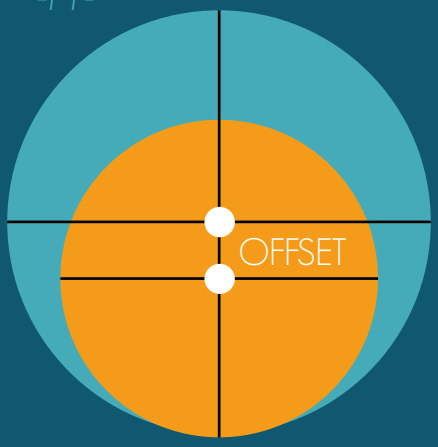
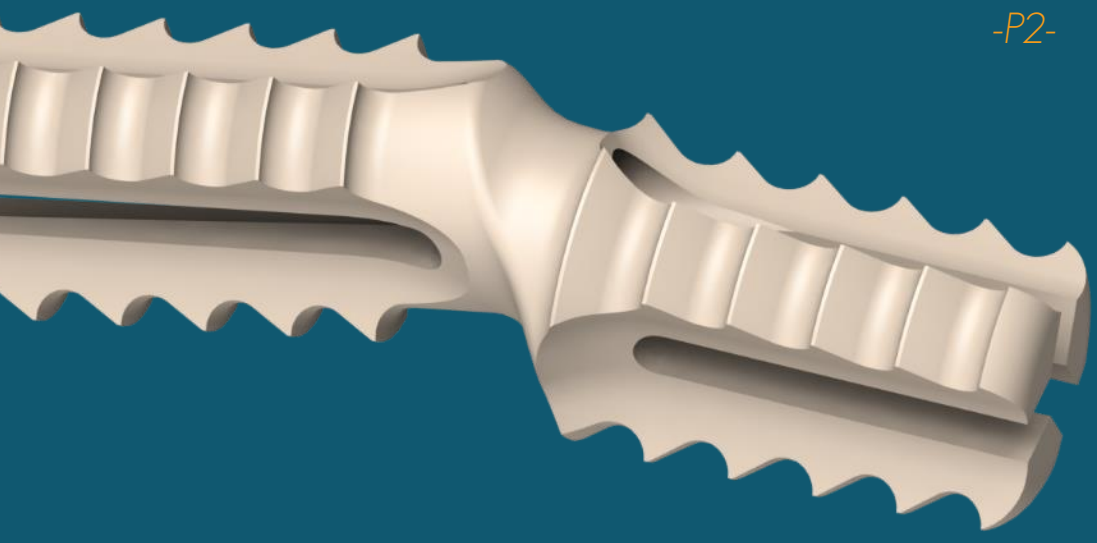
Surgical Technique
ToeGrip® Evo

Proximal Phalanx
-P1-



The ToeGrip® Evo's offset respects the anatomical offset between the center of the phalangeal joint surfaces

Middle Phalanx
-P2-



SynchroMedical
The interphalangeal reference

Based on Anatomy

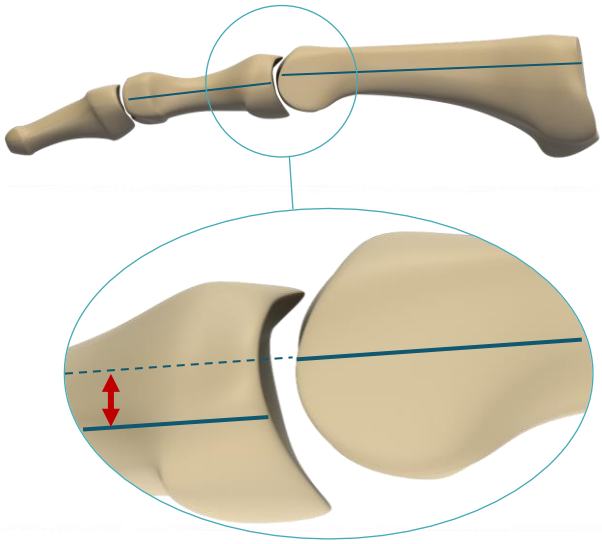
non alignement of middle and proximal phalanx

The ToeGrip® EVO implant consists of a single part implant with three flexible intramedullary prongs on each side. The prongs are inserted into each the proximal and distal phalanx. The prongs are connected by a cylindrical structure with a sagittal height offset between the proximal and distal Phalange to mimic the toe anatomy. The device anchorage relies on a press-fit contact that is supported by its tapered shape and the macrostructure, which solidly anchored once impacted. Primary stability and avoiding any displacement is key for a successful bone consolidation.

The ToeGrip® EVO is provided sterile packed and is available in a range of 5 sizes with 3 possible angulations: 0°, 10° or 20°.

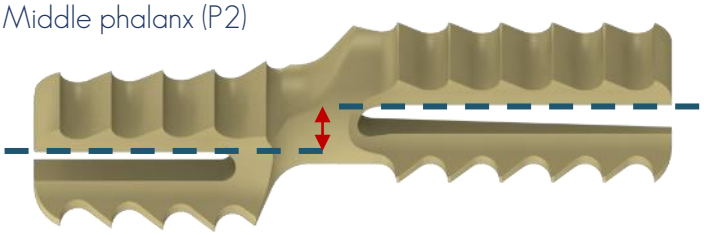
The ToeGrip® EVO is made from PEEK as per standard ASTM F2026.

Offset between 2 axes – Proximal and middle Phalanx

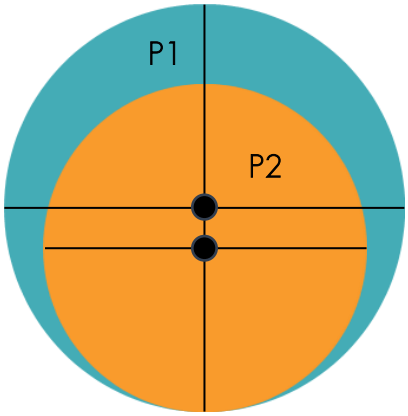


Proximal phalanx (P1)

Middle phalanx (P2)



= offset



Intramedullary Channel

The intramedullary canal of the middle phalanx is offset towards plantar compared to the channel of the proximal phalanx.

In more than 80% of the cases, after the reduction, a step remains between the first and middle phalanx.

The offset of the ToeGrip® EVO is anatomically adapted to the offset between axis of the two phalanx.

Indications and Contraindications

The ToeGrip® EVO interphalangeal implant is designed to relieve pain and disability of the forefoot by restoring and/or maintaining the alignment of two adjacent digital bone segments to optimize the achievement of a correct bone fusion for the concerned segments. These devices are only intended to be used for the forefoot of a mature skeleton.

Indications:

ToeGrip® EVO implant is indicated for the reconstruction of minor bones limited to the interdigital fusion of the toes on the mature skeleton in the following cases:

Rigid/fixed deformations:

- Affecting the proximal interphalangeal joint (PIJ).
- Hammertoe deformities.
- Claw toe deformities (PIP and DIP joints).
- Hammer toe revision surgeries.
- Shortening osteotomies of the proximal phalanx.

ATTENTION: to be used by or on the order of a licensed physician.

The licensed physician must take note of the documents accompanying the device. (IFU and surgical technique). No specific training is required for the understanding and implantation of the device. The medical doctor's qualifications and the reading of the accompanying documents are sufficient

Contraindications:

A non-exhaustive list of contraindications is as follows:

1. Any sign of generalized or local infection
2. Pathological obesity.
3. Pregnancy.
4. Any other medical or surgical condition that may compromise the success of surgery with instruments, such as the presence of malignant tumors, or serious congenital anomalies, an increase in sedimentation rates that cannot be attributed to other diseases, an increase in the number of white blood cells or a downward trend in such blood cells.
5. Suspected or known allergy or intolerance to the implant's component materials.
6. Any situation requiring the use of different materials
7. Any case not listed in the indications.
8. Any patient who is not willing to follow the postoperative instructions.
9. Any patient in whom use of the implant may interfere with anatomical organs or some expected physiological function.

The contraindications related to these devices are similar to those related to other interphalangeal devices. These interphalangeal instruments have not been designed for, intended or sold for any use other than those indicated.

→ For more information please refer to ToeGrip® EVO instruction for use reference SUP_7.015

Surgical Technique

JOINT SURFACE PREPARATION

The inter phalangeal joint is approached through a dorsal, longitudinal or transversal incision. The proximal and middle phalanx articular surfaces are resected.

PROXIMAL PHALANX PREPARATION

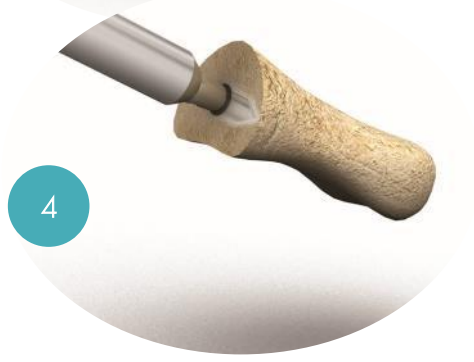
The P1 compactor marked « STARTER » (Ref: TG0240-STARTER), 2.0mm diameter is used to center the proximal phalanx (P1). Then increase sequentially size by size the next compactors until the optimal fit is found to the cortical bone.

⚠ It is important to perform the preparation carefully. Indeed, this step allows to compact cancellous bone to provide the best anchorage of the implant.

MIDDLE PHALANX PREPARATION

For the middle phalanx, the use of the calcar reamer (Ref: TG0010) is recommended to preserve as much as possible the subchondral bone.

For the middle phalanx (P2), the P1 compactor marked « STARTER » (Ref: TG0240-STARTER), is used, followed by the next compactors size until the size predefined on the proximal phalanx is reached.



NOTE: The P1 compactor is used for both P1 and P2

OPTION CANNULATED TECHNIQUE (ON REQUEST): The ToeGrip® EVO interphalangeal implant can be inserted over a Kirschner wire as guide. In this case, place the Kirschner wire (Ref: KW10100TR) in the phalanx and use the cannulated version of the instruments : cannulated calcar reamer (Ref: TGE0010), cannulated compactors (Ref: TG0242).

Surgical Technique
Holder Assembly

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Insert the short part of the implant into the holder. Laser marking indications are presents to help

When the implant is not in the right axis of the proximal phalanx, it may be break during the impaction as it is exposed to high shear stress. It is therefore necessary to ensure a good alignment of the implant with the phalanx axis. Any leverage on the implant at the time of impaction is prohibited.

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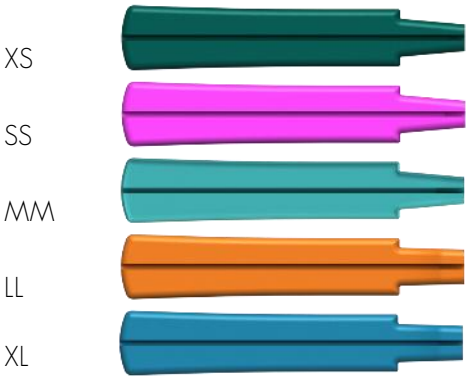
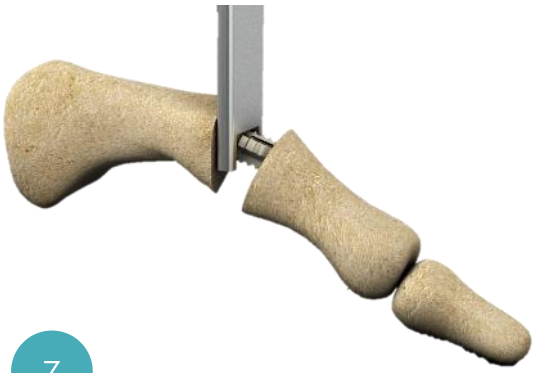
The longer part of the implant is inserted into the proximal phalanx (P1) first, with the appropriate holder.



Size - Color Coding



The holder is removed and the middle phalanx (P2) is positioned over the shorter part of the implant, using the reducer (Ref: TG0203) to center the shorter part in the middle phalanx canal.

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ToeGrip® EVO implanted

REMOVAL / REVISION

Should removal or revision of the implant be required:

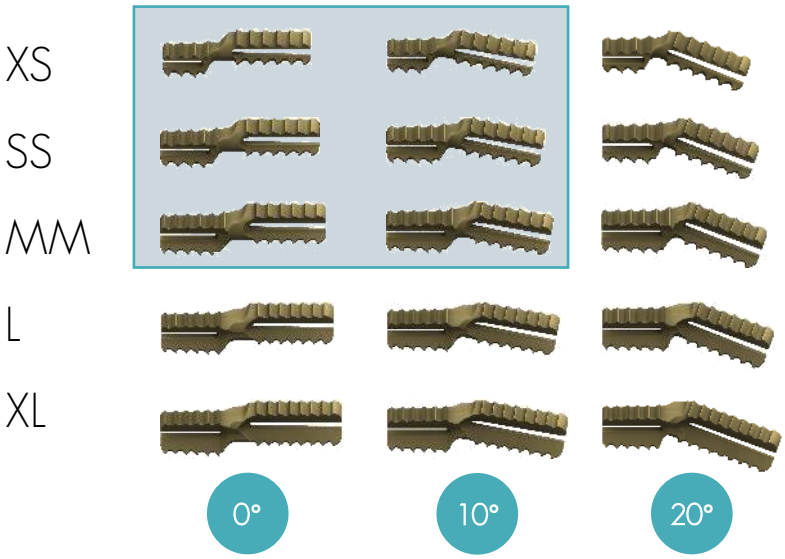
1. Expose the proximal interphalangeal joint.
2. Distract the joint space until the distal parts of the ToeGrip® EVO implant are exposed.
3. Using surgical clamp, grasp the distal side of the implant to remove it from the middle phalanx. Then, back implant out of the proximal phalanx using surgical clamp. It is also possible to cut the implant with a saw blade at the level of the joint fusion. The parts are removed from the proximal and distal phalanx with a small clamp.

Implants

ToeGrip® EVO

REFERENCE	DESIGNATION		SIZE	ANGLE
TGEXS00	ToeGrip® EVO EXTRA-SMALL 0°		XS	0°
TGEXS10	ToeGrip® EVO EXTRA-SMALL 10°		XS	10°
TGEXS20	ToeGrip® EVO EXTRA-SMALL 20°	on request	XS	20°
TGESS00	ToeGrip® EVO SMALL 0°		SS	0°
TGESS10	ToeGrip® EVO SMALL 10°		SS	10°
TGESS20	ToeGrip® EVO SMALL 20°	on request	SS	20°
TGEMM00	ToeGrip® EVO MEDIUM 0°		MM	0°
TGEMM10	ToeGrip® EVO MEDIUM 10°		MM	10°
TGEMM20	ToeGrip® EVO MEDIUM 20°	on request	MM	20°
TGELL00	ToeGrip® EVO LARGE 0°	on request	LL	0°
TGELL10	ToeGrip® EVO LARGE 10°	on request	LL	10°
TGELL20	ToeGrip® EVO LARGE 20°	on request	LL	20°
TGEXL00	ToeGrip® EVO EXTRA-LARGE 0°	on request	XL	0°
TGEXL10	ToeGrip® EVO EXTRA-LARGE 10°	on request	XL	10°
TGEXL20	ToeGrip® EVO EXTRA-LARGE 20°	on request	XL	20°

6 Sizes Core Portfolio XS, SS and MM in 0° and 10°

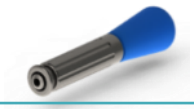


Instruments

NOTE: P1 Compactor is used for P1 and P2

TG0240-Starter	P1 COMPACTOR - STARTER - AO COUPLING
TG0240-XS	P1 COMPACTOR - XS - AO COUPLING
TG0240-SS	P1 COMPACTOR - S - AO COUPLING
TG0240-MM	P1 COMPACTOR - M - AO COUPLING
TG0240-LL	P1 COMPACTOR - L - AO COUPLING

TG0010	CALCAR REAMER



HV9010	AO HANDLE

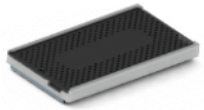
TG0203	REDUCER

TG0020	HOLDER SIZE XS 0°
TG0025	HOLDER SIZE XS 10°
TG0030	HOLDER SIZE XS 20° (on request)

TG0021	HOLDER SIZE S 0°
TG0026	HOLDER SIZE S 10°
TG0031	HOLDER SIZE S 20° (on request)

TG0022	HOLDER SIZE M 0°
TG0027	HOLDER SIZE M 10°
TG0032	HOLDER SIZE M 20° (on request)
TG0023	HOLDER SIZE L 0° (on request)

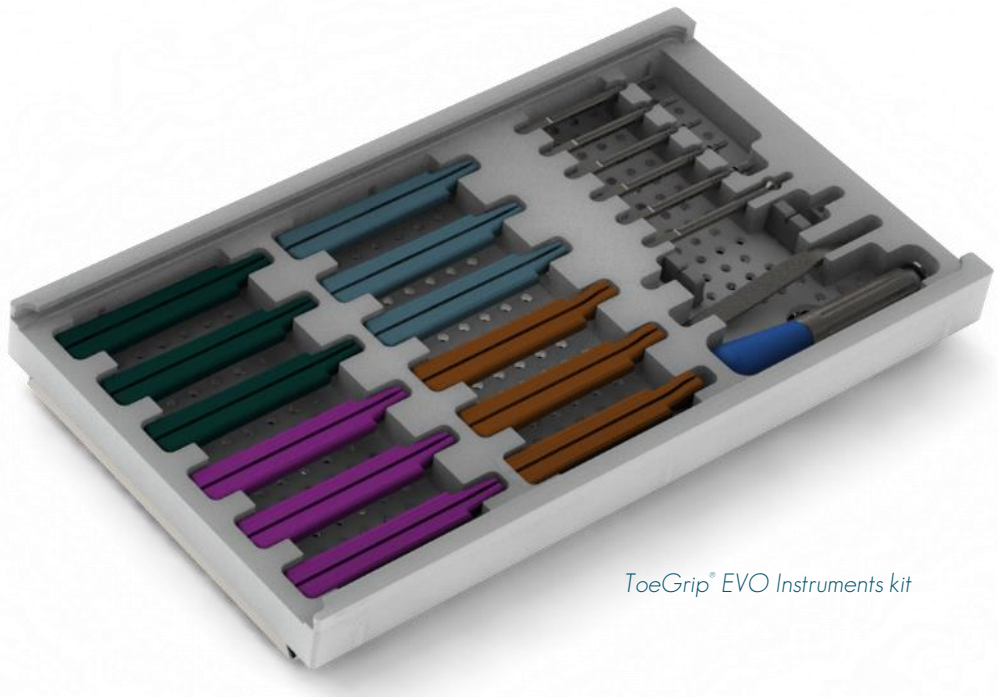
TG0028	HOLDER SIZE L 10° (on request)
TG0033	HOLDER SIZE L 20° (on request)



TGE9010	ToeGrip® EVO INSTRUMENT TRAY

Instruments

	TG0024	HOLDER SIZE XL 0° (on request)
	TG0029	HOLDER SIZE XL 10° (on request)
	TG0034	HOLDER SIZE XL 20° (on request)
	TG0242-Starter	P1 Cannulated COMPACTOR - STARTER - AO COUPLING (on request)
	TG0242-XS	P1 Cannulated COMPACTOR - XS - AO COUPLING (on request)
	TG0242-SS	P1 Cannulated COMPACTOR - S - AO COUPLING (on request)
	TG0242-MM	P1 Cannulated COMPACTOR - M - AO COUPLING (on request)
	TG0242-LL	P1 Cannulated COMPACTOR - L - AO COUPLING (on request)
	TG0243-Starter	P2 CANNULATED COMPACTOR - STARTER - AO COUPLING (on request)
	TG0243-XS	P2 CANNULATED COMPACTOR - XS - AO COUPLING (on request)
	TG0243-SS	P2 CANNULATED COMPACTOR - S - AO COUPLING (on request)
	TG0243-MM	P2 CANNULATED COMPACTOR - M - AO COUPLING (on request)
	TG0243-LL	P2 CANNULATED COMPACTOR - L - AO COUPLING (on request)
	KW10100TR	KIRSCHNER WIRE WITH TROCAR TIP (on request)
	TGE0010	CANNULATED CALCAR REAMER (on request)



ToeGrip® EVO Instruments kit

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Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

ToeGrip® is registered trademarks of ADSM.

The ToeGrip® EVO is manufactured using PEEK material as per ASTM F2026.

MEDICAL DEVICES:

- ToeGrip® EVO implants Class IIb
- ToeGrip® EVO instruments Class IIa
- ToeGrip® EVO instruments Class Ir
- ToeGrip® EVO instruments Class I

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