

Zuma™

Surgical Technique

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The **Zuma™ System** features a unique one piece design that incorporates the benefits of an anterior fixation plate and a radiolucent interbody spacer. The system includes four screws and a locking cover to provide superior stability.

Step 1 - Patient Positioning

Position the patient in a slight Trendelenburg position.

Step 2 - Site Preparation

Access the appropriate level of the anterior or lateral column from L2 to S1 using standard approach techniques.

Step 3 - Trial and Rasp

Trials and Rasps are available for each footprint in both 8 and 12 degrees of lordosis, and are undersized by ½ mm in height. All Trials and Rasps are color-coded to match the corresponding implant height.

Trial Insertion: Select the appropriate Trial and attach it to the Trial/Rasp Inserter by matching the threaded tip of the Trial/Rasp Inserter to the cavity on the back of the trial. Turn the thumb wheel clockwise until the trial is securely engaged.

Insert the trial into the implantation site. A mallet may be used to advance the Trial into the space.

Note: Plate Trials are available if needed. Plate trials are provided for each implant height.

Rasp Insertion: Select the appropriate Rasp and attach it to the Trial/Rasp Inserter by matching the threaded tip of the Trial/Rasp Inserter to the cavity on the back of the rasp. Turn the thumb wheel clockwise until the Rasp is securely engaged.



Insert the Rasp into the implantation site. A mallet may be used to advance the Rasp into the space.



Note: The T-Handle may be inserted into the top of the Trial/Rasp Inserter handle, if needed, to assist in backing the Trial/Rasp out of the implantation site.



Step 4 - Implant Selection

Select the appropriate size Zuma implant: implants are provided in three footprints: 26mm x 24mm, 32mm x 25mm, and 38mm x 26mm (width x depth). All footprints are available in heights of 10mm -18mm (2mm increments) and feature either 8° or 12° of lordosis. All implants are color-coded by height.

Step 5 - Bone Graft

Insert the Zuma implant into the appropriate Graft Packing Block. The provided Graft Packing Tamp can be used to firmly pack the Bone Graft into the implant cavity.



Step 6 - Implantation

Attach the Zuma implant to the Inserter by first matching the pin at the tip of the inserter with one of the small holes on the face of the plate. Next, thread the inserter into the implant by rotating the wheel at the top of the handle clockwise until the implant is secure.



Insert the Zuma implant into the implantation site. A mallet may be used to advance the implant into the space.

Once the desired placement is achieved, remove the Implant from the Inserter by rotating the wheel at the top of the handle counter-clockwise.

Note: An Impactor is provided standard in the set. This may be used to adjust the implant if necessary.



Step 7 - Screw Hole Preparation

Option 1 - Awl

Prepare the screw insertion site by creating an entry hole using the Awl. At the entry hole location, insert the Awl through the Drill Guide shaft and apply a downward, twisting force until the sharp tip of the Awl penetrates the bone. Depth of penetration is limited to 20mm.

Repeat this process for the remaining screw holes.



(Step 7 Continued)

Option 2 - Drill

Straight and Flexible Drills are provided standard in the Zuma set.

Select the appropriate Drill. Attach the Drill to the Quick Connect Drill Handle, insert through the Drill Guide shaft and advance the Drill until the stop hits the top of the Guide. Depth of penetration is limited to 20mm.

Repeat this process for the remaining screw holes.



Step 8 - Screw Insertion

The Zuma system offers 5.5mm diameter screws in three lengths: 20mm, 25mm and 30mm and 6.0mm diameter screws in three lengths: 25mm, 30mm, and 35mm.

Straight and Flexible Screwdrivers are provided in the Zuma set. Select the appropriate 3mm Driver Shaft and attach it to the Ratcheting Handle.

Select the appropriate screw length and load it onto the Driver. Insert the screw into the first screw hole.

Repeat this process for the remaining screws.



Step 9 - Locking Cover

Color Coded Locking Covers are provided for each of the corresponding implant heights.

Select the appropriate Locking Cover. Using the 3mm Driver Shaft and the Torque Limiting Handle, screw the Locking Cover into the plate. This handle limits the maximum torque to the recommended 35 in-lbs.



Step 10 - Placement Verification

Each Zuma Implant has four tantalum radiographic markers which aid in visualization. Below are three views which depict location of the markers. All markers are approximately 1mm from the edge of the implant.



Lateral View



Off- Lateral View



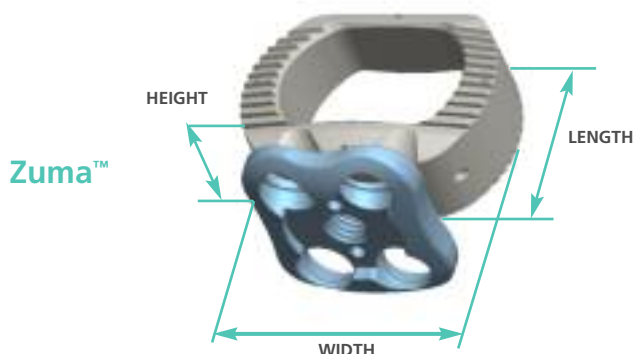
Anterior View



Catalog



Implants



26mm x 24mm	32mm x 25mm	38mm x 26mm	Height	Lordotic Angle	Color
55-2610	55-3210	55-3810	10	8°	Purple
55-2612	55-3212	55-3812	12	8°	Green
55-2614	55-3214	55-3814	14	8°	Light Blue
55-2616	55-3216	55-3816	16	8°	Copper
55-2618	55-3218	55-3818	18	8°	Magenta
55-2710	55-3310	55-3910	10	12°	Purple
55-2712	55-3312	55-3912	12	12°	Green
55-2714	55-3314	55-3914	14	12°	Light Blue
55-2716	55-3316	55-3916	16	12°	Copper
55-2718	55-3318	55-3918	18	12°	Magenta

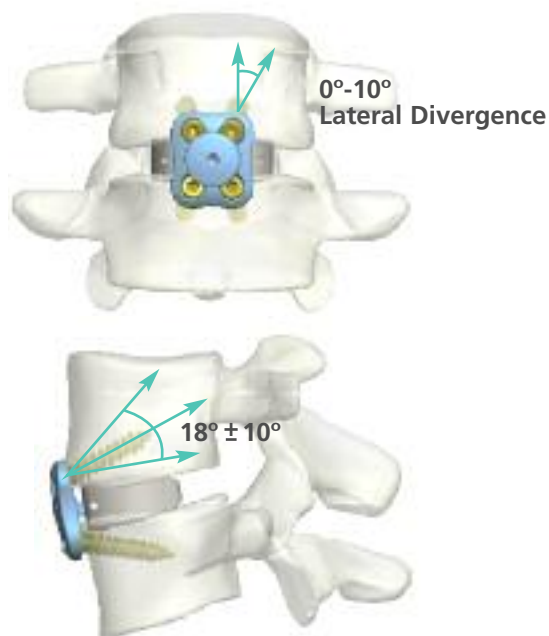
Note: Implants are measure by width x length x height

Variable Bone Screws

- Single Lead
- Self-Tapping
- Titanium Alloy (Ti-6Al-4V ELI)

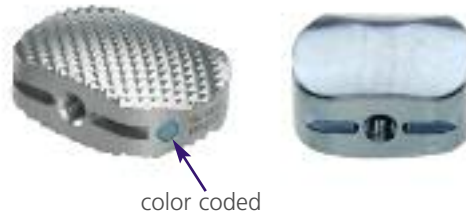


Part Number	Diameter	Length
55-5520	5.5	20
55-5525	5.5	25
55-5530	5.5	30
55-7025	6.0	25
55-7030	6.0	30
55-7035	6.0	35



Zuma Trials and Rasps

- Color-Coded by height
- 1/2mm undersized from the Interbody device
- Modular



Optional Plate Trials

- Color-Coded by height
- Easily slide down the Trial/Rasp Inserter Shaft into position



Locking Covers

- Color-Coded by height
- Provide smooth surface with no additional profile



Instruments

Trail/Rasp Inserter

95-5105



Impactor

95-5103



Inserter

95-5105



T-Handle

95-5106



3mm Hex Shaft

95-5131



3mm Driver Shaft, Flexible

95-5133



Drill Guide

95-5160



Cannulated Guide

95-5165



Drill

95-5161



Drill, Flexible

95-5162



Awl

95-5170



Ratchet Handle

95-5510



Drill Handle, Quick Connect

95-5515



Graft Tamp

95-5190



Graft Packing Block

95-5191, 95-5192, 95-5193



Indications:

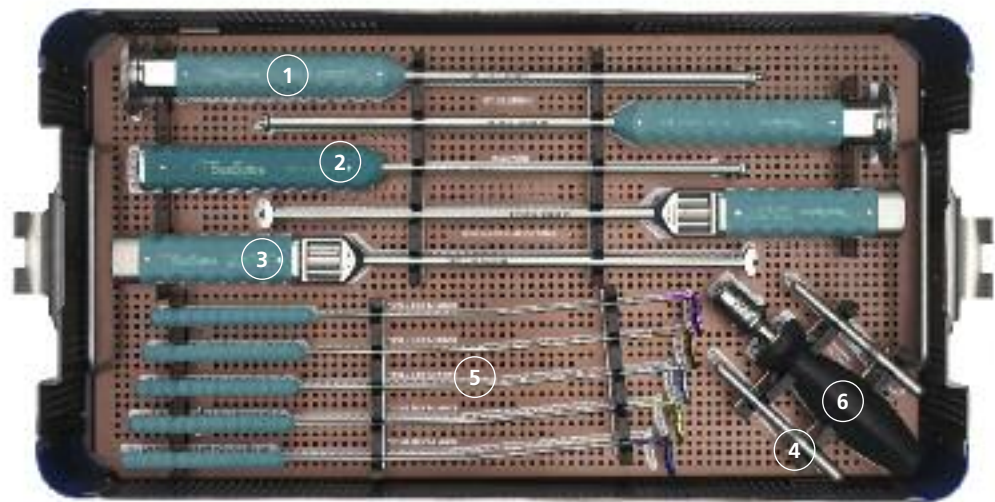
When used as an intervertebral body fusion device, the Zuma System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autograft. Zuma is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

For additional information, please refer to the Instructions for Use, included in each product package.

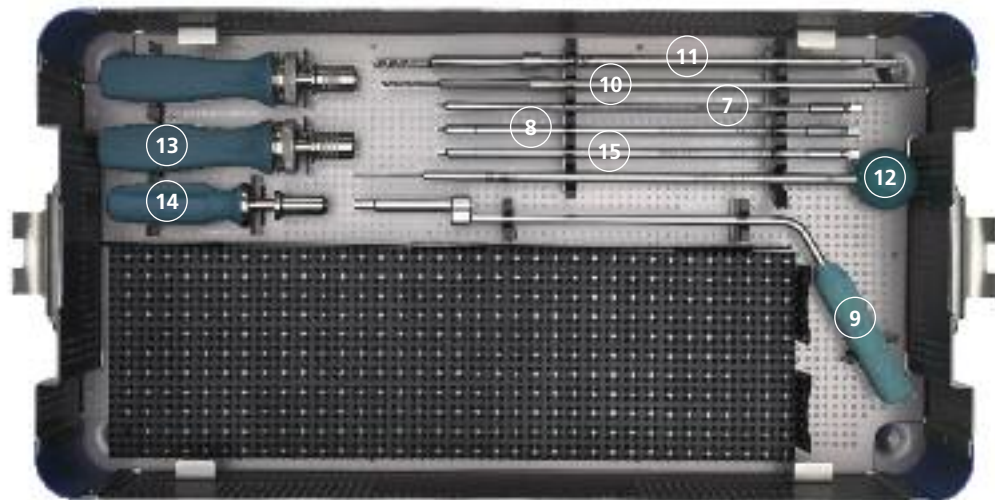
Part #	Description	Location
95-5101	Inserter	1
95-5103	Impactor	2
95-5105	Trial/Rasp Inserter	3
95-5106	T-Handle	4
95-50xx	Plate Trial, 10mm – 18mm	5
95-0127	Torque Limiting Handle, 35 in-lb	6
95-5131	3mm Hex Shaft	7
95-5133	3mm Driver Shaft, Flexible	8

Part #	Description	Location
95-5160	Drill Guide	9
95-5161	Drill	10
95-5162	Drill, Flexible	11
95-5170	Awl	12
95-5510	Ratchet Handle	13
95-5515	Drill Handle, Quick Connect	14
95-5535	EZ Out, 3mm Hex	15

Level 1



Level 2



Sterility:

This product is supplied "NON-STERILE" and must be sterilized before use. Pre-cleaning is not required. The recommended sterilization process is high temperature steam autoclave sterilization. The following validation cycle is recommended:

The validation cycle is:

Method: Steam / Cycle: Pre-vacuum / Temperatures and Exposure Times: 270° F (132° C) for 8 minutes

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Based in Southern California, SeaSpine is dedicated to the advancement of spine surgery by providing innovative, cost-effective solutions to the surgical community.



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