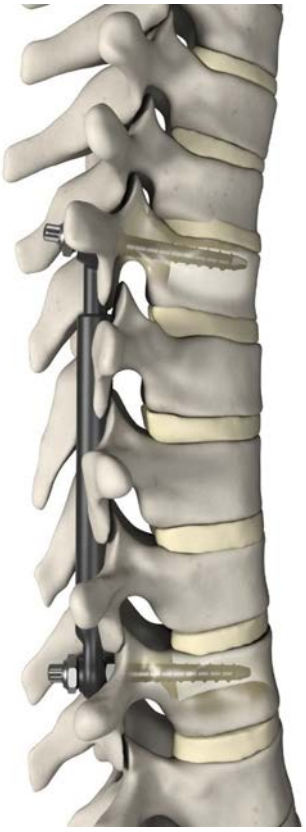
Product Description:

The Minimally Invasive Deformity Correction (MID-C) System is a ratchet-based, expandable rod that attaches to the spine using two pedicle screws. The device is implanted at the concave side, around the apex of a flexible single major curve in adolescent idiopathic scoliosis (AIS) patients and acts as an internal brace to correct and stabilize scoliotic deformity. The MID-C System is made of medical-grade titanium alloy (Ti-6Al-4V ELI) components, with some components coated in an amorphous diamond-like coating.

Figure 1: Placement of the MID-C System on spine model using two pedicle screws



Indications For Use

The ApiFix MID-C System is indicated for use in patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve)

or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 45 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12.

Contraindications

The MID-C System should not be implanted in patients meeting any of the following conditions:

- Any type of non-idiopathic scoliosis[1];
- Thoracic kyphosis in excess of 55 degrees measured between T5 to T12;
- Any main thoracic deformity that includes vertebral levels including cranial to T2;
- Known history of existing malignancy, or any systemic infection, local infection, or skin compromise at the surgical site;
- Spinal cord abnormalities that require treatment;
- Presence of neurological deficit (defined as a motor grade of 5 out of 5); or
- Known poor bone quality defined as a T-score -1.5 or less.

Warnings

- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.

Precautions

- Safety and probable benefit of the ApiFix MID-C System in skeletally immature patients with a Risser Grade status less than or equal to 1 have not been established.
- The MID-C System implants are supplied sterile and are for single use only and cannot be reused or re-sterilized.
- Do not use if the sterile package has been damaged or is open.
- Examine implant carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.

[1] idiopathic scoliosis defined as a lateral spine curve of more than 10 degrees of unknown cause (Weinstein, SL et al. Effect of Bracing in Adolescents with Idiopathic Scoliosis. *N Engl J Med.* 2013, 369: 1512-1521.)

- Do not use this device without proper training.
- Patients implanted with the MID-C System should not participate in contact or high demand sports such as weightlifting, tumbling, gymnastics, rowing, or other high-risk activities.
- Do not attempt to re-sterilize the MID-C System Implantable components.
- Do not use if package is damaged or sterile barrier is broken.
- The surgeon should weigh the risks and benefits of using the MID-C System in patients with the following conditions:
  - Insulin-dependent diabetes;
  - Cardiopulmonary or other systemic disease;
  - Bleeding disorder(s);
  - Ataxia;
  - Documented HIV or hepatitis infection;
  - Family history of neurofibromatosis or Marfan's syndrome;
  - Medical contraindications to anesthesia;
  - Patients who have major psychiatric disorders, or a history of substance abuse. These conditions should be defined per standard criteria, such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-V).

Potential Risks Associated with the MID-C System and Spinal Surgery Generally:

The following adverse events can potentially occur in patients implanted with the ApiFix MID-C System:

Potential Device or procedure-related adverse events (AEs)

- Screw/nut loosening
- Device loosening, migration, breakage, malposition
- Sizing issues
- Anatomic/technical difficulty
- Inability to implant the device
- Intraoperative device revision
- Inadequate curve correction
- Loss of curve correction
- Curve development above and/or below the instrumented levels

- Requirement for subsequent surgical intervention
- Neurologic
- Heterotopic ossification
- Trunk imbalance
- Interference with imaging
- Unintended spontaneous fusion
- Bone fracture
- Dural tear/leakage
- Surgical site seroma, bursitis, crepitus
- Skin penetration by device
- Wound dehiscence
- Hematoma
- Wound infection, superficial, deep
- Intraoperative neurologic injury
- Intraoperative vascular injury, excessive blood loss, hypotension
- Anesthesia, airway, ventilation
- Visceral injury
- Blood transfusion
- Allergic reaction
- Ophthalmic injury, including blindness
- Pain (back, surgical site, extremity, other)

Potential Systemic AEs

- Deep vein thrombosis
- Pulmonary embolism
- Atelectasis, pneumonia
- Cardiac
- Dysphagia
- Dysphonia
- Gastrointestinal (ileus, ulceration, bleeding, malnutrition)
- Foreign body reaction
- Pressure sores
- Genitourinary (infection, urine retention)
- CSF leak/meningocele
- Chest tube insertion
- Infection (systemic)
- Hematologic
- Endocrine/metabolic
- Hepatobiliary
- Immunologic

- Gynecologic
- Ophthalmologic
- Psychological
- Surgical procedure: non-spinal
- Wound infection: non-spinal
- Death

MRI Safety Information

The MID-C 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 is unknown. The safety of the MID-C System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Table 1: Model Number and Description

Product	Reference Number	Barcodes	Description
MID-C	AF85L	7290014993129	Extension of 30 mm
	AF95	7290014993136	Extension of 30 mm
	AF105L	7290014993051	Extension of 40 mm
	AF115	7290014993150	Extension of 40 mm
	AF125	7290014993068	Extension of 40 mm
Pedicle Screws	AF6550	7290014993228	Pedicle screw 6.5X50 mm
	AF6545	7290014993235	Pedicle screw 6.5X45 mm
	AF6540	7290014993242	Pedicle screw 6.5X40 mm
	AF6045	7290014993532	Pedicle screw 6.0X45 mm
	AF6040	7290014993525	Pedicle screw 6.0X40 mm

Product	Reference Number	Barcodes	Description
	AF6035	7290014993518	Pedicle screw 6.0X35 mm
	AF5545	7290014993266	Pedicle screw 5.5X45 mm
	AF5540	7290014993273	Pedicle screw 5.5X40 mm
	AF5535	7290014993280	Pedicle screw 5.5X35 mm
	AF5035	7290014993495	Pedicle screw 5.0X35 mm
	AF5030	7290014993488	Pedicle screw 5.0X30 mm
	AF4540	7290014993297	Pedicle screw 4.5X40 mm
	AF4535	7290014993303	Pedicle screw 4.5X35 mm

Detail of System:

Several models representing the MID-C System are listed in Table 1. Each component of the MID-C System is provided sterile using gamma irradiation and packed individually in double PETG blister trays (tray within a tray) with Tyvek peel. Correct selection of the appropriate model of the MID-C System is extremely important to assure the correct function of the device, detailed in MID-C Surgical Technique Guide.

The MID-C System includes the implantable components, which are provided sterile, and the following surgical instruments:

- Pedicle Screw Holder: Holds the pedicle screw and drives it into the pedicle
- Screw Extender: Connected to the first pedicle screw. Guides the surgeon to insert the second screw in a generally parallel path, within anatomical limitations.
- Size Selection Gauge: Measures the distance between the heads of the two pedicle screws after insertion, to select the appropriate length of the MID-C implant

- Control Pin Driver: Switches the Control Pin between Ratchet, Idle, and Locked Positions
- Nut Holder: Holds the nut of the pedicle screw when placed on the screw's upper thread, prior to final tightening
- Torque Wrench: Tightens the nut on the pedicle screw to the right torque. Comprises of torque wrench handle, counter torque handle, and torque rod.
- Distractor: Used by surgeon to initially distract the MID-C System

The surgical instruments are provided non-sterile and must be cleaned, disinfected, and sterilized prior to use. Cleaning, disinfection, and sterilization instructions, as well as reprocessing instructions, for the surgical instruments are provided in the MID-C Instrumentation Instructions for Use (DMS-769).

Procedure:

Use of the MID-C System should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, has proper experience with posterior spinal surgeries and completed proper training in the implantation of the device.

Selecting suitable patients for the implantation of the MID-C System is extremely important. The MID-C System should be implanted only in patients who meet all of the indications of use and none of the contraindications.

For the details of the surgical procedure refer as appropriate to the MID-C Surgical Technique Guide (DMS-5449). The implantation of the MID-C system can only be performed with the MID-C Instrumentation set. Please refer the MID-C Instrumentation Instructions for Use (DMS-769).

Note: Physical therapy is recommended post operatively to help the body alignment after curve correction.

Non-Clinical Testing:

A number of non-clinical (e.g., mechanical and biomechanical tests) were conducted on the MID-C System.

Clinical Experience:

ApiFix conducted a prospective, multi-center, non-randomized, open label clinical study in Hungary, Romania, and Israel in twenty (N=20) subjects. The purpose of the study was to assess the safety and probable benefit of the device in AIS patients. In addition, the company has collected data outside the United States (OUS) from post-market clinical studies (N=26), through commercial use (N=197) in the European Union, Singapore, and

Israel, and from special access cases in Canada (N=9). A total of 252 OUS patients have been implanted with the MID-C System.

Given that the clinical data provided to support this HDE comes from OUS sources, including post-marketing experience, practitioners have, in some cases, elected to use the MID-C System outside of the recommended indications for use. Also, in the first 3 years of use in Europe (2012 to 2015) a portion of these patients were operated using older versions of the device.

A common primary assessment collected for all patients was curve magnitude as determined by Cobb angle, though radiographic data were collected without a uniform radiographic protocol. Radiographic images were analyzed using a single core laboratory for assessment of Risser grade (skeletal maturity status), Lenke classification, magnitude of major and minor curves, lumbar lordosis, thoracic kyphosis, bridging bone, and safety data related to pedicle screw migration, pedicle screw pullout, device loosening, and device failure/breakage.

The purpose of the clinical evaluation was to demonstrate the safety and probable benefit of the MID-C System when used in the indicated population.

Safety Endpoint and Analysis Populations

The primary safety endpoint evaluated was reoperation performed for any reason at any timepoint and included all serious adverse events (SAEs) that resulted in reoperation. Other AEs related to the device or procedure that did not result in reoperation were only captured within the first 3-months post-operatively in a subset of patients at 4 centers (63 out of 252 patients). Safety data was analyzed for three populations:

1. **All** (N=252): This population includes all OUS patients implanted with the MID-C System as of September 15, 2018.

2. **Target Population** (N=25): This includes all patients implanted with the HDE Device Version of the MID-C System, as of September 15, 2018, that meet the US Indications for Use defined by the following criteria:
   - Lenke type 1 or 5 curves;
   - Risser grade 2 or above;
   - Pre-operative Cobb angle between 45 to 60 degrees;
   - Flexible major curve (defined as lateral bending correction to 30 degrees or less);
   - Thoracic kyphosis less than 55 degrees.

3. **Expanded Target Population** (N=49): This includes all patients implanted with the HDE Device Version of the MID-C System, as of September 15, 2018, that meet an

Expanded US Indications for Use which includes patients (N=24) with 40 to 44-degree curves as defined by the following criteria:

- Lenke type 1 or 5 curves;
- Risser grade 2 or above;
- Pre-operative Cobb angle between 40 to 60 degrees;
- Flexible major curve (defined as lateral bending correction to 30 degrees or less);
- Thoracic kyphosis less than 55 degrees.

Note that a 5-degree difference in the 2-dimensional Cobb angle measurement is within the range of intra- and inter-observer reliability.[2] The Expanded Target Population safety analysis population was a combination of the Target Population (N=25) and patients (N=24) with 40 to 44-degree curves.

Probable Benefit Endpoint and Analysis Populations

The probable benefit endpoint for evaluation is defined as primary Cobb angle less than or equal to 35 degrees and no curve progression at 24-months compared to baseline following treatment with the MID-C System. There are two patient populations for evaluation of probable benefit: Target Population and Expanded Target Population. These analysis populations are defined using the same criterion for the safety analysis above, with the additional requirement of reaching the post-operative timepoint of 12- and 24-months. A summary of the probable benefit patient populations is outlined below.

1. **Target Population**
   - Reached post-operative timepoint of 12-months (N=17)
   - Reached post-operative timepoint of 24-months (N=10)

2. **Expanded Target Population**
   - Reached post-operative timepoint of 12-months (N=32)
   - Reached post-operative timepoint of 24-months (N=22)

Patient Demographics

A summary of the patient demographics for the Target Population and Expanded Target Population can be found in Table 2, with the number of patients with evaluable data for each demographic parameter identified.

[2] Gstoettner M et al. Inter- and intraobserver reliability assessment of the Cobb angle: manual versus digital measurement tools. Eur Spine J. 2007: 16 (10), 1587–1592.

Table 2: Key Patient Demographics

	Target Population	Expanded Target Population
Gender		
N	24	47
Female	21 (87.5%)	42 (89.4%)
Male	3 (12.5%)	5 (10. 6%)
Age (Years)		
N	20	36
Mean ± SD	14.7±1.7	15.0±1.7
Median	14.2	15.0
Min, Max	13.0, 18.7	13.0, 19.0
Risser Grade		
N	25	49
2	2 (8%)	6 (12.2%)
3	2 (8%)	7 (14.3%)
4	16 (64%)	22 (44.9%)
5	5 (20%)	14 (28.6%)
Pre-op Major Cobb Angle		
N	25	49
Mean ± SD	49.5±4.4	45.9±4.9
Median	48.0	45.0
Min, Max	45.0, 59.0	40.0, 59.0
Pre-op Secondary Cobb Angle		
N	24	48
Mean ± SD	29.7±8.3	27.7±8.0
Median	29.0	25.5
Min, Max	16.0, 46.0	16.0, 46.0
Pre-op Lumbar Lordosis (superior endplate of L1 to the superior endplate of S1)		
N	8	17
Mean ± SD	55.5±14.8	53.8±12.3
Median	54.5	52.0
Min, Max	26.0, 78.0	26.0, 78.0
Pre-op Thoracic Kyphosis (superior endplate of T5 to the superior endplate of T12)		
N	9	19
Mean ± SD	23.2±12.8	20.2±12.3
Median	23.0	19.0
Min, Max	4.0, 45.0	3.0, 45.0

	Target Population	Expanded Target Population
Pre-op Major Cobb Angle on Lateral Bending		
N	25	49
Mean ± SD	19.3±6.6	16.6±7.8
Median	20.0	18.0
Min, Max	1.0, 30	0.0, 30
Lenke Curve Pattern*		
N	25	49
1a	9	17
1b	2	6
1c	2	5
5a	3	4
5b	0	2
5c	9	15

***The Lenke Classification System relies on measurements taken from standard x-rays. The surgeon evaluates x-rays of the patient from the front, side, and in bending positions. Each scoliosis curve is then classified in three ways:**

- **By the curve type based on which of the three regions of the spine; the proximal thoracic, main thoracic and thoracolumbar/lumbar is structural or non-structural.**
- **A lumbar spine modifier based on the distance of the center of the lumbar spine to the midline; and**
- **A sagittal thoracic modifier based on the amount of side (lateral) curvature to the thoracic region.**

Every aspect of the curve is also evaluated for its relative stiffness or flexibility on side bending x-rays. The triad system, therefore, combines the curve type (1-6) with the lumbar modifier (A, B, C) and the sagittal thoracic modifier (-, N, +) to form the complete classification. For example, the most common type is a 1AN curve classification.[3]

Safety Results

Reoperations

Overall, 45 reoperations were reported for the 252 (17.9%) patients treated with the MID-C System. Reoperation rates according to analysis population are reported in Table 3. For the All population the reoperation rate was 17.9% (45 out of 252 patients). The rates for any reoperations in the Target Population and Expanded Target Population are 12% (3 out of 25 patients) and 12.2% (6 out of 49 patients), respectively.

[3] Lenke L, Edwards C, Bridwell K. The Lenke classification of adolescent idiopathic scoliosis: how it organizes curve patterns as a template to perform selective fusions of the spine. Spine. 2003: 28 (20), 199-207.

Table 3: Reoperation Rates

Population	Total (N)	Reoperations (N)	Reoperation Rate (%)
All	252	45	**17.9%**
Expanded Target Population	49	6	**12.2%**
Target Population	25	3	**12.0%**

Reoperations According to Post-Procedure Timepoint

For the 45 reported reoperations, the mean post-operative timepoint of the reoperation was 13 months. Furthermore, 26 of the 45 (57.8%) reoperations occurred within the first 12-months post-procedure as shown in Table 4. Reoperations within the first 12-months were performed for the following reasons: device malfunctions, nut loosening, misplaced screws, screw pullout, infection, screw fracture, and rod fracture.

Table 4: Number of Reoperations at Post-Procedure Timepoints

Timepoint of reoperation (months post-procedure)	Number of reoperations
≤ 6 months	15
7 to 12 months	11
13 to 24 months	13
> 24 months	6

Relationship of Reoperation to Device or Procedure

The number of patients determined to have a reoperation that was definitely, probably, or possibly related to the device was 6 out of 252 (2.4%). The number of patients determined to have a reoperation that was definitely, probably, or possibly related to the procedure was 27 out of 252 (10.7%) patients. It was noted that 12 of the 252 (4.8%) re-operations could not be attributed to either the device or the procedure.

Reoperations Reported as Serious Adverse Events (SAEs)

Table 5 below lists the number of patients for all the reoperations reported as SAEs (N=45) within the clinical dataset (N=252). The most common reason for reoperation was pedicle screw misplacement/migration, which resulted in 9 reoperations (3.6%). There were 8 reoperations reported (3.2%) due to insufficient curve correction, and 6 of these patients are known to have undergone conversion to spinal fusion. Infection was reported as the

reason for 8 reoperations (3.2%), with one case of infection potentially causing screw migration. Additionally, screw pull-out was observed in 5 patients (2.0%) and nut loosening was observed in 5 patients (2.0%) and resulted in reoperations. One (1) patient experienced screw fracture that resulted in reoperation. There were 6 reoperations reported for device malfunctions: unspecified device failure (N=1), ratchet failure (N=1), screw dislocation from the rod (N=2) and rod breakage (N=2). Other reported reoperations were for pain (N=1), unintended additional distraction of the device (N=1), and misalignment of the extender component (N=1), which is not a current component of the MID-C System.

As shown in Table 5 below, 13 patients (5.2%) underwent reoperation with conversion to spinal fusion and instrumentation or treatment with another non-fusion spinal device. It is known that 11 out of 252 patients (4.4%) have undergone conversion to spinal fusion and instrumentation, and 2 patients were treated with non-fusion devices. Reasons for reoperation with conversion to spinal fusion were insufficient curve correction, screw misplacement, screw breakage, and infection. The MID-C System was removed in 12 patients (4.8%) and it is unknown if any of these patients required further surgical intervention for the treatment of their scoliotic curve. One patient was converted to the Shilla Growth Guidance System (a marketed device) during a reoperation procedure after observation of screw pull-out. Also, one patient was converted to a vertebral body tethering device during a reoperation procedure after observation of rod breakage. A total of 15 patients (6.0%) underwent a reoperation procedure to modify the MID-C System due to pedicle screw placement, nut tightening, or device alignment issues. An additional 5 patients (2.0%) required MID-C System replacement.

Table 5: Listing of Reoperations Reported as SAEs by Procedure Type

Reoperation Type	Total Number of Reoperations	Number of Conversions to Fusion or Other or Non-fusion Device	Number of Device Removals	Number of Device Corrections	Number of Device Replacements
Screw misplacement/migration	9	3	3	3	-
Insufficient curve correction	8	6	1	-	1
Infection	8	1	4	2	1
Screw pullout	5	1	1	1	2
Locking nut loosening	5	-	-	5	-
Rod fracture	2	1	1	-	-
Screw dislocation from rod	2	-	-	1	1

Reoperation Type	Total Number of Reoperations	Number of Conversions to Fusion or Other or Non-fusion Device	Number of Device Removals	Number of Device Corrections	Number of Device Replacements
Unexpected rod movement	1	-	-	1	-
Additional device distraction	1	-	-	1	-
Screw fracture	1	1	-	-	-
Pain	1	-	1	-	-
Extender misalignment	1	-	-	1	-
Unspecified device failure	1	-	1	-	-
Total	**45**	**13**	**12**	**15**	**5**

Non-Serious Adverse Events

Non-serious AE data was collected within the first 3 months post-operatively for 63 patients from 4 centers. This additional safety data (Table 6) reported that 21 out of 63 patients experienced a non-serious AE. These AEs were: seroma (N=2); local hematoma (N=1); headaches (N=1); pain (N=13); limited range of motion of the spine (N=3); screw pull-out (N=1); vasovagal syncope (N=2); superficial wound infection (N=1); skin hypersensitivity(N=1); nausea (N=3); and knee hypoesthesia (N=1). Of note, screw pull-out occurred in one patient at 6 weeks follow-up and was reported as a non-serious AE. This patient was observed and at the 24-month follow-up visit, the screw position was reported as stable and unchanged.

Table 6: Listing of Non-serious AEs through 3 Months from 4 Centers

AE Type	Number of AEs	Number of patients
Seroma	2	2
Local Hematoma	1	1
Headaches due to Epidural Hematoma	1	1
Pain	13	11
Limited movement range of spine	3	3
Screw pull out	1	1
Vasovagal Syncope	2	2
Superficial wound infection	1	1
Hypersensitivity of skin	1	1
Nausea and vomiting	3	3
Hypoesthesia knee	1	1

Probable Benefit Results

Probable benefit was assessed within this HDE as a Cobb angle of less than or equal to 35 degrees and no curve progression at 24-months compared to baseline following treatment with the MID-C System. In addition, probable benefit was also assessed for patients with at least 12-months of follow-up data. Probable benefit results at 12-months and 24-months are reported in Table 7 below. In both analysis populations and at both timepoints, the probable benefit success using this endpoint was greater than 75% based on data available for analysis.

Analysis of the 24-month radiographic data for the Target Population showed that all 8 patients had improvement of the major curve (greater than 5 degrees compared to baseline), including the 2 patients who did not meet the primary probable benefit endpoint.

Table 7: Probable Benefit Analysis at 12- and 24-Months

Probable Benefit Population	12-month Results			24-month Results		
	Total (N)	Success (N)	Success Rate (%)	Total (N)	Success (N)	Success Rate (%)
Target Population	12	9	**75.0%**	8	6	**75.0%**
Expanded Target Population	26	22	**84.6%**	10	18	**90.0%**

Table 8 shows the average improvement in the major curve for these 8 patients was 21 degrees compared to the mean baseline Cobb angle of 49 degrees, which represented a 43% correction of the major curve. Similarly, analysis of the 24-month radiographic data for the Expanded Target Population showed a mean 47% correction of the major curve in 20 patients.

Table 8: Assessment of Major Curve Correction following MID-C System Treatment

Probable Benefit Population	Baseline Major Curve	Major Curve at 24-months	Degree Correction of Major Curve	Percent Correction of Major Curve
Target Population (N=8)	Mean: 49° Range: 45-59°	Mean: 28° Range: 19-37°	Mean: 21° Range: 9-33°	Mean: 43% Range: 20-58%
Expanded Target Population (N=20)	Mean: 45° Range: 40-59°	Mean: 24° Range: 7-37°	Mean: 21° Range: 9-35°	Mean: 47% Range: 20-83%

In assessment of probable benefit, it is relevant to consider skeletal maturity as a factor that affects the risk of curve progression. Probable benefit results are more informative if a patient has reached or is beyond skeletal maturity as the risk of future curve progression is decreased compared to skeletally immature patients. Table 9 shows the percentage of the patient population that was skeletally mature at 24-months for both populations (Target Population – 90.0%; Expanded Target Population – 86.4%).

Table 9: Percent of Skeletally Mature* Patients at 24-Months Follow up

Probable Benefit Population	Skeletally Mature at 24-Months Follow-Up	Not Skeletally Mature at 24-Months Follow-Up
Target Population with HDE Device Version (N=10)	9 (90.0%)	1 (10.0%)
Expanded Target Population with HDE Device Version (N=22)	19 (86.4%)	3 (13.6%)

* Skeletal maturity defined in the Radiographic Protocol as Risser Grade 5 by the North American Risser grading system

Secondary probable benefit endpoints of blood loss, operative time, and length of stay in hospital were retrospectively evaluated, and the MID-C System was compared to spinal fusion treatment at two centers. The retrospective analysis included 43 patients treated with the MID-C System and 33 patients treated with spinal fusion. Results of these secondary probable benefit endpoints report shorter operative time, less blood loss, and shorter hospital stay for the patients treated with the MID-C System as compared to patients treated with spinal fusion (Table 10).

Table 10: Secondary Probable Benefit Endpoints Analysis

	MID-C System (N=43)	Spinal Fusion (N=33)
Average number of spinal levels spanned	5.3	9.4
Average number of anchor points	2.1	14.1
Average operative time (hours)	1.2	3.5
Average blood loss (ml)	15.7	728
Average length of hospital stay (days)	2.2 (N=18)	7.4 (N=15)

Overall Conclusions

The data support the reasonable assurance of safety and probable benefit of the MID-C System when used in accordance with the indications for use. As described above, the overall reoperation rate is 17.9% for the 252 patients and 12.0% for the Target Population. Although the available MID-C System data representative of the target population shows a higher reoperation rate than reported in the literature for spinal instrumentation and fusion for AIS (12% versus 4.1 to 9.9%), the MID-C System can be considered to be safe for its indications for use considering the type of AEs presented and mitigation measures taken such as modifications to the device design and surgical technique. The probable benefit success rate, as described above, is 75 to 90% for the analysis populations at 24-months. This probable benefit endpoint can be considered representative of likelihood of avoidance of the need for spinal fusion during this time period.

Therefore, it is reasonable to conclude that the probable benefit to health from using the device for the target population outweighs the risk of illness or injury, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment when used as indicated in accordance with the directions for use.

Device Disposal:

Should it be necessary to dispose the MID-C device it should be treated as medical waste.

Device Retrieval Efforts:

In the event that an implanted device needs to be removed, please refer to the Retrieval and Analysis Protocol for MID-C System (DMS-5587). Surgeons conducting a retrieval procedure should follow the guidelines described in DMS-5587 (e.g., surgical procedure, handling of specimen, and packaging of specimen) to ensure patient safety and to ensure that the specimen may be analyzed appropriately.

Should it be necessary to retrieve a MID-C device, please contact ApiFix.

Symbol Legend:

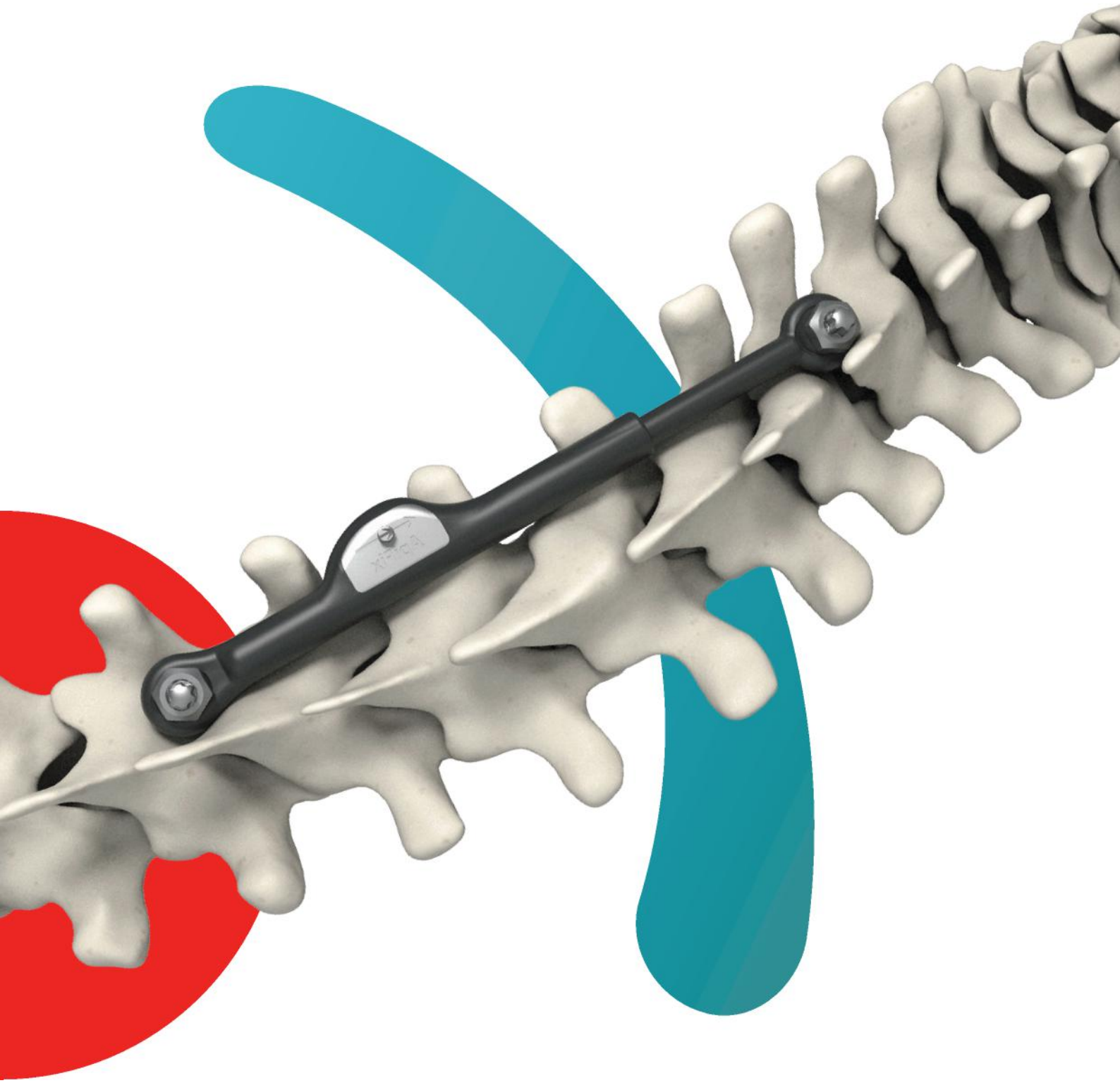
Symbol	Definition
	For prescription use only.
NON-STERILE	Device has not been sterilized.
	Consult instructions for use.
	Sterilized using gamma irradiation.
	Do not re-sterilize
	Do not use if package is damaged
	Attention, see instructions for use.
	Use by
	Single Use Only
	Manufacture
	Date of manufacture
	Lot number
	Catalog number

ApiFix, Ltd
17 Tehelet Street
Misgav Business Park, 20174
Israel
Mail: info@apifix.com

ApiFix

THE INTERNAL BRACE OPTION

MID-C SURGICAL TECHNIQUE GUIDE



MID-C SURGICAL TECHNIQUE GUIDE

Indications for Use

The MID-C System is indicated for treatment of adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 45 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12.

Humanitarian Device. Authorized by Federal law for use in the treatment of adolescent idiopathic scoliosis (AIS). The effectiveness of this device for this use has not been demonstrated.

℞ ONLY

Contraindications

The MID-C System should not be implanted in patients meeting any of the following conditions:

- Any type of non-idiopathic scoliosis[1];
- Thoracic kyphosis in excess of 55 degrees measured between T5-T12;
- Any main thoracic deformity that includes vertebral levels including cranial to T2;
- Known history of existing malignancy, or any systemic infection, local infection, or skin compromise at the surgical site;
- Spinal cord abnormalities that require treatment;
- Presence of neurological deficit (defined as a motor grade of less than 5 out of 5); or
- Known poor bone quality defined as a T-score -1.5 or less.

Warnings

- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.

[1]idiopathic scoliosis defined as a lateral spine curve of more than 10 degrees of unknown cause.

Precautions

- Safety and probable benefit of the ApiFix MID-C System in skeletally immature patients with a Risser Grade status less than or equal to 1 have not been established.
- The MID-C System implants are supplied sterile and are for single use only and cannot be reused or re-sterilized.
- Do not use if the sterile package has been damaged or is open.
- Examine implant carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.
- Do not use this device without proper training.
- Patients implanted with the MID-C System should not participate in contact or high demand sports such as weightlifting, tumbling, gymnastics, rowing, or other high-risk activities.
- Do not attempt to re-sterilize the MID-C System Implantable components.
- Do not use if package is damaged or sterile barrier is broken.
- The surgeon should weigh the risks and benefits of using the MID-C System in patients with the following conditions:
  - Insulin-dependent diabetes;
  - Cardiopulmonary or other systemic disease;
  - Bleeding disorder(s);
  - Ataxia;
  - Documented HIV or hepatitis infection;
  - Family history of neurofibromatosis or Marfan's syndrome;
  - Medical contraindications to anesthesia;
  - Patients who have major psychiatric disorders, or a history of substance abuse. These conditions should be defined per standard criteria, such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-V).

MRI Safety Information

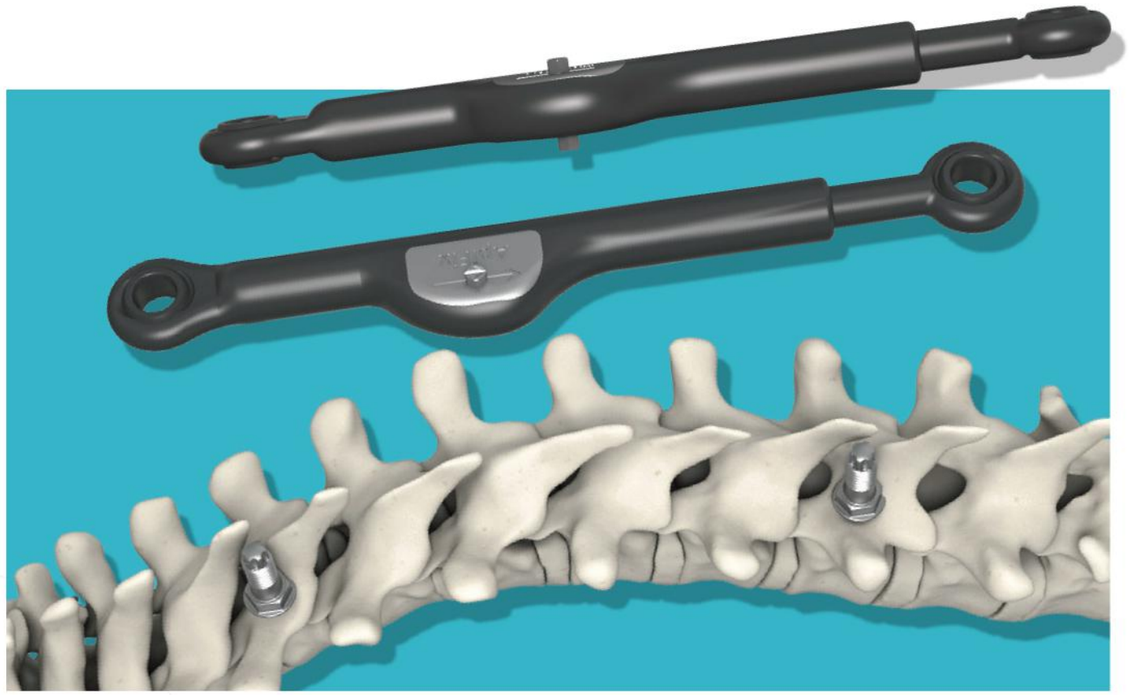
The MID-C System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment is unknown. The safety of the MID-C System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Summary of Clinical Experience

For a summary of clinical experience, please see the MID-C System's Instructions for Use.

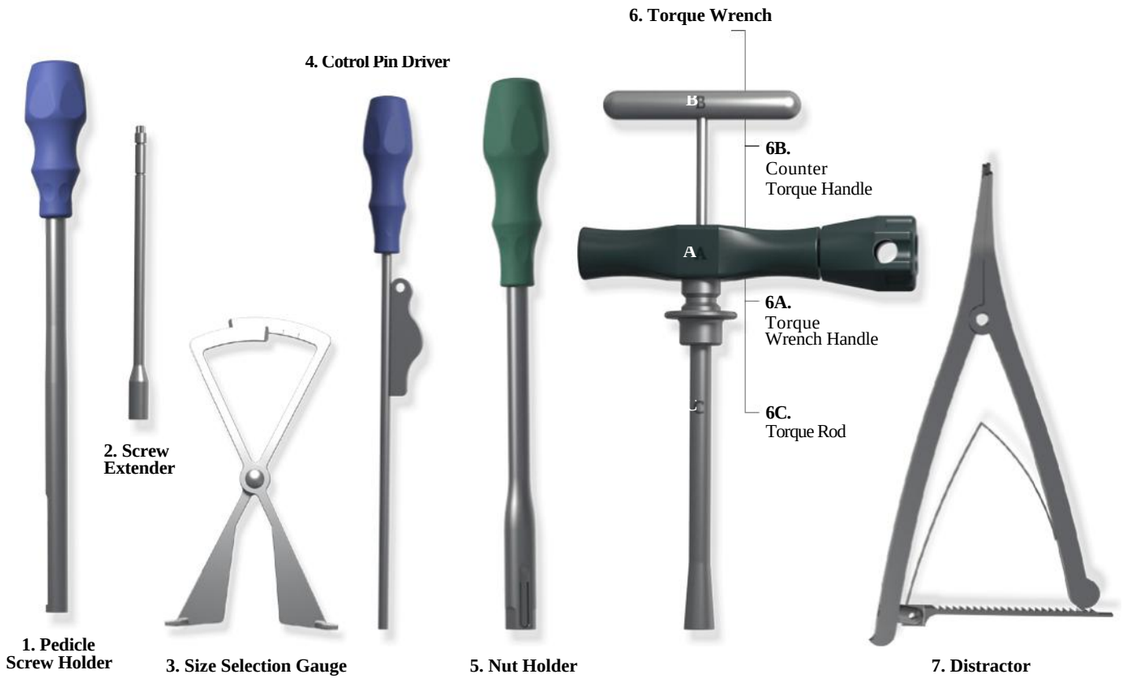
MID-C SURGICAL TECHNIQUE GUIDE

The MID-C System is a ratchet-based, expandable rod, for the treatment of adolescent idiopathic scoliosis.



* For product indication refer to document DMS-4472 Mid-C Instruction for Use or page 2 of this manual.

1 MID-C SYSTEM INSTRUMENTATION SET



1.1 INSTRUMENTS UTILIZATION CHART

1	**Pedicle Screw Holder**	Holds the pedicle screw and drives it into the pedicle.
2	**Screw Extender**	Connected to the first pedicle screw. Guides the surgeon to insert the second screw in a generally parallel path, within anatomical limitations.
3	**Size Selection Gauge**	Measures the distance between the heads of the two pedicle screws after insertion, to select the appropriate length of the MID-C implant.
4	**Control Pin driver**	Switches the Control Pin between Ratchet, Idle, and Locked positions.
5	**Nut Holder**	Holds the nut of the pedicle screw when placed on the screw's upper thread, prior to final tightening.
6	**Torque Wrench**	**Tightens the nut on the pedicle screw to the right torque. Comprises:** **A.** Torque Wrench Handle **B.** Counter Torque Handle **C.** Torque Rod
7	**Distractor**	Used by the surgeon to initially distract the MID-C system.

1.2 INSTRUMENTS CATALOG NO. CHART

No.	Tool	Catalog No.
1.	**Pedicle Screw Holder**	AFT001
2.	**Screw Extender**	AFT020
3.	**Size Selection Gauge**	AFT003
4.	**Control Pin Driver**	AFT004
5.	**Nut Holder**	AFT002
6.	**Torque Wrench Handle**	AFT005
7.	**Counter Torque Handle**	AFT006
8.	**Torque Rod**	AFT008
9.	**Distractor**	AFT021

Refer to the MID-C System Instrumentation Set IFU for proper reprocessing instructions (Doc No. DMS-769, ApiFix Ltd MID-C System Instrumentation Instructions for Use).

2 BEFORE YOU BEGIN

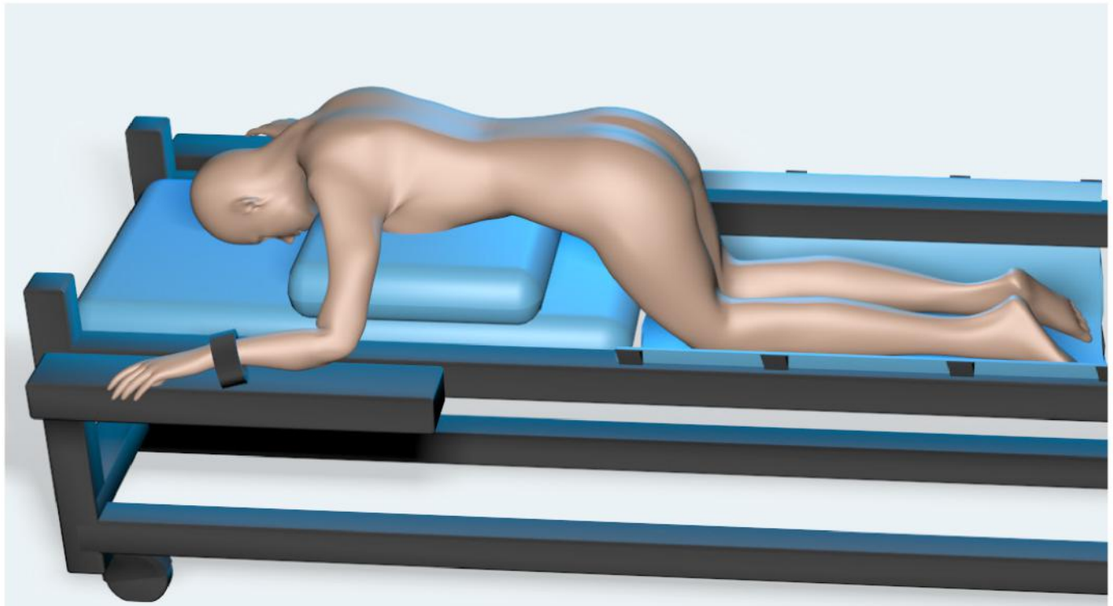
Use the MID-C system only with pedicle screws supplied by ApiFix Ltd.

To ensure proper performance of the system all the steps listed below must be followed carefully.

3 PREOPERATIVE PLANNING

Preoperative planning using x-ray guidance (plain films or CT scan) is important for determining the location of the screws, implant size, and the pedicle screw length and diameter.

- Base the diameter of the screw on the inner mediolateral pedicle diameter at its isthmus.
- Measure the length from the pedicle screw entry point to the anterior edge of the vertebrae.
- Patient must be prone on a radiolucent table suitable for AP and lateral fluoroscopy, which are performed during the course of surgery.



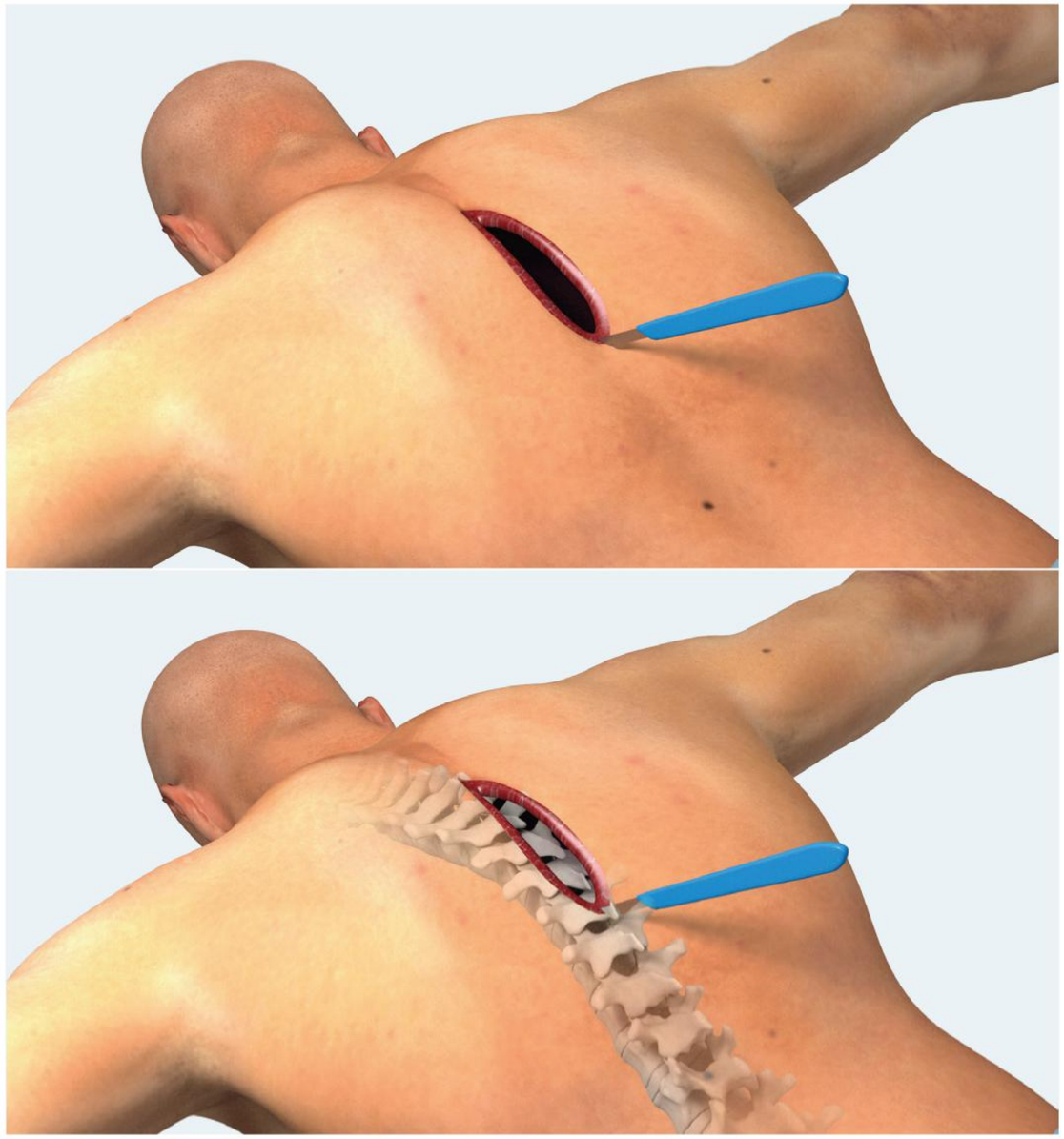
Patient positioning on OR table

4 SURGICAL EXPOSURE

The surgical process for implantation of the MID-C System is a posterior approach with a vertical midline incision. The MID-C system is designed to be implanted unilaterally on the concave side of the curvature. In general, the MID-C surgical procedure requires a visualization of the facet joints and medial aspects of the transverse processes on both the superior and inferior vertebra where screws are to be inserted. Once achieved, the surgeon should place the screws in the End Vertebra of the curve to be defined per the Cobb Measurement methodology. The surgeon should then assemble the MID-C device to the pedicle screws, perform final torquing and initial distraction. Each of these steps is described in detail below.

5 MUSCLE DISSECTION AND RETRACTION

As with all surgical procedures, minimize damage to surrounding soft tissues. Use standard monopolar and bipolar cautery to control bleeding during muscle and soft tissue dissection.



6 PEDICLE SCREW INSERTION

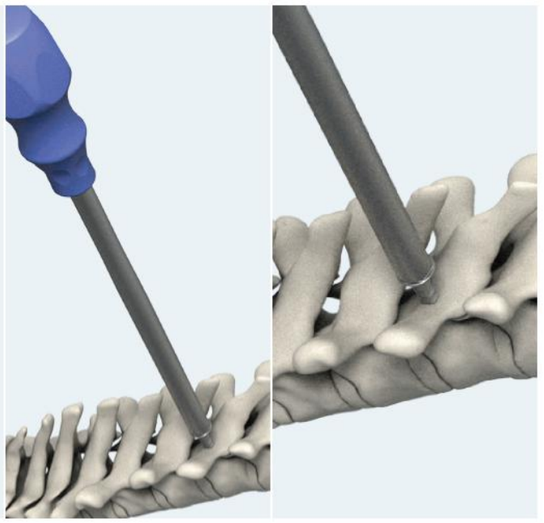
6.1

Connect the screw to the pedicle screw holder.

6.2

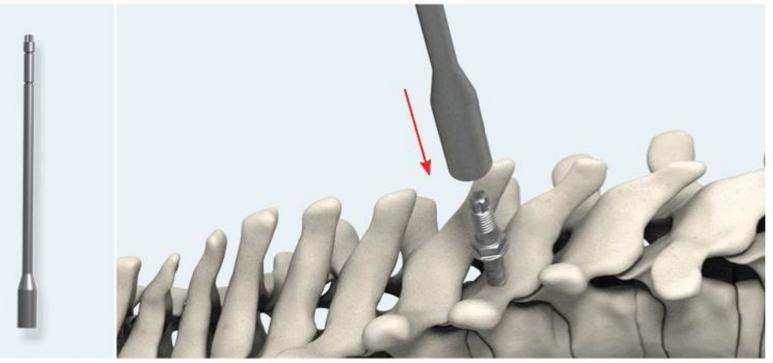
Use the MID-C System only with pedicle screws supplied by ApiFix Ltd. **Always start with placement of the upper pedicle screw.** Locate the screw's entry points and prepare the initial screw hole using standard tools and methods. Select the appropriate screw, and connect it to the pedicle screw holder.

NOTE:
The implant is supported by two screws only. Always use longest and thickest screws the anatomy can maintain. **Verify optimal screw placement using the available methods (navigation system, O-arm, electronic pedicle finder etc.).**



6.3

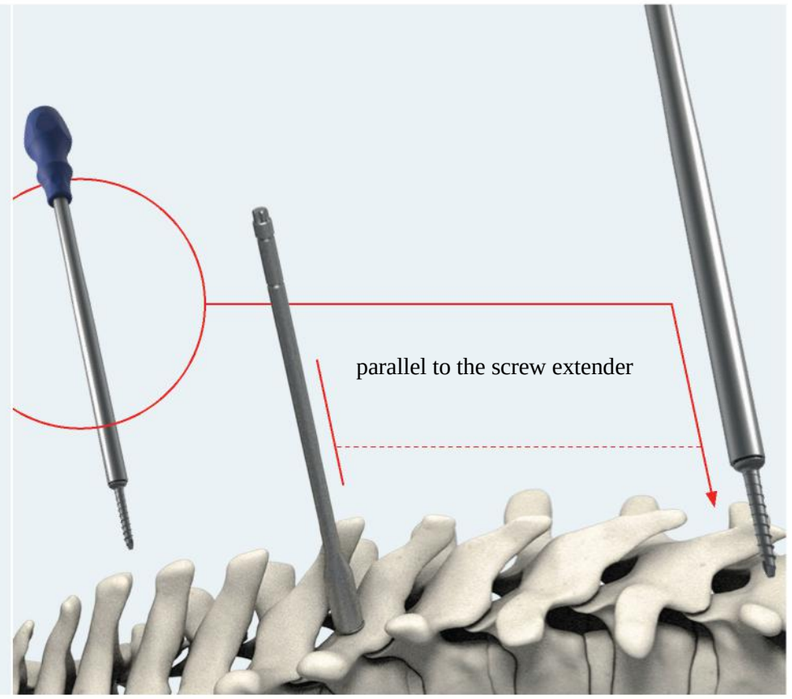
Fix the Screw Extender to the first pedicle screw.



6.4

Insert the second screw while making an effort to insert it parallel to the screw extender, within the anatomical limitations.

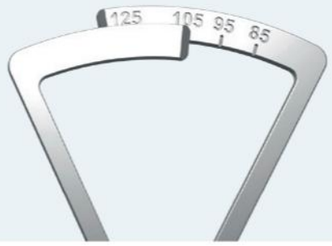
Clean the area between the two screws to make sure the implant can be easily placed without interference from muscles, ligaments, or bony elements.

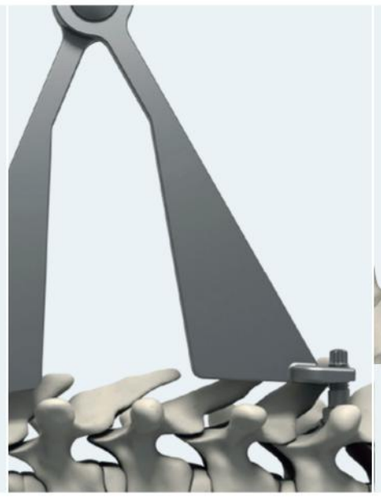


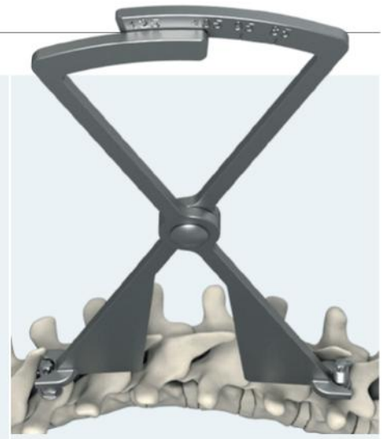
7 ROD SELECTION

7.1

Use the Size Selection Gauge to select the proper implant length.







8 ROD ATTACHMENT

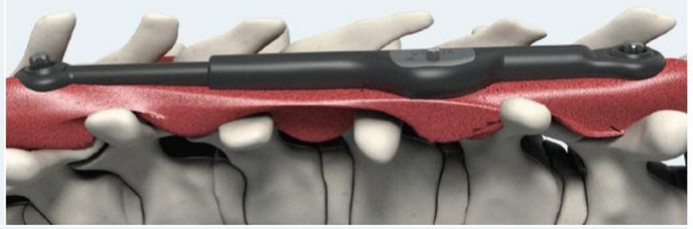
8.1

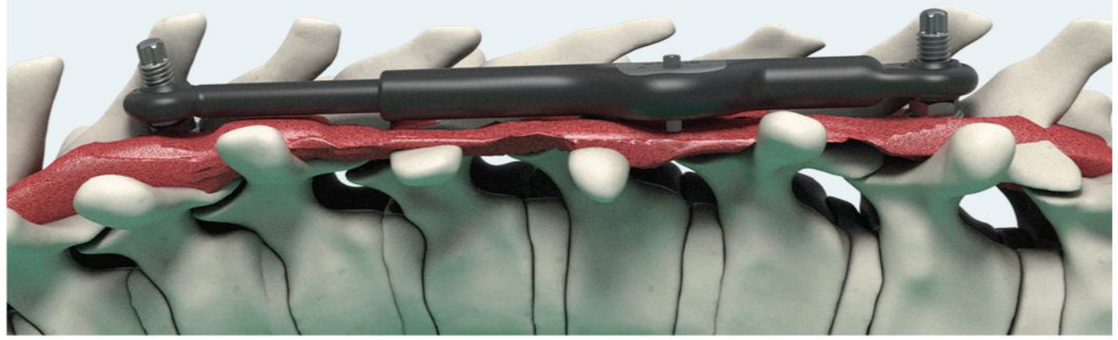
Take the selected MID-C main rod out of the sterile double blister and gently place it on the two screws. If you can not clearly see the full length of the screw threads on both sides, remove the implant and make sure there is no interference by removing the implant and cleaning the area below it.”

- In the lower picture of this section you should be able to see the threads. *, **

NOTE:
***** It is easier to place the rod if the control pin is on idle.

NOTE:
****** If the threads of both screws cannot be fully seen take the device out and further clean under it to make sure there is no interference with soft or hard tissues.

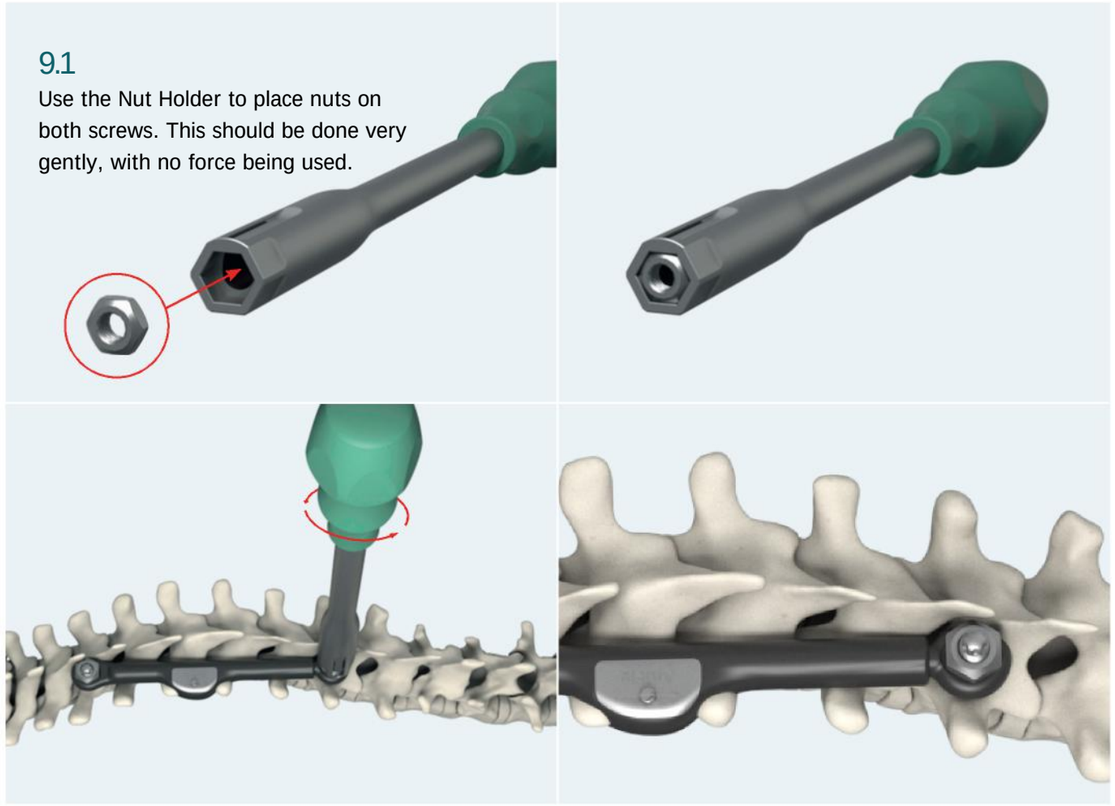




9 AND TORQUING NUT PLACEMENT

9.1

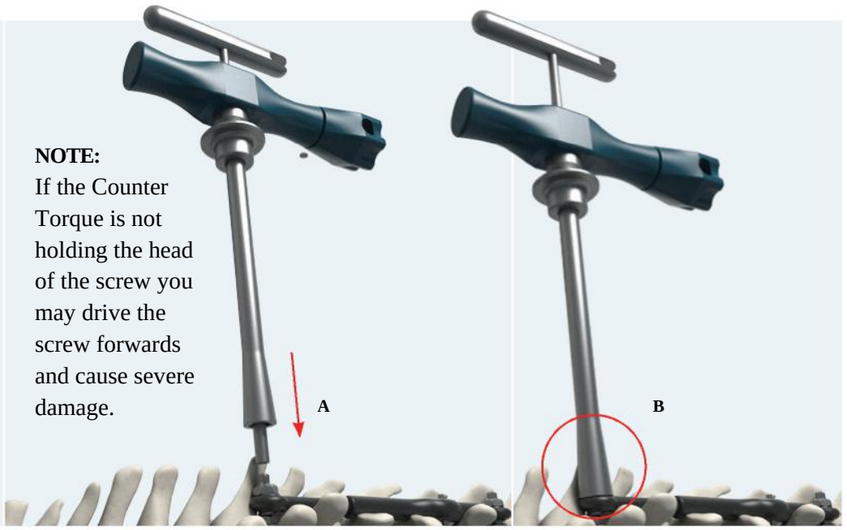
Use the Nut Holder to place nuts on both screws. This should be done very gently, with no force being used.



9.2

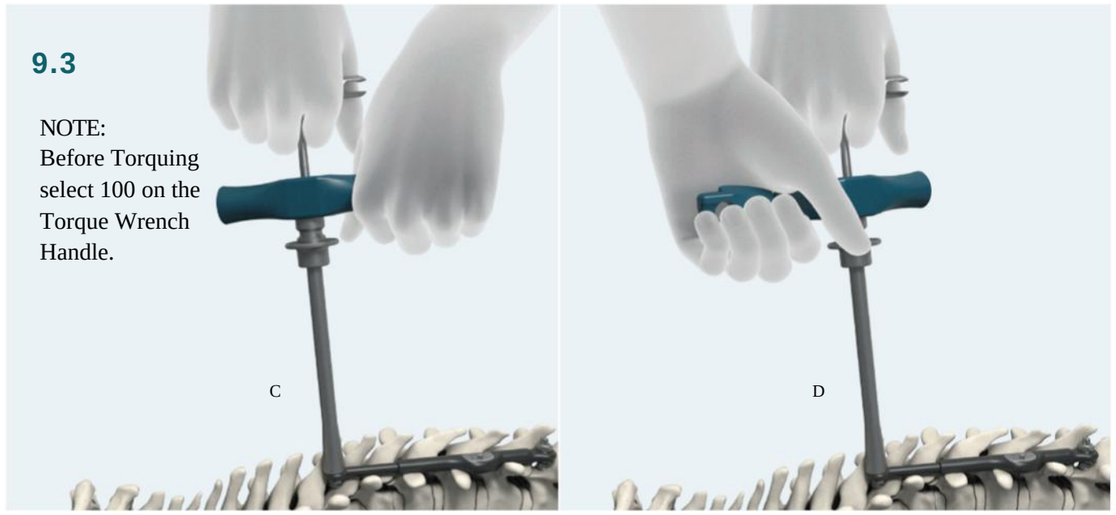
First, make sure the Counter Torque Handle is holding the head of the screw, then use the Torque Wrench Handle and the Counter Torque Handle to tighten the nuts to the proper torque.

NOTE:
If the Counter Torque is not holding the head of the screw you may drive the screw forwards and cause severe damage.



9.3

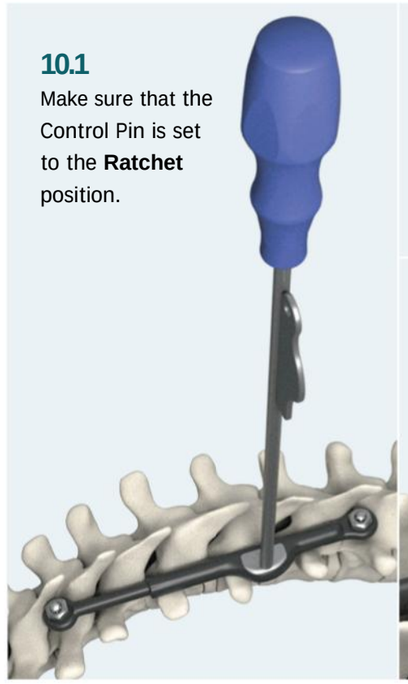
NOTE:
Before Torquing select 100 on the Torque Wrench Handle.

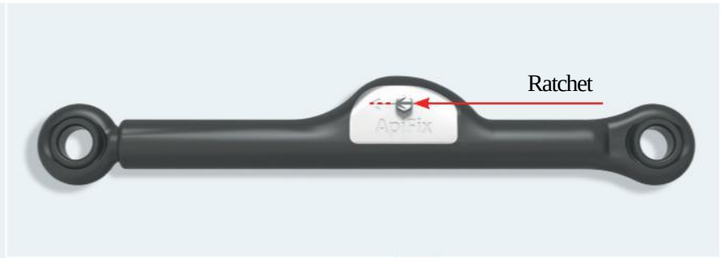


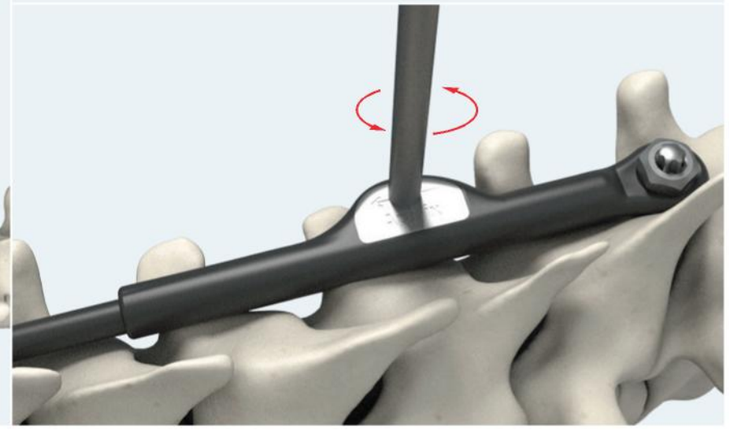
10 CONTROL PIN TO RATCHET

10.1

Make sure that the Control Pin is set to the **Ratchet** position.



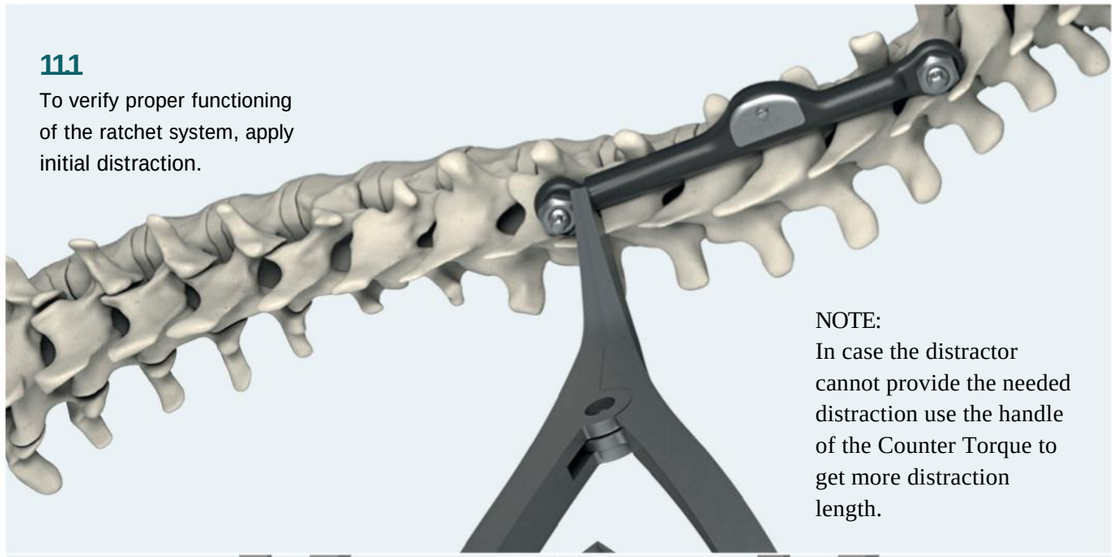




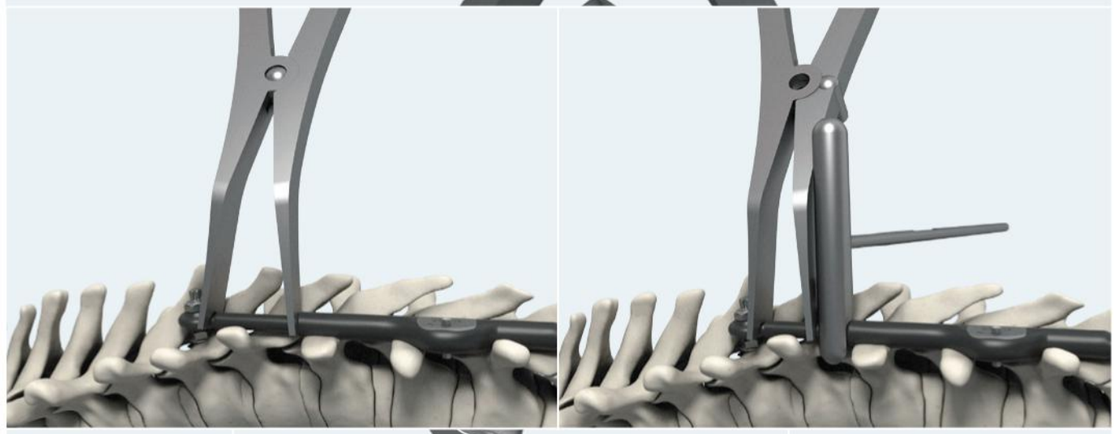
11 ROD DISTRACTION

11.1

To verify proper functioning of the ratchet system, apply initial distraction.



NOTE:
In case the distractor cannot provide the needed distraction use the handle of the Counter Torque to get more distraction length.



11.2

In case where there is no space for initial distraction, use the Size Selection Tool to open the first 5-6 mm.

11.3

Verify final result: Take final AP and lateral X-rays to verify proper positioning of the screws and the implant.

12 RETRIEVAL

In the event that an implanted device needs to be removed, please refer to the Retrieval and Analysis Protocol for MID-C System (DMS-5587). Surgeons conducting a retrieval procedure should follow the guidelines described in DMS-5587 (e.g., surgical procedure, handling of specimen, and packaging of specimen) to ensure patient safety and to ensure that the specimen may be analyzed appropriately.

Should it be necessary to retrieve a MID-C device, please contact ApiFix.

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ApiFix
THE INTERNAL BRACE OPTION

MID-C SURGICAL TECHNIQUE GUIDE