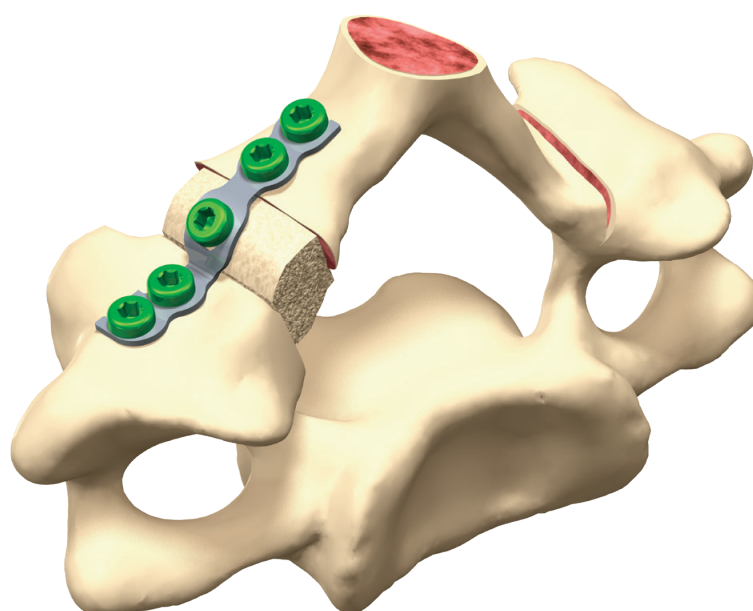




XspanTM

Laminoplasty Fixation System

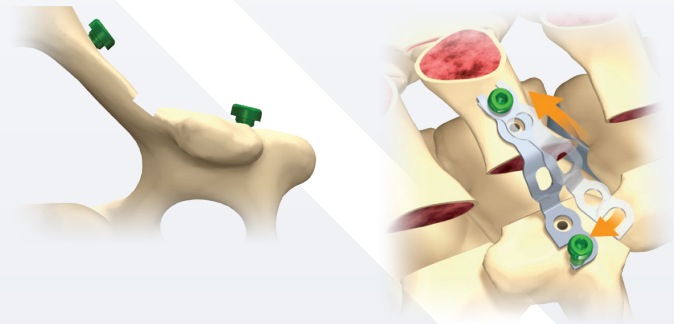


SURGICAL TECHNIQUE

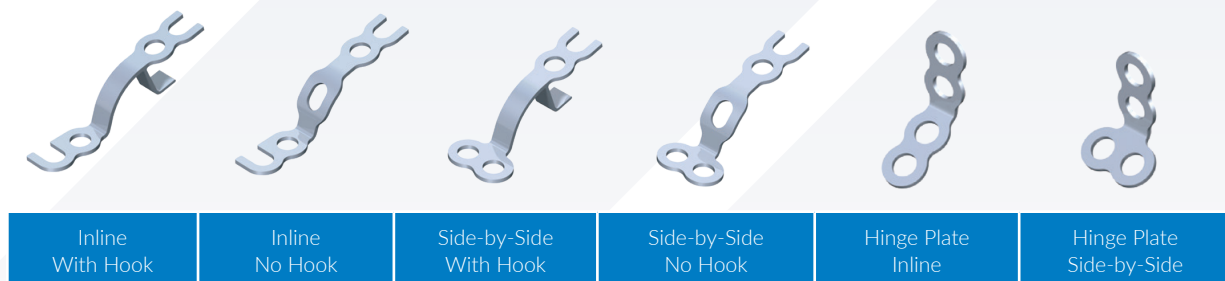
The Xspan Laminoplasty Fixation System provides the option of safely placing the screws prior to destabilizing the lamina. Multiple plate options including hinge plates are available to manage varying pathology and instability.

Safer Technique

Screws may be inserted prior to transection, followed by fast plate insertion to minimize duration of instability.



- Reduced lateral exposure is required using the side-by-side plate
- Maintain an increased distance from facets or foramina using the inline plate
- Plates are available with a malleable laminar hook, or with a mid-plate hole to secure an allograft block
- Hinge plates stabilize hinge side fractures or instability



In patients free of cervical kyphosis and/or unstable spine presenting with multilevel spondylotic myeloradiculopathy, ossification of the posterior longitudinal ligament (OPLL), ossification of the ligamentum flavum (OLF), or congenital/developmental canal stenosis, laminoplasty coupled with foraminotomies, if necessary, is a proven, effective, motion sparing, low risk alternative to multilevel anterior operations, and to laminectomies. Compared to laminectomy, perispinous atrophy and postlaminectomy deformity is lessened as preservation of the posterior elements affords the musculature a reattachment anchor. In our institution it is one of the most employed decompressive techniques. While gaining in popularity, laminoplasty still remains an underutilized option.

The Xspan Laminoplasty System has been designed to make the open door laminoplasty technique safer, more adaptable to spondylotic variations in the dorsal element anatomy, and simpler to perform.

This brief guide should be read through so that the reader is familiar with procedural options including the “drill first/screw first” option, for preparing the drill holes prior to performing the laminotomy.

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XSPAN™ LAMINOPLASTY FIXATION SYSTEM SURGICAL TECHNIQUE

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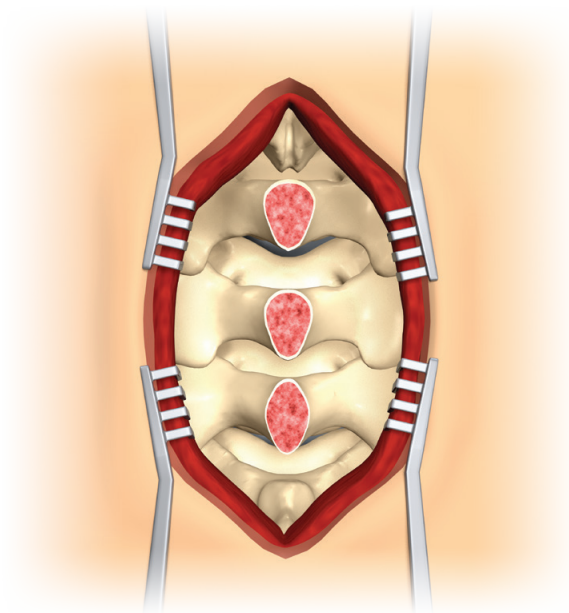
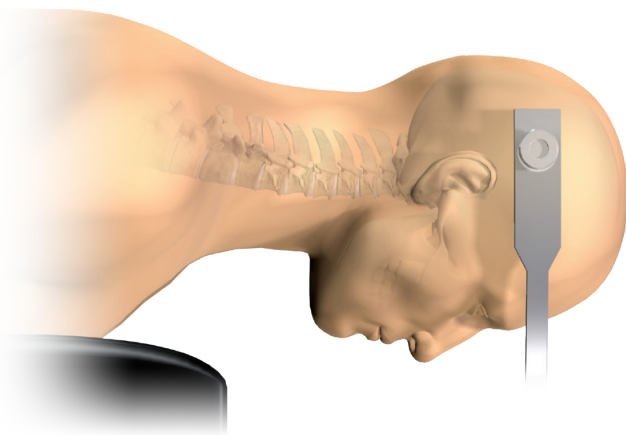
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Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

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Patient Positioning and Surgical Exposure

- Place the patient in the prone position with the head supported and the neck slightly flexed.
- Perform a standard midline approach to expose the laminae, out to the mid-portion of the lateral masses at the desired levels. Care should be taken to preserve the facet capsules and the muscular attachments to the lateral half of the lateral masses.
- The spinous process at each level may be resected to maintain post-operative muscular symmetry,

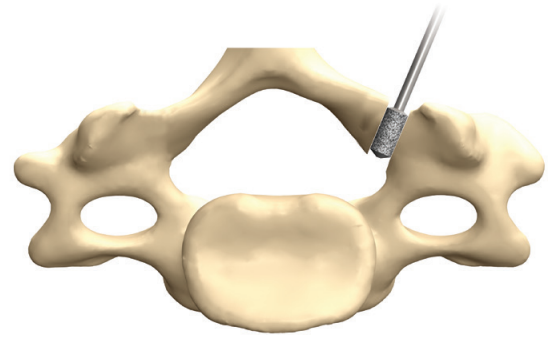


Note: It is recommended to compare the local anatomy with the pre-operative axial images. Intra-operative imaging can be used to confirm implant placement.

Step 1: Open Side Preparation

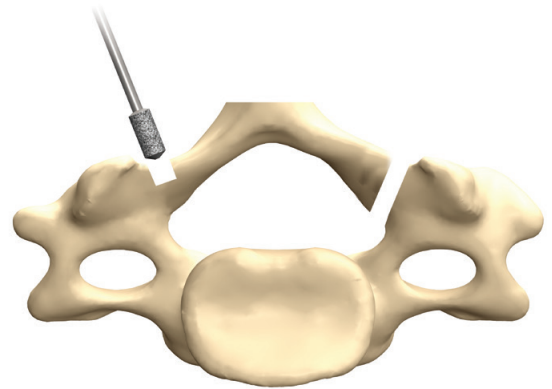
- Select the open side, transect the lamina at the junction of the lamina and the medial edge of the pedicle,

Note: Care must be taken to avoid impingement of the underlying dura.



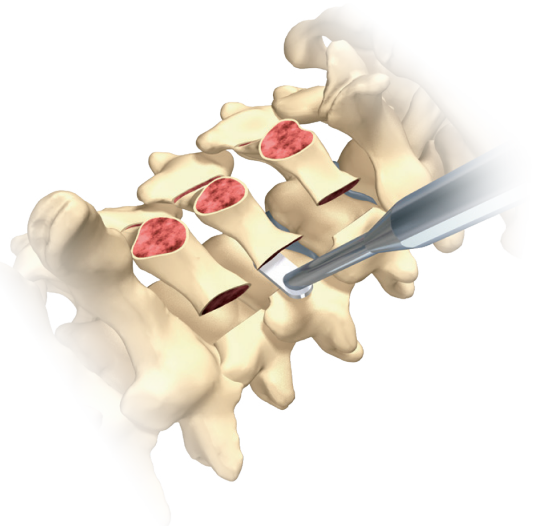
Step 2: Hinge Side Preparation

- On the contralateral side, enable a greenstick fracture by decorticating the dorsal cortex and into the cancellous layer, slightly more lateral than the medial edge of the pedicle. Check the stiffness of the hinge at each level and “fine tune” the depth of the decortication as needed.



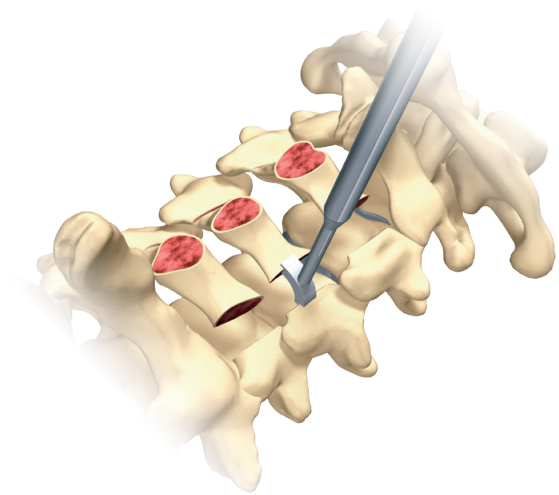
Step 3: Opening The Lamina

- Use the Lamina Holder or Lamina Elevator to open the lamina away from the spinal cord. The hinge should remain contiguous with bone and facet capsule so as not to be subject to inward migration or instability.



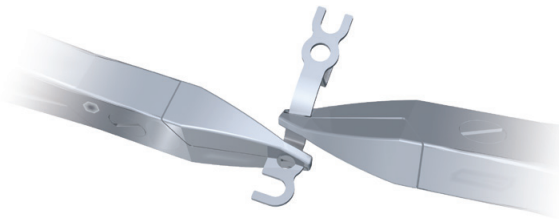
Step 4: Plate Sizing

- Use either the Sizing Trials or Plate Trials to determine the size of the plate needed to create the desired laminar gap.
- Screw holes may be prepared through the Plate Trials, if desired. If so, the penetration of the drill is reduced by 1 mm.



Step 5: Plate Selection and Placement

- Select the desired configuration and length of plate.
- Using the Plate Holder, fit the Plate to the lamina and lateral mass. The assistant may hold the lamina in the correct position using the Lamina Holder.
- The Plate and the hook are malleable and can be shaped using the Plate Benders.



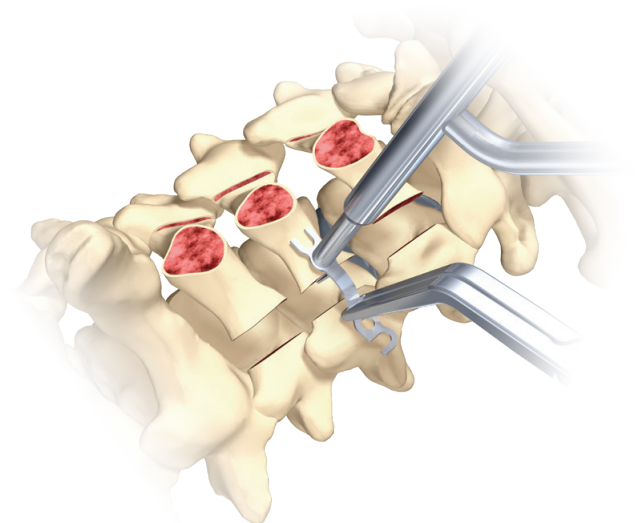
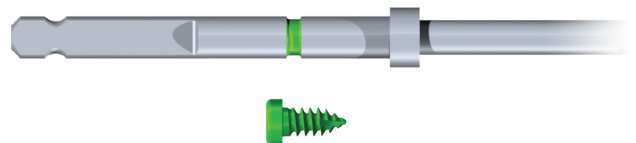
Step 6: Screw Hole Preparation and Screw Insertion

- Drill in the center of each hole using the appropriate length Drill in the Drill Guide, or the 5mm Freehand Drill.

Note: The guided Drills have a colored band for each length which corresponds to the color of the Screw.

Screw/Drill Length	Color
5mm	Green
7mm	Blue
9mm	Magenta

- Insert the Screws using the self-retaining Screwdriver.



OPTIONAL TECHNIQUE

Drill First / Screw First Method

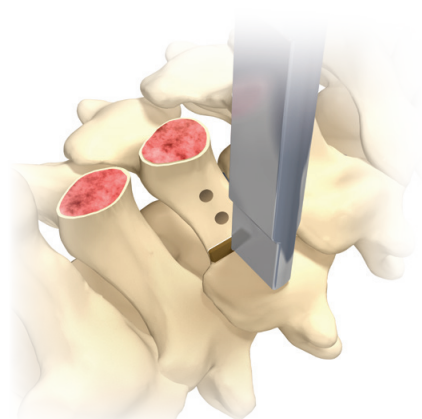
The Xspan system allows for screw holes to be prepared and/or Screws to be placed while the laminae remain stable prior to transecting the lamina.

Step 1: Screw Hole Preparation

- On the intended open side, decorticate where the completed cut is planned to a depth of at least 1 mm but not all the way through.
- Using the Inline Drill-First Guide, place the rudder at the distal end of the decorticated lamina, and drill into the lamina with the appropriate length Drill.
- For preparing holes in the lateral mass, select the Inline or the Side-by-Side Drill-First Guide and the appropriate length Drill.

Note: The Inline Drill-First Guide and plate is required if a lateral mass screw is intended to be placed prior to transecting the lamina.

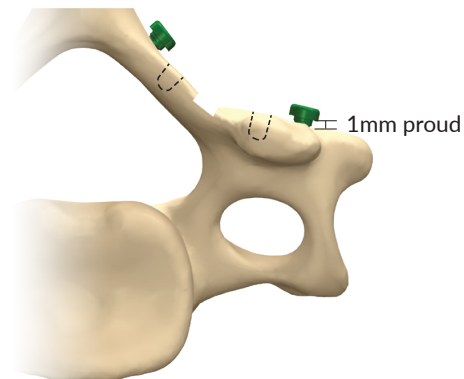
- If the Screws are to be inserted after placing the Plate, proceed with opening the lamina and insertion of the implants as described in the standard technique, Steps 1 to 6.



Step 2: Provisional Screw Insertion

With the Xspan system, it is possible to insert a lamina and/or lateral mass screw prior to transecting the lamina.

- Insert the medial lamina Screw, leaving the head at least 1 mm proud to allow for the Plate to slide under.
- For Inline Plates, the lateral Screw in the lateral mass may also be provisionally inserted, leaving the head proud.

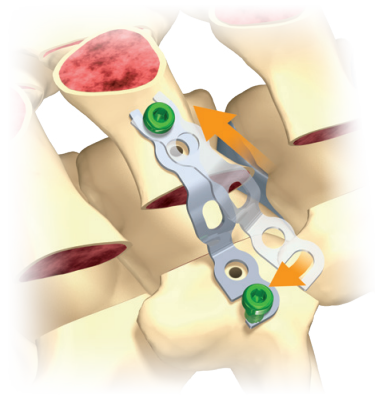


Step 3: Opening the Lamina and Plate Sizing

- Proceed with the preparation and opening of the lamina, and the sizing of the Plate using the Trials, as described in the standard technique, Steps 1 to 4.

Step 4: Plate Insertion and Final Screw Insertion

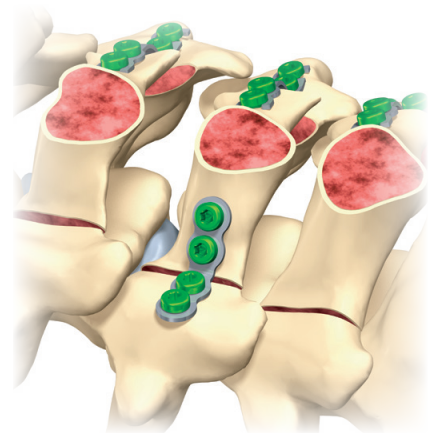
- Using the Plate Holder, slide the open slot of the lamina end of the Plate under the head of the lamina Screw.
- For Inline Plates, rotate the lateral end of the plate such that the open slot slides under the head of the lateral mass Screw.
- Tighten the Screw(s) until the Plate is secure.
- Insert the remaining Screws and tighten.



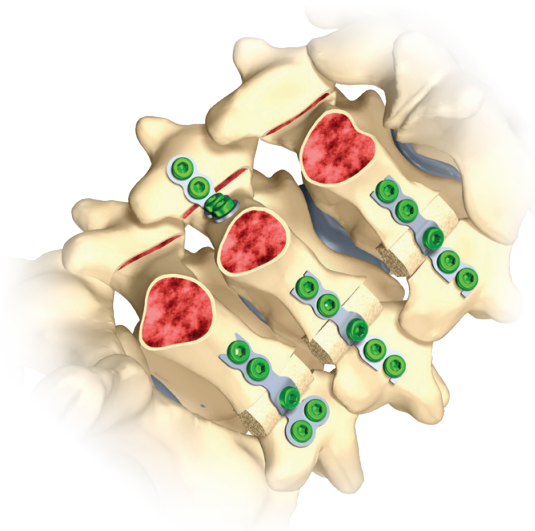
Hinge Plates

A Hinge Plate can be used to provide additional support to a weakened or displaced hinge.

- Select the Inline or the Side-by-Side configuration of Hinge Plate.
- Drill holes and insert Screws into the lamina holes of the Hinge Plate while holding the lamina firmly with the Lamina Holder.
- Drill holes and insert Screws into the lateral mass.



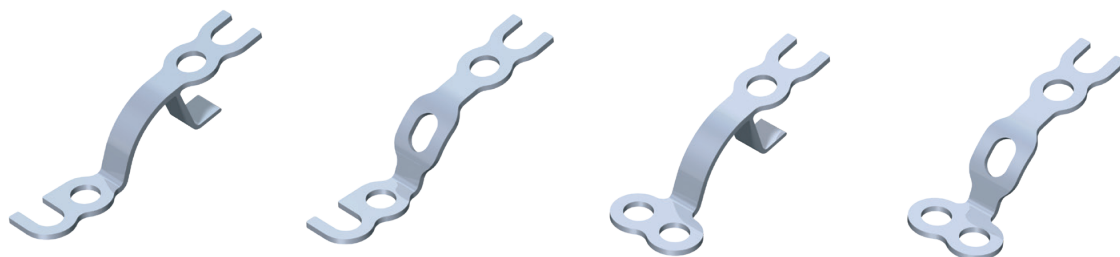
Final Construct



Implant Removal

- Unscrew the Screws using the self-retaining Screwdriver.
- The plate can be freely removed.

XSPAN™ IMPLANTS



Plates

Length	Inline with Hook	Inline no Hook	Side-by-Side with Hook	Side-By-Side no Hook
6mm	X085-0106-H06-STR	X085-0106-STR	X085-0206-H06-STR	X085-0206-STR
8mm	X085-0108-H06-STR	X085-0108-STR	X085-0208-H06-STR	X085-0208-STR
10mm	X085-0110-H06-STR	X085-0110-STR	X085-0210-H06-STR	X085-0210-STR
12mm	X085-0112-H06-STR	X085-0112-STR	X085-0212-H06-STR	X085-0212-STR



Hinge Plates

Inline	Side-by-Side
X085-0150-STR	X085-0250-STR

Screws

Length	Standard (2.6mm)	Rescue (3.0mm)
5mm	X085-2605-STR	X085-3005-STR
7mm	X085-2607-STR	X085-3007-STR
9mm	X085-2609-STR	X085-3009-STR



XSPAN™ INSTRUMENTS

Sizing Trial 6mm / 8mm – T085-0040-0608



Sizing Trial 10mm / 12mm – T085-0040-1012



Plate Trials



Length	Inline	Side-by-Side
6mm	T085-0041-06	T085-0042-06
8mm	T085-0041-08	T085-0042-08
10mm	T085-0041-10	T085-0042-10
12mm	T085-0041-12	T085-0042-12

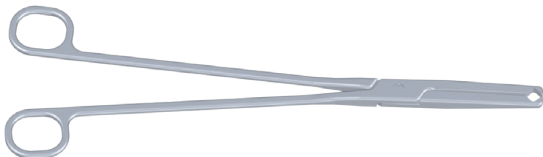
Plate Trial Handle – T085-0043



Lamina Elevator – T085-0016



Lamina Holder Straight – T085-0012



Lamina Holder Angled – T085-0013

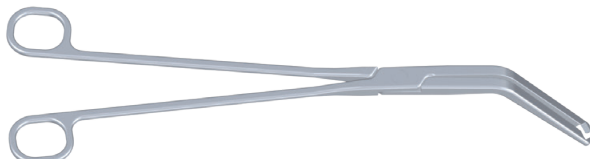


Plate Holder – T085-0011

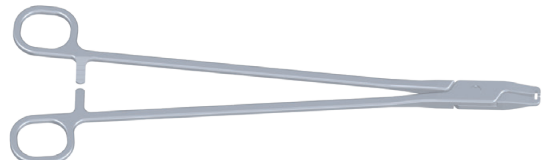


Plate Bender – T085-0014

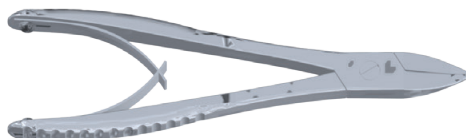
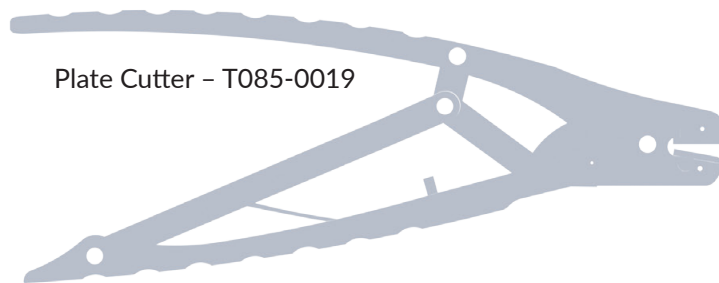


Plate Cutter – T085-0019



Ball End Probe – T085-0018



Freehand Drill 5mm – T085-0021



Guided Drills

5mm – T085-0020-05



7mm – T085-0020-07



9mm – T085-0020-09



Drill Guide – T085-0030



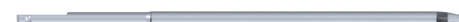
Drill-First Guide Inline – T085-0031



Drill-First Guide Side-by-Side – T085-0032



Screwdriver – T085-0010



Handle A/O Connect – X067-0500





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INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

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