



SYNTROPIQ
SPINAL
IMPLANTS

SURGICAL TECHNIQUE

ARIES

ACDF

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.

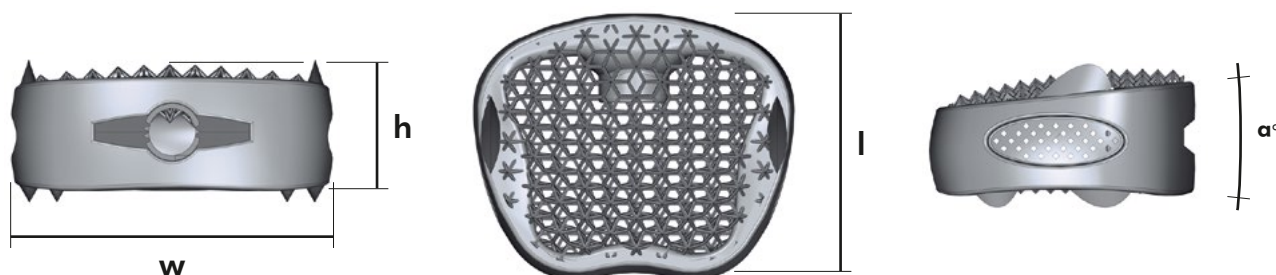
✧ RESPECTING SAGITTAL BALANCE

- 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



12×14 (l × w) Flat, Small

h	2°	6°
4 mm	1012140204	1012140604
5 mm	1012140205	1012140605
6 mm	1012140206	1012140606
7 mm	1012140207	1012140607
8 mm	1012140208	1012140608
9 mm	1012140209	1012140609

12×14 (l × w) Anatomic, Small

h	2°	6°
4 mm	1112140204	1112140604
5 mm	1112140205	1112140605
6 mm	1112140206	1112140606
7 mm	1112140207	1112140607
8 mm	1112140208	1112140608
9 mm	1112140209	1112140609

14×17 (l × w) Flat, Medium

h	2°	6°
4 mm	1014170204	1014170604
5 mm	1014170205	1014170605
6 mm	1014170206	1014170606
7 mm	1014170207	1014170607
8 mm	1014170208	1014170608
9 mm	1014170209	1014170609

14×17 (l × w) Anatomic, Medium

h	2°	6°
4 mm	1114170204	1114170604
5 mm	1114170205	1114170605
6 mm	1114170206	1114170606
7 mm	1114170207	1114170607
8 mm	1114170208	1114170608
9 mm	1114170209	1114170609

16×19 (l × w) Flat, Large

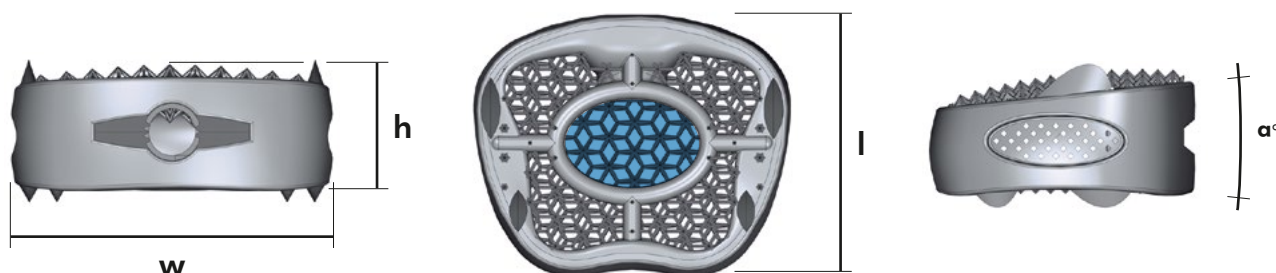
h	2°	6°
4 mm	1016190204	1016190604
5 mm	1016190205	1016190605
6 mm	1016190206	1016190606
7 mm	1016190207	1016190607
8 mm	1016190208	1016190608
9 mm	1016190209	1016190609

16×19 (l × w) Anatomic, Large

h	2°	6°
4 mm	1116190204	1116190604
5 mm	1116190205	1116190605
6 mm	1116190206	1116190606
7 mm	1116190207	1116190607
8 mm	1116190208	1116190608
9 mm	1116190209	1116190609

Items highlighted in grey are available upon request.

IMPLANTS



12×14 (l × w) Flat, Hollowed, Small

h	2°	6°
4 mm	1212140204	1212140604
5 mm	1212140205	1212140605
6 mm	1212140206	1212140606
7 mm	1212140207	1212140607
8 mm	1212140208	1212140608
9 mm	1212140209	1212140609

12×14 (l × w) Anatomic, Hollowed, Small

h	2°	6°
4 mm	1312140204	1312140604
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7 mm	1312140207	1312140607
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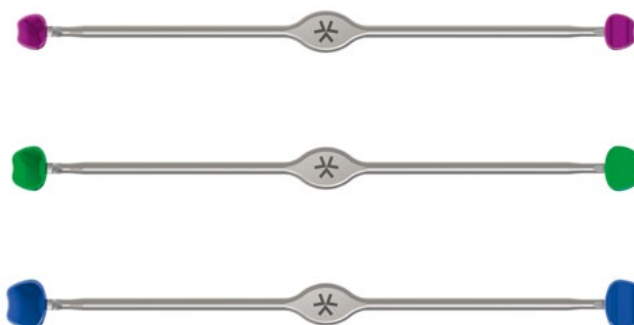
Items highlighted in grey are available upon request.

INSTRUMENTS



IMPLANT TRIAL

size	type	2°	6°
SMALL	4-5	102016	107016
	6-7	102017	107017
	8-9	102018	107018
MEDIUM	4-5	102019	107019
	6-7	102020	107020
	8-9	102021	107021
LARGE	4-5	102022	107022
	6-7	102023	107023
	8-9	102024	107024



DESCRIPTION

REF NUMBER

IMPLANT HOLDER

100001



SHAFT FOR IMPLANT HOLDER

100002



IMPLANT HOLDER – SLIM

100003



SHAFT FOR SLIM IMPLANT HOLDER

100004



DEPTH LOCKING DEVICE

100005



ENDPLATE RASP

100006



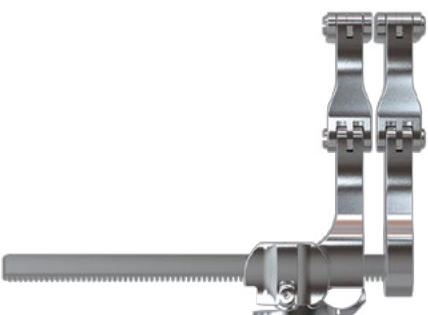
NERVE HOOK

100007



INSTRUMENTS



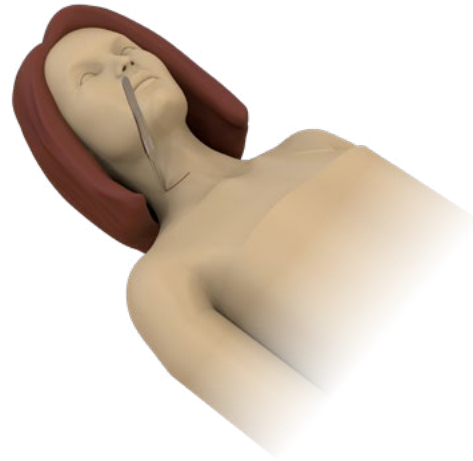
DESCRIPTION	REF NUMBER	
NERVE PROBE	100008	
CASPAR DISTRACTOR – DOUBLE ANGLED	100009	
CASPAR PINS		
length		
8 mm	100010	
10 mm	100011	
12 mm	100012	
14 mm	100013	
CASPAR PINS DRIVER	100014	
PIN LOCKING NUT	100015	
IMPLANT FILLING SUPPORT	100025	
VERTEBRAL BODY PUNCTURER	100026	

PATIENT POSITIONING



Patient position should expose spine level which going to be fused. Overlordosis or hyperkyphosis should be avoided. By using C-Arm proper level of cervical spine must be verified. Skin incision should allow adequate approach to stabilising spine segment(s). Additional instruments like vertebral distractor, soft tissue retractors is subject of additional space requirements.

To maintain comfortable surgical field tissue retractor system is highly recommended.



VERTEBRAL DISTRACTION



1. Determine length of Distraction Screw on lateral x-ray. Assemble appropriate Distraction Screw into Distractor Screw Driver.



2. Define the midline and mark up the entering point by Vertebral Body Puncturer.



Please keep positioning Distraction Screws parallel in order to facilitates further distractor engagement.



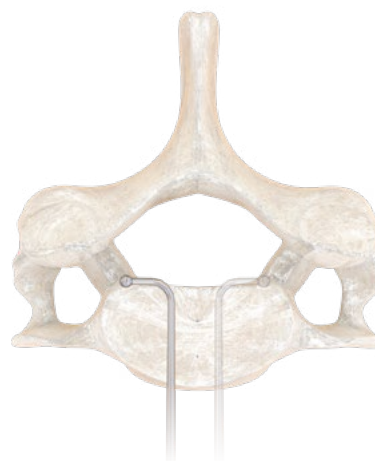
3. Insert the Distraction Screws, install Caspar Distractor and perform vertebral distraction.



DECOMPRESSION AND CAGE TRIALING



1. Remove the disc and cartilage layer on the vertebral plates. Use Square Curette facilitate cartilage removal. In order to check root decompression Cervical Nerve Hook may be used.

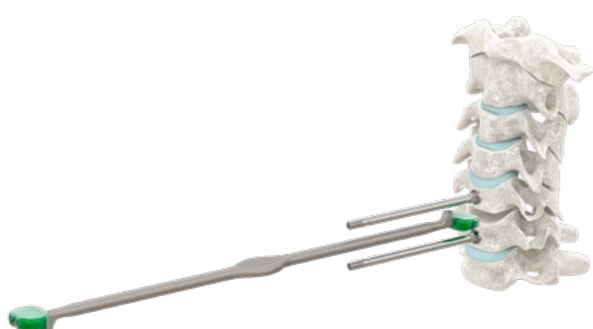


Aries Cage incorporates multispikes titanium net which allows free flow of bone cells. Using Cervical Endplate Rasp is recommended when preparing the endplate in order to create efficient bone contact.

DECOMPRESSION AND CAGE TRIALING



2. Temporary remove the distractor while leaving the distractors pins perform implant trailing. When trailing is performed lateral x-ray is highly recommended in order to assess implant's high, angulations and foot print size. Implant Trial should be inserted in middle line. If distractor is not being removed release the distraction on device and check if the Implant Trial fits firmly between endplates.



Please note that Implant Trial are designed in both 2 or 6 degrees. In case of lordosis restoration is intended please select cage with 6 degrees inclination. Once appropriate size is selected please follow the implant preparation in accordance to marking on Implant Trial. Please note that the **Aries** implant is designed to create "prepress" of the elastic net on vertebral endplates. Therefore the height of implants is approximately 0.6 mm bigger than the height of the Implant Trials.



IMPLANT PREPARATION



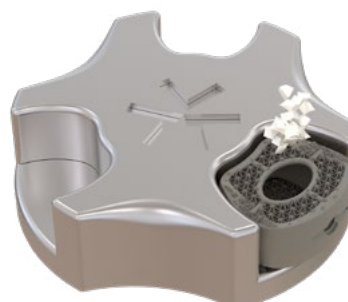
- 1. Aries Cage** is intended to be filled by bone substitute or harvest allograft. Both substitution can be delivered into the cage. Implant can be filled before or after implantation procedure. In case of postimplantation filling procedure only paste or gel formulation can be used.
- Please place cage into Filling Support. By using Syringe and cannula inject the bone substitute into the cage. Please see the table with recommended volume for every size.



- Optional depth stopper allows controlled insertion and limit the position of implant holder on anterior wall of vertebral body. In case of application click on stopper on implant holder before attach the cage.



- 4. Aries 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.



Cage Height	Cage Foot Print		
	12×14	14×16	16×19
4 mm	0,4 cc	0,6 cc	0,8 cc
5 mm	0,5 cc	0,75 cc	1,0 cc
6 mm	0,7 cc	0,9 cc	1,2 cc
7 mm	0,8 cc	1,0 cc	1,4 cc
8 mm	0,9 cc	1,2 cc	1,6 cc
9 mm	1,0 cc	1,4 cc	1,8 cc

IMPLANT PREPARATION



5. Aries System offer two implant inserters. Regular Implant holder with comfortable handle for ordinary application and slim for limited surgical space application. Connect the selected Implant Holder to Cage and secure the position by clockwise turning the knob on silicone handle. Double check is the UP sign correspond to upper side of the cages.



UP



IMPLANTATION



1. Instal Caspar Distractor and If necessary increase distraction to facilitate device insertion. Insert cage by gentle hammering. Keep midline as guidance for insertion. Lateral x-ray is highly recommended during implantation procedure.



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



IMPLANTATION



3. The **Aries Cage** can be filled after the implantation.
Please ask your Syntropiq Representative for details.

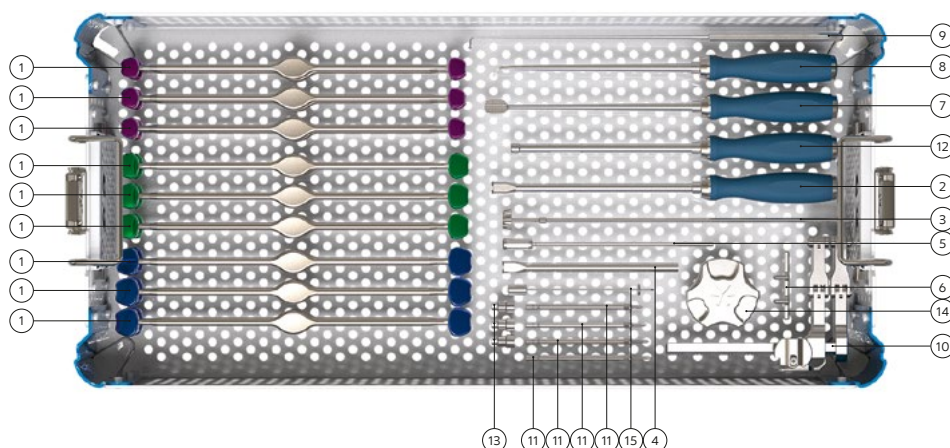


CONTAINERS

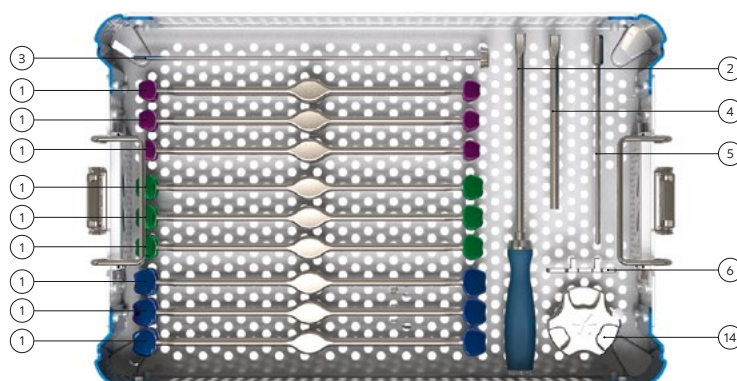


DESCRIPTION REF
NUMBER

ARIES MAIN
INSTRUMENTS
CASE 110001



ARIES REDUCED
INSTRUMENTS
CASE 110003



- ① 10x0xx IMPLANT TRIALS
- ② 100001 IMPLANT HOLDER
- ③ 100002 SHAFT FOR IMPLANT HOLDER
- ④ 100003 IMPLANT HOLDER – SLIM
- ⑤ 100004 SHAFT FOR SLIM IMPLANT HOLDER
- ⑥ 100005 DEPTH LOCKING DEVICE
- ⑦ 100006 ENDPLATE RASP
- ⑧ 100007 NERVE HOOK
- ⑨ 100008 NERVE PROBE

- ⑩ 100009 CASPAR DISTRACTOR – DOUBLE ANGLED
- 100010
- 100011
- ⑪ CASPAR PINS
- 100012
- 100013
- ⑫ 100014 CASPAR PINS DRIVER
- ⑬ 100015 PIN LOCKING NUT
- ⑭ 100025 IMPLANT FILLING SUPPORT
- ⑮ 100026 VERTEBRAL BODY PUNCTURER

NOTES

[illegible]

GENERAL INFORMATION



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.
- multiplicated titanium net for direct contact between implant and vertebra endplates to involve biomechanics of bone fusion based on Wolff's Law.

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

- Model Aries and related instruments set for dissection, discectomy, sizing, graft packing and insertion of the Aries device during Anterior Cervical Discectomy and Fusion procedure (ACDF)
- Model Perseus and related instruments set for dissection, discectomy, sizing, graft packing and insertion of the Perseus device during Posterior Lumbar Interbody Fusion procedure (PLIF)
- Model Taurus and related instruments set for dissection, discectomy, sizing, graft packing and insertion of the Taurus device during Transforaminal Lumbar Interbody Fusion procedure (TLIF)
- Model Andromeda and related instruments set for dissection, discectomy, sizing, graft packing and insertion of the Andromeda device during Anterior Lumbar Interbody Fusion procedure (ALIF)
- Model Ursus and related instruments set for dissection, 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 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 solely 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:

- Degenerative disc disease.
- Spinal stenosis.
- Spondylolisthesis.
- Revision surgery for failed disc surgery or progressive degenerative discopathies
- Spinal disc or nerve compression
- Pseudoarthrosis.
- Instability of motion segments.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Risk of infection or infection in progress, or fever or inflammation.
- Obesity.
- Pregnancy.
- Mental illness.
- Allergy to any chemical components (specially aluminium, titanium, vanadium).
- Any anatomical, medical or surgical conditions which may preclude potential or intentional benefits of spinal implants application.
- 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.
- Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
- Mixing of implants with other manufacturers or with other fixation systems.
- Potential risk of unexpected patients anatomy destruction, interference with neurological, functional or other deficits.
- Any risk of patient's unwillingness to follow postoperative instructions.
- 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:

- Disassembly, bending, and/or breakage of any or all of the system components.

- Migrations any of system components.
- Pressure on the skin from component parts in patients with inadequate tissue coverage.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Dura leakage, distortion or damage.
- Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, shoulder/pain, paralysis is hyperthermia, if any others related to general surgery associated to anaesthesia.
- Infections.
- Loss of urinary functions.
- Permanent or temporary or developing sexual dysfunctions.
- Postoperative change of body curvature, change of physiological range of movement.
- Pseudoarthrosis or non-fusion or delayed fusion.
- Bone loss or overgrowth, or any other bone malformations.
- Permanent or temporary limitation or inability to perform daily activities.
- Changing in mental behaviour.
- Permanent or temporary or developing respiratory problems.
- Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
- 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, lysis, 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, disassembly 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, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

Based on 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 5°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

- Patients meet the criteria described in the indications should be only selected.
- Patients conditions should be checked prior surgery. Any required diagnostics should be performed.
- The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
- 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.
- Implants and instruments should be stored in certain conditions to warranty the sterility and protection from any contamination or corrosive environment.
- 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

- Extreme caution should be used when working close or around the spinal cord and nerve roots.
- Whenever possible or required intraoperative diagnostic system should be used to facilitate surgery.
- 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.
- 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.
- It's very important to follow carefully surgical technique. Proper application of any instrument or implant may facilitate surgery.
- 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.

- Detailed instructions on the use and limitations of the device should be given to the patient.
- The patient should be warned to avoid falls or sudden jolts in spinal position.
- 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-steroids or anti-inflammatory medications such as aspirin during the bone graft healing process.
- 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.
- 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, 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

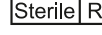
 As with all orthopaedic implants, the Dynam'X Spinal System components must be never reprocessed nor reused under any circumstances.

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 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.

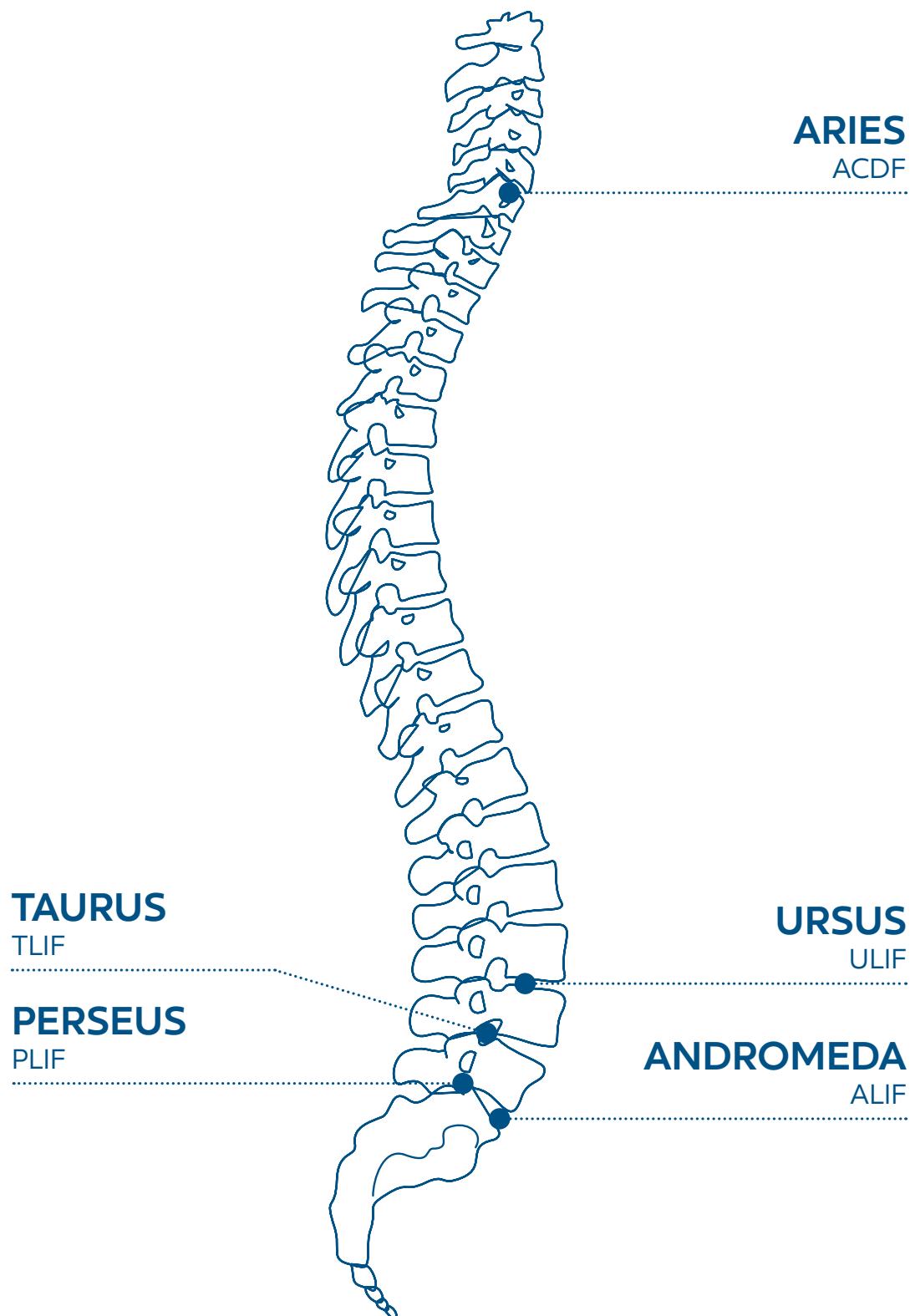
SYMBOLS USED

	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.

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