CORRIDOR®

Fixation System

SURGICAL TECHNIQUE GUIDE

GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

SURGICAL TECHNIQUE GUIDE

CORRIDOR®

CORRIDOR®

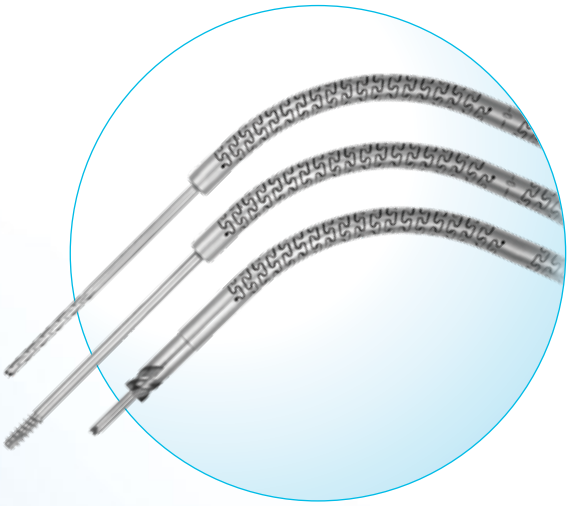
Fixation System

Specialized Screw Guide

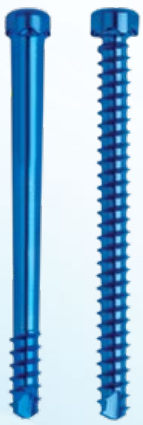
Facilitates minimally invasive access and positioning

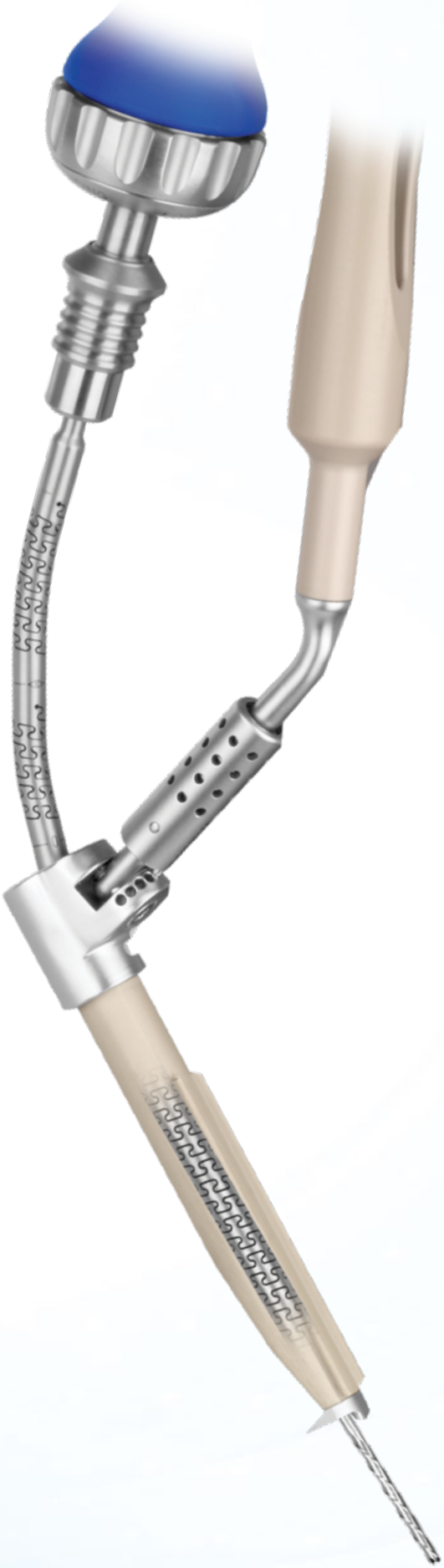
Flexible Instruments

Allow off-axis insertion



Wide Range of Screws



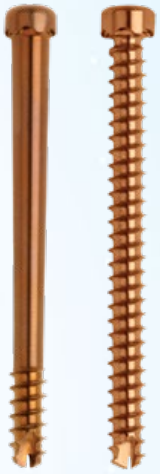


Bone Screws

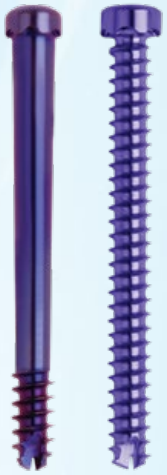
- 3.5mm, 4.0mm and 4.5mm diameters
- Lengths from 30mm-60mm
- Partially threaded screw or fully threaded screw available in cannulated and non-cannulated options

Cannulated Screws

3.5mm
Cannulated Screw



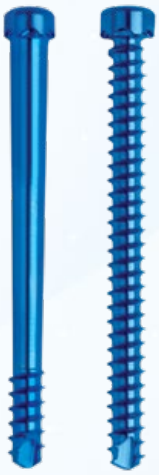
4.0mm
Cannulated Screw



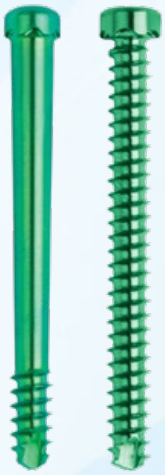
4.5mm
Cannulated Screw

Solid Screws

3.5mm
Solid Screw



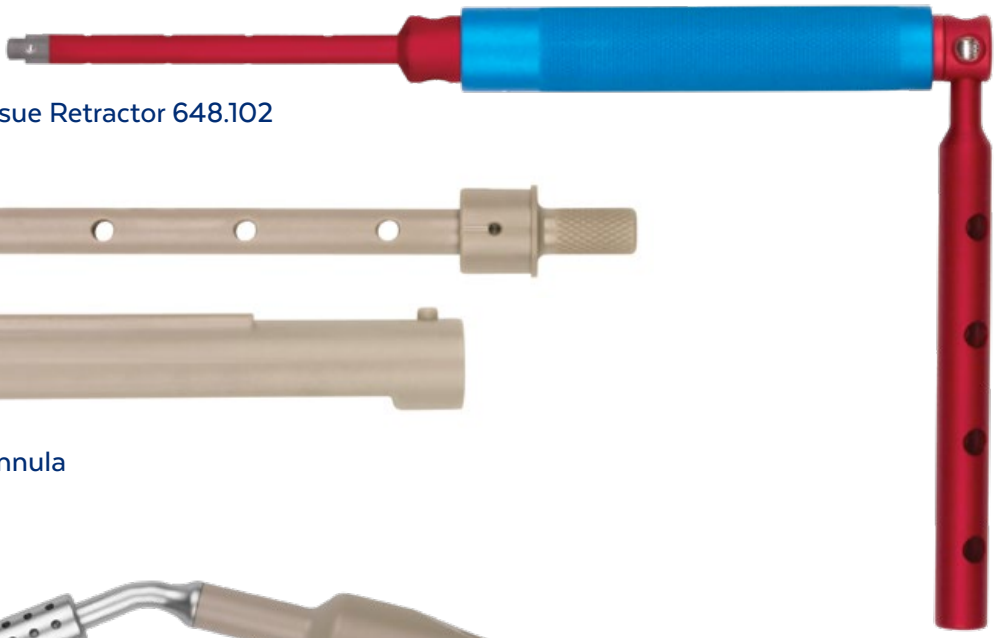
4.0mm
Solid Screw



4.5mm
Solid Screw

INSTRUMENT OVERVIEW

Soft Tissue Retractor 648.101



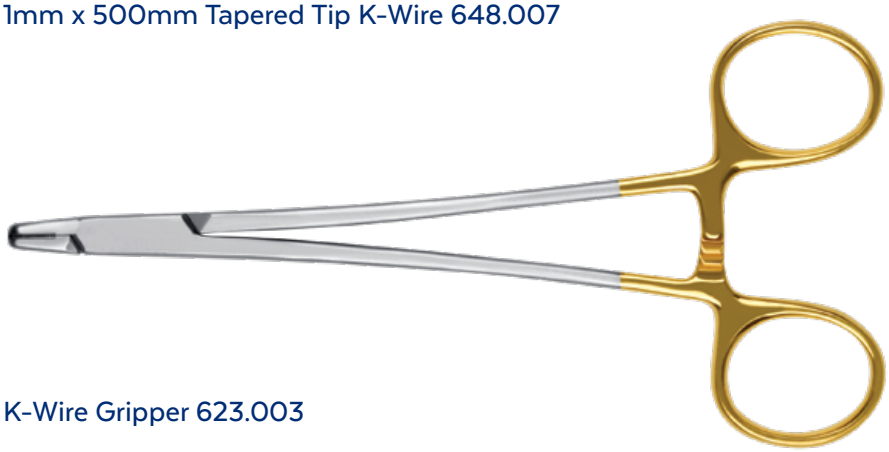
Handle for Soft Tissue Retractor 648.102

K-Wire Guiding Cannula
Screw Guide
648.010S

Screw Guide Handle 648.001

1mm x 500mm Blunt Tip K-Wire 648.005

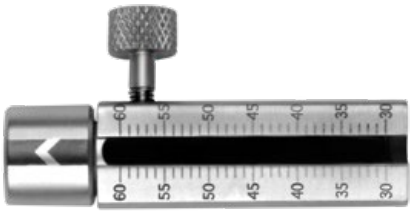
1mm x 500mm Tapered Tip K-Wire 648.007



K-Wire Gripper 623.003

Quick Connect Ratcheting Handle, Cannulated 648.401

Quick Connect Handle, Cannulated 648.400

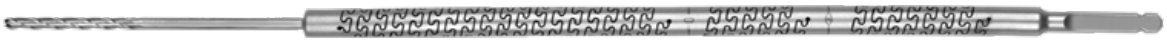


Adjustable Depth Indicator 648.103

Flexible Cannulated 2.5mm Awl/6.0mm Burr 648.220

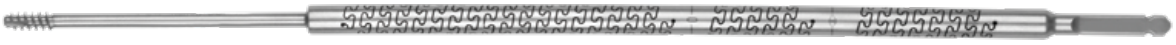
Flexible 2.5mm Awl/6.0mm Burr 648.221

Drill Bits

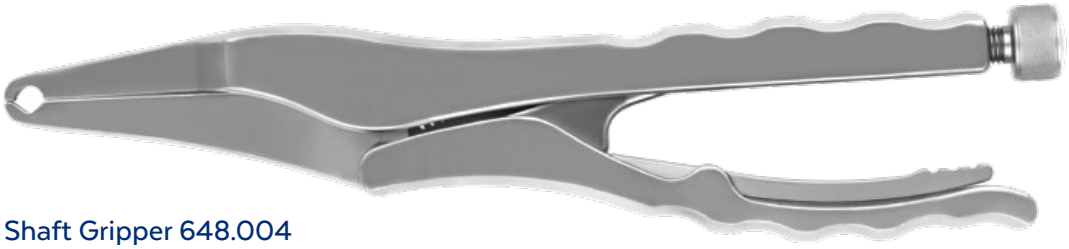


2.5mm Flexible Cannulated Drill 648.206
3.0mm Flexible Cannulated Drill 648.207

Taps



3.4mm Flexible Cannulated Tap 648.208
3.9mm Flexible Cannulated Tap 648.209



Shaft Gripper 648.004

Mallet 648.003

2.5mm Flexible Cannulated Hex Driver 648.301

2.5mm Screw Removal Tool 648.303

SURGICAL TECHNIQUE

CORRIDOR®

Refer to the package insert for information on the intended usage/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

CORRIDOR® screws may be used for transfacet, translaminar facet, or odontoid fixation.

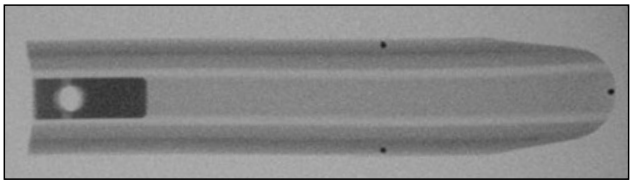
STEP 1 PREPARATION

The operative area is carefully cleaned and an incision is made at the appropriate level. Attach the **Soft Tissue Retractor** to its handle as shown at left and insert into the incision at the appropriate trajectory.

Soft Tissue Retractor insertion

The Soft Tissue Retractor is radiolucent to permit visualization during surgery. Radiopaque pins are embedded within the retractor for location reference. One pin is located on the midline tip, and two pins are located on the lateral sides, 35mm from the tip (see below).

Tip of Soft Tissue Retractor - axial view



Placement of the stainless steel pins on the Soft Tissue Retractor

Push handle forward

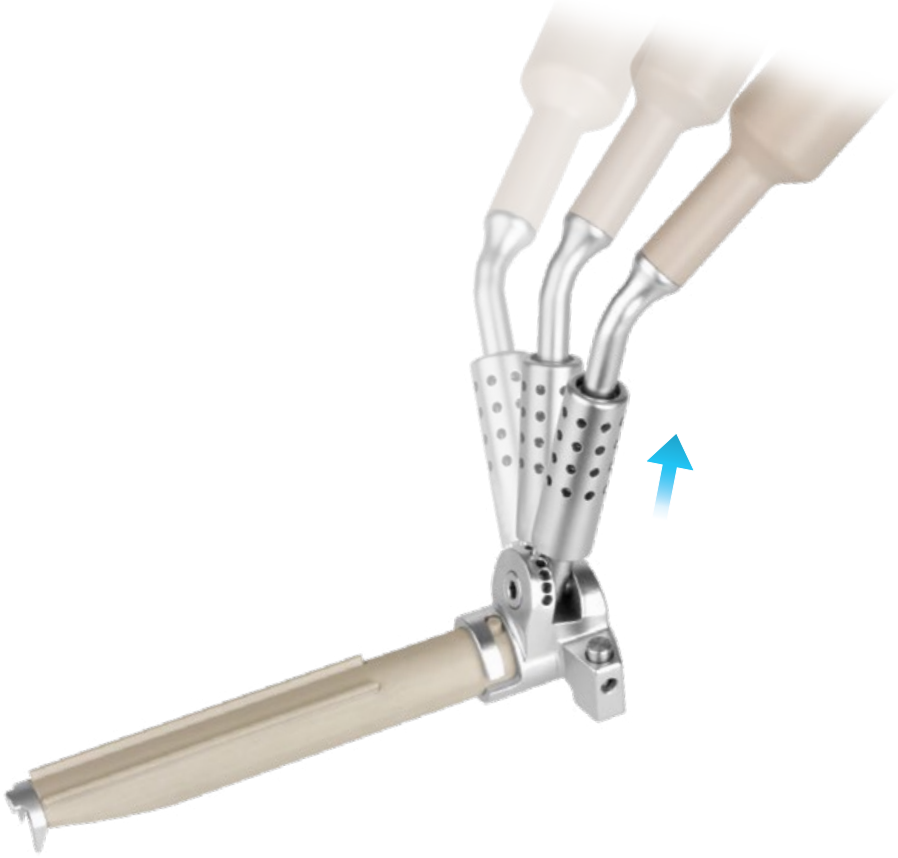
Pull sleeve back

LOADING THE SOFT TISSUE RETRACTOR ONTO THE HANDLE

To load and unload the Soft Tissue Retractor from the handle, pull back on the tapered sleeve of the handle while pushing the back of the handle forward.

STEP 2 SCREW GUIDE INSERTION

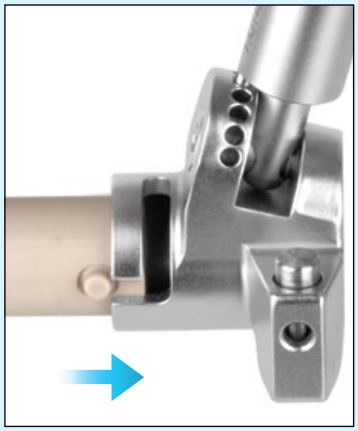
Load the **Screw Guide**, onto the **Screw Guide Handle** as described below. The orientation of the Screw Guide Handle can be adjusted by pulling up on the sleeve and rotating the handle to the desired angle.



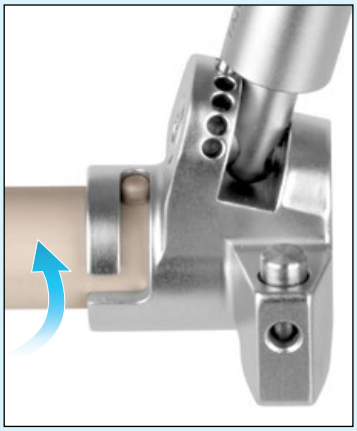
Adjusting orientation of Screw Guide Handle

LOADING THE SCREW GUIDE ONTO THE SCREW GUIDE HANDLE

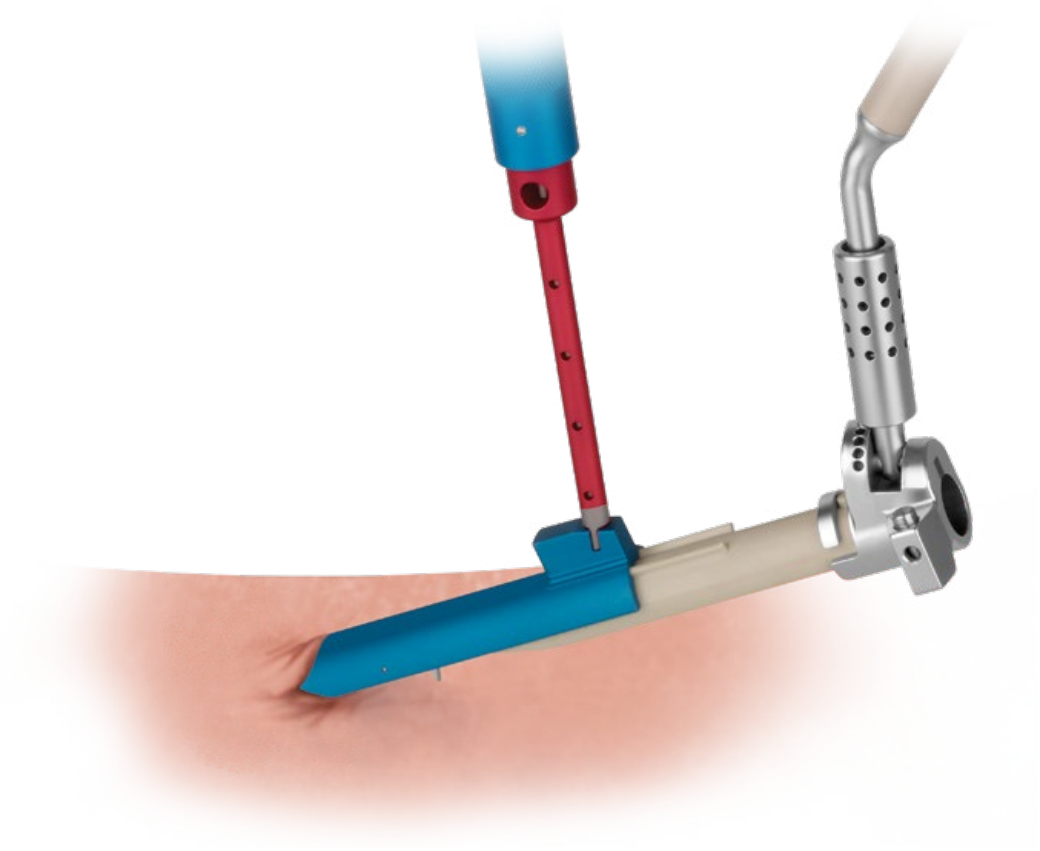
Align the tab on the Screw Guide with the opening of the key-slot in the Screw Guide Handle.



Insert the tab and rotate 90° counterclockwise into the channel until it snaps securely into place.



The top rails of the Screw Guide key into the grooves under the retractor to direct the guide. The Soft Tissue Retractor Handle may now be removed, with the retractor blade remaining in place.



Screw Guide Assembly keying into Soft Tissue Retractor

Use imaging to verify that the tip is correctly positioned. Three small radiopaque rods are located in the walls of the Screw Guide, from the handle to the screw exiting location (shown below). The rod on the right side is scalloped to identify orientation under fluoroscopy.

Placement of stainless steel rods in Screw Guide

ODONTOID FIXATION

Insert the Screw Guide Assembly anteriorly. Place the prongs of the guide against the C2 vertebral body.

TRANSLAMINAR FIXATION

Insert the Screw Guide Assembly posteriorly. Place the guide on the lamina of the superior vertebra, contralateral to the facet to be stabilized.

TRANSFACET FIXATION

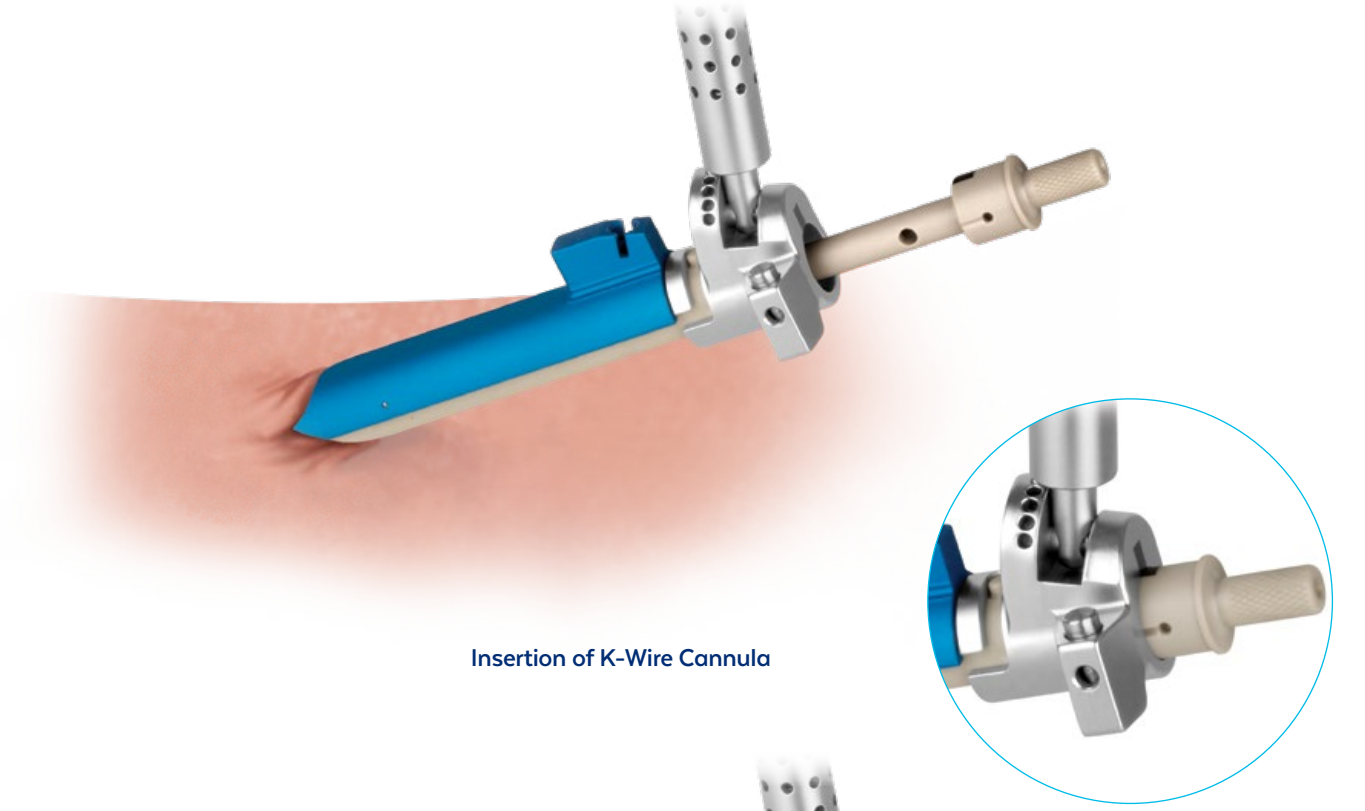
Insert the Screw Guide Assembly posteriorly. Place the guide on the facet of the superior vertebra.

STEP 3 SCREW HOLE PREPARATION

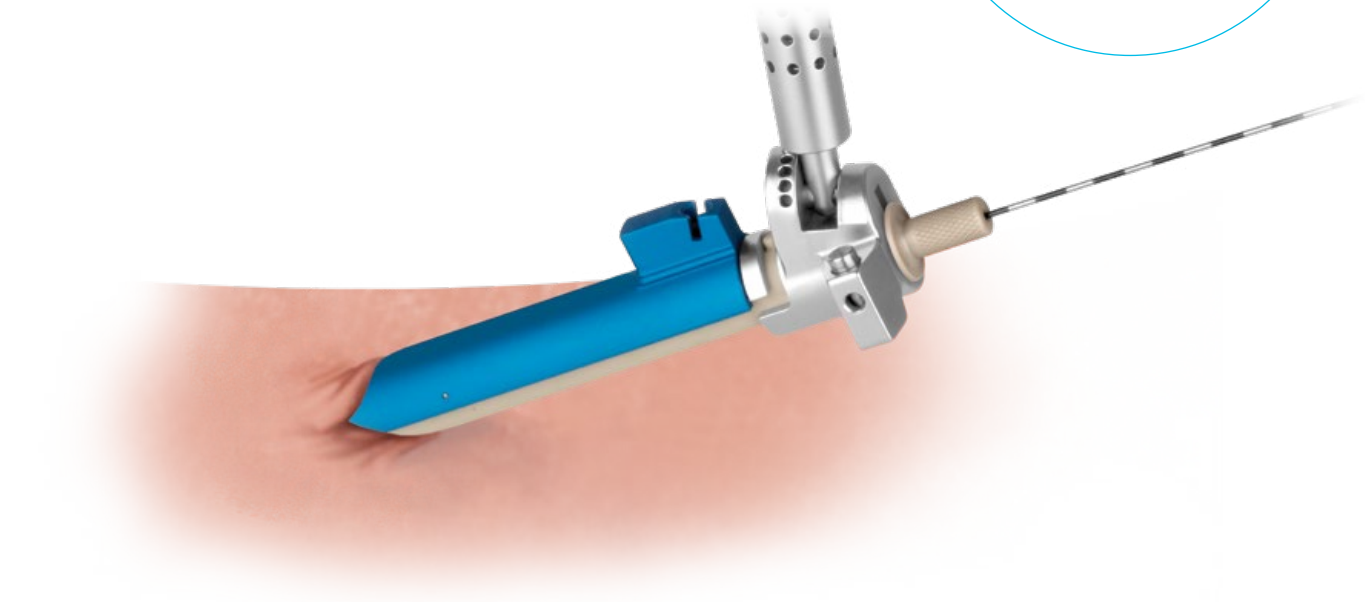
Insert the **K-Wire Cannula** into the Screw Guide Assembly, ensuring that the laser marks on both pieces are aligned. The K-Wire Cannula will provide a controlled path for k-wire insertion. Using the **K-Wire Gripper**, insert the k-wire using imaging to confirm appropriate trajectory and depth. The K-wire is inserted across the fracture site.

Alternately, the Cannulated Awl/Burr may be inserted in order to break through the cortex of the bone. The k-wire can then be inserted through this cannulated instrument.

Note: It is recommended that the K-Wire Cannula or a cannulated flexible instrument be used when inserting the k-wire to control the insertion path.



Insertion of K-Wire Cannula

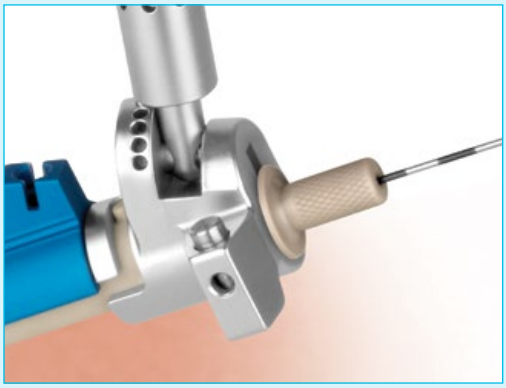


Insertion of K-Wire through cannula

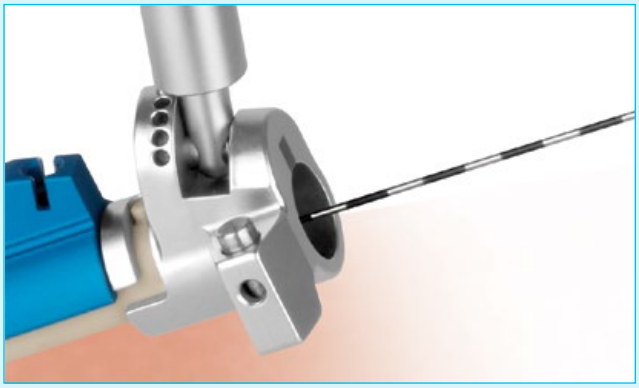
REMOVING THE K-WIRE CANNULA

Press and hold the button on the left side of the screw guide to release the cannula. Remove the cannula carefully, holding the k-wire in position with the K-Wire Gripper. Markings every 5mm on the k-wire assist in identifying any k-wire movement.

Note: Use caution to maintain k-wire position during instrument removal.

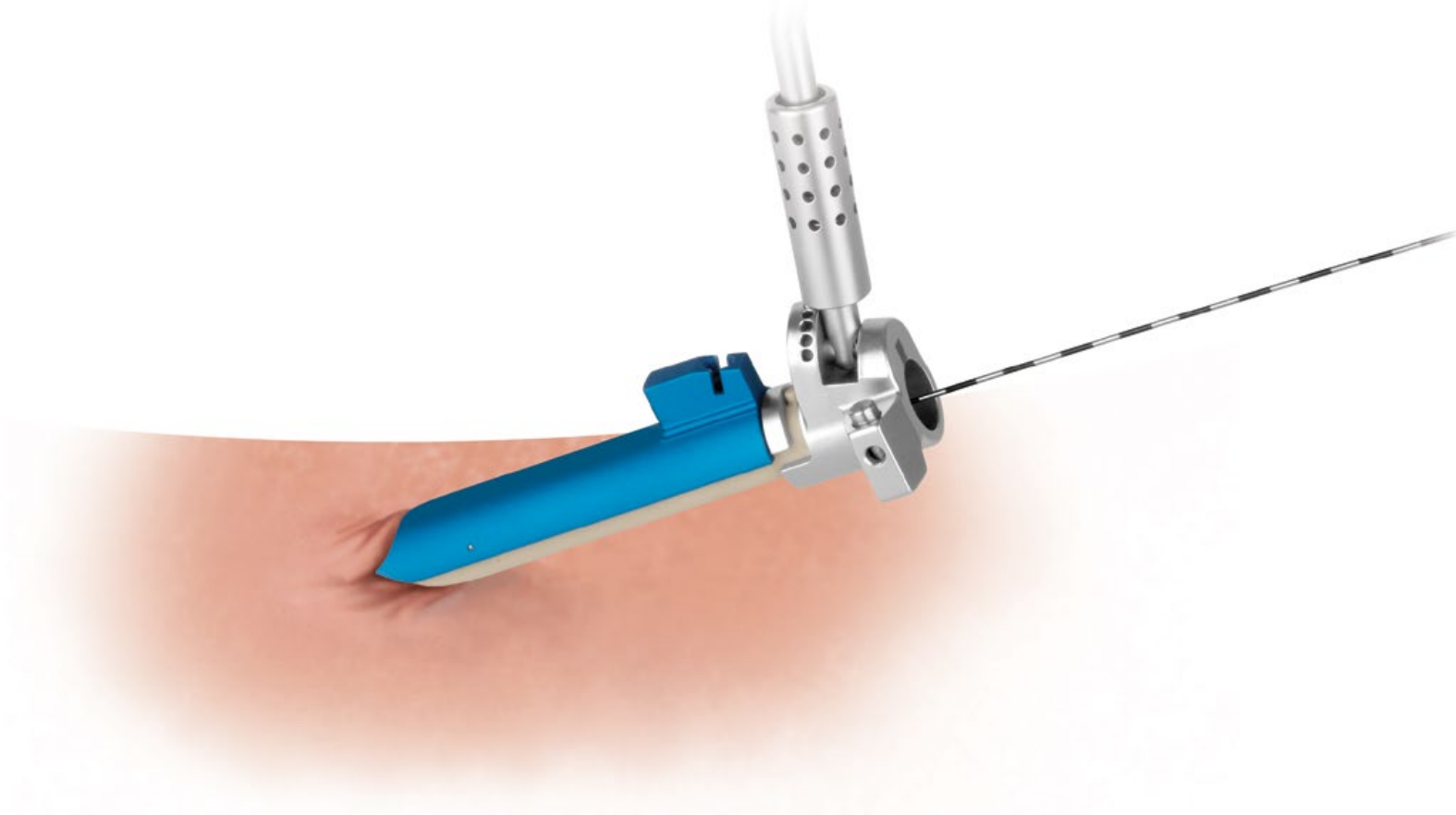


Push button to release K-Wire Cannula



K-Wire markings every 5mm

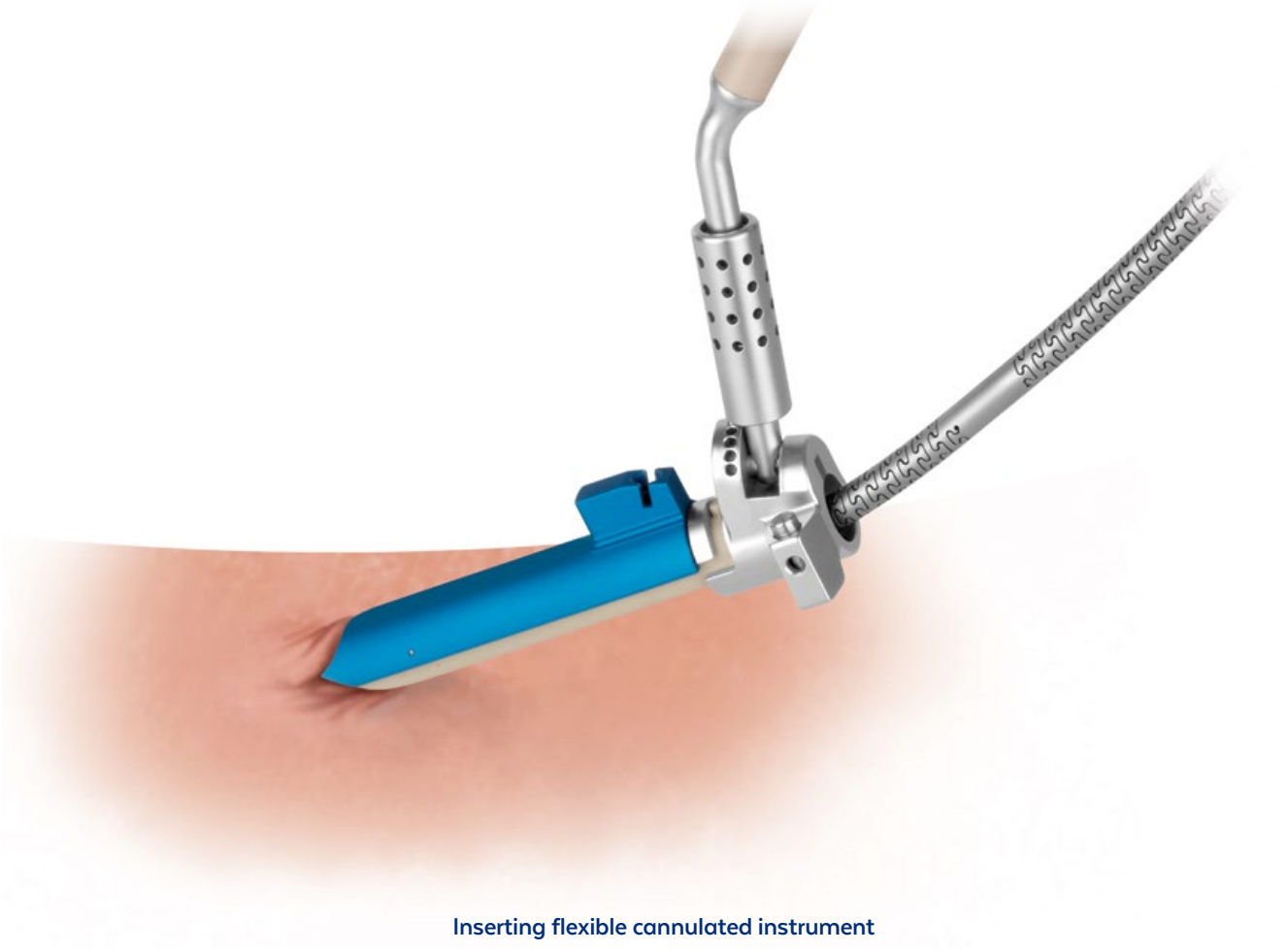
Once proper k-wire depth and trajectory are confirmed via fluoroscopy, the K-Wire Cannula may be removed as shown.



K-Wire Cannula removed

SCREW HOLE PREPARATION (CONT'D)

The bone may need to be burred to permit straight insertion of the drill and tap. Insert the **Flexible Cannulated 2.5mm Awl/6.0mm Burr** over the k-wire to prepare the bone. Use the **Shaft Gripper** and **Mallet** as described below if impaction is needed.



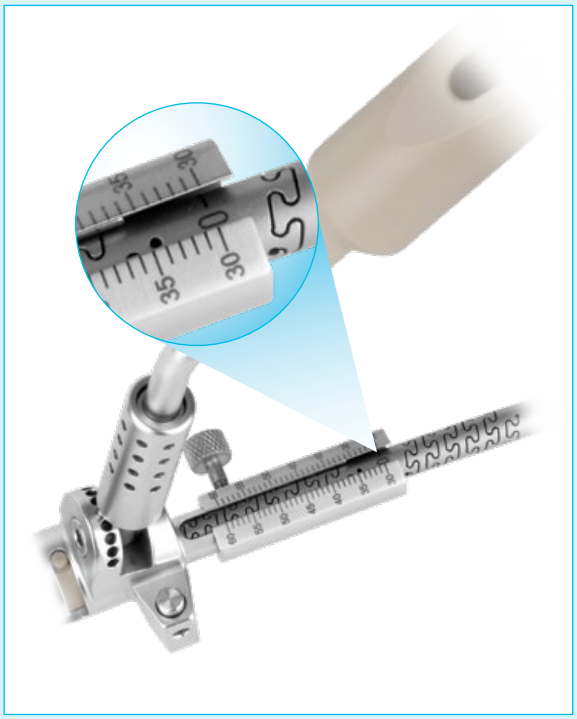
Inserting flexible cannulated instrument

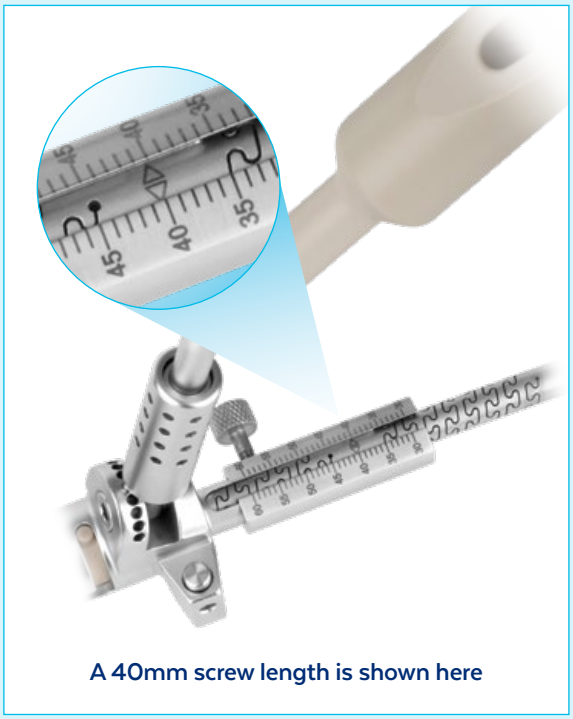
Remove the Awl/Burr carefully, holding the k-wire in position with the K-Wire Gripper.

Note: Use caution to maintain k-wire position during instrument removal.

USING THE SHAFT GRIPPER AND MALLET

For impaction, grasp a solid portion of the instrument shaft using the Shaft Gripper. Impact on the Shaft Gripper using the Mallet, as shown at right.





A 40mm screw length is shown here

PREPARING DEPTH INDICATOR

Rotate the knob on the Adjustable Depth Indicator counter-clockwise to slide the indicator along the shaft of the drill bit. Align the “30” mark on the indicator with the “0” laser mark on the drill bit. Tighten the knob to lock this position.

READING DEPTH INDICATOR

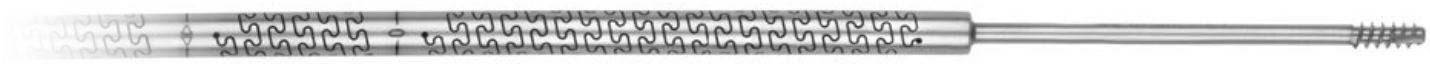
Advance the drill bit into the bone to the desired depth. The arrows on the drill bit indicate the depth, corresponding to screw length.

Determine the desired screw diameter and select the corresponding drill bit.

Attach the **Adjustable Depth Indicator** to the Screw Guide Assembly. Insert the **Flexible Cannulated Drill** over the k-wire and through the depth indicator. Using fluoroscopy, identify when the drill bit contacts bone. Before drilling through the bone, take the steps above to use the depth indicator.

The bone screws are self-tapping, however the screw hole may be tapped using the **Flexible Cannulated Tap**. Insert the tap over the k-wire and into the depth indicator. Tap to the desired depth. Remove the depth indicator by pressing the button on the left side of the screw guide.

Note: Use caution to maintain k-wire position during instrument removal.

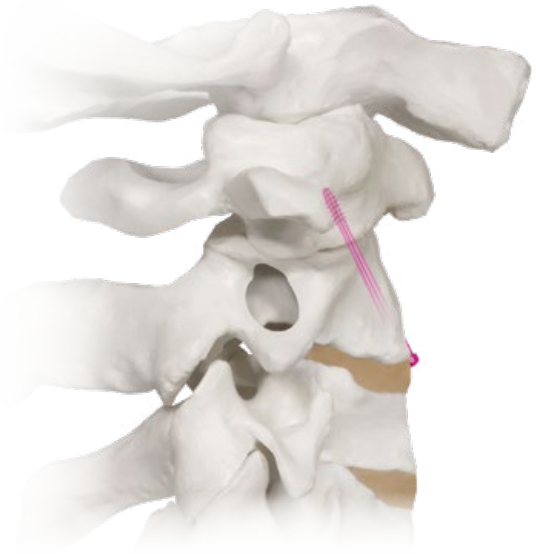


STEP 4 SCREW INSERTION

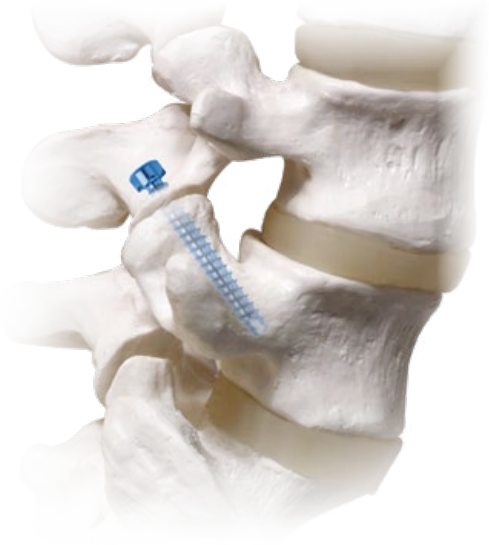
Load the appropriate screw onto the **2.5mm Flexible Cannulated Hex Driver**. Insert the screw through the Screw Guide Assembly and across the fracture site. Use imaging to verify the screw position. For the odontoid, insert additional screws as needed to achieve fixation.

Remove the k-wire. Then remove the Screw Guide Assembly and Soft Tissue Retractor. Disengage the Screw Guide from the Screw Guide Handle by reversing the steps on page 10. Dispose of the k-wire, Drill Bit, K-Wire Cannula and Screw Guide.

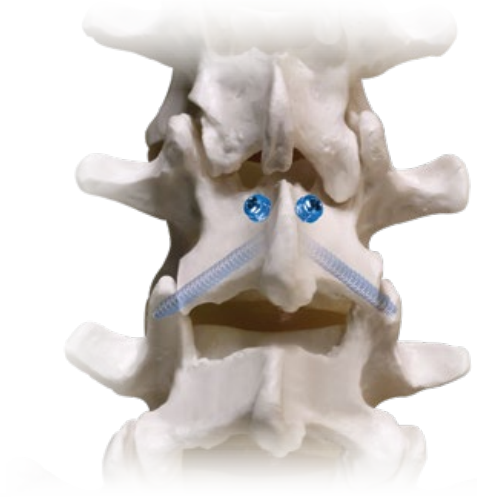
FINAL CONSTRUCT



Odontoid fixation (lateral view)



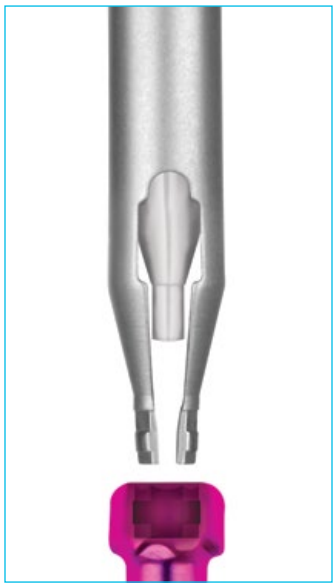
Transfacet fixation (lateral view)

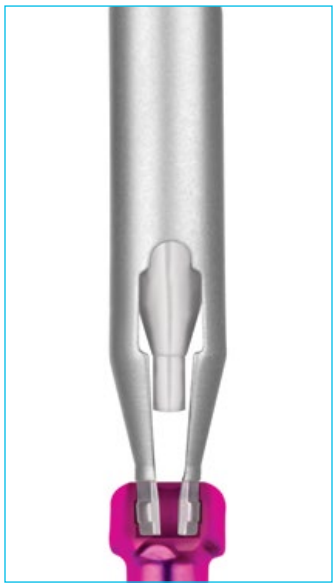


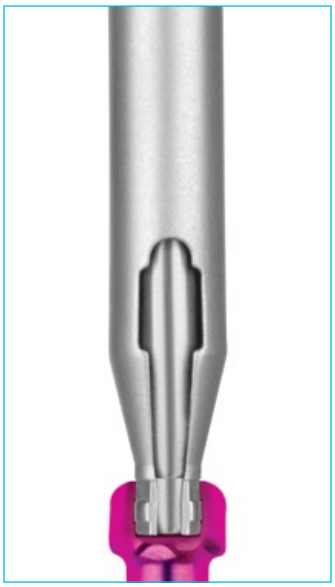
Translaminar facet fixation (AP view)

OPTIONAL TECHNIQUE: SCREW REMOVAL

For screw removal, a **2.5mm Screw Removal Tool** is available. The screw removal tool may be used with or without the guide. Insert the male end of the removal tool into the female hex on the screw, and snap into place. Rotate the knob on the handle clockwise to expand the instrument tip and secure it into the screw head. Remove the screw by rotating the screw removal tool counter-clockwise.







CORRIDOR®
SCREW SETS

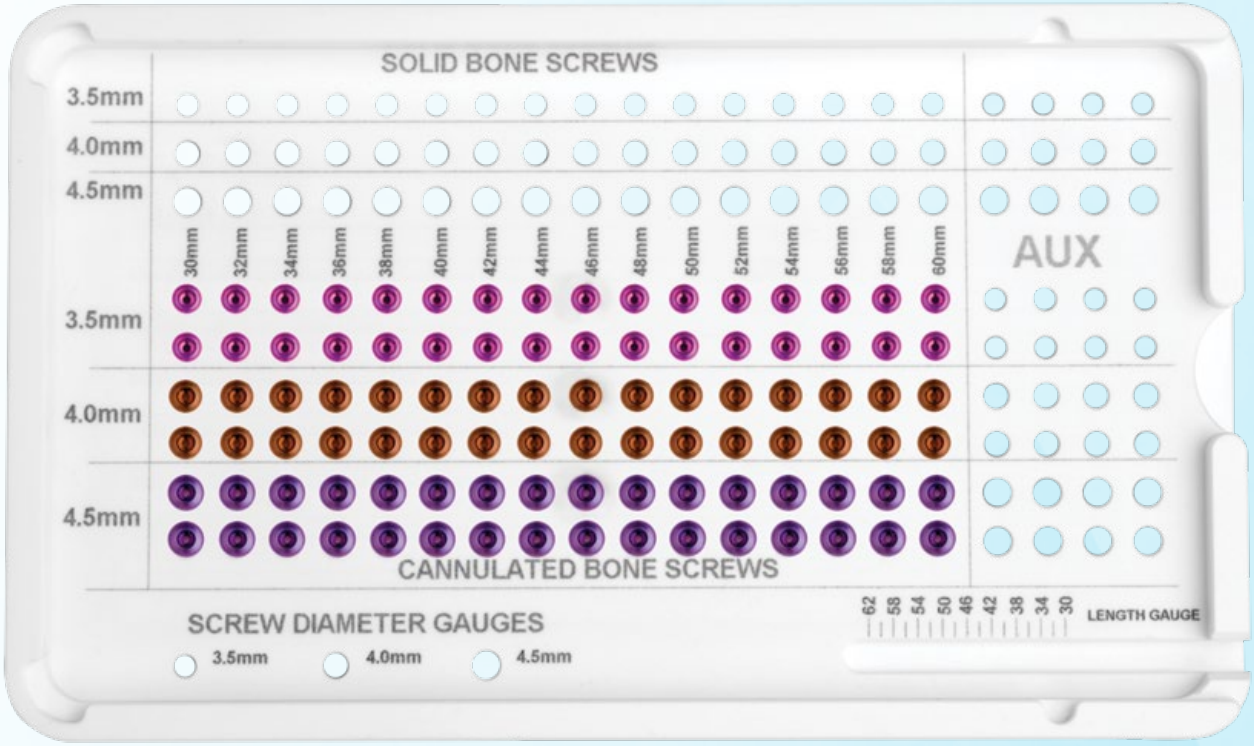
Implants (Set Qty - 2 each Cannulated Screws)

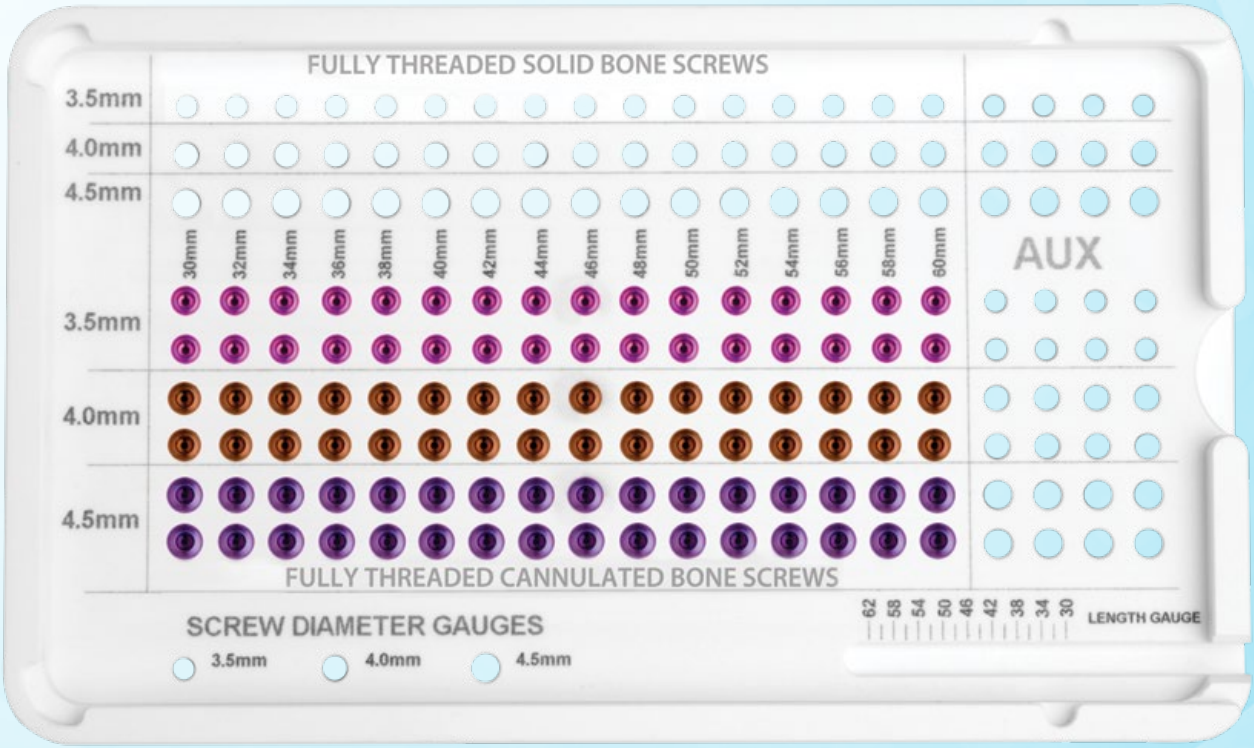
CORRIDOR® Screw Set 948.903 (Partially Threaded)

	3.5mm Diameter		4.0mm Diameter		4.5mm Diameter	
Length	**Cannulated**	**Non-Cannulated**	**Cannulated**	**Non-Cannulated**	**Cannulated**	**Non-Cannulated**
30mm	148.130	148.030	148.330	148.230	148.530	148.430
32mm	148.132	148.032	148.332	148.232	148.532	148.432
34mm	148.134	148.034	148.334	148.234	148.534	148.434
36mm	148.136	148.036	148.336	148.236	148.536	148.436
38mm	148.138	148.038	148.338	148.238	148.538	148.438
40mm	148.140	148.040	148.340	148.240	148.540	148.440
42mm	148.142	148.042	148.342	148.242	148.542	148.442
44mm	148.144	148.044	148.344	148.244	148.544	148.444
46mm	148.146	148.046	148.346	148.246	148.546	148.446
48mm	148.148	148.048	148.348	148.248	148.548	148.448
50mm	148.150	148.050	148.350	148.250	148.550	148.450
52mm	148.152	148.052	148.352	148.252	148.552	148.452
54mm	148.154	148.054	148.354	148.254	148.554	148.454
56mm	148.156	148.056	148.356	148.256	148.556	148.456
58mm	148.158	148.058	148.358	148.258	148.558	148.458
60mm	148.160	148.060	148.360	148.260	148.560	148.460

CORRIDOR® Fully Threaded Screw Set 948.904

	3.5mm Diameter		4.0mm Diameter		4.5mm Diameter	
Length	**Cannulated**	**Non-Cannulated**	**Cannulated**	**Non-Cannulated**	**Cannulated**	**Non-Cannulated**
30mm	148.170	148.070	148.370	148.270	148.570	148.470
32mm	148.172	148.072	148.372	148.272	148.572	148.472
34mm	148.174	148.074	148.374	148.274	148.574	148.474
36mm	148.176	148.076	148.376	148.276	148.576	148.476
38mm	148.178	148.078	148.378	148.278	148.578	148.478
40mm	148.180	148.080	148.380	148.280	148.580	148.480
42mm	148.182	148.082	148.382	148.282	148.582	148.482
44mm	148.184	148.084	148.384	148.284	148.584	148.484
46mm	148.186	148.086	148.386	148.286	148.586	148.486
48mm	148.188	148.088	148.388	148.288	148.588	148.488
50mm	148.190	148.090	148.390	148.290	148.590	148.490
52mm	148.192	148.092	148.392	148.292	148.592	148.492
54mm	148.194	148.094	148.394	148.294	148.594	148.494
56mm	148.196	148.096	148.396	148.296	148.596	148.496
58mm	148.198	148.098	148.398	148.298	148.598	148.498
60mm	148.200	148.100	148.400	148.300	148.600	148.500


SOLID BONE SCREWS
3.5mm
4.0mm
4.5mm
30mm
32mm
34mm
36mm
38mm
40mm
42mm
44mm
46mm
48mm
50mm
52mm
54mm
56mm
58mm
60mm
AUX
3.5mm
4.0mm
4.5mm
CANNULATED BONE SCREWS
SCREW DIAMETER GAUGES
3.5mm
4.0mm
4.5mm
62
58
54
50
46
42
38
34
30
LENGTH GAUGE


FULLY THREADED SOLID BONE SCREWS
3.5mm
4.0mm
4.5mm
30mm
32mm
34mm
36mm
38mm
40mm
42mm
44mm
46mm
48mm
50mm
52mm
54mm
56mm
58mm
60mm
AUX
3.5mm
4.0mm
4.5mm
FULLY THREADED CANNULATED BONE SCREWS
SCREW DIAMETER GAUGES
3.5mm
4.0mm
4.5mm
62
58
54
50
46
42
38
34
30
LENGTH GAUGE

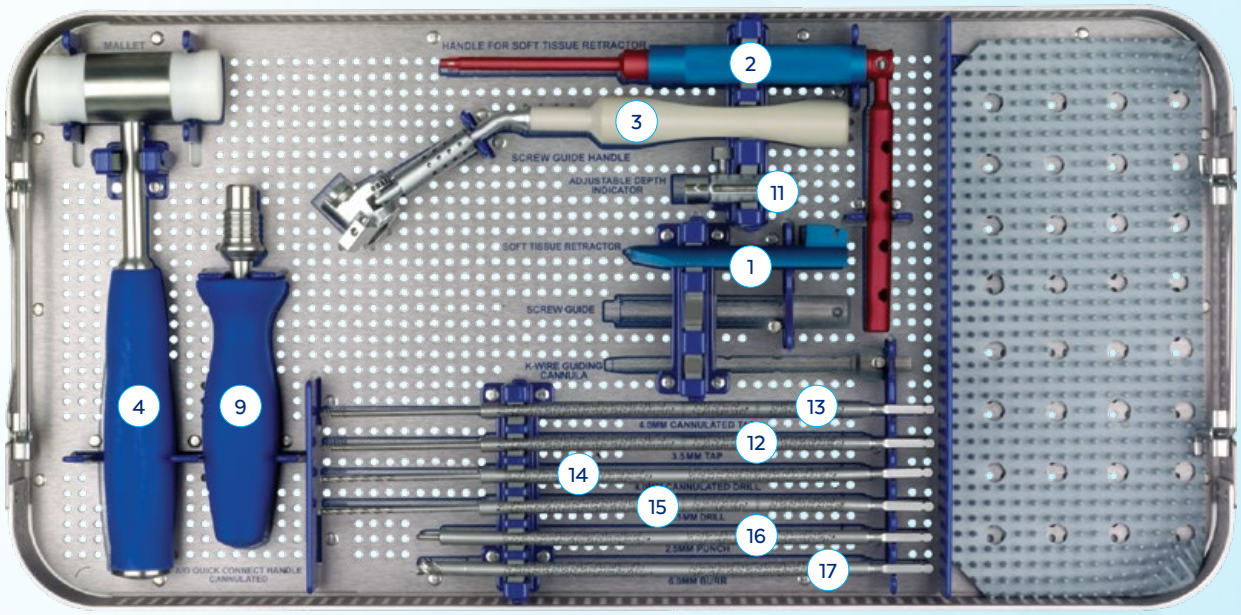
CORRIDOR®
INSTRUMENT SET 948.901

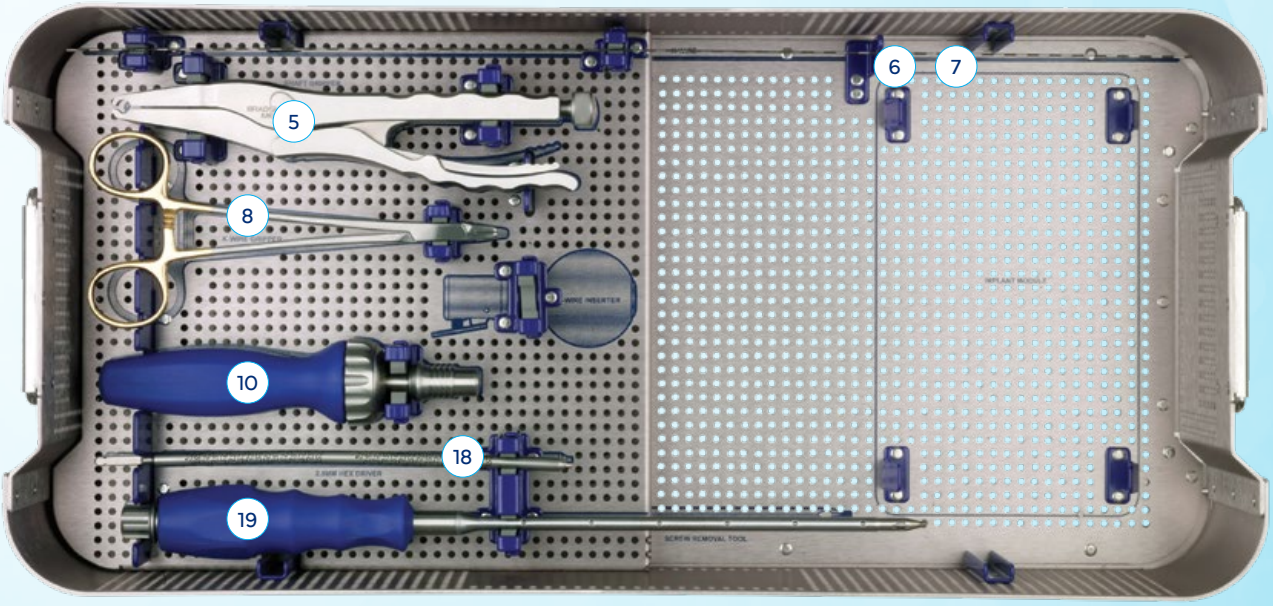
		Instrument	QTY
1	6648.101	Soft Tissue Retractor	1
2	648.102	Handle for Soft Tissue Retractor	1
3	648.001	Screw Guide Handle	1
4	648.003	Mallet	1
5	648.004	Shaft Gripper	1
6	648.005	1mm K-Wire x 500mm, Blunt-Tip	1
7	648.007	1mm K-Wire x 500mm, Tapered Tip	1
8	623.003	K-Wire Gripper	1
9	648.400	Quick Connect Handle, Cannulated	1
10	648.401	Quick Connect Ratcheting Handle, Cannulated	1
11	648.103	Adjustable Depth Indicator	1
12	648.208	3.4mm Flexible Cannulated Tap	2
13	648.209	3.9mm Flexible Cannulated Tap	2
14	648.206	2.5mm Flexible Cannulated Drill	2
15	648.207	3.0mm Flexible Cannulated Drill	2
16	648.220	Flexible Cannulated 2.5mm Awl/6.0mm Burr	1
17	648.221	Flexible 2.5m Awl/6.0mm Burr	1
18	648.301	2.5mm Flexible Cannulated Hex Driver	1
19	648.303	2.5mm Screw Removal Tool	1
	GMO64801	Monitor Trajectory Tape	1
	648.305	2.5mm Universal Removal Tool, Cannulated	1
	948.001	CORRIDOR® Graphic Case	

Sterile Packaged Instruments		QTY
648.010S	Screw Guide	1
	K-Wire Guiding Cannula	1

Additionally Available

648.203	6.0mm Flexible Cannulated Burr
648.205	2.5mm Flexible Cannulated Awl
648.213	6.0mm Cannulated Burr
648.215	2.5mm Cannulated Awl
648.216	Cannulated Drill for 3.5mm Screws
648.217	Cannulated Drill for 4.0mm Screws
648.218	Cannulated Tap for 3.5mm Screws
648.219	Cannulated Tap for 4.0mm Screws
648.311	2.5mm Hex Driver, Cannulated Shaft


MALLET
HANDLE FOR SOFT TISSUE RETRACTOR
SCREW GUIDE HANDLE
ADJUSTABLE DEPTH INDICATOR
SOFT TISSUE RETRACTOR
SCREW GUIDE
K-WIRE GUIDING CANNULA
4.0MM CANNULATED T
3.5MM TAP
CANNULATED DRILL
2.5MM PUNCH
2
3
11
1
4
9
13
12
14
15
16
17


6
7
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18
19

IMPORTANT INFORMATION ON THE CORRIDOR® FIXATION SYSTEM

DESCRIPTION

The CORRIDOR® Fixation system consists of screws designed to compact juxtaposed facet articular processes to enhance spinal fusion, and also for fracture fixation of small bones and bone fragments including odontoid fractures. The screws are available partially threaded or fully threaded, cannulated or non-cannulated, and in various diameters and lengths to accommodate patient anatomy. The CORRIDOR® Fixation System screws are fabricated for medical grade titanium alloy as specified in ASTM F136 and F1295. Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be used in the same construct as stainless steel implants.

INDICATIONS

The CORRIDOR® Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5mm and 4.0mm screws and from L1 to S1 for 4.5mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle.

The CORRIDOR® Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

The CORRIDOR® Fixation System is also indicated for fracture fixation of small bones and bone fragments including odontoid fractures.

CONTRAINDICATIONS

The contraindications include, but are not limited to: Active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented metal allergy or intolerance; any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; any patient unwilling to follow post-operative instructions; any case not described in the indications.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

Possible adverse effects which may occur include, but are not limited to: failed fusion or pseudoarthosis leading to implant breakage; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; infection; device fracture or failure; device migration or loosening; decrease in bone density; loss of spinal mobility or function; inability to perform activities of daily living; fracture of any spinal bone including the pedicles, spinous process, pars interarticularis, vertebral body, or sacrum; change in spinal curvature or disc height; herniated nucleus pulposus, disc degeneration or disruption; graft donor site complications including pain, fracture and wound healing problems; tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, dural tears, development of radiculopathy, numbness or tingling; cauda equina syndrome; injury to vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional surgery may be necessary to correct some of these effects.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

PRECAUTIONS

Implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of the system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

Surgical implants must never be reused. An explanted metal implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery. To insert a cannulated screw, a guide wire may be used, followed by a sharp tap. Ensure that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Also ensure that the guide wire does not advance during tapping or screw insertion. Remove the guide wire and confirm that it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Correct selection of the implant is extremely important. The potential for success on fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load- bearing. A higher risk of device loosening, bending, or breaking exists with fractures involving severe comminution, displacement or other difficult fracture management situations.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to constantly changing environment of salts, acids and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn can enhance fatigue fractures of implants. Thus, every effort should be made to use compatible metals and alloys in conjunction with each other.

MRI SAFETY INFORMATION

CORRIDOR® has not been evaluated for safety and compatibility in the MR environment. CORRIDOR® has not been tested for heating, migration, or image artifact in the MR environment. The safety of CORRIDOR® in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

IMPORTANT INFORMATION ON THE CORRIDOR® FIXATION SYSTEM

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure a SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants provided NONSTERILE, sterilization is recommended (wrapped only) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	40 Minutes

For instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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Audubon, PA 19403
www.globusmedical.com

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