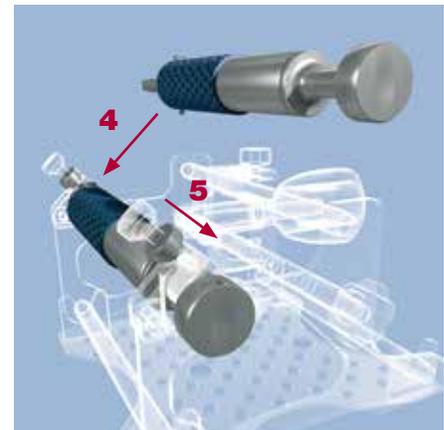
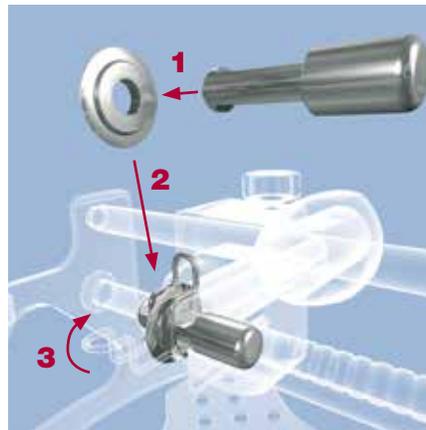
4.3 Blade and Shaft assembly

General view of the Cage Cutter with all assembled components.



Blade and shaft are provided disassembled in the tray.

1. Assemble the blade and the shaft as specified.
2. Slide this assembly into the blade holder notch. Depending on the length of the cage to cut, place the knob accordingly (left or right).
3. Secure the blade assembly with the spring.
4. Slide the mandrel into the dedicated bearings of the Cage Cutter.
5. Lock the secure pins.



LIFE EXPECTANCY RECOMMENDATIONS

Cutting Blades: For optimal cutting performance, it is highly recommended to use a new blade for each procedure.

Cutting Blade Shafts: 5 cuts

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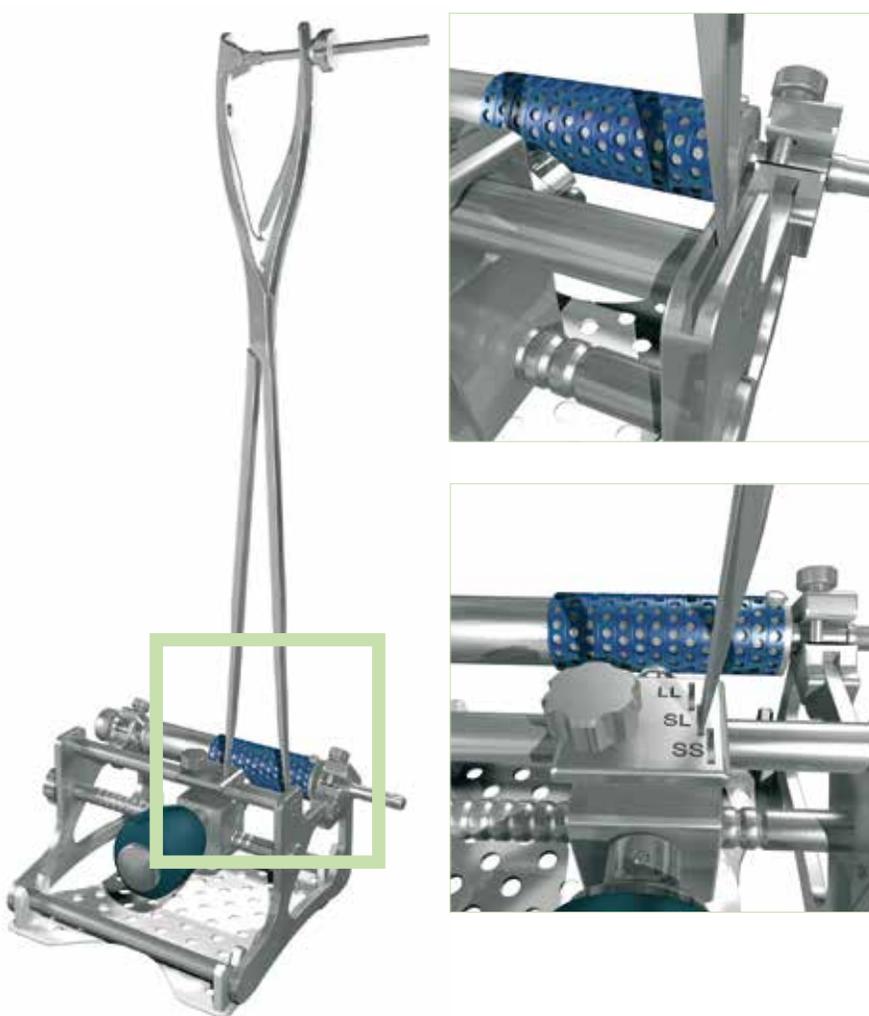
Insert one tip of the Caliper into the dedicated notch located on the right side of the Cage Cutter.

The other tip, on the left side, must fall into one of the three notches of the blade holder (lateral adjustment of the blade holder is usually necessary to match the opening of the Caliper).

The position of the left tip gives the combination of end caps to be assembled on the cage body:

Small / Small (SS), Small / Large (SL), Large / Large (LL) – see zoom at right.

Small and Large represent the thickness of the end caps, respectively 1.65mm and 3.3mm.

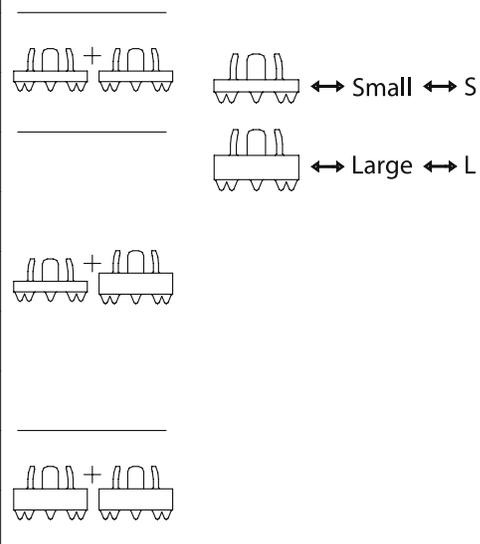


NOTE

Ø12mm and Ø14mm short cage bodies (8mm, 9mm, 10mm, 11mm, 12mm high) do not need to be cut.

In order to find the correct combination of end caps, place the Caliper tips on the laser-marked chart, engraved on the cage bodies insert, in the “Implants, insertion and impaction instruments” container upper tray of the implants container, in the dedicated measurement chart.

Length of Construct	Cage Body	End Cap Combination
11	8	SS
12	9	SS
13	8	SL
14	9	SL
15	10	SL
16	11	SL
17	12	SL
18	11	LL
19	12	LL



For Ø12mm and Ø14mm only
All values in mm

4.4 Cutting and deburring

Turn the knob clockwise until the blade is touching the cage to cut. Apply a FINGER TIGHT pressure on the handle.

The blade should be positioned into a groove before starting the cutting procedure.

Connect the ratcheting handle to the square extremity of the mandrel.

Rotate the ratcheting handle by applying a CLOCKWISE (away from your body) motion.

Gently tighten the knob again to ensure appropriate 'cutting force.' Complete about 10 movements before tightening again the blade on the cage. Repeat the cycle until the cage is cut.

Visual check: when the cage is about to be cut, the groove will widen substantially. Now is the time to apply stronger torque and finish the cutting.

An audible click usually signals that the cage has been cut. Avoid additional rotations of the cutter because this will dull the blade and may mark a groove in the mandrel making it difficult to remove the cage. The cage cutting procedure typically takes around two minutes, less with an experienced user.

IMPORTANT SURGEONS' TIPS

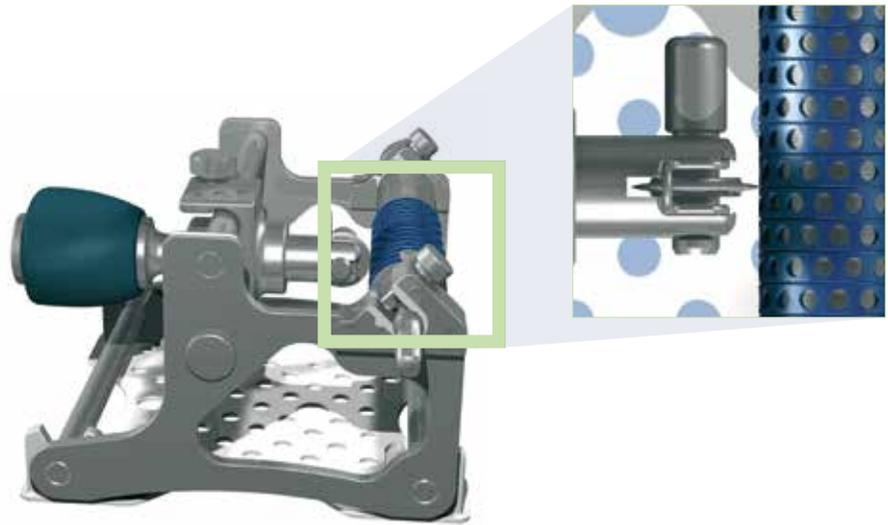
Begin the cage cutting process using a light amount of torque. Apply additional torque as necessary while rotating the cage.

For optimal cutting performance, it is highly recommended to use a new blade for each procedure.

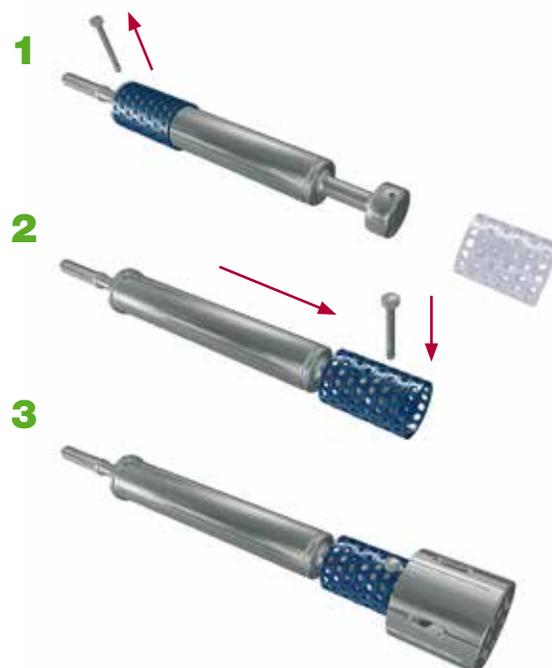
The deburring occurs as follows:

If the extremity of the cut cage needs to be deburred, assemble it on the end of the mandrel using the pin. It becomes easy to hold the cage, through the mandrel, and then deburr it. This will provide a secure grasp of the cage for deburring.

The cage is not to be cut *in situ*.



The deburring occurs as follows:



4.5 Implant assembly and filling

VBOSS offers different angles (0°, 5°, 10°) and shapes (round and oval) for end caps.

A round end cap should be used in standard cases that do not require special consideration based on the shape of the vertebra or vertebral body to be replaced. If increased surface area is desired, oval end caps should be used. Angled end caps are available for those cases in which an angled implant would provide increased stabilization.



4.5.1.

Assemble the end caps on the cage body by press-fitting these components.

Depending on the end cap angle (0°, 5° or 10°), place the end cap on its corresponding Base End Cap Impactor, taking care of the angular position (align laser-marked lines).



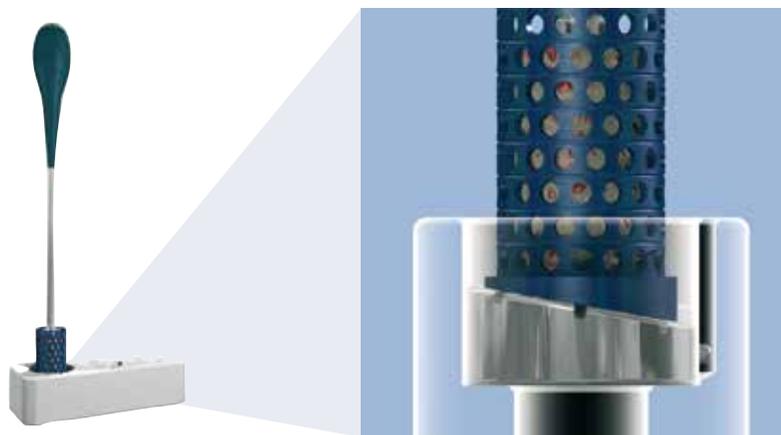
4.5.2.

When using bone graft, pack the VBOSS cage with the Graft Impactor before assembly.



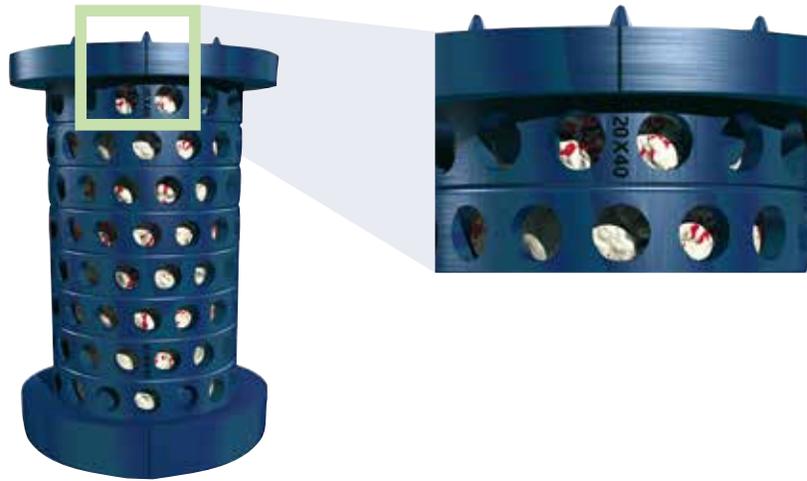
Take the End Cap Impactor and place it on the top end cap. Hit on the End Cap Impactor until parts are completely aligned.

Once both end caps have been impacted, fill in the void with more bone graft. The cage is now ready to be inserted.



NOTE

In order to get the correct alignment between end caps (oval and/or angled), align vertical laser-marked lines. For the long constructs, the lot numbers marked on cage bodies can be used as an intermediate landmark of alignment between end caps.



4.6 Implant insertion

Two Cage Inserters are provided.

The Standard Cage Inserter is intended for cages greater than 25mm in height. It provides a tight grasp of the cage through two of the cage perforations.

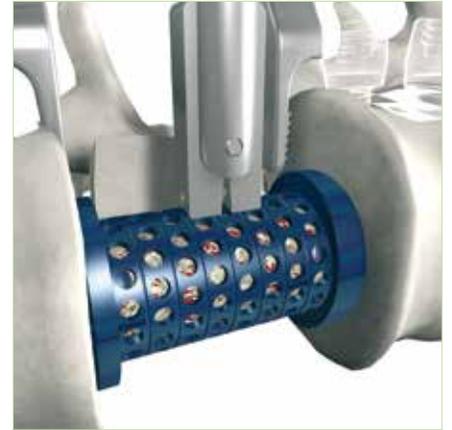


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Using the same locking function, the Small Cage Inserter is intended for smaller cages.

NOTE

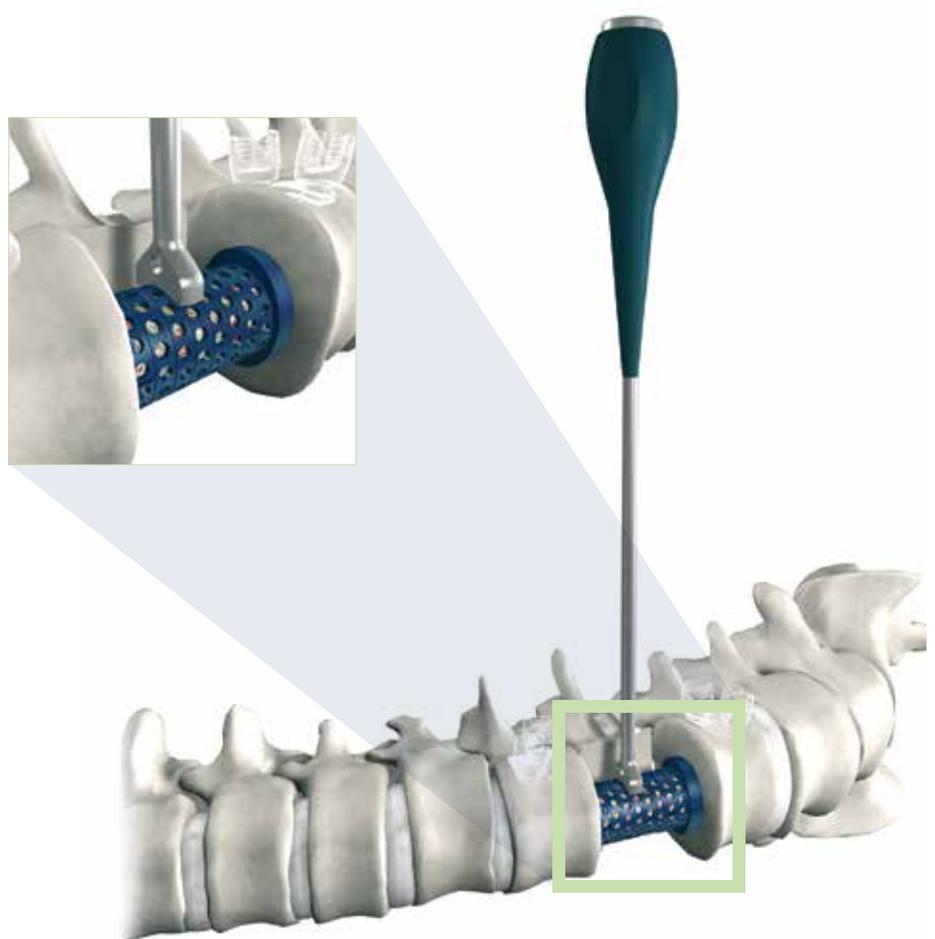
The Small Cage Inserter is holding on one level of holes only, whereas the Standard Cage Inserter holds the cage on three levels.



4.7 Final Implant fitting

If the cage needs to be adjusted once in position, use the Cage Impactor.

The impactor has a pin at the tip which is intended to engage the perforations of the cage and to prevent unintentional slippage.



FINAL CONSTRUCT

The Stryker Spine anterior solution
(Featured with the Xia Anterior spinal
fixation system)

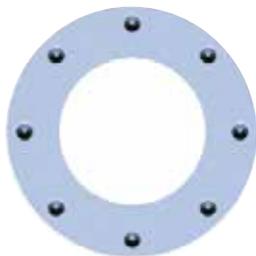


5. Appropriate Supplemental Fixation

For both corpectomy and vertebrectomy procedures, the VBOSS cage is intended for use with supplemental fixation.

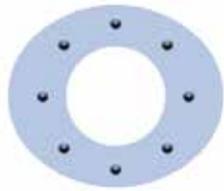
The supplemental fixation should be applied at this point. Anterior plates and pedicle screw and rod systems are among the options for the surgeon to use.

6. Standard Set and Ordering Information



6.1 Implants

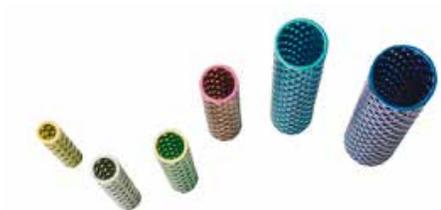
Endcaps – Round Shape	
Reference #	Description
33661200SR	12mm Small Round End Cap
33661200MR	12mm Large Round End Cap
33661205SR	12mm Small Round End Cap 5°
33661205MR	12mm Large Round End Cap 5°
33661400SR	14mm Small Round End Cap
33661400MR	14mm Large Round End Cap
33661405SR	14mm Small Round End Cap 5°
33661405MR	14mm Large Round End Cap 5°
33661600SR	16mm Small Round End Cap
33661600MR	16mm Large Round End Cap
33661605SR	16mm Small Round End Cap 5°
33661605MR	16mm Large Round End Cap 5°
33662000SR	20mm Small Round End Cap
33662000MR	20mm Large Round End Cap
33662005SR	20mm Small Round End Cap 5°
33662005MR	20mm Large Round End Cap 5°
33662500SR	25mm Small Round End Cap
33662500MR	25mm Large Round End Cap
33662505SR	25mm Small Round End Cap 5°
33662505MR	25mm Large Round End Cap 5°



Implants

Endcaps – Oval Shape

Reference #	Description
33662000SO	20mm Small Oval End Cap
33662000MO	20mm Large Oval End Cap
33662005SO	20mm Small Oval End Cap 5°
33662005MO	20mm Large Oval End Cap 5°
33662010SO	20mm Small Oval End Cap 10°
33662010MO	20mm Large Oval End Cap 10°
33662500SO	25mm Small Oval End Cap
33662500MO	25mm Large Oval End Cap
33662505SO	25mm Small Oval End Cap 5°
33662505MO	25mm Large Oval End Cap 5°
33662510SO	25mm Small Oval End Cap 10°
33662510MO	25mm Large Oval End Cap 10°



Implants

Cage Bodies

Reference #	Description
336612008	Cage 8mm x Ø12
336612009	Cage 9mm x Ø12
336612010	Cage 10mm x Ø12
336612011	Cage 11mm x Ø12
336612012	Cage 12mm x Ø12
336612040	Cage 40mm x Ø12
336612080	Cage 80mm x Ø12
336614008	Cage 8mm x Ø14
336614009	Cage 9mm x Ø14
336614010	Cage 10mm x Ø14
336614011	Cage 11mm x Ø14
336614012	Cage 12mm x Ø14
336614040	Cage 40mm x Ø14
336614080	Cage 80mm x Ø14
336616040	Cage 40mm x Ø16
336616080	Cage 80mm x Ø16
336620040	Cage 40mm x Ø20
336620080	Cage 80mm x Ø20
336620120	Cage 120mm x Ø20
336625040	Cage 40mm x Ø25
336625080	Cage 80mm x Ø25
336625120	Cage 120mm x Ø25

6.2 Instruments



Reference #	Description
33660300	Parallel Distractor
33660310	Endplate Tip Small (Pair)
33660320	Endplate Tip Medium (Pair)
33660330	Endplate Tip Large (Pair)
33660340	Endplate Tip Finger (Pair)
33660350	Endplate Tip Offset (Pair)
33660100	Cage Cutter
33660111	Cutting Blade Shaft
33660112	Cutting Blade
33660212	Mandrel Ø12
33660214	Mandrel Ø14
33660216	Mandrel Ø16
33660220	Mandrel Ø20
33660225	Mandrel Ø25
33660412	Pin Ø12
33660414	Pin Ø14

NOTE

#: Can be ordered if replacement needed. Original pins are already fitted on the mandrels.

6.2 Instruments

Reference #	Description
33660416	Pin Ø16
33660420	Pin Ø20
33660425	Pin Ø25
33660500	Standard Cage Inserter
33660250	Cage Deburring Tool
33660700	Small Cage Inserter
33660050	Caliper
33660650	Base End Cap Impactor
33660652	End Cap Impactor Angle 5°
33660450	Small Graft Impactor
33660460	Graft Impactor
33660600	Cage Impactor
33660800	Ratcheting Handle
33660850	End Cap Remover
33660002	Implant Box USA
33660003	Instrument Box USA

NOTE

#: Can be ordered if replacement needed. Original pins are already fitted on the mandrels.

Reconstructive

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