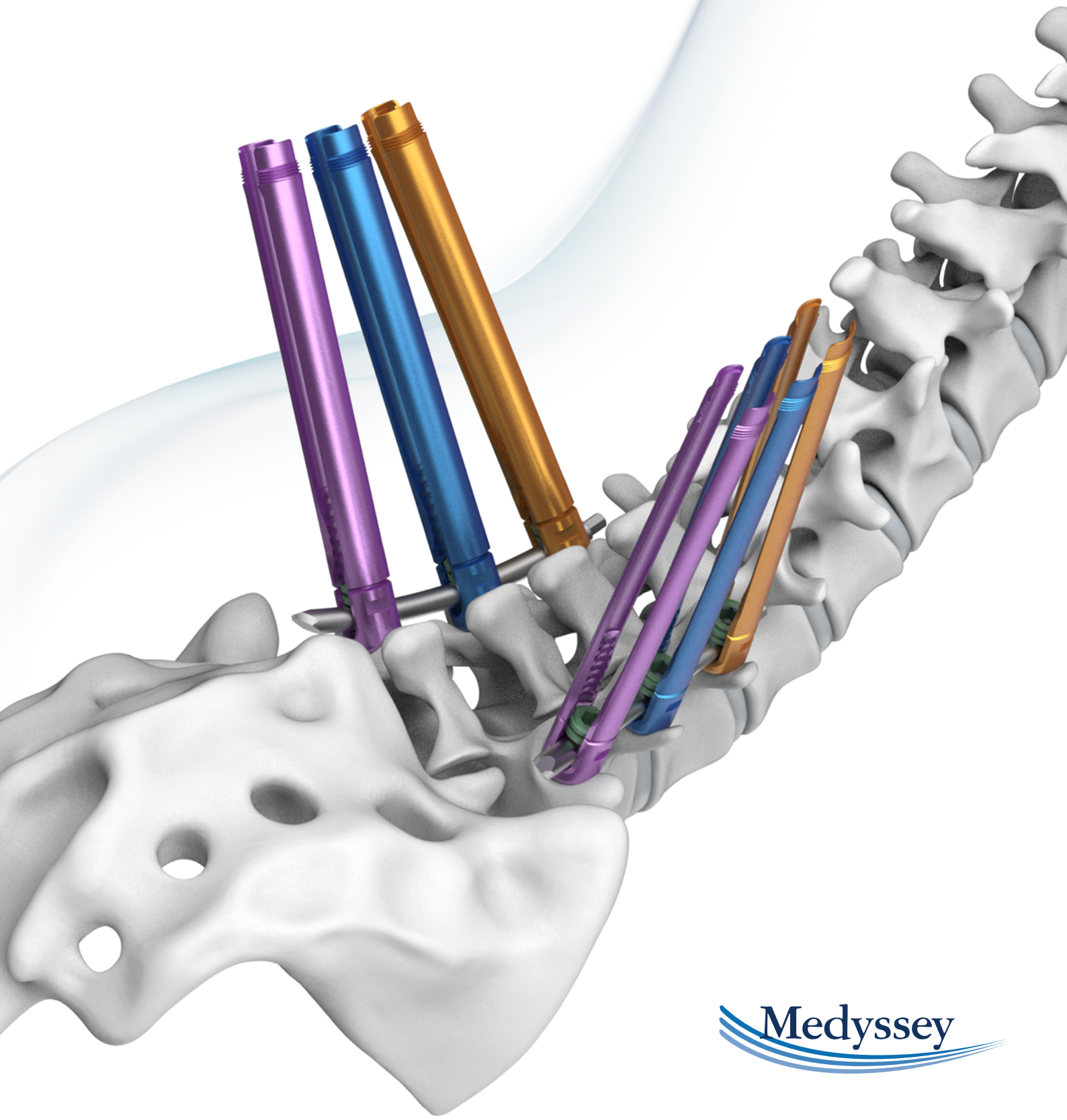
ARTeMIS®

Art of MIS

Minimally Invasive Spinal Fixation System



Medyssey

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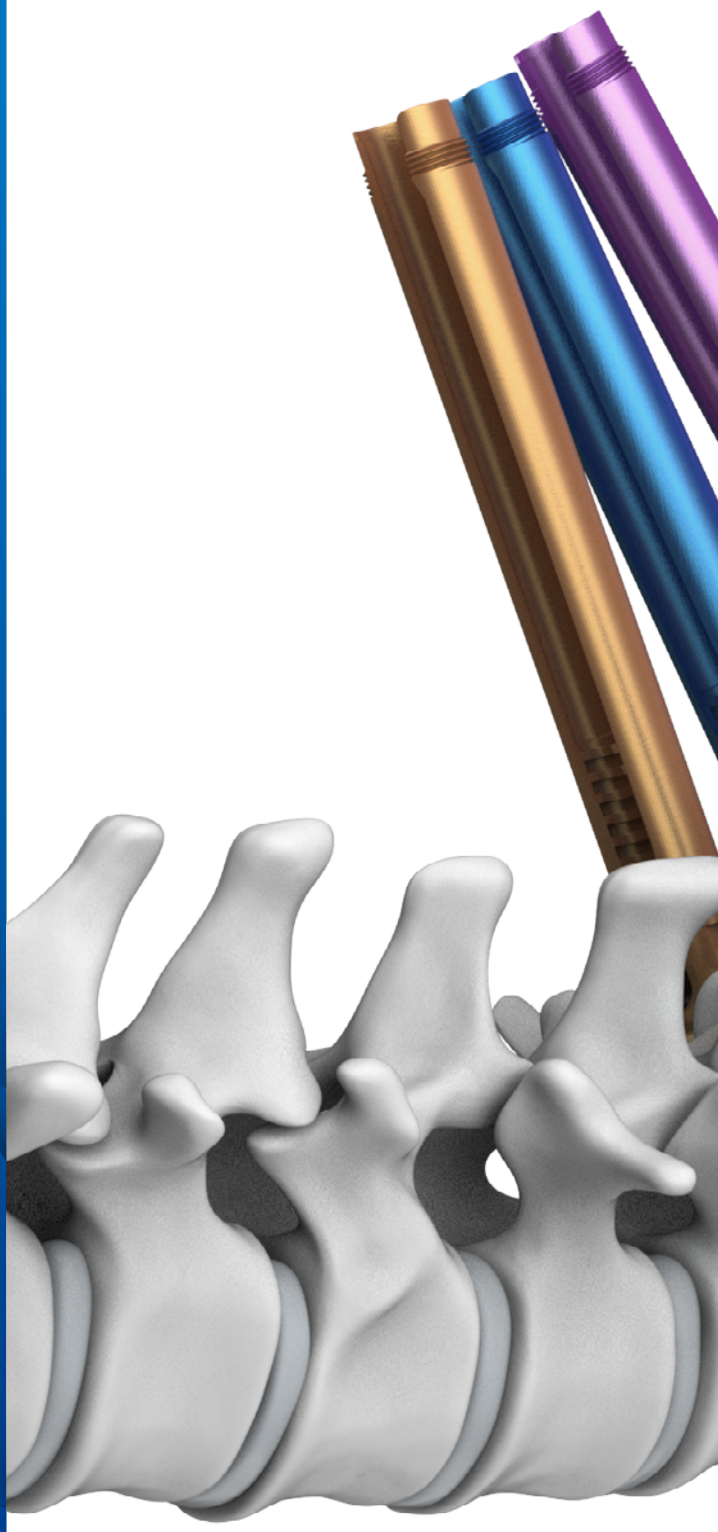
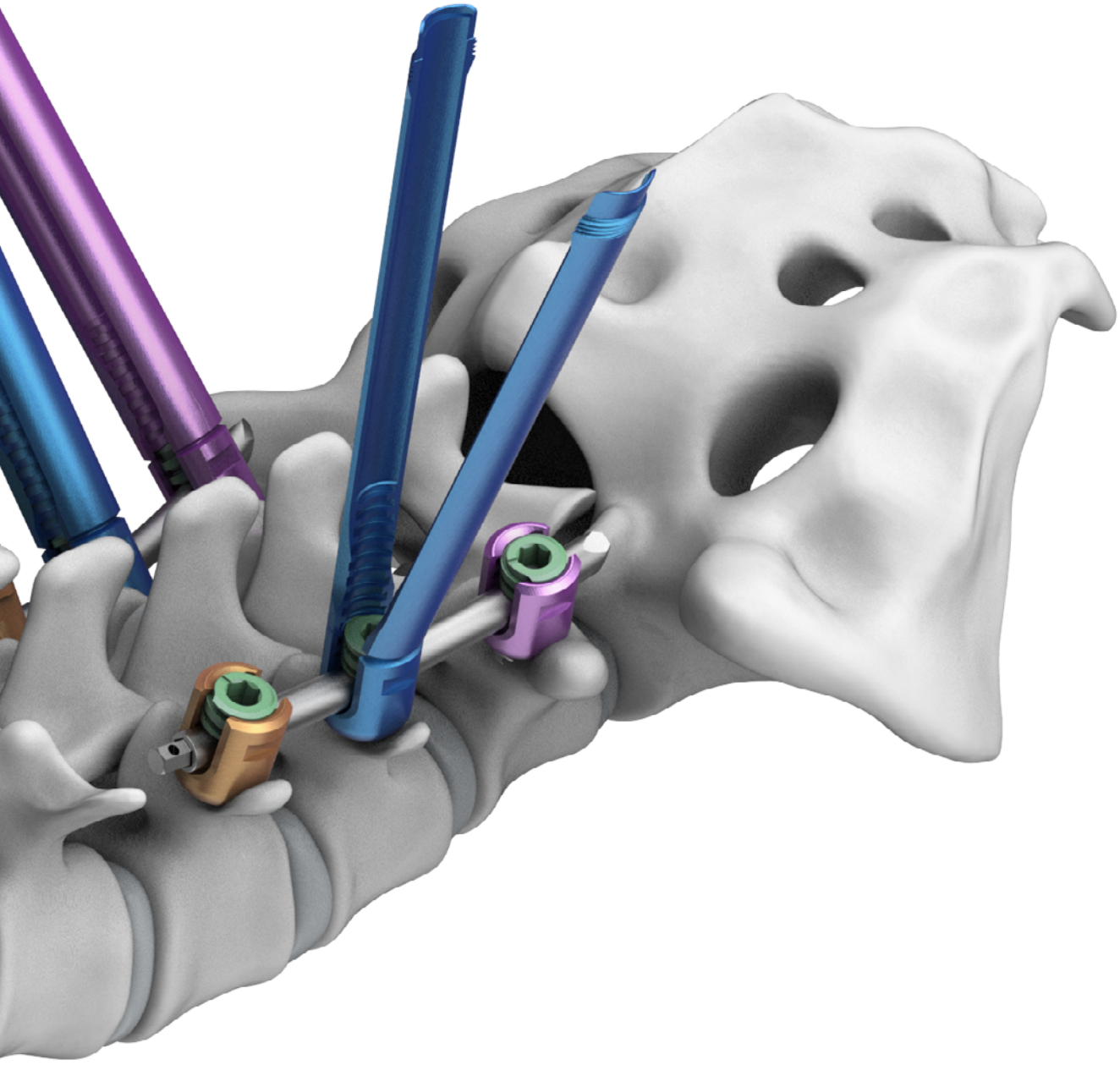


ArteMIS Spinal Fixation System is a percutaneous screw delivery system that offers a broad range of implants and intuitive instrumentation for a minimized, percutaneous or mini-open approach. ArteMIS System provides reliable rod delivery and the unique Dovetail joint locking mechanism of the screw head with cap helps surgeons to reduce surgery time in an easier way while minimizing the incision and tissue dissection.



Disclaimer
The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

Implant Features

ArteMIS Percutaneous Polyaxial Screw

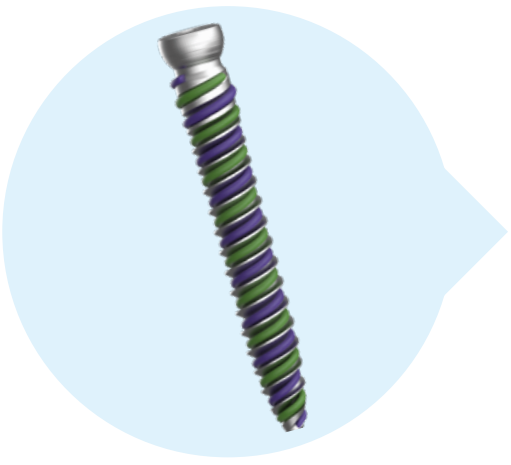
- Color coded tulip heads
- 88mm and 118mm two different extension tabs
- 22mm of reduction threads

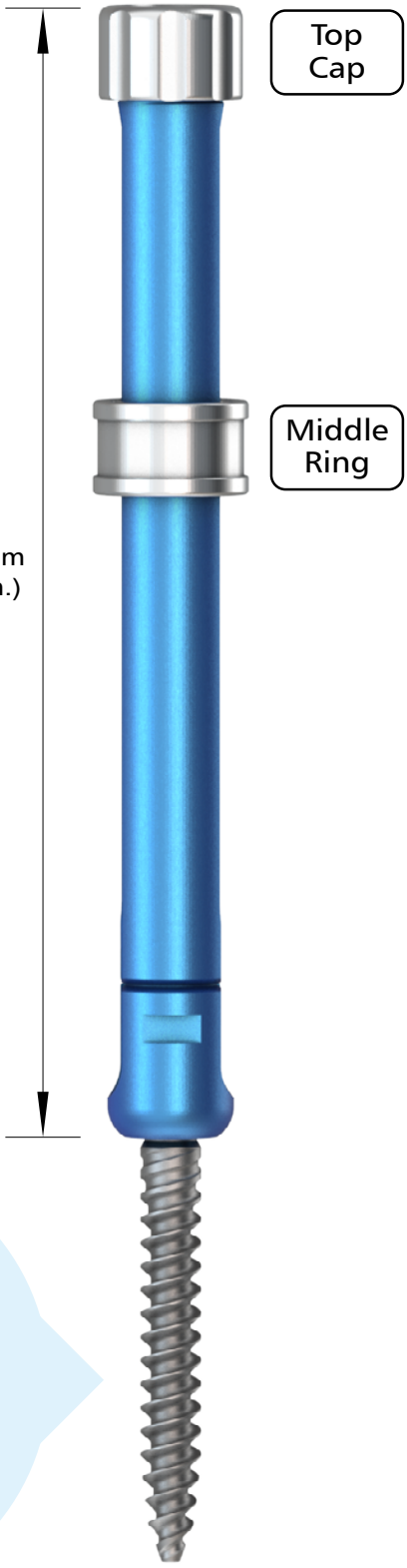
ArteMIS Cap & Ring

- Top Cap eliminates a nuisance step to cut off the top links of the extended tabs.
- Middle Ring to prevent tulip head splaying

ArteMIS Double-Lead Screw Shank

- Double Lead Screw Shank for faster screw insertion
- Self-tapping fully threaded cannulated screw shank
- 60 degrees of friction head rotation
- Hole type screw shank for cement injection
- 4.5 and 5.0mm screw shanks for a complex surgery

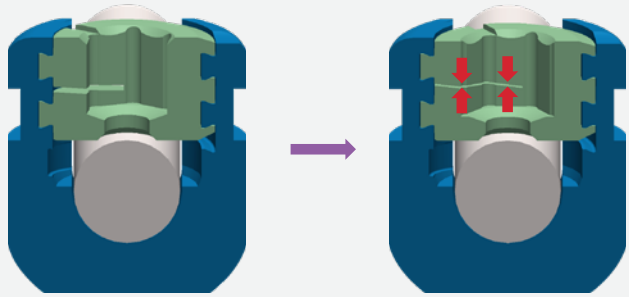




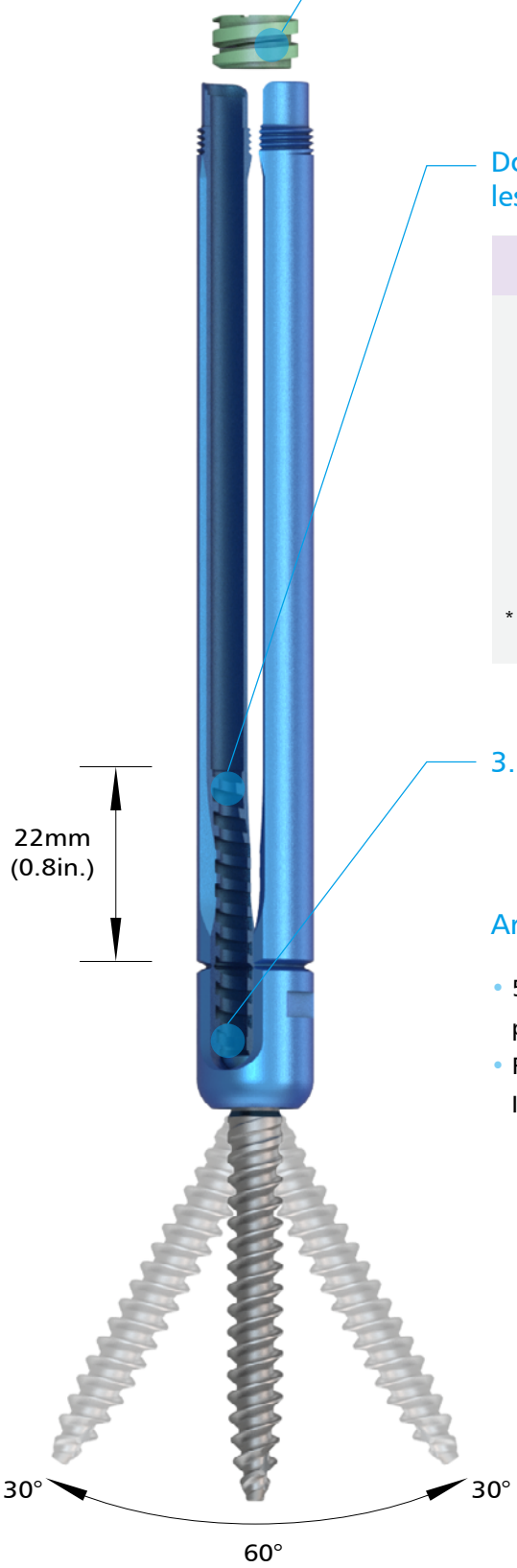
Linear Slot in Cap
4.5 Hexagonal Drive Feature

Dove Tail Joint Mechanism with less reduction threads

Provisional tightened set screw	Final tightened set screw with Linear Slot compressed



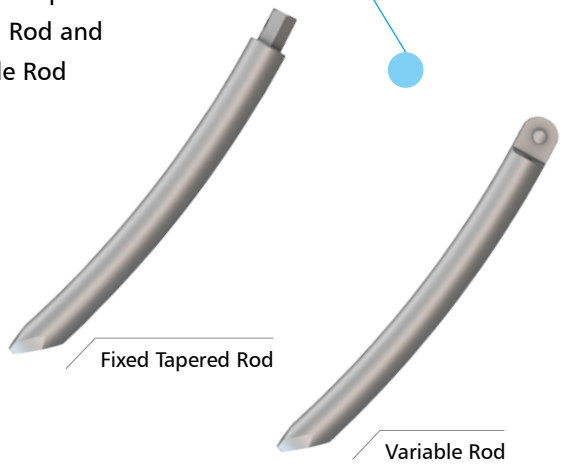
* Linear Slot design built into the threads allows increasing holding force during the final tightening and also it prevents from cross threading.



3.5 Hexagonal Drive Feature

ArteMIS Percutaneous Rod

- 5.5mm pre-bent and pre-cut bulleted tip
- Fixed Tapered Rod and In-situ Variable Rod



Competitiveness | Faster Cap Delivery

ArteMIS Screws

Less threads designed for Dovetail Joint Mechanism makes a cap delivery time much faster and easier than another MIS screws with a general buttress threads without a cross-threading issue.

What makes a cap delivery faster and easier?

General buttress threads

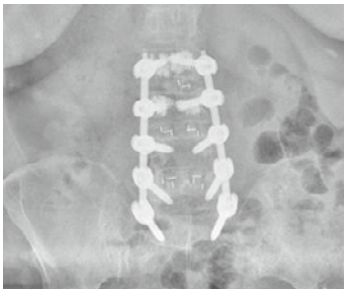
ArteMIS less reduction threads

Double-Lead Screw Shank

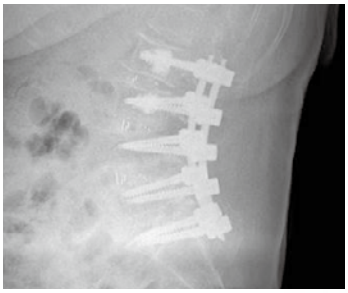
Double lead screw shank allows screw insertion faster as twice as a single-lead screws without sacrificing a pull-out strength.

Different Profiles

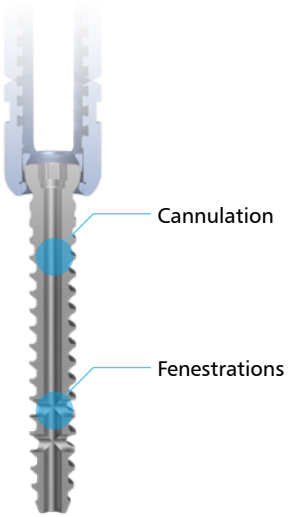
Both 88mm short along with a 118mm regular open extension tab screws allow for a patient profiles by preventing a possible interference among the screws in line during the procedure.



AP View of ArteMIS Screw



Lateral View of ArteMIS Screw



Cannulation

1.6mm diameter allows for cement injection through the screw shaft (1.2mm under 5.0mm screw diameter).

Fenestrations

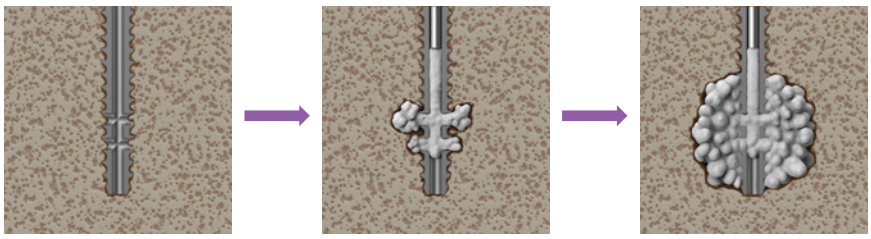
1.6 and 2.5mm fenestration diameters allow for optimal cement delivery and screw fixation(* 2.5mm fenestration is our main size).

Simple Surgical Guide

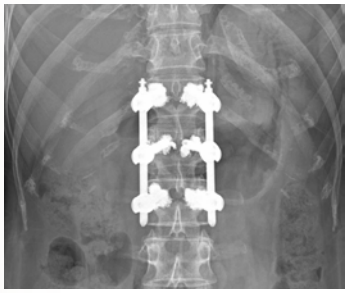
Once the screws are in place at the levels to be augmented, place MVP filler into the screw shaft and make sure if MVP filler is completely positioned and engaged with an entry of cannulation of the screw shaft (Top Cap should be engaged at the top of the screw head for an accuracy).
Push the cement which is injected inside the cannula with MVP Pusher by using fluoroscopy throughout the procedure to verify and monitor cement flow as appropriate and disengage MVP Pusher from the screw shaft after ensuring the cement gets hard.

(Caution)

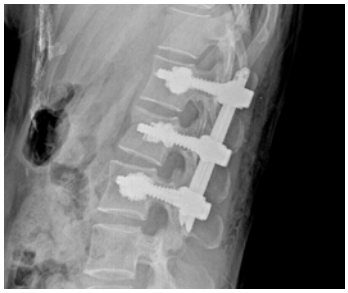
- Keep making sure if the cement is leaked at the entry of the cannula of the screw shaft while the cement is injected by MVP Filler.
- Cement can overflow if the MVP Pusher gets disengaged from the screw shaft.
- 1.5cc of is an appropriate amount of cement to fill in.



Cement Delivery and Flow



AP View of ArteMIS Cement Screw



Lateral View of ArteMIS Cement Screw

Implant Guide

ArteMIS Cannulated Screws / Self-Tapping / Double Leads		
Part Number	Descripton	Quantity
SXCP5535	5.5mm / 35mm	4
SXCP5540	5.5mm / 40mm	4
SXCP5545	5.5mm / 45mm	4
SXCP6535	6.5mm / 35mm	4
SXCP6540	6.5mm / 40mm	12
SXCP6545	6.5mm / 45mm	16
SXCP6550	6.5mm / 50mm	8
SXCP7535	7.5mm / 35mm	4
SXCP7540	7.5mm / 40mm	8
SXCP7545	7.5mm / 45mm	6
SXCP7550	7.5mm / 50mm	6
ArteMIS Bulleted Tappered Lordotic Rods with Hex (5.5mm Diameter)		
Part Number	Descripton	Quantity
TR55040	Pre-bent and Pre-cut Tapered Rod 40mm	4
TR55045	Pre-bent and Pre-cut Tapered Rod 45mm	4
TR55050	Pre-bent and Pre-cut Tapered Rod 50mm	4
TR55055	Pre-bent and Pre-cut Tapered Rod 55mm	4
TR55060	Pre-bent and Pre-cut Tapered Rod 60mm	4
TR55065	Pre-bent and Pre-cut Tapered Rod 65mm	4
TR55070	Pre-bent and Pre-cut Tapered Rod 70mm	4
TR55075	Pre-bent and Pre-cut Tapered Rod 75mm	4
TR55080	Pre-bent and Pre-cut Tapered Rod 80mm	4
TR55085	Pre-bent and Pre-cut Tapered Rod 85mm	4
TR55090	Pre-bent and Pre-cut Tapered Rod 90mm	4
TR55100	Pre-bent and Pre-cut Tapered Rod 100mm	4
TR55110	Pre-bent and Pre-cut Tapered Rod 110mm	4
TR55120	Pre-bent and Pre-cut Tapered Rod 120mm	4
TR55130	Pre-bent and Pre-cut Tapered Rod 130mm	4
TR55140	Pre-bent and Pre-cut Tapered Rod 140mm	4
TR55150	Pre-bent and Pre-cut Tapered Rod 150mm	4
TR55160	Pre-bent and Pre-cut Tapered Rod 160mm	4
TR55180	Pre-bent and Pre-cut Tapered Rod 180mm	4
TR55200	Pre-bent and Pre-cut Tapered Rod 200mm	4
ArteMIS Set Screw		
Part Number	Descripton	Quantity
ZA100	Set Screw (Cap)	20

* Standard part number of ArteMIS set screw is ZA100 which can be compatible with SA100
* Implants listed above are the standard sizes in our tray.
* Separate product list can be provided for more specification at your request.

Instrument Guide

ArteMIS Instrument Case			
Part Number	Description	Descripton	Quantity
NNRI-201	Straight Ratchet Handle	.	2
NNRT-201	T-Shaped Ratchet Handle	.	2
NNSO-001	Set Screw Starter	Double-Ended (Hex 4.5)	1
NNTW-S13	Torque Driver (Torque Wrench)	Standard	1
NNX-R01	MIS Cap & Middle Ring Caddy	Blue Plastic Small Caddy	1
NTRB-001	Rod Bender	.	1
NXAR-001	Alignment Tool	Screw Aligner	1
NXAT-002	Anti-Torque Handle	Modular	1
NXAT-003	Anti-Torque Driver	-	1
NXCA-C15	Awl (Cannulated)	15 mm	1
NXCP-003	Compressor	-	1
NXCS-003	Compression Sleeve (Modular)	Ø 15.8	4
NXDA-013	Dilator	Ø 13.4	1
NXDA-206	Dilator	Ø6	1
NXDA-210	Dilator	Ø10	1
NXDA-216	Dilator	Ø16.4	1
NXHA-001	Head Adjuster	-	1
NXKW-101	K-Wire	Nitinol Blunt Type	8
NXPD-560	Polyaxial Screw Driver	Modular	2
NXRI-003	Rod Inserter	Fixed type (105° Rod Angle)	2
NXRR-001	Reduction Tap Remover	Extension Tab Cutter	1
NXSC-001	Top Cap	.	8
NXSD-001	Set Screw driver	Modular	1
NXSR-001	Middle Ring	SUS	8
NXTP-001	T-Plate	-	1
NXTS-S55	Modular Tap	Ø 5.5 (0.5mm Undersized)	1
NXTS-S60	Moduar Tap	Ø 6.0 (0.5mm Undersized)	1
NXTS-S65	Modular Tap	Ø 6.5 (0.5mm Undersized)	1
NXTS-S75	Modular Tap	Ø 7.5 (0.5mm Undersized)	1
NXVC-001	Rod Measurer (Caliper)	Scissors Type	1
NXWH-002	K-Wire Holder	Palm Handle Type	1

* Instruments listed above are the standard instruments in our tray.
* Custom instruments can be provided at your request for your user' surgical technique.

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ZENIUS System Instruction For Use

Important Note
The users acknowledge that they have read and agreed on the conditions in this surgical technique brochure, which are to be considered as contractual.

Basic Structure
ZENIUS Systems, internal fixation devices for spinal surgery comprise rods, pedicle screws, cross link as well as set screw. Various forms and sizes of these implants are available, so that adaptations can always be made to take into account the pathology and individual patient.

Materials
The pedicle screw and most components are made with Ti6Al4V alloy, Ti6Al7Nb alloy, and CCM alloy, a titanium based alloy which complies with ASTM F136, ASTM F1295 and CCM rod is made with CCM alloy which complies with ASTM F1537.

Indication
ZENIUS Systems are indicated for temporary or permanent correction or stabilization of the vertebral column and with the aim of helping consolidation of bone fusion. This Spinal System must be used with interbody fusion cage at the surgery for successful fusion. They are indicated for:
•Primary surgery for advanced discopathies or extensive decompressions(laminectomy, facetectomy, foraminotomy, etc.)
• Spondylotic spinal stenosis
• Revision surgery for failed disc operation
• Post-operative instability
• Disc herniation
• Spondylosis with bone spurring, foraminal narrowing and nerve root impingement
• Chronic and disabling discogenic low back pain
• Spinal pseudarthrosis

General Conditions of Use
•The implants must be implanted only by physicians having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks and limitations related to this type of surgery, the contra-indications, side effects, and precautions defined, and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants to be used.
•It is recommended that ZENIUS Systems should not be used together with implants from a different source, a different manufacturer, or made from a different material. If this should occur, ZENIUS Systems decline all responsibility.
•Under no circumstances may the implants be re-used; although the device may appear intact on removal, internal modifications due to the stresses and strains placed on it, or small defects may exist, which may lead to the fracture of the implant.
•ZENIUS Systems may be implanted in children on condition that the overall size of the assembly and the size of the implants are checked beforehand to verify whether they are suited to the height and the size of the bone structures of the child.

Contra-indications
•Any active or suspected latent infection in or about the spine.
•Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
•Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
•Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
•Recent infection, fever, or leukocytosis.
•Bony abnormalities preventing safe screw fixation.
•Suspected or documented metal allergy or intolerance.
•Open wounds
•Metal sensitivity, documented or suspected
•Bone absorption, osteopenia and/or osteoporosis. (Osteoporosis is a relative contraindication, as the condition may limit the degree of correction obtainable and the amount of mechanical fixation.)
•Patient having inadequate tissue coverage over the operative site.
•Pregnancy
•Excessive local inflammation
•Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count(WBC), or marked left shift in the WBC differential count.

Side Effects
•Late bone grafting or no visible fusion mass and pseudarthrosis
•Neurological complications, paralysis, soft tissue lesions, pain due to the surgical procedure, the breakage, the deformation and/or migration of the implant
•Pedicle failure while preparing and inserting pedicle screw
•Superficial or deep-set infection and inflammatory phenomena
•Allergic reaction to the Ti6Al4V ELI alloy or Ti6Al7Nb alloy or CCM alloy.
•Reduction in bone density due to a different distribution of mechanical stresses
•Pain and abnormal sensations due to hardware bulkness
•Neurological and spinal dura mater lesions from surgical trauma
•Bursitis
•Presence of microparticles around the implants
•Growth of the fused vertebrae is altered
•Partial loss of the degree of correction achieved during surgery
•Modification of spinal curvature and stiffness of the vertebral column
The above list of side effect is not exhaustive. These side effect can sometimes necessitate further surgical treatment.

Precautions
•Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
•If the patient is involved in an occupation or activity which applies inordinate stress upon the implant(e.g., substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device.
•In some cases, progression of degenerative disease may be so advanced at the time of implantation that they may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
•Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the ZENIUS systems requires detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome.
•Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
•Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these componen is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service li Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants
•Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produ defects in surface finish and internal stresses which n become the focal point for eventual breakage of the implant.

Warning
•Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established i patients with stable spines
•Potential risks associated with the use of this system which may require additional surgery, include: devic component fracture, loss of fixation, non-union, fract of the vertebra, neurological injury, and vascular or visceral injury.
•Discard all damaged or mishandled implants.
•Never reuse an implant, even though it may appear undamaged.
•If device will be reused, it may cause the patient infection . It may also cause the breakage of device. Therefore, the reuse of the device may cause unexpected problems.
•Internal fixation devices cannot withstand activity a load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirme do not subject this device to the stress of full weight bearing, or implant failure may result.
•Contouring or bending of a screw may reduce its fatigue strength and cause failure under load. If spina screws or hooks are bent or otherwise damaged durin insertion or adjustment, they must not be implanted a must be replaced. Rods should only be contoured wit the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly o excessively contoured must not be implanted.
•Mixing Metal: Some degree of corrosion occurs on implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion proce The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hook screws, wires, etc., which come into contact with oth metal objects, must be made from like or compatible metals.
•Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of ZENIUS System should not be used i conjunction with components from any other manufacture's spinal system. Any such use will negat the responsibility of Medyssey Co., Ltd. for the performance of the resulting mixed component impla
•Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface the implant surface. This technique may require pract in the laboratory before being attempted clinically.
•Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of remova
•Implant removal should be followed by adequate postoperative management to avoid fracture.

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'ackaging, Labeling and Storage

The implants are supplied non-sterile. They must be leaned and sterilized (see below)
The implants are delivered in packages; these must be ıtact at the time of receipt. All the legal information equired for this type of implants is given on the label of ach package.
The implants may be delivered as a complete set : implants nd instrumentation are set out on specially designed trays r in boxes which can be sterilized directly.
Use care in handing and storage of implant components. Cutting, sharply bending, or scratching the surface can ignificantly reduce the strength and fatigue resistance of he implant system. This, in turn, could induce cracks nd/or non-visible internal stresses that could lead to racture of the implants. Implants and instruments in torage should be protected from corrosive environments uch as salt air, moisture, etc. Inspection and trial assembly re recommended prior to surgery to determine if ıstrument components or implants have been damaged uring storage or prior procedures.

'terilization Procedures

I. Pre-cleaning (Instruments only)
. Pre wash
Remove contaminants using a nylon brush after soaking for '0 minutes in Enzymatic Detergent.
'. 1st rinsing
Rinse using the water for 3 minutes to remove Enzymatic Detergent of product.
'. Detergent wash
Wash using the Enzymatic Detergent in the ultrasound leaner at 45~55°C for 10 minutes.
Rinse 3 times using the water for 30 seconds
'. Purified water rinse
Perform the ultrasound rinsing repeatedly subjected 3 imes for 3 minutes using the purified water at 45~55°C.
'. Alcohol disinfection
Wipe using dustabsorbent after the product soaked in lcohol(70%) for 30 seconds.
'. Dry Dry using the heating device at 100°C (±10°C) for '0 minutes.
8. Sterilization (Implants and Instruments)
Auto clave : recommended method to achieve a degree of terility equal to at least 10^{-6}
'terilize by the autoclaving procedure regularly used in the ospital,
'uggested method : Steam, Wrapped Pre-vaccum cycle at 32°C(270 °F) for 4 minutes.
Any other procedure is the sole responsibility of the user nd Medyssey Co., Ltd. declines all responsibility. Detailed nformation concerning these procedures will be supplied y Medyssey Co., Ltd. on the specific request of the user.
※ The number of Instruments re-sterilization : Medyssey uarantee a number of re-sterilization number for surgical nstrument within 200 cycles. If user wants to do the more terilization additionally, the appearance of products or its erformance should be considered.

Guarantee

The guarantee is only applicable if the device is used in ccordance with normal conditions, as defined in this ınstructions and in conformity with the recommended urgical technique.

Removal of Implants

The ZENIUS Spinal System implants are temporary ınternal fixation devices. Internal fixation devices are esigned to stabilize the operative site during the normal ealing process. After the spine is fused, these devices erve no functional purpose and may be removed by screw river. While the final decision on implant removal is, of ourse, up to the surgeon and patient, in most patients, emoval is indicated because the implants are not intended o transfer or support forces developed during normal ctivities.

Surgical Technique

A. Pre-operative preparation

○ Pre-operative examination
First, spinal pathology and geometry were recognized by pre-operative radiographic or CT examination. Then, the exact position, direction and size of the pedicle screw are established. In this way it is possible to plan the operation in terms of positioning the material to be implanted, the levels to be stabilized as well as the eventual compression or distraction required.
○ Before the operation, fixators and surgical instruments are sterilized on condition of over 132°C, 4min.

Surgical Technique

B. Surgical procedures

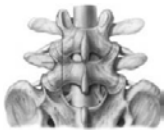
○ Position of the patient

The posterior approach to the dorso-lumbar region of the spine requires the patient be positioned on a special frame which to place the iliac bones in such a way that the abdomen remains free from pressure, hip and knees bent.

○ Surgical approach

Incise the midline of the lumbar spine under general anesthesia. Perform subperioseal dissection of the musculature from the spinous processes.

○ Pedicle screw entry level



Determine the pedicle entry level. Before resection of the vertabral joints, establish the location of the pedicle entry level in the region of the segment to be fused. Open the pedicle and insert marking wires. Next, perform an X-ray check to determine the exact position of the drill channel.

○ Pedicle screw insertion

After determining the diameter and length of the pedicle screw, screws are inserted into the channels of the pedicle. After inserting the screw and checking their exact position, resect the vertebral joint bilaterally and remove the cartilage and facet joints.

○ Fixing the rod

Assemble the rod and set screw. When you assemble the set screw, firstly match the starting point of the housing and set screw(Each groove have to meet at same point). Apply set screw starter when set screw inserted to pedicle screw to fixate with the rod.

C. Post-operative procedures

The physician's post-operative 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. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
2. If a non-union develops or the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device.
3. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the ZENIUS Spinal System components should ever be reused under any circumstances.

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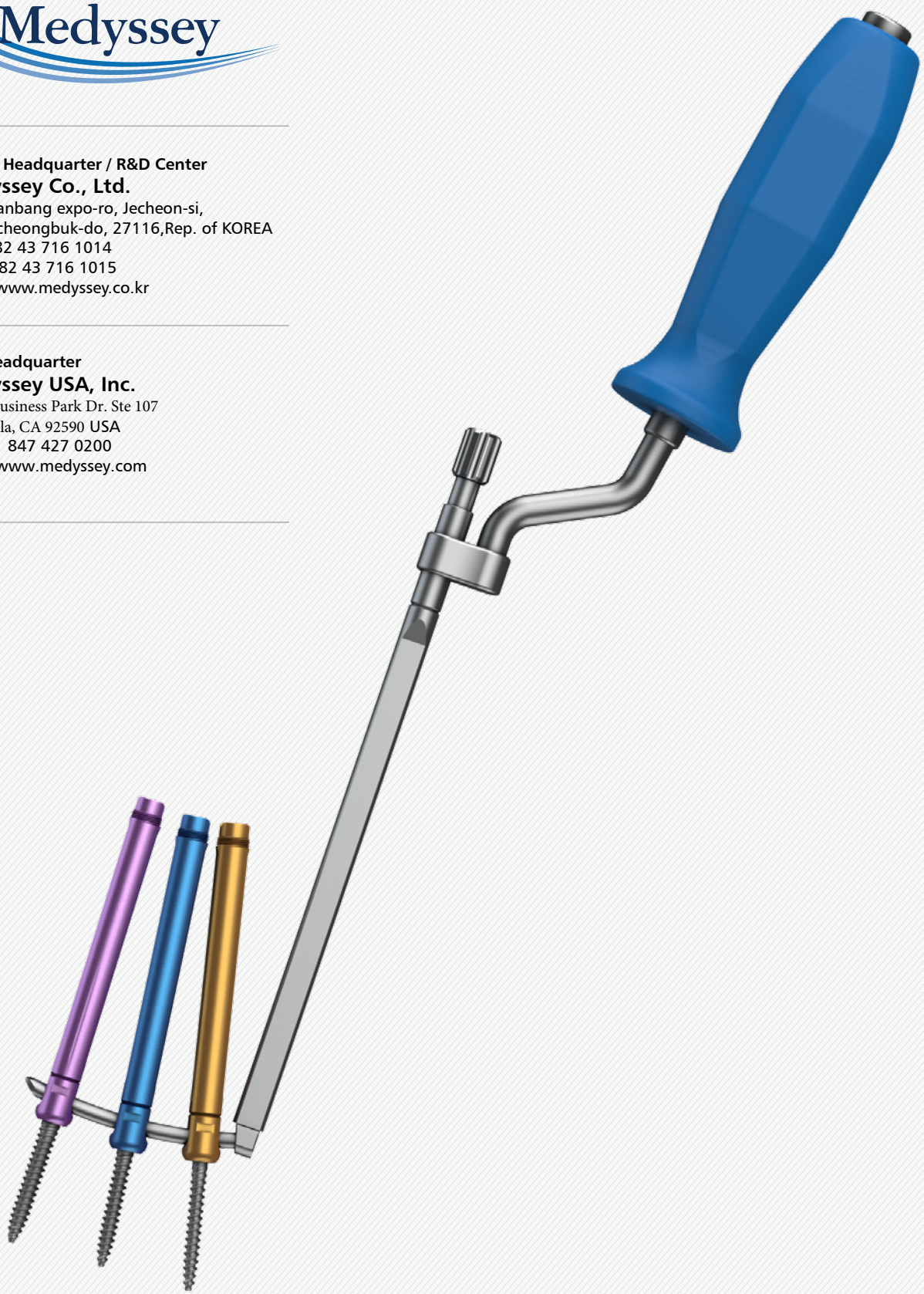

MDAD-CL-MIS-00 Rev.2 (21-1220)