sintea PLUSTEK

3 LOCK MIS

Minimally Invasive System for Posterior Lumbar Fusion

3LOCK-MIS

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SURGICAL TECHNIQUE

STEP 01 - GUIDE WIRE PLACEMENT AND SOFT TISSUE DILATION

Locate the access point of the pedicle using the guide wire [2] , insert the stainless steel dilators [1,1 e 1,2] then insert the anodized aluminum dilator[1,3]. Penetrate the cortical bone using the awl [3] or the reaming awl [4]. Advance the tap [5]down to the pedicle. Maintain position of the guide wire during this phase.

STEP 02 - SCREW INSERTION

Remove the dilators [1,1 e 1,2] leaving both the retractor [1,3] and the guide wire in situ. Once the proper length of screw has been identified by the markings on the taps, load the screw onto the cannulated screw driver [6] preassembled with the ratcheting handle [16]. Advance the screwdriver hex into the corresponding hole located at the base of the screw head and connect the thread of the head of the latter to the screwdriver sleeve. Position the poliaxial screw over the guide wire and screw it down into the already threaded pedicle up to the base of the head. Disassemble the instrument from the implant and repeat this step for all the devices required. Avoid unwanted guide wire displacment during this step.

INTENDED USE

Appropriately used, the purpose of spinal stabilization system Sintea Plustek 3Lock-Mis is to facilitate the development of a solid vertebral arthrodesis. It is recomended in cases of scoliosis, hyperkyphosis, fractures, instability also caused by neoplasm, spinal stenosis, spondylolisthesis, pseudarthrosis, and previous attempts attempts of spinal arthrodesis that have been successful.

STEP 03 – ROD SIZING AND PLACEMENT

Remove the guide wire and dilator [1,3]. Use the caliper [21] to determine proper rod length.

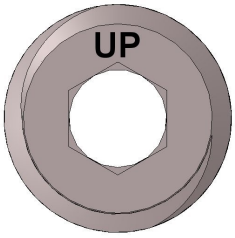
Slide the rings [14] on the screw extension and use the muscle tissue separator [23] to facilitate the insertion of the bar in situ. Maintain control of the sliding rings inserted into the screw extensions while performing these maneuvers on the screws heads.

Install the selected rod on the rod holder [7] and lock it using the special screwdriver [8]

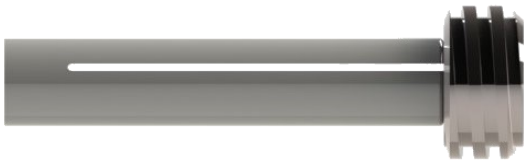
Insert the rod in place. Perform AP and Lateral image to re-confirm proper rod placement. The tapered end of the bar must exceed the last screw head. To adjust the insertion of the bar, the sliding rings may be moved along the screws extensions. The sliding ring positioned on the first screw may be temporarily removed to facilitate the insertion of the bar holder.

SURGICAL TECHNIQUE

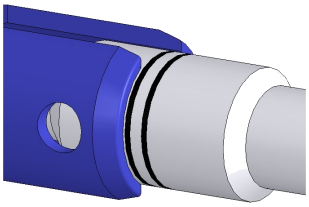
STEP 04 - LOCKING SCREW PLACEMENT



Load a loking cap onto the screwdriver delivery-cap [19] (The locking nut has a single direction of insertion possible, bearing the inscription "UP" upward).



Screw the locking cap on the screw head. Once you positioned all nuts, using the screwdriver for cap [20] proceed with a possible reduction, until completely screwed (first mark on the screwdriver)



INDICATIONS

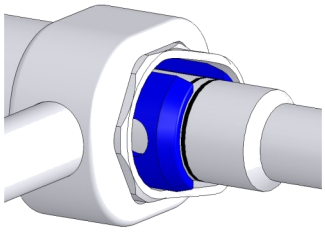
Appropriately used, the purpose of spinal stabilization system Sintea Plustek 3Lock-Mis is to facilitate the development of a solid vertebral arthrodesis. It is recomended in cases of scoliosis, hyperkyphosis, fractures, instability also caused by neoplasm, spinal stenosis, spondylolisthesis, pseudarthrosis, and previous attempts attempts of spinal arthrodesis that have been successful.

STEP 05 - COMPRESSION / DISTRACTION

Remove the sliding ring and insert the working cannula [15] on the extension of the screw to be locked; advance on the latter the counter torque wrench [13] and final tighten the locking nut using the dynamometer T-handle [18] assembled on the screwdriver for cap [20]. When the torque ring performs an audible click the final tightening of locking cap will be accomplished. After having fitted the second working cannula, perform the desired compression or distraction using the compressor / spreader [12] and by properly positioning the pivot [11], and then perform the tightening of the second cap. The correctness of the maneuver is testified by the second notch marked on the screwdriver.

Note:
To obtain the compression position the pivot higher up the prongs of the forceps.

To obtain the distraction position the pivot further down the prongs.



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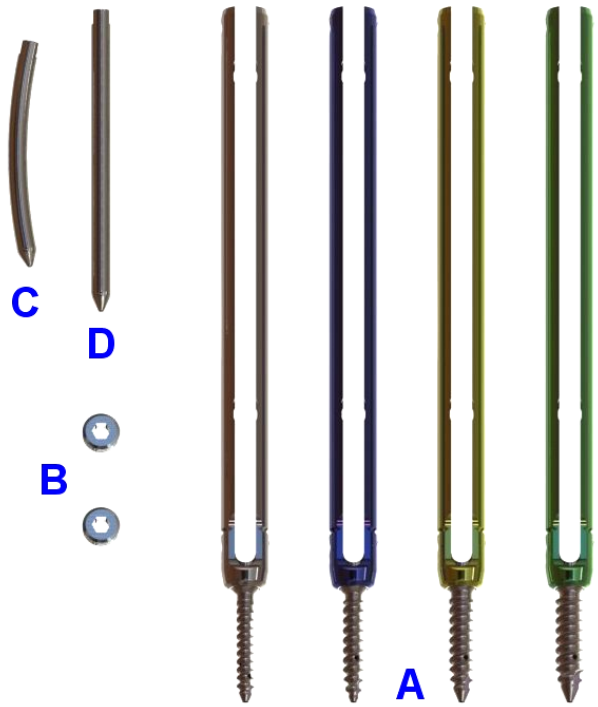
STEP 06 - SCREW EXTENSION REMOVAL

After removing all the tools use the tab remover [22] to remove the screws extensions: slide the tool down and pool outward to remove the extensions.

IMPLANTS

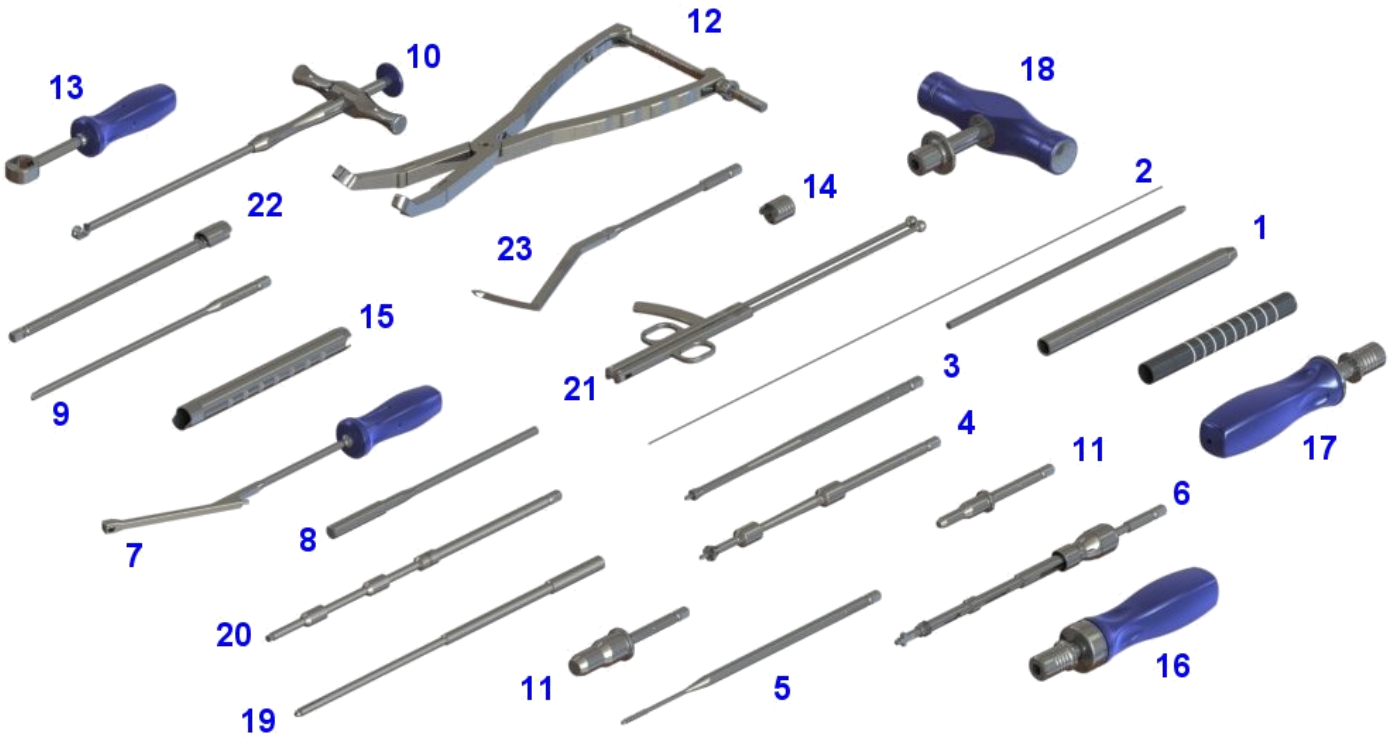
Double lead multi axial percutaneous screws Ø 5mm-6mm-7mm-8mm Length 30mm-35mm-40mm-45mm-50mm-55mm-60-mm-65mm-70mm-75mm 80mm-85mm-90mm-95mm-100mm	PLS-9XXT5X	A
Locking cap for 3LOCK MIS Screw and hook	PLS-133T50	B
Percutaneous rod Ø 5,5 mm Length 30mm - 35mm - 40mm - 45mm - 50 mm - 55mm - 60mm - 65mm - 70mm –75mm - 80mm - 85mm - 90mm - 100 mm - 110mm - 120mm - 130mm - 140mm - 150mm - 200mm - 300mm	PLS-48T5XXX	C
Percutaneous pre-curved rod Ø 5,5 mm Length 30mm - 35mm - 40mm - 45mm - 50 mm - 55mm - 60mm - 65mm - 70mm –75mm - 80mm - 85mm - 90mm - 100 mm - 110mm - 120mm - 130mm - 140mm - 150mm - 200mm - 300mm	PLS-49T5XXX	D



INSTRUMENTS

Tissue dilator 5,5x2mm Tissue dilator 13,5x6mm Tissue dilator 16x14mm	PLS-2605S PLS-2613S PLS-2616S	1
Guide wire	PLS-2701S	2
Cannulated awl	PLS-0330S	3
Cannulated reaming awl	PLS-0331S	4
Cannulated tap 5 mm Cannulated tap 6 mm Cannulated tap 7 mm Cannulated tap 8 mm	PLS-0335S PLS-0336S PLS-0337S PLS-0338S	5
3LOCK MIS screwdriver	PLS-0506S	6
Rod holder	PLS-0605S	7
Rod holder screwdriver	PLS-0606S	8
Rod pusher	PLS-0203S	9
Rod catcher	PLS-0607S	10

Pivot 1 Pivot 2	PLS-1302S PLS-1303S	11
Compressor/Spreader	PLS-1301S	12
Counter torque wrench MIS	PLS-1703S	13
Sliding ring short	PLS-2801S	14
Working cannula	PLS-1002S	15
Cannulated ratcheting handle	PLS-2008S	16
Cannulated fixed handle	PLS-2009S	17
Dynamometric handle 9Nm 3LOCK	PLS-2007S	18
Cacciavite porta cap	PLS-0902S	19
Cap screwdriver MIS	PLS-0904S	20
Rod caliper	PLS-2301S	21
Tab remover	PLS-2900S	22
Muscle tissue separator	PLS– 3000S	23



CONTRAINDICATIONS

The implant contraindications of the spinal stabilization system 3-Lock MIS of Sintea Plustek are are analogous to those of existing similar products on the market, and include, but are not limited to:

ABSOLUTE
Infections in the active phase
Allergy to metal components
Uncooperative patients and unable to follow the prescriptions

RELATED:
Metastasis
Severe muscle diseases, neurological or vascular
Fever or leukocytosis
Pregnancy, except for the treatment of unstable vertebral fractures
Signs of inflammation at the implantation site
Inadequate coverage of soft tissue at the surgical site
High grade of osteoporosis

If the minimally invasive system of spinal stabilization 3Lock - MIS of Sintea Plustek is considered the best solution for the patient, and if the latter has one or more of the above contraindications, it is essential to inform him of the possible negative consequences that this involves in the success of the surgery .

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