

DePuy Synthes CONDUIT™ SYNFIX™ Evolution Secured Spacer System

Instructions for Use

PART LIST

Part Number	Description	GTIN
431106105	Cage AH 10.5mm 6DEG S	00190776385835
431106120	Cage AH 12mm 6DEG S	00190776385842
431106135	Cage AH 13.5mm 6DEG S	00190776385859
431106150	Cage AH 15mm 6DEG S	00190776385866
431106170	Cage AH 17mm 6DEG S	00190776385873
431106190	Cage AH 19mm 6DEG S	00190776385880
431110105	Cage AH 10.5mm 10DEG S	00190776385897
431110120	Cage AH 12mm 10DEG S	00190776385903
431110135	Cage AH 13.5mm 10DEG S	00190776385910
431110150	Cage AH 15mm 10DEG S	00190776385927
431110170	Cage AH 17mm 10DEG S	00190776385934
431110190	Cage AH 19mm 10DEG S	00190776385941
431114120	Cage AH 12mm 14DEG S	00190776385958
431114135	Cage AH 13.5mm 14DEG S	00190776385965
431114150	Cage AH 15mm 14DEG S	00190776385972
431114170	Cage AH 17mm 14DEG S	00190776385989
431114190	Cage AH 19mm 14DEG S	00190776385996
431118135	Cage AH 13.5mm 18DEG S	00190776386009
431118150	Cage AH 15mm 18DEG S	00190776386016
431118170	Cage AH 17mm 18DEG S	00190776386023
431118190	Cage AH 19mm 18DEG S	00190776386030
431206105	Cage AH 10.5mm 6DEG M	00190776386047
431206120	Cage AH 12mm 6DEG M	00190776386054
431206135	Cage AH 13.5mm 6DEG M	00190776386061
431206150	Cage AH 15mm 6DEG M	00190776386078
431206170	Cage AH 17mm 6DEG M	00190776386085
431206190	Cage AH 19mm 6DEG M	00190776386092
431210105	Cage AH 10.5mm 10DEG M	00190776386108
431210120	Cage AH 12mm 10DEG M	00190776386115
431210135	Cage AH 13.5mm 10DEG M	00190776386122
431210150	Cage AH 15mm 10DEG M	00190776386139
431210170	Cage AH 17mm 10DEG M	00190776386146
431210190	Cage AH 19mm 10DEG M	00190776386153
431214120	Cage AH 12mm 14DEG M	00190776386160
431214135	Cage AH 13.5mm 14DEG M	00190776386177
431214150	Cage AH 15mm 14DEG M	00190776386184
431214170	Cage AH 17mm 14DEG M	00190776386191
431214190	Cage AH 19mm 14DEG M	00190776386207
431218135	Cage AH 13.5mm 18DEG M	00190776386214

Part Number	Description	GTIN
431218150	Cage AH 15mm 18DEG M	00190776386221
431218170	Cage AH 17mm 18DEG M	00190776386238
431218190	Cage AH 19mm 18DEG M	00190776386245
431306105	Cage AH 10.5mm 6DEG L	00190776386252
431306120	Cage AH 12mm 6DEG L	00190776386269
431306135	Cage AH 13.5mm 6DEG L	00190776386276
431306150	Cage AH 15mm 6DEG L	00190776386283
431306170	Cage AH 17mm 6DEG L	00190776386290
431306190	Cage AH 19mm 6DEG L	00190776386306
431310105	Cage AH 10.5mm 10DEG L	00190776386313
431310120	Cage AH 12mm 10DEG L	00190776386320
431310135	Cage AH 13.5mm 10DEG L	00190776386337
431310150	Cage AH 15mm 10DEG L	00190776386344
431310170	Cage AH 17mm 10DEG L	00190776386351
431310190	Cage AH 19mm 10DEG L	00190776386368
431314120	Cage AH 12mm 14DEG L	00190776386375
431314135	Cage AH 13.5mm 14DEG L	00190776386382
431314150	Cage AH 15mm 14DEG L	00190776386399
431314170	Cage AH 17mm 14DEG L	00190776386405
431314190	Cage AH 19mm 14DEG L	00190776386412
431318135	Cage AH 13.5mm 18DEG L	00190776386429
431318150	Cage AH 15mm 18DEG L	00190776386436
431318170	Cage AH 17mm 18DEG L	00190776386443
431318190	Cage AH 19mm 18DEG L	00190776386450
431125150	Cage AH 15mm 25DEG S	00190776386474
431125170	Cage AH 17mm 25DEG S	00190776386481
431125190	Cage AH 19mm 25DEG S	00190776386498
431130190	Cage AH 19mm 30DEG S	00190776386528
431225170	Cage AH 17mm 25DEG M	00190776386542
431225190	Cage AH 19mm 25DEG M	00190776386559
431230190	Cage AH 19mm 30DEG M	00190776386573
431325190	Cage AH 19mm 25DEG L	00190776386597
432010500	Plate H 10.5mm	00190776386610
432012000	Plate H 12mm	00190776386627
432013500	Plate H 13.5mm	00190776386634
432015000	Plate H 15mm	00190776386641
432017000	Plate H 17mm	00190776386658
432019000	Plate H 19mm	00190776386665
440300001	Locking Key	00190776386825
04.835.220.02S*	Locking Screw D4.0x20	20705034816149
04.835.225.02S*	Locking Screw D4.0x25	20705034816156
04.835.230.02S*	Locking Screw D4.0x30	20705034816163
04.835.120.02S*	Locking Screw D4.0x20 Fine Tip	20705034816118
04.835.125.02S*	Locking Screw D4.0x25 Fine Tip	20705034816125

Part Number	Description	GTIN
04.835.130.02S*	Locking Screw D4.0x30 Fine Tip	20705034816132

*Product Manufactured by DePuy Synthes

DePuy Synthes CONDUIT™ SYNFIX™ Evolution Secured Spacer System Instructions For Use

DESCRIPTION

The CONDUIT SYNFIX Evolution Secured Spacers are intervertebral body fusion devices intended for lumbar interbody fusion (ALIF). Four Screws are inserted through the anteriorly-located Plate into the adjacent vertebral bodies. The Screws lock securely to the Plate using a tapered- thread locking mechanism.

The CONDUIT SYNFIX Evolution Secured Spacer System is available as non-assembled Cage and Plate components in various heights and geometries to suit individual pathology and anatomical conditions. The Cage and Plate components are intended to be assembled at the point of use prior to implantation.

The CONDUIT SYNFIX Evolution 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 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 SYNFIX Evolution Cages are manufactured from Ti-6AL-4V alloy (per ASTM F3001 and ASTM F136).
- The CONDUIT SYNFIX Evolution Plates are manufactured from Ti-6AL-4V alloy (per ASTM F136).
- The SYNFIX Evolution Locking Screws are manufactured from Ti-6AL-7Nb (per ISO 5832).
- A single use, disposable Locking Key (P/N: 440300001) is manufactured from Ti-6AL-4V alloy (per ASTM F2924) and offered in two packaging configurations:
 - packaged with the Plate
 - individually sterile-packed

INTENDED USE/INDICATIONS

The CONDUIT SYNFIX Evolution Secured Spacer System is a stand-alone anterior interbody fusion device with a microscopic roughened surface and micro and nano-scale features indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the CONDUIT SYNFIX Evolution can be packed with autograft. If used with less than the four integrated bone screws, or for hyperlordotic implants (>20Deg), implants must be used with supplemental fixation systems cleared by the FDA for use in the lumbosacral spine.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

CONTRAINDICATIONS

Do not use the CONDUIT SYNFIX Evolution 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
- Vertebral body fractures
- 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
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material
- Patient anatomy or pathology that prevents insertion of all four locking screws


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

	<ul style="list-style-type: none">• Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
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- 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 SYNFIX Evolution Secured Spacer with the applicable SYNFIX Evolution Secured Spacer instruments. Components of this system should not be used with components from other systems or manufacturers.
- The labeled heights of the selected CONDUIT SYNFIX Evolution Cage and Plate must match.
- Ensure proper assembly of the CONDUIT SYNFIX Evolution Cage and Plate via provided Locking Key, per surgical technique guide, prior to implantation.
- 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 SYNFIX Evolution 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.


	<ul style="list-style-type: none">• Never reuse an implant or Locking Key. Although the device may appear undamaged, previous stresses may have created nonvisible damage that could result in failure.
	<ul style="list-style-type: none">• Never use an implant or Locking Key if its packaging is damaged.
	<ul style="list-style-type: none">• An implant or Locking Key with damaged packaging might be damaged itself and thus may not be resterilized or used.

	<ul style="list-style-type: none"> Never use an implant or Locking Key that is past its expiration date.
	<ul style="list-style-type: none"> 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.

	The implant is sterilized with radiation (25 kGy minimum) and packaged in a double sterile barrier system.
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- Always store the implant in the original protective packaging.
- Do not remove the implant from the original packaging until immediately before use.

	<ul style="list-style-type: none"> Store the implant in a dry and dust-free place (standard hospital environment).
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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.
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MAGNETIC RESONANCE (MR) COMPATIBILITY

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MRI Safety Information	
A patient with the CONDUIT Synfix Evolution System 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 Synfix Evolution System
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 (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 41 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

- Dispose of Locking Key after use per healthcare facility biohazardous waste protocols.
- 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



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 serious 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.





















Manufactured by:
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1-877-289-1096
www.avalign.com
product.questions@avalign.com



Distributed by:
DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
USA

Label Glossary

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