

# MID-C Surgical Technique Guide

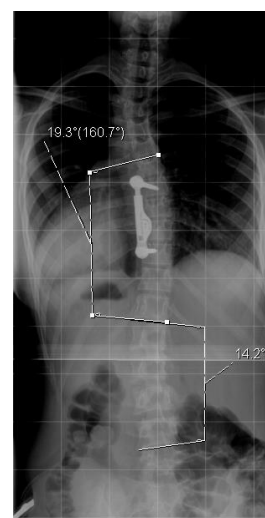
## **Introduction:**

The MID-C System is a ratchet based expandable rod designed to gradually correct AIS over period of time, with the aid of unique physical therapy performed by the patient along several months. A Control Pin that can be accessed percutaneously provides the option of interfering the process at any time and lock the system so that it becomes a rigid rod or release the ratchet mechanism.

This Surgical technique document will guide you through the implantation process.



Pre-Op



6 Months

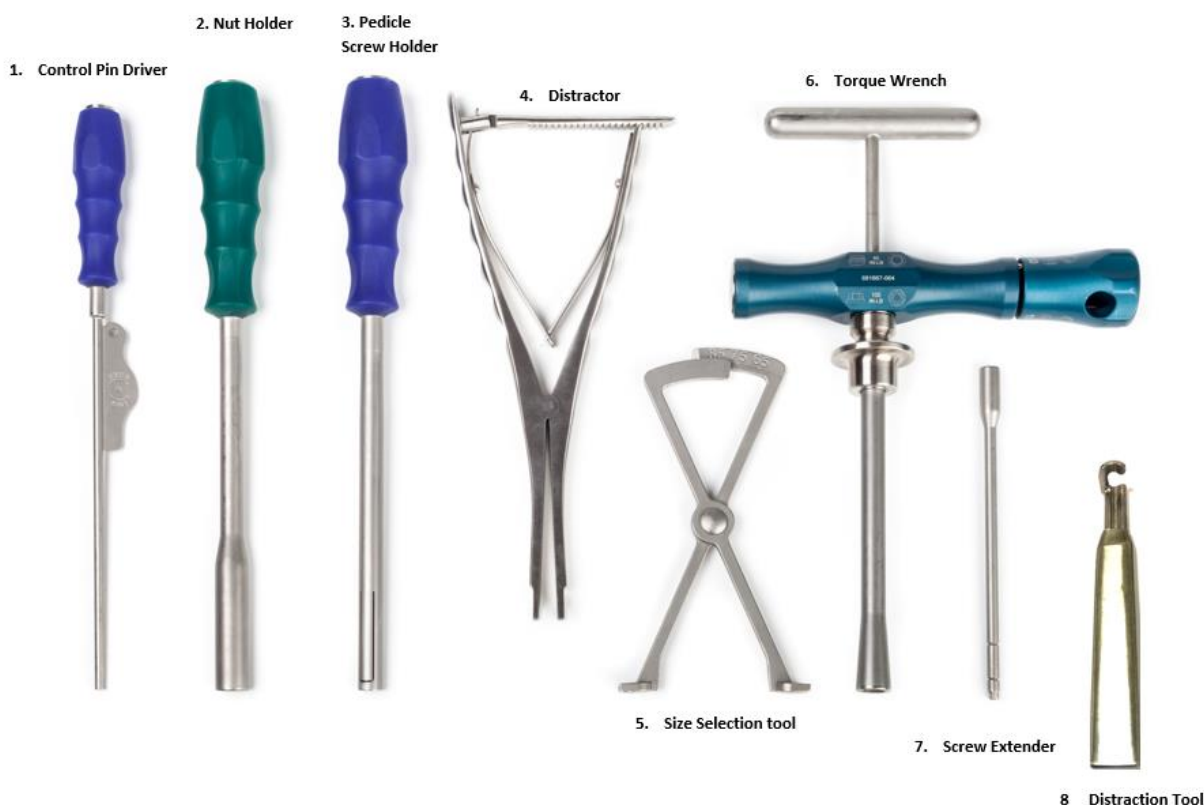
## **Indications:**

The MID-C System is indicated for patients:

- Having Adolescent Idiopathic Scoliosis (AIS) classified as Lenke type 1 or 5
- Above the age of 10 years old
- Having Cobb angle of up to 60 degrees
- Have Flexible curve with mild to moderate rotation
- Appropriate candidate for posterior surgical approach

# MID-C Surgical Technique Guide

## MID-C System Instrumentation Set



1. Control Pin Driver: This tool is used to hold the Control Pin and switch it between Ratchet, Idle and Locked positions.
2. Nut Holder: This tool is used to hold the Nut of the Pedicle Screw and place it on the screw's upper thread, before final tightening.
3. Pedicle Screw Holder: This tool is used to hold the Pedicle Screw and drive it into the pedicle.
4. Distractor: This tool is used to perform initial distraction of the MID-C system, if desired by the surgeon.
5. Size Selection tool: This tool is used to measure the distance between the heads of the two Pedicle Screws after insertion in order to select the proper length version of the MID-C implant.
6. Torque Wrench: This tool is used to tighten the Nut on the Pedicle Screw to the right torque. It comprise of :
  - Torque handle
  - Nut Holding shaft
  - Counter torque handle
7. Screw Extender: This tool is connected to the first pedicle screw to guide the surgeon to insert the second screw in a generally parallel path, within the anatomy limitations
8. Distraction Tool: This tool help to locate and adjust the joint of the implant onto the pedicle screw.

\*Refer to the MID-C System Instrumentation Set IFU for proper reprocessing instructions (Doc No. IL-01-05, ApiFix Ltd MID-C System Instrumentation Instructions for Us).

# MID-C Surgical Technique Guide

## Surgical Technique:

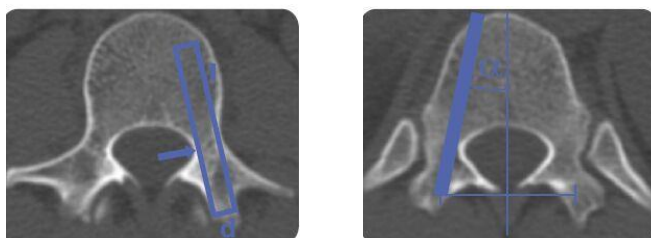
### 1. General:

The MID-C System is to be used only with pedicle screws supplied by ApiFix Ltd.

Correct selection of the appropriate size of the MID-C and Pedicle Screws is extremely important to assure the correct function of the device and for optimal performance.

### 2. Preoperative Planning:

- Preoperative planning using x-ray guidance (plain films or CT scan) may assist in the determination of pedicle screw length. The diameter of the screw should be based on the inner mediolateral pedicle diameter at its isthmus. The length should be measured from the pedicle screw entry point to the anterior edge of the vertebrae.



Note: magnification markers must be used during x-ray evaluation to accurately calculate the necessary screw sizes.

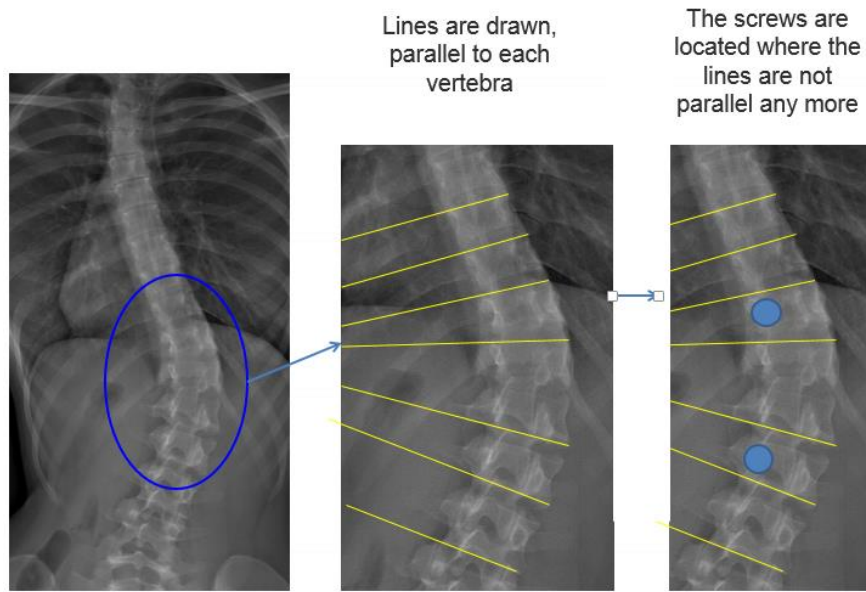
- Positioning of the patient must be prone on a radiolucent table suitable for AP and lateral fluoroscopy, which will be performed during the course of surgery.



- As in every spine surgery, preoperative fluoroscopic confirmation of the spinal alignment and the location of the target levels for incision should be obtained.

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### 3. Calculation of the MID-C system Screws Placement

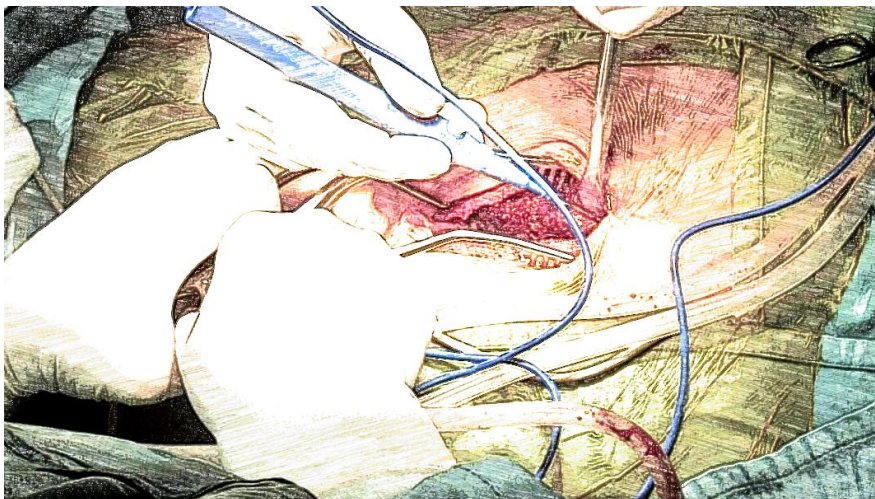


### 4. Surgical Exposure

The surgical exposure for implantation of the MID-C System is a posterior approach with a vertical midline incision of approximately 10-12 cm. In general, the MID-C surgical procedure will require a visualization of the facet joints and medial aspects of the transverse processes on both the superior and inferior operative levels, located on both sides of the apex of the major curve. Once achieved, the surgeon can proceed with pedicle screw insertion and assembly of the MID-C device to the pedicle screws. Each of these steps is described in details below.

### 4. Muscle Dissection and Retraction

As in all surgical procedures, damage to surrounding soft tissues should be minimized. Standard monopolar and bipolar cautery should be used to control bleeding during muscle and soft tissue dissection.



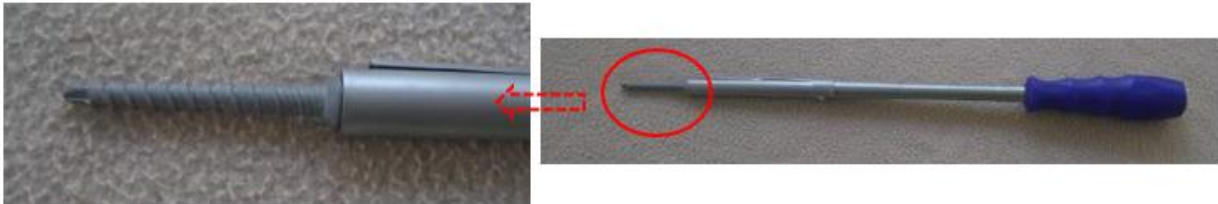


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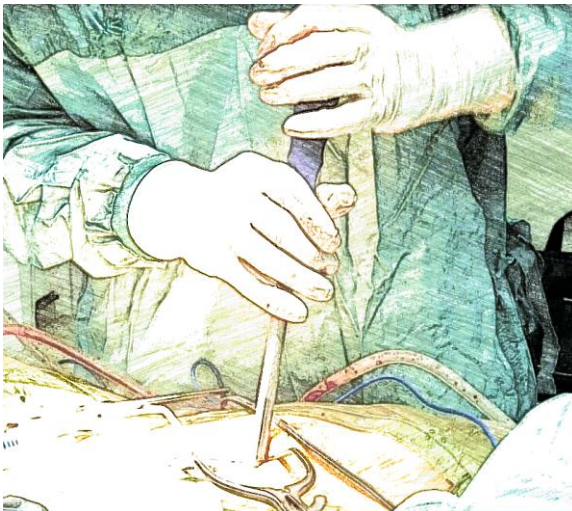
## 5. Pedicle Screw Insertion

The MID-C System is to be used only with pedicle screws supplied by ApiFix Ltd.

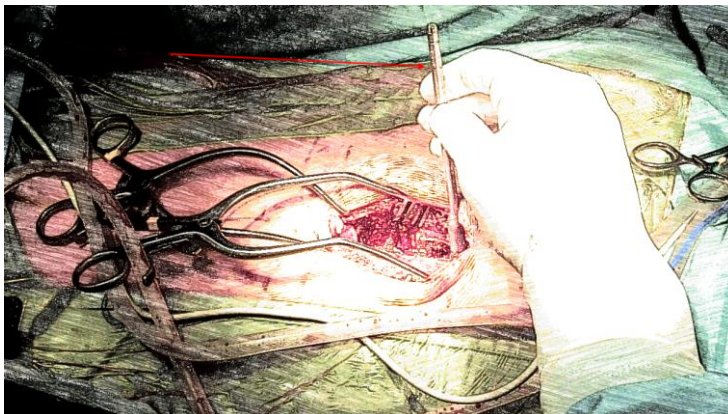
- Always start with placement of the upper pedicle screw.
- Locate the screws entry points and prepare the initial screw hole using standard tools and methods
- Select the appropriate first screw, Diameter and Length, and connect it to the Pedicle Screw Holder



- Insert the first screw all the way into the pedicle

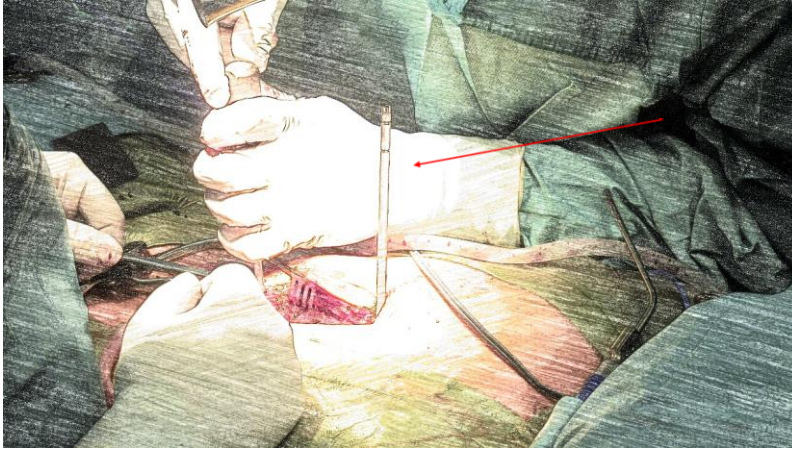


- Fix the Screw Extender to the first Pedicle Screw



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- Continue with inserting the second screw while making an effort to insert it parallel to the Screw Extender, within the anatomical limitations.



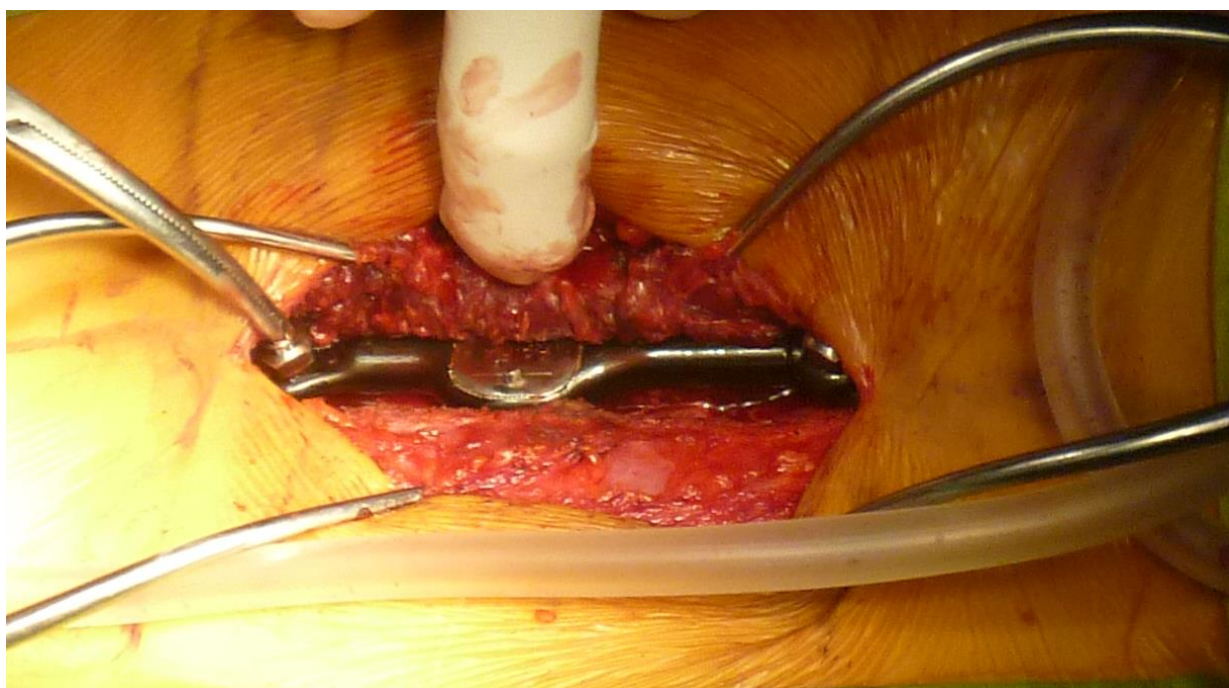
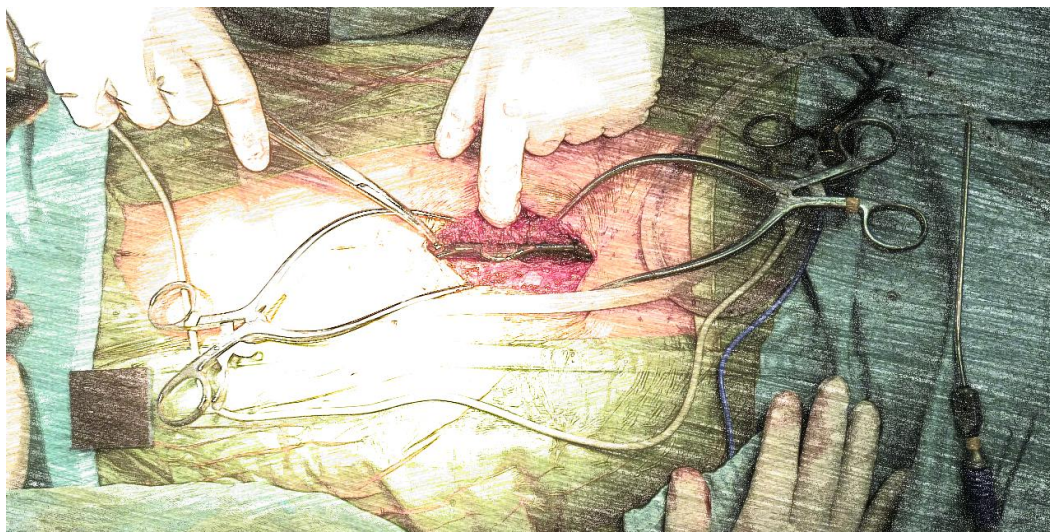
- Use the Implant Sizing Gauge to select the proper implant length





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- Place the selected MID-C implant on the two screws



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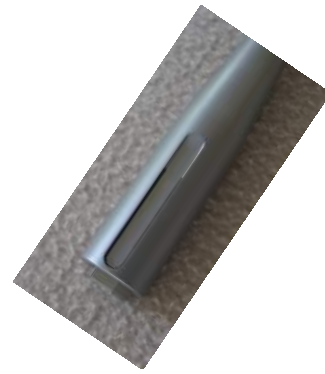
- The Distraction Tool may help to locate and adjust the implant into the screw when the implant joint may be mildly longer than the location of the screw:
  - i. Lock one side of the implant with the nut
  - ii. Rotate the Distraction Tool curved lip and lock it on the cylindrical part of the screw
  - iii. Push the Distraction Tool toward the implant in order to adjust the screw with the implant joint
  - iv. Push the implant down while inserting the screw into the joint
  - v. Tilt the Distraction Tool to take it out



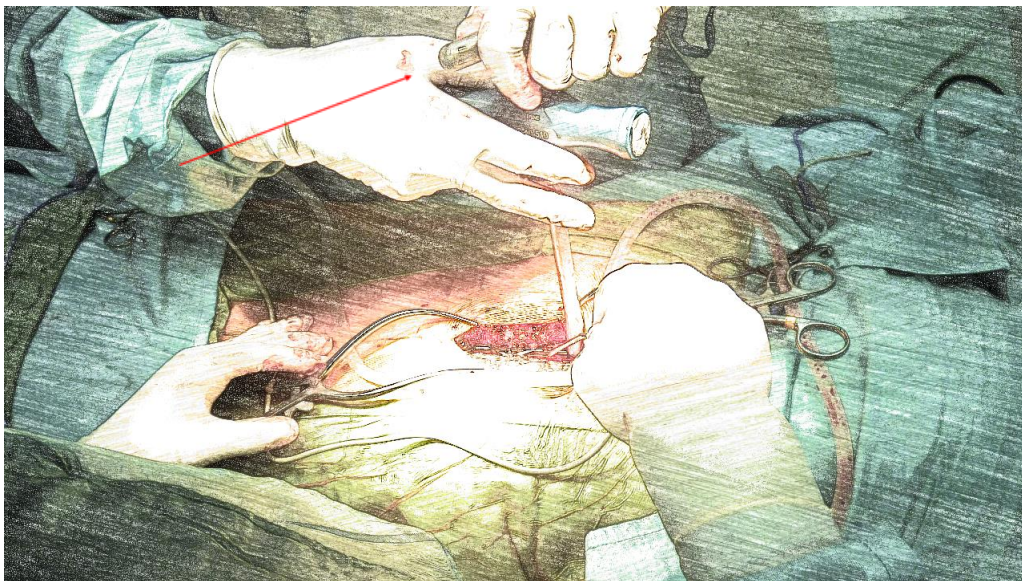


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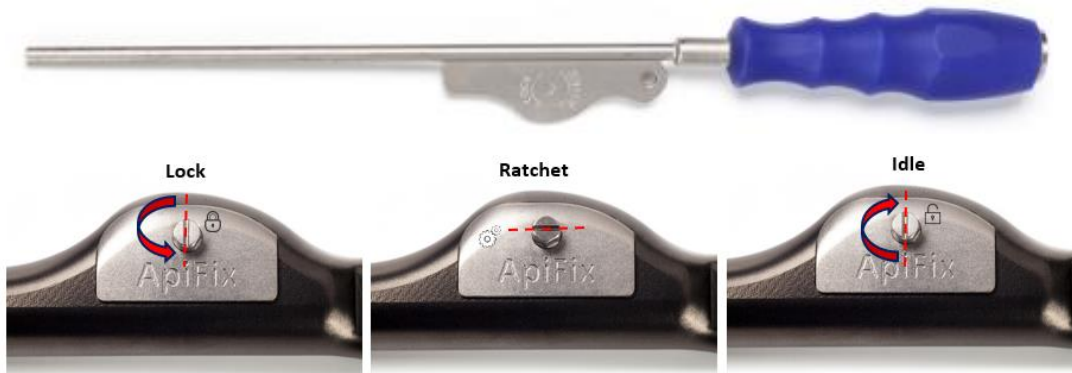
- Use the Nut Holder to place nuts on both screw



- Use the Torque Wrench and the Counter Torque Handle to tighten the nuts to the proper torque (100 should be indicated on the Torque Wrench)

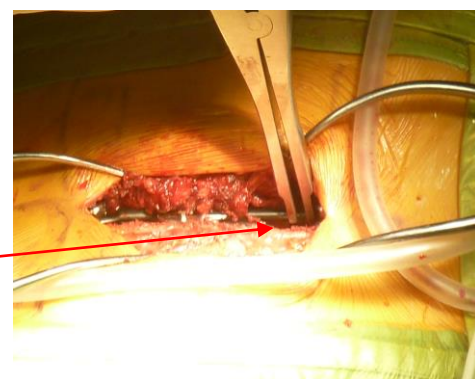
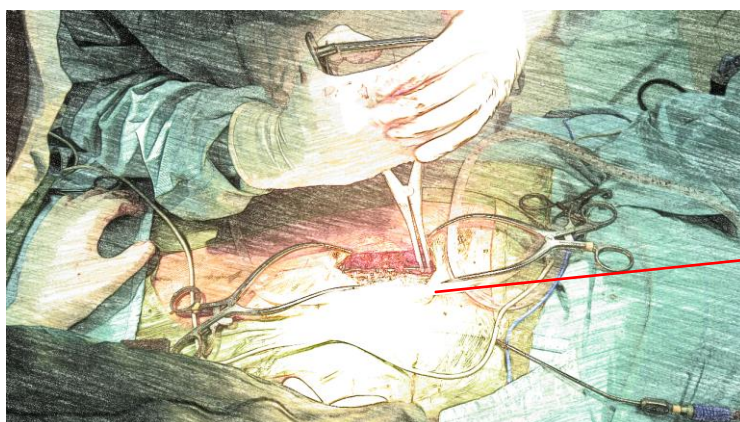


- Make sure that the control pin is set on the Ratchet position

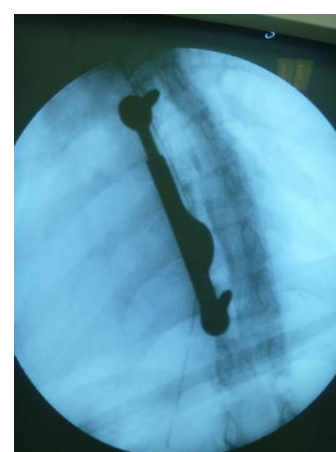
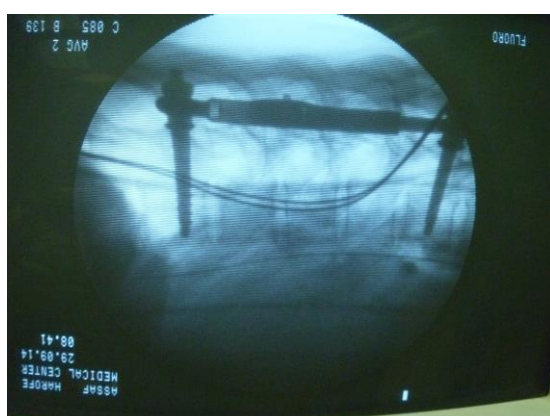


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- Apply initial distraction to verify proper function of the Ratchet system



## Verify Final result



\*Instructions for Use

See package insert MID-C System IFU (Doc. No. IL-01-04)



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