Adaptix™ Interbody System

with Titan nanoLOCK™ Surface Technology

FEATURES AND BENEFITS INFORMATION SHEET

PRODUCT **OVERVIEW**

Modeled from the Capstone™ Spinal System with improved features for increased strength,[5] subsidence resistance,[3,5,6] easy insertion, and bony on-growth.[1,2]

Shape

Convex shape for anatomical fit with patient anatomy

Sizes

Width = 10mm

Length	Height
24mm	6-16mm
28mm	6-16mm
34mm	7-16mm

Heights are in 1mm increments

Lordosis

Up to 12° can be achieved with posterior compression and final locking of screw-rod instrumentation.[7]

Instrumentation & Equipment

Adaptix Interbody System is compatible with:

- Capstone Spinal Instruments.
- StealthStation™ Navigation System and O-Arm™ Imaging Acquisition System.

PRODUCT **FEATURES**

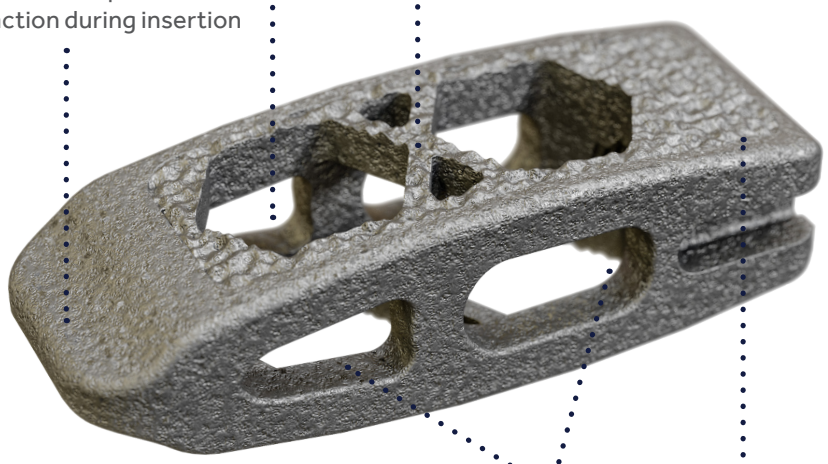
- **Navigation-compatible**
- Able to facilitate sagittal correction by ability to increase height and lordosis with the cage and posterior fixation

Open volume design for graft material placement to allow for a continuous column of graft directly in contact with the endplate

Smooth dolphin nose tip aids in disc space distraction during insertion

Honeycomb structure

- Allows for more bony surface contact area compared to an open cage design[3]
- Designed to minimize the stress load onto the end plates compared to an open cage design[3,5,6]
- Designed to decrease subsidence compared to an open cage design[3,5,6]
- Acts as an osteoconductive scaffold for bony growth into the implant[1,2]



Lateral windows to allow for visualization

Titan nanoLOCK™ Surface Technology[4]

- Proprietary blend of surfaces at macro, micro, AND nano levels
- Inspired by nature: Designed to mimic osteoclastic pits
- Driven by science: Numerous peer-reviewed *in vitro* studies

See next page for important safety information.

1. Wennerberg, A., & Albrektsson, T. (2009). Effects of titanium surface topography on bone integration: a systematic review. Clin Oral Implants Res, 20 Suppl 4, 172-184.
2. Gittens, R.A., Olivares-Navarrete, R., Schwartz, Z, Boyan, B.D. (2014). Implant osseointegration and the role of microroughness and nanostructures: lessons for spine implants. Acta Biomater., 10(8), 3363-71.
3. Based on surface area measurement.
4. Based on manufacturing process.
5. Comparison of Adaptix and Capstone testing per ASTM F2077and ASTM F2267.
6. Based on engineering principles.
7. Based on biomechanical study.

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Further, Together

Important Product Information on Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology

INDICATIONS

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

These patients should be skeletally mature and have had six months of nonoperative treatment. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used with autograft and/or allogenic bone graft comprised of cancellous, and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate . These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

CONTRAINDICATIONS

This device is not intended for cervical spine use. Contraindications include:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include:

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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