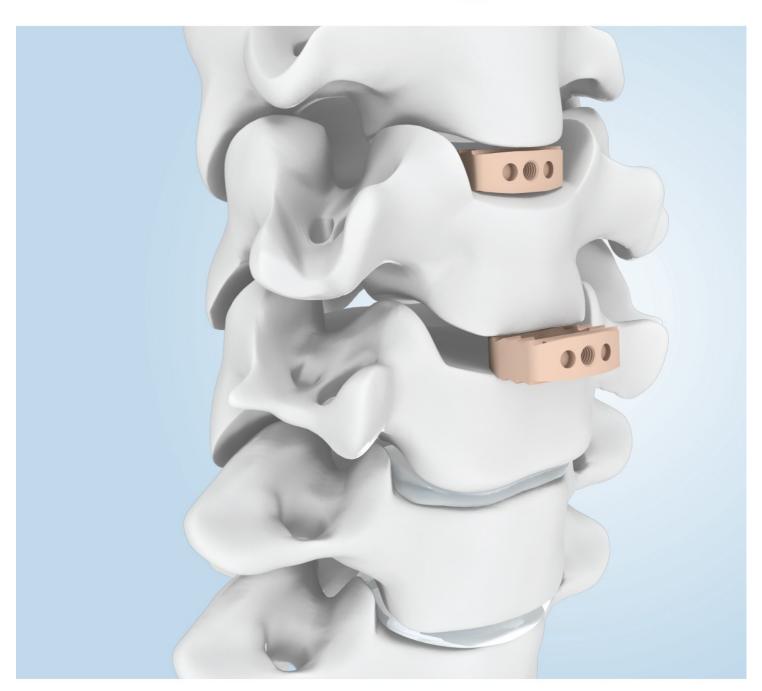
VelofixTM PEEK Cervical Cage

Surgical Technique





- 1 Rounded edges for easier insertion
- Contact surfaces with prominent serrations enhance implant stability and prevent implant migration at the endplates
- 3 Large central window
 allows for improved loading capacity for bone
 graft material, optimizing bony integration

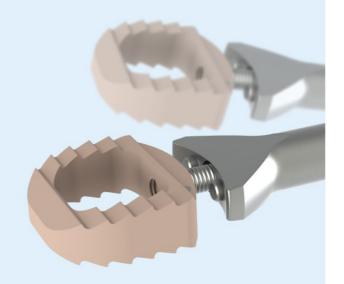




Three radiographic tantalum rod markers allow for improved fluoroscopic placement and post-operative examination with no artifact during x-ray evaluation



for securing implant while loading and easy mechanism for release



PATIENT POSITIONING AND SURGICAL EXPOSURE

The patient is placed in supine position, Fluoroscopy can be made available for interoperative check. An anterior approach to the cervical spine is used through a right or left cervicotomy, according to the surgeon's preference. The anterior aspect of the vertebral bodies cephalad and caudal to the segment involved are exposed.

DISTRACTION OF THE DISC SPACE

Instrument		
SC7170	TEMPORARY FIXATION PIN DRIVER	
SC7230	RETRACTOR	
SC7260	RETRACTOR FIXATION PIN	

Insert the RETRACTOR FIXATION PIN in the vertebrae above and below the disc to be removed with the TEMPORARY FIXATION PIN DRIVER (Fig. 1). Insert the sleeves of the RETRACTOR on the RETRACTOR FIXATION PIN till fully seated 1. Unscrew the RETRACTOR wheel to open the intervertebral space to the desired height (Fig. 2). Care should be taken in order to avoid over distraction.

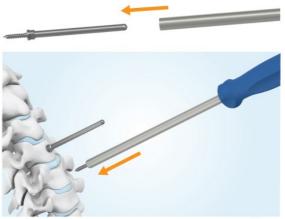
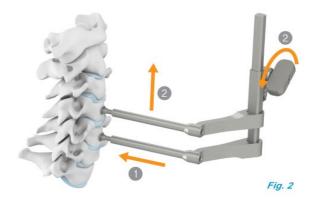


Fig. 1

DISCECTOMY

A conventional scalpel discectomy is performed by incising the annulus. Bilaterally, soft fragments from the intradiscal space or extruded fragments are removed with the disc rongeur in a conventional

A complete discectomy may not be possible at this stage until the disc space distraction is accomplished.



ENDPLATE PREPARATION

Under distraction, complete a neural decompression by trimming large posterior osteophytes (if present).

To remove the cartilaginous endplates, thereby creating a flat surface of bleeding bone, choose one of the following options:

Option 1

	Instrument
PE1001	PEEK C CAGE INSERTER
PE141205R~10R	PEEK CAGE RASP, W14D12H5~10
PE141405R~10R	PEEK CAGE RASP, W14D14H5~10
PE161405R~10R	PEEK CAGE RASP, W16D14H5~10

Connect the size-specific RASP to the PEEK C CAGE INSERTER (Fig. 3).

Introduce the RASP into the intervertebral space to scrape the cartilaginous endplates (Fig.4).





Fig. 4

Option 2

	Instrument	
PE2010	SINGLE SIDE RASP SMALL	
PE2020	SINGLE SIDE RASP MEDIUM	
PE2030	SINGLE SIDE RASP LARGE	

• Size in small (W14D12), medium (W14D14), large (W16D14)

The SINGLE SIDE RASP can be alternatively used (Fig.5).

Option 3

Instrument		
PE1040	CERVICAL CAGE CURETTE	

The CURRETE is another option for scraping (Fig.6).



Fig. 5

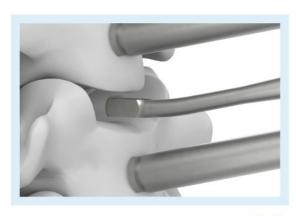


Fig. 6

SELECTION OF THE CAGE

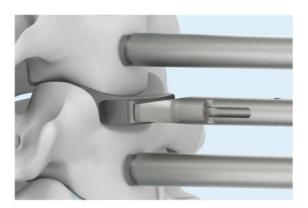
	Instrument
PE1001	PEEK C CAGE INSERTER
PE141200T *	PEEK CAGE TRIAL

• Size in small (W14D12), medium (W14D14), large (W16D14)

Connect the TRIAL to the PEEK C CAGE INSERTER. The TRIAL is then introduced into the intervertebral space under fluoroscopic control (Fig.7)

Make sure the cranial faces upwards when inserting the trial. It is generally advisable to select the minimal TRIAL height for which proper stability is obtained. To test this stability, distraction is momentarily relaxed.





FILLING IN THE CAGE

Instrument		
PE1001	PEEK C CAGE INSERTER	
PE1020	PACKING PLATFORM	
CC0932	PEEK-C BONE PACKING BAR	

Connect the selected PEEK Cervical Cage to the PEEK C CAGE INSERTER (Fig. 8) and place the cage on the PACKING PLATFORM.



Fig. 8

Autologous bone or biologics are options for filling the cage with the PEEK-C BONE PACKING BAR (Fig. 9).

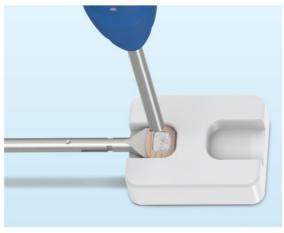


Fig. 9

INSERTION OF THE IMPLANT

Instrument		
PE1030	DEPTH LIMITER 0 mm	
PE1032	DEPTH LIMITER 2 mm	
PE1034	DEPTH LIMITER 4 mm	

Insert the cage into the disc space (Fig. 10).

The cage is impacted while distraction of the interbody space is maintained in such a manner that minimal resistance is felt during insertion.

Optionally, the DEPTH LIMITER can be used to control the insertion depth of the cage (Fig. 11).

Use image intensifier to confirm the position of the implant (Fig. 12).

When the cage positioning is satisfactory, apply compression to the treated segment: first release the retractor ramp brake 1, then turn the wheel 2 (Fig.13).

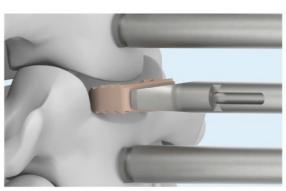


Fig. 10

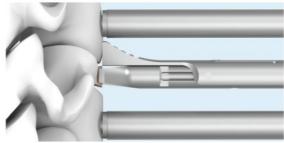
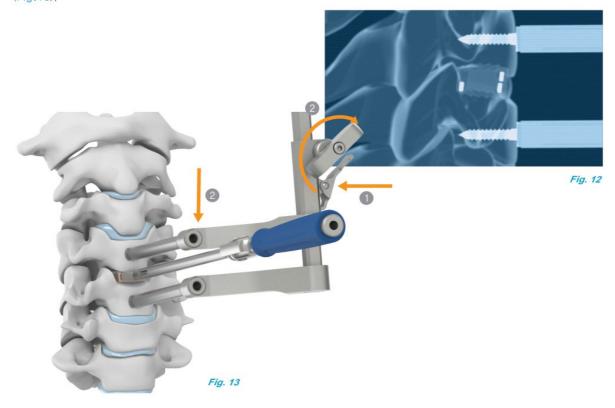


Fig. 11



SUPPLEMENTAL FIXATION

For multi-segmental instrumentation, Velofix[™] PEEK Cervical Cage is intended to be used with U&I supplemental fixation, e.g. ASPIRON[™] or MAXIMA[™] ACP.

IMPLANT REMOVAL/REVISION

Should removal/revision of the device be determined necessary by the surgeon, an osteotome can be used at the interface between the bone and both superior and inferior faces of the implant. This effectively cuts the fused column of bone at the level of the boundaries of the implant. Once the fused column is completely cut, forceps can be used to remove the implant from the space. This may be done under slight distraction.

For a revision, follow the standard surgical technique.

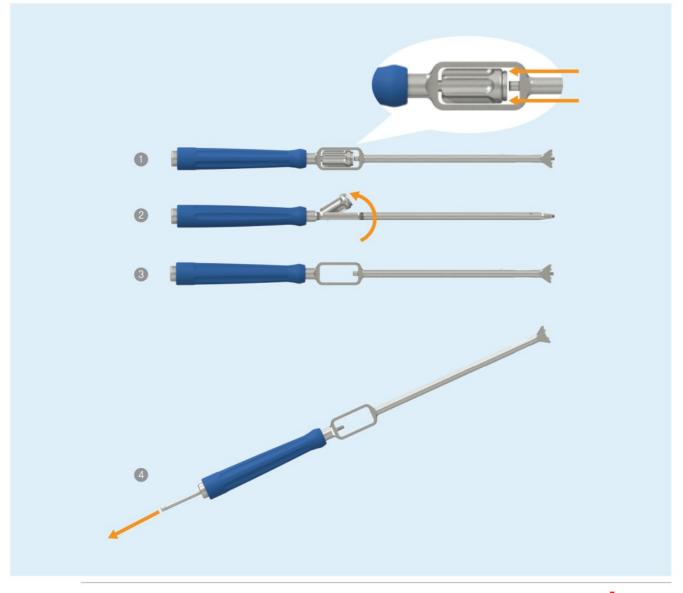


DISASSEMBLE CAGE INSERTER

Instrument PE1010 PEEK-C CAGE INSERTER

Disassemble the CAGE INSERTER prior to cleaning according to the disassembling instruction shown here.

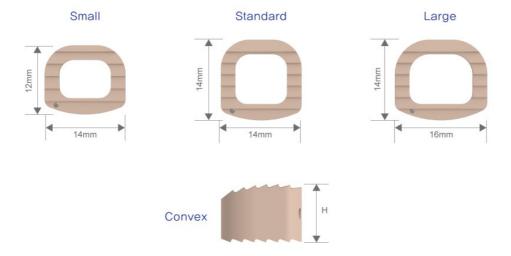
To assemble the CAGE INSERTER, follow the instruction in reverse order.



Ordering Information

Implant (Single-Use Only)

Cat. No.	W (mm)	D (mm)	H (mm)	Size
PE141205	14	12	5	
PE141206	14	12	6	
PE141207	14	12	7	Small
PE141208	14	12	8	
PE141209	14	12	9	
PE141210	14	12	10	
PE141405	14	14	5	
PE141406	14	14	6	
PE141407	14	14	7	Standard
PE141408	14	14	8	
PE141409	14	14	9	
PE141410	14	14	10	
PE161405	16	14	5	
PE161406	16	14	6	
PE161407	16	14	7	Large
PE161408	16	14	8	
PE161409	16	14	9	
PE161410	16	14	10	



Instruments

TRIAL

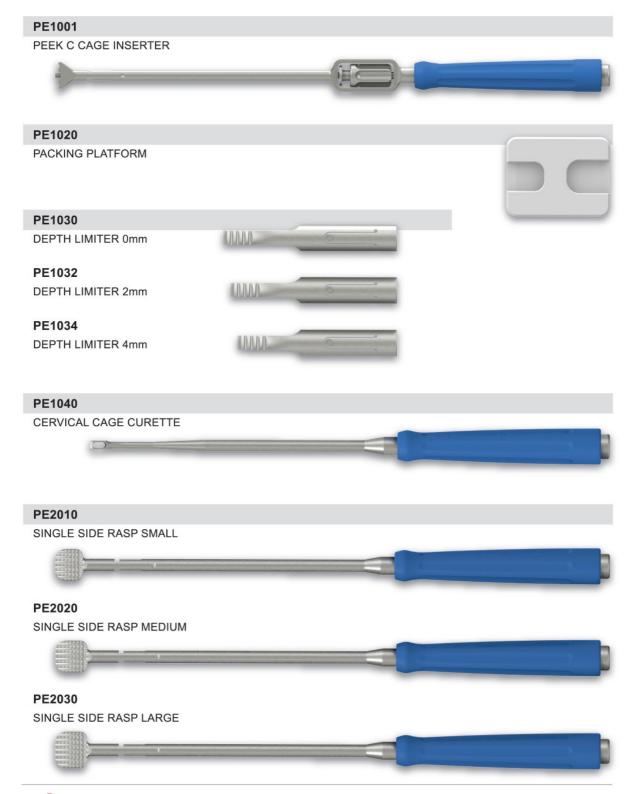
Cat. No.	W (mm)	D (mm)	H (mm)
PE141205T	14	12	5
PE141206T	14	12	6
PE141207T	14	12	7
PE141208T	14	12	8
PE141209T	14	12	9
PE141210T	14	12	10
PE141405T	14	14	5
PE141406T	14	14	6
PE141407T	14	14	7
PE141408T	14	14	8
PE141409T	14	14	9
PE141410T	14	14	10
PE161405T	16	14	5
PE161406T	16	14	6
PE161407T	16	14	7
PE161408T	16	14	8
PE161409T	16	14	9
PE161410T	16	14	10



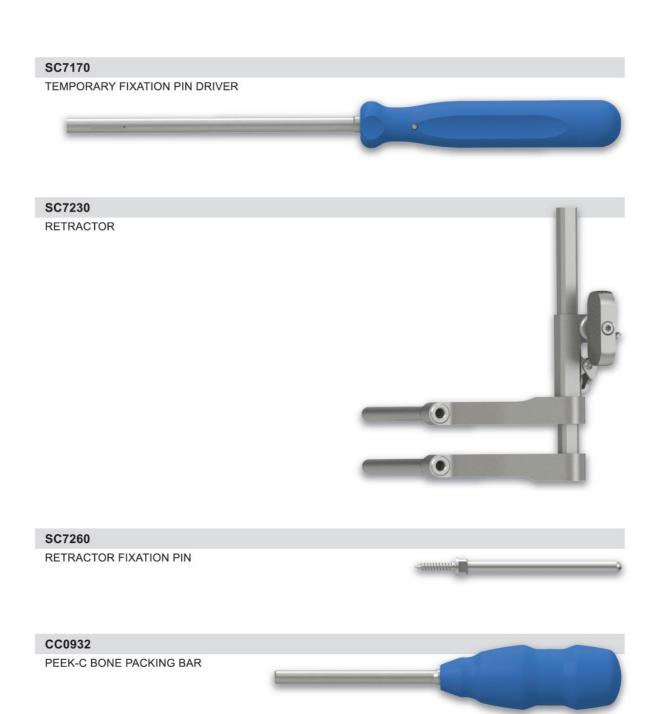
RASP

Cat. No.	W (mm)	D (mm)	H (mm)
PE141205R	14	12	5
PE141206R	14	12	6
PE141207R	14	12	7
PE141208R	14	12	8
PE141209R	14	12	9
PE141210R	14	12	10
PE141405R	14	14	5
PE141406R	14	14	6
PE141407R	14	14	7
PE141408R	14	14	8
PE141409R	14	14	9
PE141410R	14	14	10
PE161405R	16	14	5
PE161406R	16	14	6
PE161407R	16	14	7
PE161408R	16	14	8
PE161409R	16	14	9
PE161410R	16	14	10









Important Information on the Velofix™ PEEK Cervical Cage

PURPOSE
The Velotival PEEK Cervical Cage is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. This system is indicated for single-level use only in the nervinal and thoracic anterior spine.

DESCRIPTION
The Velofix PEEK Cervical Cage is intended to be radiolucent and the interior space of the product is to be used with autograft or bone graft substitutes. The Velofix PEEK Cervical Cage is available in several sizes with implant selection based on each individual clinical rases.

#MOVEMENT CHIEF CONTROL CONTR

After made or Invitance in the International Control of the International Control of Internation

COMBINATION SYSTEM Velofix™ PEEK Cervical Cage is is used with anterior cervical plate system and posterior fixation system. (screws, hooks, transverse

- links, connectors, etc.)

 CONTRAINDICATIONS

 Contraindications include, but are not limited to:

 Any case needing to mix metals from different components.

 Any case not described in the indications.

 Any case not described in the indications.

 Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital ahonomalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count/WEO, or a marked left shift in the WEO differential count.

 Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.

 Any patient numilling to co-operate with postoperative instructions.

 Fewor or lexicocytosis.

 Infection, local to the operative site.

- Pegnancy
 Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation
 Signs of local inflammation
 Signs of local inflammation
 Suspected or documented metal allergy or intolerance.
 These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
 Prior fusion at the level(s) to be treated.
 Contraindications of this device are consistent with those of other spinal system.

POSSIBLE ADVERSE EVENTS All of the possible adverse events or co

- POSSIBLE ADVERSE EVENTS
 All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation is stained of possible adverse events or complications includes, but is not limited to:

 Sone loss or decrease in bone density, possibly caused by stesses shietding, and an adversarial possible and adversarial possible and
- autoimmune disease.

 Fracture, microfacture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the autograft, or at the bone graft harvest situ-at, above, and/or below the level of surgery.

 Gastrointestinal complications.

 Graft donor site complications including pain, fracture, infection, or wound healing problems.

 Hemorrhage, hematoma, coclusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.

 Wound necrois or wound defisience.

 Heminated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.

- Infection
 Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neurona, tingling sensation, sensory loss and/or spatams.
 Non-minol (no peacudarthoses), Delayed union. Mal-union.
 Postoperative change in spiral curvature, loss of correction, height, and/or reduction.
 Subsidence of the development of pain curvature, loss of correction, height, and/or reduction.
 Subsidence of the development of pain curvature, loss of correction are reversed and pain.
 Subsidence of the development of pain and/or pain caused by improper positioning and placement of implants or instruments.
 NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNING
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autogriaf or bone graft substitutes may not be successful. No spinal implient can withstand body loads without the support of bone. In this event, bending, boxening, dissessembly and/or benealing to other developed by the eventually occur? Predepenties and operating procedures, including workedge of surgical bedringes, proper of the developed by the eventual product in the properties of the eventual products, including workedge of surgical bedringes, proper of the developed products, including workedge of surgical bedringes, proper Newer rouse an implicat under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patients that may lead to early presslage. Damage of the thread will reduce the stability of the instrumentation. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warred of this consequence. Obese, maintoinshed, and/or alcohol abuse patients are also poor "armifetates for storie fusion fusion."

- PRECAUTIONS

 PRYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

 CAUTION FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE CRODER OF A PHYSICIAN.

 CAUTION FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE CRODER OF A PHYSICIAN.

 Patients who since have been shown to have an increased incidence of non-unions. Such patients whould be advised of this fact and wamend 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.

 Safety and effectiveness have not been established for patients with the following conditions; previous fusion attempt at the involved levels), spondyloitshesis greater than Creden is the control of the patient is expected useful life of the appliance. In such case, should be the use of patients of the previous strains and pregnancy decreases the expected useful life of the appliance. In such case, on the patients of the patient should be reported useful life of the appliance. In such case, on the patients of the patients of the propagate patients of the patients of the propagate patients of the propagate patients and surgical techniques, cautions, potential risks associated with such spinal surgery. Those devices are propagated to the consideration of the patient should be instructed in detail about the imitations of the implication and pregnancy and the patients and surgical techniques, cautions, potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre-ipost-operative patient management are considerations or reduction of the patient weight or other patients when the patient weight or the patient weight or other shall be the many including a tran
- placed of it. An active, coestitated, or deministed patient who cannot properly use weight supporting devices may be particularly at this during processor and the property of the property of

MRI INFORMATION

PEEK Cervical Cage has not been evaluated for safety and compatibility in the MRI environment.

PEEK Cervical Cage has not been tested for heating or migration in the MRI environment.

IMPLANT SELECTION

PRLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure.
Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to
the size and shape of human bones. Utless great care is taken in patient selection, proper placement of the implant, and
prostoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent
breakage, bending or lossening of the device before the healing process is complete, which may result in further rigury or the
need to remove the device prematurely.

- 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. Implications and instruments should be protected during storage, especially from corresive environments.

 Since mechanical parts are involved, the surgeor should be familiar with the various components before using the equipment and should personally assemble the devices to evily that all parts and necessary instruments are present before the surgery.
- begins.

 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate invited of impaint sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used to be used. Or lines sterile processing the start of the sterile components should be deaned and sterilized before use. Additional sterile components should be available to the sterile components should be available.

- railable applicable surgical technique manual should be carefully followed. tion should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of
- The instructions in any available approximate projection in a projection of the spiral cord and nerve roots. Disnayor or was a first project and in a spiral cord and nerve roots. Disnayor or was a first project pro

POSTOPERATIVE The physician's postop

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

 Detailment and a search of the patient of the patient of the patient of the patient of the patient. If partial weight bearing is a more complications which can course as a result of excessive weight bearing or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debitiated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jobs 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 losen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially infline and wisting motions and any bye of sport participation. The patient should be advised not to smoke or consume excess alcohol during the tone healing process.

 **Faiture 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 bedraing, losening, or breakage of the device. It is important that immobilization of the union is established and confirmed by reentiquengraphic examination. Where there is a non-union, or if the components losen, beat marked restricts in such a manner that reuse in another surgical procedure is not possible.

 **Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.
 PACKAGING, LABELING AND STORAGE
 The implants are supplied clean and NON-STERILE. They must be sterilized prior to use(see below).
 The implants are delivered in package.
 The implants are delivered in package.
 Implant is given in the labeling of each package.
 Implant is given in the labeling of each package.
 Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the steringth and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants, implants and instrument in storage should be protected from corrosive environments such as salt air mosture, etc. Inspection and trial assembly are recommended prior to surgery to determine if the instruments or implants have been disreaged during storage or protective.
 Durningel packages or protective storage of the protection and trial assembly are recommended prior to surgery to determine if the instruments or implants have been disreaged ording storage or protective.

CLEANING AND DECONTAMINATION

- CLEANING AND DECONTAMINATION

 Preparation of Cleaning Agents

 Prepare neutral pit enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Manual Cleaning Procedure

 Manual Cleaning Procedure

 Lise the restrict pit enzyme and cleaning agents at the use-dilution and allow to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (perficular attention shall be given to crevices, luminers, maked surfaces and other hard-to-clean acess) until all visibles soil has been removed. Lumens should be changed when it becomes grossly contaminated (bloody and/or turbid).

 Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid). Remove the device from the enzyme solution and miner 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.

 Prepare the neutral pit cleaning detergent solution and sonicate for 10 minutes, preferably at 4-5-50 kHz.

 Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 4-5-50 kHz.

 Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) throoughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.

 Prepared then pages and 6 with freshy prepared cleaning solution.

 Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

 Automated Cleaning Procedure

- 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
- se instruments should be cleared following the manual cleaning procedure above. An automated system way membed by fine for required UTION. Use of sodium hydroxide (NaOH) is prohibited of corrective products and/or instruments including abrasive sponges and metal brushes should be av-caused in the control of the product of the control of the cont

STERILIZATION
The Velotive PEEK Cervical Cage and general instruments are provided non-sterile.
All implants and instruments used in surgery must be sterilized by the hospital prior to use. The products must be unpackaged, disassembled (if applicable) and cleaned as specified above, prior to sterilization. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Gravity	132°C (270°F)	20 min	20 min
Steam	Pre-Vacuum	132°C (270°F)	4 min	20 min

PRODUCT COMPLAINTS

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaints or who has experienced any dissalifaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or U&I. Further, if any of the implanted spins system component(s) ever "inalitunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, the distributor should be notified immediately, if any U&I product ever "inalitunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately in your name and address, the nature of the complant and notification of whether a written report from the distributor is requested. The use-life of all instruments used with Velotix™ PEEK Cervical Cage is 5 years.

FURTHER INFORMATION

INFORMATION ed directions for use of this system (surgical operative techniques) are available at no charge upon request. If further needed or required, please contact US.



Manufactured by U&i Corporation

20, Sandan-to 76beon-gil(Rd), Ujeonghu-si (Syeonggi-do, 480-859, Korea
Telephone: +82-31.852.0102 Fax: +82-31.852.0107
E-mai: information@youic.com
Web-site: http://www.youic.com

Represented in the U.S. by RCRI Inc.
Principal Regulatory and Quality Advisor
Regulatory & Clinical Research Institute, Inc.
5353 Vibryata Boulevard, Suite 505
Wimmapple, MR 55416-1354
Wimmapple,

NOTEC	
NOTES	



Headquarter

20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea 480-859 Tel. + 82 (31) 852 0102 Fax. +82 (31) 852 9025

USA Office

555 W Lambert Road Suite F Brea, CA 92821 Tel. + 1 (714) 280 4955

Fax. +1 (714) 209 7571