DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Lapidus Procedure
Featuring BME ELITE® Implant 90-90 Construct

ENGINEERED TO PROVIDE CONTINUOUS, ACTIVE COMPRESSION THROUGHOUT THE HEALING PROCESS

THE UNION OF COMPRESSION & STABILITY

DEPUY SYNTHES IS WITH YOU—AND YOUR PATIENTS

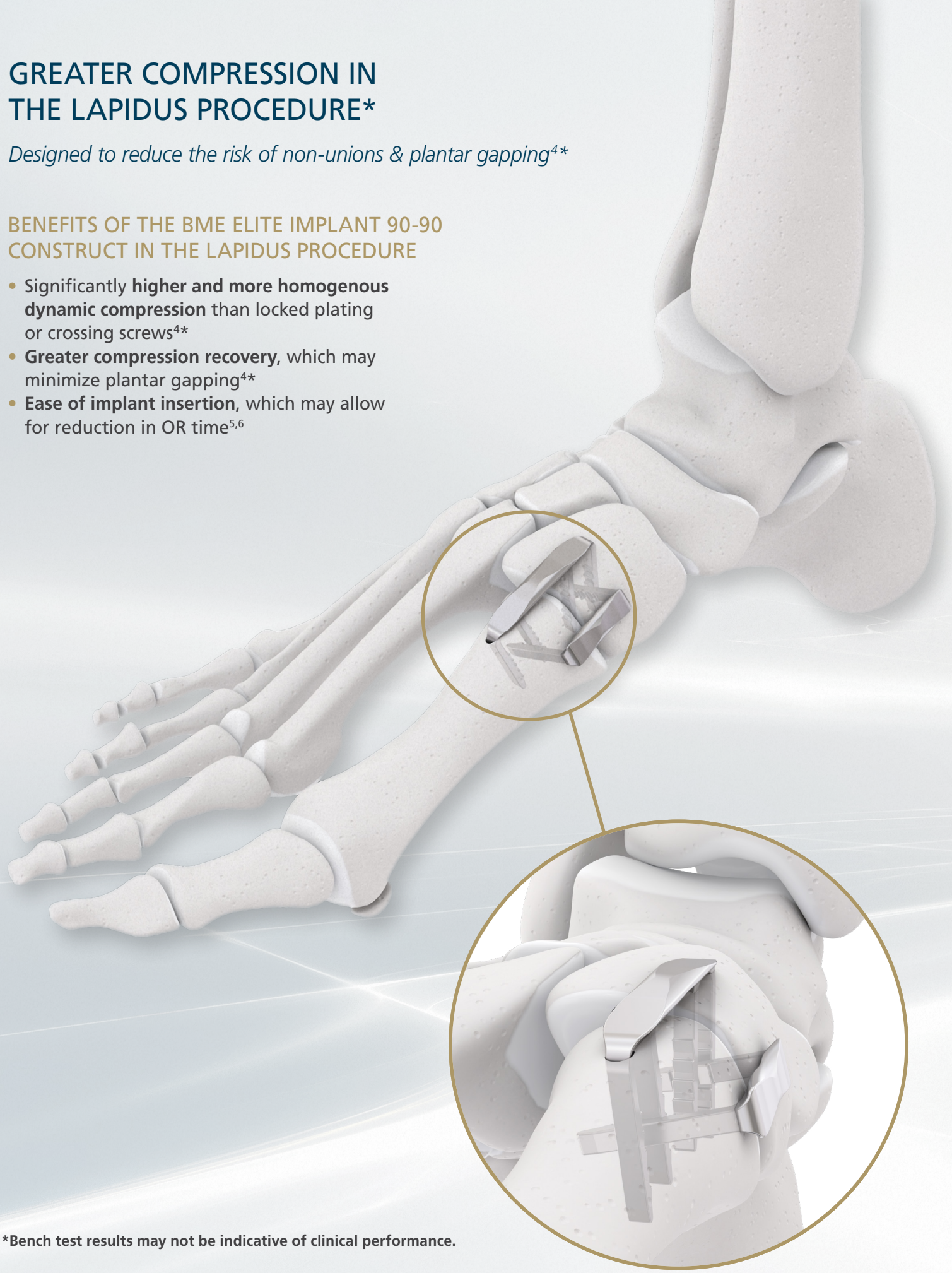
EVERY STEP OF THE WAY

GREATER COMPRESSION IN THE LAPIDUS PROCEDURE*

*Designed to reduce the risk of non-unions & plantar gapping[4]**

BENEFITS OF THE BME ELITE IMPLANT 90-90 CONSTRUCT IN THE LAPIDUS PROCEDURE

- Significantly **higher and more homogenous dynamic compression** than locked plating or crossing screws[4]*
- **Greater compression recovery,** which may minimize plantar gapping[4]*
- **Ease of implant insertion,** which may allow for reduction in OR time[5,6]



***Bench test results may not be indicative of clinical performance.**

DESIGNED TO MEET THE CHALLENGES OF LAPIDUS IN HALLUX VALGUS

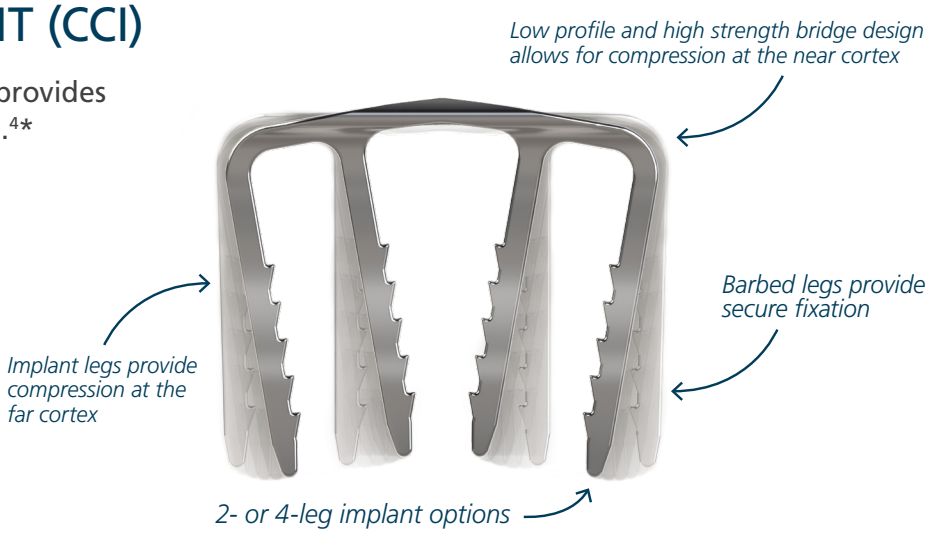
PROCEDURAL CHALLENGES

- Non-union rates for the Lapidus bunionectomy are reported to be as high as 10%, depending on fixation methods and weight-bearing protocols. Poor fixation is one of the main contributors to non-union.[1,2]
- Excessive plantar gapping has been shown to have a negative effect on prognosis.[3]

Fixation	Non-union Rate[1]
Locked Plate	3.0%
2 Crossed Screws	4.6%
3 Crossed Screws	10.4%

BME ELITE® CONTINUOUS COMPRESSION IMPLANT (CCI)

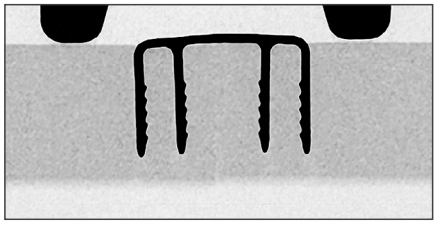
Nitinol "shape memory" technology provides continuous and dynamic compression.[4]*



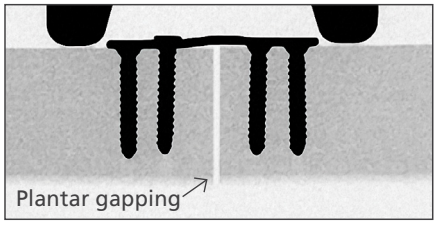
GREATER COMPRESSION RECOVERY MINIMIZES PLANTAR GAPPING

Compression extends plantarly through the legs of the CCI, achieving **significantly higher contact area after repetitive loading** compared to a 4-hole compression plate and to 2 crossing screws.[4]*

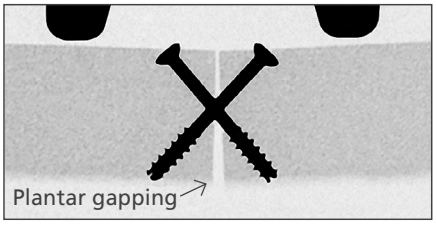
Scan this code to watch a video on compression recovery



4-Legged BME ELITE CCI at 100th Cycle



Midfoot Compression Plate at 1st Cycle

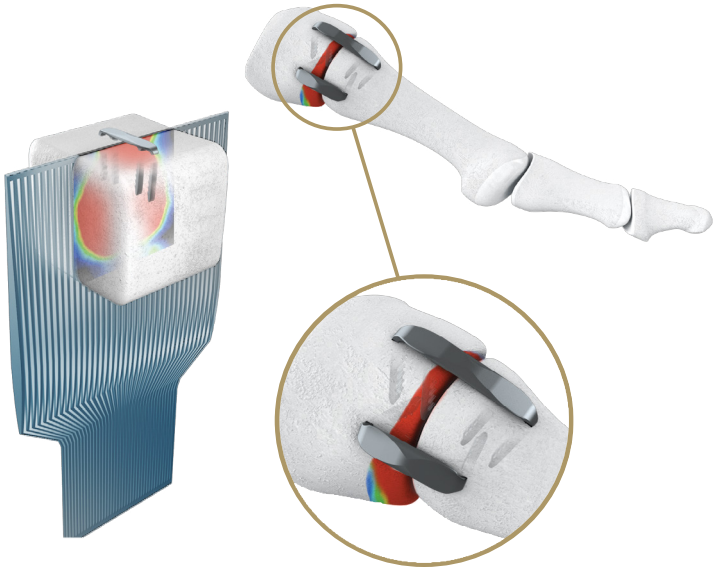


Crossing Screws at 1st Cycle

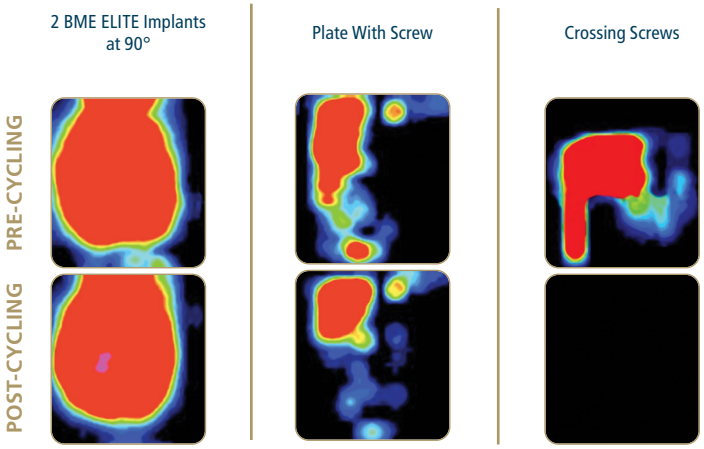
***Bench test results may not be indicative of clinical performance.**

MORE HOMOGENOUS COMPRESSION ACROSS THE FUSION SITE

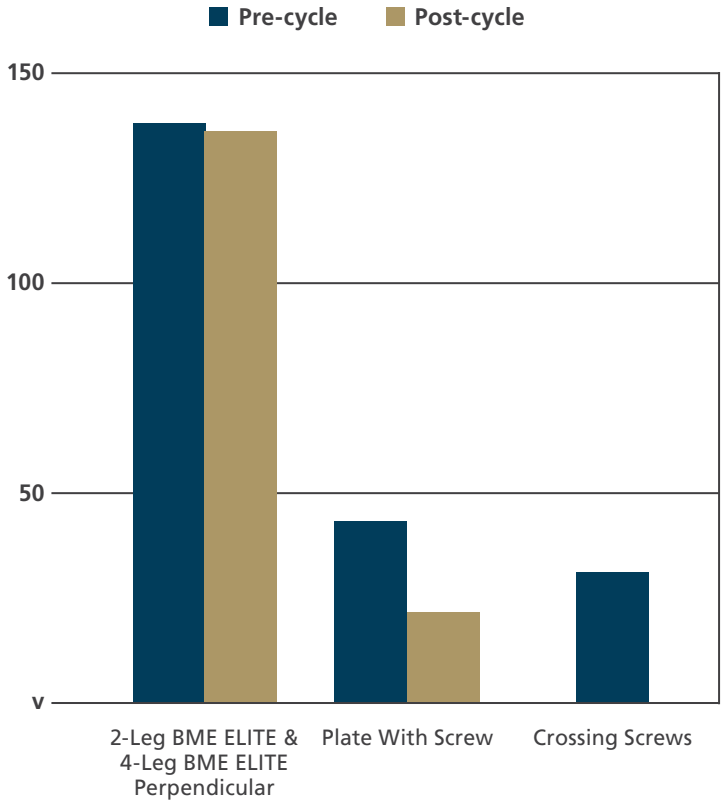
Lapidus constructs using the BME ELITE Implants provided **significantly more compression** than a locking titanium midfoot compression plate with and without a 4.0 mm lag screw and 2 crossing 4.0 mm lag screws.[4]*



Demonstrated Superior Compression Even After 100 Stress Cycles[4]*



Compressive Force (N)[4]*



HIGHER CONTINUOUS COMPRESSIVE FORCE

The BME ELITE Implant 90-90 construct provides at least **2x greater compressive force** than locking titanium midfoot compression plate with a 4.0 mm lag screw and two 4.0 mm crossing screws.[4]*

***Bench test results may not be indicative of clinical performance.**

EASE OF IMPLANT PLACEMENT

TECHNIQUE OVERVIEW

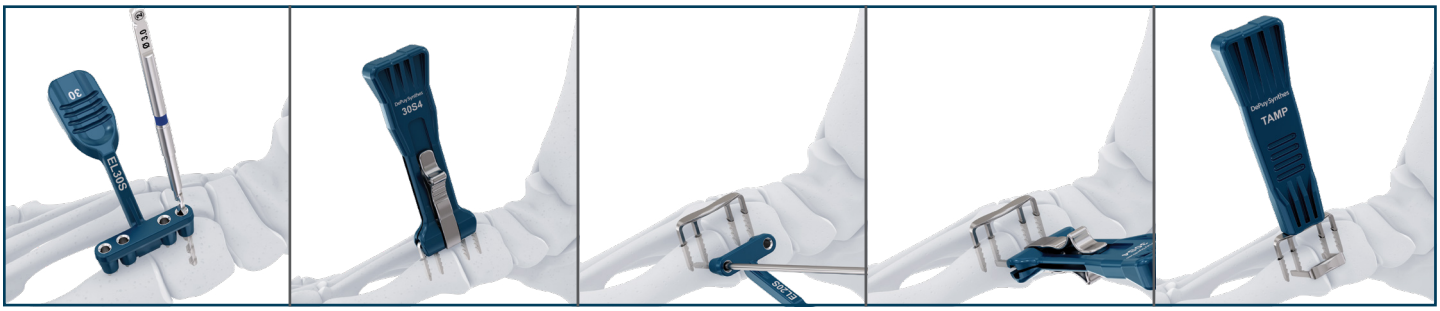
Technique

Place 2 BME ELITE Implants with the first implant placed in the dorsal position and the second placed in the dorsomedial or medial position.

Available Constructs

Dorsal-4 Leg*	Medial-2 Leg*
25 x 20 ELITE S	18 x 18 ELITE S
30 x 20 ELITE Y†	15 x 15 ELITE S

*Sizes in mm.
†May require additional bone surface preparation.



1. Determine implant placement and drill.
2. Deploy dorsal 4-legged implant. Do not tamp.
3. Insert K-wire through drill guide to confirm second implant placement.
4. Insert medial 2-legged implant.
5. Tamp both implants.

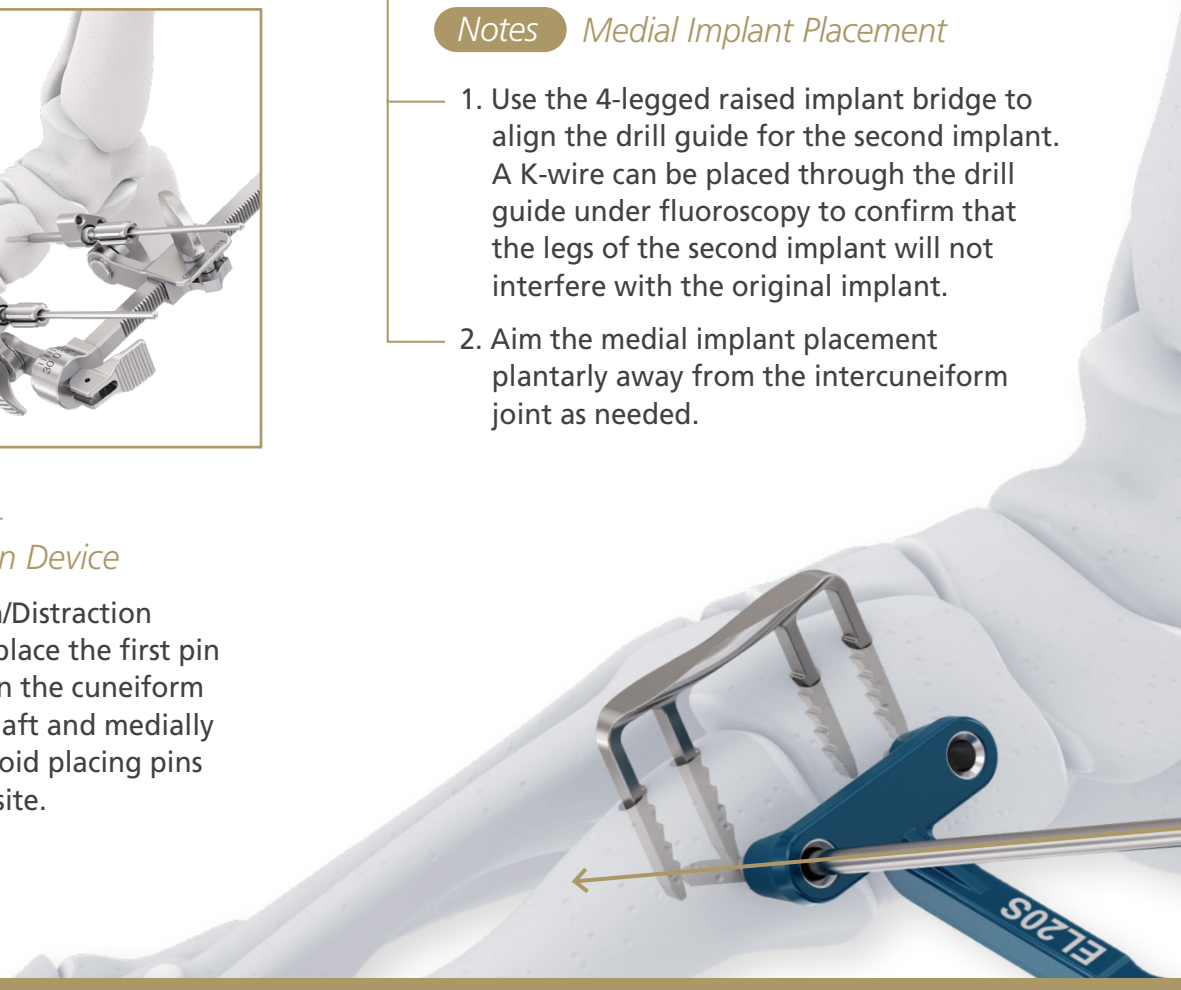
See notes 1 & 2

Notes *Medial Implant Placement*

1. Use the 4-legged raised implant bridge to align the drill guide for the second implant. A K-wire can be placed through the drill guide under fluoroscopy to confirm that the legs of the second implant will not interfere with the original implant.
2. Aim the medial implant placement plantarly away from the intercuneiform joint as needed.

Additionally Available – Compression/Distraction Device

Utilizing the Compression/Distraction Device to prep the joint, place the first pin proximally and medially in the cuneiform and the second pin midshaft and medially in the first metatarsal. Avoid placing pins through desired implant site.



THE UNION OF COMPRESSION AND STABILITY IN LAPIDUS

	BME ELITE IMPLANT CONSTRUCT		
	Implant Kit	Bridge*	Legs*
Dorsal-4 Leg	EL-2520S4	25	20
Medial-2 Leg	EL-1818S2	18	18

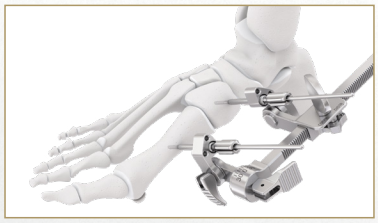
Utilizes the DK-300 drill kit and EL-DTS template

	BME ELITE Y IMPLANT CONSTRUCT		
	Implant Kit	Bridge*	Legs*
Dorsal-4 Leg	EL-302007Y4	30	20
Medial-2 Leg	EL-1515S2	15	15

Utilizes the DK-300 drill kit and EL-DTY template

*Sizes in mm.

PROCEDURAL ENHANCEMENTS



COMPRESSION/DISTRACTION DEVICE

The Compression/Distraction Device provides an adjustable and minimally invasive approach for manipulation of the fusion site to achieve precise indirect reduction and compression.[7]

JOINT PREPARATION SET

Adequate joint preparation is a requirement for fusion success. DePuy Synthes offers a variety of chisel shapes and a cartilage remover to facilitate proper joint preparation.

VIVIGEN® AND VIVIGEN FORMABLE® CELLULAR BONE MATRIX†

ViviGen® Cellular Bone Matrix provides an alternative to autograft bone to pack the fusion site. It contains viable, lineage committed bone cells within a corticocancellous bone matrix and demineralized bone, delivering all of the properties necessary for bone formation.[8]

†ViviGen and ViviGen Formable are registered trademarks of LifeNet Health.

References: 1. Prissel MA, Hyer CF, Grambart ST, et al. A multicenter, retrospective study of early weightbearing for modified Lapidus arthrodesis. *J Foot Ankle Surg.* 2016;55(2):226-229. **2.** Crowell A, Van JC, Meyr AJ. Early weightbearing after arthrodesis of the first metatarsal-medial cuneiform joint: a systematic review of the incidence of nonunion. *J Foot Ankle Surg.* 2018;57(6):1204-1206. **3.** Lee KT, Park YU, Jegal H, Park JW, Choi JP, Kim JS. Prognostic classification of fifth metatarsal stress fracture using plantar gap. *Foot Ankle Int.* 2013;34(5):691-696. **4.** DePuy Synthes Test Report. Compression Heat Map Test. #TR-132-03-15131. 2015. **5.** Harden JL, Hiscox JA. Cost savings and quality improvement—single-use suture instruments? *Scott Med J.* 2006;51(3):30-33. **6.** Wong J, Khu KJ, Kaderali Z, Bernstein M. Delays in the operating room: signs of an imperfect system. *Can J Surg.* 2010;53(3):189-195. **7.** Porteous M, Bauerle S. *Techniques and Principles for the Operating Room.* AO Foundation; 2010:210-213. **8.** Data on file. LifeNet Health 65-0347.

Please also refer to the Instructions For Use, surgical technique, or other labeling associated with the devices identified in this brochure for additional information.
CAUTION: Federal law restricts these devices to sale by or on the order of a physician.
Complete information regarding indications, contraindications, warnings, care, and caution can be found in the Instructions For Use.

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