Surgical Technique

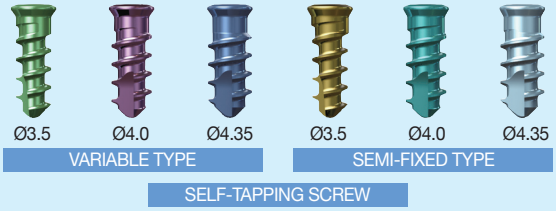
ASPIRON™

Anterior Cervical Plate System

U&I CORPORATION

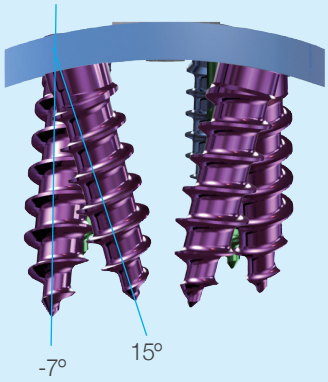
Self-tapping/-drilling bone screws

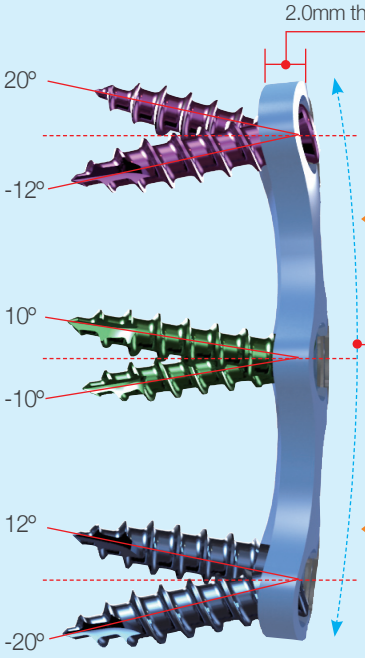
to eliminate the need for preliminary bone preparation



color-coded semi-fixed and variable screws

to offer surgeons flexibility with technique for rigid or hybrid stabilization





Low-profile design

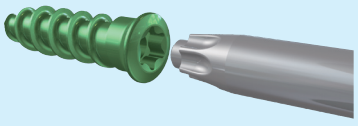
to minimizes interference with anatomical soft tissue structures to reduce esophageal irritation or potential of dysphagia

Additional bending zone

Anatomical lordotic curvature

to fit the anatomy of the patient which simplifies the surgery time by reducing the need to further bend the plate

Additional bending zone

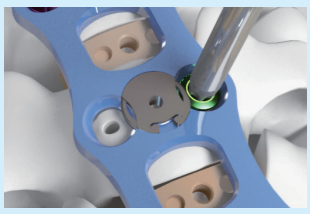


Torx screw head

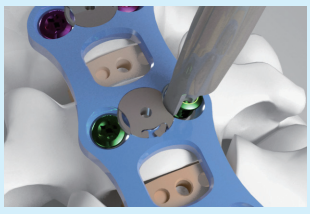
for a strong interface with a screwdriver

One-step locking mechanism

Pre-assembled one-step locking mechanism enables one instrument to insert and lock screws into place, white preventing screw rotation and backout



Screw insertion



Screw Removal

PREPARATION and EXPOSURE

Patient is placed in a supine position for optimal exposure of the anterior cervical spine (Fig. 1).
A transverse or oblique incision is performed depending on the number of levels.

The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate interbody/ bone graft insertion on surgeon's preference.

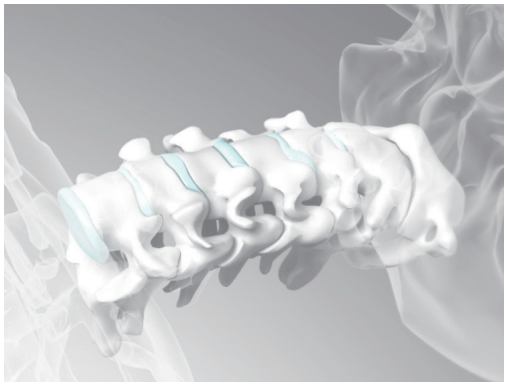


Fig. 1

CAGE INSERTION (OPTIONAL)

Instrument	
SC7230	RETRACTOR
SC7261	RETRACTOR FIXATION PIN-L
SC7262	RETRACTOR FIXATION PIN NUT
NC7330	RETRACTOR FIXATION PIN DRIVER

Insert the RETRACTOR FIXATION PIN-L to vertebral body.
The RETRACTOR FIXATION PIN-Ls must be parallel to the vertebral endplates (Fig. 2).

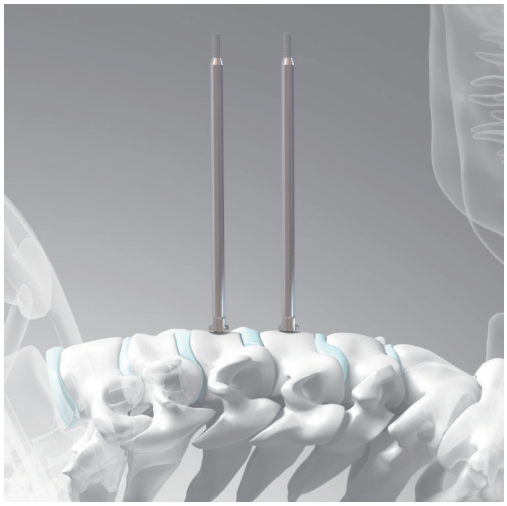


Fig. 2

Attach the RETRACTOR to the RETRACTOR FIXATION PIN-Ls, followed by the RETRACTOR FIXATION PIN NUTs and compress or distract the RETRACTOR to desired position (Fig. 3).

Care should be taken to perform appropriate soft tissue dissection and to remove anterior osteophytes to provide optimal bone-plate interface. When satisfied with the graft position, remove both the RETRACTOR and the RETRACTOR FIXATION PIN-Ls.

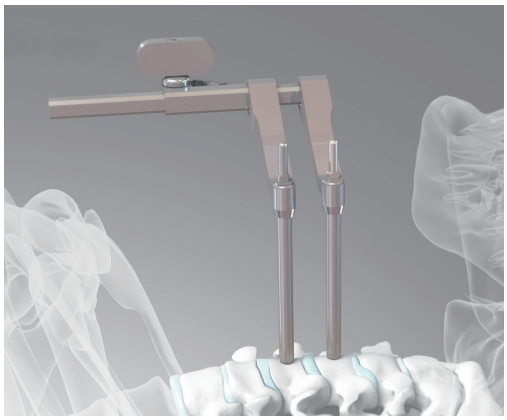


Fig. 3

SUPPLEMENTAL FIXATION

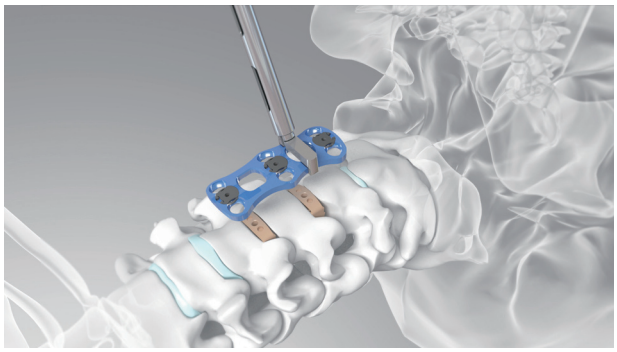
For multi-segmental instrumentation, ASPIRON™ ACP System is intended to be used with U&I supplemental implant, e.g. Velofix™ or Neo IC™ PEEK Cervical Cage.

IMPLANT SELECTION

Instrument	
NC7020	PLATE HOLDER

Choose the appropriate plate for the patient according to the size of cervical vertebra visible through the incision.
Use the PLATE HOLDER to position the appropriate plate on the cervical vertebrae (Fig. 4).
Push the lever downwards to hold the plate; push upwards to release the plate.

The size of ASPIRON™ ACP System is measured from end to end of the plate.
The edge of the plate must not interfere with the adjacent unfused disc spaces.



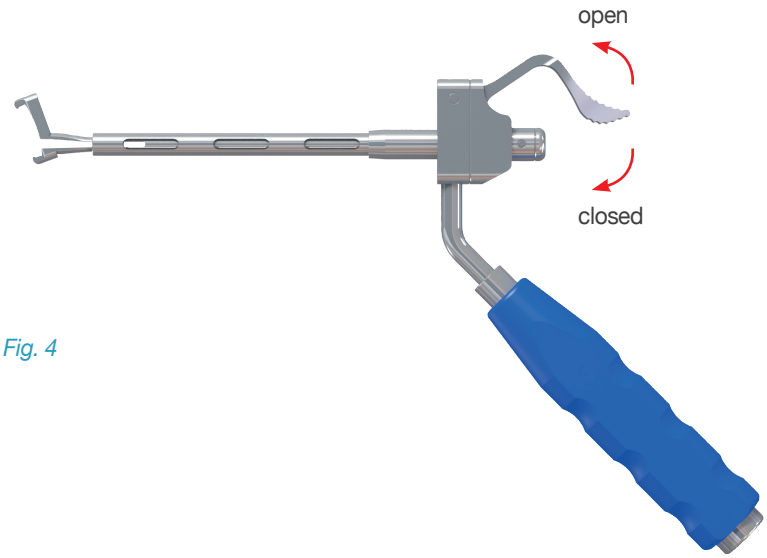


Fig. 4

PLATE CONTOURING

Instrument	
NC7010	PLATE BENDER

The plate is machined to have lordotic curve.
If required, the plate may be contoured to increase or decrease the amount of lordotic curvature by using the PLATE BENDER (Fig. 5).

Note
The following plates should be used without bending.

NCA1019, NCA1021, NCA1023, NCA1025
NCA2031, NCA2033, NCA2035, NCA2037
NCA3051, NCA3054, NCA4063, NCA4067

Caution
- Repeated bending may weaken the plate.
- Do not bend the plate over the holes and the sub-plate (anti-backout mechanism).

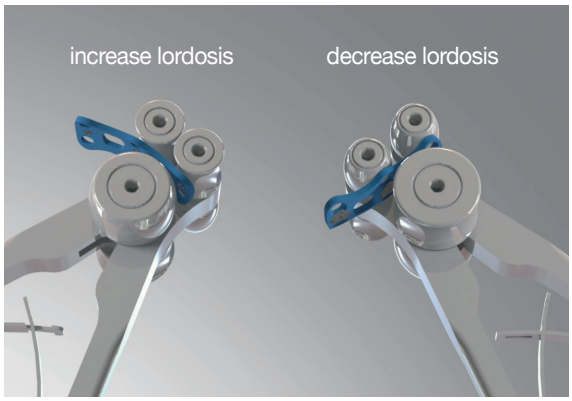
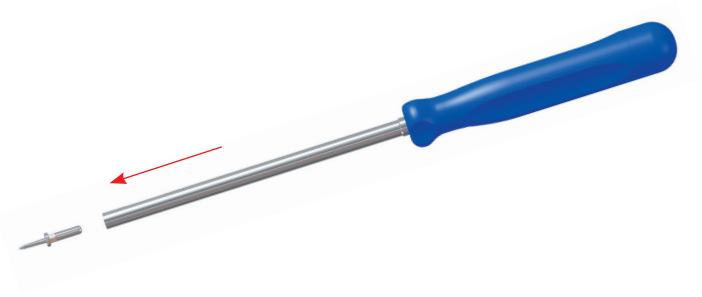


Fig. 5

PLATE POSITION

Instrument	
NC7020	PLATE HOLDER
NC7170	TEMPORARY FIXATION PIN DRIVER
NC7180	TEMPORARY FIXATION PIN
NC7350	TEMPORARY FIXATION PIN for SCREW HOLE

Using the PLATE HOLDER, place the plate in the desired position on the vertebral body.



If desired, after the plate is placed in the appropriate position, secure it with the TEMPORARY FIXATION PINs, being inserted using the TEMPORARY FIXATION PIN DRIVER into the midline holes (center of anti-backout mechanism) (Fig. 6).

Fig. 6

Alternatively, the plate can be secured with the TEMPORARY FIXATION PIN for SCREW HOLE, being inserted into the screw holes in place of the midline holes (Fig. 7).

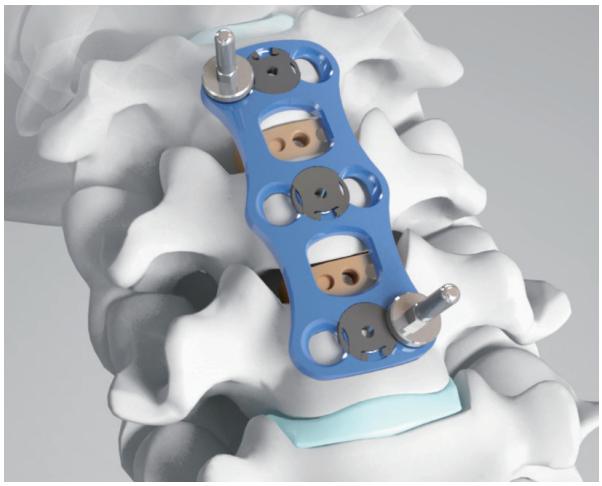


Fig. 7

SCREW INSERTION TECHNIQUE

Depending on screw selection to be inserted, method for screw hole preparation is accordingly varied as per below :

- Self-tapping screw with semi-fixed type
- Self-tapping screw with variable type
- Self-drilling screw

1. SELF-TAPPING SCREW WITH SEMI-FIXED TYPE

A. Drilling

Instrument	
SC7160	DRIVING HANDLE
NC7250, 7260, 7270	N-DRILL BIT Ø2.0x12,14,16 mm
NC7280, 7290, 7300	N-DRILL BIT Ø2.5x12,14,16 mm
NC7030	N-DRILL GUIDE-FIXED TYPE
NC7340	DRILL SLEEVE FOR FIXED DRILL GUIDE

Place the DRILL GUIDE FIXED TYPE onto the desired hole so that the correct fixed angle screw trajectory is given (Fig. 8).

Insert the DRILL SLEEVE FOR FIXED DRILL GUIDE into the DRILL GUIDE-FIXED TYPE ❶.
When the DRILL SLEEVE FOR FIXED DRILL GUIDE contacts the DRILL GUIDE-FIXED TYPE, rotate it either clockwise or counterclockwise according to the slot direction of the DRILL GUIDE-FIXED TYPE ❷.

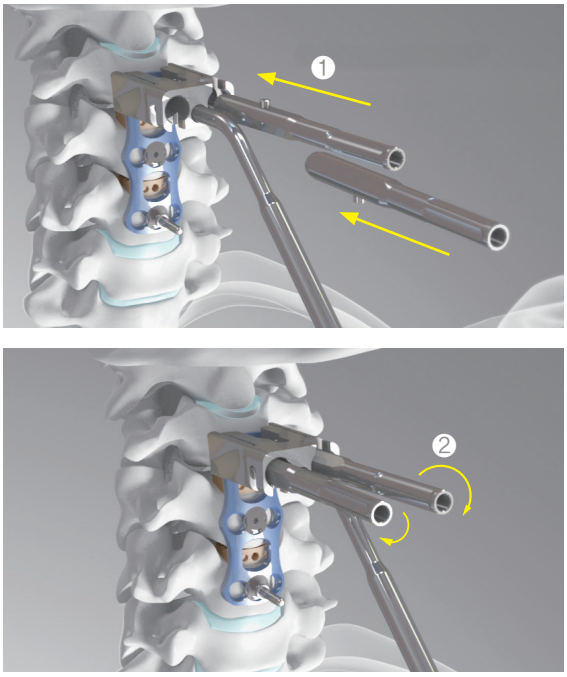


Fig. 8

Semi-fixed screw orientation is preset by the DRILL GUIDE-FIXED TYPE as follows :
- Convergence : at 5° (Per side)
- Cephalad and caudal : at 6° (Per side)

Insert the DRILL BIT attached to the DRIVING HANDLE into the DRILL SLEEVE FOR FIXED DRILL GUIDE and drill to desired depth. The DRILL will stop when the stop contacts the top of the DRILL SLEEVE FOR FIXED DRILL GUIDE (Fig. 9).

Note
The DRILL GUIDE-FIXED TYPE must be engaged securely to the plate prior to screw hole preparation.

Caution
Do not apply cantilever loads while the DRILL is engaged in the bone.

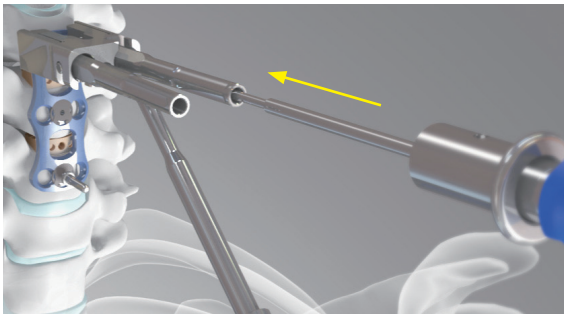


Fig. 9

B. Tapping (Optional)

Instrument	
SC7160	DRIVING HANDLE
NC7310	N-TAP Ø3.5x10 mm
NC7320	N-TAP Ø4.0x10 mm

Remove the DRILL SLEEVE FOR FIXED DRILL GUIDE ❶.
Insert the TAP attached to the DRIVING HANDLE in the desired bone site through the DRILL GUIDE-FIXED TYPE.
Rotate the TAP clockwise until it contacts the plate.
Once contact is obtained, rotate the tap counterclockwise until it is free of the bone ❷ (Fig.10).

Caution
Do not apply cantilever loads while the TAP is engaged in the bone.

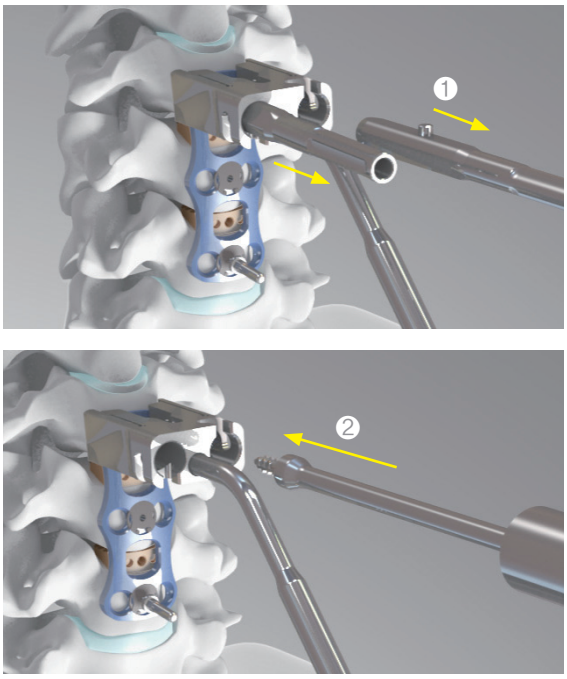


Fig. 10

C. Screw Insertion

Instrument	
NC7150	N-SCREW DRIVER & HOLDER

Select the screw of desired length from the screw caddy.
Insert the tip of the SCREW DRIVER & HOLDER into the socket of the screw using downward pressure on the SCREW DRIVER & HOLDER to secure the screw to the SCREW DRIVER & HOLDER tip (tight adjustment between the screw head socket and the screwdriver tip makes the system self-retaining).

Insert the screw in the desired bone site through the DRILL GUIDE-FIXED TYPE and rotate the SCREW DRIVER & HOLDER clockwise to advance the screw until the screw head is under the sub-plate (Fig.11).

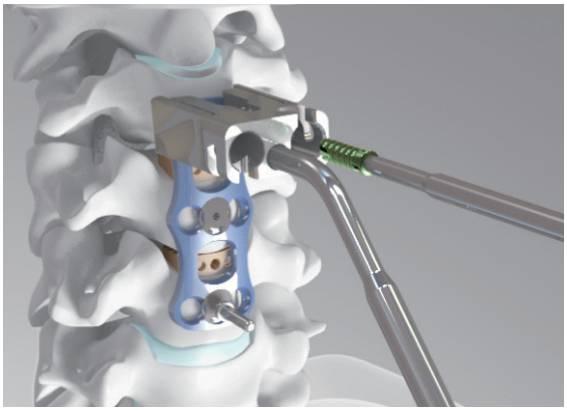


Fig. 11

2. SELF-TAPPING SCREW WITH VARIALBE TYPE

A. Drilling

Instrument	
SC7160	DRIVING HANDLE
NC7040	N-DRILL GUIDE-VARIABLE TYPE
NC7250, 7260, 7270	N-DRILL BIT Ø2.0x12,14,16 mm
NC7280, 7290, 7300	N-DRILL BIT Ø2.5x12,14,16 mm

Insert the DRILL GUIDE-VARIABLE TYPE into the desired hole inclined to appropriate direction for drilling (Fig.12).

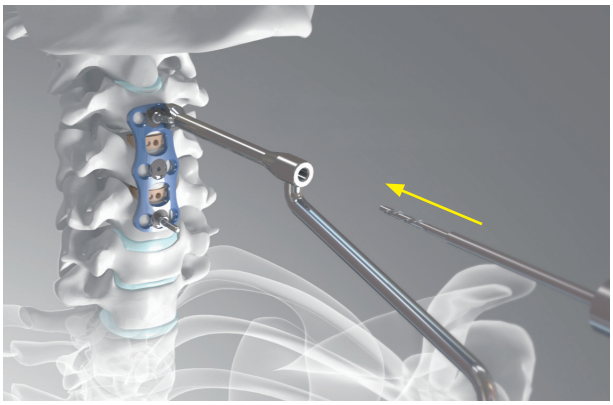


Fig. 12

Possible variable screw orientation is as follows :
- Convergence : 15° ~ -7° (Per side)
- Cephalad and caudal : 20° ~ -12° (Per side)

Insert the DRILL BIT into the DRILL GUIDE-VARIABLE TYPE and drill to desired depth.
The drill will stop when the stop contacts the top of the DRILL GUIDE-VARIABLE TYPE.

Note
The DRILL GUIDE-VARIABLE TYPE must be engaged securely to the plate prior to screw hole preparation.

Caution
Do not apply cantilever loads while the DRILL is engaged in the bone.

B. Tapping (Optional)

Instrument	
NC7310	N-TAP Ø3.5x10 mm
NC7320	N-TAP Ø4.0x10 mm

Rotate the TAP clockwise until it contacts the plate.
Once contact is obtained, rotate the TAP counterclockwise until it is free of the bone (Fig.13).

Caution
Do not apply cantilever loads while the tap is engaged in the bone.

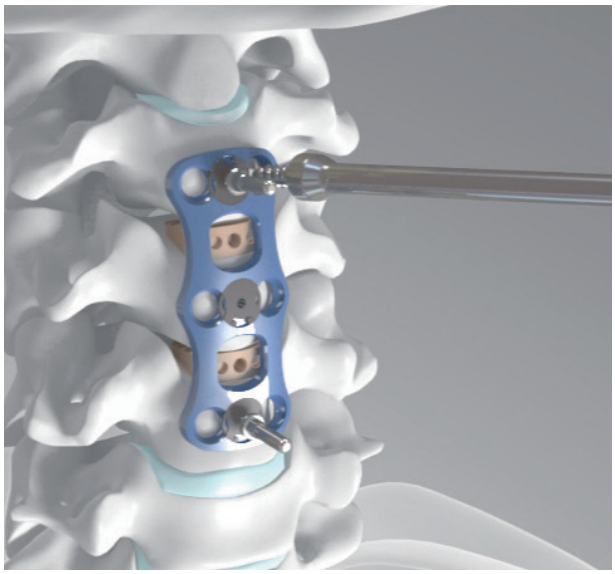


Fig. 13

C. Screw Insertion

Instrument	
NC7150	SCREW DRIVER & HOLDER

Select the screw of desired length from the screw caddy. Insert the tip of the SCREW DRIVER & HOLDER into the socket of the screw using downward pressure on the SCREW DRIVER & HOLDER to secure the screw to the SCREW DRIVER & HOLDER tip (tight adjustment between the screw head socket and the screw driver tip makes the system self-retaining).

Insert the screw in the desired bone site and rotate the SCREW DRIVER & HOLDER clockwise to advance the screw until the screw head is under the sub-plate (Fig.14).

Fig. 14

3. SELF-DRILLING SCREW

A. Awl

Instrument	
NC7210	AWL
NC7230	AWL SLEEVE
NC7240	AWL SLEEVE-FIXED TYPE

As an alternative to the DRILL GUIDE, the AWL may be used to center and direct the pathway of the self-drilling screw.
When fully deployed, the AWL can penetrate up to 8mm of bone (Fig.15).

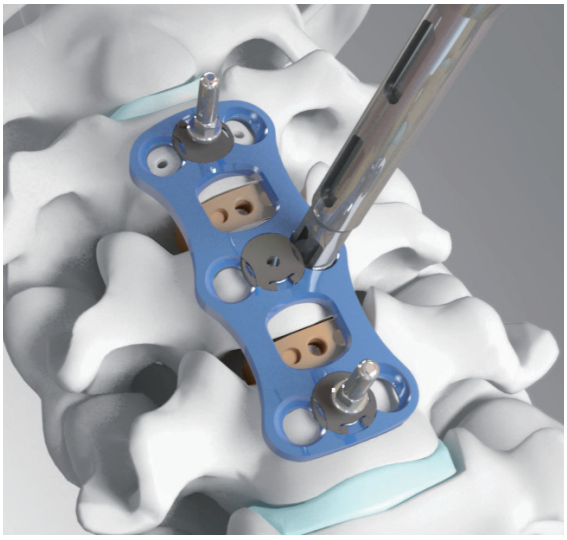


Fig. 15

Use either the AWL SLEEVE or AWL SLEEVE-FIXED TYPE on surgeon's preference.
They are designed to seat into the screw hole of the plate and to provide the AWL the correct range of angulation for screws (Fig.16).

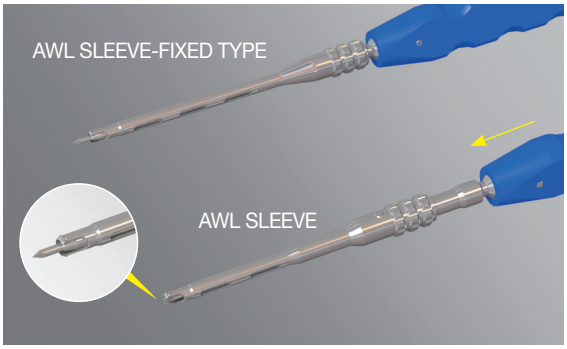


Fig. 16

Caution
Do not use the AWL without the AWL SLEEVE.

Caution
Do not apply cantilever loads while the awl is engaged in the bone.

Semi-fixed screw orientation is preset by the fixed drill guide as follows :
- Convergence : at 5° (Per side)
- Cephalad and caudal : at 6° (Per side)

Possible variable screw orientation is as follows :
- Preset convergence : 15° ~ -7° (Per side)
- Cephalad and caudal : 20° ~ -12° (Per side)

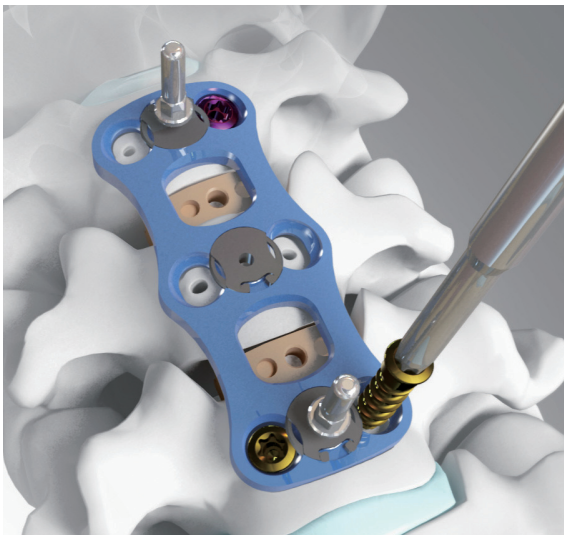


Fig. 17

B. Screw Insertion

Instrument	
NC7150	SCREW DRIVER & HOLDER

Do the screw insertion in the same manner as the self-tapping screw with variable type (Fig.17).

SCREW FINAL TIGHTENING

Instrument	
NC7150	SCREW DRIVER & HOLDER

After inserting all the screws in the plate, final tighten of the screws by turning (clockwise) the screws a half turn or 1 full turn using the SCREW DRIVER & HOLDER (Fig.18).

Caution
Do not continue to advance the bone screw once the screw is firmly seated in the plate.
Continued screw tightening may strip the bone and loosen the bone/screw purchase.

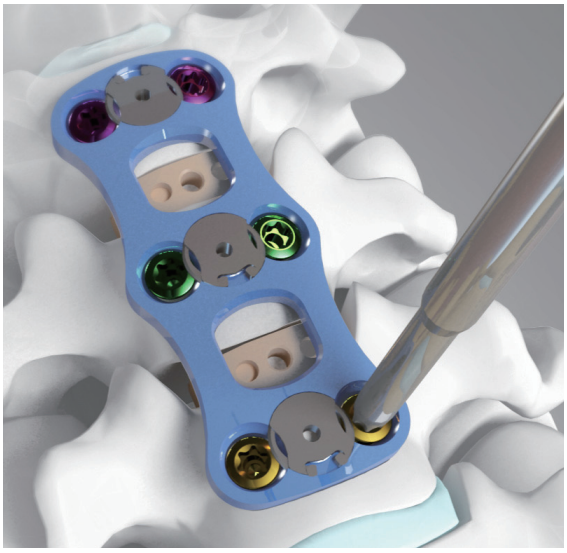
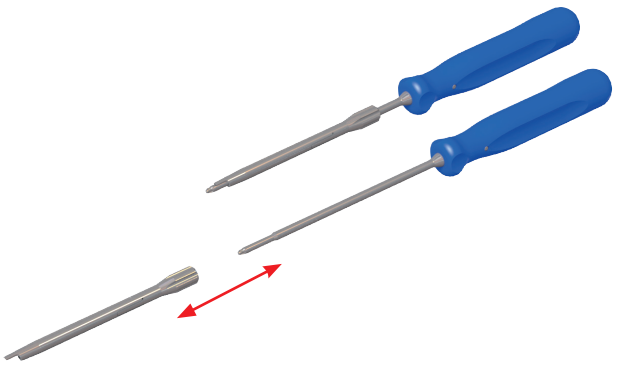


Fig. 18

SCREW REMOVAL (REVISION)

Instrument	
NC7150	SCREW DRIVER & HOLDER
NC7190	SLEEVE FOR REMOVAL

Attach the SLEEVE FOR REMOVAL to the SCREW DRIVER & HOLDER. Place them in the screw head.
The cutout at the working end of the SLEEVE FOR REMOVAL should be placed over the sub-plate on the plate ❶.



The flat surface of the SLEEVE FOR REMOVAL should be rotated clockwise or counterclockwise to deflect the sub-plate ❷.
Turn the SCREW DRIVER & HOLDER counterclockwise until the screw head passes the sub-plate (Fig.19).

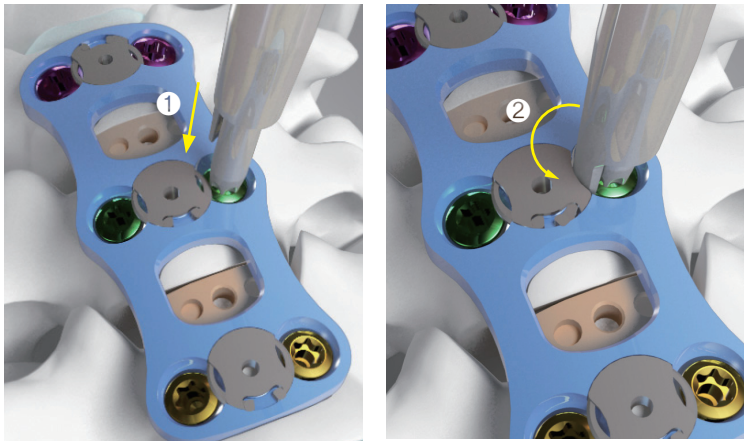


Fig. 19

Ordering Information

Implant (Single Use Only)

	Cat. No.	Size (mm)
ONE - LEVEL PLATES	** NCA1019	19
	** NCA1021	21
	** NCA1023	23
	** NCA1025	25
	NCA1027	27
	NCA1029	29
	NCA1031	31
	NCA1033	33
	NCA1035	35
	NCA1037	37
	NCA1039	39
	NCA1041	41
	NCA1043	43
	NCA1045	45

	Cat. No.	Size (mm)
TWO - LEVEL PLATES	** NCA2031	31
	** NCA2033	33
	** NCA2035	35
	** NCA2037	37
	NCA2039	39
	NCA2041	41
	NCA2043	43
	NCA2045	45
	NCA2047	47
	NCA2049	49
	NCA2051	51
	NCA2053	53
	NCA2055	55

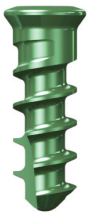
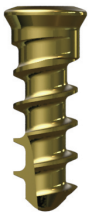
** Do not bend the plates

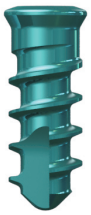
	Cat. No.	Size (mm)
THREE - LEVEL PLATES	** NCA3051	51
	** NCA3054	54
	NCA3057	57
	NCA3060	60
	NCA3063	63
	NCA3066	66
	NCA3069	69
	NCA3072	72
	NCA3075	75
	NCA3078	78
	NCA3081	81

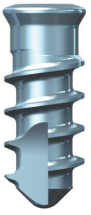
	Cat. No.	Size (mm)
FOUR - LEVEL PLATES	** NCA4063	63
	** NCA4067	67
	NCA4071	71
	NCA4075	75
	NCA4079	79
	NCA4083	83
	NCA4087	87
	NCA4091	91
	NCA4095	95
	NCA4099	99
	NCA4103	103
	NCA4107	107
	NCA4111	111

** Do not bend the plates

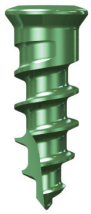
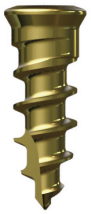
SELF-TAPPING SCREW

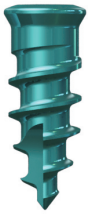
Ø3.5 Screw				
Cat. No.	Variable	Cat. No.	Semi-Fixed	Description
NC3510VT		NC3510FT		Ø3.5x10mm
NC3511VT		NC3511FT		Ø3.5x11mm
NC3512VT		NC3512FT		Ø3.5x12mm
NC3513VT		NC3513FT		Ø3.5x13mm
NC3514VT		NC3514FT		Ø3.5x14mm
NC3515VT		NC3515FT		Ø3.5x15mm
NC3516VT		NC3516FT		Ø3.5x16mm
NC3517VT		NC3517FT		Ø3.5x17mm
NC3518VT		NC3518FT		Ø3.5x18mm
NC3519VT		NC3519FT		Ø3.5x19mm
NC3520VT		NC3520FT		Ø3.5x20mm

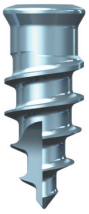
Ø 4.0 Screw				
Cat. No.	Variable	Cat. No.	Semi-Fixed	Description
NC4010VT		NC4010FT		Ø4.0x10mm
NC4011VT		NC4011FT		Ø4.0x11mm
NC4012VT		NC4012FT		Ø4.0x12mm
NC4013VT		NC4013FT		Ø4.0x13mm
NC4014VT		NC4014FT		Ø4.0x14mm
NC4015VT		NC4015FT		Ø4.0x15mm
NC4016VT		NC4016FT		Ø4.0x16mm
NC4017VT		NC4017FT		Ø4.0x17mm
NC4018VT		NC4018FT		Ø4.0x18mm
NC4019VT		NC4019FT		Ø4.0x19mm
NC4020VT		NC4020FT		Ø4.0x20mm

Ø 4.35 Screw				
Cat. No.	Variable	Cat. No.	Semi-Fixed	Description
NC4310VT		NC4310FT		Ø4.35x10mm
NC4311VT		NC4311FT		Ø4.35x11mm
NC4312VT		NC4312FT		Ø4.35x12mm
NC4313VT		NC4313FT		Ø4.35x13mm
NC4314VT		NC4314FT		Ø4.35x14mm
NC4315VT		NC4315FT		Ø4.35x15mm
NC4316VT		NC4316FT		Ø4.35x16mm
NC4317VT		NC4317FT		Ø4.35x17mm
NC4318VT		NC4318FT		Ø4.35x18mm
NC4319VT		NC4319FT		Ø4.35x19mm
NC4320VT		NC4320FT		Ø4.35x20mm

SELF-DRILLING SCREW

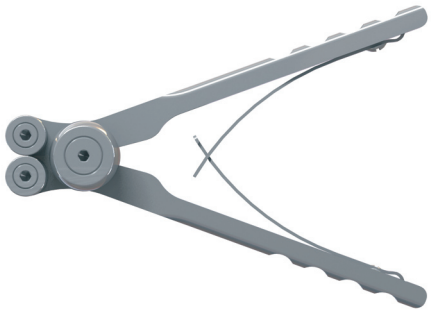
Ø3.5 Screw				
Cat. No.	Variable	Cat. No.	Semi-Fixed	Description
NC3510VD		NC3510FD		Ø3.5x10mm
NC3511VD		NC3511FD		Ø3.5x11mm
NC3512VD		NC3512FD		Ø3.5x12mm
NC3513VD		NC3513FD		Ø3.5x13mm
NC3514VD		NC3514FD		Ø3.5x14mm
NC3515VD		NC3515FD		Ø3.5x15mm
NC3516VD		NC3516FD		Ø3.5x16mm
NC3517VD		NC3517FD		Ø3.5x17mm
NC3518VD		NC3518FD		Ø3.5x18mm
NC3519VD		NC3519FD		Ø3.5x19mm
NC3520VD		NC3520FD		Ø3.5x20mm

Ø 4.0 Screw				
Cat. No.	Variable	Cat. No.	Semi-Fixed	Description
NC4010VD		NC4010FD		Ø4.0x10mm
NC4011VD		NC4011FD		Ø4.0x11mm
NC4012VD		NC4012FD		Ø4.0x12mm
NC4013VD		NC4013FD		Ø4.0x13mm
NC4014VD		NC4014FD		Ø4.0x14mm
NC4015VD		NC4015FD		Ø4.0x15mm
NC4016VD		NC4016FD		Ø4.0x16mm
NC4017VD		NC4017FD		Ø4.0x17mm
NC4018VD		NC4018FD		Ø4.0x18mm
NC4019VD		NC4019FD		Ø4.0x19mm
NC4020VD		NC4020FD		Ø4.0x20mm

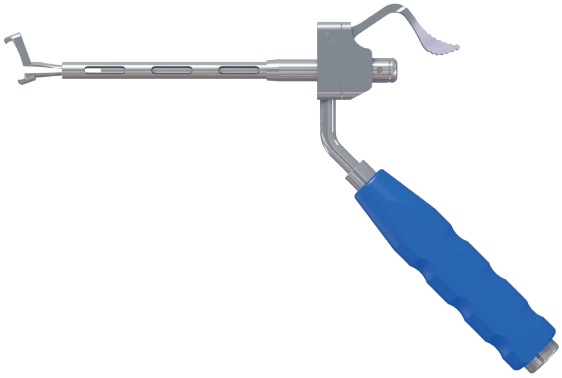
Ø 4.35 Screw				
Cat. No.	Variable	Cat. No.	Semi-Fixed	Description
NC4310VD		NC4310FD		Ø4.35x10mm
NC4311VD		NC4311FD		Ø4.35x11mm
NC4312VD		NC4312FD		Ø4.35x12mm
NC4313VD		NC4313FD		Ø4.35x13mm
NC4314VD		NC4314FD		Ø4.35x14mm
NC4315VD		NC4315FD		Ø4.35x15mm
NC4316VD		NC4316FD		Ø4.35x16mm
NC4317VD		NC4317FD		Ø4.35x17mm
NC4318VD		NC4318FD		Ø4.35x18mm
NC4319VD		NC4319FD		Ø4.35x19mm
NC4320VD		NC4320FD		Ø4.35x20mm

Instruments

NC7010 N-PLATE BENDER



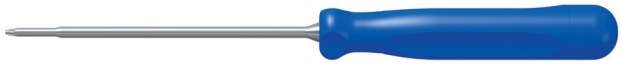
NC7020 N-PLATE HOLDER



NC7030 N-DRILL GUIDE-FIXED TYPE

NC7040 N-DRILL GUIDE-VARIABLE TYPE

NC7150 N-SCREW DRIVER & HOLDER

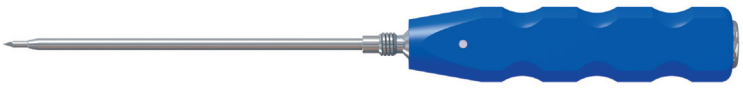


NC7170 TEMPORARY FIXATION PIN DRIVER

NC7180 TEMPORARY FIXATION PIN

NC7190 SLEEVE FOR REMOVAL

NC7210 AWL



NC7230 AWL SLEEVE

NC7240 AWL SLEEVE-FIXED TYPE

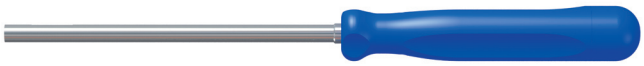
NC7250, 7260, 7270 N-DRILL BIT Ø2.0x12, 14, 16mm

NC7280, 7290, 7300 N-DRILL BIT Ø2.5x12, 14, 16mm

NC7310 N-TAP Ø3.5x10mm

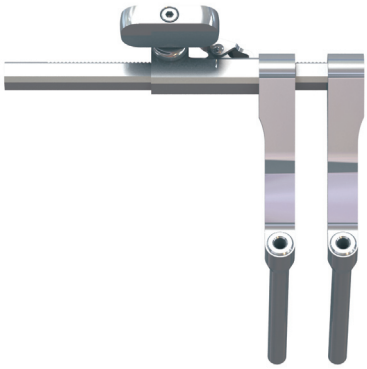
NC7320 N-TAP Ø4.0x10mm

NC7330 RETRACTOR FIXATION PIN DRIVER



SC7160 DRIVING HANDLE

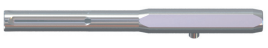
SC7230 RETRACTOR



SC7261 RETRACTOR FIXATION PIN-L

SC7262 RETRACTOR FIXATION NUT

NC7340 DRILL SLEEVE FOR FIXED DRILL GUIDE



NC7350 TEMPORARY FIXATION PIN for SCREW HOLE

Important Information on the ASPIRON™ ACP SYSTEM

PURPOSE
The ASPIRON™ Anterior Cervical Plate System components are temporary implants that are intended for anterior interbody screw/plate fixation of the cervical spine during the development of a cervical spinal fusion.

DESCRIPTION
The ASPIRON™ ACP System consists of a variety of shapes and sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. All implant components are made from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136. The main plate and screws are anodized according to the internal process (5% Phospheric acid solution under pH 1.5). The same anodizing process is also applied to the conventional ASPIRON™ ACP System (K131200) and Maxima (K061002). This material is not compatible with other metal alloys. Stainless steel and titanium implant components should not be used together in a construct. U&I Corporation expressly warrants that these devices are fabricated from the foregoing material specification. No other warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Do not use any of the ASPIRON™ ACP System components with the components from any other system or manufacturer. All implants are single use only. The Type 2 of screws and short plates are added to the conventional ASPIRON™ ACP System in this submission. Type 2 screw has thread until the tip of screw for easy insertion.

INTENDED USE / INDICATIONS FOR USE
The ASPIRON™ ACP System is intended for anterior inter-vertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications :
- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration disc confirmed by patient history and radiographic studies);
- Spondylolisthesis
- Trauma (including fractures, dislocation)
- Spinal stenosis
- Tumors
- Deformity (defined as scoliosis, kyphosis, or lordosis)
- Pseudoarthrosis
- Failed previous fusion

WARNING : The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CONSTRAINDICATIONS
Contraindications include, but are not limited to:
- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality or anatomical definition.
- Any case not described in the indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

POTENTIAL ADVERSE EVENTS
All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible.
With instrumentation, a listing of possible adverse events includes, but is not limited to:
- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) react to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- Infection
- Dural tears.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status
- Death.

Note : Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNINGS AND PRECAUTIONS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system. The ASPIRON™ Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the ASPIRON™ Anterior Cervical Plate System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction and proper selection and placement of the implant are important considerations in the successful utilization of the ASPIRON™ Anterior Cervical Plate by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been show to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Surgical Technique manual can be obtained by contacting U&i corporation.
CAUTION : For use on or by the order of a physician only.
CAUTION : Federal law (USA) restricts these devices to sale by or on the order of a physician.

Other preoperative, intraoperative, and postoperative warnings are as follows:
PREOPERATIVE
- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. If the "C" shaped Sub-plate in the plate is shrunk, do not use the plate. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The ASPIRON™ Anterior Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- All components and instruments should be cleaned and sterilized before use as below description. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE
- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing; make sure that none has loosened during the tightening of the other screws. Also secure the "C" shaped sub-plate to be expanded fully on the screw. Failure to do so may result in screw loosening.

CAUTION : Excessive torque on the threads of screw may cause the threads to strip in the bone, reducing fixation.

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. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. 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 or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone 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(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed b roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- The ASPIRON™ Anterior Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain. (2) Migration of implant position possibly resulting in injury, (3) Risk of additional injury from post-operative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult. (5) Pain, discomfort, or abnormal sensations due to the presence of the device. (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding.
- While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.
- 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 ASPIRONTM Anterior Cervical Plate System components should ever be reused under any circumstances.

PACKAGING
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to U&I Corporation or distributor.

CLEANING AND DECONTAMINATION
Manual Cleaning Procedure
1. Before starting the cleaning procedure, all dismantable instruments should be disassembled.
2. Use the neutral pH enzyme soaking solution that has been prepared.
3. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes.
   Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
   Note : The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
4. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
5. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
6. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
7. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
8. Thoroughly clean by repeating Steps 5 and 6 with freshly prepared cleaning solution.
9. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
10. Finish the cleaning procedure when the instruments are visually clean. If the instruments are not visually clean, repeat the cleaning procedure when instruments has no visual contamination.

Note : The DEPTH GAUGE(NC7220) and RETRACTOR(SC7230) should be disassembled before cleaning.

Automated Cleaning Procedure
Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.
- CAUTION : Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Implants removed from a patient or that contact bodily tissues or fluids should never be reused.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
- Verify that the instruments are in operation condition.

STERILIZATION
Unless noted otherwise on the package labeling, the ASPIRON™ Anterior Cervical Plate System components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods: Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

- Recommended method to achieve a degree of sterility equal to at least 10^{-6}.
- Sterilize by the autoclaving procedure regularly used in the hospital.
- All products should be disassembled as Part No. unit before the sterilization.
- Only FDA-cleared wraps should be used when you perform the sterilization.
- Over-killed Method was applied to the steam sterilization.

	Steam Condition	Temperature	Sterilization Time	Drying Time
Method 1	Steam, Gravity Cycle	132℃	20 min	20 min
Method 2	Steam, Pre-vacuum Cycle	132℃	4 min	20 min

* Wrapped method was used for the steam sterilization validation.

This gravity-displacement cycle, 132 °C, exposure time 20 minute cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

SAFETY AND CONDITIONALITY IN THE MR ENVIRONMENT
- The ASPIRON™ Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment.
- The ASPIRON™ Anterior Cervical Plate System has not been tested for heating or migration in the MR environment.

GUARANTEE
The guarantee is only applicable if the device is used in accordance with normal conditions as defined in these instructions and in conformity with the recommended surgical technique.

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