TalarLift
Subtalar System

Fusion ORTHOPEDICS

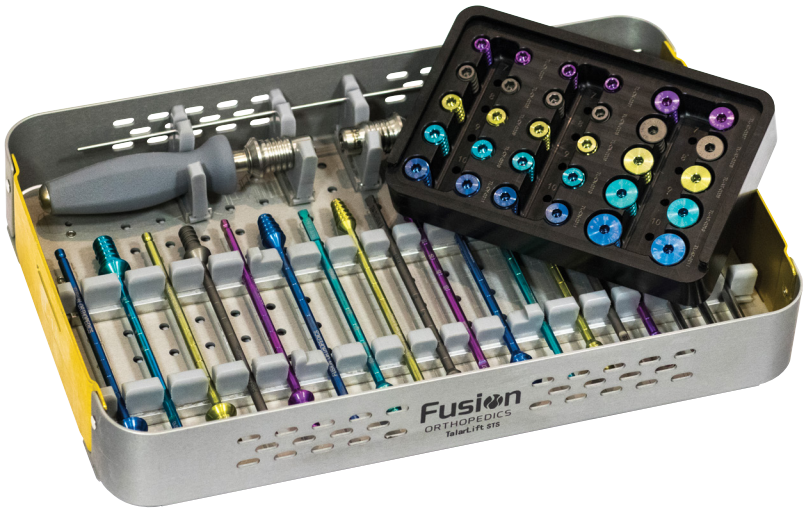
Surgical Technique

TalarLift™ STS

Fusion ORTHOPEDICS

DESCRIPTION OF THE MEDICAL DEVICE

The TalarLift™ Subtalar System consists of threaded bone screws designed for stabilization of the subtalar joint with corresponding instrumentation to facilitate insertion. The TalarLift™ STS Implants are available in Cylindrical, Conical, and Anatomical configurations in order to address a variety of patient anatomy and surgeon preference. The implants are offered in lengths ranging from 7mm to 11mm. System instrumentation includes guide wires, trial spacers, removal drivers, driver shafts, and handles to facilitate the placement of the screws. The implants and guide wires are intended for single use only.



INDICATIONS FOR USE

The Fusion Orthopedics TalarLift™ STS arthroereisis implant is designed for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequelae. The TalarLift™ STS is intended for the following pathological conditions resulting from disease, injury, or other trauma:

- Hypermobile pes valgus;
- Posterior tibial tendon dysfunction;
- Hypermobile flexible congenital flat foot;
- Subtalar instability;
- Severe pronation.

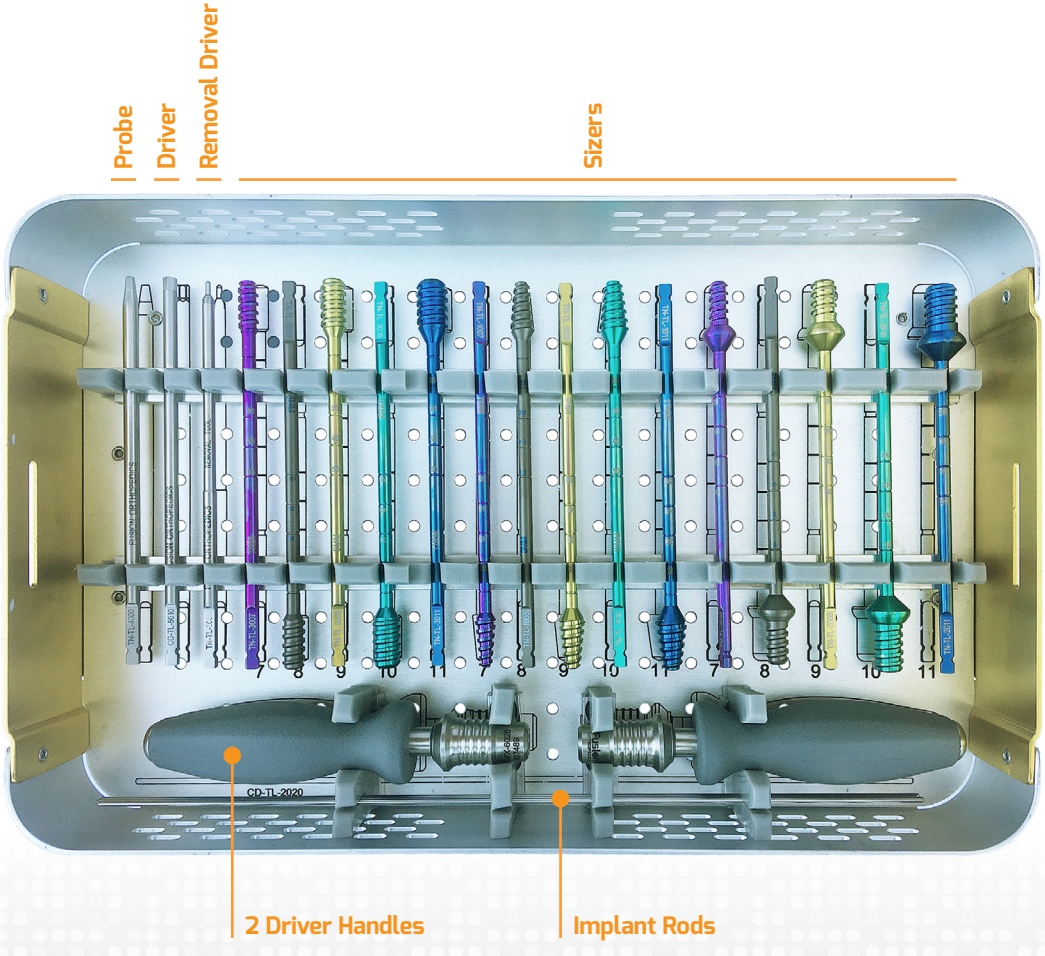
CONTRAINDICATIONS

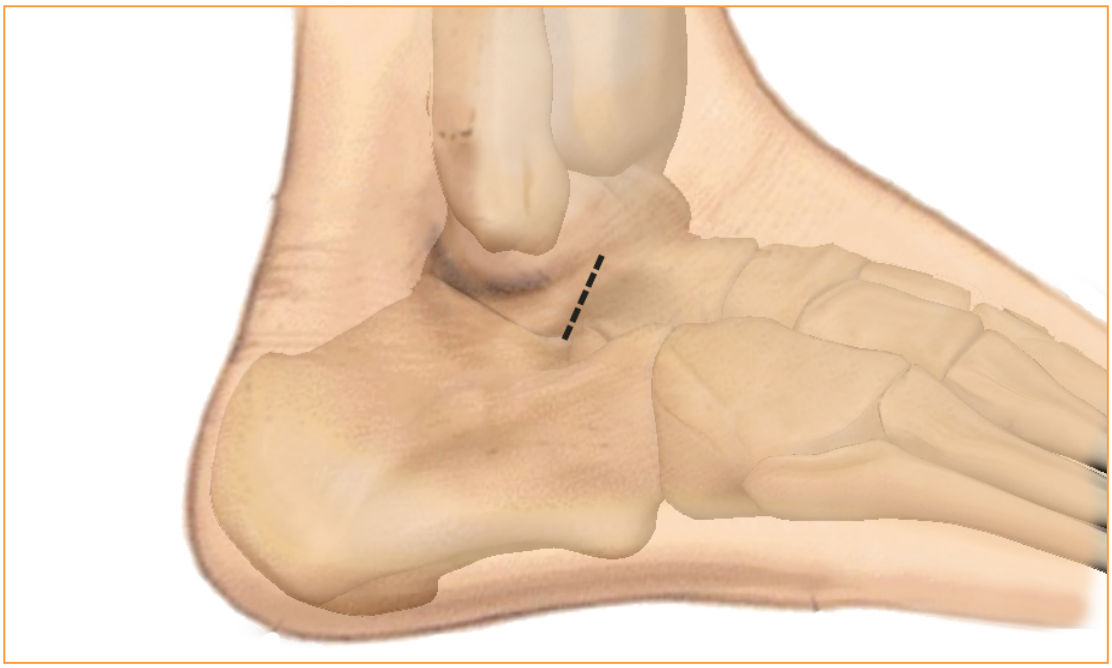
- Local or systemic, acute or chronic inflammation;
- Active infection or inflammation;
- Compromised immune systems;
- Poor or insufficient bone stock;
- Metal sensitivity or allergic reaction to foreign bodies;
- Material conditions that preclude cooperation with the rehabilitation regimen.

PRECAUTIONS

- Only experienced surgeons should perform the implantation of the TalarLift™ STS device with specific training in treating its associated indications. Because of the technically demanding nature of procedure, surgeons should preoperatively plan to ensure that the risks presented to the patient are minimized. Pre-operative assessment of the suitability of the patients' anatomy for accepting implants is made on the basis of X-Rays, CT scans and other radiological studies.
- Only patients that meet the criteria described in the Indications for Use section should be selected.
- Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be re-sterilized and are for single use only.
- Proper Implant handling before and during the operation is crucial. Handle the implant components properly. If applicable, ensure packaging integrity. Do not allow the implant surfaces to be damaged.

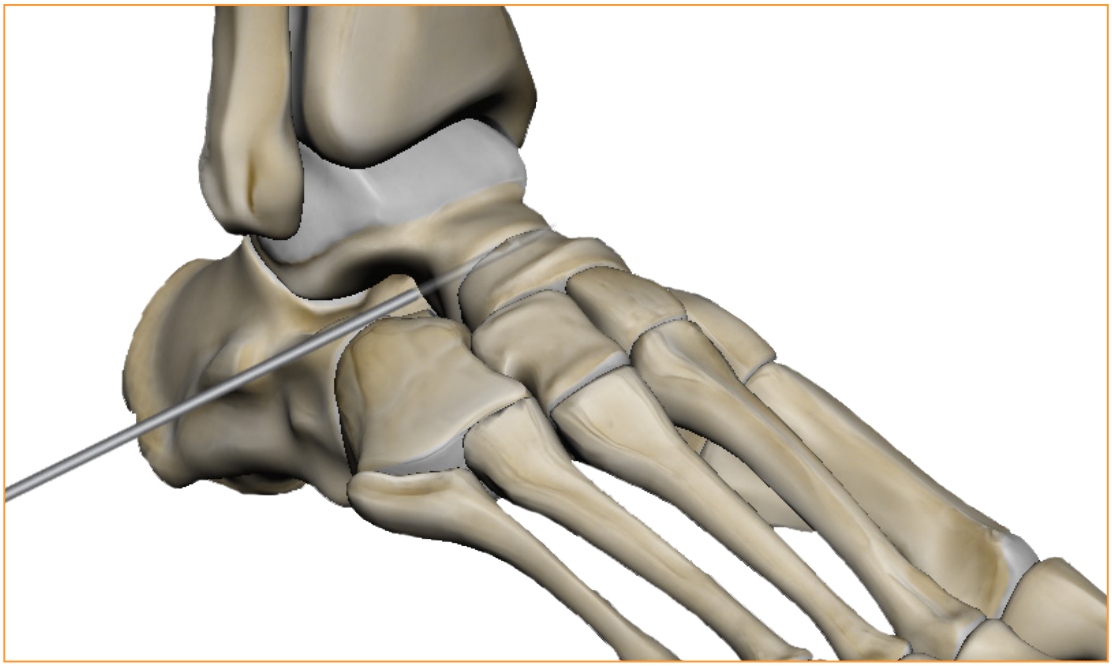
2 implants included for each length and style





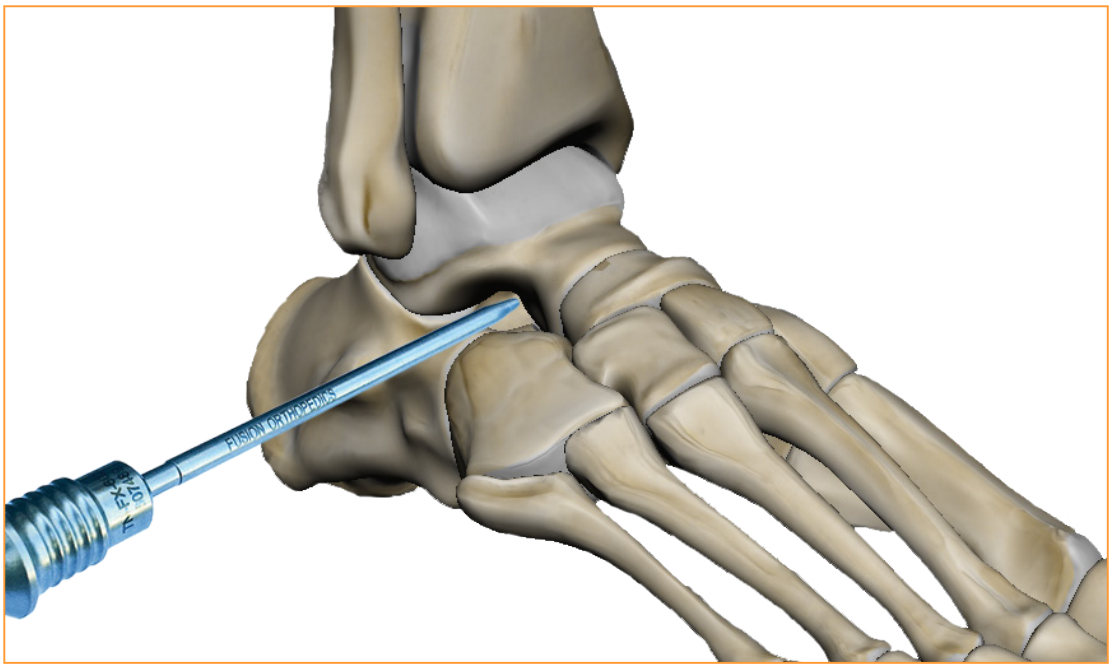
1

Create an incision 2-3mm long in the relaxed skin tension lines over the sinus tarsi, just superior to the peroneal brevis tendon. Dissect through the dermis and into the subcutaneous tissue, avoiding the intermediate dorsal cutaneous nerve at the end of the superior aspect of the incision as well as the sural nerve which should course inferior to the incision.

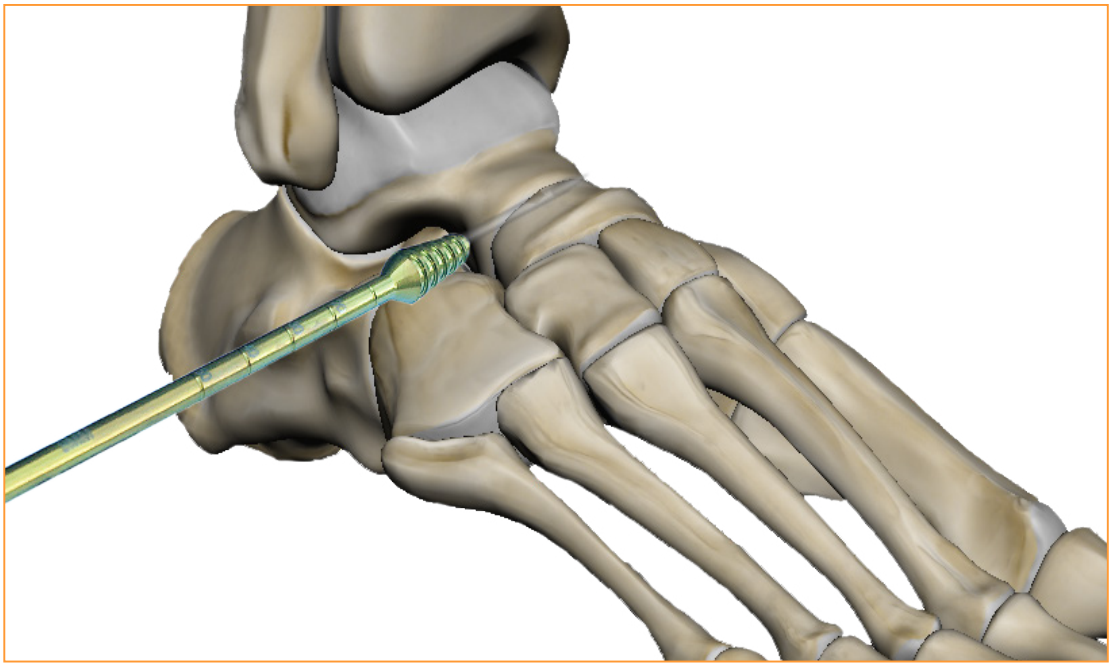


2

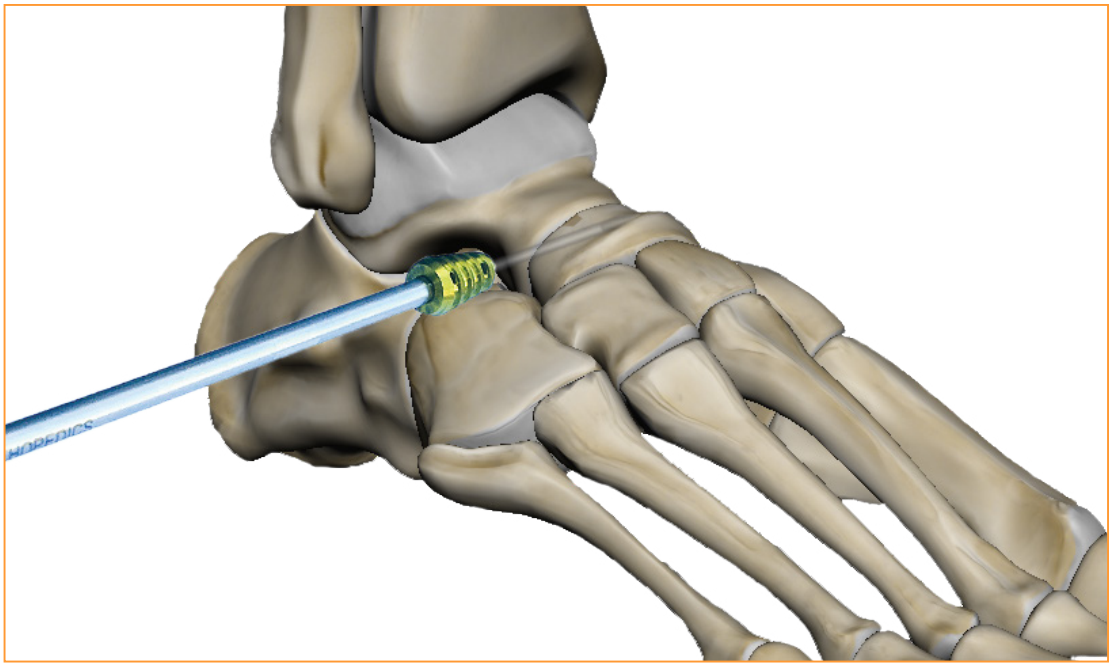
Identify the deep fascia and bluntly dissect allowing entrance into the lateral sinus tarsi. Insert the Implant Rod into the sinus tarsi from lateral to medial until tenting is noted in the surface of the skin anterior and slightly inferior to the medial malleolus. A medial incision to advance the Implant Rod may be done according to surgeon preference.



3 The Probe is then placed over the Implant Rod along the floor of the sinus tarsi and advanced from lateral to medial to dilate the soft tissue. The Interosseus talar calcaneal ligament need not be resected, nor should a sinus tarsectomy be performed.

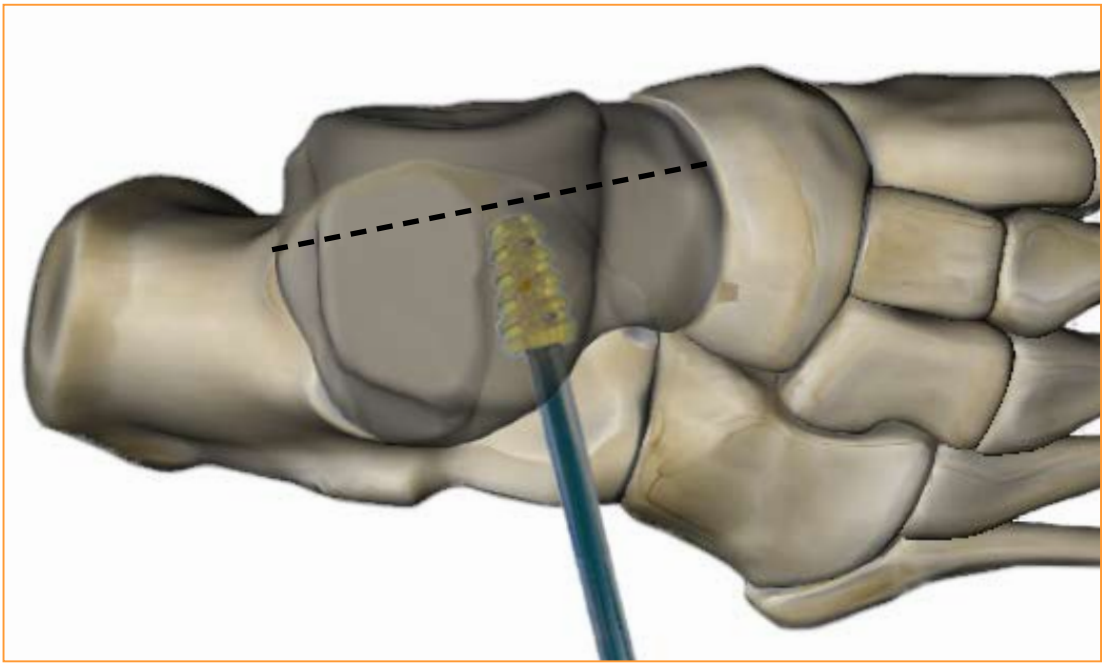


4 With the Implant Rod left in place, the Subtalar Implant Trial Sizers can then be placed over the Implant Rod into the sinus tarsi and the subtalar joint is then taken through a range of motion. The appropriate size is determined when the calcaneus everts to perpendicular or 2-3 degrees valgus.



5

Once the appropriate size has been determined, the Trial Sizer is then removed and the corresponding implant can be placed over the Implant Rod. With the Driver the implant is then advanced into the sinus tarsi in a clockwise direction.



Once final placement has been achieved, assess the range of motion and remove the Implant Rod.

6

The implant is advanced until the leading edge of the implant is 1/3 to 1/2 way across the subtalar joint. The leading edge of the implant should not cross the longitudinal bisection of the neck of the talus while the trailing edge should be more than 5mm medial to the lateral wall of the calcaneus. The use of intra-operative AP and lateral view imaging is recommended to evaluate the final placement of the implant.

Conical Implants	Description	Sterile
	Conical ST Implant 7mm	TL-CN-0007
	Conical ST Implant 8mm	TL-CN-0008
	Conical ST Implant 9mm	TL-CN-0009
	Conical ST Implant 10mm	TL-CN-0010
	Conical ST Implant 11mm	TL-CN-0011

Cylindrical Implants	Description	Sterile
	Cylindrical ST Implant 7mm	TL-CY-0007
	Cylindrical ST Implant 8mm	TL-CY-0008
	Cylindrical ST Implant 9mm	TL-CY-0009
	Cylindrical ST Implant 10mm	TL-CY-0010
	Cylindrical ST Implant 11mm	TL-CY-0011

Anatomical Implants	Description	Sterile
	Anatomical ST Implant 7mm	TL-AT-0007
	Anatomical ST Implant 8mm	TL-AT-0008
	Anatomical ST Implant 9mm	TL-AT-0009
	Anatomical ST Implant 10mm	TL-AT-0010
	Anatomical ST Implant 11mm	TL-AT-0011

Instruments	Description	SKU
	CoCr Implant Rod	CD-TL-2020
	Removal Driver STS	TN-TL-5050
	Driver STS	CD-TL-5010
	Driver Handle Non-Ratcheting	TN-FX-6020
	Probe 5.0mm	TN-TL-4000
	Trial Conical 7mm	TN-TL-1007
	Trial Conical 8mm	TN-TL-1008
	Trial Conical 9mm	TN-TL-1009
	Trial Conical 10mm	TN-TL-1010
	Trial Conical 11mm	TN-TL-1011
	Trial Cylindrical 7mm	TN-TL-3007
	Trial Cylindrical 8mm	TN-TL-3008
	Trial Cylindrical 9mm	TN-TL-3009
	Trial Cylindrical 10mm	TN-TL-3010
	Trial Cylindrical 11mm	TN-TL-3011
	Trial Anatomical 7mm	TN-TL-2007
	Trial Anatomical 8mm	TN-TL-2008
	Trial Anatomical 9mm	TN-TL-2009
	Trial Anatomical 10mm	TN-TL-2010
	Trial Anatomical 11mm	TN-TL-2011

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Fusion Orthopedics does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Fusion Orthopedics' product offerings. A surgeon must always refer to the package insert, product label, and instructions for use before using any Fusion Orthopedics product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of products in your area.

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