Medart

Surgical Technique Guide

SACRONOVA

MIS SI Joint Fusion Surgical Technique

Contents

DEVICE DESCRIPTION

The Medart technology Pvt. Ltd. Sacronova SI Screw System consists of screws manufactured from Ti-6Al-4V ELI per ASTM F136. The screws are available in a variety of lengths and diameters to accommodate varying patient anatomy.

INDICATIONS FOR USE

The Medart technology Pvt. Ltd. Sacronova SI Screw Systemis intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

SURGICAL TECHNIQUE

STEP 1: PRE-OPERATIVE PLANNING

The appropriate size implant should be estimated based on radiographic imaging prior to surgery.

STEP 2: SITE PREPARATION AND TARGETING

The patient is placed in the prone position on the operative table to enable the surgical approach. C-arm fluoroscopy is used to provide imaging during the procedure. EMG or similar neuromonitoring may be used to monitor muscles throughout the procedure for increased safety. If using neuromonitoring, the Insulating Sleeve may be used.

The Sacronova technique is intended to deliver the screw perpendicular to the SI joint and differs from some other lateral surgical techniques.

The anatomy of the SI Joint is variable. Specific training in pelvic radiographic imaging is required.

Lateral fluoroscopy should be used to visualize the greater sciatic notch, sacral endplate [pink line] and ala.Mark the skin at the shadow of the sacrum [red and blue lines] using a GuideWire and marking pen. Mark from the posterior edge of the sacral endplate to the middle of the sciaticnotch [green line]. Pull back the tip of the Guide Wire to the middle of the sciatic notch along the green line and draw a perpendicular mark [black line] to 1 inch above this location.

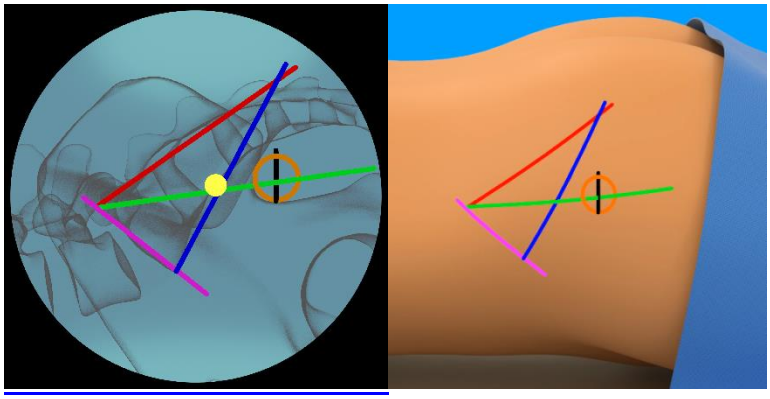


Figure 1: Example of X-Ray overlaid with skin markings

STEP 3: INCISION AND GUIDE WIRE INSERTION

Make an incision along the 1-inchvertical line. Insert the Guide Wire from lateral to medial through the incision and placethe blunt tip ofthe Guide Wire 1.5 to 2 inches above the ala[yellow circle in lateral view] and perpendicular to the SI joint. When the Guide Wire is in this approximate location, deliver the 8mm Dilator over the Guide Wire up to the surface of the ilium. Remove and re-insert the Guide Wire with the trocar tip against the ilium. Tap the Guide Wire slightly to advance a few millimeters into the cortical surface and adjust the C-arm from lateral to inlet and outlet views to confirm the correct trajectory.

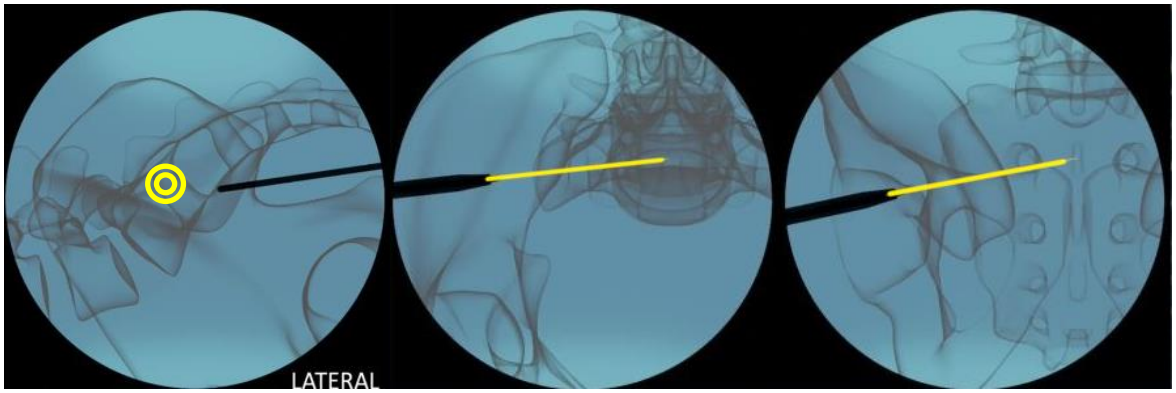


Figure 2: Fluoroscopic image replicas of Guide Wire placement
[LATERAL-left, INLET-center, OUTLET-right]

Once the correct iliac contact point and approach angle areconfirmed, advance the Guide Wire past the sacroiliac joint using a drill. The usual target in the outlet view is just inferior to the S1 foramen. The trajectory should place the Guide Wire into the center of mass of the S1-S2-S3 segment of the sacrum.

When the Guide Wire is at the full depth intended, the Measuring Sleeve may be used with the 8 mm Dilator to confirm the pre-operative Ø13 mm Main Screw length selection. The Measuring Sleeve indicates the distance of the Guide Wire past the tip of the 8 mm Dilator.

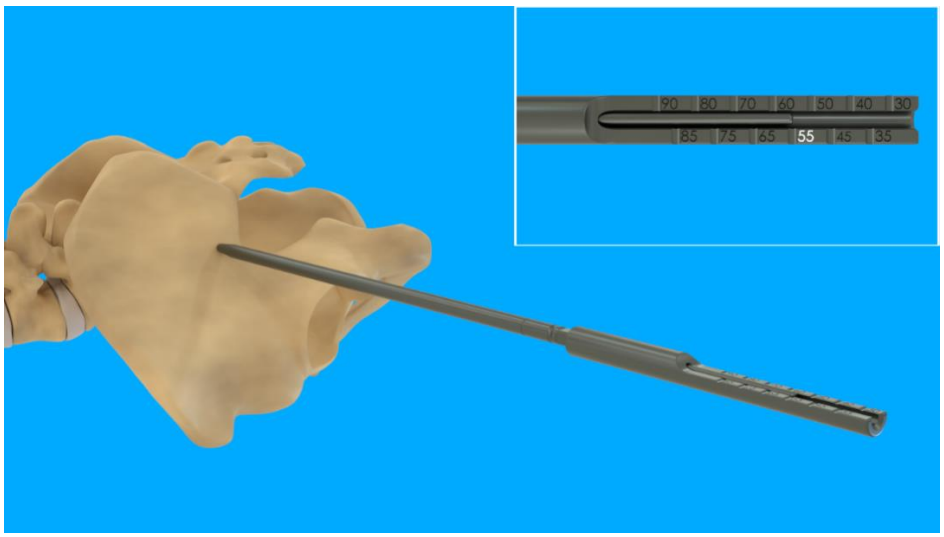


Figure 3: Image of Guide Wire with 8mm Dilator and Measuring Sleeve to show implant length

STEP 4: IMPLANT PLACEMENT

Preparation – Ø13mm Main Screw

Place the 22 mm Dilator over the 8mm Dilator.
Remove the 8mm Dilator while leaving the Guide Wire in place.
Use the 8mm Cannulated Drill to create a small cavity in the cortical surface of the ilium, without extending more than a few millimeters into the cancellous bone. This will allow the tip of the 13mm Trident Screw to easily enter the space so that the self-tapping flutes may engage the cortical bone.
Remove the 8 mm Cannulated Drill and leave the Guide Wire in place.
If the Insulating Sleeve is to be used, insert it over the 22 mm Dilator.
Remove the 22 mmDilator.

Instrument Assembly – Ø13mmMain Screw

Select the implants based on the Measuring Sleeve and preoperative measurements. (The same length of implant may be appropriate for the Ø13 mm Main Screw and the Ø6 mm Side Screw. Use fluoroscopic imaging and pre-surgical planning to determine this after the Ø13 mm Main Screw is in place.)Assemble a Trident Ø13 mm Main Screw onto the IntroducerSleeve by matching the protruding tabs of the sleeve to the corresponding spaces in the screw head and twist clockwise. [see figure 4] Place theSquare Driver into the cannulation of the IntroducerSleeve. Attach the preferred Handle to the proximal end of the Square Driver.

The Multifunctional Handle may be used axially or as a T-handle. There are corresponding cutouts on one end and in the middle of the Multifunctional Handle to allow it to be used in both orientations. Or use one of the ¼" Square Quick Connect Handles provided with the system.

Do not use the Introducer Sleeve without the Square Driverto drive the Ø13mm Main Screw.

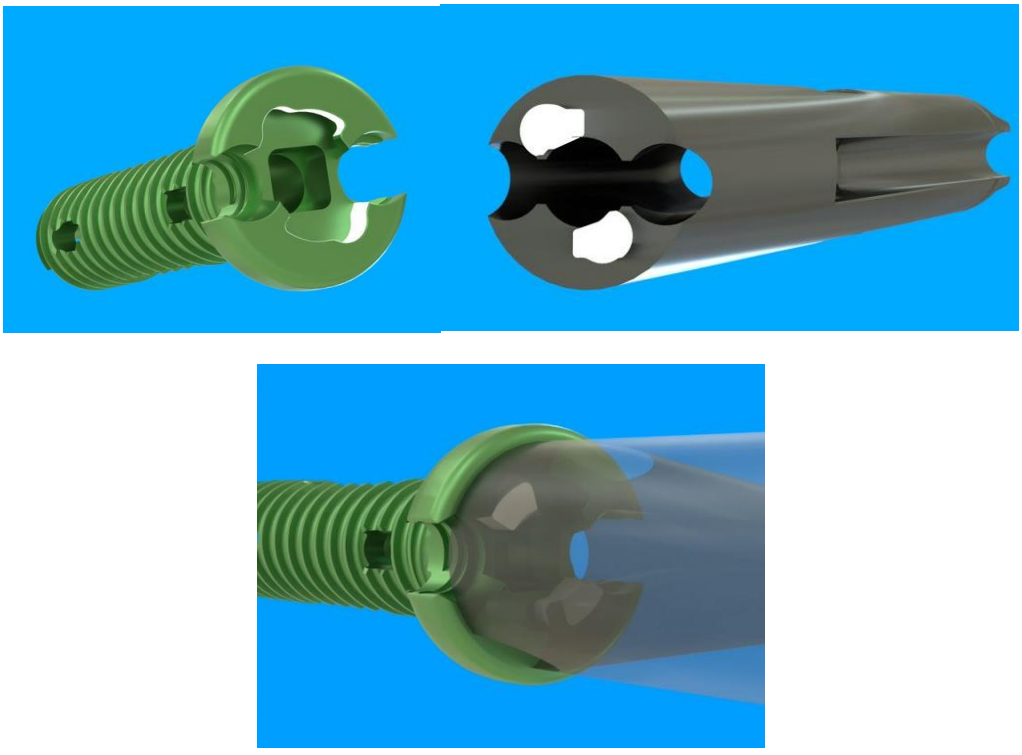
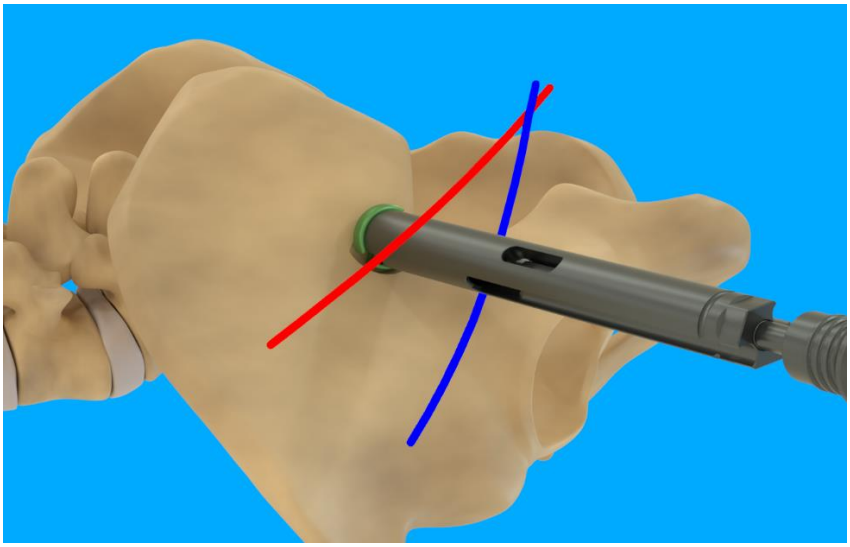


Figure 4: Image of Introducer Sleeve assembled with Trident Ø13 mm Main Screw

Insert the 13 mmMain Screw, Square Driver and Introducer Sleeve over the Guide Wire.

When the tip of the Trident Ø13 mm Main Screw contacts bone, begin screwing into the ilium. Check neuromonitoring (if using) during insertion of the Ø13 mm Main Screw. Advance the Ø13 mm Main Screw until the flange contacts the ilium. Use the inlet view of the pelvis to align the Trident Ø13 mm Main Screw to allow proper orientation of the Trident Ø6 mm Side Screws.

After the flange is in contact with the cortical surface of the ilium, continue rotating until the two small windows of the Sacronova Ø13 mm Main Screw are aligned and overlapping in the inlet view. Use the skin markings for the anterior and posterior walls of the sacrum as a second reference to confirm that the orientation of the Ø6 mm Side Screw trajectory is within the sacrum.



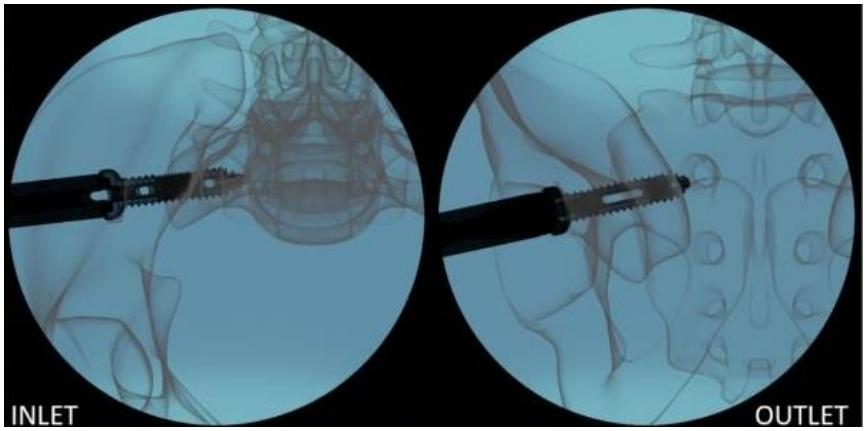


Figure 5: Image of SacronovaØ13 mm Main Screw insertion in appropriate alignment

Remove the Handle,Square Driver, and Guide Wire, but **leave the IntroducerSleeve in place**. Take care that the Introducer Sleeve does not rotate after the Square Driver is removed.

Preparation– Ø6 mm SideScrews

Connect the Awl to the Quick Connect Palm Handle. Note the orientation of the Awl tip and the correlation to the alignment flat near the Quick Connect Handle. The alignment flat will be facing the Introducer Sleeve when the tip of the Awl is oriented properly.

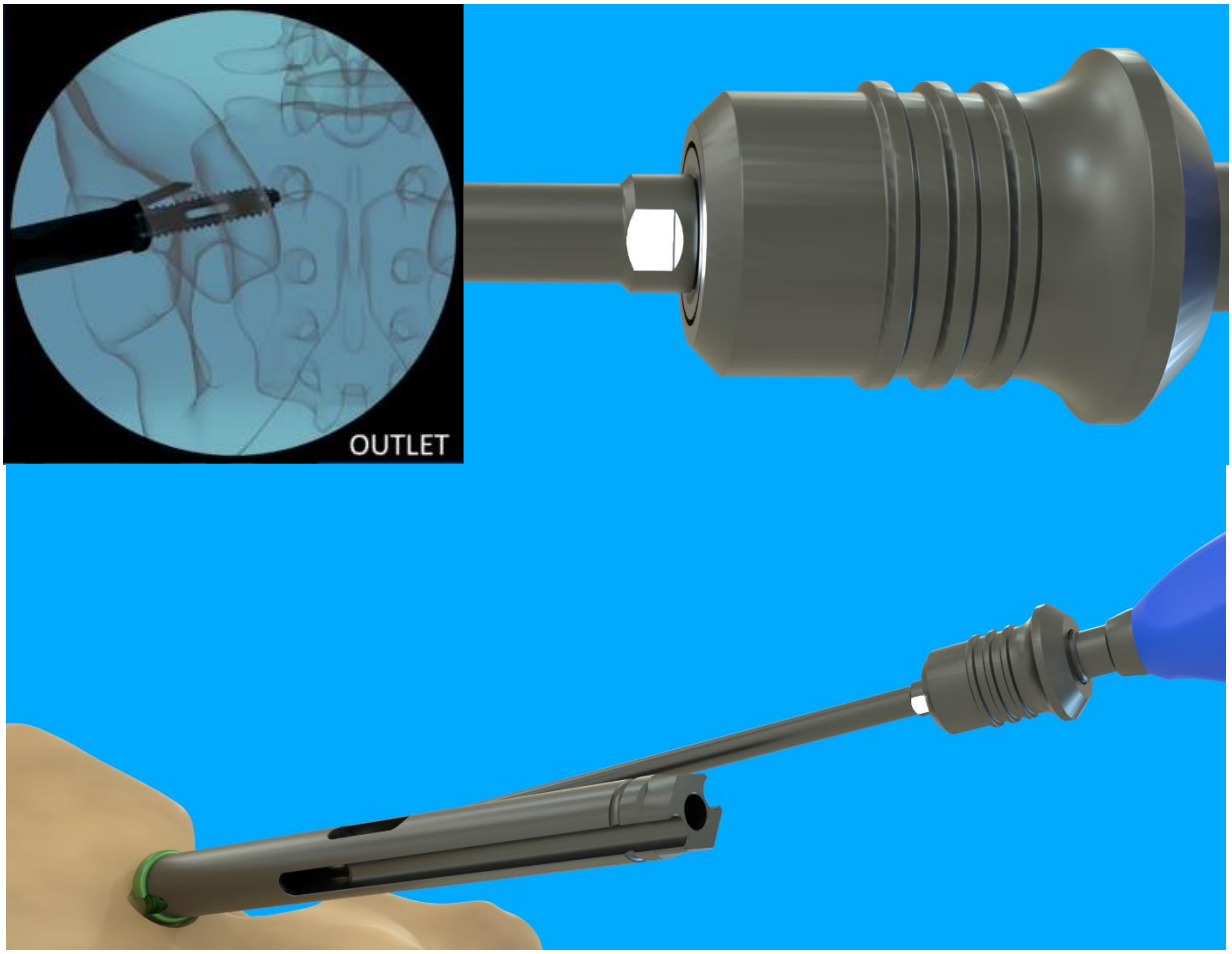


Figure 6: Orientation of Awl for Ø6 mm SideScrew preparation

Place the Awl through the Introducer Sleeve and use a Mallet to advance up to 25mm into the cortical surface of the ilium to prepare a pathway for the Ø6 mm Side Screw. Repeat for the opposite side.

Implant Delivery - Ø6 mm SideScrews

Connect theSide Screw Driver [Self Retaining] to the appropriate lengthØ6 mm Side Screw. The Side Screw Driver [Self Retaining] has a threaded tip that must be advanced by turning clockwise until the hexalobe can be engaged. The hexalobe is friction fit on eitherSide Screw Driver when engaged completely.

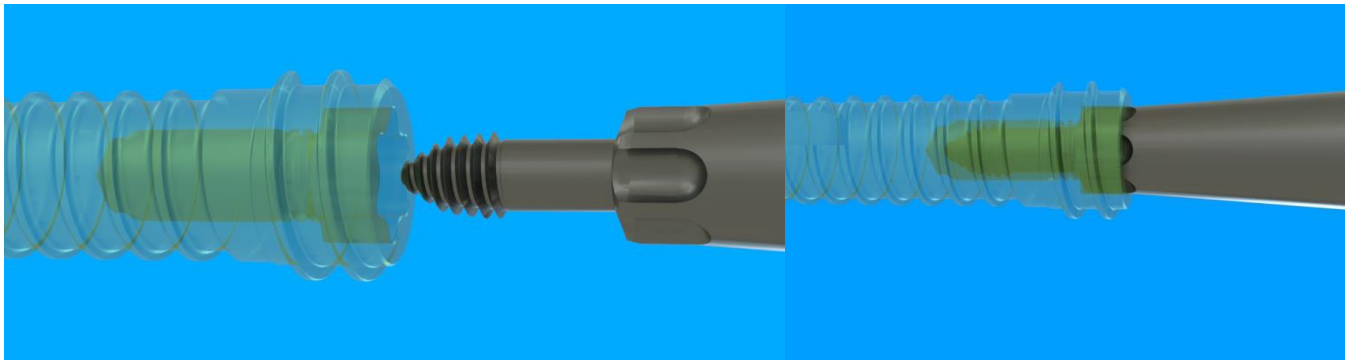


Figure 7: Side Screw Driver [Self Retaining]Assembly

As the Ø6 mm Side Screw is close to its final location, the cavity inside the Ø6mm Side Screw head will be visible on fluoro images.

Continue rotating the Side Screw Driver [Self Retaining]until the Ø6 mm SideScrew stops within theØ13 mm Main Screw.

The final half turn of the Ø6 mm Side Screw will be preceded by a small resistance where the threads reach an interference fit. After this interference, a half turn is required to place theØ6 mm SideScrew in its final location and set the anti-backout feature.

Remove the Side Screw Driver [Self Retaining]by pulling it back 3mm to disengage the hexalobe drive and then rotating counterclockwise to unthread the retainer tip.

Repeat Ø6 mm Side Screw delivery steps for the opposing Ø6 mm Side Screw.

Confirm placement of Trident Ø6 mm Side Screws on the outlet view of fluoroscopy.

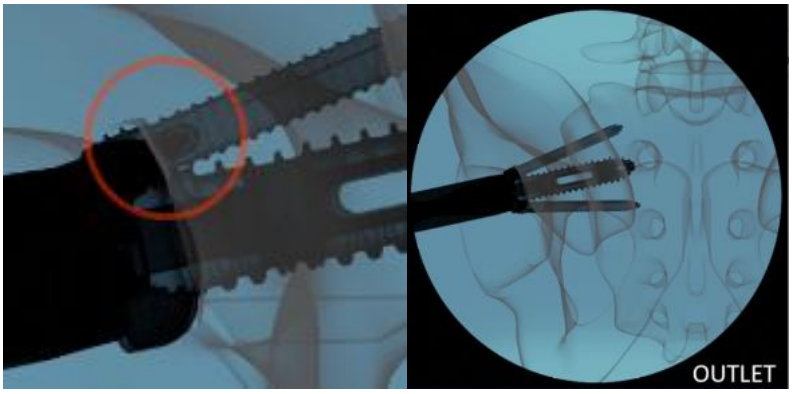


Figure 8: Ø6 mm Side Screws in position

Graft Delivery

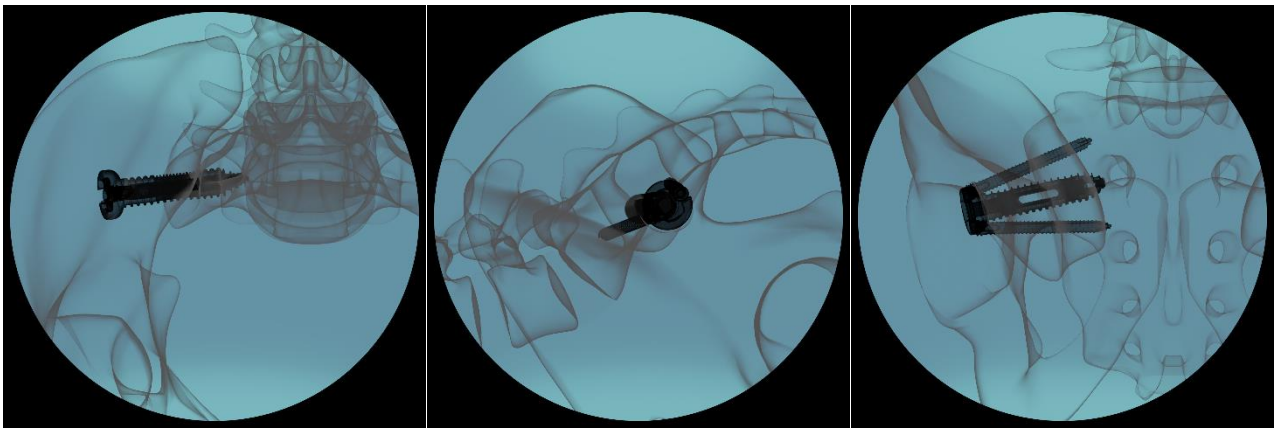
Figure 9: Graft delivery

Place the Graft Delivery Sleeve into the Introducer Sleeve. Use the Graft Tamp to place bone graft materials into the core of the SacronovaØ13 mm MainScrew.
Remove the Graft Tamp and Graft Delivery Sleeve by pulling them out of the Introducer Sleeve.
Remove the Introducer Sleeve from the Sacronova Ø13 mm Main Screw by turning it counterclockwise and pulling out.
Perform typical closure and suture procedures to close the surgical site.

Adjusting the Ø6 mm Side Screws

The Non-RetainingSide Screw Driver is intended to adjust the Ø6 mm Side Screw if the Side Screw Driver [Self Retaining]cannot reconnect to the internal threads of the Ø6 mm Side Screw after it is released.

Final Images



EXPLANTATION

The Medart Technology Pvt. Ltd. Sacronova SI Screw System is not intended to be explanted. However, should the need for explantation occur, follow these steps:

- Target the center of the Ø13 mmMain Screw with a Guide Wire and advance aGuide Wire until it is centered in the flange of the Ø13 mmMain Screw.
- Sequentially insert the 8mm and 22mm Dilators over the Guide Wire
- Place the Insulting Sleeve over the 22mm Dilator and as much around the flange of the Ø13mm Main Screw as possible.
- Remove the 8 mm Dilator, leaving the Guide Wire, 22 mm Dilator and the Insulting Sleeve.
- Insert the Square Driver over the Guide Wire to make connection with the square drive feature of the Ø13 mm Main Screw.
- Remove the 22 mm Dilator, leaving the Guide Wire, Square Driver and Insulating Sleeve.
- Insert the Removal Sleeve over the Square Driver and align the tabs with the slots in the Ø13 mm Main Screw.
- Rotate the Removal Sleeve clockwise to engage the retainer mechanism.
- Remove the Square Driver, Guide Wire and Insulating Sleeve. Only the Removal Sleeve is connected.
- Use the alignment slots in the side of the Removal Sleeve to align the Side Screw Driver [self-retaining] with the Ø6mm Side Screws.
- Advance the Side Screw Driver [self-retaining] until the threaded retaining tip engages the inner threads of the Ø6 mm Side Screw and rotate clockwise several turns to pass the retainer threads until the hexalobe tip engages the Screw.
- *The Non-Retaining Side Screw Driver is an option to use if the Side Screw Driver [Self Retaining] cannot connect the threaded tip due to misalignment of the screw axis or foreign material blocking the internal cavity.*
- Remove the Ø6 mm Side Screw by rotating the Side Screw Driver counterclockwise.
- Repeat for the opposite Ø6 mm SideScrew.
- After both Ø6 mm Side Screws are removed, place the Square Driver with desired Handle through the Removal Sleeve and connect to the Ø13 mm Main Screw.
- Rotate the Square Driver and Removal Sleeve together in a counterclockwise direction to remove the Ø13mm Main Screw.**The Removal Sleeve does not have a feature to lock the rotation of the Ø13 mm Main Screw and Square Driver to the rotation of the Removal Sleeve.**Take care not to rotate the Removal Sleeve in a way that will disconnect it from the Ø13 mm Main Screw.

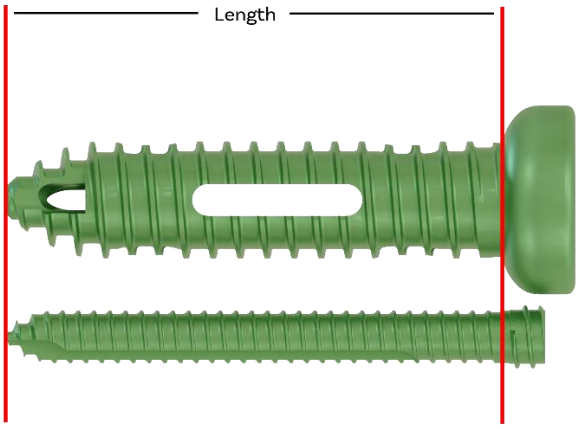
PRODUCT OFFERING

Sacronova Implant Size Availability

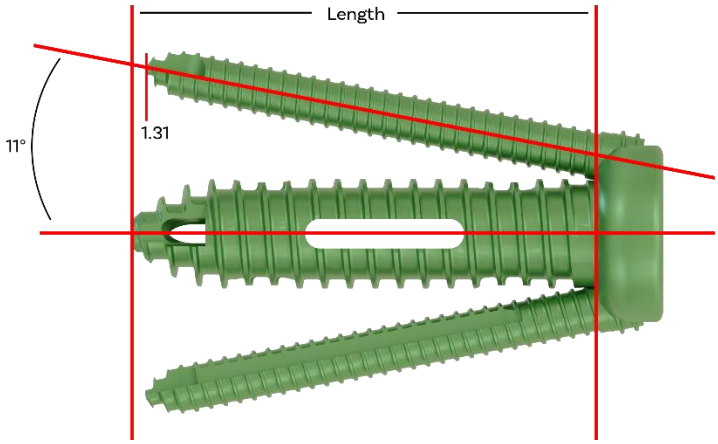
Implant Description	Part Number
Ø13 mm X 30 mm Sacronova Main Screw	03-30-13
Ø13 mm X 35 mm Sacronova Main Screw	03-35-13
Ø13 mm X 40 mm Sacronova Main Screw	03-40-13
Ø13 mm X 45 mm Sacronova Main Screw	03-45-13
Ø13 mm X 50 mm Sacronova Main Screw	03-50-13
Ø13 mm X 55 mm Sacronova Main Screw	03-55-13
Ø13 mm X 60 mm Sacronova Main Screw	03-60-13
Ø13 mm X 65 mm Sacronova Main Screw	03-65-13
Ø6 mm X 30 mm Sacronova Side Screw	03-30-6
Ø6 mm X 35 mm Sacronova Side Screw	03-35-6
Ø6 mm X 40 mm Sacronova Side Screw	03-40-6
Ø6 mm X 45 mm Sacronova Side Screw	03-45-6
Ø6 mm X 50 mm Sacronova Side Screw	03-50-6
Ø6 mm X 55 mm Sacronova Side Screw	03-55-6
Ø6 mm X 60 mm T Sacronova Side Screw	03-60-6
Ø6 mm X 65 mm Sacronova Side Screw	03-65-6

6 mm Side Screws size 30 – 65

13 mm Main Screwssize 30 – 65



The nominal length of the Sacronova Screws are measured from the tip to the end of the threads on the body of the screw



The nominal angle between the Ø13 mm Main Screw and the Ø6 mm Side Screw is 11 degrees.

TRIDENT INSTRUMENT BOM

Instrument Description	Part Number
Quick Connect Ratcheting T-Handle	00-210
Quick Connect Palm Handle	00-100
Guide Wire	00-9028-18T
Square Driver	03-02
Introducer Sleeve	03-03
Multifunctional Handle	03-04
Side Screw Driver [Self Retaining]	03-05
Side Screw Driver [Non-Retaining]	03-06
Removal Sleeve	03-07
Awl	03-08
Graft Delivery Sleeve	03-09
Graft Tamp	03-10
8 mm Dilator	03-11-1
22 mm Dilator	03-11-2
Insulating Sleeve	03-13
Measuring Sleeve	03-14
8 mm Cannulated Drill	03-15

CONTRAINDICATIONS:

Contraindications include but are not limited to:

- Acute or chronic infections, diseases of any etiology and localization
- Morbid obesity
- Signs of local inflammation
- Fever or leukocytosis
- Metal/polymer sensitivity/allergies to the implant materials
- Medical or surgical conditions, which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of bone graft)
- Any case not needing a bone graft and fusion, or where fracture healing is not required
- Any case requiring the mixing of metals from different components
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Unsuitable or insufficient bone support, bone immaturity
- Any case not described in the indications for use
- A patient unwilling to cooperate with the postoperative instructions
- Alcoholism, smoking, or drug abuse
- Any time implant utilization would interfere with anatomical structures or expected physiological performance

MATERIALS:

Sacronova SI Screw System Implants are manufactured entirely of Ti-6Al-4V ELI with no markers or wires. Surgical instruments provided with the implants are manufactured from stainless steel, silicone, andpolyphenylsulfone (PPSU).

CLEANING OF IMPLANTS AND INSTRUMENTS:

1. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.
3. Immerse the instruments and implants in a neutral pH detergent prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard to clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard to clean areas.

6. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturer's recommended practices. Medart Technology Pvt. Ltd. recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions. It is also recommended to remove implants (in caddies) from kits (cases).

The instruments, case, and caddy can be reprocessed for use. They must be cleaned prior to sterilization. If there are any visual signs of contaminants, soil, or debris, the cleaning steps must be repeated prior to sterilization.

INSPECTION:

Carefully inspect each instrument to ensure all visible blood and soil has been removed.

1. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
2. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact Medart Technology Pvt. Ltd. customer service or your representative for a replacement.
3. If corrosion is noted, do not use and contact Medart Technology Pvt. Ltd. customer service or your representative for a replacement.

STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been validated:

Method:	**Steam**
Cycle:	**Pre-Vacuum**
Temperature:	**270°F (132°C)**
Exposure Time	**6 minutes**
Number of pulses:	**4**
Dry Time:	**30 minutes**

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged.
Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.
Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery.
Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it must be cleaned and re-sterilized after surgery.

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79 Current Version – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: Current Version – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging.

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:

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 but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a. A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
   b. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
   c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
   d. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
   e. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
   f. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS:

1. THE IMPLANTATION OF SPINALFIXATION DEVICESSHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use radiographic imaging and the Guide Wire to determine the appropriate implant to use.
3. PREVIOUSLY IMPLANTED DEVICES MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. SCREW TYPES. The Ø6 mm Side Screws of the Sacronova SI Screw System are intended to be used only in conjunction with the Ø13 mm main screw.
6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.

7. MAGNETIC RESONANCE ENVIRONMENT. The Sacronova SI Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Sacronova SI Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:

1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
9. Paralysis.
10. Death.
11. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:

Medart Technology Pvt. Ltd. Spinal 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 merchantability or fitness, are hereby disclaimed.
If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Medart Technology Pvt. Ltd. for current information.

PRODUCT COMPLAINTS

Any healthcare professional (e.g. customer or user) who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify:

Medart Technology Pvt. Ltd.
ADD-PLOT No-718 New Gundlav GIDC,
Gundlav,Valsad
Gujrat-396035,India

When reporting a complaint, please provide the component name, lot number, UDI, your name and phone number, and the nature of the problem.

Manufactured by Medart Technology Pvt. Ltd.
ADD-PLOT No-718 New Gundlav GIDC,
Gundlav,Valsad
Gujrat-396035,India

Phone: +91 9879769519

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