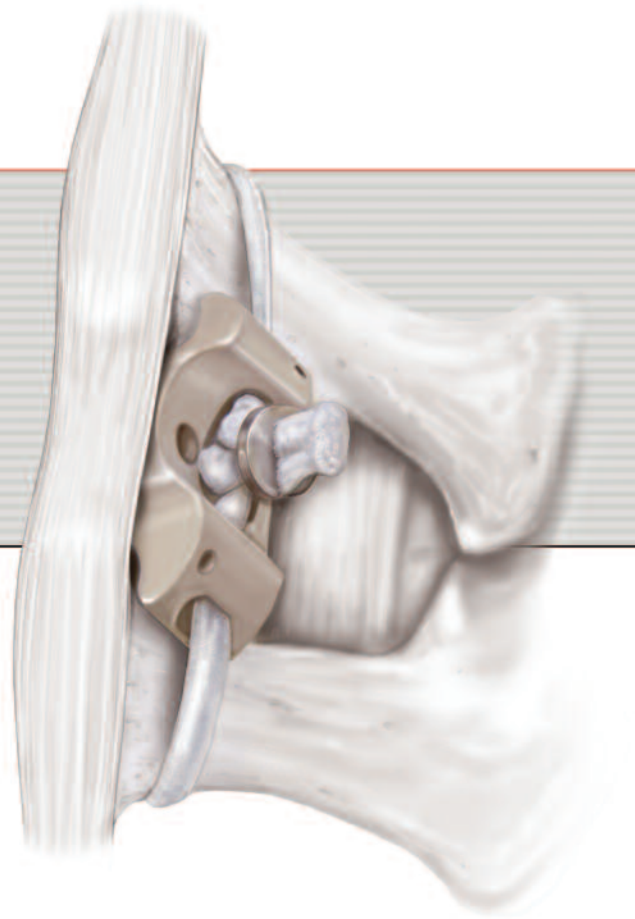
Surgical Technique



InSWing™

Interspinous Spacer

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Draft

Not available for sale in the U.S.

BLACKSTONE MEDICAL INC
Breakthrough Thinking®
an Orthofix Company

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Introduction

InSWing Interspinous Spacers are designed to alleviate the leg and back pain suffered by individuals with lumbar spinal stenosis (LSS). This innovative device can be used in a minimally invasive surgical procedure involving minimal or local anesthesia, significantly less blood loss and a shorter rehabilitation period than alternative surgical procedures.

Designed to be placed between the spinous processes of the lumbar spine, the InSWing spacer uses a unique unilateral approach. It is secured through the deployment of an innovative double-wing structure resulting in the widening of the spinal canal and decompression of the spinal nerve that was causing the patient's leg and back pain.

Acquired by Blackstone Medical and its parent Orthofix International N.V. in September 2007, InSWing was developed by a team at LFC Sp. Zo.o. that included Dr. Marek Szpalski M.D., Dr. Robert Gunzburg M.D., Ph. D. and Dr. Lechoslaw F. Ciupik, Ph.D., a bioengineer who was the team's chief designer.

InSWing technology is an important addition to the broad array of Motion Preservation and other products in our broad spine portfolio. It underscores our continuing commitment to make minimally invasive devices available to surgeons and advance the treatment of spine conditions for patients around the world.

Pre-Operative

1.

Step 1

Patient positioning

Place the patient in the prone position.

Use padded supports under the anterior iliac crests and at the chest level. The abdomen must be free to avoid venous compression. A physiological lordotic position is thus created.

Operative

2.

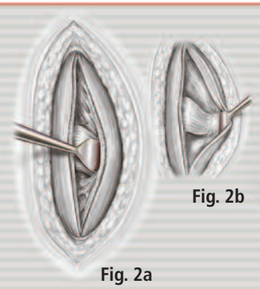

Fig. 2a

Fig. 2b

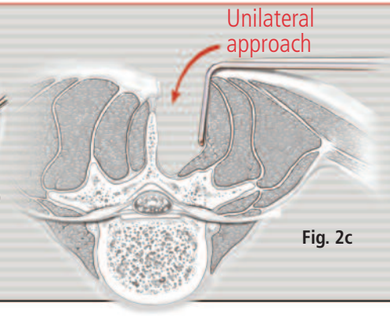

Fig. 2c

3.

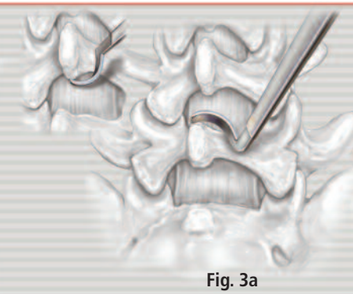

Fig. 3a

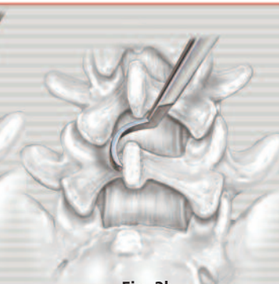

Fig. 3b

Step 2

Midline incision

Paraspinal muscles are detached subperiostally on ONE side with a Cobb elevator (see figs. 2a and 2b).

A retractor is then used to expose the interspinous space (see fig. 2c).

Using a scalpel or angled knife, open the interspinous ligament close to lamina in order to respect the supraspinous ligament.

Remove remains of interspinous ligament with Kerison or knife.

Step 3

Interspinous preparation

Use spinous process scraper to clean the remains of the interspinous ligament from spinous process (see fig. 3a).

Note: Ensure to detach muscle on the contralateral side with the scraper to allow the wings to deploy in an optimal way (see fig. 3b).

Surgical Technique

Operative

4.

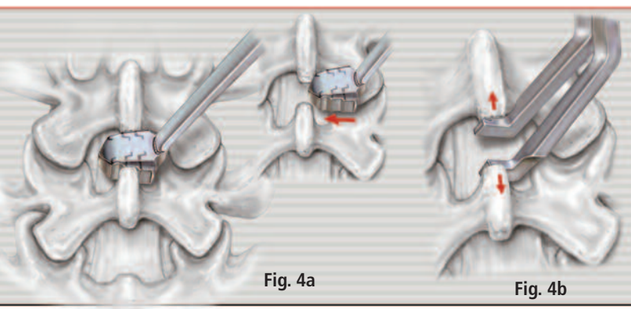

Fig. 4a

Fig. 4b

5.

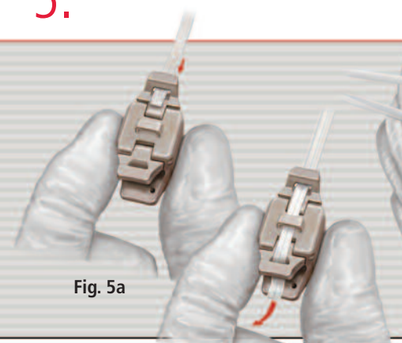

Fig. 5a

Fig. 5b

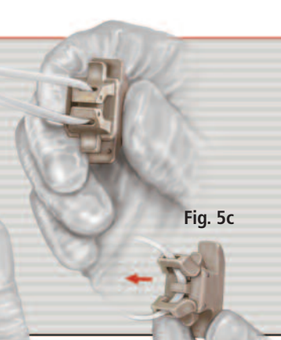

Fig. 5c

6.

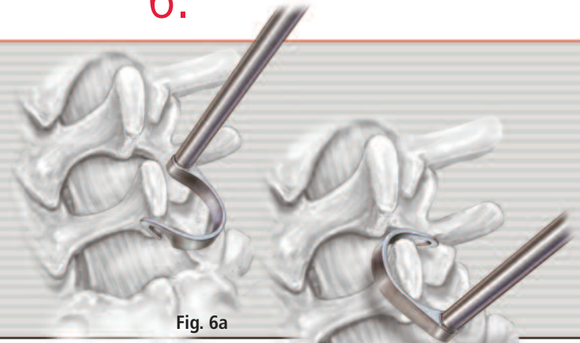

Fig. 6a

Fig. 6b

7.

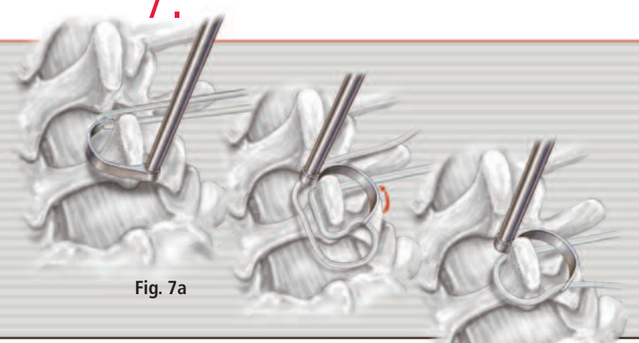

Fig. 7a

Fig. 7b

Fig. 7c

Step 4

Sizing

Start with the smaller sizing trial and insert it into the interspinous space (see fig. 4a). Push until resistance is felt. Read the number on the sizing trial where resistance is found. This will be the implant size.

The distractor can be used to verify the implant size (see fig. 4b). The distractor has indicator marks corresponding to each implant size.

***Note:** When using the sizing trial or distractor be careful not to over distract. Too much distraction will induce kyphosis.*

Step 5

Implant preparation

Make sure the implant wings are open.

Starting at either side of the implant, thread the band through the slot in the first wing (see fig. 5a). Next, continue threading through the center slot. Finally, continue threading the band through the second wing (see fig. 5b).

Close the implant wings (see fig. 5c).

***Note:** Ensure the band has equal band lengths once passed through to the implant.*

Step 6

Preparation for band

Identify above and below interspinous spaces. Angled forceps can be used for that purpose.

Pass awl through caudal interspinous space until you reach the operative interspinous space (see figs. 6a and 6b).

Awls are available in several radii to accommodate patient anatomy.

Step 7

Band reeving

With the awl passed through the caudal interspinous space, attach one band end to the eyelet on the awl tip (see fig. 7a).

Pass the band around the spinous process by rotating the awl back through the operative interspinous space (see figs. 7b and 7c).

Repeat steps 6 and 7 for the cephalad in cephalad interspinous space using the using the second awl.

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8.

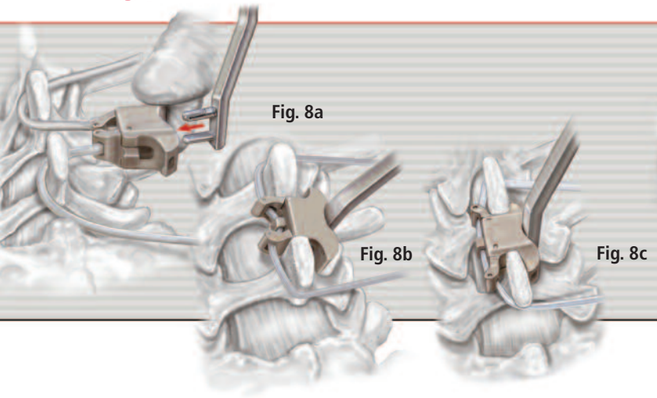


Fig. 8a

Fig. 8b

Fig. 8c

9.

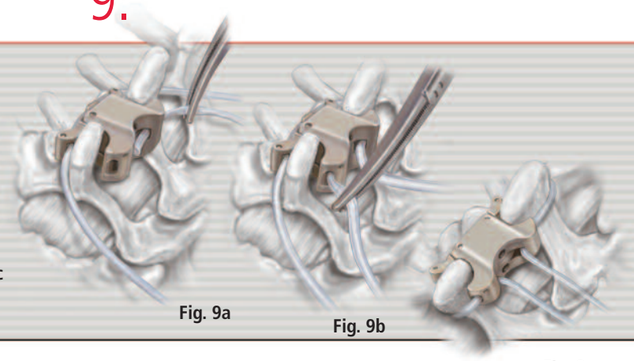


Fig. 9a

Fig. 9b

Fig. 9c

10.

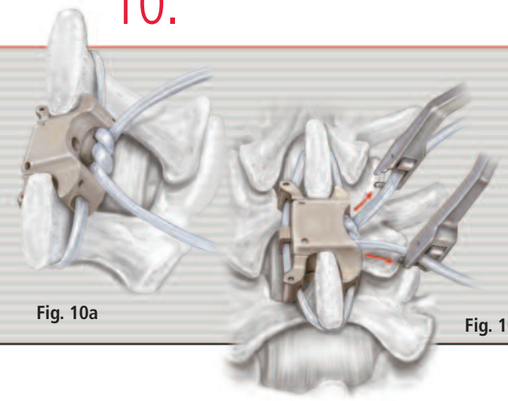


Fig. 10a

Fig. 10b

11.

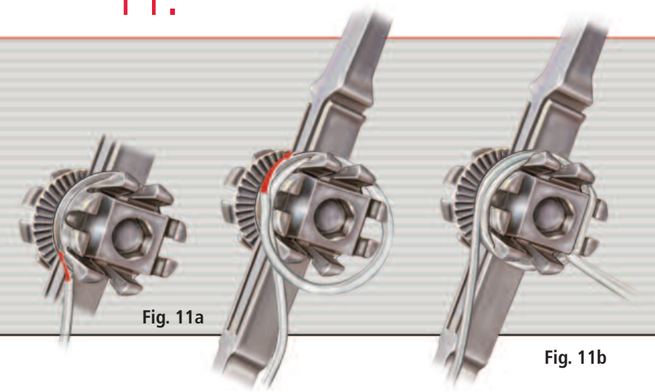


Fig. 11a

Fig. 11b

Step 8

Implant insertion

Insert implant holder into implant (see fig. 8a).

While pulling band ends, introduce the implant with closed wings into the interspinous space until wings completely open and are in contact with spinous process (see figs. 8b and 8c).

If resistance is encountered, the distractor can be used to gently open the interspinous space.

Alternatively, introduce one wing at a time by holding the implant in a laterally skewed position and roll it into place.

Step 9

Complete band reeving

Using forceps, complete the band reeving through the slots on the fixed wings of the implant (see figs. 9a, 9b and 9c).

Note: *During the reeving process, ensure the band is not tangled.*

Step 10

Knot the band

First, create a flat knot and tighten by hand (see fig. 10a).

Next, pass band ends through distal guides of tensioning instrument (see fig. 10b).

Step 11

Tension the band

Interlace band around ratcheting spindles of the tensioning instrument (see fig. 11a and 11b).

Surgical Technique

Operative

12.

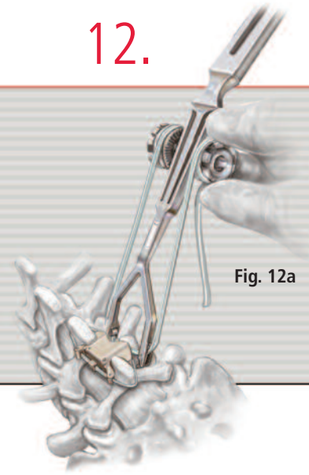


Fig. 12a

Fig. 12b

13.

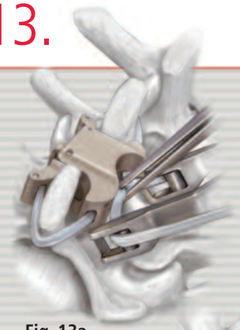


Fig. 13a

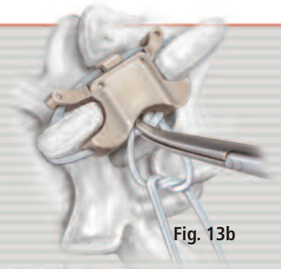


Fig. 13b

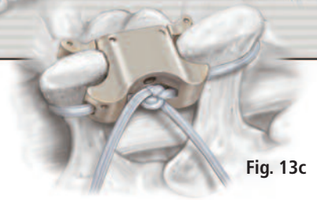


Fig. 13c

14.

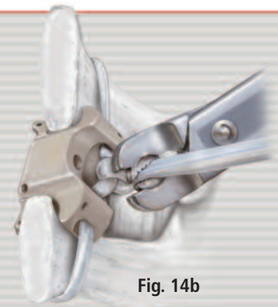


Fig. 14b

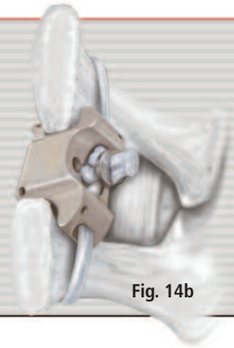
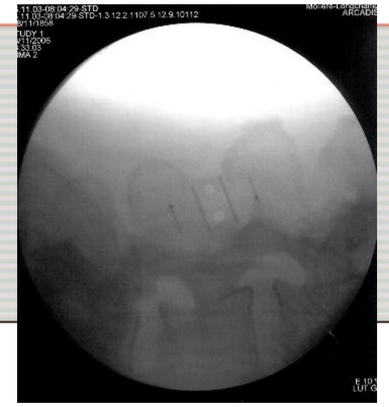


Fig. 14b

15.



Step 12

Tension the band

Tighten band by hand turning towards you until tension is achieved (see fig. 12a).

Use torque wrench on both sides alternating until needle on torque wrench indicates appropriate tension (see fig. 12b).

Note: *It is important to maintain tension on the knot for the next step.*

Step 13

Prepare 2nd knot

Maintain tension on the first knot using 2 forceps (see fig. 13a).

Release the tension on the tensioning instrument by pressing the release tabs.

Create a second flat knot by hand (see fig. 13b and 13c).

Repeat tensioning process to accurately tighten the second knot.

Step 14

Protect the knot

Protect the knot with the included clip and crimping instrument (see figs. 14a and 14b).

Alternatively, suture the knot with non-resorbable sutures.

Step 15

Final Position Verification

Before closing, use fluoroscopy to verify the final implant position.

Complete the surgery using standard posterior lumbar closure procedures.

Instructions for Use

Device System Name:
InSWing Interspinous Spacer

Execution

The products fulfill the requirements of Directive 93/42/EEC, "Medical Devices" in compliance with the European Union safety requirements, certification mark CE. The Administrative quality requirements are compatible with PN-ENISO 9001:2001 and compliant with requirements of medical devices of PN-EN ISO 13485:2005. The manufactured products are in compliance with international recommendations in the field of dimensional-profiling(shaping?) and surface finishing processing (machining) providing satisfactory characteristics for this class of products.

Material

Products are made from special, high-quality materials: implant steel, titanium alloys, polymers, polyesters meeting the requirements contained in: ISO 5832 " Implants for Surgery", ISO 10993, "Biocompatibility Test Reports for Peek-Optima", Vol. I, Vol. II. Materials used are allowed (appropriate) for implantation and suitable for typical technical diagnosis.

Purpose and Direction

InSWing products are intended for the assistance to the skeletal system, skeletal-muscular system and the motor system, in orthopedic surgery and neurosurgery. InSWing includes multi-functional, compatible (interchangeable), universal surgical implants, designated for biomechanical assistance and reconstruction of anatomical structures, comprising a specialized surgical instrumentarium enabling true and safe chirurgical functions.

Negative Indicators

- Local or systematic (?) state of inflammation
- Reduced bone strength caused by, for example Osteoporosis which would prevent proper positioning (placing) and/or attachment of implant,
- Patient allergic to implant material or contained implant elements,
- Poor overall patient condition indicating a high risk for health deterioration and/or loss of life as a result of the surgical procedure.
- Lack of patient consent for treatment by operation and abide by the recommendations of healers,
- Pregnancy, obesity
- Patient mental illness
- Patient dependency on alcohol, drugs, and other
- Other general or patient related/associated negative indicators that would exclude/prevent any potential benefit from the operation.

Recommendations

- Product is available for sale as indicated in the catalog description, exclusively by an order from a doctor or an authorized medical individual.
- Products not listed in the catalog (special, for purpose of research) are sold on the basis of an order with a legible signature by the client; responsibility for the application/use of the product is assumed by the client.
- Operations with the implant should be directed by a properly prepared operating team, trained surgeons and in a properly supplied medical center.
- It is recommended that, prior to use of the instrumentarium, proper training and experience be obtained in the medical specialty.
- The surgeon must know the biomechanical properties and material limitations pertaining to the use of the implant as well as the technique and installation requirements.
- Patient must be warned and fully aware that the implant:
  - Does not completely replace normal, healthy bone (or other structures) and may not be able to withstand excessive loads, may be susceptible to working loose, distortion and even fracture.
  - May be susceptible to damage in the event all post-operative warnings (instructions) are not followed.
  - May influence/affect sensitization favorably in locally developed, detrimental, bio-physical-chemical surface appearances, and mechanical affects.
- Patient must be warned that in the event of any and all treatment in the future, must disclose of the presence of the implant.
- It is recommended that the patient be checked for sensitization (allergy?) to the elements of the implant system.
- Each and every time, selection of a proper implant must be conducted/made by the surgeon with consideration to the patient's clinical data, biological, biomechanical and other personal factors that may affect the patient's treatment.
- Implant must be situated in an adequate (suitable), surgically prepared location and attached with in accordance with biomechanical principals.
- It is recommended that the implant –stabilizer reside/remain in the organism until it's treatment function is completed, but not longer than two years, unless the treatment requirements and other medical factors indicate otherwise, or the implant constitutes prosthesis.
- Patient must be aware that a longer presence of the stabilizer-foreign body in the organism, presents an increased risk for complications, compounded with complications associated with the normal mechanical and bio-physic-chemical wear and tear.
- The application of diagnostic and therapeutic techniques after operation requires specialized knowledge associated with installed implants.
- It is recommended for the future for caution and prompt consultation with physicians, after possible exposure to energy sources, such as, for example, vibration, half (medium?)-High frequency emissions, dia (?) dynamic currents and other external occurrences/events, which may affect the implant resulting in, negative consequences for the patient.
- In the event of observing/noting changes in the functionality of the implant, the patient must contact the physician without delay.

Note: Prior to the operational procedure the patient or his/her legal guardian must be informed about the advantages, potential limitations and dangers resulting from the implantation, wear and tear of implant in the body during the course of treatment, as well as consequences of non-removal or, knowingly retaining the implant after completion of implant-related treatment benefits.

Use

- InSWing Implants are exclusively intended for single use.
- Implantation as well as removal of InSWing implants can be performed only with use of specialized InSWing instrumentarium.
- Each operation must be properly planned: type and quantity of implants must be chosen by the specialist physician, based on the appropriate diagnostic data and other individual patient conditions.
- It is not permissible to perform any kind of changes in the implant geometry before and during the course of the operation, unless otherwise specified by manufacture of the particular product.
- It is not permissible to use the InSWing implant together with implants of other producers as well as mixing or matching available supplies.
- Any mechanical or other damage to the surface of implants is not permissible.
- It is important to do everything possible to minimize the loading upon the implants and that the points of transfer be compatible with the purpose and principles of biomechanics.
- The manufacturer does not bear any responsibility for damage in the course of improper use of the products.

Threats

- Lack of bone synostosis (caused by rejection of implant by the organism.
- Patient allergy to chemical elements contained in the material from which the implant is made of.
- Skin irritation, for example allergic or mechanical.
- Feeling of uncomfort, sense of lack of normalcy, pain caused by presence of a foreign body in the organism.
- Mechanical wear and tear of the implant, degradation of physical-chemical processes, especially in implant joints.
- Loosening/slack, fracture, displacement, breakage or migration of implant; destabilization of system/arrangement, caused by improper biomechanical selection, improper installation, usage wear and tear, not observing post-operative recommendations.
- Temporary or permanent paralysis resulting from improper attachment, implant slippage or its displacement caused by extreme life functions/activity
- Bleeding, cicatrisation (scarring, scar formation?), infection, damage to vessels (vasomotor?) or other organs.
- Other general surgical or hospital threats.

Instructions for Use

Removal

- Properly selected implants requirements for chronic illness/disease are intended to satisfy biomechanical functions solely (only) in incidents in which bone fusion occurs during treatment, and acceptance of temporary implant functions by the skeletal-muscular system.
- After completion of the treatment, the implant should be removed, unless there are other important factors/indications affecting patient life and health that may justify retaining the implant in the organism. The patient must be informed of this position. /situation.
- Implant removal must be documented and conducted in accordance with general procedures/principles regulated by law in compliance to implant removal procedure and with the enclosed "Implant Log Sheet"

* The product is protected by patent laws; Last review: 05.16.2006

** Firm Lfc is the exclusive owner of model; Date of issue:06.16.2006

Additional information may be obtained at the address:

Lfc Sp. z.o.o.; 41 Kozuchowska Street; 65-364 Zielona Gora/Poland CE0434

Tel. 68 321-92-00, fax 68 320-47 lfc@lfc.com.pl, www.lfc.com.pl

Storage and Sterilization

- Products should be properly stored in original, undamaged packaging, in a dry location, at room temperature,
- Damage to packaging and/or product during transport and storage eliminates it from further use,
- Before use the date to which product and sterilization are valid should be checked; condition of product and product packaging should also be checked,
- In the event the products not sterilized proceed as follows:
  - If the delivered product in transportation type trays and boxes, or single sleeve (liner?) metallic foil paper, product should be washed and sterilized according to standards EN 550, 552, 554.
  - If the product is delivered in double sleeve (liner) metallic foil paper, (shipped in cartons or without cartons), sterilize according to recommended standards EN 550, 552, 554,
- Valid date is provide on the label.

Note: Manufacturer does not bear any responsibility for a product in the event that the Usage Instructions are not followed

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Part Numbers

InSWing™ Interspinous Spacer

InSWing Interspinous Spacer

IMPLANTS	
796DPY	Polyester Band
781DT	Clamp
DP-795.01.21	8mm inSWing Assembly
DP-795.01.22	10mm inSWing Assembly
DP-795.01.23	12mm inSWing Assembly
DP-795.01.24	14mm inSWing Assembly
DP-795.01.25	16mm inSWing Assembly

INSTRUMENTS	
TN-016	Sterlilization Case
IN-780	Circular Awl, Right
IN-781	Circular Awl, Left
IN-783	Interspinous Sizer, Large
IN-784	Interspinous Sizer, Small
IN-785	inSwing Inserter
IN-786	Band Stretcher
IN-787	Clip Clamp
IN-788	Interspinous Distractor
IN-789	Interspinous Scraper
IN-792	Band Holder
IN-793	Stretching Controller

Package Insert

Package insert will be placed here upon approval

Notes

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U.S.A.

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