SYNTROPIQ
SPINAL
IMPLANTS

SURGICAL TECHNIQUE

TAURUS

TLIF

DYNAM'X
SPINAL INTERBODY CAGE SYSTEM

The universe is ruled by Entropy,
the unforgiving tendency of decay
into disorder. Domination of entropy
in a life-less universe is inevitable.

It is the life that makes the difference.
Life is the moving force that creates
the complex out of the basic, **Syntropy**.

Syntropy is the tendency towards
energy and matter **concentration**,
tendency to create order out of disorder.

We are Syntropiq.

Syntropy, noun
the tendency towards energy concentration,
order, organization and life.

From Greek **syn** "together" + **tropos** "tendency".
The term was first coined by the mathematician
Luigi Fantappiè in 1941 as a term contrary to entropy.

ABOUT US

We are a privately held spine interbody implant and surface technology company. Our team members with rich experience more than 15 years in spine have seen over 10 000 spine surgeries and had hundreds of hours of discussions with you – spine surgeons – to obtain much appreciated feedback on how to treat patients with spine disorders most successfully. And here are cool things you are going to like about our implants:

TITANIUM POWDER MATERIAL

- one of the best materials for bone fusion in the medical industry.
- its low density allows MRi and CT diagnostic compatibility.
- highly porous implants with a large contact area to achieve the best fusion.

FRAME-NET PHILOSOPHY

- Dynam'X System is based on a circumferential frame which bears the main stress load and a multi-spiked dynamic net that increases the contact area.
- the empty construction allows artificial bone or allograft chips to be used.

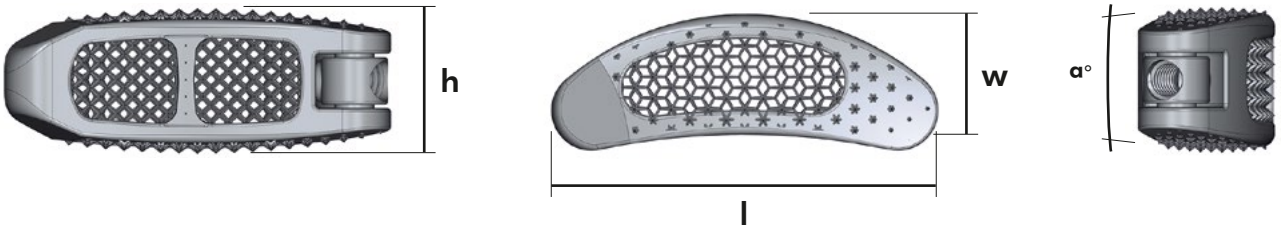
RESPECTING SAGITTAL BALANCE

- to avoid sagittal imbalance in spine our broad product portfolio offers different angulations of the cages including hyperlordotic cages.

DYNAMIC CONCEPT

- our Dynam'X Interbody Cage System respects **Wolff's Law**.
- the cage's design allows dynamization of fusion by controlled elastic micro deformation of the contact net. This phenomenon stimulates dynamization of the bone rebuilding process in accordance with **Wolff's Law**.
- the open construction of the implant facilitates free blood flow and accelerates bone formation to achieve best fusion.

IMPLANTS



9×26 (w × l) Anatomic, Small

h	6°	9°	12°
7 mm	2109260607	2109260907	2109261207
8 mm	2109260608	2109260908	2109261208
9 mm	2109260609	2109260909	2109261209
10 mm	2109260610	2109260910	2109261210
11 mm	2109260611	2109260911	2109261211
12 mm	2109260612	2109260912	2109261212
13 mm	2109260613	2109260913	2109261213
14 mm	2109260614	2109260914	2109261214

9×29 (w × l) Anatomic, Medium

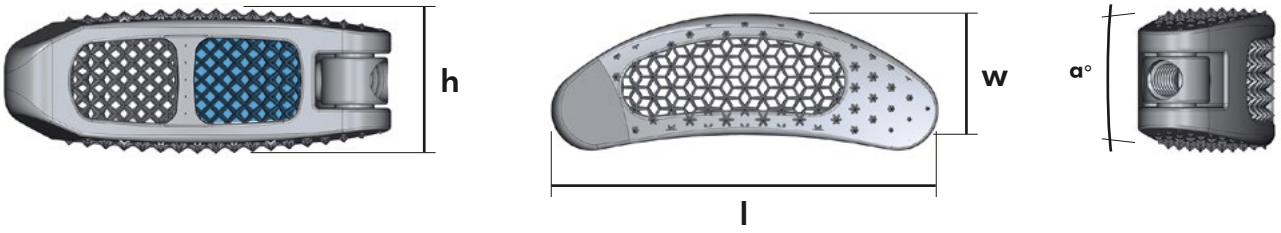
h	6°	9°	12°
7 mm	2109290607	2109290907	2109291207
8 mm	2109290608	2109290908	2109291208
9 mm	2109290609	2109290909	2109291209
10 mm	2109290610	2109290910	2109291210
11 mm	2109290611	2109290911	2109291211
12 mm	2109290612	2109290912	2109291212
13 mm	2109290613	2109290913	2109291213
14 mm	2109290614	2109290914	2109291214

9×32 (w × l) Anatomic, Large

h	6°	9°	12°
7 mm	2109320607	2109320907	2109321207
8 mm	2109320608	2109320908	2109321208
9 mm	2109320609	2109320909	2109321209
10 mm	2109320610	2109320910	2109321210
11 mm	2109320611	2109320911	2109321211
12 mm	2109320612	2109320912	2109321212
13 mm	2109320613	2109320913	2109321213
14 mm	2109320614	2109320914	2109321214

Items highlighted in grey are available upon request.

IMPLANTS



9×26 (w × l) Anatomic, Hollowed, Small

h	6°	9°	12°
7 mm	2509260607	2509260907	2509261207
8 mm	2509260608	2509260908	2509261208
9 mm	2509260609	2509260909	2509261209
10 mm	2509260610	2509260910	2509261210
11 mm	2509260611	2509260911	2509261211
12 mm	2509260612	2509260912	2509261212
13 mm	2509260613	2509260913	2509261213
14 mm	2509260614	2509260914	2509261214

9×29 (w × l) Anatomic, Hollowed, Medium

h	6°	9°	12°
7 mm	2509290607	2509290907	2509291207
8 mm	2509290608	2509290908	2509291208
9 mm	2509290609	2509290909	2509291209
10 mm	2509290610	2509290910	2509291210
11 mm	2509290611	2509290911	2509291211
12 mm	2509290612	2509290912	2509291212
13 mm	2509290613	2509290913	2509291213
14 mm	2509290614	2509290914	2509291214

9×32 (w × l) Anatomic, Hollowed, Large

h	6°	9°	12°
7 mm	2509320607	2509320907	2509321207
8 mm	2509320608	2509320908	2509321208
9 mm	2509320609	2509320909	2509321209
10 mm	2509320610	2509320910	2509321210
11 mm	2509320611	2509320911	2509321211
12 mm	2509320612	2509320912	2509321212
13 mm	2509320613	2509320913	2509321213
14 mm	2509320614	2509320914	2509321214

Items highlighted in grey are available upon request.

INSTRUMENTS

IMPLANT TRIAL

height	26 mm, 6°
7 mm	302507
8 mm	302508
9 mm	302509
10 mm	302510
11 mm	302511
12 mm	302512
13 mm	302513
14 mm	302514

INTERBODY DISTRACTOR

height	33 mm
7 mm	211107
8 mm	211108
9 mm	211109
10 mm	211110
11 mm	211111
12 mm	211112
13 mm	211113
14 mm	211114

DISC SHAVER

height	33 mm
7 mm	230007
8 mm	230008
9 mm	230009
10 mm	230010
11 mm	230011
12 mm	230012
13 mm	230013
14 mm	230014

DISC SHAVER – QUATRO

height	33 mm
7 mm	231007
8 mm	231008
9 mm	231009
10 mm	231010
11 mm	231011
12 mm	231012
13 mm	231013
14 mm	231014

INSTRUMENTS

DESCRIPTION	REF NUMBER	
IMPLANT HOLDER	300001	
HANDLE – T-SHAPE	200005	
HANDLE – STRAIGHT	200006	
HANDLE – STRAIGHT FOR HAMMERING	200006A	
HAMMER	200059	
IMPLANT FILLING SUPPORT	300060	
ENDPLATE CURRETTE – RECTANGULAR	300055	
ENDPLATE CURRETTE	300056	
IMPLANT PUSHER	300002	
IMPLANT PUSHER ANGLED	300003	
TRIAL EXPACTOR	200061	

IMPORTANT INFORMATION

INDICATIONS

Degenerative lumbar and lumbosacral conditions requiring segmental spondylodesis:

- Degenerative disc disease and instability
- Degenerative spondylolisthesis, grade I or II
- Spondylolisthesis with stenosis, grade I or II
- Pseudarthrosis or failed spondylodese

NOTES

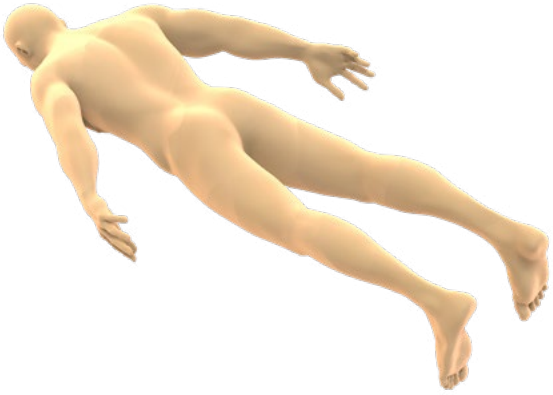
- The Taurus Cage has not been developed as a "stand-alone" implant. The use of an additional posterior instrumentation (e.g. with pedicle screws) is therefore mandatory.
- The management of spondylolisthesis in grades III and IV, or higher levels of scarring deserves special attention. The same applies to destructive tumors. (Note that the Taurus Cage with porous contact structure was not primarily developed for the restoration of the natural anatomy if three or more motion segments are involved.)

CONTRAINDICATIONS

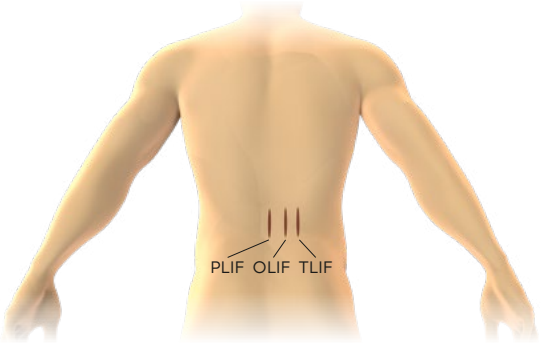
- Severe osteoporosis
- Unstable burst and compression fractures
- Acute infections
- Tumors

PATIENT POSITIONING

The position of the patient shall expose the spine level to be fused. Surgeons shall evaluate the most appropriate position taking into consideration approach, decompression procedure and fusion technique. By using C-Arm proper level of lumbar spine must be verified. The incision should allow the adequate approach to reach the targeted spine segment(s). Additional instruments like vertebral distractor, soft tissue retractors are subject to additional room requirements.

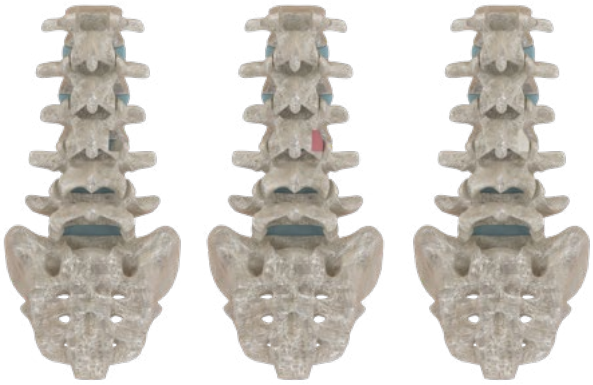


To maintain comfortable surgical field tissue retractor system is highly recommended. It is up to surgeon experience to define and perform soft tissue approach and bone decompression procedure. In some cases specific patients positioning may be required.



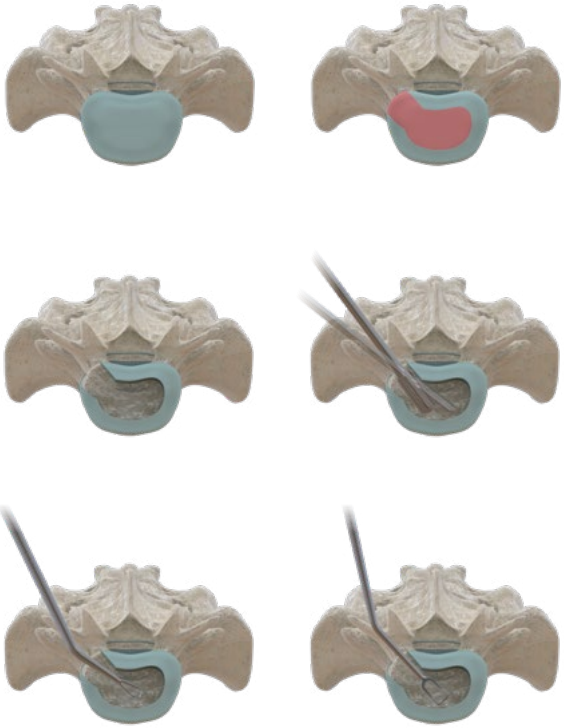
DISC REMOVAL AND ENDPLATE PREPARATION

1. Standard facetectomy for classical TLIF approach should be performed



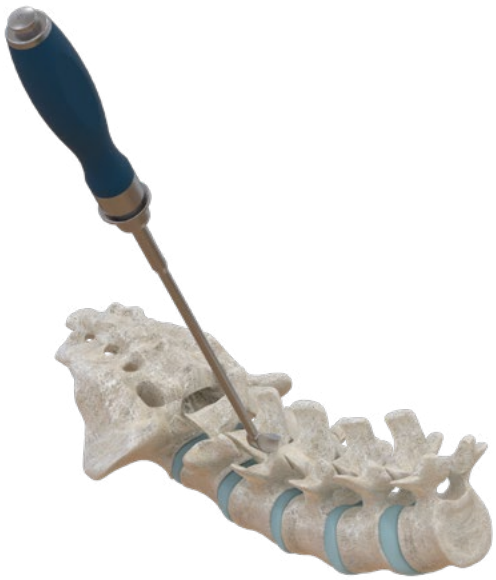
2. Syntropiq offers various types of endplate scrapers to facilitates endplates preparation. Choice appropriate depends on approach, surgical preferences or expected results.

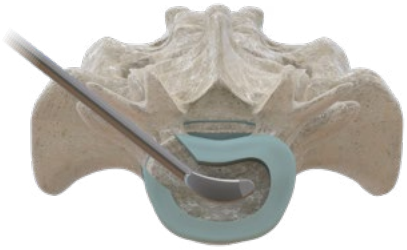
3. Using standard instruments extralateral discectomy procedure should be performed. **Taurus Lumbar Cage** incorporates titanium net which allows free flow of bone cells. Using rasp and scrapers is recommended when preparing the endplate in order to create efficient bone contact.



IMPLANT TRIALING

1. In order to select the appropriate size of the **Taurus** cage implant, several trials of different sizes of implants shall be used. Attach implant implant trial to the straight handle with hammering zone. By slightly hammering insert the implant trial into intervertebral disc space, increase the high of trial until firmly seat in intervertebral disc space will be achieved. Keep the same trajectory and angle as intended for the introduction of the implant.





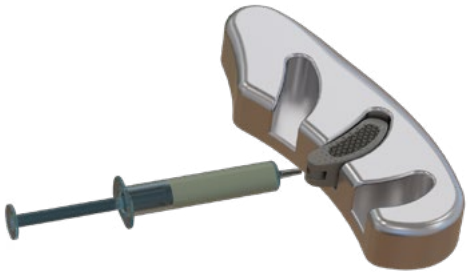
2. When trailing is performed lateral x-ray is highly recommended in order to asset implant's high, angulations and length. In case of difficulties of removing the trial Syntropiq expactor may be used.

Please note that TLIF Implant Trial are designed in 5 degrees of lordosis. In case of larger lordosis restoration is intended please select cage with 8 degrees angulation.

3. Syntropiq offers 3 types of handles:
T-Shape – dedicated to rotational tools, like scrapers
Straight – intended for insertion, like trials
Straight with hammering – intended for insertion when hammering forces are required

IMPLANT PREPARATION

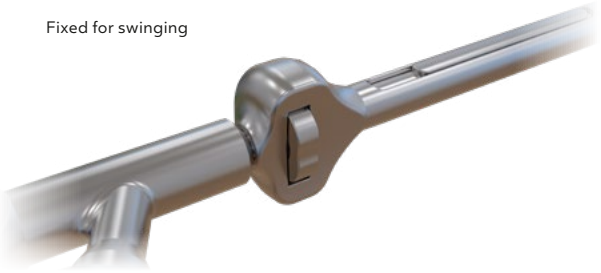
1. **Taurus Cage** is intended to be filled by bone substitute or harvest allograft. Both substitution can be delivered into the cage. Implant can be filled before or after implantation procedure. In case of postimplantation filling procedure only paste or gel formulation can be used.
2. Please place the cage into the Filling Support. By using Syringe with Cannula inject the bone substitute into the cage.



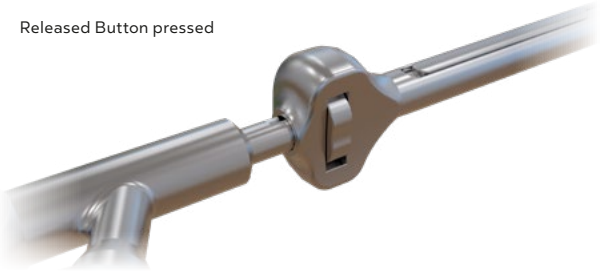
3. **Taurus System** offers unique possibility to fill cage by autograft. Model Hollowed has incorporated open net which facilitates grafting. Place cage with hole up and use standard instruments to place and push bone graft into the cage. For hollowed version availability please contact with your local Syntropiq Representative.contact with your local Syntropiq Representative.

4. **Taurus** Implant Holder is designed to facilitate implantation due to mutil-axiality of the implants positioning during the entire procedure. Taurus Implant holder has locking shaft which holds implant on holder while allowing free swinging. External tube locks the implant in “inserting” or “swinging” position. Status of implant’s mobility can be changed by moving up or down external tube. Tube can be moved when locking mechanism is released. Pressing button releases locking mechanism.

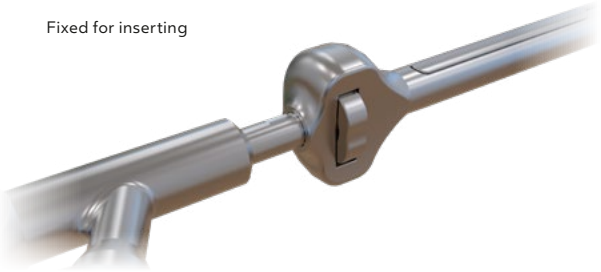
Fixed for swinging



Released Button pressed



Fixed for inserting

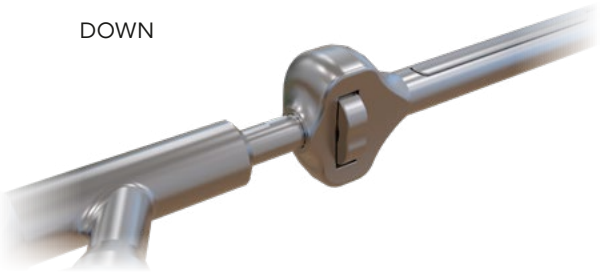


IMPLANT PREPARATION

5. Make sure the locking tube is in swinging position (up). Connect and grip the implant into implant holder by turning the locking knob. Push the button and slip down the external tube to lock implant into inserting position (down).

UP

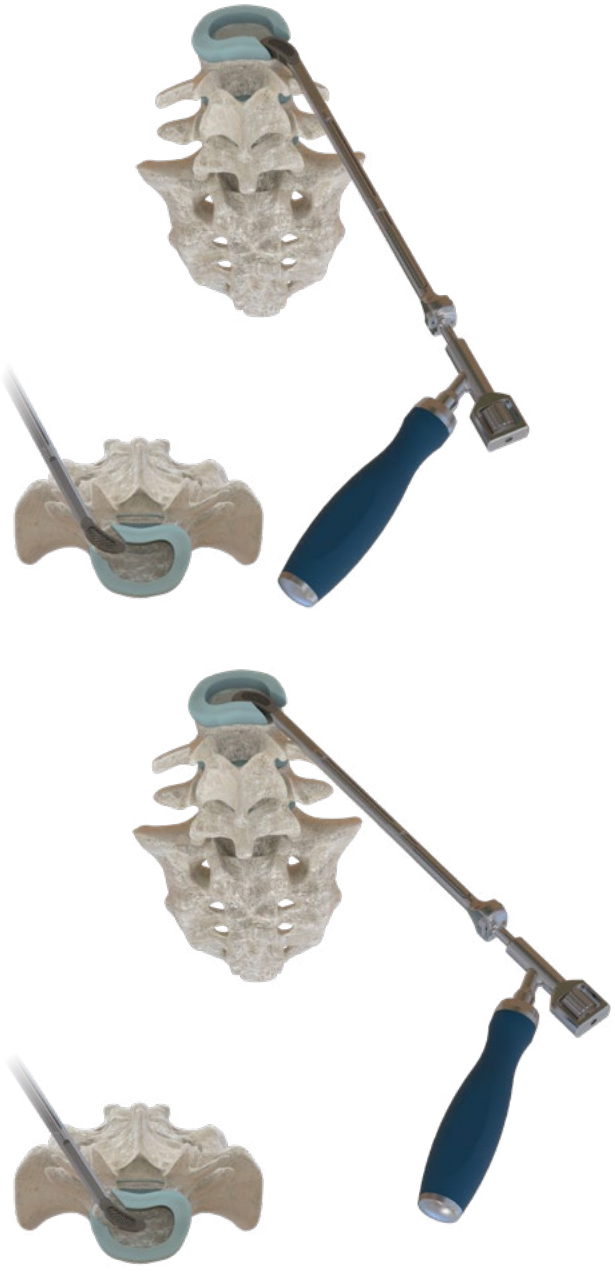
DOWN



IMPLANTATION

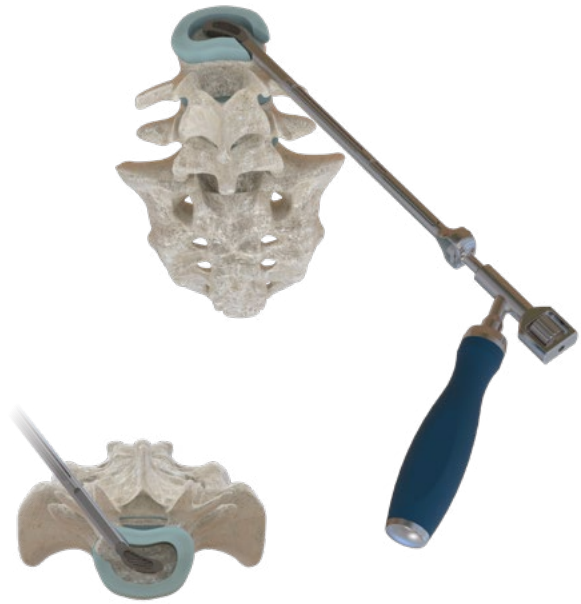
1. If necessary increase distraction to facilitate device insertion. Insert cage by gentle hammering. Keep appropriate plane for insertion. Lateral x-ray is highly recommended during implantation procedure.

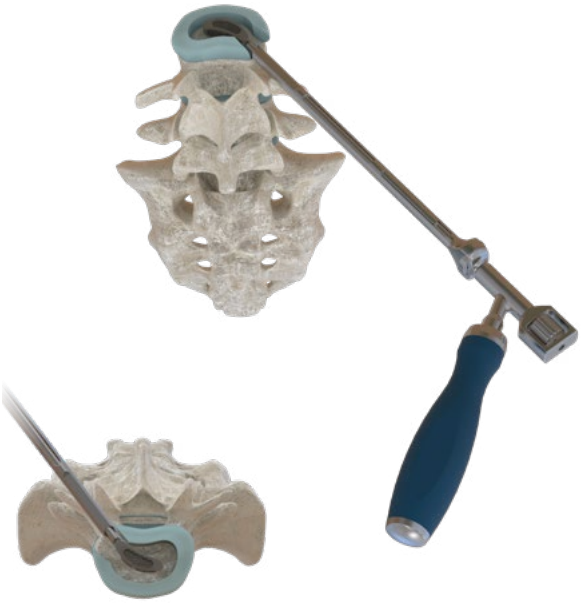
2. Make sure the implant is locked and by hammering start insertion



IMPLANTATION

3. After crossing posterior wall of vertebra by moving external tube up change the implant status into swinging position.



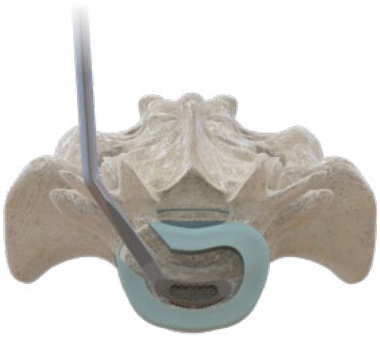


4. Change the sagittal angulation of implant holder. Changing angulation of implant holder to middle line increases turning forces and facilities implant's rotation procedure.

IMPLANTATION

5. By continuing gentle hammering rotate the TLIF implant into proper positioning. Changing angulation of implant holder to midle line increases turning forces and facilities implant's rotation procedure.

6. After final positioning has been confirmed detach the implant from holder by turing the knob counterclockwise. Remove the Implant Holder and check the implant positioning both in AP and lateral x-rays.

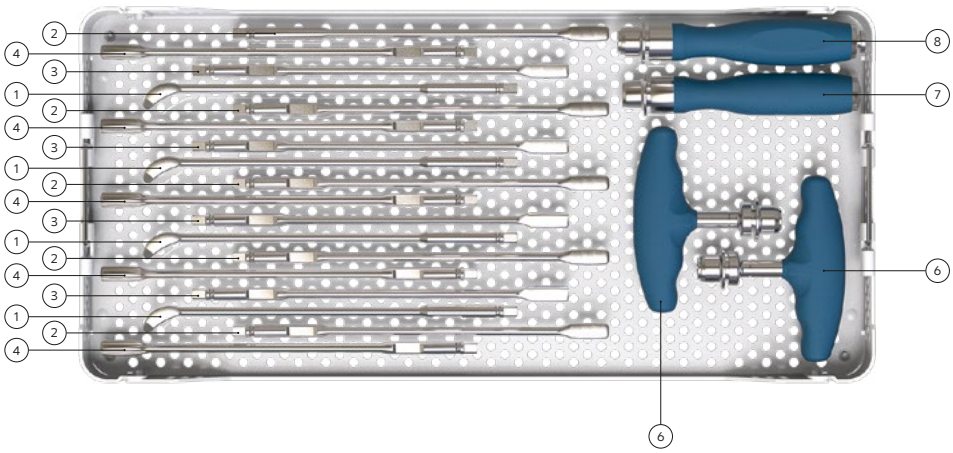


7. Before final closing, autologous bone or bone substitutes should be injected into the intervertebral disc space. When necessary Implant pusher will allow correction of implant position.

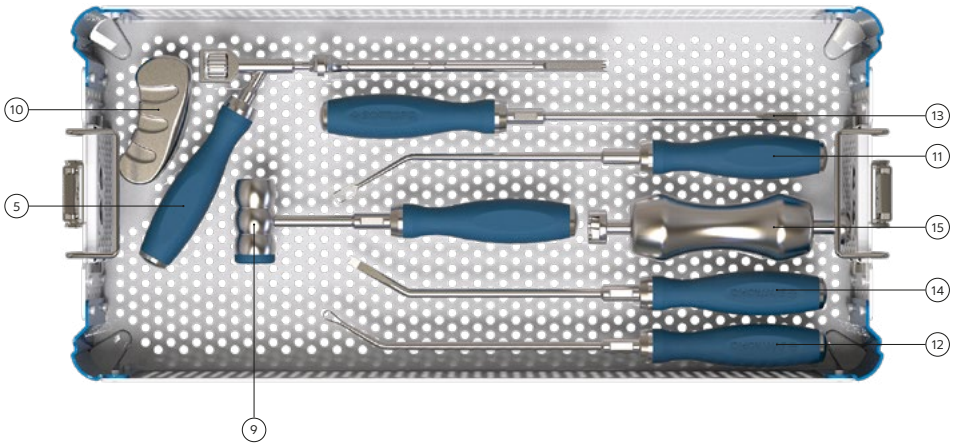
8. The **Taurus Cage** can be filled after implantation using canula system. Please ask Syntropiq Representative formore information

CONTAINERS

DESCRIPTION	REF NUMBER
TAURUS INSTRUMENTS CASE – TOP TRAY	310005



TAURUS INSTRUMENTS CASE – MAIN BOX	310001



1. 3025xx IMPLANT TRIALS
2. 2011xx INTERBODY DISTRACTORS
3. 2300xx DISC SHAVERS
4. 2310xx DISC SHAVERS – QUATRO
5. 300001 IMPLANT HOLDER
6. 200005 HANDLE – T-SHAPE
7. 200006 HANDLE – STRAIGHT
8. 200006A HANDLE – STRAIGHT FOR HAMMERING
9. 200059 HAMMER
10. 300060 IMPLANT FILLING SUPPORT
11. 300055 ENDPLATE CURRETTE – RECTANGULAR
12. 300056 ENDPLATE CURRETTE
13. 300002 IMPLANT PUSHER
14. 300003 IMPLANT PUSHER ANGLED
15. 200061 TRIAL EXPACTOR

GENERAL INFORMATION

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CE 2274

IMPORTANT INFORMATION FOR IMPLANTS FROM THE DYNAM'X SPINAL INTERBODY CAGE SYSTEM

The Dynam'X System implants are devices whose primary functions are to add a solid structure to a graft so as to enable the stabilization of intervertebral height, after discectomy, during the time of graft setting and achieve a maximum surface of fusion. Various models and sizes of implants are available in order to adopt to the surgical approach, operating level(s) and to the pathology and individual patient anatomy. In addition, so as to favor bone growth, the Dynam'X System Cage should be filled with bone graft.

INTENDED USE AND PATIENTS POPULATIONS

Dynam'X System is indicated for intervertebral body fusion procedures in skeletally mature patients which have had six months of non-operative therapy. Final decision of the application of the Dynam'X Spinal System should be always taken by experienced surgeons with extensive knowledge about spinal surgery. The intended use is to recreate the intervertebral disc high and give structural support for loading forces during the healing process and support fusion process. The Dynam'X Cages are complementary implants to posterior or anterior or lateral fixation systems and should NOT be used as standalone.

DESCRIPTION

The Dynam'X Spinal System is designed for spinal arthrodesis. It consists of the cages in variable sizes and shapes. The main design of the whole family based on the same concept

- titanium solid frame which holds and transfer all forces occurring in human spine during patients activities.
- multispiked titanium net for direct contact between implant and vertebra endplates to involve biomechanics of bone fusion based on Wolf's Law.

System recognizes following models of interbody devices with intended application approach and spine levels:

1. Model Aries and related instruments set for distraction, discectomy, sizing, graft packing and insertion of the Aries device during Anterior Cervical Disectomy and Fusion procedure (ACDF)
2. Model Perseus and related instruments set for distraction, discectomy, sizing, graft packing and insertion of the Perseus device during Posterior Lumbar Interbody Fusion procedure (PLIF)
3. Model Taurus and related instruments set for distraction, discectomy, sizing, graft packing and insertion of the Taurus device during Transforaminal Lumbar Interbody Fusion procedure (TLIF)
4. Model Andromeda and related instruments set for distraction, discectomy, sizing, graft packing and insertion of the Andromeda device during Anterior Lumbar Interbody Fusion procedure (ALIF)
5. Model Ursus and related instruments set for distraction, discectomy, sizing, graft packing and insertion of the Ursus device during Unilateral Lumbar Interbody Fusion procedure (ULIF)

Model selection depends on physician decision about the way how to approach the treatment of the spinal disorder. The composition of implants may be vary depends on anatomical conditions and physician decision. Products Brochures and Surgical Techniques should be read and analyzed before select suitable implants (including correct size and model), and its accessories in order to obtain safe combination.

Dynam'X Spinal System components must NOT be used with direct contact to any other spinal systems or any other fixation systems. Do NOT never mix titanium implant and stainless steel implant in the same construct. Any application of any components from Dynam'X Spinal System together with any other systems or other manufactures releases Syntropiq for any liabilities.

All components of Dynam'X Spinal System should be never reused under any circumstances.

MATERIALS

The entire system is be made out of medical grade titanium or titanium alloy Ti-6Al-4V ELI described by ISO 5832-3 or ASTM F3001-14 or ASTM F136-13 standards. Syntropiq sorely warrants that all devices are manufacture from one of the foregoing material specifications. No other warranties, express or implied, are made. Please see the Syntropiq product brochure for further information.

INDICATIONS

Dynam'X Spinal System is intended for intervertebral body fusion in cervical, thoracic and lumbar spine for the following indications:

1. Degenerative disc disease.
2. Spinal stenosis.
3. Spondylolisthesis.
4. Revision surgery for failed disc surgery or progressive degenerative discopathies
5. Spinal disc or nerve compression
6. Pseudoarthrosis.
7. Instability of motion segments.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Risk of infection or infection in progress, or fever or inflammation.
2. Obesity.
3. Pregnancy.
4. Mental illness.
5. Allergy on any chemical components (specially aluminium, titanium, vanadium).
6. Any anatomical, medical or surgical conditions witch may preclude potential or intentional benefits of spinal implants application.
7. Bone, joints or ligaments conditions such but not limited as: osteopenia, bone absorption, osteomalacia. Osteoporosis is relative contraindications an must be carefully evaluated prior surgery.
8. Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
9. Mixing of implants with other manufacturers or with other fixation systems.
10. Potential risk of unexpected patients anatomy destruction, interference with neurological, functional or other deficits.
11. Any risk of patient's unwillingness to follow postoperative instructions.
12. Any other not described in indications.

POTENTIAL ADVERSE EVENTS

Possible adverse events which might occur after spinal surgery with or without instrumentation include, but are not limited to:

1. Disassembly, bending, and/or breakage of any or all of the system components.
2. Migrations any of system components.
3. Pressure on the skin from component parts in patients with inadequate tissue coverage.
4. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Dura leakage, distortion or damage.
6. Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hyperthesia, or any others related to general surgery associated to anaesthesia.
7. Infections.
8. Loss of urinary functions.
9. Permanent or temporary or developing sexual dysfunctions.
10. Postoperative change of body curvature, change of physiological range of movement.
11. Pseudoarthrosis or non-fusion or delayed fusion.
12. Bone loss or overgrowth, or any other bone malformations.
13. Permanent or temporary limitation or inability to perform daily activities.
14. Changing in mental behaviour.
15. Permanent or temporary or developing respiratory problems.
16. Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
17. Death.

In some of cases additional surgery or surgeries might be necessary to correct or change potential adverse events.

WARNINGS

The effectiveness and safety of interbody fixation is only applicable for certain conditions with significant instability which require the fusion supported by medical device. The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.

PRECAUTIONS

The Dynam'X Cages are complementary implants to posterior or anterior or lateral fixation systems and should NOT be used as standalone. The applications of pedicle screw, plates, rods and/or interbody cages should be performed by experienced surgeons with specific training in use of Dynam'X Spinal System.

As the Dynam'X T implants must be used with supplemental fixation, close attention should be paid during the insertion of the anchoring plates, in order to limit risk of contact between the anchoring plates and additional spinal hardware (e.g., pedicle screws).

Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of Dynam'X System should be performed only by experienced spine surgeons with specific training in the use of this system and who have knowledge of the present instructions for use. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with spinal surgery. Knowledge of surgical techniques, proper implant selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome.

The spinal screw fixation system and/or inter body cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support. Therefore bends, breakages, loosening, disassembling may occur over the time. A successful results are not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant's size and type are considerably important in treatment process. Patients with obesity, smokers, alcohol abused are risk of non-fusion surgery. Also patients in weak muscle or bone conditions, nervous system dysfunctions are poor candidates for spinal fusion. Prior or during or after the surgery in order to evaluate or check the positioning of the implants or patients anatomy or any other patients or implants correction X-ray or CT or any other invasive diagnostic examinations may be necessary to be performed.

The proper, patient's individual implants selection in terms of type, size, shape or design is vital to successful surgery performance. Proper implants and instruments handling is crucial. Extensive bending or contouring should be avoided. Sharp edges cutting, reversed bending, scratching or notching may generate internal stressing which may weak the implants or construct. In some cases, progression of degenerative disease may be so advanced at the time of implantation that they substantially decrease the expected useful life to the implant. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.

Based on of the non-clinical testing has demonstrated the Dynam'X Spinal Interbody Cage System implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the Dynam'X Spinal Interbody Cage System implants is expected to produce a maximum temperature rise of less than 5º C after 15 minutes of continuous scanning.

Prior MRI diagnostic procedure MRI technical staff should be informed about the model of Dynam'X implant(s) and implantation anatomical region(s).

IMPORTANT

All necessary informations about surgery, potential risks, benefits and adverse effects should be conveyed to the patient prior to surgery.

Prior surgery consult with patient any allergy or other reactions on implants chemical components (specially aluminium, titanium, vanadium).

PREOPERATIVE

1. Patients meet the criteria described in the indications should be only selected.
2. Patients conditions should be checked prior surgery. Any required diagnostics should be performed.
3. The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
4. All implants, instruments and any other components should be cleaned and sterilised before use. Any implants, instruments or components delivered as sterile must be checked due to sterility and expiration time prior surgery.
5. Implants and instruments should be stored in certain conditions to warranty the sterility and protection from any contamination or corrosive environment.
6. It's highly recommended that all personnel interacting with any mechanical components from the spinal system should be familiar with all components before using.

INTRAOPERATIVE

1. Extreme caution should be used when working close or around the spinal cord and nerve roots.
2. Whenever possible or required intraoperative diagnostic system should be used to facilitate surgery.
3. Before implanting the Dynam'X System Cage, the vertebral plates must be carefully prepared, being careful not to weaken the cortical bone to avoid implant subsidence.
4. Breakage, bends, scratch slippage, part loosening or improper use of any implant or instrument during the surgery may cause injury to OR personal or patient.
5. It's very important to follow carefully surgical technique. Proper application of any instrument or implant may facilitate surgery.
6. Before closing of soft tissue double check of all implants positioning, geometrical relations, and fixing, tightening or mounting manoeuvres for all screws, nuts or other fixing parts should be performed. Image diagnostics is highly recommended at this stage.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient.
2. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
4. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the Dynam'X Spinal System components should never be reused under any circumstances.

PACKAGING

Dynam'X Spinal System is delivered as sterile. Each of the implant's components should be stored in original packages. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

Prior to use double check of sterility conditions and expiration date should be performed.

WARNINGS

Do not use when sterility expired.
Do not use if packaging is damaged.

STORAGE

The components of Dynam'X Spinal System should be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

Sterile parts should be stored in original packages and prevented to any damages. When storing do not exceed 60% of humidity or 50°C of temperature.

DEVICE REMOVAL AND DISPOSAL

The implants from Dynam'X System are intended to remain in the patient's body throughout life. Any decision by a surgeon to remove the device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. However if medical or non medical reasons require device removal its disposal procedure should be performed in accordance of local hospital's requirements and protocols.

IMPORTANT

As with all orthopaedic implants, the Dynam'X Spinal System components must be never reprocessed nor reused under any circumstances.

WARRANTY AND PRODUCT COMPLAINTS

Every spinal product from Syntropiq is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any implant or instrument delivered from Syntropiq proving to be defective will be replaced or repaired, at Syntropiq discretion, with no any charge.

Any customer or user, who has any complaint or who has experienced any dissatisfaction in the product quality, durability, reliability should inform Syntropiq or its Distributor. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the description of the complaint. Please provide the report directly to Syntropiq or to its Distributor.

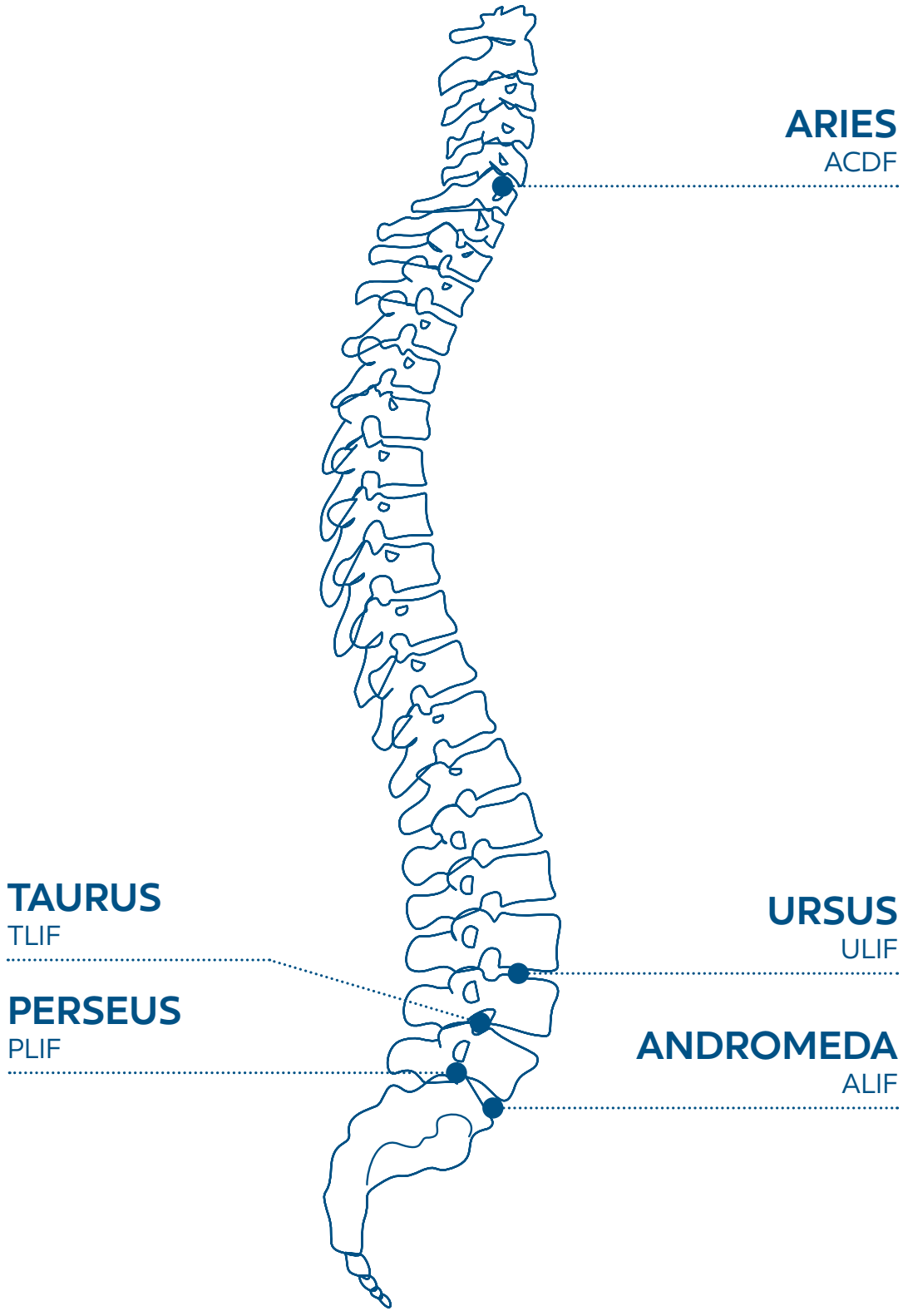
SYMBOLS USED

Manufacturer	**Consult instructions for use**
Date of Manufacture	**Cautions**
Use by date	**Batch code**
Do not re-use	**Catalogue number**
Do not use if package is damaged	**Do not resterilise**
Sterilised using irradiation	

CUSTOMER SERVICE

Additional information about the Dynam'X Spinal System or any other Spinal Systems is available from Syntropiq. You may also want to contact your local Syntropiq Sales Representative.

SYNTROPIQ PRODUCTS



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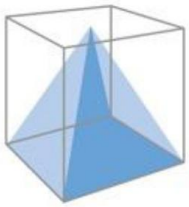

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