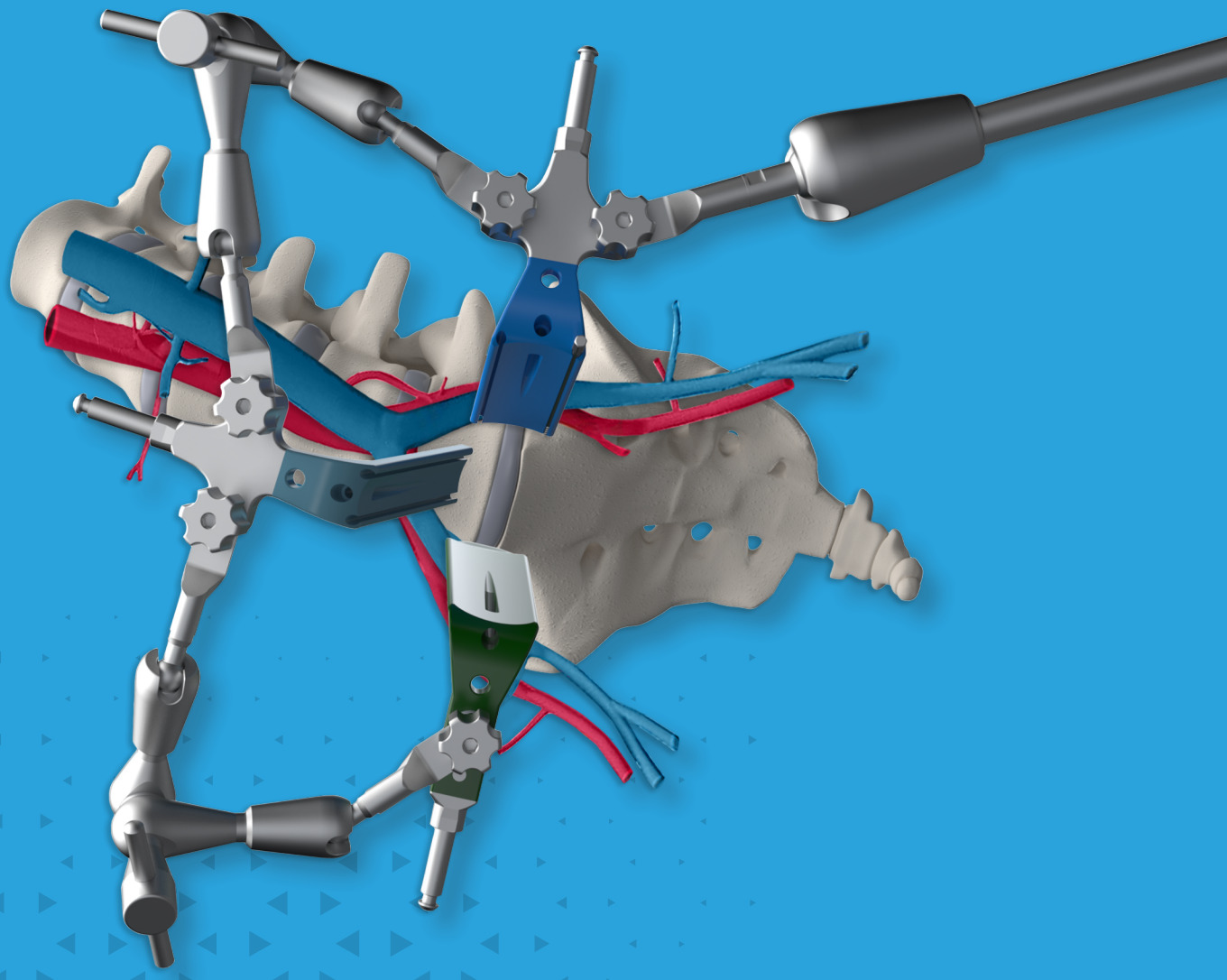
SURGICAL TECHNIQUE GUIDE

OA51S (OASIS) OBLIQUE ACCESS L5-S1 SYSTEM



4WEB®

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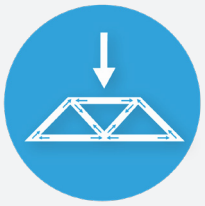
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, the surgeon should refer to the product's Instructions For Use (IFU) for complete warnings, precautions, indications, contraindications and adverse effects. IFUs are available by contacting 4WEB® at +1(800) 285-7090.

TRUSS IMPLANT TECHNOLOGY™

Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate which minimizes point loading and reduces the risk of subsidence.[1]

Hierarchical surface roughness spans from the macro to nano scale. These surface features have been shown to stimulate increased gene expression of certain osteogenic markers when compared to other interbody surfaces and materials.[2, 3]

Open architecture design allows for greater graft volume and bone growth throughout the entire construct.[1]



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.[2]

Truss Implant design provides maximum strength with a minimal amount of material, which limits imaging artifacts.

[1] Data on file
[2] Lee et al., ORS, 2023 Annual Meeting, Dallas, TX
[3] Rowe et al., SMISS, Annual Forum '19, p.52

OA51S OVERVIEW

The OA51S "Oasis" System consists of a table arm, articulated connector arms, and a set of retractor blades of varying lengths and widths to enable retraction of soft tissue and anatomical features during access to the lumbar spine via an anterior oblique lateral approach. The blades are available in multiple configurations, including a Large Vein Blade (LVB), Large Wylie Blade (LWB), Small Vein Blade (SVB), Small Wylie Blade (SWB), and Hohmann Blade (HB). The system also includes a lighting system to aid in visualization of the surgical site.

INDICATIONS

The 4WEB OA51S Retractor System is intended to be used to provide retraction and direct visualization of targeted anatomy during implantation of a lumbar interbody fusion device.

CONTRAINDICATIONS

The OA51S Retractor System should not be used for patients with:

- An active infection at the operative site or other active systemic infections
- Tumor involvement at the operative site
- Prior fusion at the level(s) to be treated
- Known sensitivity to the material

WARNINGS AND PRECAUTIONS

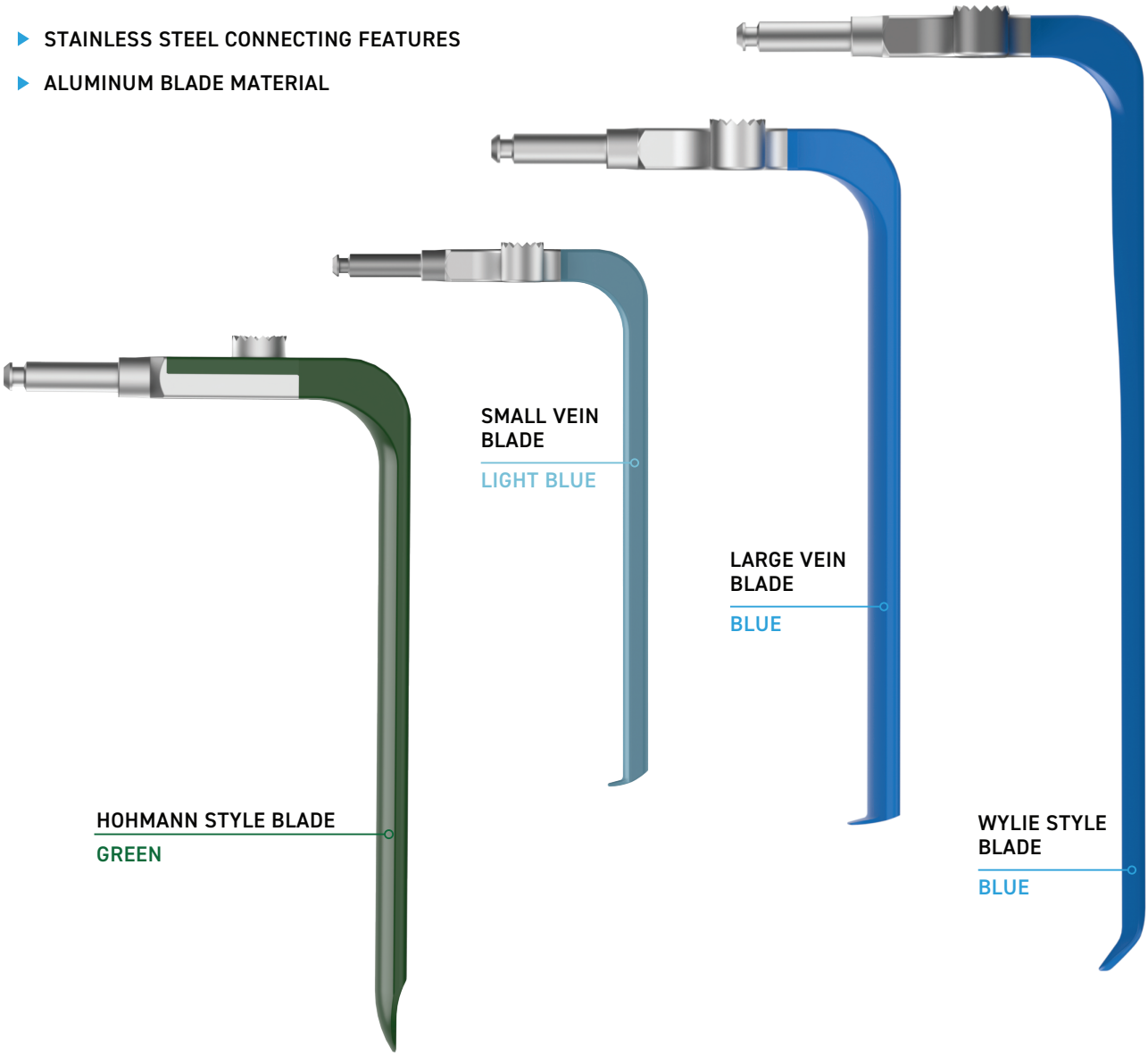
See package insert for warnings, precautions, adverse effects, and other essential product information. Before using the OA51S Instrumentation, verify:

- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-OA51S-05.

INSTRUMENT OVERVIEW

- STAINLESS STEEL CONNECTING FEATURES
- ALUMINUM BLADE MATERIAL



PREOPERATIVE PLANNING

Please refer to the LSTS Surgical Technique Guide (ST-LSTS-01) for implant related pre-operative planning.

PATIENT POSITIONING & PADDING

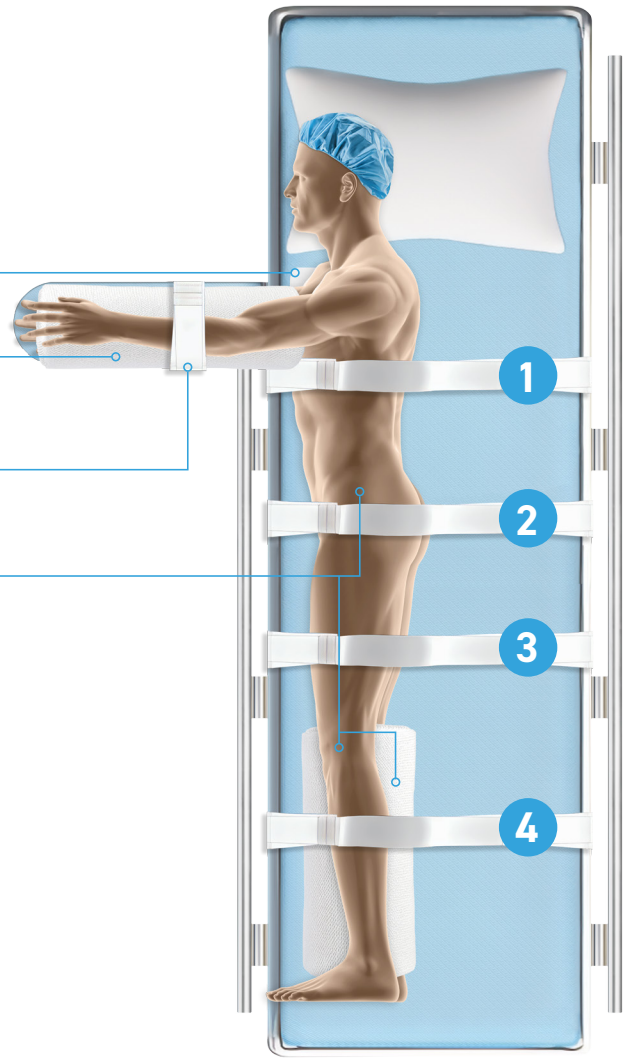
The patient should be placed on a flat surgical table, flexing the table to maximize disc space access is not necessary for the oblique approach. Padding should be placed in the following positions:

Axillary roll protecting the brachial plexus

Arm padding to secure patient in a safe neutral position

Bilateral upper extremities fixed to padded arm boards

Bilateral lower extremities positioned with hips and knees fully extended with pillows between the legs. This increases lordosis in the lumbar spine.



TAPING THE PATIENT

The patient is secured to the table using surgical tape at the following locations:

1. **Over the thoracic region, just inferior the shoulder**
2. **Inferior to the left greater trochanter, low enough to provide access to the L5-L1 disc space**
3. **From the back of the table, over the thigh to the front of the table**
4. **From the back of the table, over the calf to the front of the table**

Once the patient is properly positioned on the table, confirm positioning with AP and lateral films.

SURGICAL PROCEDURE

ATTACH HANDLE

Attach the Handle to the LVB or LWB (Fig. 1).

After dissecting to L5-S1 disc space, use an LVB ***(Blue)*** or LWB ***(Blue)*** and an HB ***(Green)*** with an attached Illuminator to identify the L5-S1 disc via direct visualization. Quick Connect Handles may be used to assist with blade manipulation.

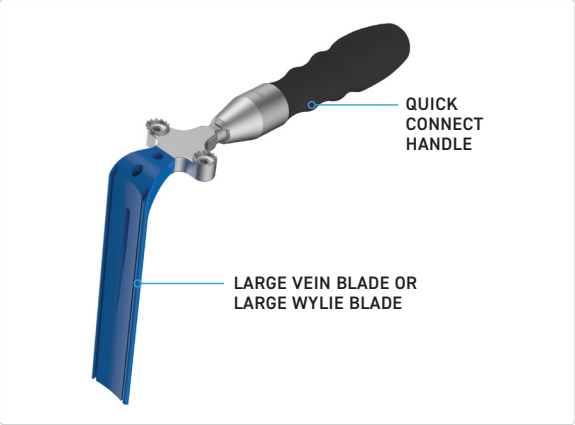


Figure 1

BLADE PLACEMENT

Use the HB to retract the medial aspect of the incision and the LVB or LWB to retract the lateral aspect of the incision (Fig. 2).

After releasing the adventitial layer, under direct visualization, the LVB or LWB should be placed under the iliac vein. This step secures protection and lateralization of the left common iliac vein and artery. (Prior to securing and locking down the construct the LVB or LWB and the HB may be used for direct visualization of the vessels.

The HB is placed medially. When in the proper position, it wraps around the contralateral side of the disc space. The vessels on the right side are located more laterally than those on the left side.

Tip: Endoscopic Kittner can be utilized to assist in dissecting and moving any layers or soft tissue.

Tip: Once the LVB or LWB is placed, it can be pinned into the sacrum for additional stability.

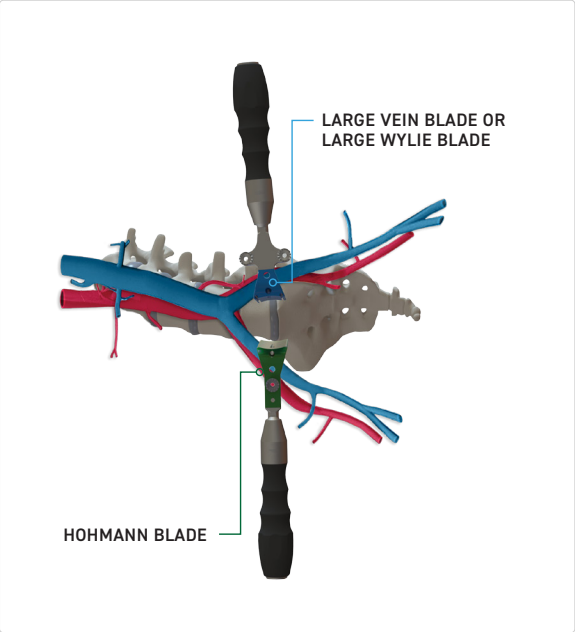


Figure 2

ATTACH TO TABLE ARM

The LVB or LWB can now be provisionally attached to a posteriorly placed Table Arm (Fig. 3).

The Table Arm should be attached to the surgical table just inferior to the tape over the greater trochanter (see page 6, TAPING THE PATIENT, number 2).

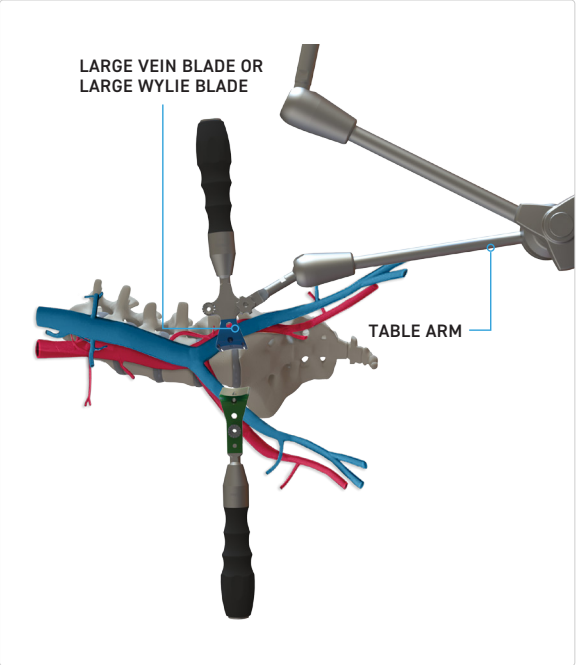


Figure 3

TIGHTEN BLADE TO TABLE ARM

Provisionally tighten the LVB or LWB to the Table Arm with either the Socket Wrench or the 4mm Hex Driver (Fig. 4).

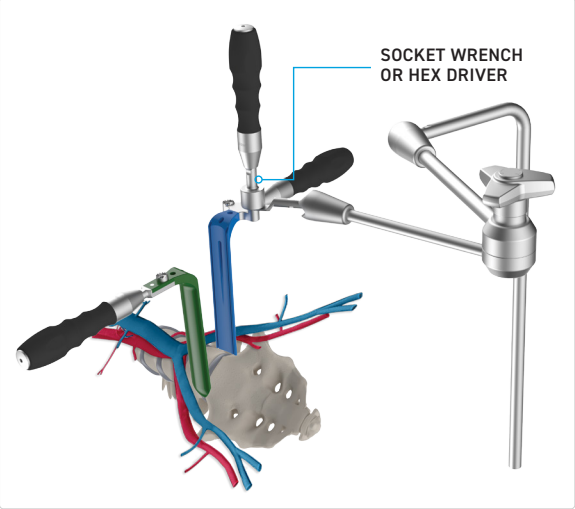


Figure 4

PIN BLADE TO SACRUM

Use the HB and an Endoscopic Kittner for final identification and mobilization of the vasculature. The LVB or LWB can then be placed in its final position and pinned to the Sacrum using an appropriate length Steinmann Pin. Attach the Pin Driver to the Steinmann Pin and drive to fully insert (Fig. 5).

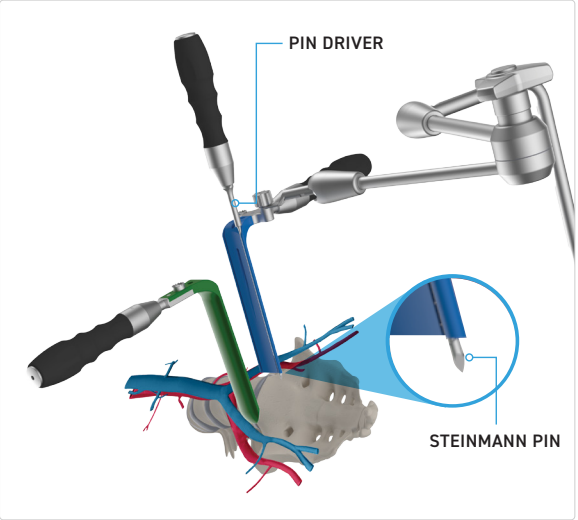


Figure 5

PLACE SMALL VEIN/WYLIE BLADE

Once the LVB or LWB is pinned to the Sacrum, perform a final tightening of the Blade to the Table Arm. The Quick Connect Handle can be removed if desired. While the HB is held in position, the Small Vein Blade (SVB) *(Light Blue)* or Small Wylie Blade (SWB) *(Light Blue)* is placed on the L5 body to protect the bifurcation. The SVB or SWB can be pinned as an option. (Fig. 6).

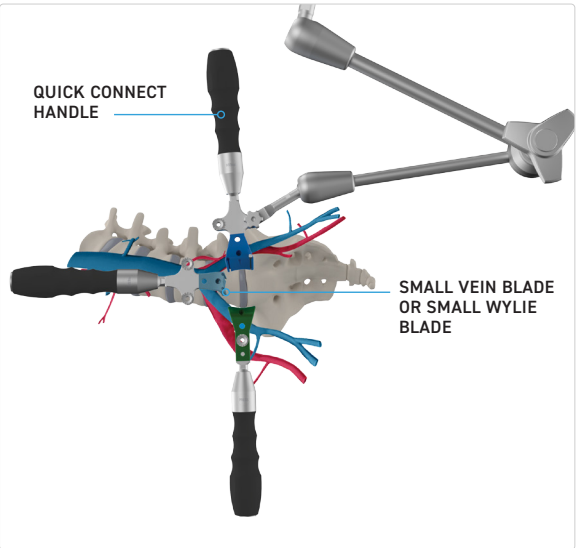


Figure 6

LOCK BLADES

The SVB or SWB can now be locked to the LVB or LWB using a Small or Large Articulated Arm (Fig. 7). Finger tighten, or use the Socket Wrench or 4mm Hex Driver to attach the Blade to the Long or Short Articulated Arm.

Optional: Remove the Quick Connect Handle if desired.

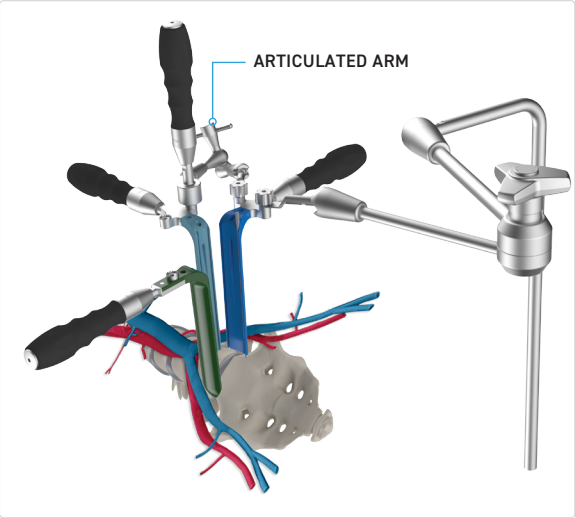


Figure 7

SECURE HOHMANN BLADE

The HB can now be secured to the SVB or SWB with a second Articulated Arm (Fig. 8).

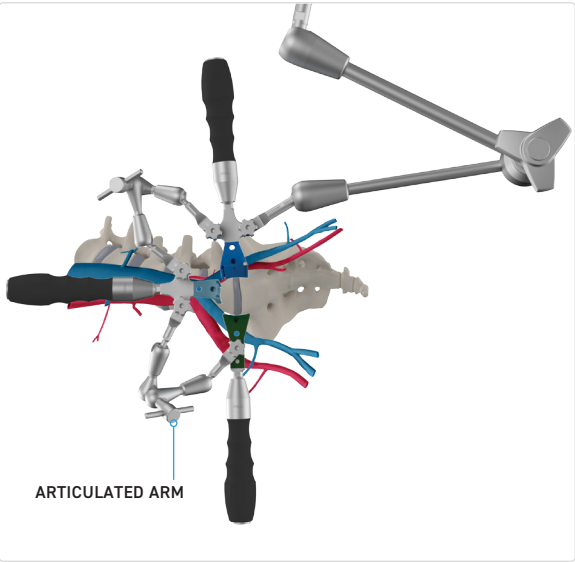


Figure 8

SECURE BLADES

Once final placement of the blades is completed, the Quick Connect Handles can be removed, if desired (Fig. 9).

After completion of the Oblique L5-S1 procedure, carefully remove the blades in reverse order of insertion and confirm positioning of the vasculature.

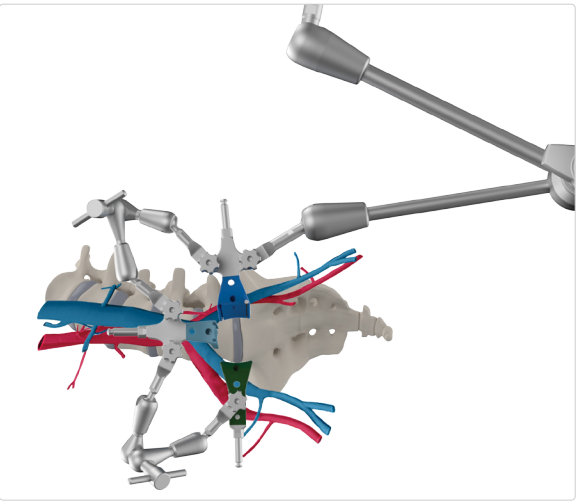
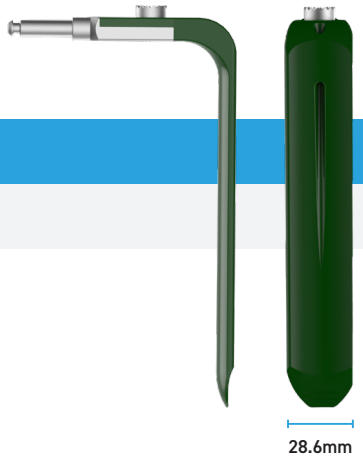


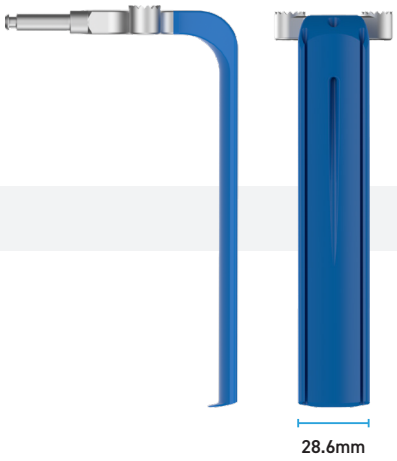
Figure 9

INSTRUMENT CATALOG



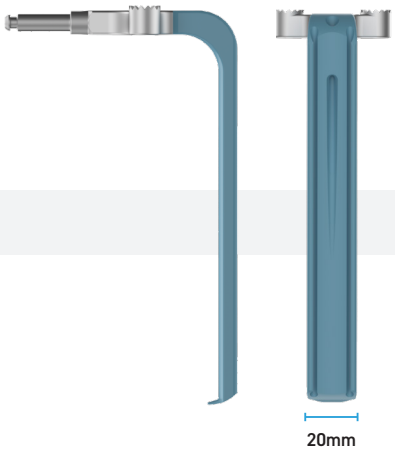
PART NUMBER	DESCRIPTION
4WEB-OA51S-HXXX	HOHMANN BLADE - **GREEN**

Available Sizes: 125mm, 145mm, 175mm, 205mm



4WEB-OA51S-LVXXX	LARGE VEIN BLADE - **BLUE**

Available Sizes: 125mm, 145mm, 175mm, 205mm



4WEB-OA51S-SVXXX	SMALL VEIN BLADE - **LIGHT BLUE**

Available Sizes: 125mm, 145mm, 175mm, 205mm

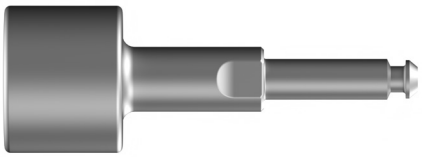
PART NUMBER	DESCRIPTION
4WEB-OA51S-LSVXXX	LARGE WYLIE BLADE - **BLUE**

Available Sizes: 125mm, 145mm, 175mm, 205mm

4WEB-OA51S-SSVXXX	SMALL WYLIE BLADE - **LIGHT BLUE**

Available Sizes: 125mm, 145mm, 175mm, 205mm

4WEB-OA51S-000001	SOCKET WRENCH



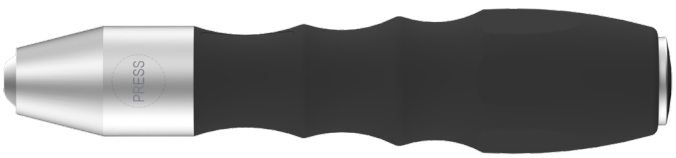
PART NUMBER	DESCRIPTION
4WEB-OA51S-000002	PIN DRIVER

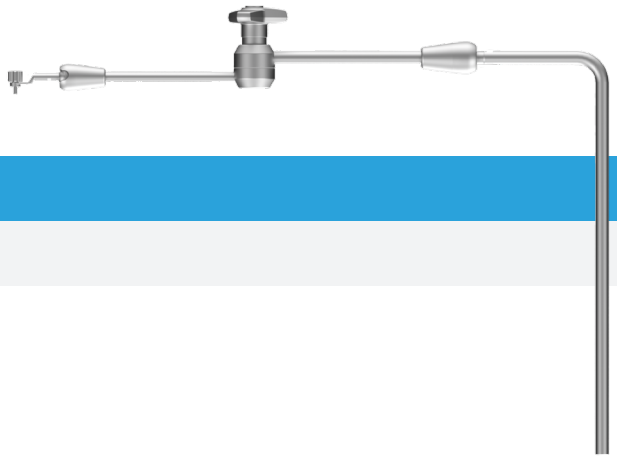
4WEB-OA51S-000003	4MM HEX DRIVER

4WEB-OA51S-PXXX	STEINMANN PIN

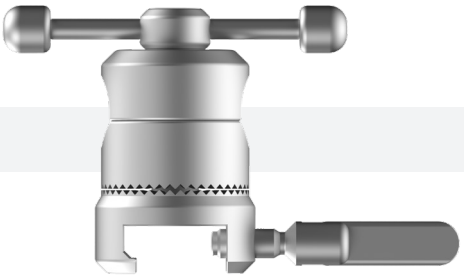
Available Sizes: 125mm, 145mm, 175mm, 205mm

PSTS-000013	QUICK CONNECT HANDLE

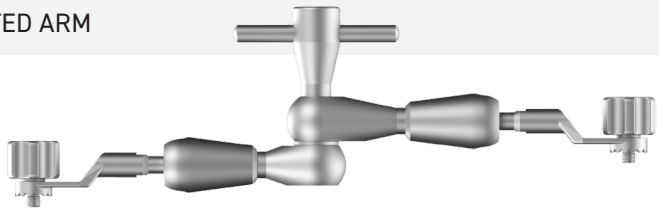




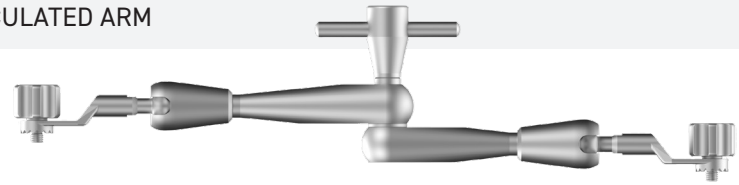
PART NUMBER	DESCRIPTION
4WEB-OA51S-000004	TABLE ARM



4WEB-OA51S-000005	TABLE CLAMP



4WEB-OA51S-000006	SHORT ARTICULATED ARM

PART NUMBER	DESCRIPTION	
4WEB-OA51S-000007	LONG ARTICULATED ARM	
005011	LIGHT CABLE CONNECTOR	
4WEB-OA51S-LC	LIGHT CABLE	

2801 NETWORK BLVD. SUITE 620
FRISCO, TX 75034
4WEBMEDICAL.COM
INFO@4WEBMEDICAL.COM
800.285.7090
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