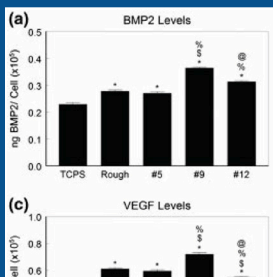
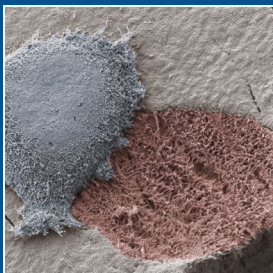
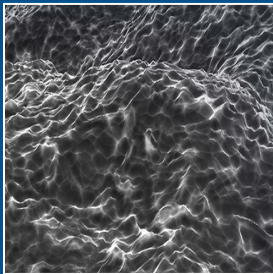
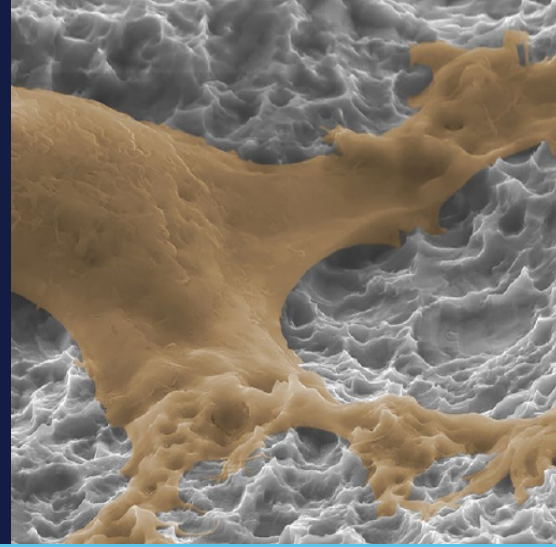


# INSPIRED BY NATURE

Titan nanoLOCK®



## Nano surface technology

- Proprietary blend of surfaces at the macro, micro, and nano levels
- Macro texture on endplate contact surfaces for initial fixation†
- Micro and nano textures present on all surfaces

## Inspired by nature

- Utilizes “biomimicry” of structures involved in the bone remodeling process‡
- Micro texture designed to mimic osteoclastic pit geometry
- Nano texture mimics the nano “spike” topography within these osteoclastic pits

## Driven by science

- Research-first approach to development
- Six peer reviewed published *in vitro* studies on Titan nanoLOCK Surface Technologies
- NanoLOCK selected from 36 surface iterations evaluated for nano-architecture and *in vitro* response§

† Internal Testing.

‡ Internal Testing.

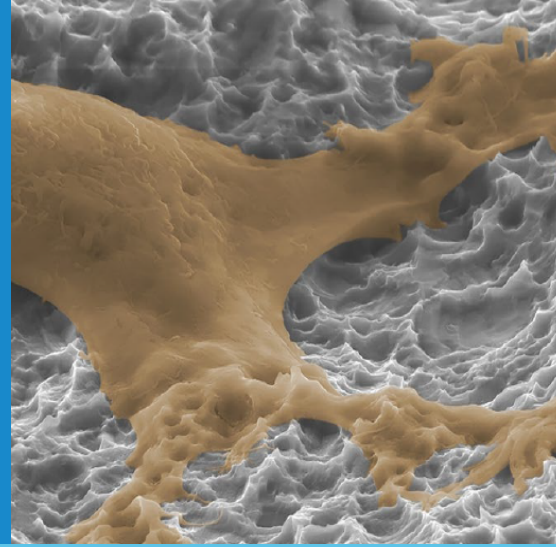
§ Internal Testing. Animal and *in vitro* testing not necessarily indicative of human outcomes.

**Medtronic**  
Further, Together



# NANO SURFACE TECHNOLOGY

## Titan nanoLOCK



The next generation surface technology from Titan Spine features a proprietary blend of textures at the macro, micro, and nano (MMN™) levels.

**NanoLOCK is created through a subtractive manufacturing process that removes material to enable textures at three levels.†**

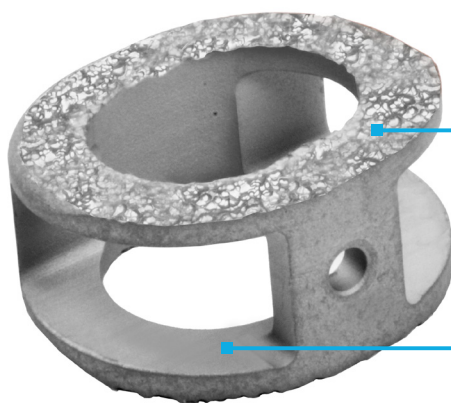
- FDA-cleared nanotechnology for the spine
- A surface with access to the new CMS nanotextured ICD-10 code
- Technology backed by more than 10 years of biomaterial know-how

† Internal Testing.

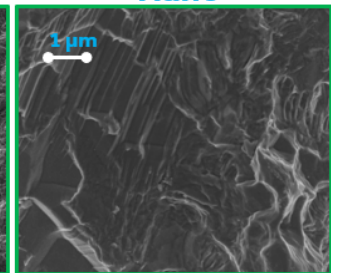
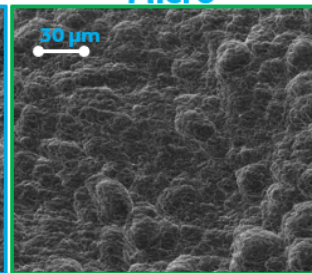
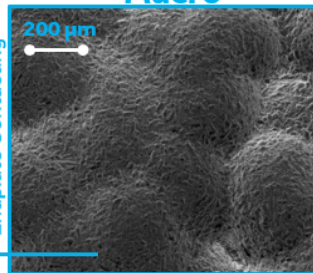
### Macro

### Micro

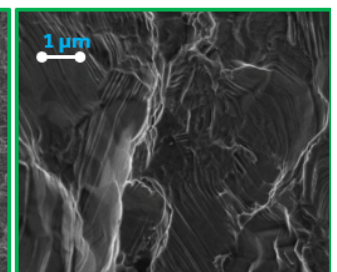
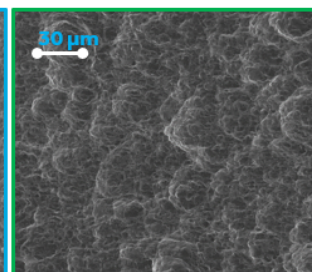
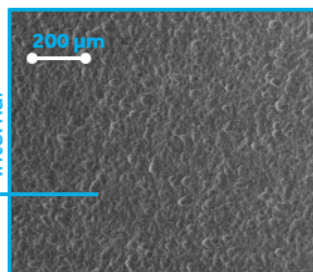
### Nano



Endplate Contacting



Internal



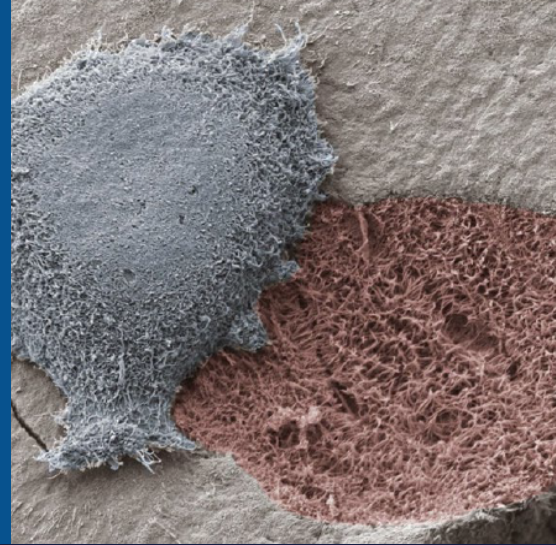
**Macro level**  
Anti-expulsion surface on superior and inferior surfaces.

**Micro level ( $10^{-6}m$ )**  
Osteoclastic-sized pits on all external and interior surfaces.

**Nano level ( $10^{-9}m$ )**  
Nano-sized textures within the osteoclastic-sized pits on all surfaces.

# INSPIRED BY NATURE

## Titan nanoLOCK



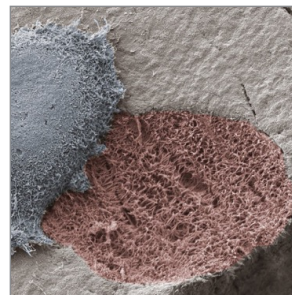
Titan nanoLOCK utilizes the inspiration of nature (biomimicry) to offer surface technology based on the bone remodeling process.

Biomimicry is an approach to innovation that seeks sustainable solutions to human challenges by emulating nature's time-tested patterns and strategies.

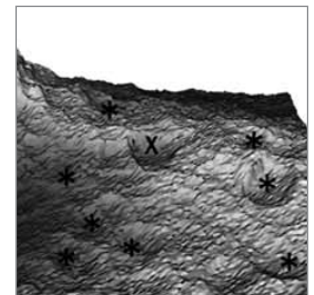
– Biomimicry Institute

## DESIGNED TO MIMIC OSTEOCLASTIC PITS

In nature, osteoblasts form bone after osteoclastic pits have been created.<sup>1</sup> The Titan nanoLOCK surface technology was designed to offer osteoclastic-like pits that mirror the micro geometry of the pit and nano texture within them.

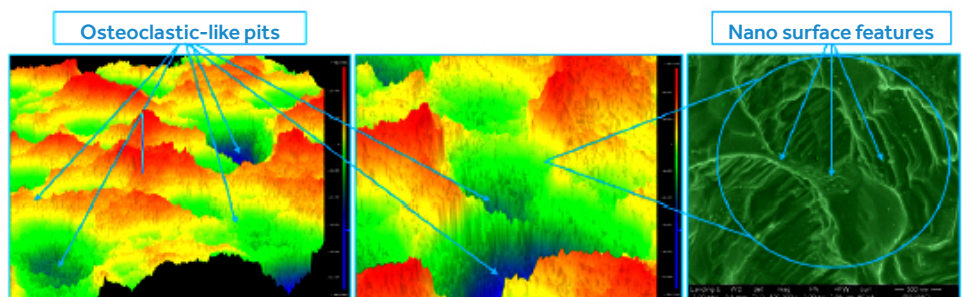


Osteoclastic Pit



nanoLOCK

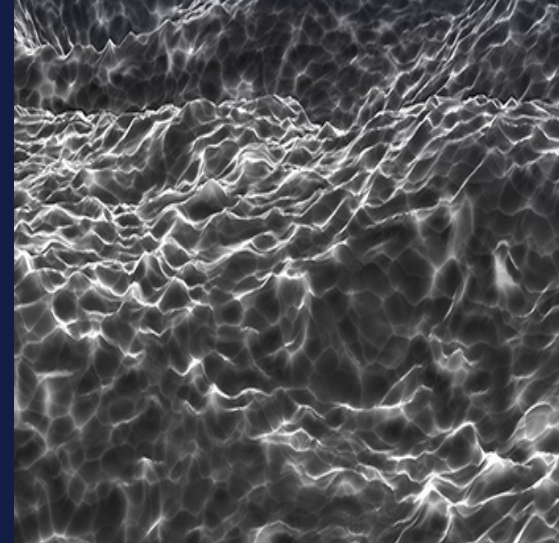
## MICRO PIT GEOMETRY AND NANO- SCALED TEXTURE WITHIN THEM





# DRIVEN BY SCIENCE

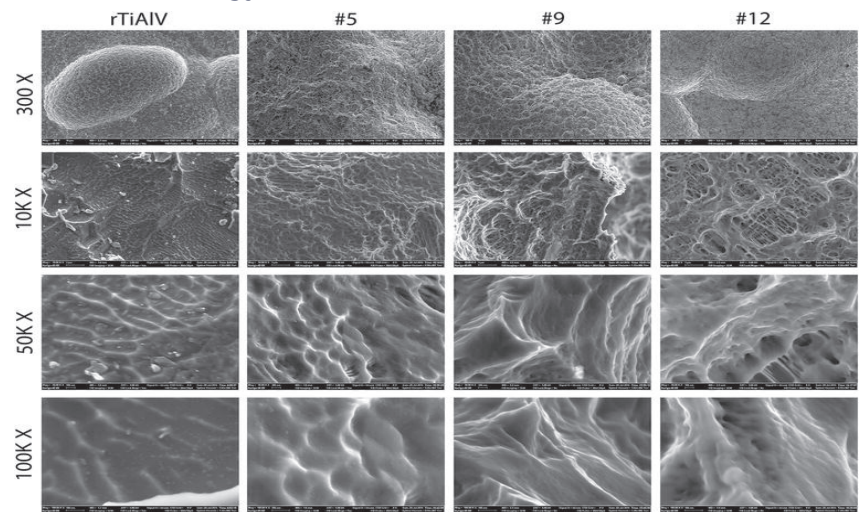
## Titan nanoLOCK



**Research-first approach to the development of the Titan nanoLOCK Surface Technology.**

Six peer reviewed *in vitro* studies on Titan Surface Technology.

**36 surface variations evaluated to select final nanoLOCK (#9) surface technology.†**

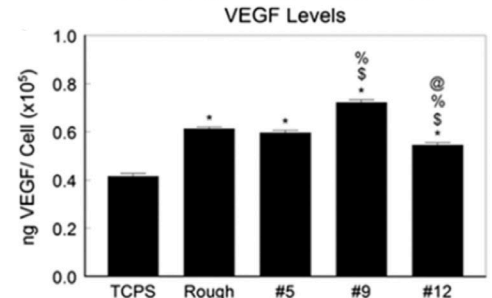
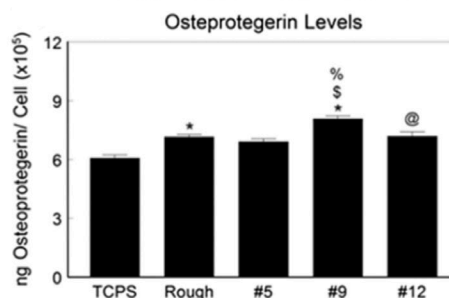
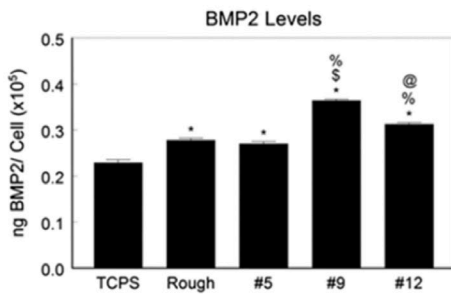
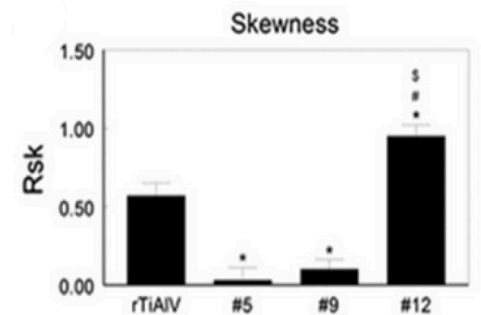
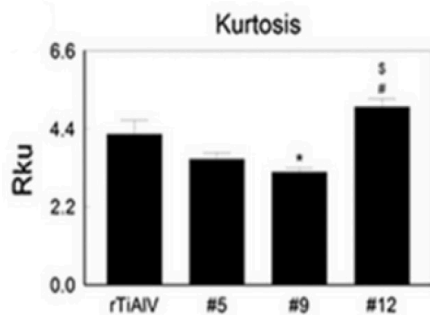


† Internal Testing.

Multiple surface characteristics were measured; two parameters were identified that play a key role in the nano architecture:

**Low Skewness**  
(peak to valley ratio)

**High Kurtosis**  
(peak sharpness)



Three factors were examined when selecting the nanoLOCK (#9) surface: up-regulation of osteoblasts (BMP2), down-regulation of osteoclasts (Osteoprotegerin), up-regulation of blood growth factors (VEGF).

Animal and *in vitro* testing not necessarily indicative of human outcomes.

## Six peer reviewed published *in vitro* studies on Titan surface technology.

1. Matteson, J.L., Greenspan, D.C., Tighe, T.B., Gilfoy, N., Stapleton, J.J. Assessing the hierarchical structure of titanium implant surfaces. *J Biomed Mater Res B*. [In Press] EPub 29 May 2015.
2. Olivares-Navarrete, R., Hyzy S.L., Gittens, R.A., Schneider, J.M., Haithcock, D., Ullrich, P., Schwartz, Z., Boyan, B.D. Rough titanium alloys regulate osteoblast production of angiogenic factors. *Spine J*. 2013 Nov; 13(11):1563-70.
3. Gittens, R.A., Olivares-Navarrete, R., Schwartz, Z., Boyan, B.D. Implant osseointegration and the role of microroughness and nanostructures: Lessons for spine implants. *Acta Biomater* 2014 Aug; 10(8): 3363-3371.
4. Olivares-Navarrete, R., Hyzy S.L., Gittens, R.A., Berg, M.E., Schneider, J.M., Hotchkiss, K., Schwartz, Z., Boyan, B. D. Osteoblast lineage cells can discriminate microscale topographic features on titanium-aluminum-vanadium surfaces. *Ann Biomed Eng*. 2014 Dec; 42(12): 2551-61.
5. Olivares-Navarrete, R., Hyzy S.L., Slosar, P.J., Schneider, J.M., Schwartz, Z., Boyan, B.D. Implant materials generate different peri-implant inflammatory factors: PEEK promotes fibrosis and micro-textured titanium promotes osteogenic factors. *Spine*. 2015 Mar; 40(6): 399-404.
6. Banik, B., Riley, T., Platt, C., Brown, J. Human mesenchymal stem cell morphology and migration on microtextured titanium. *Front Bioeng Biotechnol*. 2016 May; 4(41) doi: 10.3389/fbioe.2016.00041.

### TITAN INDICATIONS

The ENDOSKELETON® TA, ENDOSKELETON® TL, ENDOSKELETON® TT, ENDOSKELETON® TO Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental fixation that has been cleared by the FDA for use in the lumbar spine. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). ENDOSKELETON® TA is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

The ENDOSKELETON® TC Interbody Fusion Device is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The ENDOSKELETON® TC Interbody Fusion Device is indicated to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine and autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

The Endoskeleton® TCS Interbody Fusion Device System is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one disc level from C2 to T1. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The device is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone. The device is a standalone system when used with Endoskeleton® TCS integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared for the cervical spine.

The ENDOSKELETON® TAS Interbody Fusion device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of nonoperative treatment prior to treatment with the devices. The device is a standalone system that is intended to be used with the bone screws provided and requires no additional supplementary fixation. The Device is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

Hyperlordotic Devices >16°: The ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device (>16°) is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone. The ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device must be used with a posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar spine.

### RISKS

Possible adverse effects include, but are not limited to, bending, loosening, or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral fluid leakage; gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium; pain or discomfort; bone loss due to resorption or stress shielding, or bone fracture at, above, or below the level of surgery (fracture of the vertebra); hemorrhage of blood vessels and/or hematomas; malalignment of anatomical structures, including loss of proper spine curvature, correction, reduction, and/or height; bursitis; bone graft donor site pain; inability to resume activities of normal daily living; reoperation or death.

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