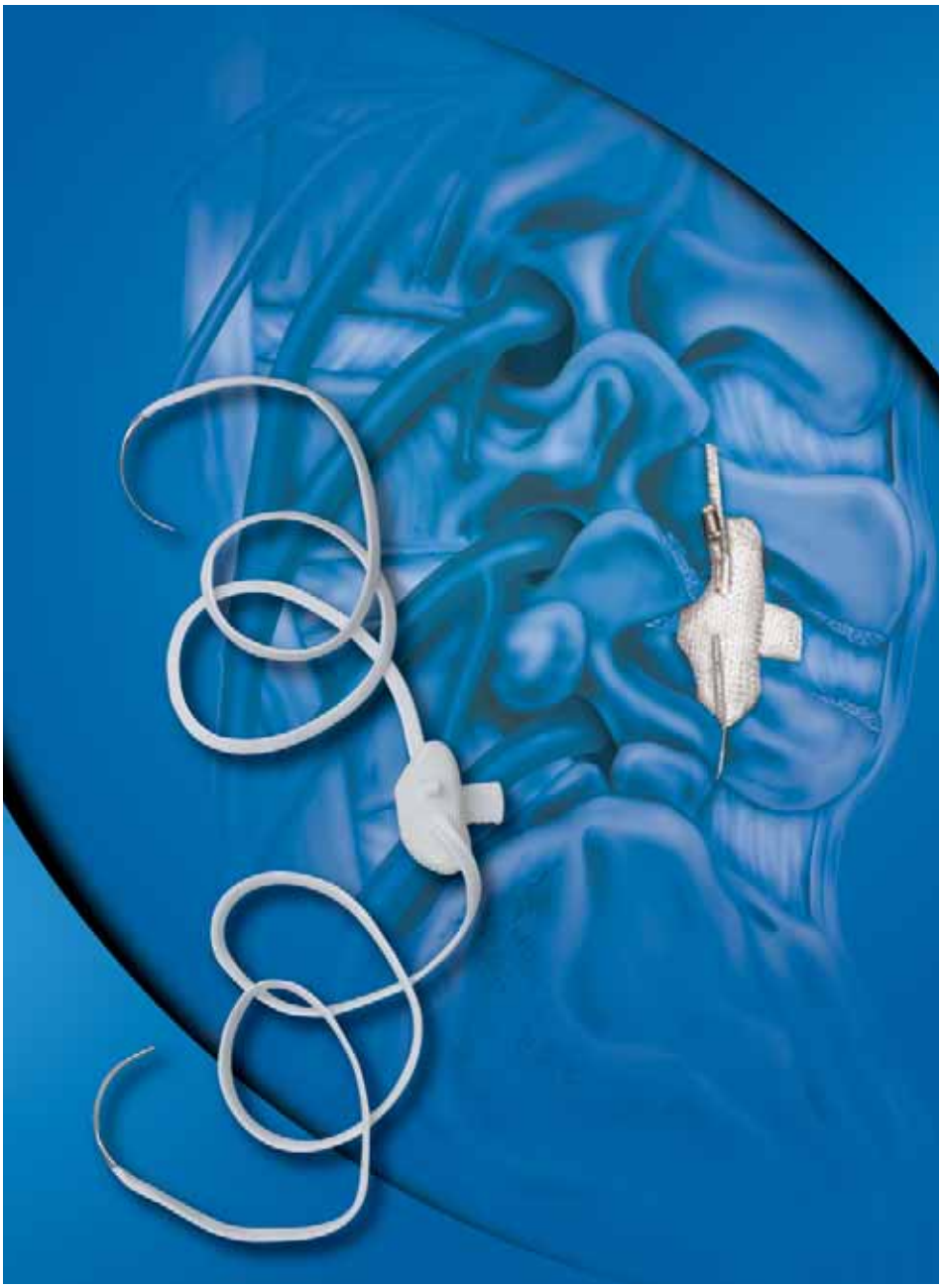
DIAM™ Spinal Stabilization System

Surgical Technique



The DIAM™ (Device for Intervertebral Assisted Motion) Spinal Stabilization System provides flexible support of the lumbar spine while treating spinal degeneration.

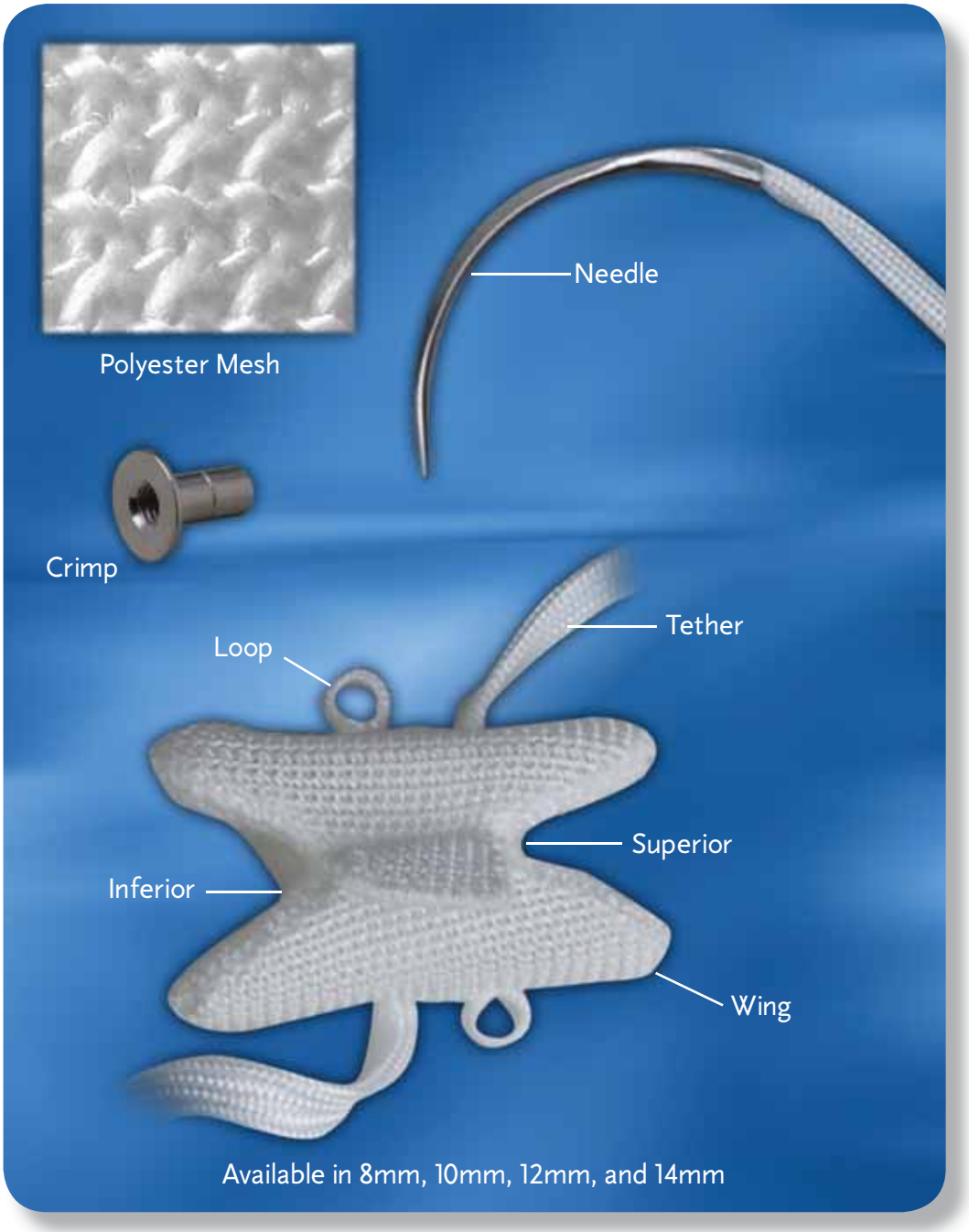
Potential benefits of the DIAM™ Spinal Stabilization System:

- Provides an alternative to spinal fusion
- Fits between the interspinous processes and functions as a shock absorber that reduces loads on the surrounding vertebrae
- Only requires a small incision to implant, which can reduce scarring, shorten surgery time and decrease recovery time

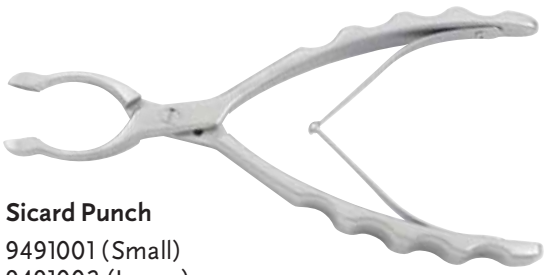
TABLE OF CONTENTS

IMPLANT FEATURES AND BENEFITS

- Assists in both flexion and extension
- Implant placement is done with a surgeon-familiar approach
- Streamlined instrument set for ease of insertion
- Implant design is compatible with minimally invasive procedures
- Available in four sizes for excellent patient anatomy matching



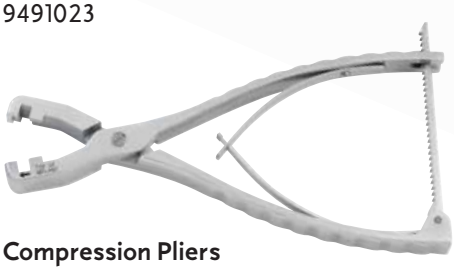
INSTRUMENT SET



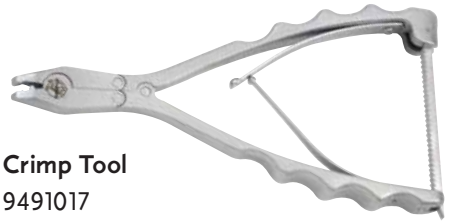
Sicard Punch
9491001 (Small)
9491002 (Large)

Unilateral Inserter
9491011

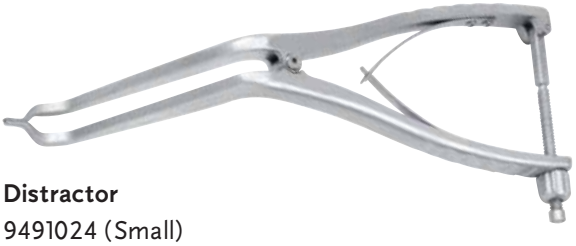
Implant Holder
9491023



Compression Pliers
9491018



Crimp Tool
9491017



Distractor
9491024 (Small)
9491034 (Large)

Template
9491030 (8mm)
9491031 (10mm)
9491032 (12mm)
9491033 (14mm)

Left Tissue Resector
9491012

Right Tissue Resector
9491013

Bullet-nosed Staple
9491026 (8mm)
9491027 (10mm)
9491028 (12mm)
9491029 (14mm)

Bilateral Impactor
9491015

Unilateral Impactor
9491008

Curved Kerrison
9491014

PATIENT POSITIONING AND APPROACH

DIAM™ Spinal Stabilization System procedures can be performed under general anesthesia. The patient is positioned prone with the abdomen free and the spine slightly flexed to aid in the intraoperative exposure of the interlaminar space. The table and frame should be compatible with lateral fluoroscopy and/or x-ray imaging.

A 20-gauge needle is inserted into the paraspinal musculature at the appropriate level. The needle position is confirmed using lateral fluoroscopy and/or x-ray. The spinal needle is removed and a 5cm incision is made at the puncture site (Figure 1).

Figure 1

The musculature is elevated bilaterally from the lamina to the level of the apophyseal joint capsules utilizing a standard technique. The apophyseal joint capsules should be carefully preserved.

The interspinous space is prepared all the way to the ligamentum flavum using blunt dissection, being careful to only remove the necessary interspinous ligament and potential bony overgrowth to allow room for insertion of the DIAM™ System implant. This should be done only as needed using a curved blade, tissue resectors, a curved kerrison and a Sicard Punch (Figure 2). Tissue resectors are introduced into the interspinous space to free the muscular and ligamentous attachments of the spinous process and lamina. This will ensure a good fit of the wings of the implant. The ligamentum flavum will be resected for decompression.

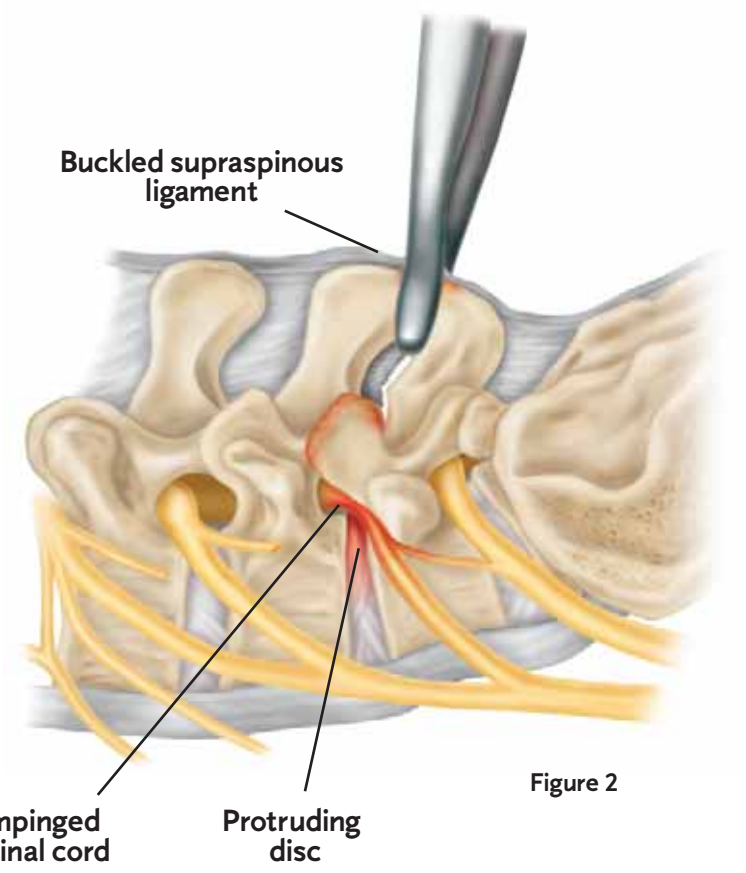


Figure 2

DISTRACTION

Reduction of the anatomy at the indicated level will optimize adequate decompression and proper lumbar spinal alignment. The reduction is achieved through distraction.

The distractor is positioned as far anteriorly as possible, ideally at the junction of the spinous process and lamina. Distraction is applied until an appropriate degree of tension is achieved in the supraspinous ligament and capsules and proper lumbar lordosis is achieved (Figure 3). Proper realignment of the facets and the interlaminar space is verified with fluoroscopy or x-ray imaging.

If resistance is felt during mechanical distraction, the interlaminar bony bridges must be resected to avoid fracture of the base of the spinous processes.

In cases of overlapping and hypertrophic laminae (kissing laminae), preliminary resection is recommended. Similarly, in cases of a kissing spine involving the spinous processes, resection of the lateral hypertrophic aspects of the spinous processes is necessary. At this stage, the interlaminar distractor can be inserted as far anteriorly as possible at the junction between the base of the spinous process and the laminae.

During distraction, the endplates should not exceed parallel alignment.

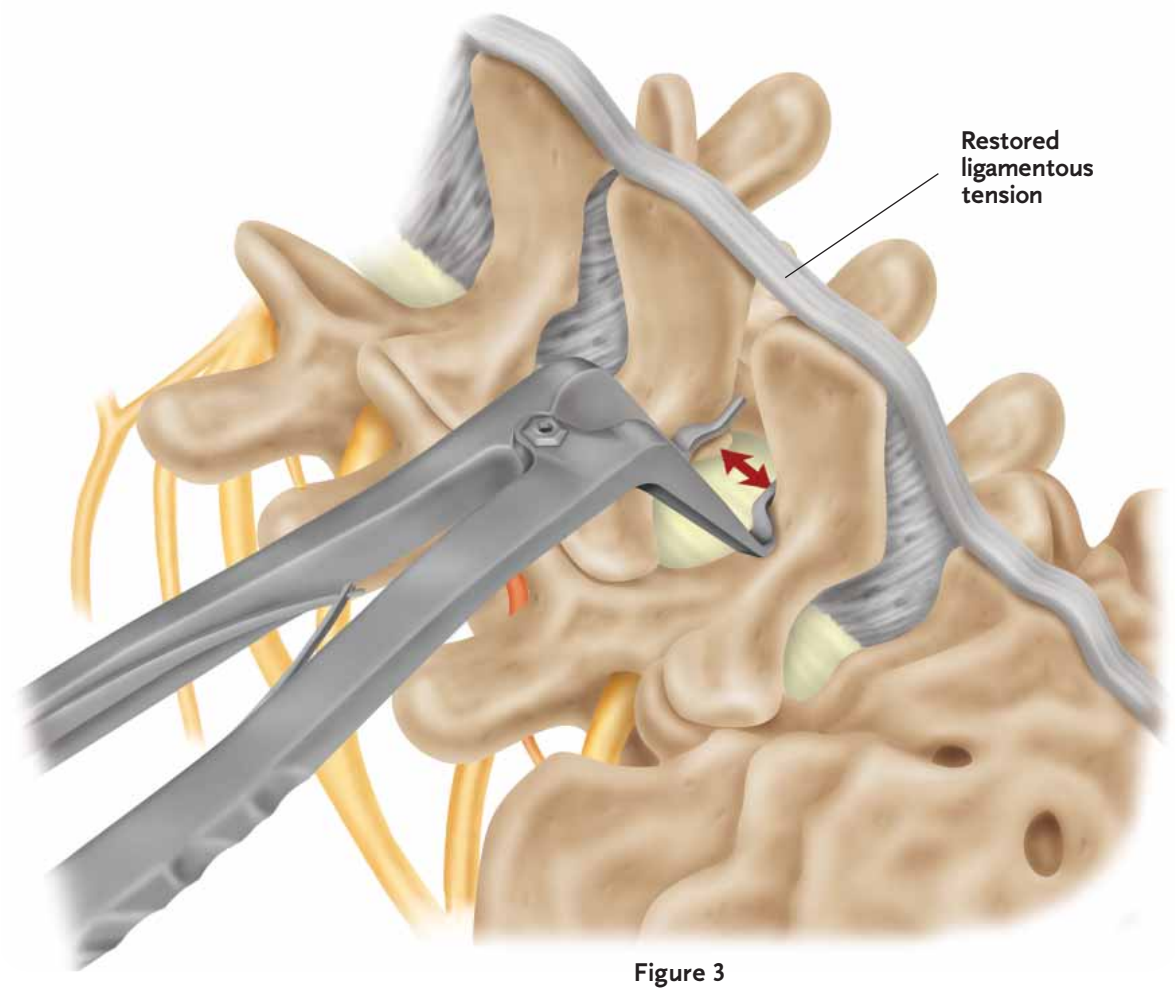


Figure 3

DECOMPRESSION

Adequate decompression must be achieved to ensure optimal resolution of the diseased level. To optimize decompression of the spinal canal and foramen, laminotomy (Figures 4a and 4b), medial facetectomy, foraminotomy, and discectomy may all be performed as needed with the optimal lumbar alignment maintained by the distractor (Figure 5). The DIAM™ Spinal Stabilization System implant will replace the distractor and maintain the adequate decompression while allowing proper motion of the treated segment.

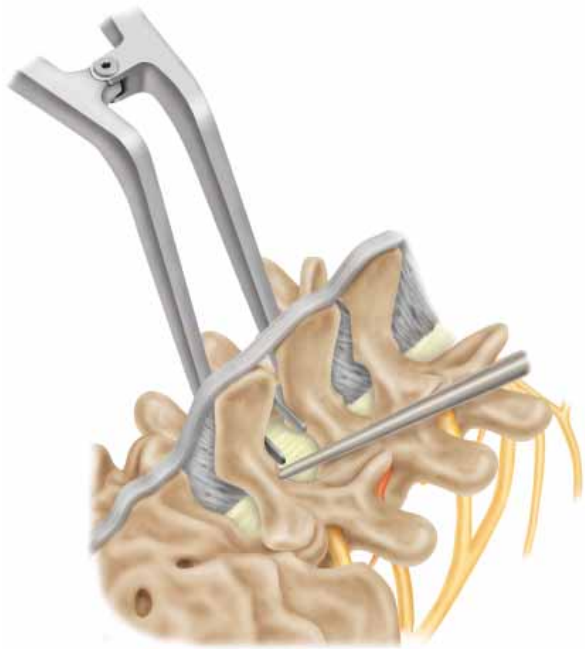


Figure 4a

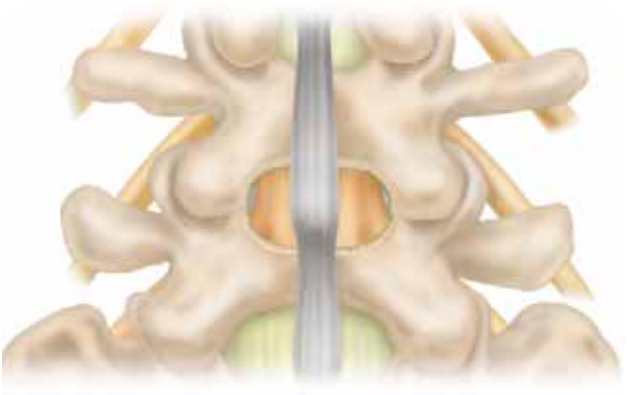


Figure 4b

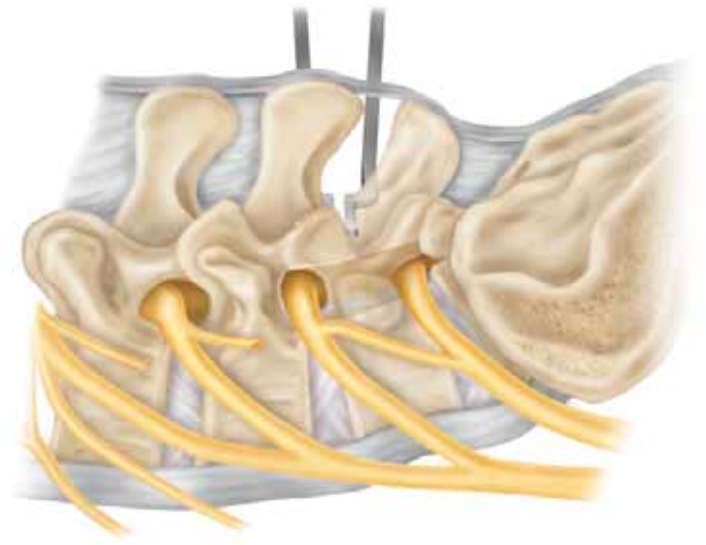


Figure 5

IMPLANT SELECTION

A series of Trials are used to select the proper size DIAM™ System device. The appropriate trial should fit firmly within the interspinous space (Figure 6). The sizes of the Trials provided with the system are 8mm, 10mm, 12mm, and 14mm.

When selecting the implant size, it is appropriate to choose the larger implant size, provided it will not create kyphosis or increase the risk of spinous process fracture. This will help ensure optimal lumbar spinal alignment and possibly improve the outcome for the patient.

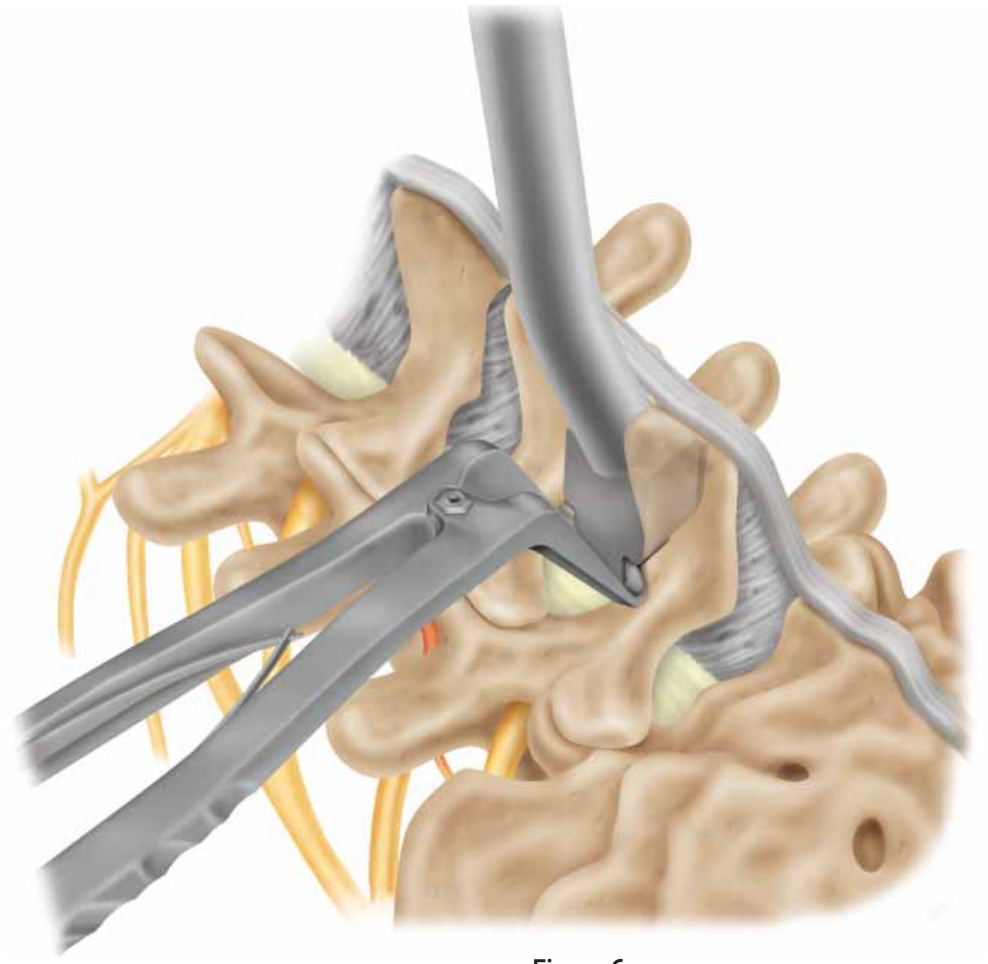


Figure 6

Folding the DIAM™ System Implant

To prepare the implant for insertion, place it on the open inserter (Figure 7a and 7b). The wings of the implant will fold as the inserter flanges are compressed (Figure 7c). Care should be taken to properly position the implant in the appropriate cranial/caudal orientation. Each corner of the implant should closely match the instrument arms. The arms are then closed to compress one side of the DIAM™ device to facilitate insertion under the supraspinous ligament.

Insertion Option One

Over-distraction may be applied temporarily to facilitate insertion of the DIAM™ device. The contralateral tether is passed through the interspinous space. The DIAM™ implant/inserter combination is then positioned within the grooves of the distractor and advanced until the jaws of the inserter are in contact with the spinous process (Figure 8). The implant is then advanced and its wings deployed along the contralateral side by squeezing the inserter handle. Ensure the implant is in the correct orientation. The superior end has a smaller curve than the inferior end. The DIAM™ device is driven as far anterior as possible using the unilateral or bilateral impactor. The distractor is then removed.

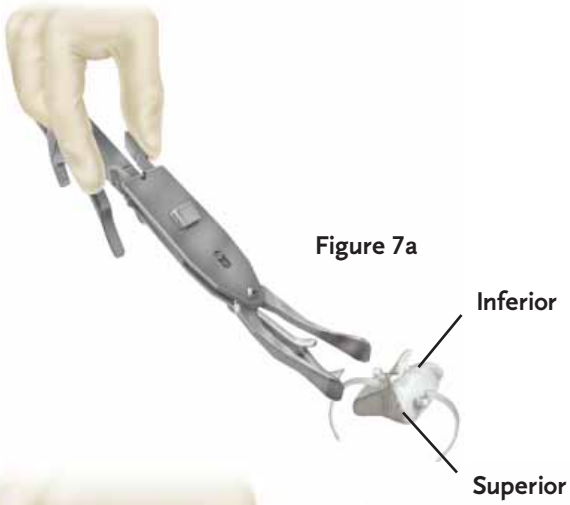


Figure 7a

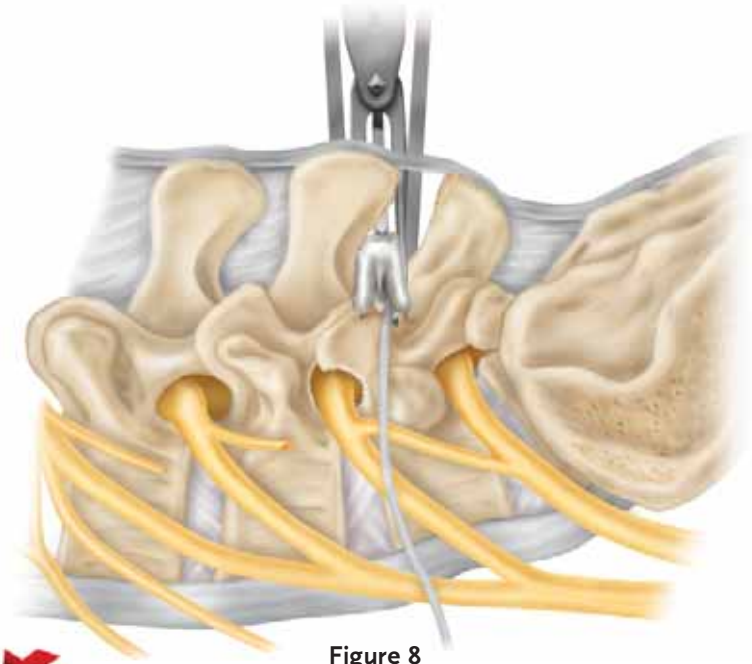


Figure 8

Figure 7b

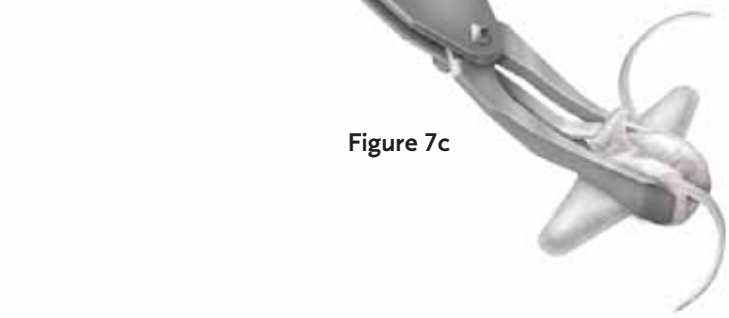


Figure 7c

IMPLANT PREPARATION/INSERTION

Insertion Option Two

Alternatively, the temporary distraction/insertion staple (Figure 9a) may be utilized to further facilitate the placement of the DIAM™ device. To use the method, place the implant into the compression pliers (Figure 9b) and squeeze the handles to compress the implant (Figure 9c). Slide the bullet staple into the pliers to secure the compressed implant (Figure 9d).

The implant can now be placed into the appropriate position (Figure 9e). Once the implant is correctly in place, the bullet staple should be removed.

Figure 9a

Figure 9b

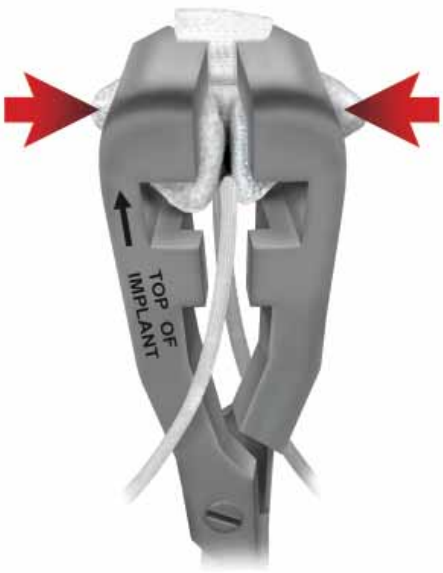


Figure 9c

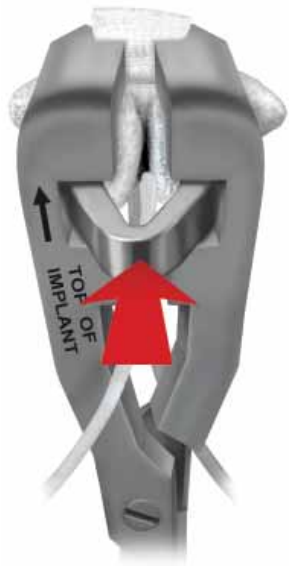


Figure 9d

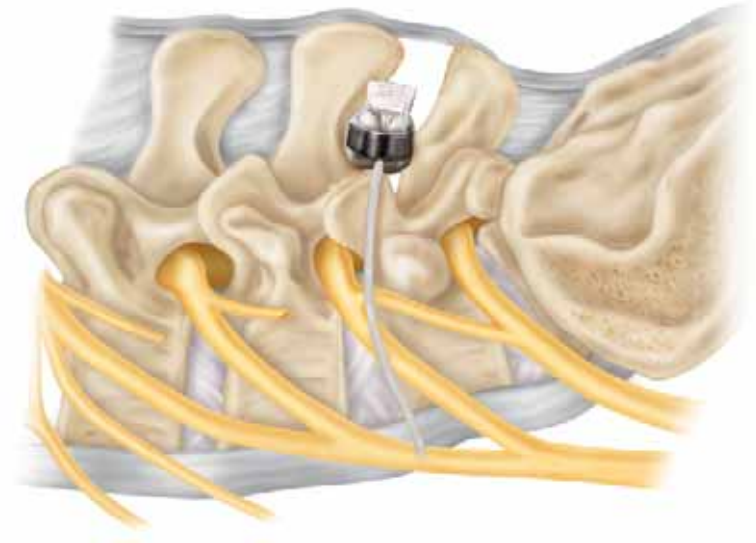


Figure 9e

TETHER ATTACHMENT

The DIAM™ System implant is secured to the adjacent spinous processes by the implant tethers. A contralateral exposure is necessary to allow passage of the tethers around the supra-adjacent and subadjacent spinous processes. The tethers are passed through the loop on the side of the implant (Figure 10a). Next, slide the Crimps onto each tether and apply longitudinal tension (Figure 10b). The Crimp Tool is then used to secure the Crimps (Figures 10c and 10d).

NOTE: only depress the Crimp Tool one time. Over crimping could result in an unsecured tether.

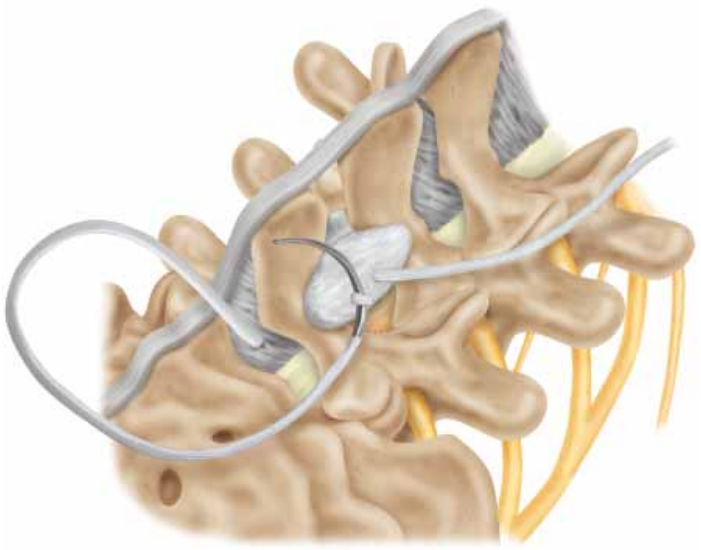


Figure 10a

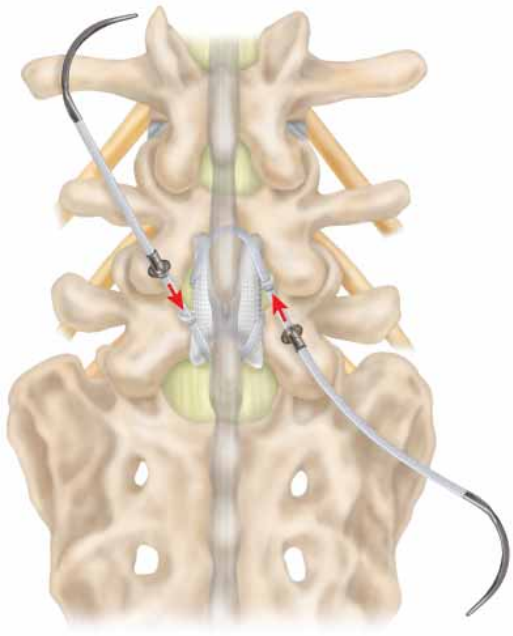


Figure 10b

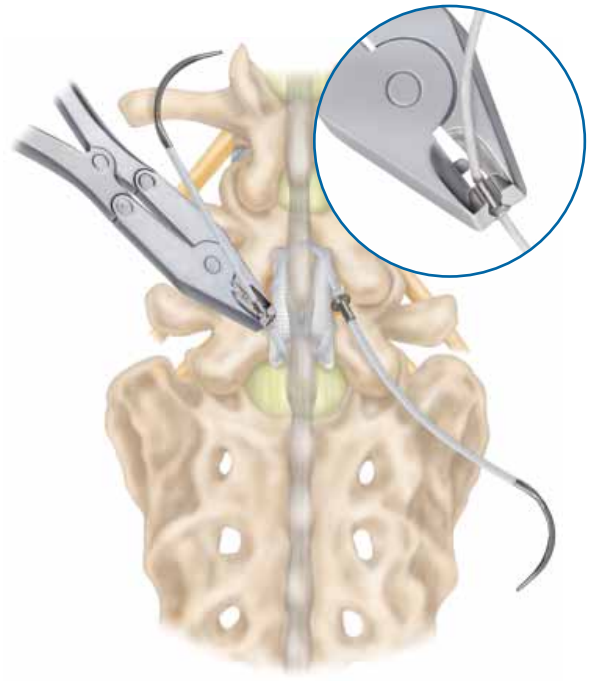


Figure 10c

Figure 10d

FINAL CONSTRUCT/CLOSURE

The final implant position (Figures 11a and 11b) should be verified prior to closure. The closure is performed following standard procedure, as per the surgeon's decision. A surgical drain is not indicated for this procedure. Preoperative and postoperative antibiotics should be administered per the surgeon's standard of care.

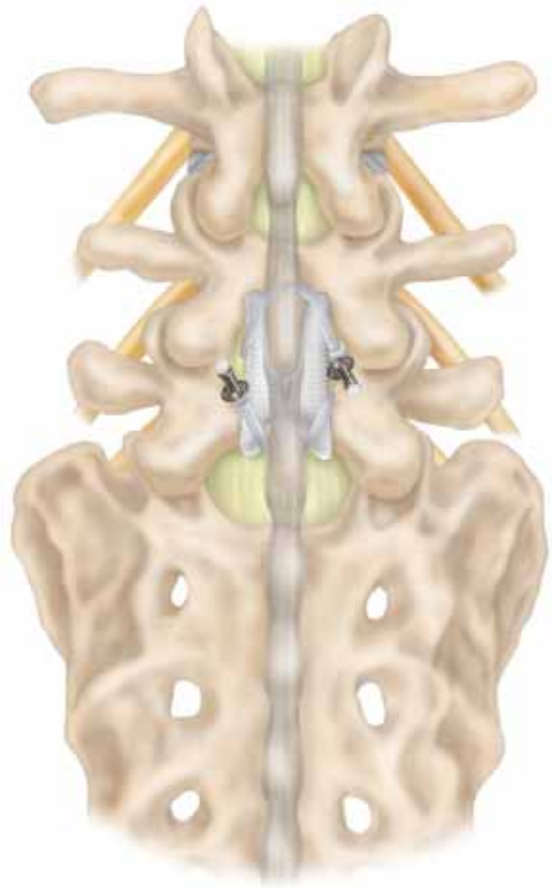


Figure 11a

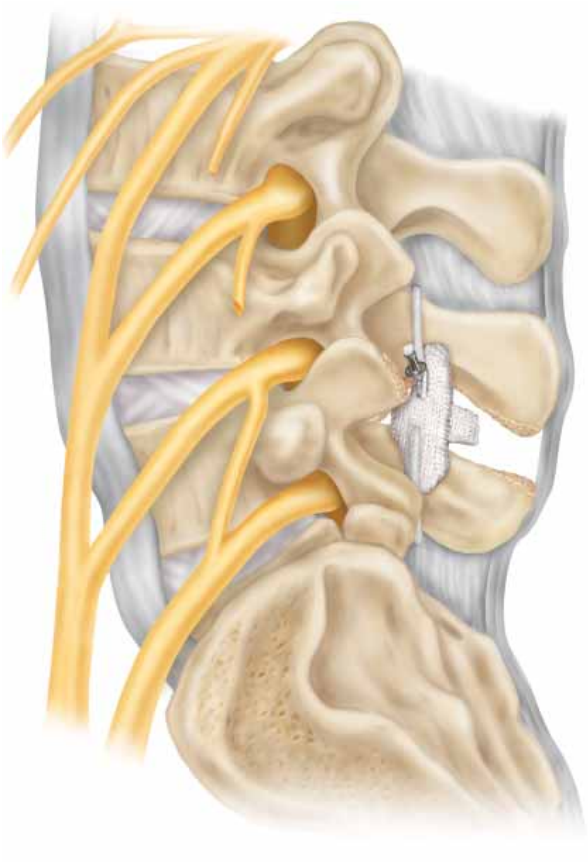


Figure 11b

EXPLANTATION

In the event that the DIAM™ System implant needs to be removed, the surgeon would decide on the best course of action. If the device must be removed, the surgeon performs a midline incision over the initial implant site. The device is exposed, the secured tethers are cut, and the entire device is removed utilizing a general instrument.

PRODUCT ORDERING INFORMATION

Item Number	Instrument Set
9491001	Sicard Punch, Small
9491002	Sicard Punch, Large
9491008	Unilateral Impactor
9491011	Inserter
9491012	Tissue Resector, Left
9491013	Tissue Resector, Right
9491014	Curved Kerrison
9491015	Bilateral Impactor
9491017	Crimp Tool
9491018	Compression Pliers
9491023	Implant Holder
9491024	Distractor, Small with Knob
9491026	Bullet-nosed Staple (8mm)
9491027	Bullet-nosed Staple (10mm)

Item Number	Instrument Set
9491028	Bullet-nosed Staple (12mm)
9491029	Bullet-nosed Staple (14mm)
9491030	8mm Template
9491031	10mm Template
9491032	12mm Template
9491033	14mm Template
9491034	Distractor, Large with Knob

Item Number	Implants
9492208	8mm DIAM™ Implant
9492210	10mm DIAM™ Implant
9492212	12mm DIAM™ Implant
9492214	14mm DIAM™ Implant
9492215	DIAM™ System Extra Crimps

IMPORTANT INFORMATION ON THE DIAM™ PROSTHESIS

Articular process stabilization and discal assistance device.

Indications

Lumbar Surgery

- Arthropatic facet-syndrome.
- Posterior prosthesis for discal assistance.
- Transitional osteosynthesis.
- Foraminal stenosis.

Material

Silicone + Polyethylene terephthalate (Polyester) + Titanium

Do not implant in case of intolerance to silicone or polyethylene terephthalate or titanium.

COUSIN BIOTECH does not guarantee or recommend any special trademark for fixation device. Properties of these devices are subjected to modifications made by the manufacturer and on which COUSIN BIOTECH has no control.
DIAM is not recommended for implantation in children.
This product must be implanted only by a trained physician.
Not of human or animal origin.

Storage

Keep in a dry place, without light, and in an ambient atmosphere.

Packaging

Devices are supplied in a sterile form.

Important Points

Please check the integrity of the implant packaging and do not use in case of damage to the package and/or label.
Do not use in case of damaged product.

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

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

DO NOT RE-USE.

DO NOT RESTERILIZE.

Possible undesirable secondary effects.

- Inflammatory reactions
- Permanent ligament injury
- Rupture of ligament
- Removal of the prosthesis

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 dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted component(s) ever "malfunctions," (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 MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information:

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Medtronic Sofamor Danek.

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NOTES

listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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