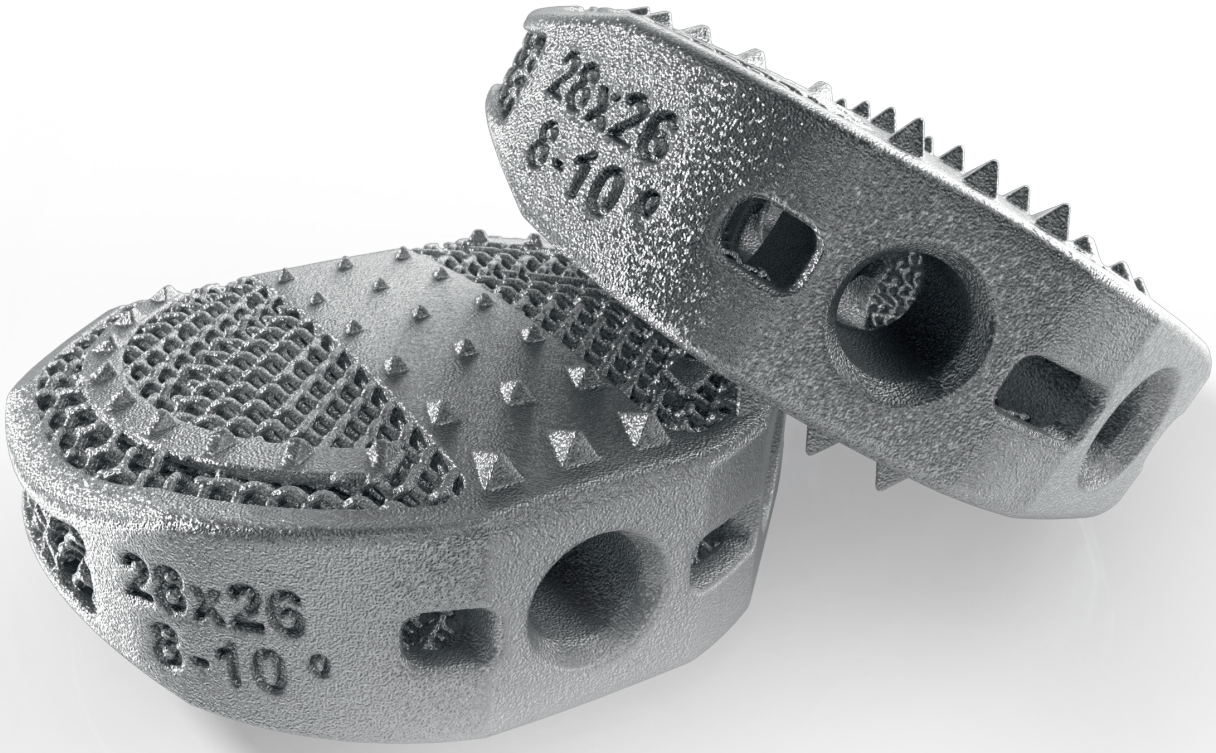
silony® MEDICAL

TRANSMAXX® ALIF

INSTRUMENTATION GUIDE



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Intended use

The Transmaxx cages are single use intervertebral body fusion cages and have been developed for single or multi-level lumbar and/or lumbosacral intervertebral body fusion. The implant is intended for insertion between two adjacent vertebrae. In combination with autograft or allograft, a posterior rod and screw system and, if applicable an anterior plate, the cages restore intervertebral height of the spinal segment and facilitate osteosynthesis. The devices are used in a standard operating room environment by orthopaedic and neurosurgeons.

See also the WARNINGS in this instrumentation guide.

Indications

The Transmaxx ALIF cage is intended for the treatment of chronic low back and leg pain due to degenerative changes in the lumbar spine:

- Degenerative Disc Disease (DDD) with a specific discogenic pain pattern
- Spondylolisthesis (up to grade 1)

Contraindications

Do not use the Transmaxx ALIF cage in cases of:

- Reduced bone quality (e.g. osteoporosis or bone decalcification)
- Fractures
- Tumors
- Active infection
- Local inflammation
- Primary spinal deformities
- Allergy to titanium or its alloys

NOT FOR STANDALONE The Transmaxx ALIF cages always require additional fixation with a posterior rod and screw system or an anterior plate. Using the Transmaxx ALIF cage for standalone applications without additional fixation can result in reduced device performance.

MR SAFETY A patient with this implant/device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence).

In all cases, the Health Care Professional is responsible for MR Conditions, MR Imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

MRI-Related Heating
In non-clinical testing, comparable devices produced a temperature rise of less than or equal to 6.0 degrees C using an MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes (per pulse sequence) of scanning in a 3-Tesla MR system.

Artifact
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant/device. In some cases, the artifact size relative to the size of the implant or device may be indicated.

Attention: Contact the manufacturer of this implant/device for further information, as needed.

Warnings

Potential risks identified with the use of this system include:

- Neurologic, pulmonary, cardio/vascular and/or urologic complications
- Infection
- Intolerance to the material
- Device fracture
- Loss of fixation
- Osteolysis
- No fusion or delayed fusion
- Implant subsidence
- Postoperative implant migration

Further adverse events identified, not directly linked to product or procedure, are:

- Degeneration of the vertebrae adjacent to the arthrodesis

TRANSMAXX® ALIF INSTRUMENTATION

Pre-surgical planning

Perform appropriate patient selection and inform patient of limitations and potential adverse effects of the surgery. Patients must be skeletally mature and have had at least six months of non-operative treatment. Ensure implants and the designated instrument set are available and ready for use (see Instructions for Use for cleaning and sterilization instructions of the instruments).

PATIENT SELECTION Appropriate patient selection is critical to the surgical outcome. Only patients who satisfy the indications AND who do not have any of the contraindications should be considered for interbody fusion surgery using the Transmaxx ALIF cage to avoid adversely affecting device performance or surgical outcome.

INSTRUMENTS Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. The surgical team must verify that the instruments are in good condition and in operating order prior to use during surgery.

PATIENT EDUCATION Preoperative instructions to the patient are essential. The patient should be made aware of the limitations and potential adverse effects of the surgery. The patient should be instructed to limit the postoperative activity as this will reduce the risk of bending, breaking and/or loosening the implants. The patient must be made aware that implant components may bend, break and/or loosen, even though restrictions in activity are followed.

TRAINING The surgeon should strictly follow the recommendations in the surgical technique and all staff involved should be familiar with the surgical procedures associated with the lumbar interbody fusion technique to avoid adversely affecting device performance or surgical outcome.

Surgical steps

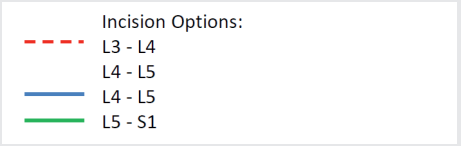
PREPARATION AND APPROACH

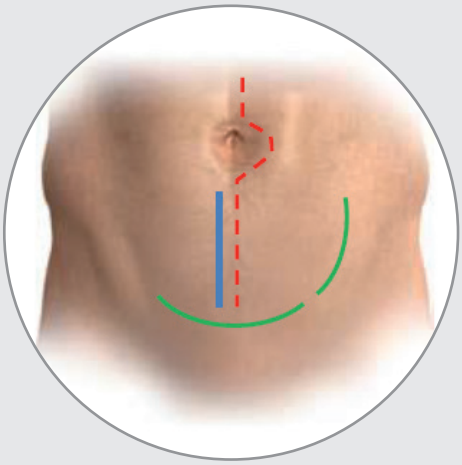
The patient is positioned in supine position on the OR table. Make sure to allow for X-ray examinations by C-arm (AP and Lateral). Support the patient in a way that increases the lordotic curve, this distracts the level to be treated and allows for better access.

Depending on the patient, a transperitoneal or retroperitoneal approach can be selected. Retroperitoneal access minimizes the risk of injury to the internal organs. For a retroperitoneal approach, make an anterior, anterolateral or lateral incision in the abdomen, depending on the level.

If the patient previously had a surgery in the abdominal area, existing scar tissue can be problematic; in such cases the transperitoneal approach is recommended.

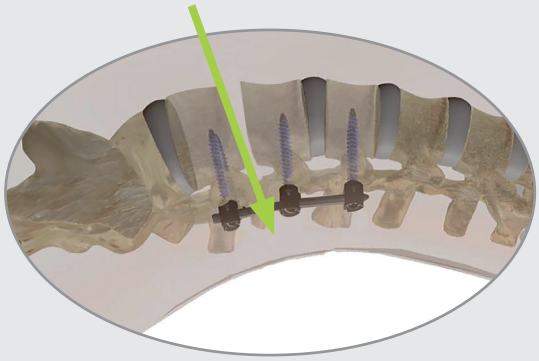
Confirm the affected level(s) using imaging techniques.

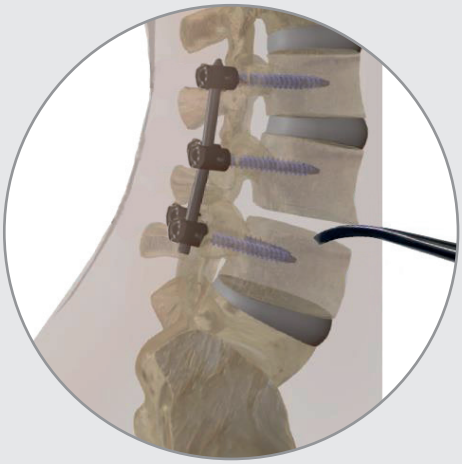




DISCECTOMY AND CURETTAGE

Resect the anterior anatomy and perform the intervertebral discectomy. Depending on the case, the anulus may not have to be removed. Perform discectomy with standard instruments (rongeurs, forceps) and expose the bony endplates.



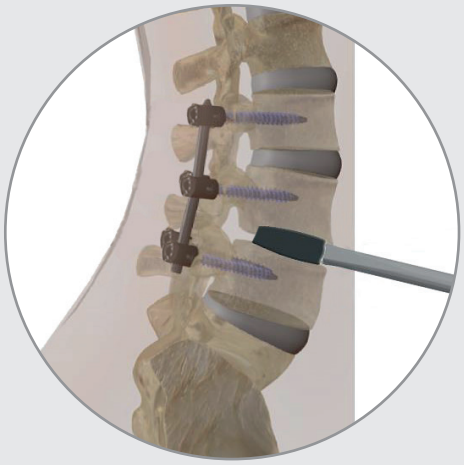


ENDPLATE PREPARATION Appropriate removal of the cartilaginous layers of the endplates is important for the vascularization of the bone graft. However, make sure to clean the endplates carefully and maintain the integrity of the underlying bony endplate, as damage of the endplate can lead to implant subsidence.

Trial insertion and determination of cage size

Attach the Trial sizer to the Inserter. Align the front of the Trial sizer with the tip of the inserter and make sure the tip slides into the openings of the interface. Rotate the knob at the back clockwise until the Trial sizer is securely seated in the tip of the inserter.

Insert the Trial sizer with gentle taps on the back of the handle until it is fully seated in the intervertebral space. Start with a small size and repeat using the next larger size, sequentially until the Trial sizer fits tightly in the disc space, the lordotic curve is reached and the nerve roots are adequately released. Check the secure fit and final position of the trial with fluoroscopy. Remove the Trial after cage size determination.



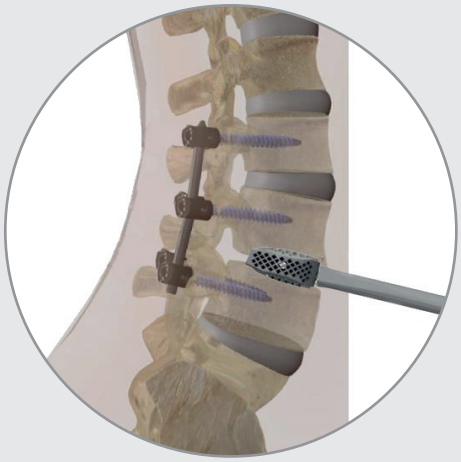
SIZE SELECTION The Transmaxx ALIF cages are available in a wide variety of sizes to ensure appropriate sizing of the implanted components. Correct size selection is critical to the surgical outcome. An under- or oversized implant can lead to premature failure of the cage.

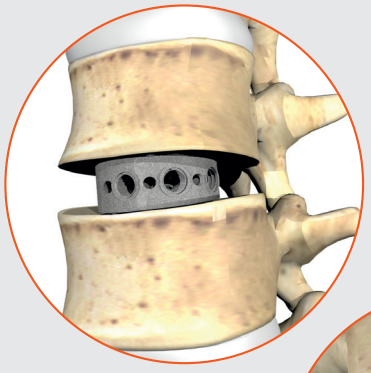
Implant insertion

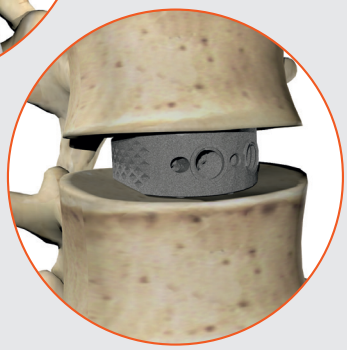
Open the sterile packaging of the implant size that was determined with the Trial. Attach the implant to the inserter. Align the front of the implant with the tip of the inserter and make sure the tip slides into the openings of the implant interface. Rotate the knob at the back clockwise until the implant is securely seated in the tip of the inserter. Bone graft and/or bone graft substitute might be added into the opening of the cage. Add this after attachment of the inserter, to avoid bone graft build up in the implant-inserter interface hindering a proper implant-inserter attachment. Insert the implant with gentle taps on the back of the inserter until the implant is in the intervertebral space.

Check the secure fit and final position of the implant with fluoroscopy. If the implant position is adequate, remove the inserter by rotating the inserter knob counter clockwise.

Depending on surgical preference, the disc space can be filled prior to and after cage implantation with remaining bone graft and /or bone graft substitute.







⚠ **USE-BY DATE AND STERILITY** Before using the Transmaxx ALIF cage check the use-by date (YYYY/MM/DD) and sterility marker on the packaging. Do not use the implant after its expiration date or if the marker does not indicate it is irradiated, this can lead to infection.

⚠ **IMPLANT HANDLING** The cages should be handled appropriately to protect them from unintentional damage. Avoid scratching or damaging the cage at any time (specifically during attachment of the implant to the inserter and implant placement), as this may lead to premature failure of the cage. Do not use damaged implants.

⚠ **PACKAGING INTEGRITY** Before use of the Transmaxx ALIF cage check the secondary packaging, labelling and sterile primary packaging are intact. The sterile packaging should be free of cracks, holes, tears and any other damage. Use of an Implant from a damaged packaging can lead to an untraceable product or infection.

⚠ **IMPLANT PLACEMENT** The Transmaxx ALIF cage has teeth to maximize primary stability, however make sure the soft tissues are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular the rough cranial and caudal surfaces). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.

Implant removal; Postoperative; Disposal

Implant removal
The Transmaxx ALIF cage is intended for permanent implantation and is not intended to be removed in case of a good outcome. However, adverse events might warrant removal of the implant.

Dissect the bone, attach the inserter to the implant and remove the implant.

Postoperative
The patient should be instructed to limit the postoperative activity as this will reduce the risk of bent, broken and/or loose implant components.
Postoperative evaluation of the fusion and the implant status are mandatory.

Disposal
The disposal of this medical product requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of the packaging material and potentially infectious items.

SINGLE USE ONLY The Transmaxx ALIF cages are provided as single use implants only, and are not to be reused, resterilized or reimplanted in any situation as this might adversely affect device performance and/or increase risk of infection.

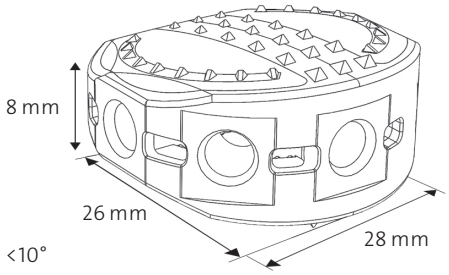
TRANSMAXX® ALIF PRODUCT INFORMATION

Transmaxx® ALIF Implants

Article number explanation for the cage, as an example

Transmaxx ALIF Cage, 28 x 26 x 08, 10° lordosis

BM	–	TTI	–	28	26	08	–	10
BAAT Medical		System		Width	Length	Height		Angle

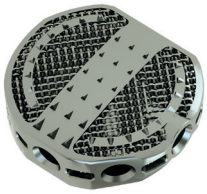


System:
Transmaxx

Implant type:
ALIF

Typing:
25 mm

Material:
Ti6Al4VELI

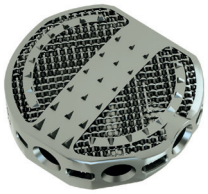
Article number	Description	Illustration
BM-TTI25230600	Transmaxx 25 x 23 x 06 x 00 deg	
BM-TTI25230800	Transmaxx 25 x 23 x 08 x 00 deg	
BM-TTI25231000	Transmaxx 25 x 23 x 10 x 00 deg	
BM-TTI25231200	Transmaxx 25 x 23 x 12 x 00 deg	
BM-TTI25230610	Transmaxx 25 x 23 x 06 x 10 deg	
BM-TTI25230810	Transmaxx 25 x 23 x 08 x 10 deg	
BM-TTI25231010	Transmaxx 25 x 23 x 10 x 10 deg	
BM-TTI25231210	Transmaxx 25 x 23 x 12 x 10 deg	
BM-TTI25231410	Transmaxx 25 x 23 x 14 x 10 deg	

System:
Transmaxx

Implant type:
ALIF

Typing:
28 mm

Material:
Ti6Al4VELI

Article number	Description	Illustration
BM-TTI28260810	Transmaxx 28 x 26 x 08 x 10 deg	
BM-TTI28261010	Transmaxx 28 x 26 x 10 x 10 deg	
BM-TTI28261210	Transmaxx 28 x 26 x 12 x 10 deg	
BM-TTI28261410	Transmaxx 28 x 26 x 14 x 10 deg	
BM-TTI28260815	Transmaxx 28 x 26 x 08 x 15 deg	
BM-TTI28261015	Transmaxx 28 x 26 x 10 x 15 deg	
BM-TTI28261215	Transmaxx 28 x 26 x 12 x 15 deg	
BM-TTI28261415	Transmaxx 28 x 26 x 14 x 15 deg	

Transmaxx® ALIF Implants

Article number	Description	Illustration
BM-TTI34281010	Transmaxx 34 x 28 x 10 x 10 deg	
BM-TTI34281015	Transmaxx 34 x 28 x 10 x 15 deg	
BM-TTI34281215	Transmaxx 34 x 28 x 12 x 15 deg	
BM-TTI38281010	Transmaxx 38 x 28 x 10 x 10 deg	
BM-TTI38281015	Transmaxx 38 x 28 x 10 x 15 deg	

System:
Transmaxx

Implant type:
ALIF

Typing:
34 + 38 mm

Material:
Ti6Al4VELI

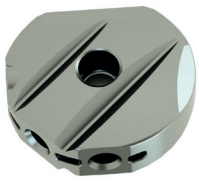
Transmaxx® ALIF Trial Implants

System:
Transmaxx

Instrument type:
Trial implant

Typing:
25 mm

Material:
stainless steel (17-4PH)

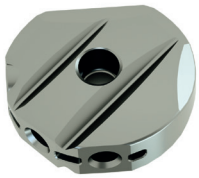
Article number	Description	Illustration
BM-TTR25230600	Transmaxx Trial sizer 25 x 23 x 06 x 00 deg	
BM-TTR25230800	Transmaxx Trial sizer 25 x 23 x 08 x 00 deg	
BM-TTR25231000	Transmaxx Trial sizer 25 x 23 x 10 x 00 deg	
BM-TTR25231200	Transmaxx Trial sizer 25 x 23 x 12 x 00 deg	
BM-TTR25230610	Transmaxx Trial sizer 25 x 23 x 06 x 10 deg	
BM-TTR25230810	Transmaxx Trial sizer 25 x 23 x 08 x 10 deg	
BM-TTR25231010	Transmaxx Trial sizer 25 x 23 x 10 x 10 deg	
BM-TTR25231210	Transmaxx Trial sizer 25 x 23 x 12 x 10 deg	
BM-TTR25231410	Transmaxx Trial sizer 25 x 23 x 14 x 10 deg	

System:
Transmaxx

Instrument type:
Trial implant

Typing:
28 mm

Material:
stainless steel (17-4PH)

Article number	Description	Illustration
BM-TTR28260810	Transmaxx Trial sizer 28 x 26 x 08 x 10 deg	
BM-TTR28261010	Transmaxx Trial sizer 28 x 26 x 10 x 10 deg	
BM-TTR28261210	Transmaxx Trial sizer 28 x 26 x 12 x 10 deg	
BM-TTR28261410	Transmaxx Trial sizer 28 x 26 x 14 x 10 deg	
BM-TTR28260815	Transmaxx Trial sizer 28 x 26 x 08 x 15 deg	
BM-TTR28261015	Transmaxx Trial sizer 28 x 26 x 10 x 15 deg	
BM-TTR28261215	Transmaxx Trial sizer 28 x 26 x 12 x 15 deg	
BM-TTR28261415	Transmaxx Trial sizer 28 x 26 x 14 x 15 deg	

System:
Transmaxx

Instrument type:
Trial implant

Typing:
34 + 38 mm

Material:
stainless steel (17-4PH)

Article number	Description	Illustration
BM-TTR34281010	Transmaxx Trial sizer 34 x 28 x 10 x 10 deg	
BM-TTR34281015	Transmaxx Trial sizer 34 x 28 x 10 x 15 deg	
BM-TTR34281215	Transmaxx Trial sizer 34 x 28 x 12 x 15 deg	
BM-TTR38281010	Transmaxx Trial sizer 38 x 28 x 10 x 10 deg	
BM-TTR38281015	Transmaxx Trial sizer 38 x 28 x 10 x 15 deg	

Article number	Description	Illustration	Page
BM-TINS	Transmaxx Inserter		8, 9
BM-EHM	Extraction Hammer		no illustration
BM-SQH	Handle, straight, 1/4 inch connection on both sides, green		no illustration

General Instruments

Article number	Description	Illustration	Page
GI-3101	T-Handle		no illustration

Transmaxx® Alphabetical Index

A–Z	Description	Article number	Page
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H	Handle, straight, 1/4 inch connection on both sides, green	BM-SQH	no illustration
T	Transmaxx Inserter	BM-TINS	8, 9
	T-Handle	GI-3101	no illustration
	Transmaxx Trial sizer	BM-TTR25230600	PI 04
	Transmaxx Trial sizer	BM-TTR25230800	PI 04
	Transmaxx Trial sizer	BM-TTR25231000	PI 04
	Transmaxx Trial sizer	BM-TTR25231200	PI 04
	Transmaxx Trial sizer	BM-TTR25230610	PI 04
	Transmaxx Trial sizer	BM-TTR25230810	PI 04
	Transmaxx Trial sizer	BM-TTR25231010	PI 04
	Transmaxx Trial sizer	BM-TTR25231210	PI 04
	Transmaxx Trial sizer	BM-TTR25231410	PI 04
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	Transmaxx Trial sizer	BM-TTR28261215	PI 04
	Transmaxx Trial sizer	BM-TTR28261415	PI 04
	Transmaxx Trial sizer	BM-TTR34281010	PI 04
	Transmaxx Trial sizer	BM-TTR34281015	PI 04
	Transmaxx Trial sizer	BM-TTR34281215	PI 04
	Transmaxx Trial sizer	BM-TTR38281010	PI 04
	Transmaxx Trial sizer	BM-TTR38281015	PI 04

Notes

Notes

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