DePuy Synthes CONDUIT™ ZERO-P™ VA Secured Spacer System Instructions for Use

PART LIST

Part Number	Description	GTIN
451401050	Cage AH 5mm Convex Standard	00190776391553
451401060	Cage AH 6mm Convex Standard	00190776391560
451401070	Cage AH 7mm Convex Standard	00190776391577
451401080	Cage AH 8mm Convex Standard	00190776391584
451401090	Cage AH 9mm Convex Standard	00190776391591
451401100	Cage AH 10mm Convex Standard	00190776391607
451401110	Cage AH 11mm Convex Standard	00190776391614
451401120	Cage AH 12mm Convex Standard	00190776391621
451402050	Cage AH 5mm Lordotic Standard	00190776391638
451402060	Cage AH 6mm Lordotic Standard	00190776391645
451402070	Cage AH 7mm Lordotic Standard	00190776391652
451402080	Cage AH 8mm Lordotic Standard	00190776391669
451402090	Cage AH 9mm Lordotic Standard	00190776391676
451402100	Cage AH 10mm Lordotic Standard	00190776391683
451402110	Cage AH 11mm Lordotic Standard	00190776391690
451402120	Cage AH 12mm Lordotic Standard	00190776391706
451403050	Cage AH 5mm Parallel Standard	00190776391713
451403060	Cage AH 6mm Parallel Standard	00190776391720
451403070	Cage AH 7mm Parallel Standard	00190776391737
451403080	Cage AH 8mm Parallel Standard	00190776391744
451403090	Cage AH 9mm Parallel Standard	00190776391751
451403100	Cage AH 10mm Parallel Standard	00190776391768
451403110	Cage AH 11mm Parallel Standard	00190776391775
451403120	Cage AH 12mm Parallel Standard	00190776391782
451501050	Cage AH 5mm Convex Large	00190776391799
451501060	Cage AH 6mm Convex Large	00190776391805
451501070	Cage AH 7mm Convex Large	00190776391812
451501080	Cage AH 8mm Convex Large	00190776391829
451501090	Cage AH 9mm Convex Large	00190776391836
451501100	Cage AH 10mm Convex Large	00190776391843
451501110	Cage AH 11mm Convex Large	00190776391850
451501120	Cage AH 12mm Convex Large	00190776391867
451502050	Cage AH 5mm Lordotic Large	00190776391874
451502060	Cage AH 6mm Lordotic Large	00190776391881
451502070	Cage AH 7mm Lordotic Large	00190776391898
451502080	Cage AH 8mm Lordotic Large	00190776391904
451502090	Cage AH 9mm Lordotic Large	00190776391911
451502100	Cage AH 10mm Lordotic Large	00190776391928
451502110	Cage AH 11mm Lordotic Large	00190776391935

Part Number	Description	GTIN
451502120	Cage AH 12mm Lordotic Large	00190776391942
451503050	Cage AH 5mm Parallel Large	00190776391959
451503060	Cage AH 6mm Parallel Large	00190776391966
451503070	Cage AH 7mm Parallel Large	00190776391973
451503080	Cage AH 8mm Parallel Large	00190776391980
451503090	Cage AH 9mm Parallel Large	00190776391997
451503100	Cage AH 10mm Parallel Large	00190776392000
451503110	Cage AH 11mm Parallel Large	00190776392017
451503120	Cage AH 12mm Parallel Large	00190776392024
04.647.832*	Cervical Spine Screw Ø 3.7mm, self-drilling, 12mm	10705034751320
04.647.834*	Cervical Spine Screw Ø 3.7mm, self-drilling, 14mm	10705034751344
04.647.836*	Cervical Spine Screw Ø 3.7mm, self-drilling, 16mm	10705034751368
04.647.872*	Cervical Spine Screw Ø 3.7mm, self-tapping, 12mm	10705034751382
04.647.874*	Cervical Spine Screw Ø 3.7mm, self-tapping, 14mm	10705034751405
04.647.876*	Cervical Spine Screw Ø 3.7mm, self-tapping, 16mm	10705034751429
04.647.878*	Cervical Spine Screw Ø 3.7mm, self-tapping, 18mm	10705034751443

*Product Manufactured by DePuy Synthes

English EN

DePuy Synthes CONDUIT™ ZERO-P™ VA Secured Spacer System Instructions For Use

DESCRIPTION

The CONDUIT ZERO-P VA Secured Spacers are intervertebral body fusion devices intended for anterior cervical interbody fusion. Two screws are inserted at convergent and variable angles into adjacent vertebral bodies with a one step blocking mechanism.

The CONDUIT ZERO-P VA Secured Spacer System is available in various heights and geometries to suit individual pathology and anatomical conditions.

The CONDUIT ZERO-P VA Cages are made from Ti-6Al-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous and/or allogeneic bone graft.

The 3D Printed Conduit Cellular Titanium Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the Cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

MATERIALS

- The CONDUIT ZERO-P VA Cages are manufactured from Ti-6AL-4V alloy (per ASTM F3001 and ASTM F136).
    - Integrated blocking mechanism contains a quantity two (2) of each of the following components:
        - Spring manufactured from Phynox® (Co40-Cr20-Ni16-Fe15-Mo7 per ASTM F1058)
        - Screw Catch manufactured from Ti-6AL-4V alloy (per ASTM F136)
        - Locking Pin manufactured from Ti-6AL-4V alloy (per ASTM F136)
- The ZERO-P VA Screws are manufactured from Ti-6AL-7Nb (per ISO 5832).

INTENDED USE/INDICATIONS

The CONDUIT Zero-P VA Spacer is a stand-alone anterior cervical interbody fusion device with a microscopic roughened surface and micro and nano-scale features indicated for use at one or two levels of the cervical spine (C2-T1) in skeletally mature patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion.

Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

The interior of the spacer component should be packed with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft and implanted via an anterior approach.

CONTRAINDICATIONS

Do not use the CONDUIT ZERO-P VA Secured Spacer in cases of:

- Any medical or surgical condition precluding the potential benefit or spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Spinal tumors in the region of implant anchoring
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Demonstrated allergy or foreign body sensitivity to the implant material

ADVERSE REACTIONS

Adverse Reactions may include:

- Pain
- Infection
- Cross Contamination
- Sepsis
- Tissue Damage
- Adverse Tissue Reaction
- Non-union
- Bone Damage
- Poor Joint Mechanics
- Vascular Damage
- Central Nervous System Damage
- Embolism
- Loss of Function
- Spinal Nerve Damage

Note: This list may not include all complications caused by the surgical procedure itself

SAFETY PRECAUTIONS

	• Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.

- Keep the instructions for use accessible to all staff.
- The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this device.
- Pre-operative planning and patient anatomy should be considered when selecting implant size.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- Only implant the CONDUIT ZERO-P VA Secured Spacer with the applicable ZERO-P VA Secured Spacer instruments. Components of this system should not be used with components from other systems or manufacturers.
- Each patient's record shall document the implant used (article number, description, and lot number).
- An electronic Patient Implant Card, indicating MRI safety of the CONDUIT ZERO-P VA Secured Spacer, can be found at the following link: www.avalign.com/ifu
- During the postoperative phase, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.

	• Never reuse an implant. Although the device may appear undamaged, previous stresses may have created nonvisible damage that could result in failure.
	• Never use an implant if its packaging is damaged.
	• An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
	• Never use an implant that is past its expiration date.

⚠	• Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

STORAGE, INSPECTION AND RESTERILIZATION

STORAGE

The implant is individually packed in a protective packaging that is labeled according to its contents.

STERILE R	The implant is sterilized with radiation (25 kGy minimum) and packaged in a double sterile barrier system.

- Always store the implant in the original protective packaging.
- Do not remove the implant from the original packaging until immediately before use.

	• Store the implant in a dry and dust-free place (standard hospital environment).

DISINFENCTION/CLEANING

The implant is not designed to be disinfected or cleaned by the user.

RESTERILIZATION

	The implant is not designed to be resterilized by the user.

MR **MAGNETIC RESONANCE (MR) COMPATIBILITY**

MRI Safety Information MR

A patient with the CONDUIT Zero-P VA may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	CONDUIT Zero-P VA
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no transmit coil restrictions
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Maximum Head SAR [W/kg]	3.2 W/kg (Normal Operating Mode)
Limits on SAR and Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 26 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

⚠	The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength

DISPOSAL

- Any implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

CAUTION

Rx ONLY

Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.

WARRANTY

- All products are guaranteed to be free from defects in material and workmanship at the time of shipping.
- The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with the instructions for use.

CONTACT

- **Notice to Patient and User**: Any incident that has occurred in relation to the medical devices should be reported to the manufacturer.
- Contact DePuy Synthes Spine for a copy of the surgical technique guide.

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Avalign Technologies, Inc.
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product.questions@avalign.com

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USA

Label Glossary

Symbol	Title	Symbol	Title
	Manufacturer & Date of Manufacture		Caution
LOT	Lot Number / Batch Code	REF	Catalogue Number
MR	Magnetic Resonance (MR) Conditional	Rx ONLY	Federal Law (USA) restricts this device to sale by or on the order of a physician
	Consult Instructions for Use		Distributor
	Use-by Date	STERILE R	Sterilized using Irradiation
	Do Not Resterilize		Do not use if package is damaged
	Keep Dry		Do Not Re-Use
UDI	Unique Device Identifier	MD	Medical Device
	Double Sterile Barrier System		Packaging Unit