



VyWasher™

Buttress
System

Surgical
Technique

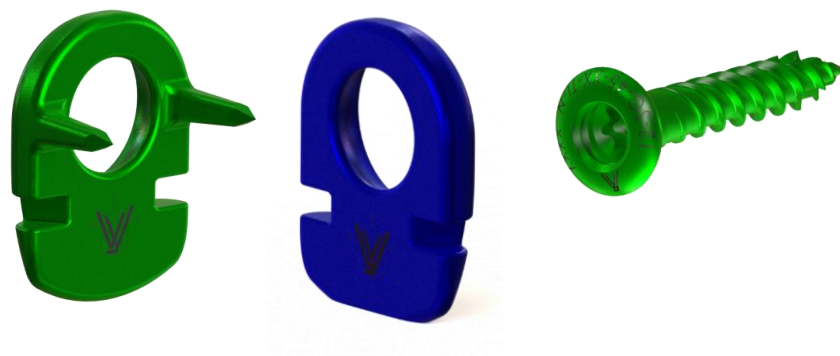


System Overview

Description:

The Vy Spine™ Vy Washer™ Buttress System consists of washers, staples, and screws. The components of the Vy Spine™ Vy Washer™ Buttress System are manufactured from titanium alloy 6AL-4V as per ASTM F136, and have a smooth anodized finish. These Anterior Spinal device systems are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. After solid fusion occurs, these devices serve no functional purpose and may be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Do not use implant components from any other manufacturer with Vy Spine™ Vy Washer™ Buttress System components. As with all orthopedic implants, in no case may the implants be re-used.



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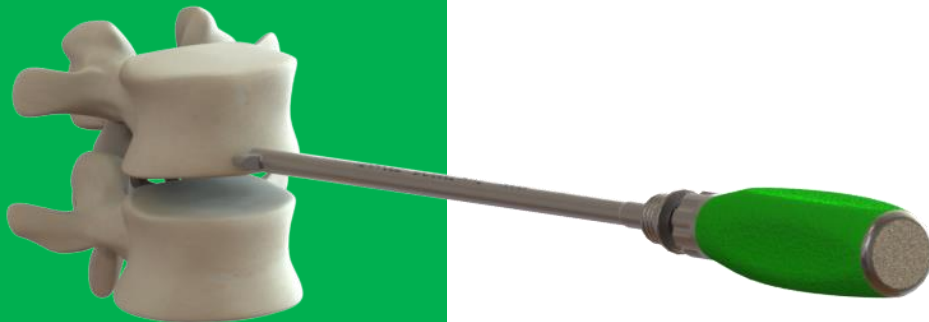
Step 1. Affected Vertebral Body

The affected vertebral body is exposed through the traditional anterior, anterolateral, or lateral, approach that is appropriate for the affected level. Following standard technique, the bone graft is placed in the interbody disc space.

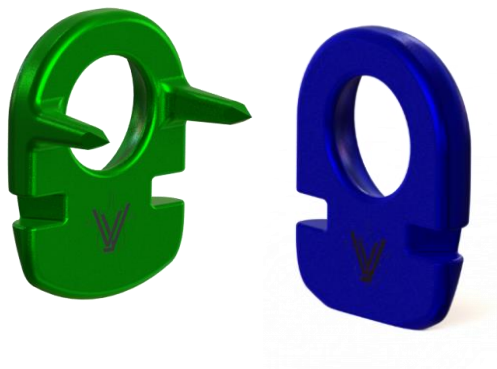


Step 2. Awl (option if using Staple)

If using the VyWasher™ Staple, the double awl can be used to prepare holes for the Staple.



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Step 3. Device Selection

The buttress component should be selected, utilizing the largest implant application for the patient's anatomy, whether the VyWasher™ Washer or the VyWasher™ Staple

Step 4. Attach Inserter

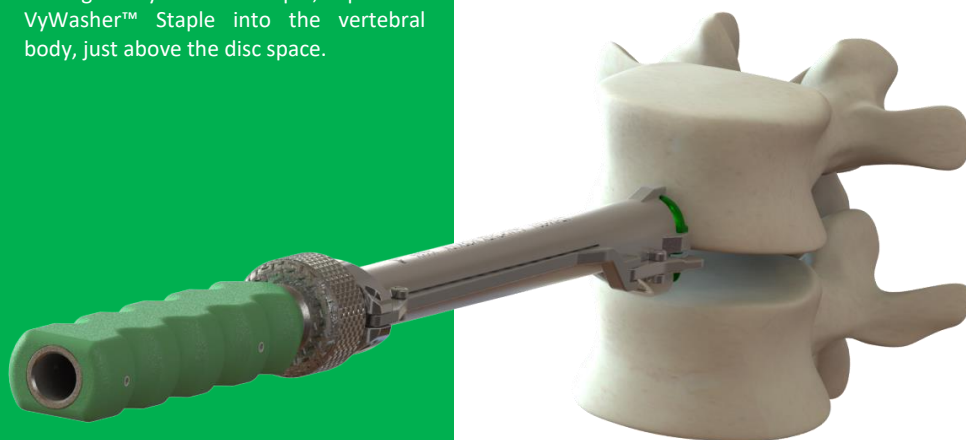
Place the VyWasher™ Washer or VyWasher™ Staple onto the Inserter. Thread the knurled knob of the Inserter forward to open the arms on the side. Once the implant is in place, thread the knurled knob back for the arms to securely grasp the implant.



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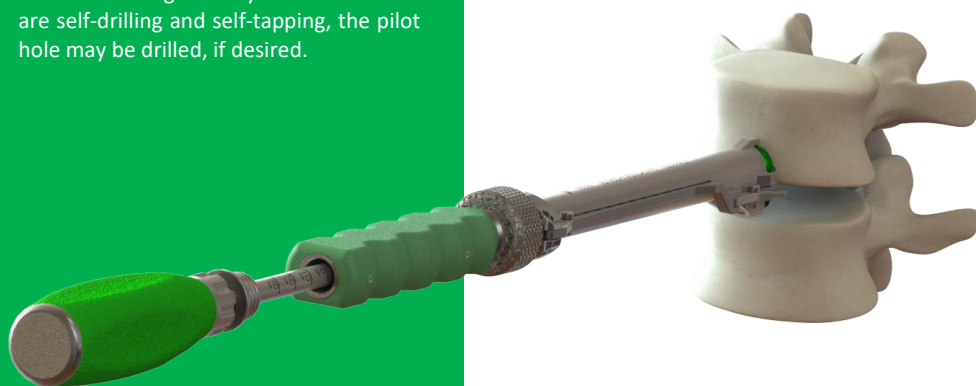
Step 5. Implant Placement

Place the VyWasher™ Washer onto the vertebral body, just above the disc space. If using the VyWasher™ Staple, impact the VyWasher™ Staple into the vertebral body, just above the disc space.



Step 6. Awl

Prepare the hole for the VyWasher™ Screw. First, use the Awl to break the cortex of the vertebral body. The Awl has depth markings to help with screw length choice. Although the VyWasher™ Screws are self-drilling and self-tapping, the pilot hole may be drilled, if desired.



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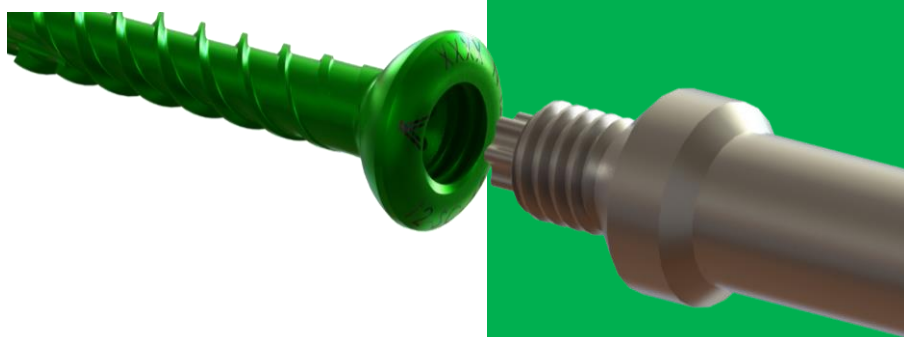
Step 7. Tap

Additionally, the pilot hole may be tapped, if desired. As with the Awl, the Taps also have depth markings. The Drill and Tap size selected should correspond with the VyWasher™ Screws size. NOTE: A Tap marked as 4.5 corresponds to the 4.5mm VyWasher™ Screws, however, the taps are undersized by 0.5mm. This step can be assisted with the use of fluoroscopy or x-ray to ensure proper placement and depth.



Step 8. Attach Screw

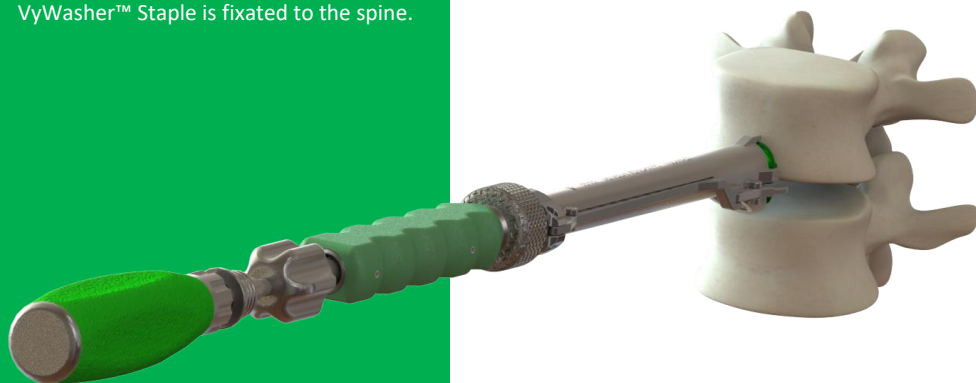
Secure the VyWasher™ Screw to the Screw Driver by threading the Driver onto the VyWasher™ Screw.



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Step 9. Place Screw

Thread the VyWasher™ Screw into place until the VyWasher™ Washer or VyWasher™ Staple is fixated to the spine.



Step 10. Remove Screwdriver

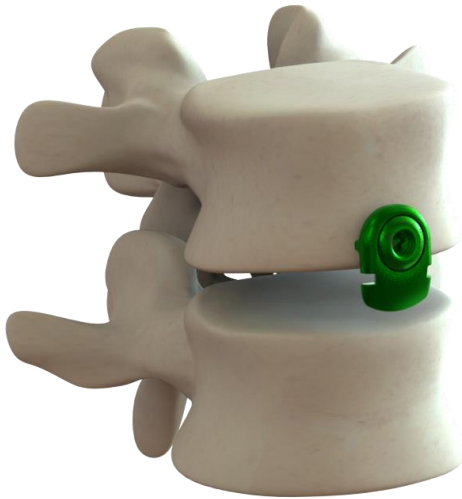
Release the VyWasher™ Screw by unthreading the knob of the Screw Driver and removing the Screw Driver from the Insert.



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Step 11. Remove Inserter

Release the VyWasher™ Washer or VyWasher™ Staple by threading the knurled knob of the Inserter forward to open the arms on the side.



Optional. Removal of Device

Reattach the Inserter the VyWasher™ Washer or Screw. Re-engage the Screw Driver to the VyWasher™ Screw. Unthread the VyWasher™ Screw from the vertebral body and remove it from the incision. Remove the VyWasher™ Washer or Screw by pulling on the Inserter.

VyWasher™ Ordering Information

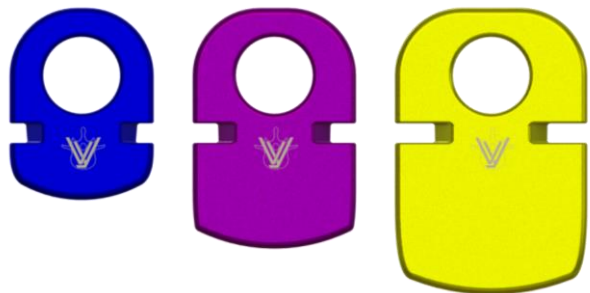
Staple Implants

Part Number	Product Size
12-ST-1520-TI-N	15mm x 20mm
12-ST-1725-TI-N	17mm x 25mm
12-ST-2030-TI-N	20mm x 30mm



Washer Implants

Part Number	Product Size
12-WA-1520-TI-N	15mm x 20mm
12-WA-1725-TI-N	17mm x 25mm
12-WA-2030-TI-N	20mm x 30mm



VyWasher™ Ordering Information

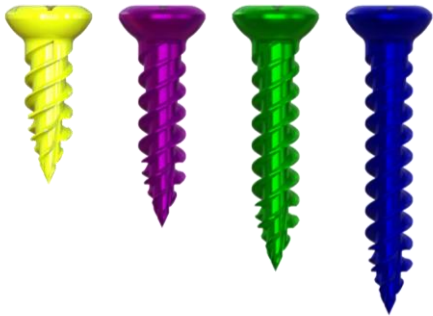
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Screw Options

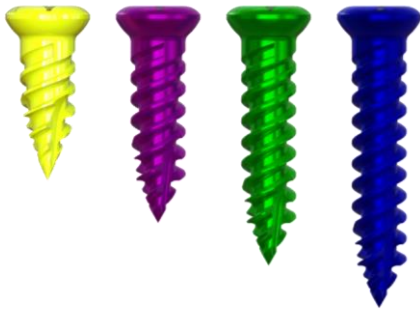
Part Number	Product Size
12-SC-45-15-TI-N	Ø4.5mm, 15mm
12-SC-45-20-TI-N	Ø4.5mm, 20mm
12-SC-45-25-TI-N	Ø4.5mm, 25mm
12-SC-45-30-TI-N	Ø4.5mm, 30mm



Part Number	Product Size
12-SC-55-15-TI-N	Ø5.5mm, 15mm
12-SC-55-20-TI-N	Ø5.5mm, 20mm
12-SC-55-25-TI-N	Ø5.5mm, 25mm
12-SC-55-30-TI-N	Ø5.5mm, 30mm



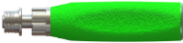





Part Number	Product Size
12-SC-65-15-TI-N	Ø6.5mm, 15mm
12-SC-65-20-TI-N	Ø6.5mm, 20mm
12-SC-65-25-TI-N	Ø6.5mm, 25mm
12-SC-65-30-TI-N	Ø6.5mm, 30mm



VyWasher™ IBF Ordering Information

Instrumentation Options

Part Number	Description	
12-IA-001	Awl	
12-IA-002	Double Awl	
12-IH-001	Handle	
12-IN-001	Insertor	
12-ISD-001	Screw Driver	
12-IT-045	Tap, Ø 4.5mm	
12-IT-055	Tap, Ø 5.5mm	
12-IT-065	Tap, Ø 6.5mm	

Indications:

The Vy Spine™ Vy Washer™ Buttress System is intended to stabilize the bone graft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

FOR ADDITIONAL INFORMATION INCLUDING PRECAUTIONS, WARNINGS, CONTRAINDICATIONS, CLEANING AND STERILIZATION, PLEASE REFER TO THE PACKAGE INSERT



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