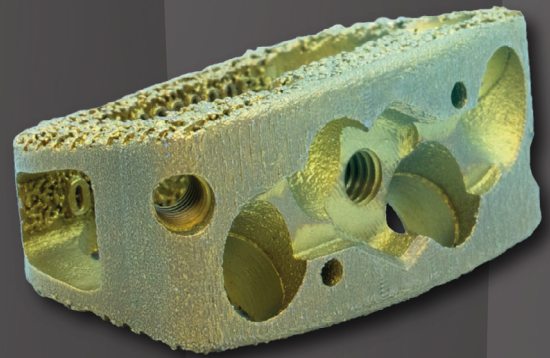
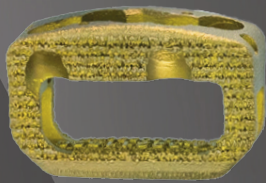


ALIGN ALIF HA

HYDROXYAPATITE COATED STAND ALONE
ANTERIOR LUMBAR SYSTEM



*Align ALIF HA is a spinal device that is **implanted in the intervertebral body space via an anterior approach to improve stability of the spine while supporting fusion.** Components are offered in different shapes and sizes to meet the requirements of the individual patient anatomy. Made from additively manufactured titanium alloy (Ti-6Al-4V ELI) **with an optional HAnano Surface® hydroxyapatite coating.***



MAXIMIZE PATIENT OPTIONS

Includes both two screw and four screw devices in various footprints to provide maximum flexibility in meeting all patient needs. All cages and screws are available with HAnano Surface® and are interchangeable with non-coated devices.

SUPPORT BONE IN-GROWTH

Enhanced porous structure improves adhesion to vertebral body endplates. With the addition of the HAnano Surface®, the improved structure is designed to increase bone in-growth to the endplate when used with allogenic bone graft and/or autograft to facilitate fusion.

NANO-SIZED RESULTS

A nominal HA coating thickness of 20-40 nm, which is up to several thousand times thinner compared to generic plasma-sprayed HA coatings.

THE GOLDEN STANDARD FOR STABILITY

Due to the thinness of the coating (less than 1µm) newly formed bone may form on the micrometer topography of the core implant surface, which is orders of magnitude larger than the HAnano Surface®, potentially providing mechanical stability independent of the coating itself.



S U R G I C A L

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ALIGN ALIF HA

HYDROXYAPATITE COATED STAND ALONE
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INDICATIONS FOR USE

Align ALIF HA is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space.

Align ALIF HA is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Align ALIF HA 2-SCREW

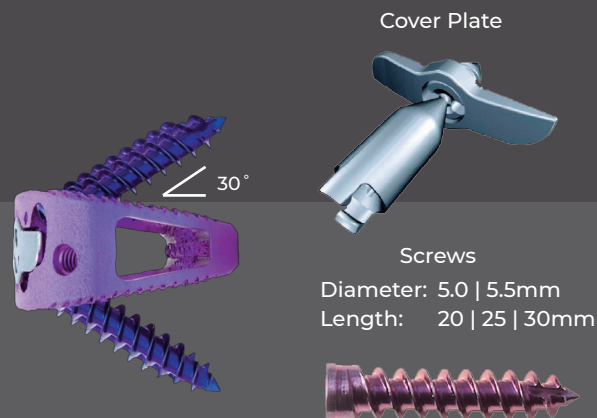
Align ALIF HA 2-screw system may be used as a stand-alone device only when two (2) vertebral body bone screws are used.

Align ALIF HA 4-SCREW

Align ALIF HA 4-screw system may be used as a stand-alone device only when at least two (2) vertebral body bone screws are inserted in the two medial fixation holes with both inferior and superior screw trajectory.

Align ALIF HA LESS THAN 2 SCREWS

If the physician chooses to use the Align ALIF HA system with fewer than two (2) screws in the two medial fixation holes with one inferior and one superior screw trajectory, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.



HAnano Surface®

All cages and screws are available with a Hydroxyapatite (HA) coating, denoted with a "- HA" suffix on the part number. Uncoated and HA-coated implants use the same instrumentation.

Implants with HAnano Surface® may promote faster and stronger osseointegration¹. Studies have been conducted for different kinds of implant material but especially for roughened titanium surfaces with micro-structures. In an in vitro study with pre-osteoblasts, the results show improved cell interaction between the HAnano Surface® and the bone cells compared to the titanium surface². Results from several in vivo studies in animal models show improved bone-to-implant contact and upregulation of osteogenic markers during the first month of healing indicating improved osseointegration for the HAnano Surface®^{3, 4, 5, 6}. In vitro performance or animal studies may not be representative of clinical performance.

¹ Data on file at Acuity Surgical

² Bezerra et al. Nano Hydroxyapatite-Blasted Titanium Surface Affects Pre-Osteoblast Morphology by Modulating Critical Intracellular Pathways. *Biotechnology and Bioengineering* 2017 Aug;114(8):1888-1898. doi: 10.1002/bit.26310.

³ de Oliveira et al. Influence of Nano-Hydroxyapatite Coating Implants on Gene Expression of Osteogenic Markers and Micro-CT Parameters. An In Vivo Study in Diabetic Rats. *Journal of Biomedical Materials Research A*. 2021 May; 109(5): 682-694.

⁴ Jimbo et al. Genetic Responses to Nanostructured Calcium-Phosphate-Coated Implants *Journal of Dental Research*, Volume 90, Issue 12, 2011, pp. 1422-1427.

⁵ de Oliveira et al. Histological and Nanomechanical Properties of a New Nanometric Hydroxyapatite Implant Surface. An In Vivo Study in Diabetic Rats. *Materials (Basel)*. 2020 Dec 13;13(24):5693.

⁶ Meirelles et al. Nano Hydroxyapatite Structures Influence Early Bone Formation *Journal of Biomedical Materials Research Part A*, 2008



Align ALIF HA Surgical Technique Guide
is available upon request

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