Small VBR® & Omni VBR®

vertebral body replacement

Surgical Technique

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Surgical Technique

Small VBR & Omni VBR

Contents

Introduction

1.

Introduction

The vertebral body replacement (VBR) is used for surgical reconstruction of defects of the thoracic and lumbar spine (T1-L5). The VBR is made from a titanium alloy. One or more vertebral bodies can be replaced. The implants are continuously expandable in situ, thus a precise bridging of the defect can be achieved. The large contact areas with spikes provide stability and anchoring of the endplates.

The Omni VBR may be filled with bone and/or bone graft substitute through openings within the inferior and superior ends, and through the holes around the implant.

This manual is only a guide for the utilization of the VBR implants and instruments. The technique guide is not sufficient as the only source for the successful application of the VBR. Using proper surgical procedures and techniques are the responsibility of the medical professional.

Indications and Contraindications

Indications

The Small VBR / Omni VBR is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

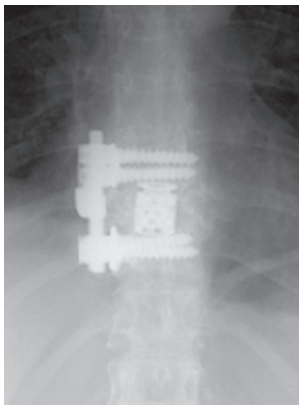
The Small VBR / Omni VBR is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Such systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the Small VBR / Omni VBR is optional.

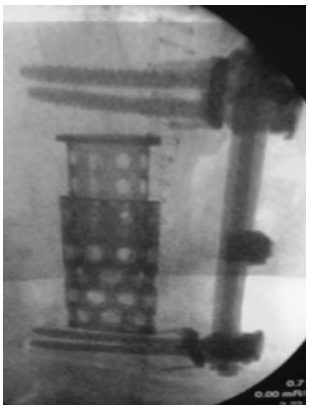
Contraindications

Contraindications of this device are consistent with those of other spinal implants. Instances in which the Small VBR / Omni VBR is contraindicated include, but are not limited to, those cases where the following conditions exist:

- Patients with acute infection
- Patients with signs of local infection
- Patients with fever or leukocytosis
- Patients with obesity
- Pregnancy
- Patients with mental illness
- Patients with drug or alcohol abuse
- Patients with suspected or documented metal allergy or intolerance
- Any patient having inadequate tissue coverage over the operative site
- Any patient unwilling to cooperate with the postoperative instructions
- Patients with rapid joint disease, bone absorption, osteopenia and/or osteoporosis
- Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and the amount of mechanical fixation.
- Any case not described in the indications
- Any other medical or surgical condition which would preclude the potential of spinal implant surgery

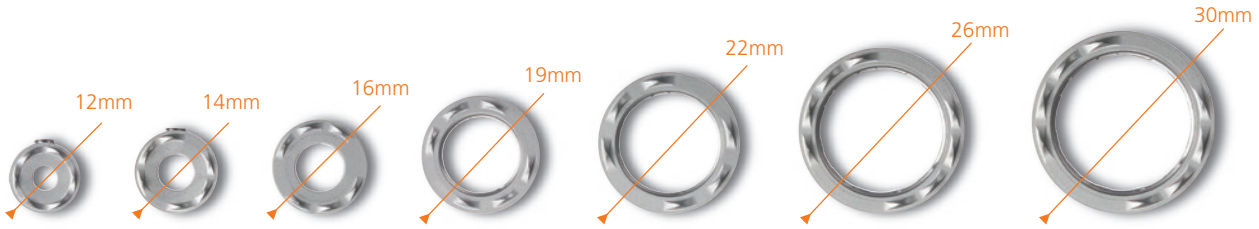


T8-T10 anterior stabilization with Small VBR
Department of Neurosurgery, Washington University, St. Louis, Missouri



Stabilization with Omni VBR
University of Alabama Birmingham

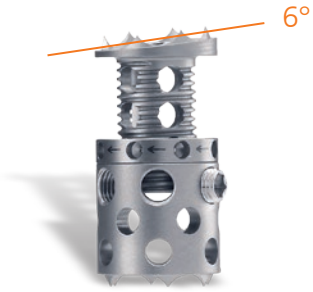
Small VBR & Omni VBR Implants

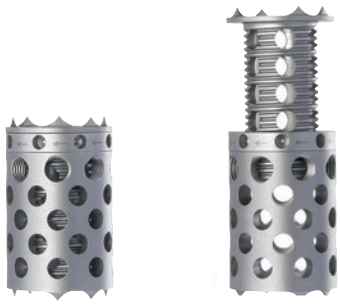


The implants are available in seven external diameters of 12, 14, 16, 19, 22, 26 and 30mm. The expansion ranges extend from 10mm to 80mm.

Diameter	Expansion Range	Expansion per handle turn	Angulation*
12mm	10 – 65mm	~0.5mm	0°, 6°
14mm	10 – 65mm	~0.5mm	0°, 6°
16mm	10 – 65mm	~0.5mm	0°, 6°
19mm	15 – 80mm	~0.3mm	0°
22mm	19 – 80mm	~0.3mm	0°, 8°
26mm	19 – 80mm	~0.3mm	0°, 8°, 16°
30mm	32 – 80mm	~0.3mm	0°, 8°

*Angulated implants have a laser etched line located at the highest point of lordosis (apex).





The **Small VBR** implants (Ø 12, 14, 16mm) are expanded by turning the expansion ring. The final expansion height becomes fixed with the application of the set screw. Implants with 6° angulation are available.

The **Omni VBR** implants (Ø 19, 22, 26, 30mm) adjust to heights ranging from 15-80mm. Angulation options include 0°, 8°, 16°.

The **Set Screws** (CS 2259 and CS 2259-01) are used for the fixation of the expanded Small VBR / Omni VBR implants.

The easy-to-use **Expansion Instrument** can be used with the Small VBR (12, 14, 16mm) cassette heads as well as Omni VBR (19, 22, 26, 30mm) cassette heads. Using the expansion instrument the implants can be expanded in situ in a continuous, frictionless manner, thus allowing for easy placement and exact bridging of the defect.

Small VBR & Omni VBR Instruments

CS 2250-930

measuring template for Omni VBR

CS 2250-940

lollipop trial, Ø 19-22mm

CS 2250-944

lollipop trial, Ø 26-30mm

CS 2252

manual expansion instrument

CS 2255-1

inserter for small heights

CS 2255-2

inserter for large heights

CS 2256-01

handle

CS 2256-02

assist handle

4.

Small VBR & Omni VBR Instruments

CS 2256-12

12mm disposable cassette head

CS 2256-14

14mm disposable cassette head

CS 2256-16

16mm disposable cassette head

CS 2256-0-19

19mm disposable cassette head

CS 2256-0-22

22mm disposable cassette head

CS 2256-0-26

26mm disposable cassette head

CS 2256-0-30

30mm disposable cassette head

CS 2256-20

outer shaft

CS 2256-21

inner shaft

CS 2256-22

implant releasing rod

CS 2261

screwdriver with holder, hex 2.5mm

CS 2265-1

lollipop trial, Ø 12-14mm

CS 2265-2

lollipop trial, Ø 16-20mm

CS 2266-3

measuring template for Small VBR

CS 2274-2

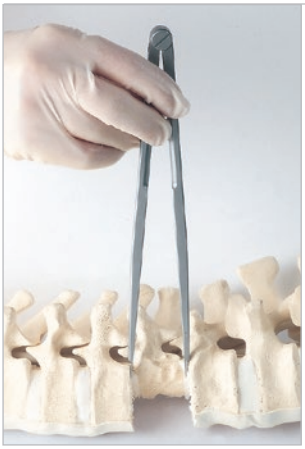
impactor, straight, height 8mm

CS 5788

measuring caliper

Surgical Technique

■ Exposure and Implant Selection



Determine the most appropriate surgical approach. Expose the involved segments of the vertebral column. Perform a complete or partial resection of the vertebral body(s) including the adjacent discs. The vertebral endplates above and below the resected bodies should be preserved.

To determine the appropriate length of the implant, measure the gap to be bridged using the measuring caliper (CS 5788). To determine the appropriate implant diameter, measure the gap with the lollipop (CS 2265-1, -2, CS 2250-940, -944).

Using the measuring template (CS 2250-930, CS 2266-3), determine the size of the implant required. The non-shaded section corresponds to the height of the pre-expanded implant. The shaded section indicates the maximum safe expansion height.

5.

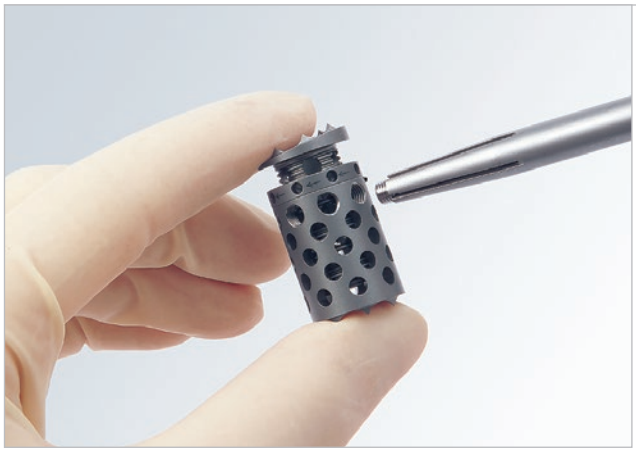
The small pictures at the bottom of pages 10-17 depict instruments that are discussed in the text of the Surgical Technique.


CS 5788


CS 2265-1/-2


CS 2250-940/-944

Cassette Head and Expansion Instrument Assembly

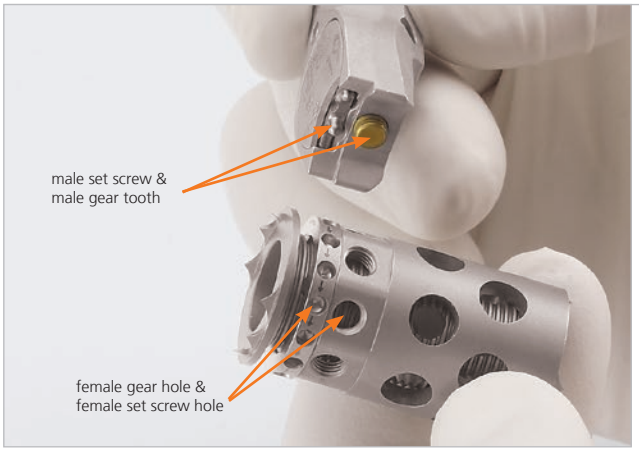


For both systems, Small VBR as well as Omni VBR the application is identical.

The Small VBR (12, 14, 16mm) and Omni VBR (19, 22, 26, 30mm) are ready to use and can be expanded by hand, so that the height is within the area of the bone defect to be bridged.

Remove set screw prior to surgery and before engaging cassettes to the implant.

Select the appropriate cassette head (CS 2256-12, -14, -16, -19, -22, -26, -30) corresponding to implant size being used (i.e. 12mm implant = CS 2256-12 cassette head). Then place the assist handle (CS 2256-02) on the opposite end of the cassette head as shown with arrow.



Vertically align the female gear hole and female set screw hole of the implant.

Vertically align the male gear tooth (any tooth on gear will work) and the male set screw of the cassette head to mirror the female implant holes.


CS 2250-930


CS 2266-3


CS 2256-02


CS 2256-xx


CS 2256-0-xx

Surgical Technique

■ Cassette Head and Expansion Instrument Assembly

Insert the aligned male gear tooth and set the screw head into the implant. Make sure the gear tooth is fully engaged in the ring (female gear) of the implant head.

Hold the implant and cassette head in one hand and with the opposite hand, grasp the assist handle (CS 2256-02) and turn clockwise to lock the implant.

Finally, remove the assist handle and check the expansion of the implant with the cassette.

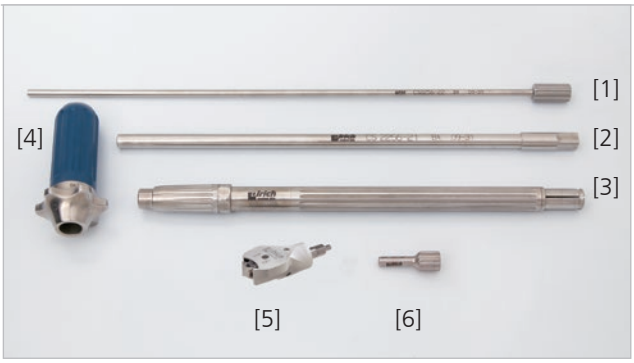
Note: Use gentle force only. Do not damage the implant.

5.

CS 2256-02

CS 2256-xx

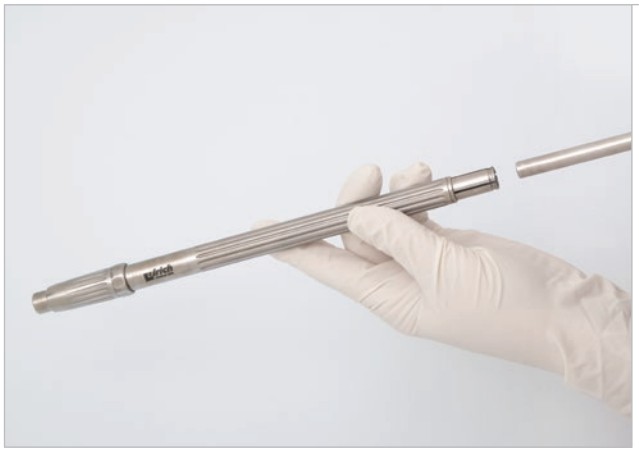
CS 2256-0-xx



Expansion Instrument Components

- [1] Implant release rod (CS 2256-22)
- [2] Inner shaft (CS 2256-21)
- [3] Outer shaft (CS 2256-20)
- [4] Handle (CS 2256-01)
- [5] Cassette head (CS 2256-xx, CS 2256-0-xx)
- [6] Assist handle (CS 2256-02)

The expander instrument (CS 2256) can be used with both the Small and Omni VBR implants (12, 14, 16, 19, 22, 26, 30mm).



Insert the inner shaft (CS 2256-21) into the outer shaft (CS 2256-20).

Firmly place the handle (CS 2256-01) on the inner shaft (CS 2256-21). You will hear an audible click.


CS 2256-21


CS 2256-20


CS 2256-01

Surgical Technique

■ Cassette Head and Expansion Instrument Assembly

Take the preloaded head (CS 2256-xx, CS 2256-0-xx) with the corresponding implant and fully insert it into the cassette head of the outer shaft (CS 2256-20).

To secure the cassette head to the expander, turn the end of the outer shaft (CS 2256-20) clockwise over the head (CS 2256-12) until firm.

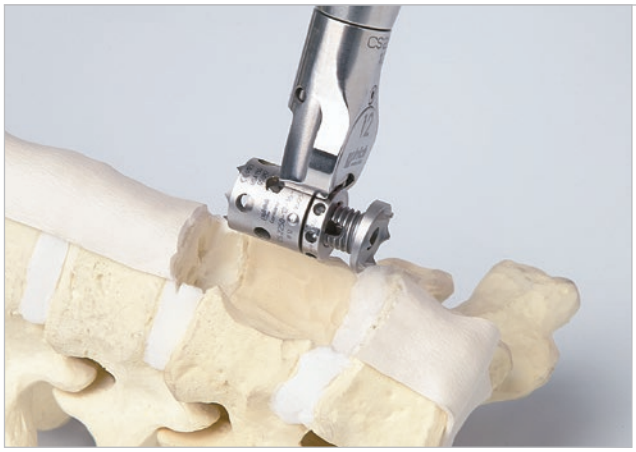
Complete assembled expansion instrument loaded with implant.

CS 2256-xx

CS 2256-0-xx

CS 2256-20

Insertion of the Implant



Insert the implant and expand it in situ continuously by turning the blue handle in a clockwise motion.

Once the implant has been expanded in situ to the correct height, feed the implant releasing rod (CS 2256-22) into the end of the handle (CS 2256-01) and turn counterclockwise until the implant is released from the expander instrument.

Once correct position of the VBR is confirmed, secure the implant with the set screw (CS 2259 or CS 2259-01)using the screwdriver (CS 2261). If desired, additional graft material can be added around the implant.


CS 2256-22

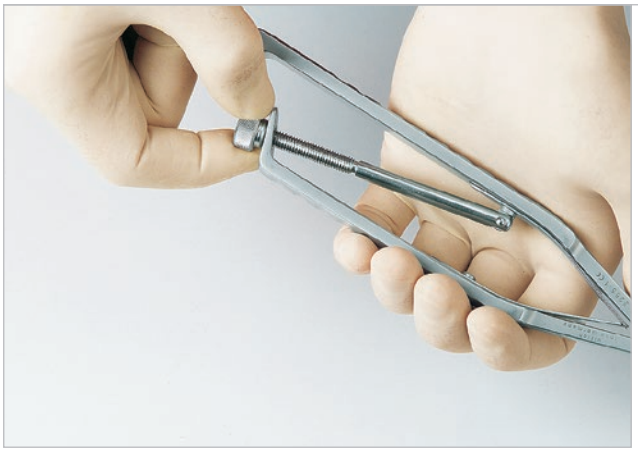

CS 2256-01


CS 2261

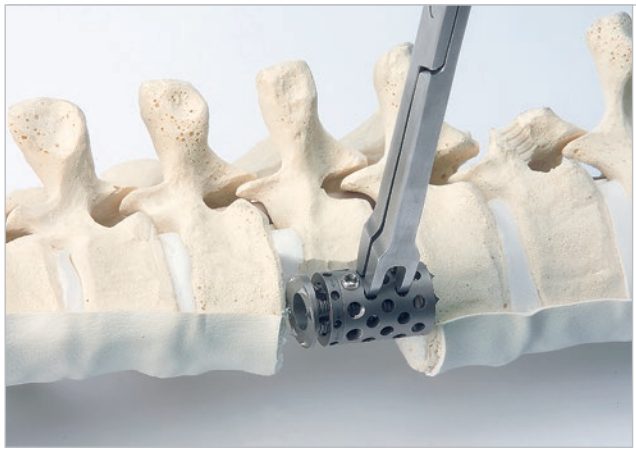
Surgical Technique

■ Optional Procedure

Expand implant by hand and insert the appropriate inserter (CS 2255-1 for small heights and CS 2255-2 for heights larger than 16mm) into the implant bores.



Tighten the knurled screw at the end of the instrument to fix the implant to the instrument.

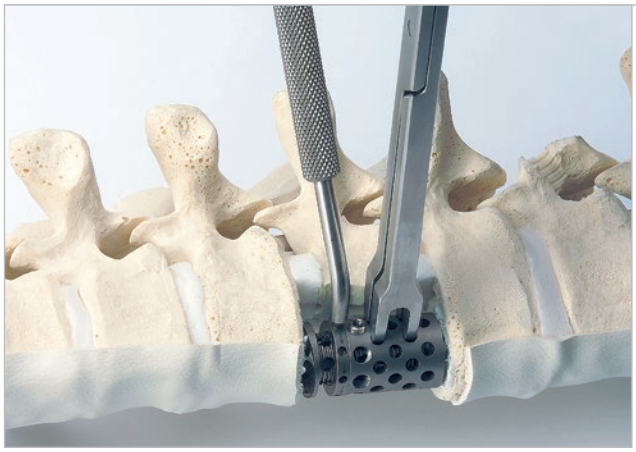


Insert the implant to the desired position.

CS 2255-1

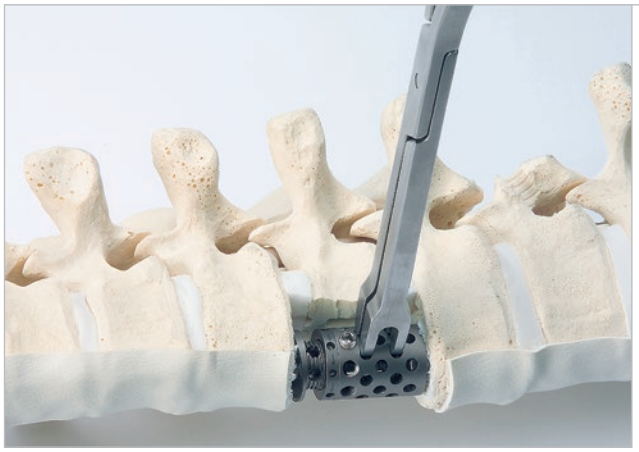
CS 2255-2

5.



Insert the manual expansion instrument (CS 2252) into a hole of the expansion ring. Expansion is achieved by turning the expansion ring in the direction of the arrows using the manual expansion instrument.

Important: No separation of the implant components due to overexpansion of the Small or Omni VBR is possible.



Confirm the implant position after the expansion. If repositioning is required, turn the expansion ring in the opposite direction of the arrows to distact the implant. As soon as the appropriate expansion height and position have been achieved, remove the inserter and secure the implant with the set screw (CS 2259 or CS 2259-01) as described on page 15.

■ Implant Removal

Loosen the set screw (CS 2259 or CS 2259-01) with a counterclockwise motion of the screwdriver (CS 2261). Attach the inserter (CS 2255-1, -2) to the implant; distract the implant using the manual expansion instrument (CS 2252) by turning the implant ring counterclockwise.


CS 2252


CS 2261


CS 2255-1


CS 2255-2

Components

Implants	Expansion Range	Angulation	Product Number
Small VBR, Ø 12mm	10–13mm	0°	CS 2250-12-10
	12–17mm	0°	CS 2250-12-12
	16–25mm	0°	CS 2250-12-16
	16–25mm	6°	CS 2250-12-166
	24–40mm	0°	CS 2250-12-24
	24–40mm	6°	CS 2250-12-246
	39–65mm	0°	CS 2250-12-39
	39–65mm	6°	CS 2250-12-396
Small VBR, Ø 14mm	10–13mm	0°	CS 2250-14-10
	12–17mm	0°	CS 2250-14-12
	16–25mm	0°	CS 2250-14-16
	16–25mm	6°	CS 2250-14-166
	24–40mm	0°	CS 2250-14-24
	24–40mm	6°	CS 2250-14-246
	39–65mm	0°	CS 2250-14-39
	39–65mm	6°	CS 2250-14-396
Small VBR, Ø 16mm	10–13mm	0°	CS 2250-16-10
	12–17mm	0°	CS 2250-16-12
	16–25mm	0°	CS 2250-16-16
	16–25mm	6°	CS 2250-16-166
	24–40mm	0°	CS 2250-16-24
	24–40mm	6°	CS 2250-16-246
	39–65mm	0°	CS 2250-16-39
Locking Screw			CS 2259

Implants	Expansion Range	Angulation	Sterile	Non-Sterile
Omni VBR, Ø 19 mm	15–22 mm	0°	CS 2250-218	CS 2250-19-15
	19–29 mm	0°	CS 2250-222	CS 2250-19-19
	24–38 mm	0°	CS 2250-226	CS 2250-19-24
	32–53 mm	0°	CS 2250-242	CS 2250-19-32
	46–80 mm	0°	CS 2250-246	CS 2250-19-46
Omni VBR, Ø 22 mm	19–29 mm	0°	CS 2250-310	CS 2250-22-19
	24–38 mm	0°	CS 2250-314	CS 2250-22-24
	32–53 mm	0°	CS 2250-318	CS 2250-22-32
	32–53 mm	8°	CS 2250-338	CS 2250-22-328
	46–80 mm	8°	CS 2250-342	CS 2250-22-468
Omni VBR, Ø 26 mm	19–29 mm	0°	CS 2250-410	CS 2250-26-19
	24–38 mm	0°	CS 2250-414	CS 2250-26-24
	32–53 mm	0°	CS 2250-418	CS 2250-26-32
	19–29 mm	8°	CS 2250-438	CS 2250-26-198
	24–38 mm	8°	CS 2250-442	CS 2250-26-248
	32–53 mm	8°	CS 2250-446	CS 2250-26-328
	46–80 mm	8°	CS 2250-450	CS 2250-26-468
	46–80 mm	16°	CS 2250-462	CS 2250-26-4616
Omni VBR, Ø 30 mm	32–53 mm	0°	CS 2250-510	CS 2250-30-32
	32–53 mm	8°	CS 2250-522	CS 2250-30-328
	46–80 mm	8°	CS 2250-526	CS 2250-30-468
Locking screw			CS 2259-01	CS 2259

Instruments	Product Number
Manual expansion instrument	CS 2252
Inserter for small heights	CS 2255-1
Inserter for large heights	CS 2255-2
Handle	CS 2256-01
Assist handle	CS 2256-02
Outer shaft	CS 2256-20
Inner shaft	CS 2256-21
Implant releasing rod	CS 2256-22
Screwdriver with holder, hex 2.5mm	CS 2261
Lollipop trial, Ø 12-14mm	CS 2265-1
Lollipop trial, Ø 16-20mm	CS 2265-2
Lollipop trial, Ø 19-22mm	CS 2250-940
Lollipop trial, Ø 26-30mm	CS 2250-944
Measuring template for Small VBR	CS 2266-3
Measuring template for Omni VBR	CS 2250-930
Impactor, straight, height 8mm	CS 2274-2
Measuring caliper	CS 5788
12mm disposable cassette head	CS 2256-12
14mm disposable cassette head	CS 2256-14
16mm disposable cassette head	CS 2256-16
19mm disposable cassette head	CS 2256-0-19
22mm disposable cassette head	CS 2256-0-22
26mm disposable cassette head	CS 2256-0-26
30mm disposable cassette head	CS 2256-0-30

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