

4WEB IMPLANTS

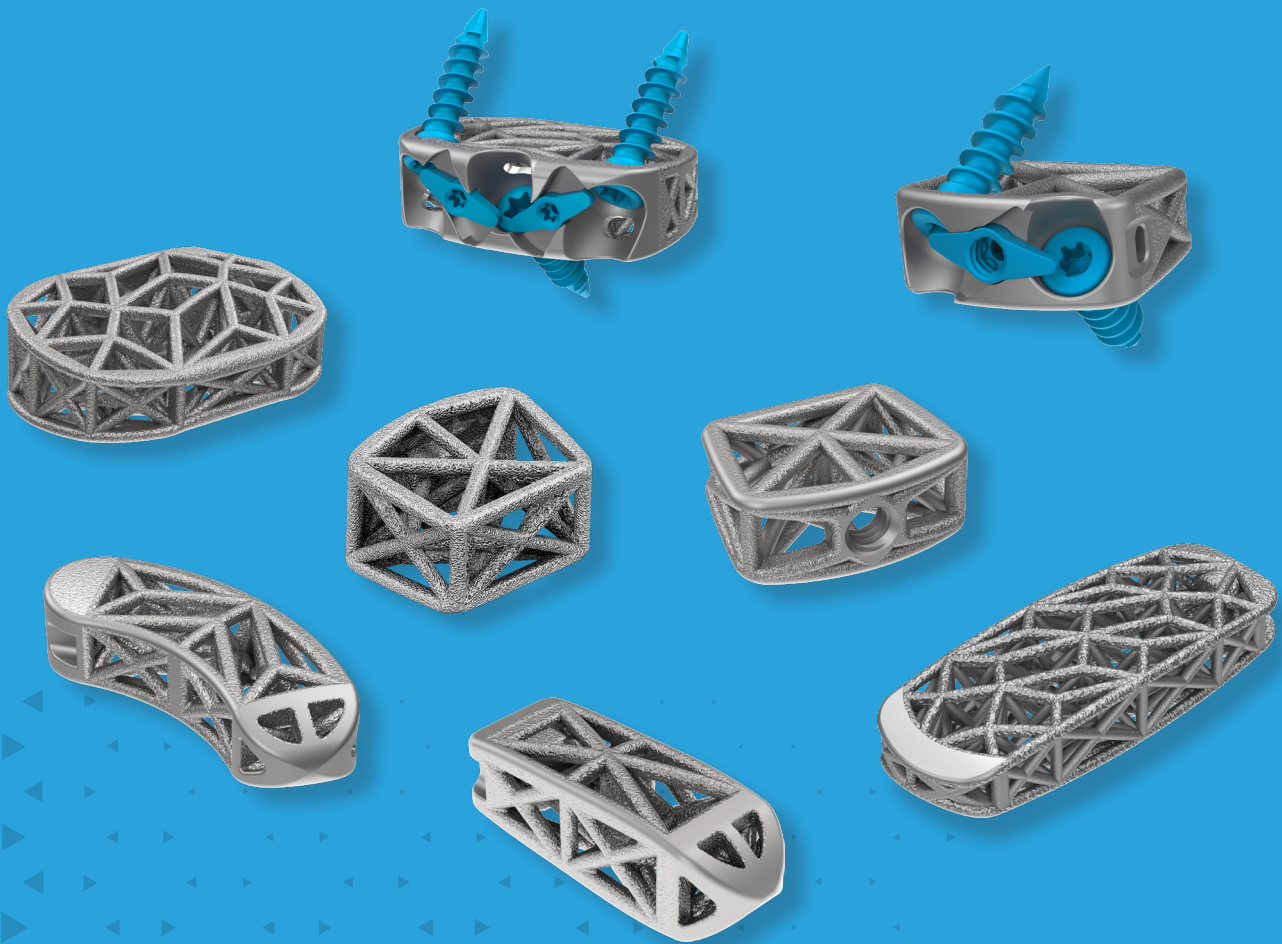




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4WEB SPINE TRUSS SYSTEM IMPLANTS



Your attending physician has diagnosed you with Degenerative Disc Disease (DDD) of your spine and has indicated for treatment a surgical spinal fusion procedure. In this procedure the affected disc(s) between the vertebral bodies at the level of the disease are removed and replaced by an interbody fusion device, which stabilizes the adjacent vertebrae and provides sufficient space for the segmental spinal nerves. Furthermore, the implanted interbody fusion device facilitates immobilization and fusing together of the vertebral bodies at the level of your spinal fusion surgery.

Please see additional information below on the 4WEB Spine Truss System Implants, which your attending physician has selected for your spinal fusion procedure.

► ANTERIOR SPINE TRUSS SYSTEM (ASTS)



The ASTS implant is used in surgery of the lower back in the lumbar spine. It is inserted between the spinal vertebrae from the front (anterior) through the abdomen while the patient lies face up (supine position). The ASTS implant is designed to provide mechanical support to the lumbar spine. The implant is indicated to be used in adult patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous disc levels.

DDD is determined by the attending physicians on the basis of your past disease and additional x-ray examination. You should have received 6 months of non-operative treatment prior to treatment with the implants. Patients may also have a vertebra displacement up to Grade I at the involved level(s). To prevent implant migration and to facilitate bone fusion, the implant must be used with supplemental fixation and bone grafting, as indicated in the device Instructions for Use.



► ANTERIOR SPINE TRUSS SYSTEM STAND ALONE (ASTS-SA)



The ASTS-SA implant is used in surgery of the lower back in the lumbar spine. It is inserted between the spinal vertebrae from the front (anterior) through the abdomen while the patient lies face up (supine position). The ASTS-SA implant is designed to provide mechanical support to the lumbar spine and is held in position with fixation screws. The implant is indicated to be used in adult patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous disc levels.

DDD is determined by the attending physicians on the basis of your past disease and additional x-ray examination. You should have received 6 months of non-operative treatment prior to treatment with the implants. Patients may also have a vertebra displacement up to Grade I at the involved level(s). To prevent implant migration and to facilitate bone fusion, the implant must be used with three titanium alloy screws and bone grafting, as indicated in the device Instructions for Use. Hyperlordotic implants ($>20^\circ$ lordosis) are intended to be used with additional supplemental fixation.

► POSTERIOR SPINE TRUSS SYSTEM (PSTS, TSTS)



The Posterior Spine Truss System implant is used in surgery of the lower back in the lumbar spine. It is inserted between the spinal vertebrae from the back (posterior), while the patient lies face down (prone position). The Posterior Spine Truss System implant is designed to provide mechanical support to the lumbar spine. The implant is indicated to be used in adult patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous disc levels.

DDD is determined by the attending physicians on the basis of your past disease and additional x-ray examination. You should have received 6 months of non-operative treatment prior to treatment with the implants. Patients may also have a vertebra displacement up to Grade I at the involved level(s). To prevent implant migration and to facilitate bone fusion, the implant must be used with supplemental fixation and bone grafting, as indicated in the device Instructions for Use.



► LATERAL SPINE TRUSS SYSTEM (LSTS)

The LSTS implant is used in surgery of the lower back in the lumbar spine. It is inserted between the spinal vertebrae from the side (lateral), while the patient lies on the opposite side (lateral position). The LSTS implant is designed to provide mechanical support to the lumbar spine. The implant is indicated to be used in adult patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous disc levels.

DDD is determined by the attending physicians on the basis of the patient's past disease and additional x-ray examination. Patients should have received 6 months of non-operative treatment prior to treatment with the implants. Patients may also have a vertebra displacement up to Grade I at the involved level(s). To prevent implant migration and to facilitate bone fusion, the implant must be used with supplemental fixation and bone grafting, as indicated in the device Instructions for Use.

► CERVICAL SPINE TRUSS SYSTEM (CSTS) CERVICAL SPINE TRUSS SYSTEM 2.0 (CSTS2)

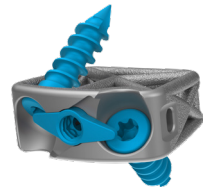


The CSTS implant is used in surgery of the neck in the cervical spine. It is inserted between the spinal vertebrae from the front (anterior) of the neck while the patient lies face up (supine position). The CSTS implant is designed to provide mechanical support to the cervical spine. The implant is indicated to be used in adult patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous disc levels.

DDD is determined by the attending physicians on the basis of your past disease and additional x-ray examination. You should have received 6 weeks of non-operative treatment prior to treatment with the implants. To prevent implant migration and to facilitate bone fusion, the implant must be used with supplemental fixation and bone grafting, as indicated in the device Instructions for Use.



► CERVICAL SPINE TRUSS SYSTEM STAND ALONE (CSTS-SA)



The CSTS-SA implant is used in surgery of the neck in the cervical spine. It is inserted between the spinal vertebrae from the front (anterior) of the neck while the patient lies face up (supine position). The CSTS-SA implant is designed to provide mechanical support to the cervical spine and is held in position with fixation screws. The implant is indicated to be used in adult patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous disc levels.

DDD is determined by the attending physicians on the basis of your past disease and additional x-ray examination. You should have received 6 weeks of non-operative treatment prior to treatment with the implants. To prevent implant migration and to facilitate bone fusion, the implant must be used with two titanium alloy screws and bone grafting, as indicated in the device Instructions for Use.

DEVICE GENERAL INFORMATION



DEVICE MATERIAL/COMPOSITION:

4WEB Truss System Implants are manufactured from medical grade Titanium Alloy (Ti6Al4V which contains 6% Aluminum, 4% Vanadium, and 90% Titanium). Toxicological studies were performed to demonstrate the implants' biocompatibility.

DEVICE LIFETIME:

4WEB Spine Truss System implants are expected to last the lifetime of the patient. There are no identified environmental conditions or external influences that are expected to shorten or lengthen the device lifetime.

SPINE TRUSS SYSTEM POTENTIAL ADVERSE EVENTS:

Potential adverse events may be related to surgery in general, spine surgery specifically, or the implant. These may include, but are not limited to the following:

- **Adverse events related to any surgery:** reactions to anesthesia (the anesthetic or other medications), bleeding, infection, ileus, blood vessel damage, nerve or soft tissue damage, atelectasis, pneumonia, hematoma, seroma, wound dehiscence or incisional hernia, urologic problems, embolism, anemia, colitis, thrombophlebitis, heart attack, stroke, or death.
- **Adverse events related specifically to spine surgery:** dural tear and CSF leak, nerve damage leading to radiculopathy, myelopathy, paraparesis, paresthesia or paralysis, meningitis, vertebral body damage or fracture, ligament damage, fractured sacrum, or retrograde ejaculation.
- **Adverse events related to the device:** implant crack or fracture, failure to achieve fusion, implant subsidence, migration or dislodgement, or sensitivity/allergy to a metal foreign body. Additional surgery may be necessary for implant removal, repositioning or replacement. Additional stabilization at the implanted level or surgery at another disc level may be necessary if non-union or anatomic change at an adjacent level develops.

SPINE TRUSS SYSTEM POSTOPERATIVE CARE:

- There are no special operating instructions for the use of the device after surgery.
- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine may result in complications such as implant loosening, and/or breakage.
- The patient must be advised not to smoke or consume alcohol during the period of the bone fusion process.



- The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is critical that immobilization of union is established and confirmed by x-ray examination. If a non-union develops or if the components loosen, migrate, and/or break, the implant must be revised and / or removed immediately before serious injury occurs.
- If symptoms related to pain, numbness, and/or instability develop or worsen postoperatively, please contact your healthcare provider.

4WEB SPINE TRUSS SYSTEM MRI SAFETY INFORMATION*:

The 4WEB Spine Truss System implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

 MRI Safety Information A patient with the 4WEB Medical Spine Truss 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	4WEB Medical Spine Truss System
Nominal Value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 15 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 28mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Under the scan conditions defined above, non-clinical testing results indicate the implants produce a maximum temperature rise of no more than 5.0°C after 15 minutes of continuous scanning.

* Studies were not performed to determine patients' safety upon another environmental condition, e.g. using another medical equipment. The doctor must be informed of patient implants prior to perform or prescribe any medical examination or submit the patient to unusual environmental conditions.

PRODUCT COMPLAINTS



AUSTRALIA

Any healthcare professional (e.g. a surgeon using the product) or patient who has experienced a serious incident with any 4WEB device should notify 4WEB or, where applicable, their distributor and the Therapeutic Goods Administration: <https://www.tga.gov.au/reporting-problems>

EUROPE, UK, AND USA

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any 4WEB products should notify 4WEB (complaints@4webmedical.com) or, where applicable, their distributor.



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