CORRIDOR™ Fixation System

Surgical Technique

CORRIDOR

GLOBUS MEDICAL

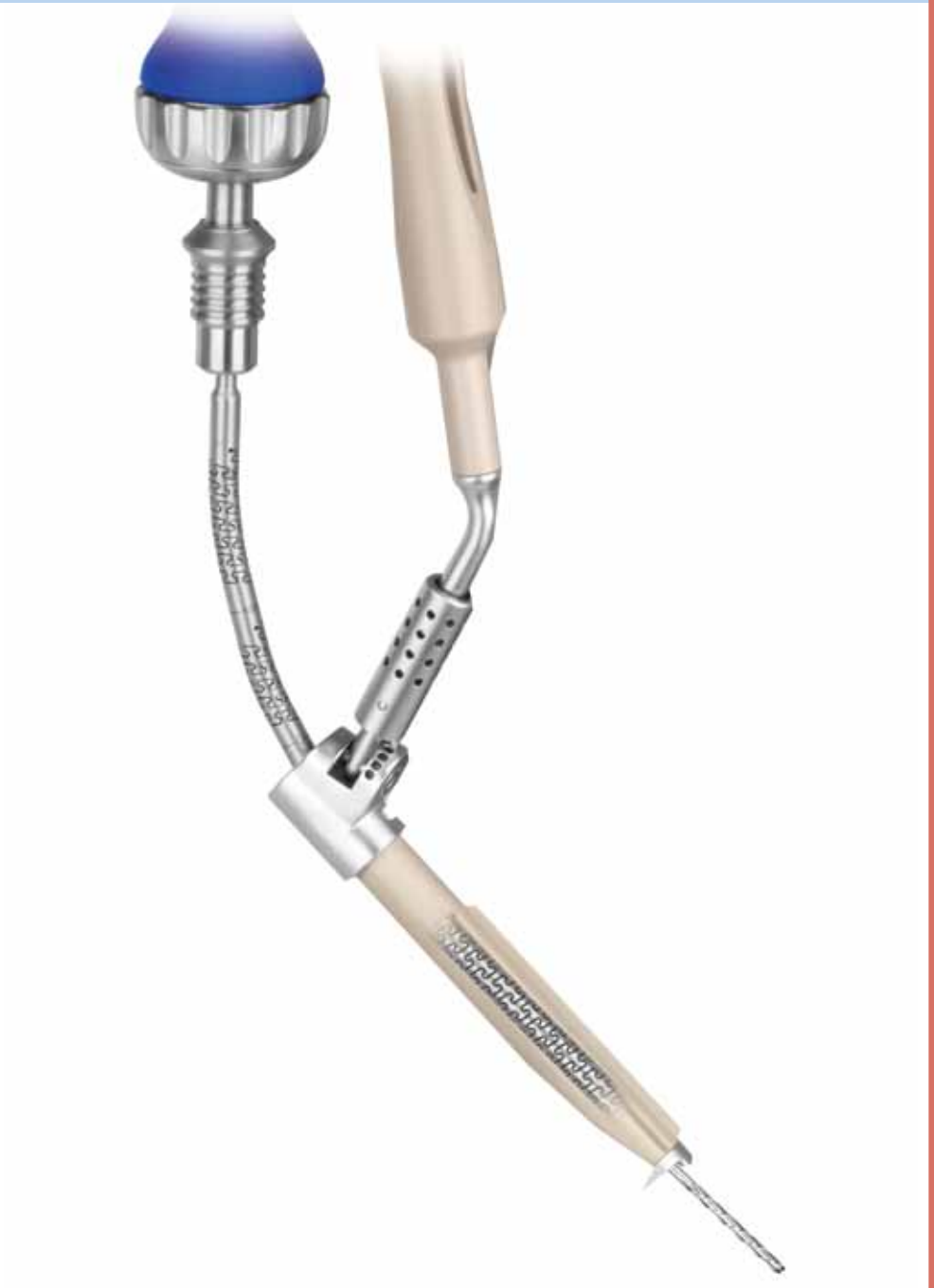
Contents

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.

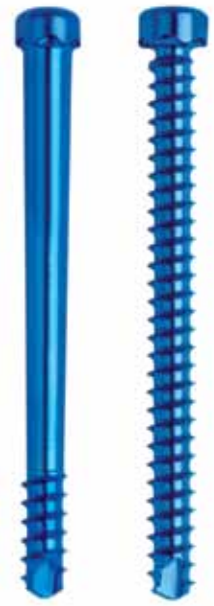
CORRIDOR™ Fixation System

Specialized Screw Guide Facilitates Minimally Invasive Access and Positioning



Flexible Instruments Allow Off-Axis Insertion

Wide Range of Screws



Implant Overview

Bone Screws

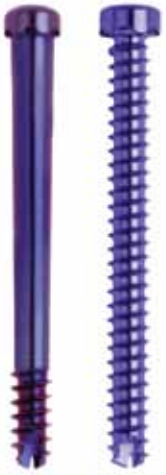
- 3.5mm, 4.0mm and 4.5mm diameters
- Lengths from 30mm-60mm
- Partially threaded screw or fully threaded screw available in cannulated and non-cannulated options

Cannulated Screws

3.5mm Cannulated Screw

4.0mm Cannulated Screw

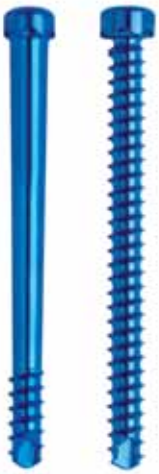
4.5mm Cannulated Screw



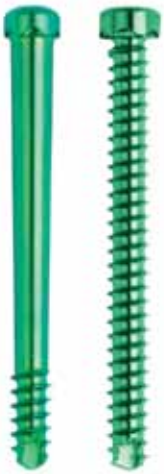
Solid Screws

3.5mm Solid Screw

4.0mm Solid Screw



4.5mm Solid Screw



Instrument Overview

Soft Tissue Retractor 648.101

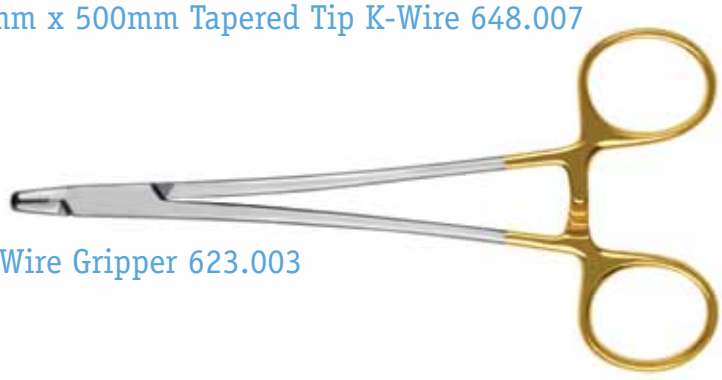
Handle for Soft Tissue Retractor 648.102

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

Instrument Overview (cont'd)

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

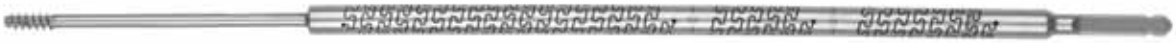
Flexible 2.5mm Awl/6.0mm Burr 648.221

Instrument Overview (cont'd)

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

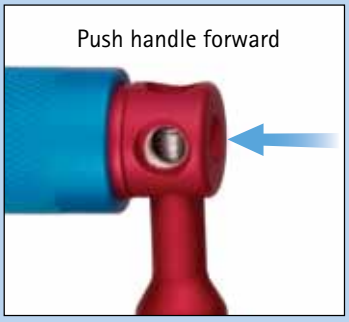
Shaft Gripper 648.004

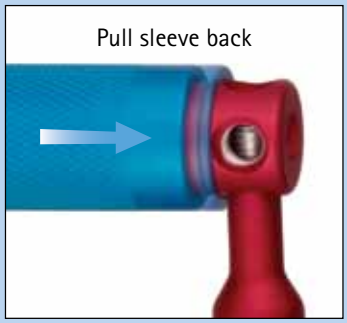
Mallet 648.003

2.5mm Flexible Cannulated Hex Driver 648.301

2.5mm Screw Removal Tool 648.303

CORRIDOR™ Surgical Technique



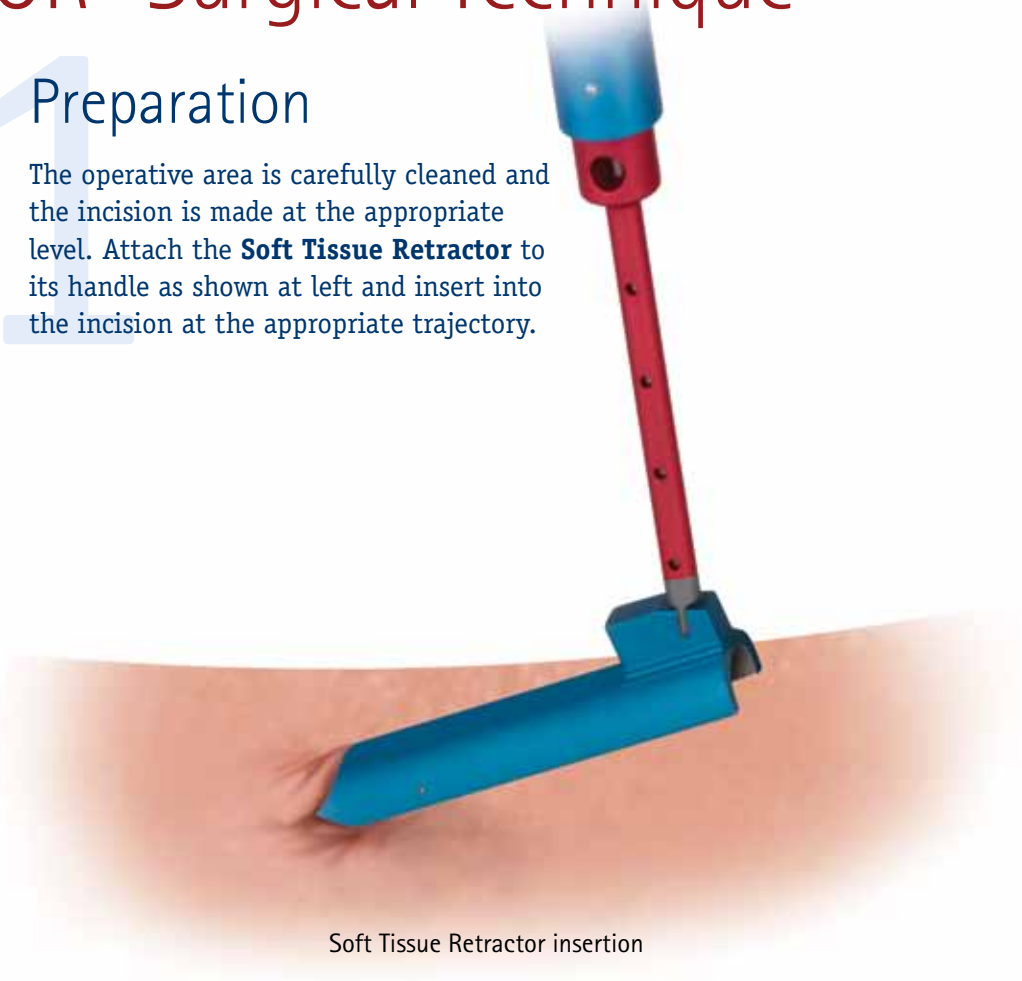


Loading the Soft Tissue Retractor onto the Handle

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.

1 Preparation

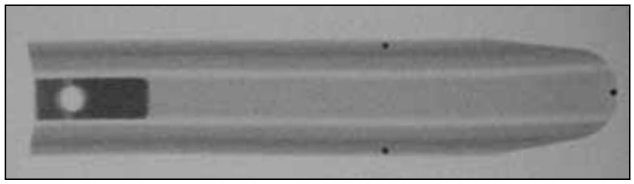
The operative area is carefully cleaned and the incision is made at the appropriate level. Attach the **Soft Tissue Retractor** to its handle as shown at left and insert into the incision at the appropriate trajectory.



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

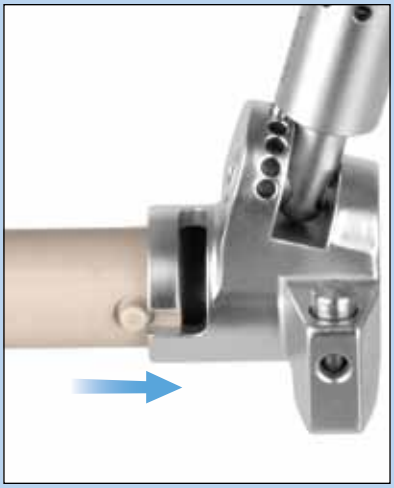
2 Screw Guide Insertion

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.

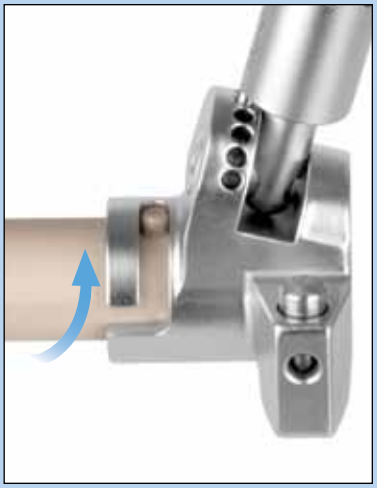
Adjusting the orientation of the Screw Guide Handle

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.

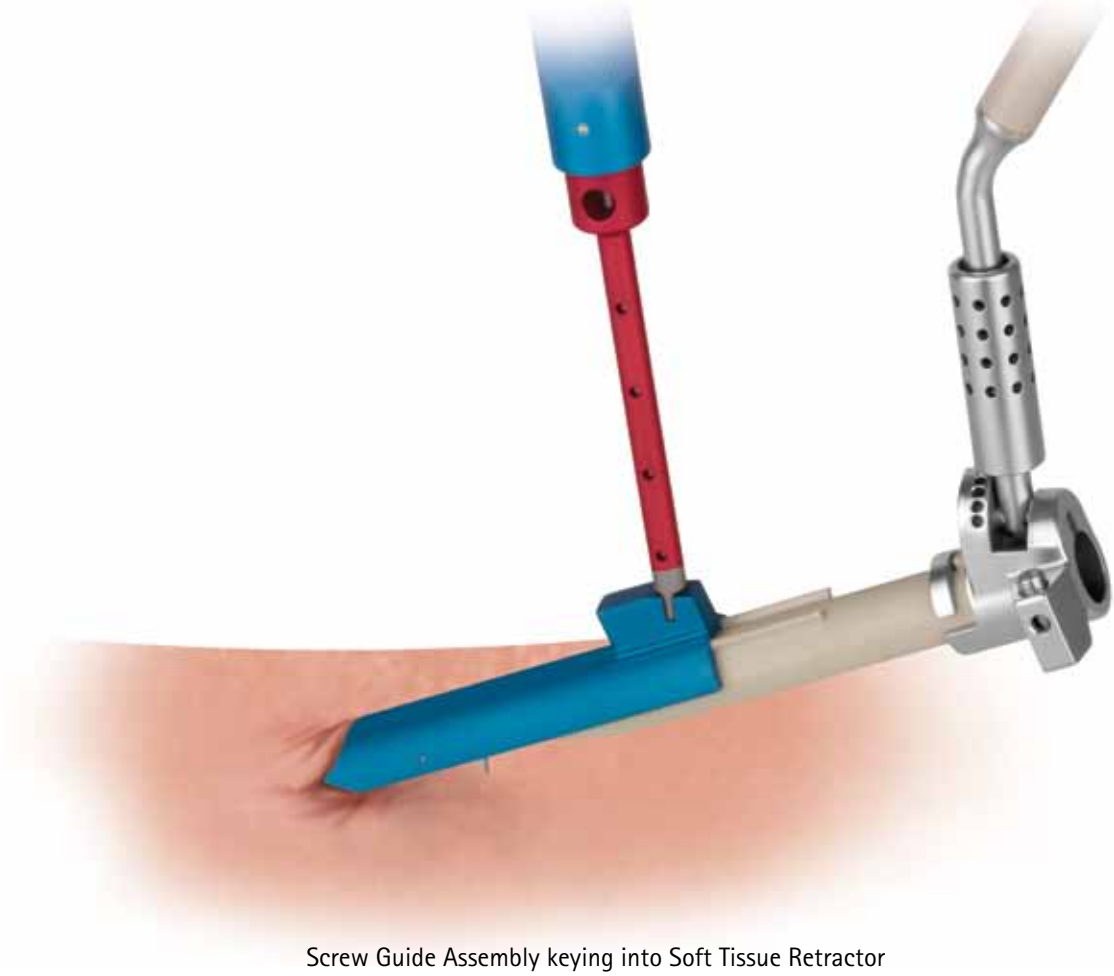


Insert the tab and rotate 90° counter-clockwise into the channel until it snaps securely into place.



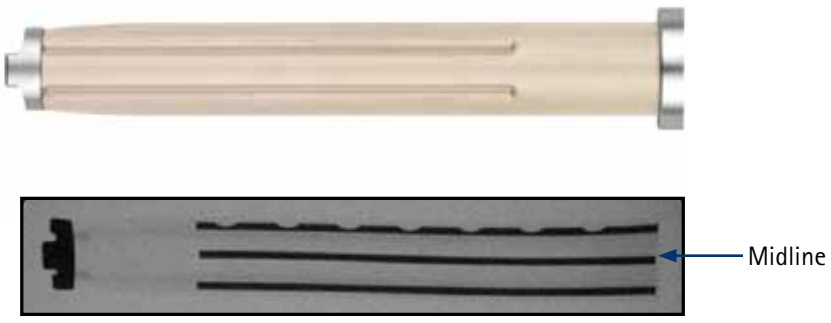
Screw Guide Insertion (Cont'd)

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 and the retractor blade left remaining.



Screw Guide Assembly keying into Soft Tissue Retractor

Once the Screw Guide Assembly is in place, use fluoroscopy to verify that the tip is correctly positioned. There are three radiopaque rods which run the length of the guide from the handle to the screw exiting location, as shown below. The rod on the right side is scalloped to permit orientation identification under fluoroscopy.



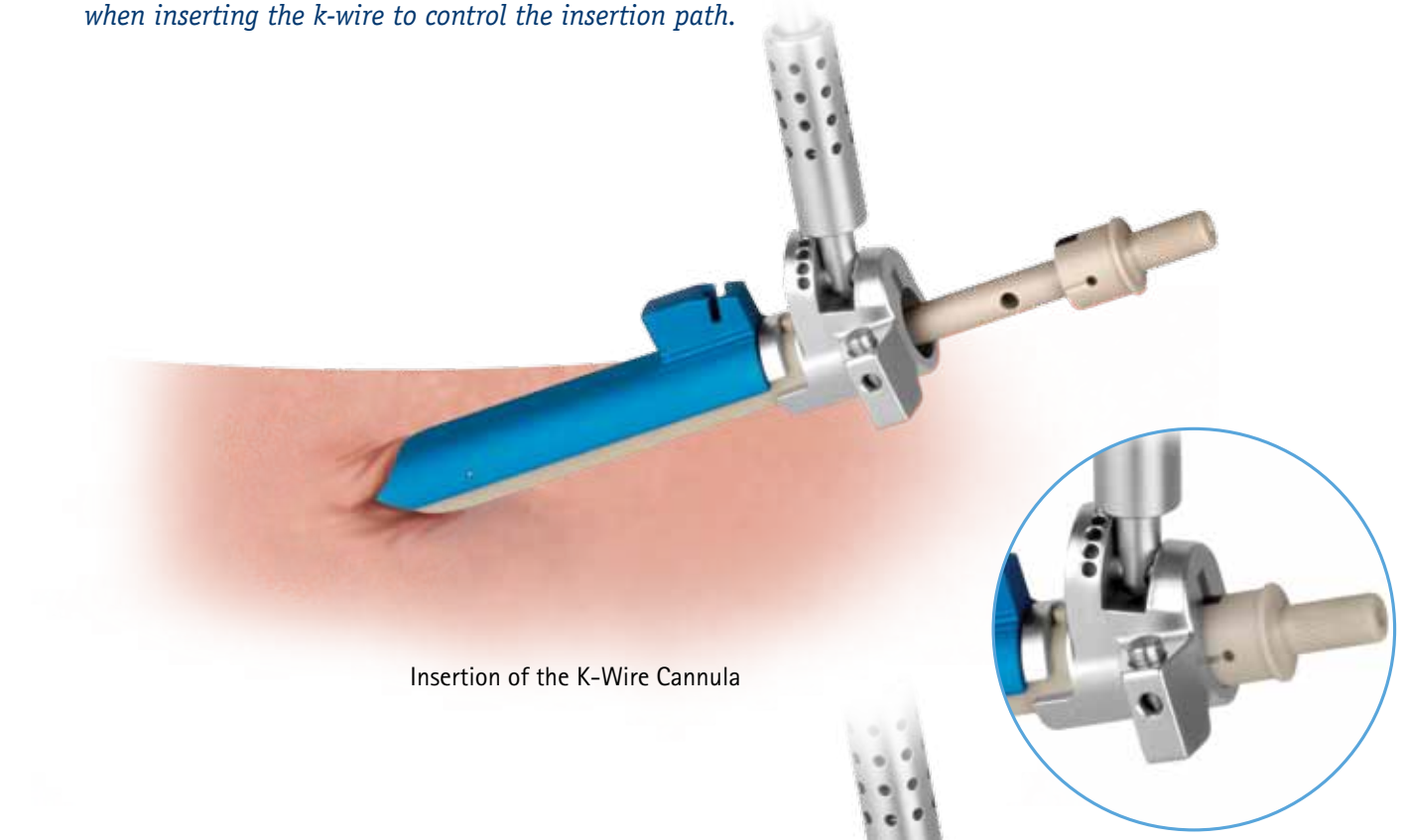
Placement of the stainless steel rods in the Screw Guide

3 Screw Hole Preparation

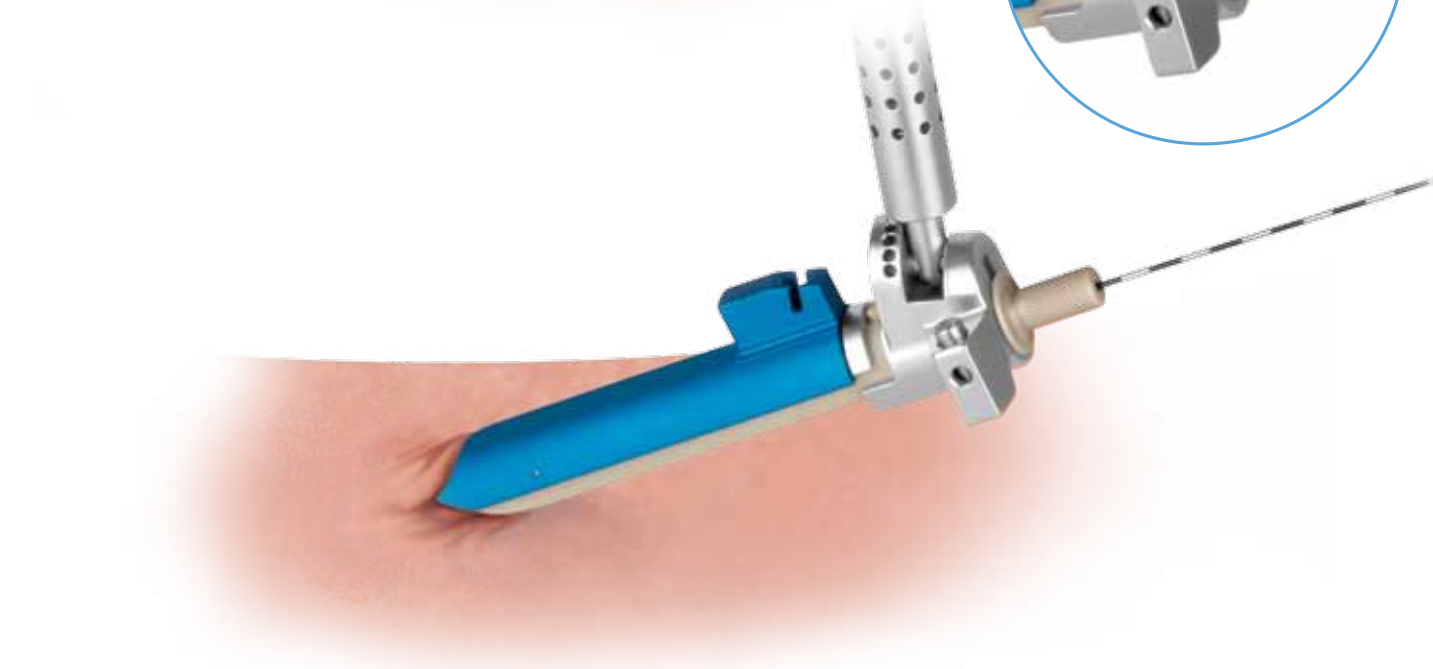
Insert the **K-Wire Cannula** into the Screw Guide Assembly, ensuring that the laser marks on both pieces are aligned. The K-Wire Cannula will provide a controlled path for k-wire insertion. Using the **K-Wire Gripper**, insert the k-wire to the appropriate trajectory and depth.

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 always be used when inserting the k-wire to control the insertion path.



Insertion of the K-Wire Cannula

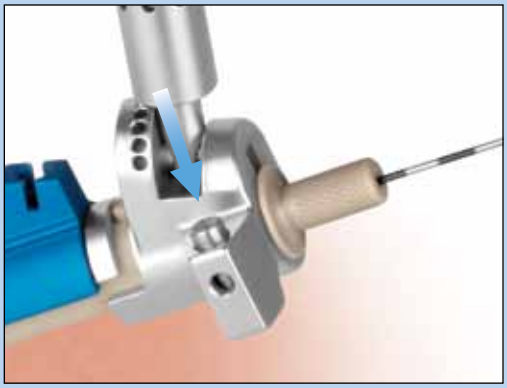


Insertion of the k-wire through the cannula

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.

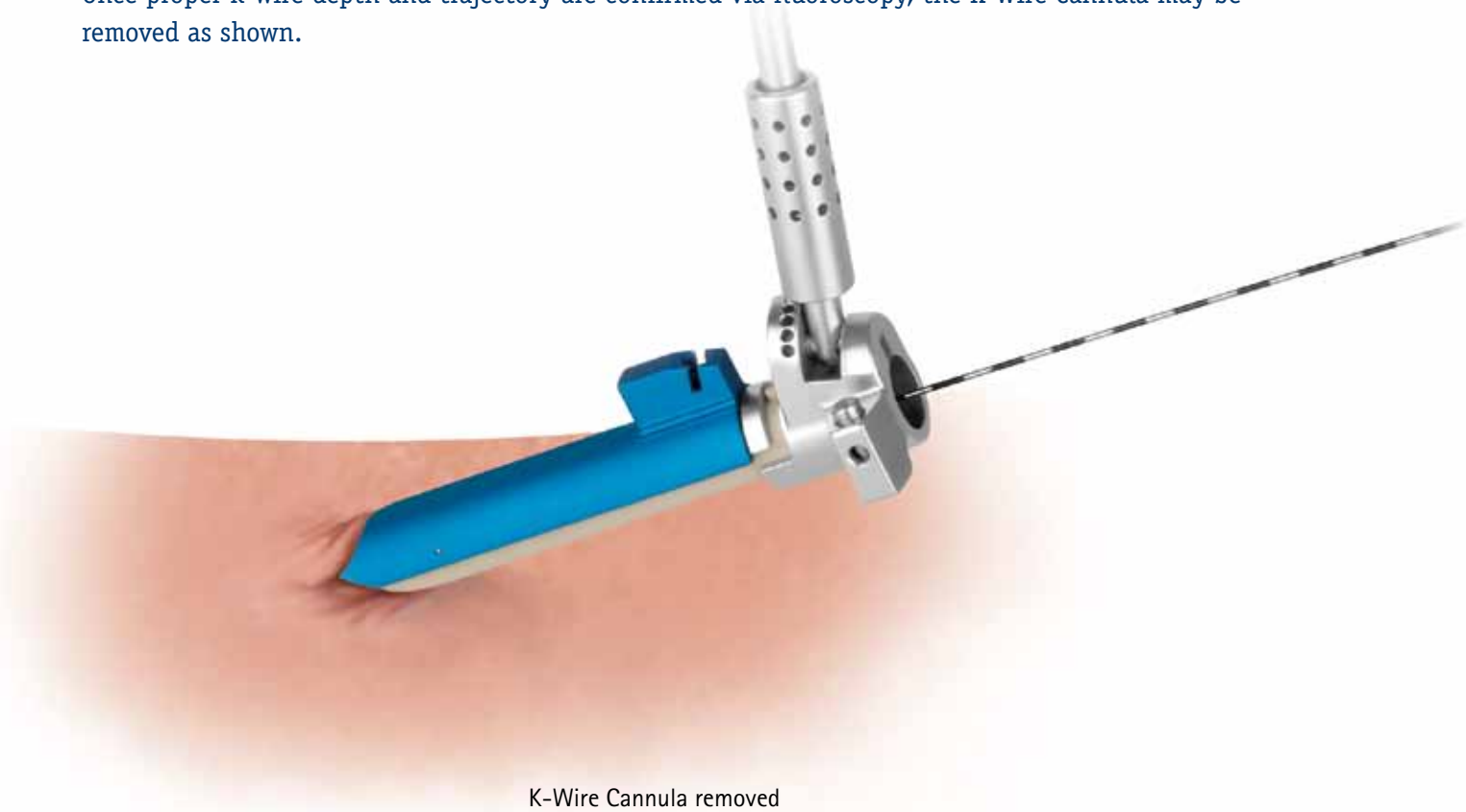


Push button to release K-Wire Cannula

K-Wire markings every 5mm

Screw Hole Preparation (Cont'd)

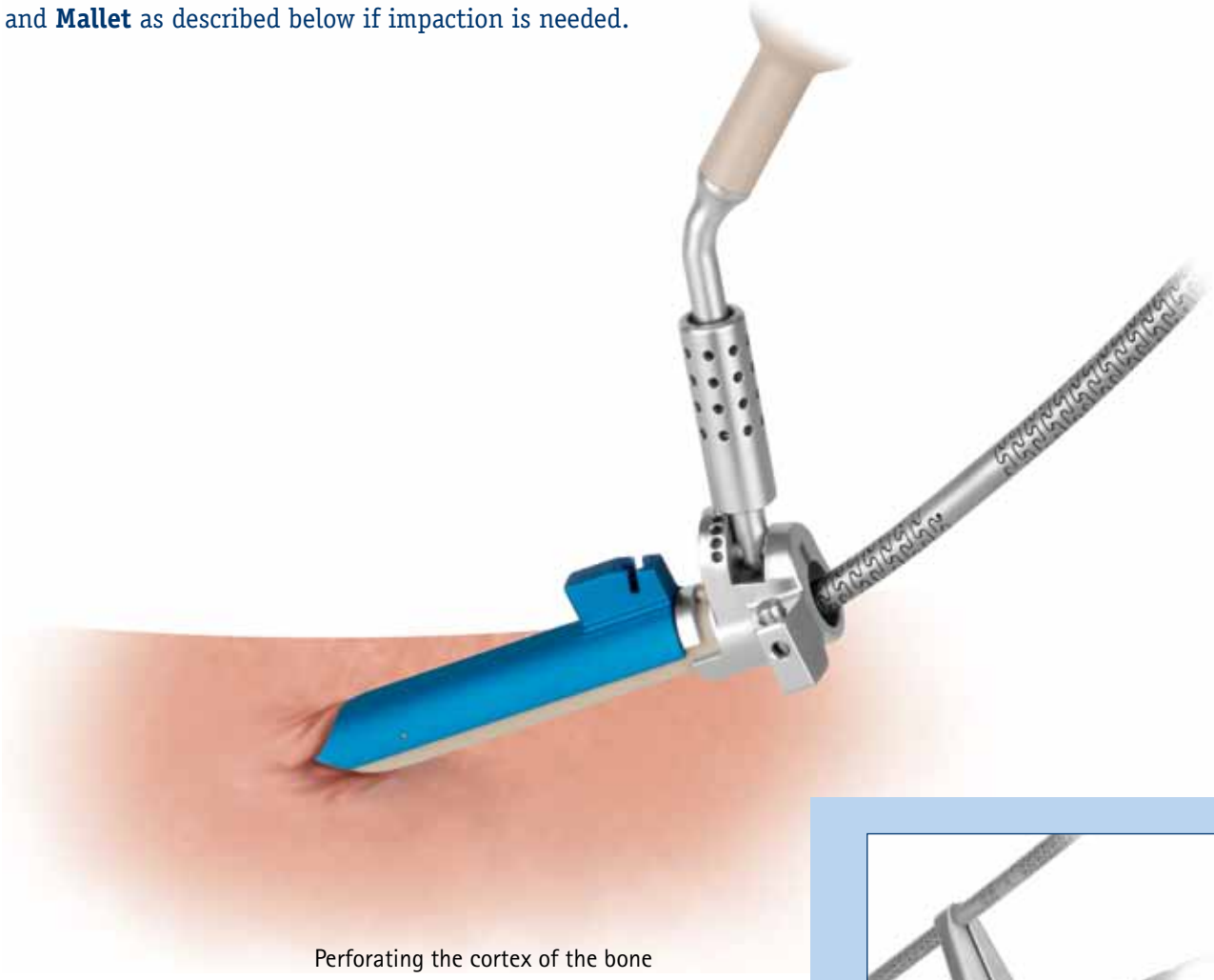
Once proper k-wire depth and trajectory are confirmed via fluoroscopy, the K-Wire Cannula may be removed as shown.



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.



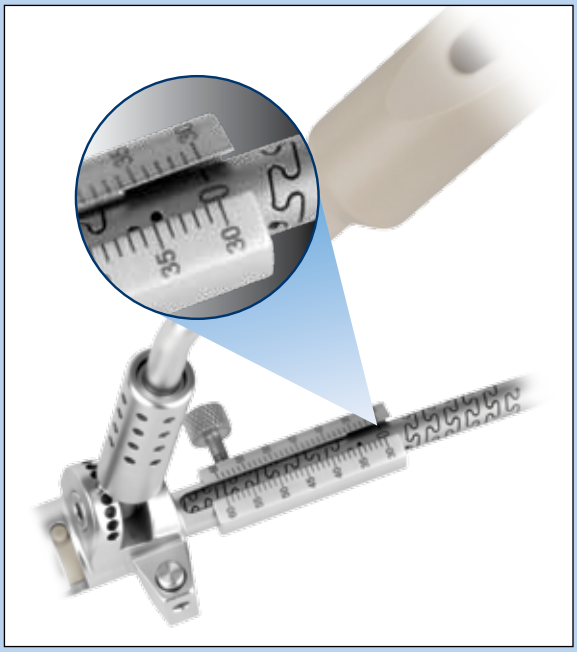
Perforating the cortex of the bone

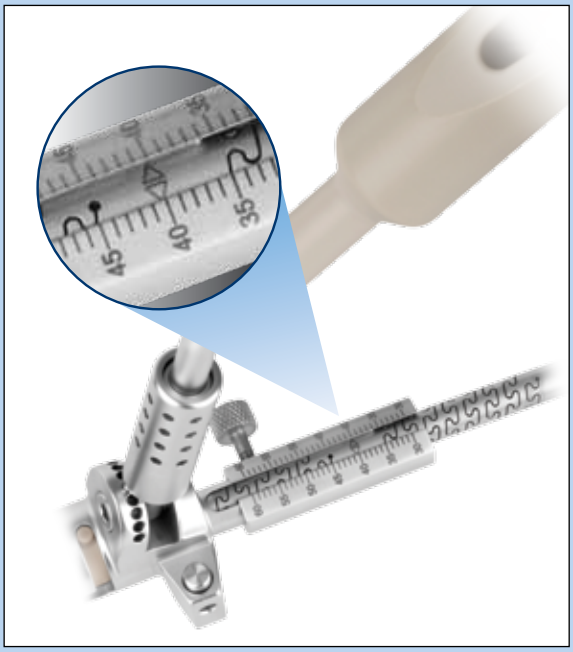
Remove the Awl/Burr carefully, holding the k-wire in position with the K-Wire Gripper.

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 above.





A 40mm screw length is shown here

Preparing the 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 the Indicator

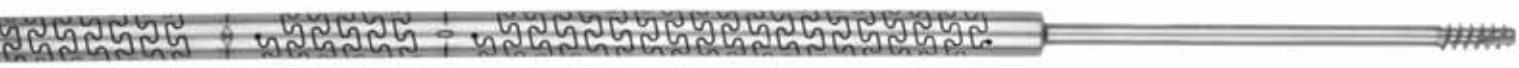
Advance the drill bit into the bone to the desired depth. The arrows on the drill bit indicate the depth, corresponding to screw length.

Screw Hole Preparation (Cont'd)

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.



Flexible Cannulated Tap
648.208

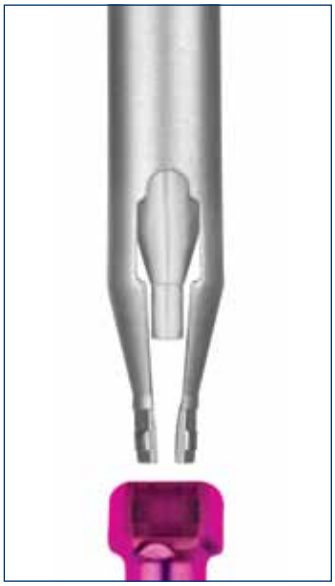
4 Screw Insertion

Load the appropriate screw onto the **2.5mm Flexible Cannulated Hex Driver**. Insert through the Screw Guide Assembly. Verify the screw position using fluoroscopy.

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 7. Dispose of the k-wire, Drill Bit, K-Wire Cannula and Screw Guide.

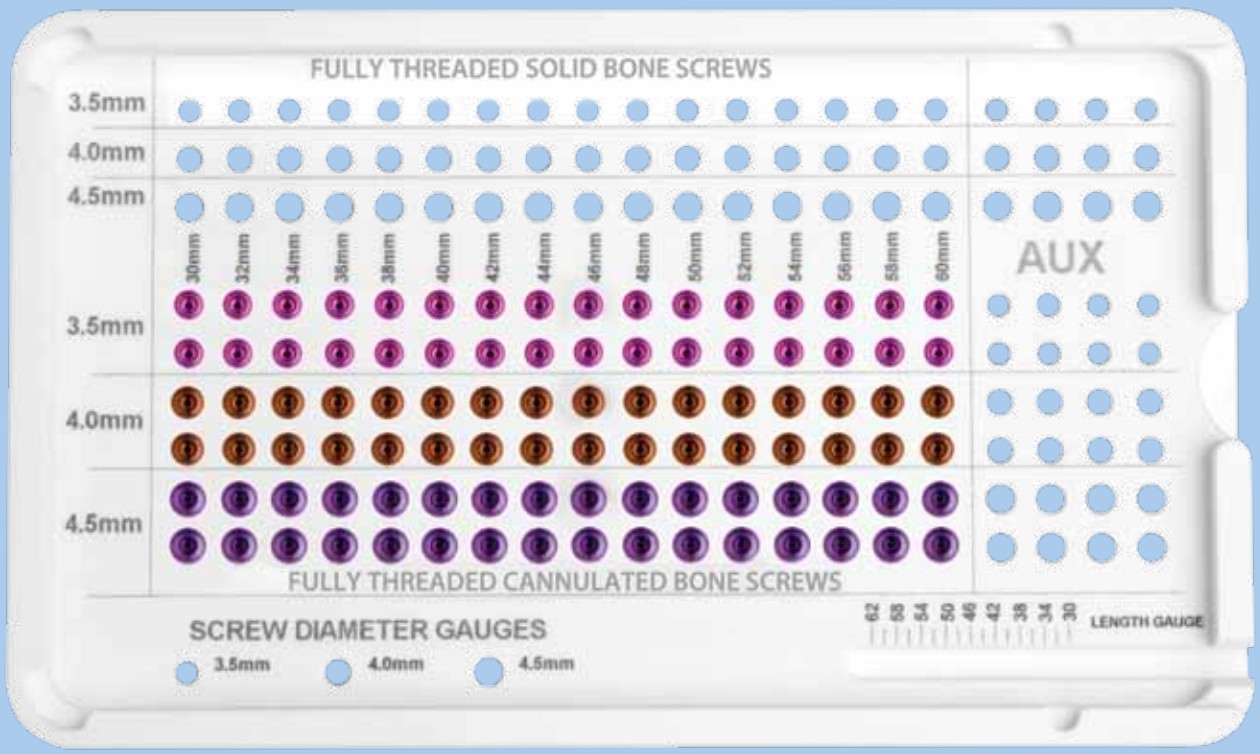
5 Optional Technique: Screw Removal

If it is necessary to remove the screw, 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.



2.5mm Screw Removal Tool 648.303

CORRIDOR™ Implant Set



CORRIDOR™ Screws

Implants (Set Qty - 2 each Cannulated Screws)

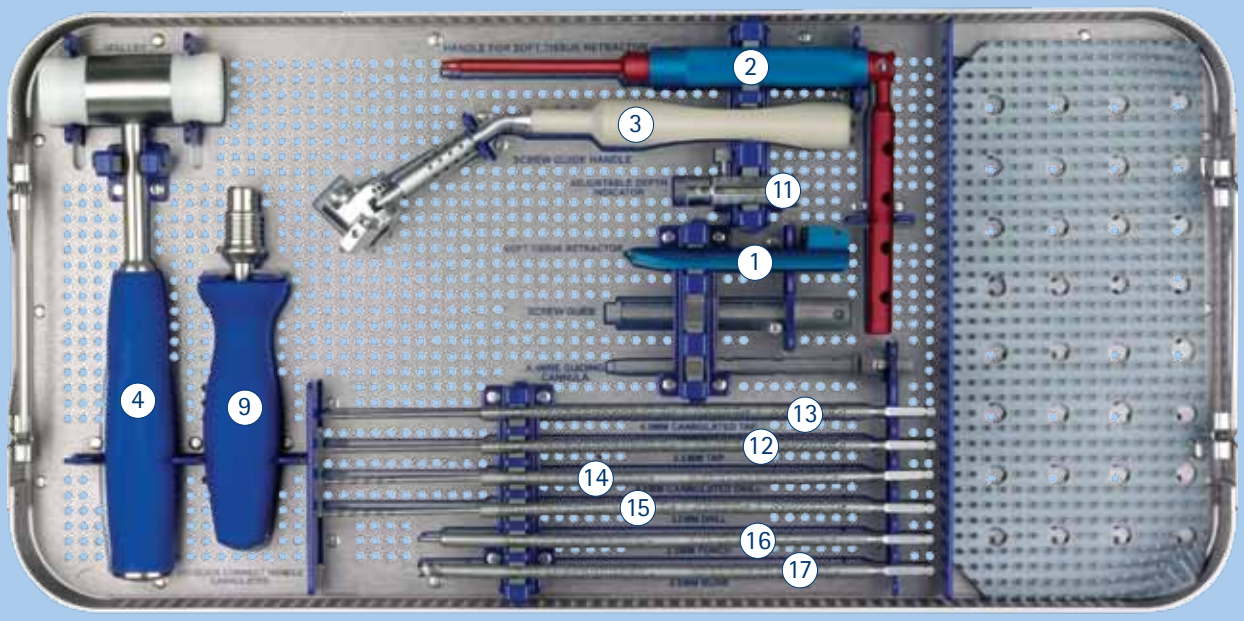
CORRIDOR™ Screw Set 948.903 (Partially Threaded)

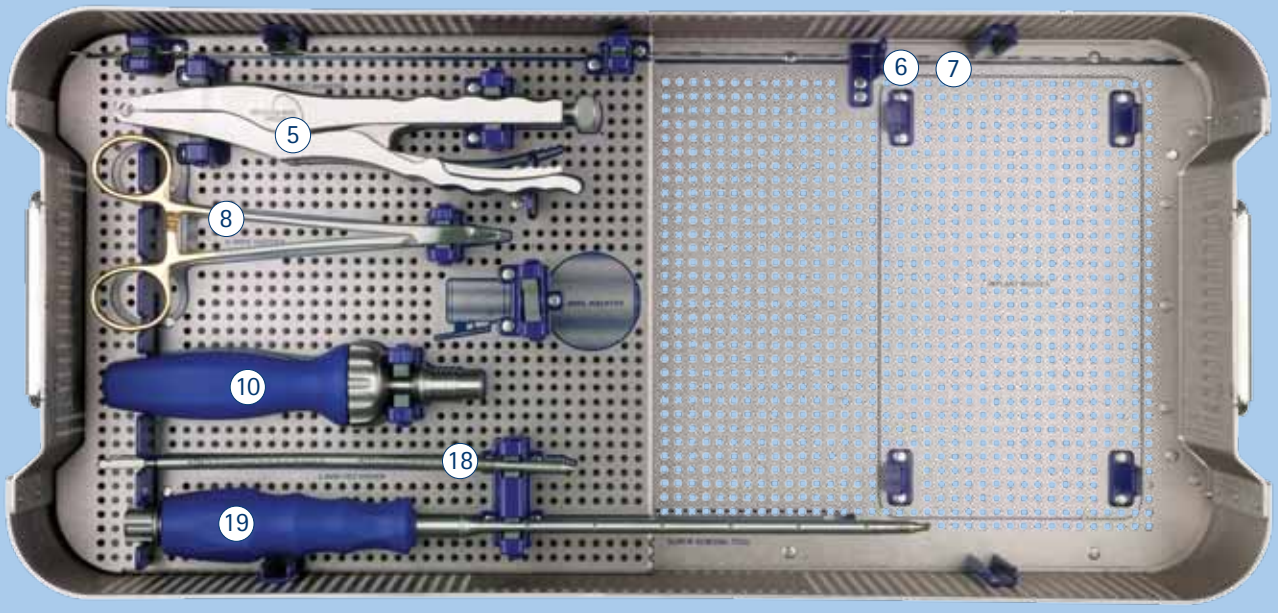
	3.5mm Diameter		4.0mm Diameter		4.5mm Diameter	
Length	**Cannulated**	**Non-Cannulated**	**Cannulated**	**Non-Cannulated**	**Cannulated**	**Non-Cannulated**
30mm	148.130	148.030	148.330	148.230	148.530	148.430
32mm	148.132	148.032	148.332	148.232	148.532	148.432
34mm	148.134	148.034	148.334	148.234	148.534	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

CORRIDOR™ Instrument Set





CORRIDOR™ Instrument Set 948.901

	Instruments		Set Qty
1	648.101	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	1

Sterile Packaged Instruments		Set 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

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. 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 from 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.

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 pseudarthosis 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 compliations 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 equine 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.

CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

CONTACT INFORMATION

Globus Medical may be contacted at 1-877-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

Implants:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time
Steam	Gravity Displacement (Wrapped)	132° - 135°C (270° - 275° F)	28 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° - 135°C (270° - 275° F)	4 Minutes

Instruments:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

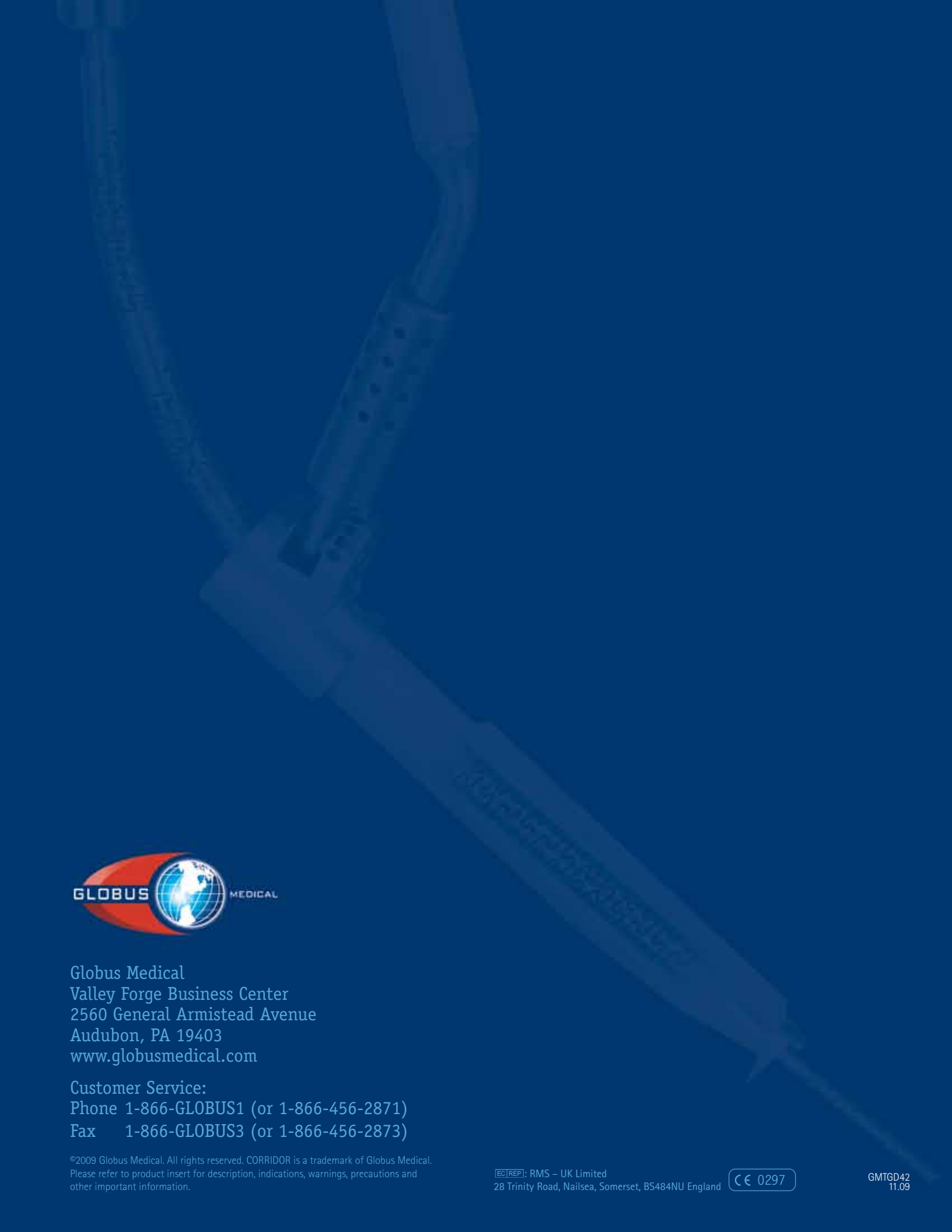
Method	Cycle	Temperature	Exposure Time
Steam	Gravity Displacement (Wrapped)	132° - 135°C (270° - 275° F)	25 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° - 135°C (270° - 275° F)	15 Minutes

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 autoclave 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.

Notes

Notes



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