Case 3:18-cv-00347-DMS-BLM Document 1-38 Filed 02/13/18 PageID.846 Page 1 of 30

# **EXHIBIT U**

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# **Battalion**<sup>™</sup>Lateral

Lumbar Spacer System

#### FEATURES

- Cranial/Caudal blades open independently
- DepthControl<sup>™</sup> allows blaces to raise and lower +/- 5mm (10mm total variability)
- LevelToe<sup>™</sup> mechanics ensure the blades stay on a parallel plane as the toe up to 15°
- CounterFlex<sup>™</sup> mechanism prevents aperture narrowing
- Robust implant/inserter interface with one step ETA<sup>™</sup> (engage, twist, attach) loading
- Forth blade features articulation and DepthControl<sup>™</sup>
- Implants designed to promote sagittal balance
- Intelligent instrumentation featuring Stealth Coating<sup>™</sup> to prevent glare, AlphaTexture<sup>™</sup> handles, and modular instruments with depth and orientation indicators

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**XAlphatec** Spine<sup>®</sup>

#### PREFACE

The Battalion Lateral Spacer System has been designed with surgeon utilization and patient outcomes in mind. The System features a three blade retractor system combined with broad disc prep and implant offerings.

The Battalion LLIF Disc Prep sets feature both standard (straight) instruments, as well as offset (cranial/caudal) options for surgeons to access each level of the lumbar spine.

Alphatec Spine has created a three-blade, hand-held Squadron<sup>™</sup> Retractor Lateral Access System and added features such as independent cranial/caudal blade movement, 0-15 degrees of LevelToe<sup>™</sup>, the ability to replace blades in-situ, and to raise and lower blades 10mm in-situ.

Implants are designed to be used in the lumbar disc spaces as interbodies.

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# PREOPERATIVE PLANNING

The Squadron<sup>™</sup> Retractor Lateral Access System has been designed to allow for the use of neuromonitoring based on the surgeon's discretion and may be used with many commercially available neuromonitoring systems.

# PATIENT POSITIONING

Ensure that the surgical table is reversed before the patient is positioned so that fluoroscopy can be used. Place the patient in a lateral decubitus position on a bendable (breaking) table so that the patient's greater trochanter sits directly above the table break.

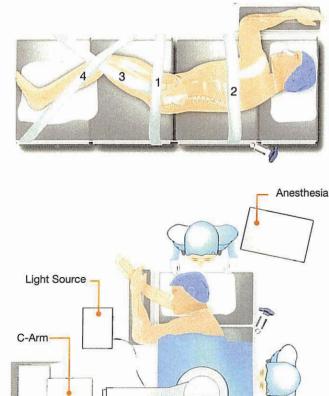
#### LUMBAR ACCESS

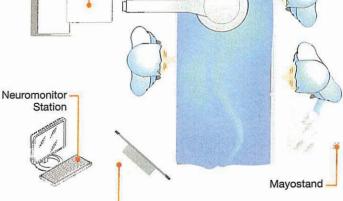
Following the patient's placement on the table, the patient will be secured with surgical tape. If the levels being accessed are the in the lumbar spine, the patient should be taped at the following locations:

- Below the iliac crest
- Over the thoracic region
- From the iliac crest to the knee, taking care to pad the perennial nerve (tape will then be secured to the table)
- From under the table on the ipsilateral side, to the knee, past the ankle and then to the contralateral side under the table

#### VERIFYING APPROPRIATE PLACEMENT

- Use fluoroscopy to verify the location of the levels to be accessed. Once the patient is properly secured, adjust the table so that the C-arm is able to provide a true A/P image when at 0 degrees, and a true lateral position at 90 degrees.
- Adjust the table to the appropriate position depending on the level or levels being accessed.





C-Arm Monitor

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ACCESS IDENTIFICATION AND INITIAL INCISION

First, localize the operative level using true lateral fluoroscopy. With ink, make a mark on the skin to serve as the location for the initial skin incision at the operative level.

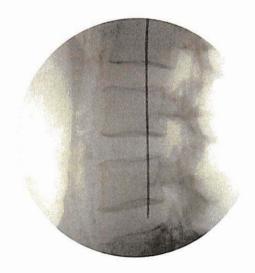
NOTE: If utilizing a two-incision technique for the transpsoas approach, another mark will be made on the skin posterolaterally between the ilium and the rib cage.

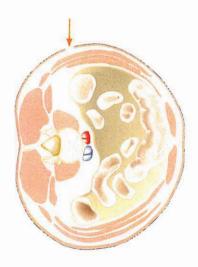
### RETROPERITONEAL ACCESS

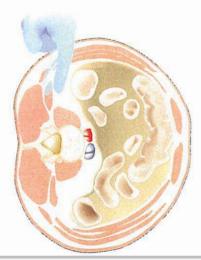
Either through the lateral or posterolateral incision, dissect subcutaneous tissue layers by alternating with blunt scissors and finger dissection until the retroperitoneal space is reached.

Once inside the retroperitoneal space, carefully sweep the peritoneum anteriorly.

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