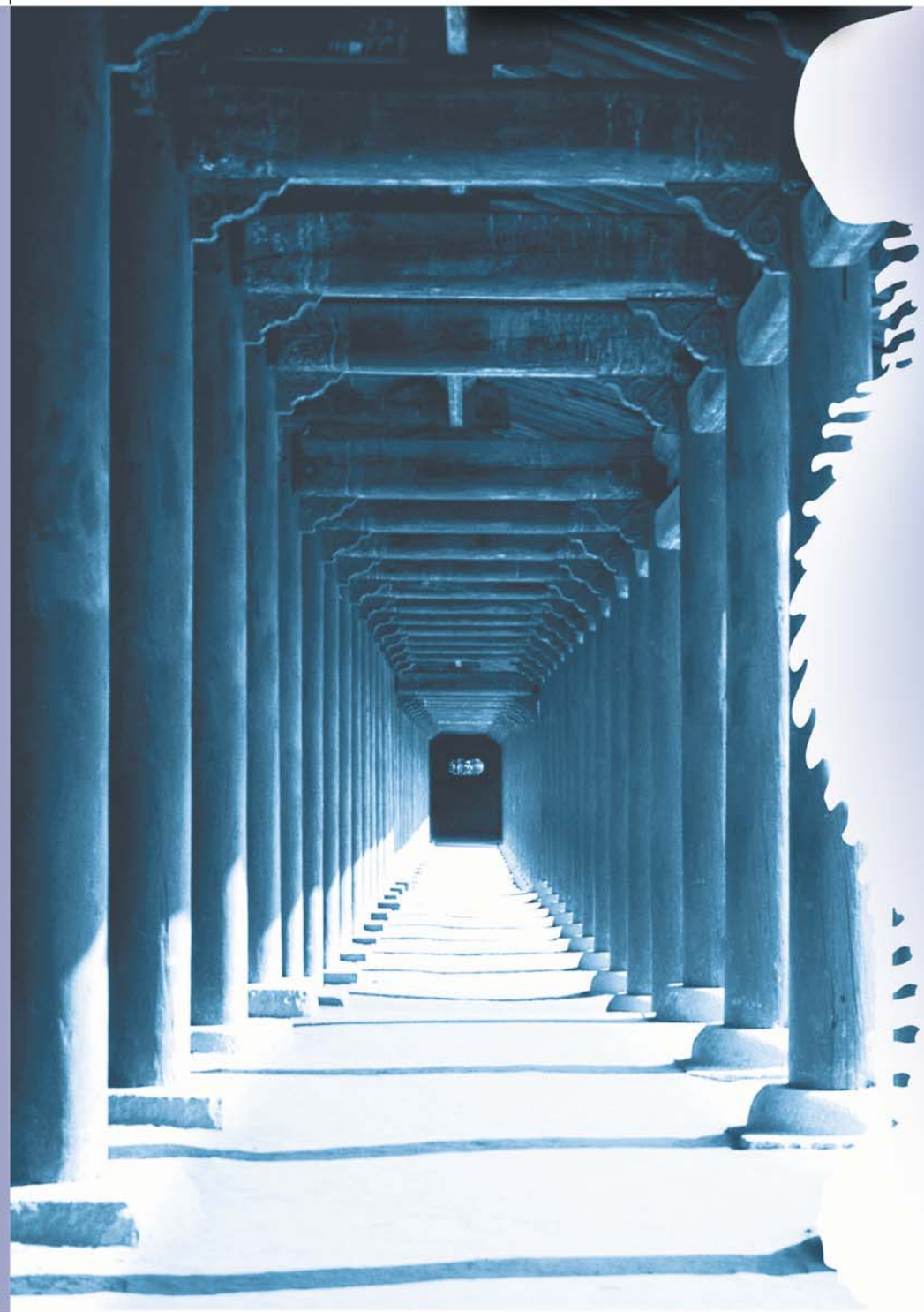


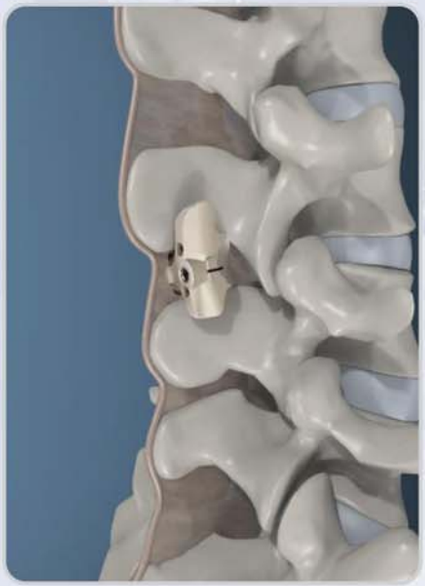
CE 0120

HEKTOR®

Interspinous Process Decompression Device

BMK®
Global Medical Company

HEKTOR®



HEKTOR® is implanted through a small incision in patient's back, often using just local anesthesia.
The procedure takes anywhere form 45-60 minutes, but the pain relief and improved physical function may last for years.

HEKTOR® is a optima peek implant that is placed between two bones, called spinous processes, in patient's back. HEKTOR® is minimally invasive.
When implanted, the HEKTOR® is not positioned close to nerves or the spinal cord, but rather behind the spinal cord, between the spinous processes.

ADVANTAGE

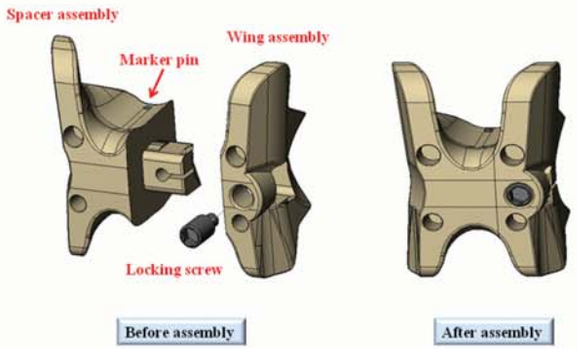
- Anatomical shape
- Minimally invasive procedure with simple steps
- preservation of the supraspinous ligament and bone tissue
- Quick functional recovery
- Fast pain relif

INDICATION

The device is indicated for surgical decompression in cases with spinal and radicular stenosis performed with a minimally invasive approach under local anesthesia.

Design Chracteritics

LOCKING MECHANISM

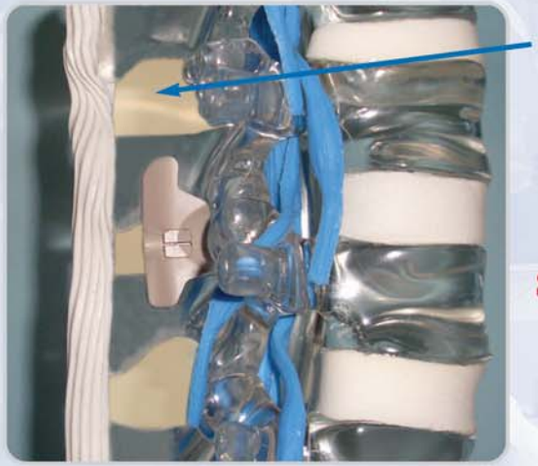


TREATMENT OF LUMBAR SPINAL STENOSIS

The HEKTOR® Interspinous Dynamic System is implanted through a small incision in patient's back, often using just local anesthesia. The procedure takes anywhere from 45~60 minutes, but the pain relief and improved physical function may last for years.

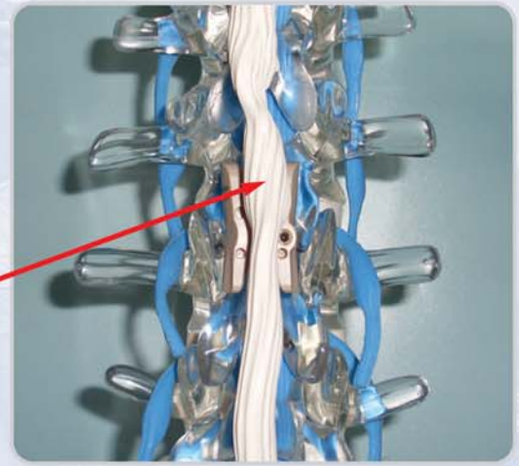
The HEKTOR® Interspinous Dynamic System is a PEEK OPTIMA implant that is placed between two adjacent spinous processes of the lumbar spine during a minimally-invasive procedure to decompress neural structures, typically to treat a patient suffering from symptomatic degenerative lumbar spinal stenosis (DLSS). When implanted, The HEKTOR® is not positioned close to nerve or the spinal cord, but rather behind the spinal cord, between the spinous processes.

Design Chracteritics



Interspinous ligament

Supraspinous ligament



ADVANTAGE

- Anatomical shape
- Minimally invasive procedure with simple steps
- Preservation of the supraspinous ligament and bone tissue
- Quick functional recovery
- Fast pain relief

Surgical Technique

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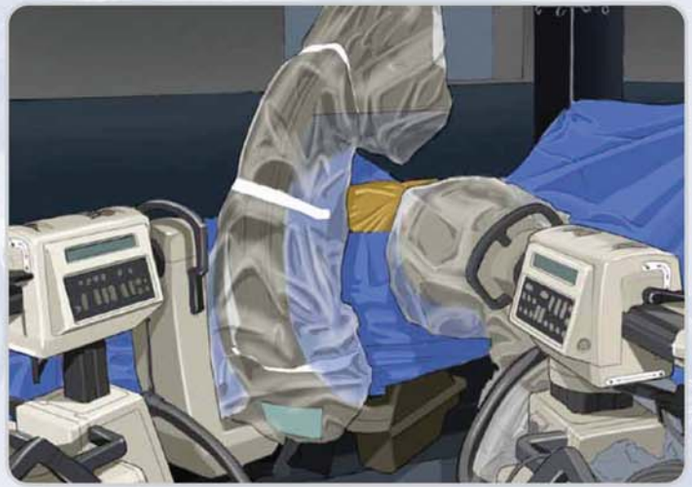
Surgical Technique

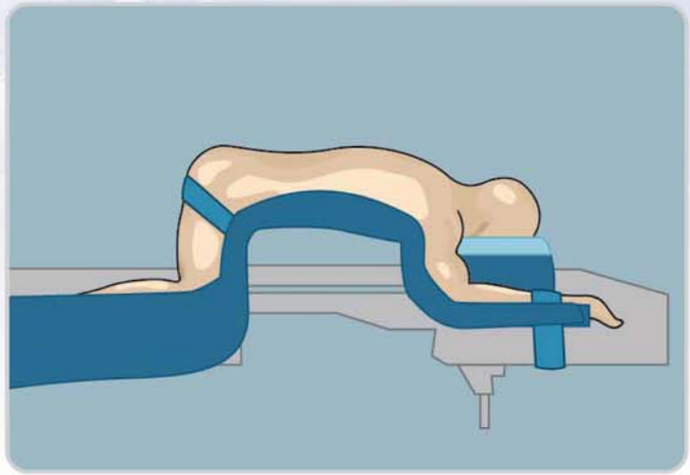
1. PREOPERATIVE PLANNING

All necessary imaging studies should be available to visualize patient anatomy and plan implant placement.



2. PATIENT POSITIONING

Patient should be positioned in the prone position on the operating table.

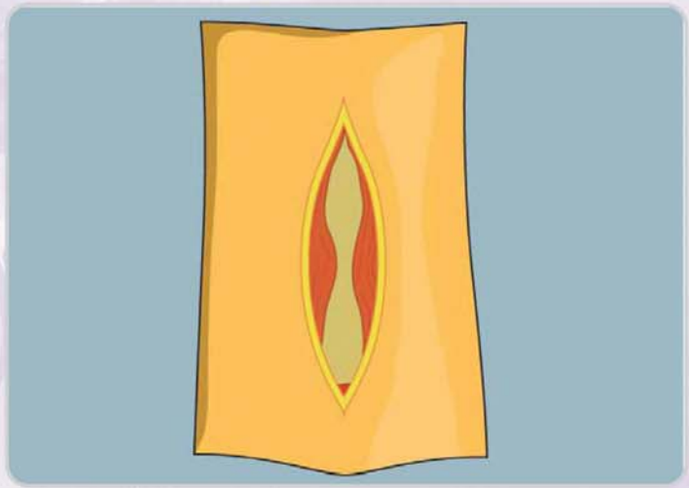


Surgical Technique

3. SITE IDENTIFICATION & INCISION

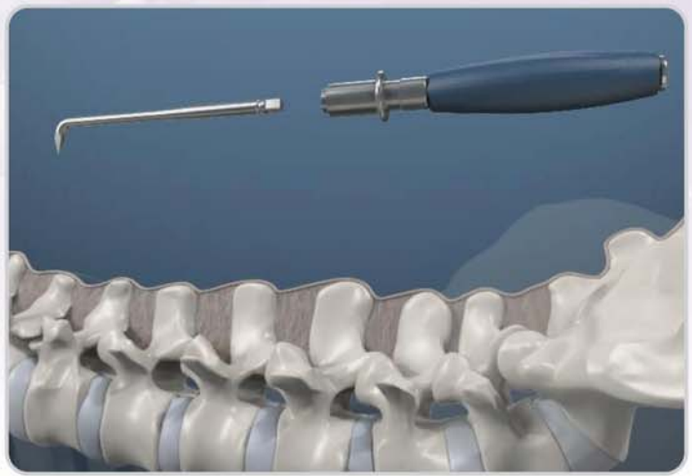
Identify the spinous processes at the level to be joined by using manual palpitation and intraoperative imaging. Make a midline incision (4-8cm) and distract, clearing tissue between spinous processes to be joined. Use Curettes and Rasps as needed to prepare device site

CAUTION: Care must be taken throughout the procedure to ensure that no damage is caused to the dura or spinous process. Overdecortication can cause weakening of the spinous process.



4. PERFORATING

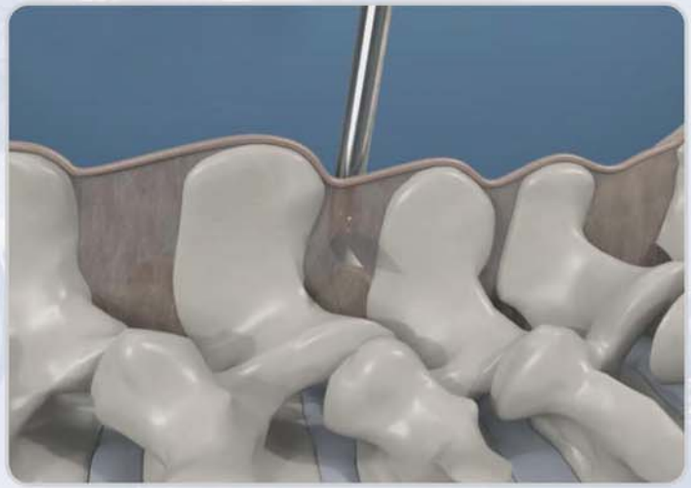
Assemble the palm handle on the perforator shaft.



Surgical Technique

Using the Perforator, punch hole through the anterior region of the interspinous ligament.

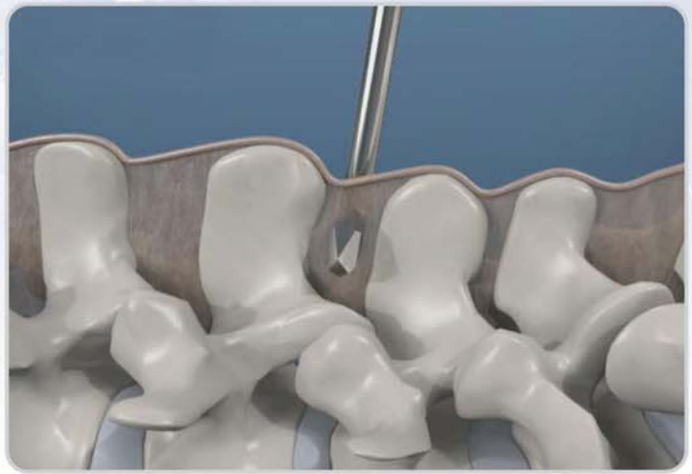
Make sure that Perforator is placed at midpoint between the adjacent spinous processes.



5. DILATING

Advance the Dilator parallel to the spinous processes until you encounter the facets.

Rotate the instrument 90° and dilate the interspinous ligament with the tip of the Dilator.



6. DISTRACTION & SIZING

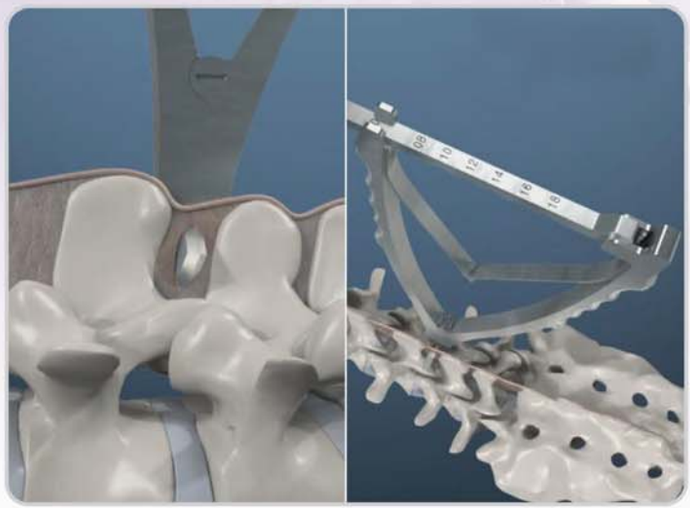
Insert the Distractor into hole created by the Dilator and spread spinous processes.

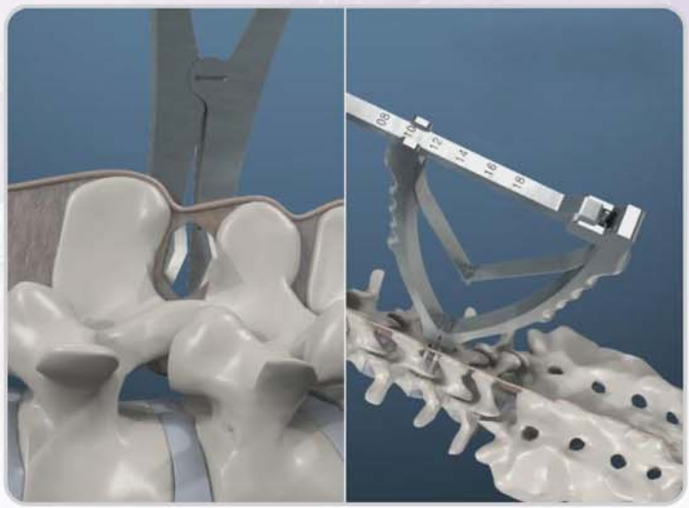
Begin to distract adjacent spinous processes and determine appropriate implant size.

The Distractor has a ratcheting bar at the top of the instrument also indicates which implant size to use.

CAUTION: Ensure the indicator is fully seated against the inside of the handle prior to use to ensure correct hub sizing.

Do not overdistract spinous processes. Overdistraction could damage the spinous process.



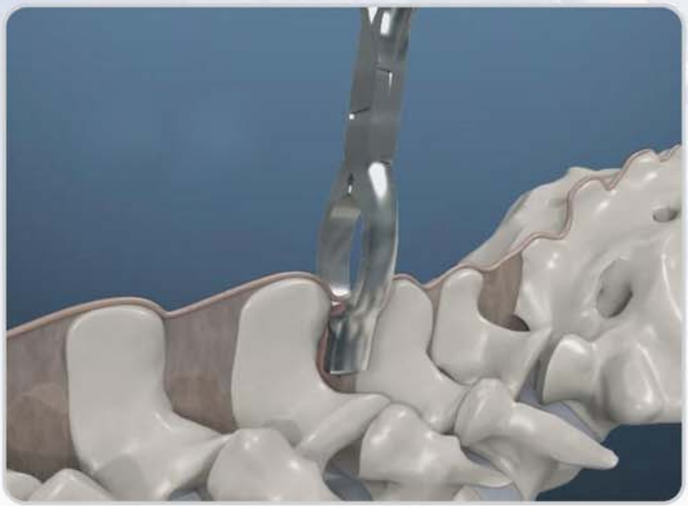


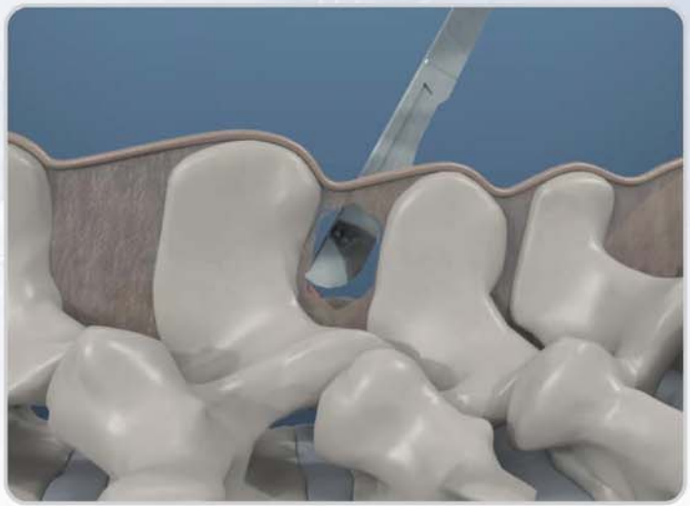
Surgical Technique

7. GOUGING

Attach the Biter into the desired interspinous space of spinous process. Gouge bone and tissue out with the Biter and/or Scalpel to expose areas for operation, and to insert a spacer assembly easily.

CAUTION: Do not Biter the supraspinous ligament.



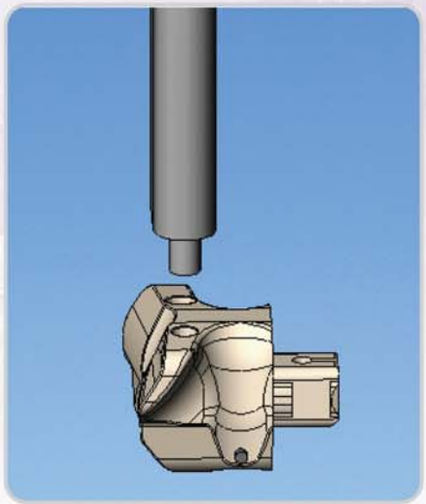


8. ATTACHING IMPLANT TO INSERTER

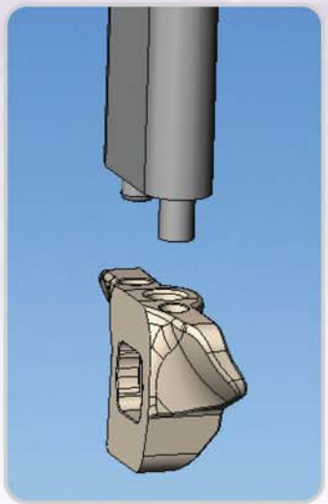
Using the size determined in step 6, select the appropriate implant.

Attach each implant (a spacer assembly and a wing assembly) to each Inserter by turning the Hold driver clockwise.

CAUTION: Ensure that the implant is fully seated onto the inserter.



A spacer assembly

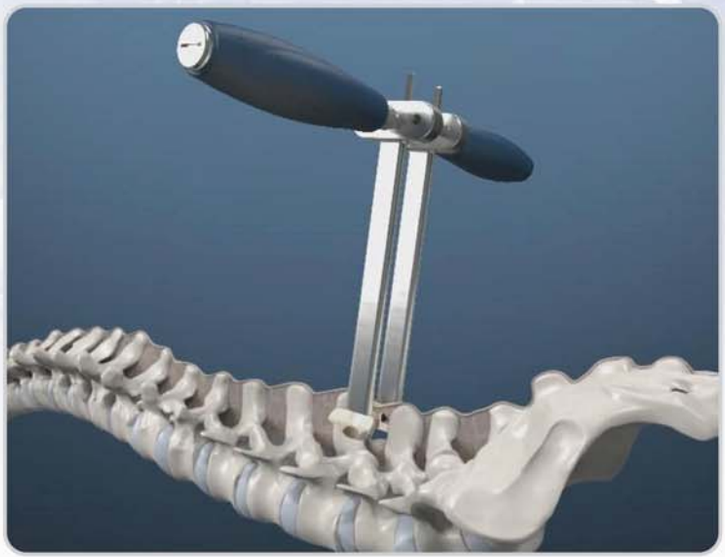


A wing assembly

9. INSERTING IMPLANT

Slide a spacer assembly attached to the Spacer assembly inserter into the cut interspinous ligament from left to right and assemble a wing assembly attached to the Wing assembly inserter in the right. Ensure the tips of the implants on the correct side facing each other. At this point, the implants should squeeze together through the cut interspinous ligament. If squeezing the implants by hand is difficult, you can use the Compressors to squeeze the distal end of the Inserters together.

CAUTION: Ensure that each spacer assembly's hub passes through the opposing wing assembly's hub cavity. If the spacers are not properly mated, the spacer system cannot be assembled.
After ensuring the implants are assembled to the hub adapters properly/securely, assemble the two inserters together.



10. COMPRESSING & TIGHTENING LOCKING SCREW

COMPRESSING

After implant is in desired position, attach the Compressor to the implants by aligning. Tighten until the Implant will click. The Implant will click once desired compression is reached. To remove the Inserters, turn the knob at the distal end of each Inserter counter clockwise until the Inserter disengages from the implant. Remove the Inserters posteriorly.

CAUTION: Ensure the locking mechanism on both Inserters is in the unlocked position before attempting to remove the Inserters. If the Inserter's locking mechanism is not unlocked, the Inserters will not release from the implant.

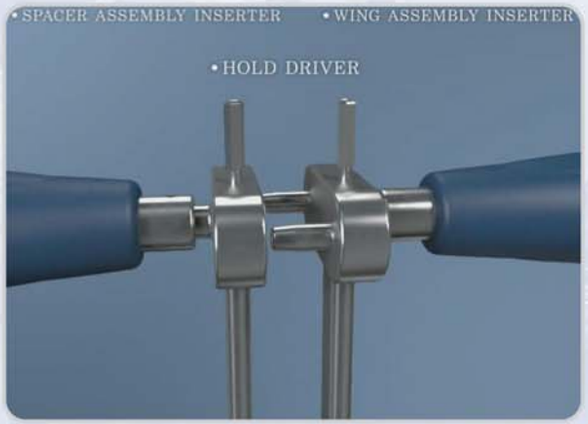
TIGHTENING LOCKING SCREW

Insert the Locking screw driver into locking screw and turn the handle clockwise only using two fingers to tighten. Turn the handle until desired resistance is reached.

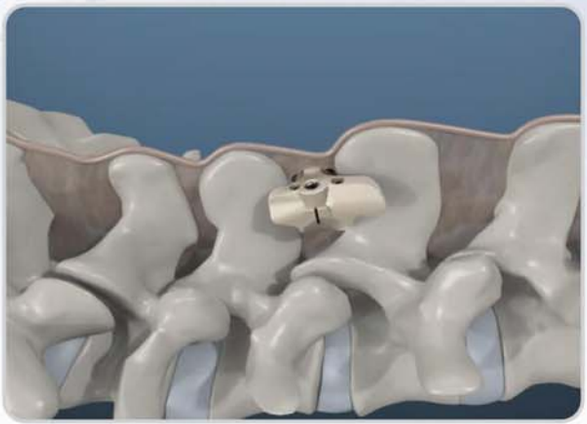
CAUTION: If the spacer's locking screw is not properly locked down, the spacers may separate from each other over time.

11. FINAL IMPLANT POSITION

Remove the Hold driver by turning counterclockwise and the Inserters.



Inspect visually the implant for secure fixation. Check placement of the implant using x-ray. Close the patient using standard techniques.



12. REMOVAL AND/OR REVISION OF IMPLANT

Revision could be necessary under the following situations:

A. Intra-operative Revision

1. Larger implant preferred after initial implant inserted
2. Misplaced implant; too anterior or not straight
3. Implant placed too far into interspinous process space
4. Implant fracture during insertion
5. Wrong level surgery
6. Loss of neurologic function of unknown cause
7. Spinous process fracture during procedure

B. Post-Operative Revision

1. Removal following fusion
2. Non-Union
3. Infection
4. Psychological patient fear of having a device in forever
5. Painful hardware irritating soft tissues or nerves
6. Spacer migration causing neural compression
7. Spinous process fracture around implant
8. Spinous process fracture

The following steps are taken to revise the implant.

Step 1: Locking screw Removal

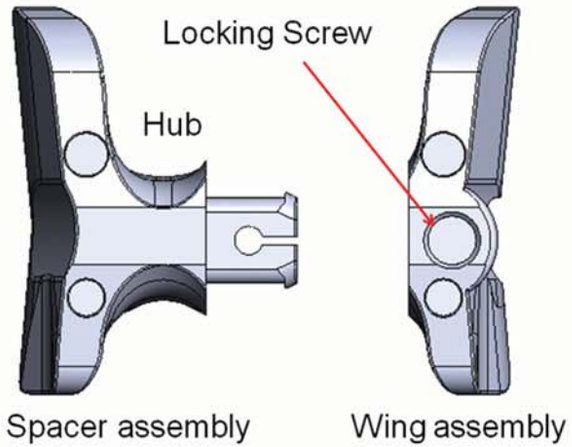
To remove a locking screw, attach the locking screw driver to the top of the locking screw.

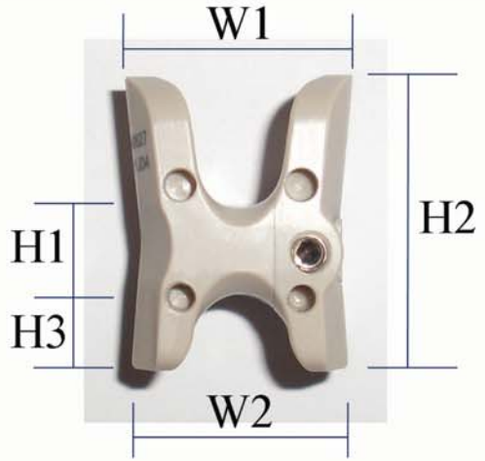
Turn the handle counter clockwise one full turn to loosen the locking screw and then remove a locking screw of the wing assembly.

Step 2: A spacer assembly and a wing assembly Removal

To remove a spacer assembly and/or a wing assembly from implant assembled, attach a spacer assembly inserter and a wing assembly inserter to the hole of a spacer assembly and a wing assembly. Spread the assembly inserter outward to loosen and may use with the distracter, and then remove a spacer assembly and/or a wing assembly completely.

13. SPECIFICATION OF INDIVIDUAL COMPONENTS

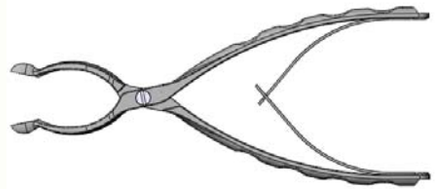




Catalogue number	H1 (mm)	H2 (mm)	H3 (mm)	W1 (mm)	W2 (mm)
HS0827	8	27	7	21.5	20.4
HS1029	10	29	7	21.5	20.4
HS1231	12	31	7	21.5	20.4
HS1433	14	33	7	21.5	20.4
HL0827	8	27	7	23.5	22.5
HL1029	10	29	7	23.5	22.5
HL1231	12	31	7	23.5	22.5
HL1433	14	33	7	23.5	22.5

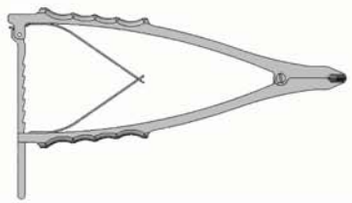
14. ACCESSORIES- SURGICAL INSTRUMENTS

No.	Catalog No.	Shape
1	HPT	

No.	Catalog No.	Shape
4	HBT	

No.	Catalog No.	Shape
2	HDL	

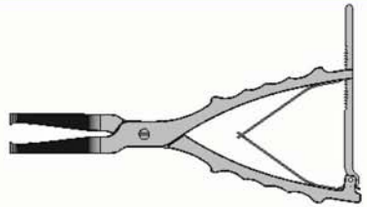
No.	Catalog No.	Shape
5	HIH	

No.	Catalog No.	Shape
3	HDT	

No.	Catalog No.	Shape
6	HSAI	

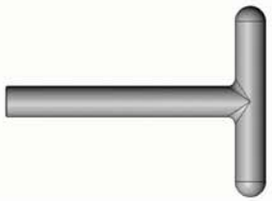
ACCESSORIES- SURGICAL INSTRUMENTS

No.	Catalog No.	Shape
7	HWAI	

No.	Catalog No.	Shape
10	HCP	

No.	Catalog No.	Shape
8	HHD	

No.	Catalog No.	Shape
11	HLSD	

No.	Catalog No.	Shape
9	HHDH	

No.	Catalog No.	Shape
12	HT	

Surgical Technique

DESCRIPTION:

The HEKTOR® Interspinous Dynamic System is a PEEK implant with locking screw and marker pin made from Ti-6Al-4V ELI alloy (ASTM F136) that is fitted between the spinous processes of the lumbar spine. It consists of two components: a spacer assembly with marker pin, a wing assembly with locking screw. The spacers are offered in four hub diameters (8mm to 14mm in 2mm increments) and four wing length configurations (27mm to 33mm in 2mm increments). The device height measured from the base of the central hub to the top of the wing is fixed across all configurations at 12mm and the device height measured from the base of the central hub to the bottom of the wing is fixed across all configurations at 7mm.

Locking screw is used to secure the assembly in its final compressed and implanted state. The HEKTOR® Interspinous Dynamic System implants are supplied non-sterile and single use. It is essential to use the HEKTOR® Interspinous Dynamic System with the instruments specifically designed for use with the system.

INDICATIONS:

The HEKTOR® Interspinous Dynamic System is a posterior, nonpedicle system intended for use in the non-cervical spine (L1-S1). It is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-Ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and /or central canal narrowing). The HEKTOR® Interspinous Dynamic System is indicated for those patients with moderately impaired physical function who experience relief in flextion from their symptons of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The HEKTOR® Interspinous Dynamic System may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels. HEKTOR® Interspinous Dynamic System is intended for stand-alone use. The device is not intended for use with bone graft material.

CONTRAINDICATIONS:

Contraindications include but are not limited to:

1. Suspected or documented PEEK and titanium alloy allergy or intolerance
2. Active infectious process or significant risk of infection (immunocompromised).
3. Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as:
   - Significant instability of the lumbar spine. e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4):
   - An ankylosed segment at the affected level(s);
   - Acute fracture of the spinous process or pars interarticularis;
   - Significant scoliosis (Cobb angle greater than 25 degrees);
4. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.
5. Diagnosis of severe osteoporosis, defined as bone mineral density (from

DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures.

6. Active systemic infection or infection localized to the site of implantation.
7. Fever or leukocytosis.
8. Morbid obesity.
9. Mental illness.
10. Grossly distorted anatomy caused by congenital abnormalities.
11. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC different count.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unable or unwilling to follow postoperative instructions.
15. Alcoholism or heavy smoking
16. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS:

The following potential adverse events may occur as a result of the HEKTOR Interspinous Dynamic System.

HEKTOR Implant Related:

1. Implant dislodgement/migration.
2. Early or late loosening of any or all of the components.
3. Disassembly, bending, and/or breakage of any or all of the components.
4. Implant not positioned correctly.
5. Fracture of the spinous process.
6. Additional surgery, which could include removal of the HEKTOR implant.
7. Foreign body (allergic) reaction to implants
8. Mechanical failure of the device.
9. Failure of the device/procedure to improve symptoms and/or function.

Surgery Related:

1. Reactions to anesthesia.
2. Myocardial infarction.
3. Bursitis.
4. Infection.
5. Blood vessel damage/bleeding.
6. Deep vein thrombosis.
7. Hematoma.
8. Pneumonia.
9. Neurological system compromise.
10. Stroke.
11. Nerve injury or spinal cord damage.
12. Paralysis.

12. Thrombus formation.
13. Wound dehiscence or delayed healing.
14. Pain/discomfort at the operative site.
15. Change in mental status.
16. Death.

Note: Medication or additional surgery may be necessary to correct some of these potential adverse events.

WARNING AND PRECAUTIONS:

WARNINGS

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general.

General surgical risks should be explained to the patient before surgery. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory insertion/attachment is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. The HEKTOR® Interspinous Dynamic System cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. If healing is delayed, or does not occur, the implant may eventually break due to PEEK fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. PATIENT SELECTION. In selecting patients for The HEKTOR® Interspinous Dynamic System, the following factors can be extremely important to the eventual success of the procedure:
   a. Previous Spinal Surgery: Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
   b. The patient's weight. An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.
   c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual

labor, he/she should not return to these activities. Even with full healing the patient may not be able to return to these activities successfully.

d. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

e. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

f. Foreign body sensitivity. Where material allergy or sensitivity is suspected, appropriate tests (such as skin sensitivity testing) should be made prior to implant selection or use.

The surgeon is advised that no pre-operative test can completely exclude the possibility f sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

g. Smoking. Smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

4. PREVENT NERVE DAMAGE. Caution should be taken when using instruments to avoid the spinal cord and nerve roots.

5. MAGNETIC RESONANCE (MR). The HEKTOR® Interspinous Dynamic System has not been evaluated for safety and compatibility in the MR environment. The HEKTOR® Interspinous Dynamic System has not been tested for heating or migration in the MR environment.

PRECAUTIONS

1. The implantation of The HEKTOR® Interspinous Dynamic System should be performed only by experienced spinal surgeons with specific training in the use of this spinous process dynamic system because this is technically demanding procedure presenting a risk of serious injury to the patient.
2. 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.
3. Surgical implants must never be reused. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, The HEKTOR® Interspinous Dynamic System components should never be reused under any circumstances.
4. Preoperative and operating procedure, including knowledge of surgical techniques and proper selection & placement of the insertion implants are important considerations in the successful utilization of the system by the surgeon.

Surgical Technique

PHYSICAN 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.

DEVICE FIXATION:

Refer to the The HEKTOR® Interspinous Dynamic System surgical technique for instructions for implant and instrument use.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before surgery begins. The HEKTOR® Interspinous Dynamic System components (described in the DESCRIPTION section) are not be combined with the components from another manufacturer. Different metal types should never be used together due to the possibility that it accelerates corrosion.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Do not over-compress the implants as this may cause fracture/breakage of the spinous process
4. Over decorticating of the spinous process may cause the bone to fracture or non-union of the implant.
5. During dilation of the interspinous ligament be sure not to tear the interspinous ligament.
6. The HEKTOR® Interspinous Dynamic System of the same hub diameter and wing length may be used for insertion/attachment to the interspinous process.
7. Before closing the soft tissue, all the locking screws should be tighten firmly to secure the assembly in its final compressed and implanted state. A locking screw and/or torque limiting driver is provided to ensure the

appropriate screw torque is applied. Failure to do so may cause loosening of the other components.

POSTOPERATIVE:

The physician's postoperative direction 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. If the partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal spacer device during postoperative rehabilitation maybe increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock 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 tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin.
3. The patient should be advised of their inability to bend and taught to compensate for this permanent physical restriction in body motion.
4. By the mechanism of fatigue, excessive and repeated stresses can cause the eventual bending, loosening, or breakage of the device(s).
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures) prophylactic antibiotics may be considered, especially for high-risk patients.

OPTIONAL-IMPLANT REVISION/REMOVAL

Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty or removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
- Pain or abnormal sensations due to the presence of the implants.
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

Revision/Removal procedures are follows:

Locking screw Removal

To remove a locking screw, attach the locking screw driver to the top of the locking screw.

Surgical Technique

Turn the handle counter clockwise one full turn to loosen the locking screw and then remove a locking screw of the wing assembly.

A spacer assembly and a wing assembly Removal

To remove a spacer assembly and/or a wing assembly from implant assembled, attach a spacer assembly inserter and a wing assembly inserter to the hole of a spacer assembly and a wing assembly. Spread the assembly inserter outward to loosen and may use with the distracter, and then remove a spacer assembly and/or a wing assembly completely.

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 including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to BMK®.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened BMK® package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to BMK® or local supplier. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

For further information of Cleaning and Decontamination (Cleaning Manual), please contact Customer Service, BM KOREA CO., LTD., 325-26, Dangjeong-dong, Gunpo-si, Gyeonggi-do, Korea Phone: + 82 31 451 9294~5, Fax: + 82 31 451 9248, Email: goyouch@bmkmedi.com

HOW SUPPLIED

HEKTOR® Interspinous Dynamic System Implant

The HEKTOR® Interspinous Spacer System components are supplied non-sterile. Laboratory testing was conducted to develop the following RECOMMENDATIONS FOR STEAM STERILIZATION:

Cycle Type	Pre-Vaccum
Configuration	Wrapped
Minimum Temperature	135 °C [275 °F]
Minimum Exposure Time	3 minutes
Minimum Dry Time	30 minutes

Surgical Technique

Table 1-Recommended Steam Sterilization Parameters for implants

HEKTOR® Interspinous Dynamic System Instrument

The HEKTOR® Interspinous Spacer System instruments are supplied non-sterile. Laboratory testing was conducted to develop the following RECOMMENDATIONS FOR STEAM STERILIZATION:

Cycle Type	Pre-Vaccum
Configuration	Wrapped
Minimum Temperature	135 °C [275 °F]
Minimum Exposure Time	3 minutes
Minimum Dry Time	30 minutes

Table 2-Recommended Steam Sterilization Parameters for surgical instruments

- See Table 1 & 2 for recommended sterilization parameters that have been validated by BMK® to provide a 10^{-6} sterility assurance level (SAL).

LIMITED WARRANTY AND DISCLAIMER: HEKTOR INTERSPINOUS DYNAMIC SYSTEM PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHAN TABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

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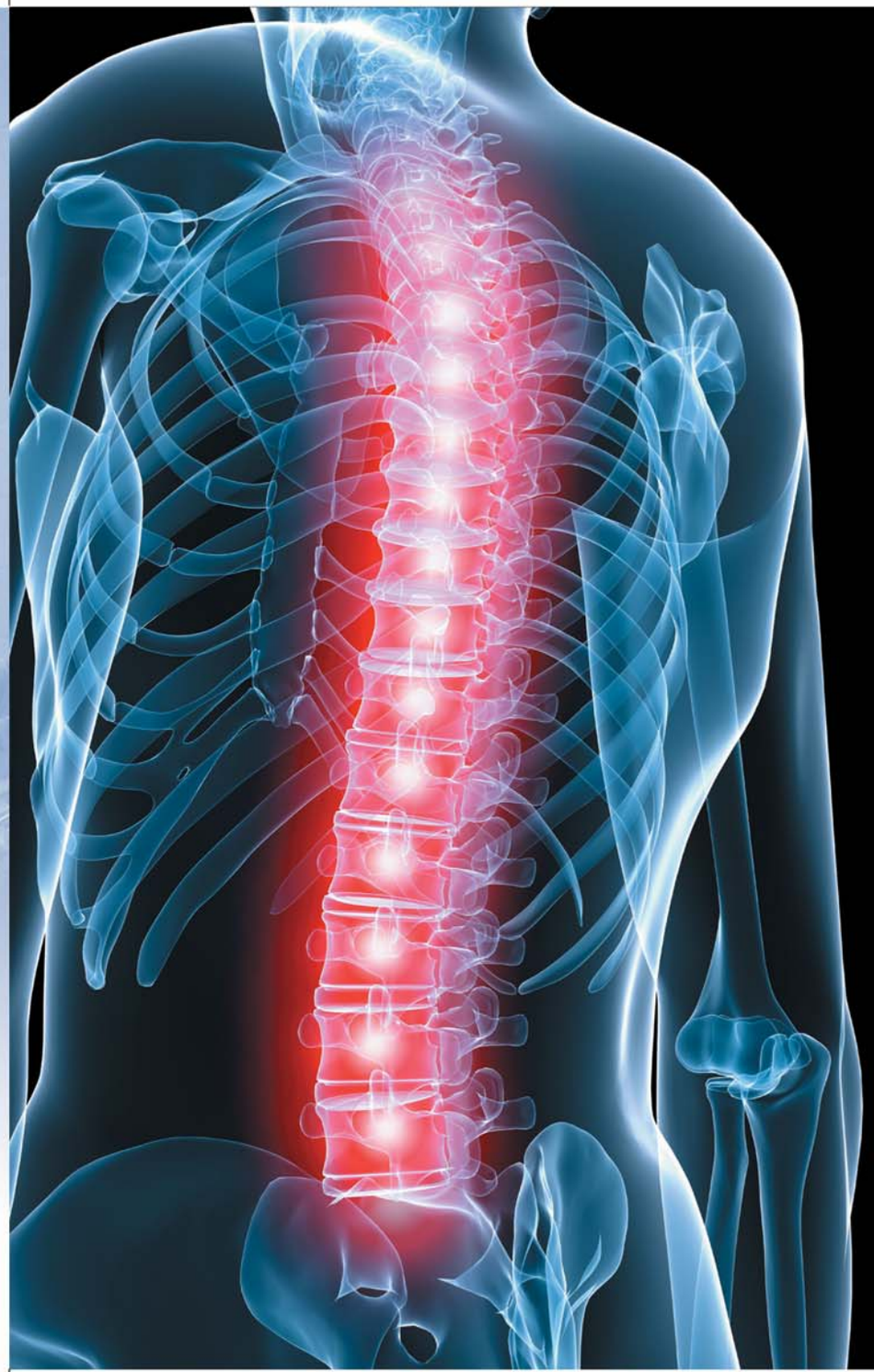
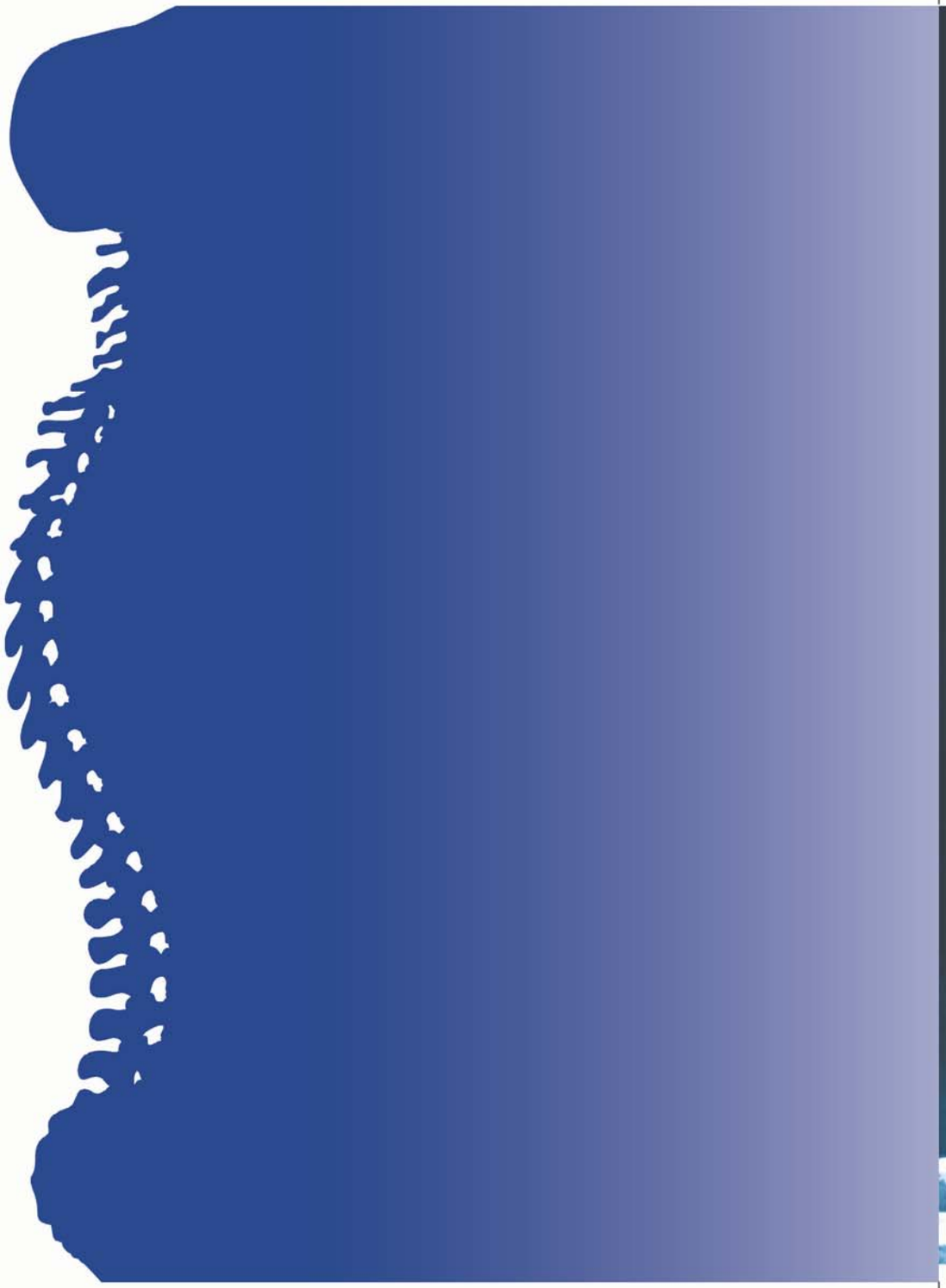


We will try our best to accomplish a company
which is **small but powerful**
and move forwards to the world with **infinite competitiveness**

BMK®
Global Medical Company

- This product is followed CE standard regulations.
- For more information, contact BM Korea Customer Service at (82) 31 451 9295



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