



Surgical Technique

ToeGrip[®] Classic



Hammer Toe
Implant with
long term
clinical
evidence



SynchroMedical

The interphalangeal reference

Based on Anatomy and a press-fit implantation

The ToeGrip® Classic implant consists of a single part implant with three flexible intramedullary rods inserted into each part of the phalanx. The prongs are attached by a T-shaped structure. The attachment concept is based on a press-fit contact due to its tapered shape and the macrostructures solidly anchored once impacted, thus avoiding any displacement of the implant.

The ToeGrip® Classic implant is intended for single use only and is available in a range of 5 sizes with 3 possible angulations: 0°, 10° or 20°.

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

Clinical Evidence

Interphalangeal Arthrodesis of the Toe With a New Radiolucent Intramedullary Implant.

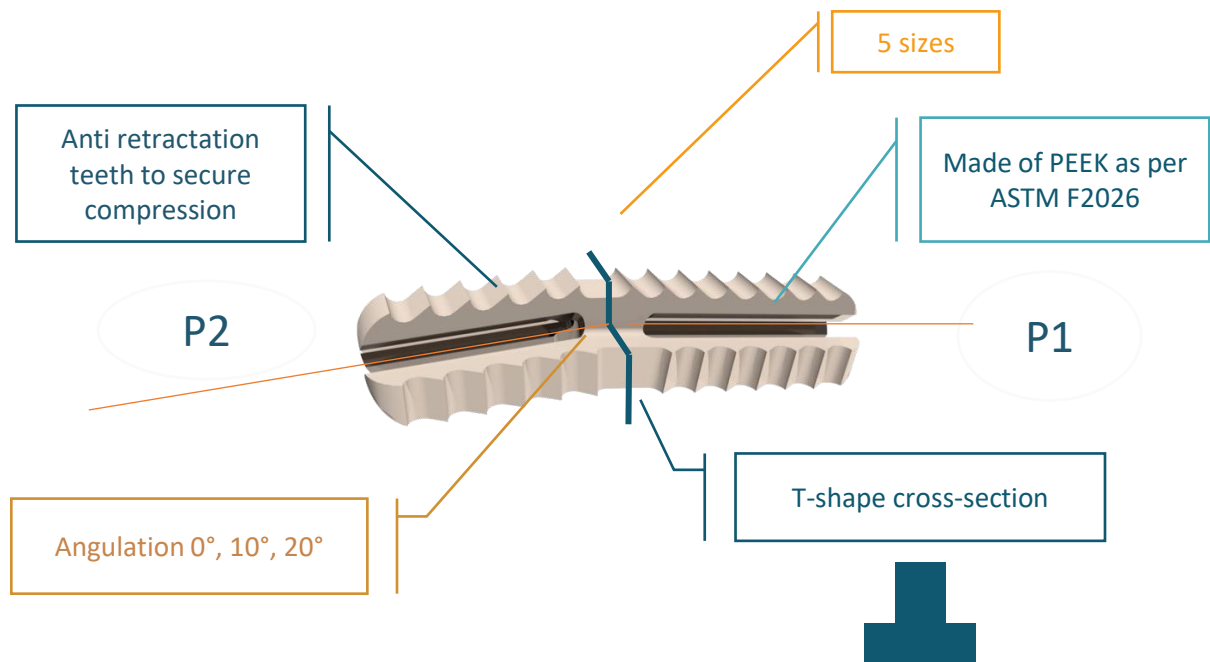
Foot & Ankle Specialist Review. Dec 2015

Diebold P, Rocher H, Determe P, Cermolacce C, Guillo S, Averous C, Lieber Wackenheim F.

A Midterm Review of Lesser Toe Arthrodesis With an Intramedullary Implant.

Foot & Ankle Specialist Review. Oct 2017

James Lee Harmer, FCPodS, MSc, BSc(Hons), Anthony Wilkinson, FCPodS, MSc, DpodM, and Anthony John Maher, FCPodS, MSc, BSc(Hons).



Indications and Contraindications

The ToeGrip® Classic 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. This device is only intended to be used for the forefoot of a mature skeleton. .

Indications:

ToeGrip® Classic 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).
 - Hammer toe 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 generalised 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 tumours, 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® Classic instruction for use reference SUP_7.015

Surgical Technique



JOINT SURFACE PREPARATION

The interphalangeal 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.

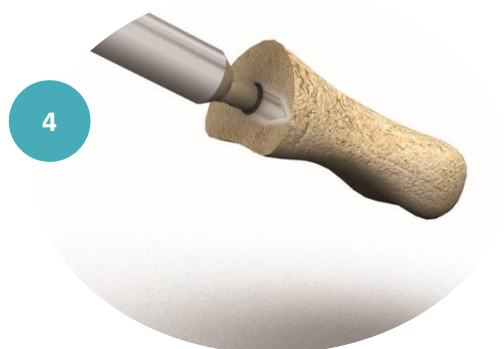


It is important to perform the preparation carefully. Indeed, this step allows to compact cancellous bone to provide the best anchorage of the implant.



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 P2 compactor marked « STARTER » (Ref: TG0241-STARTER), is used, followed by the next compactors size until the size predefined on the proximal phalanx is reached.

Surgical Technique

Holder Assembly



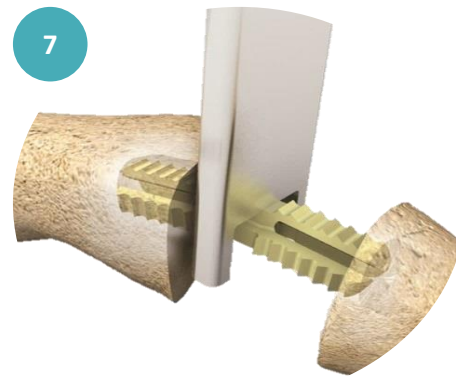
The longer part of the implant is inserted into the proximal phalanx (P1) first, with the appropriate holder.



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.



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.



ToeGrip® Classic implanted

REMOVAL / REVISION

Should removal or revision of the implant be required:

Expose the proximal interphalangeal joint.

Distract the joint space until the distal parts of the ToeGrip® Classic implant are exposed.

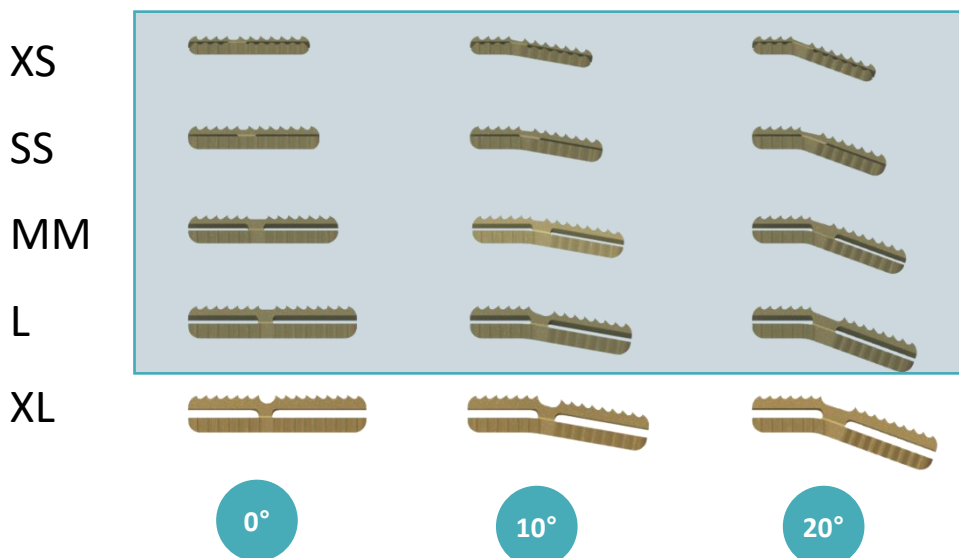
Using surgical clamp, grasp the distal side of the implant to remove it from the middle phalanx. Then, back implant out of the proximal phalanx using surgical clamp. It is also possible to cut the implant with a saw blade at the level of the joint fusion. The parts are removed from the proximal and distal phalanx with a small clamp.

Implants

ToeGrip® Classic

REFERENCE	DESIGNATION	SIZE	ANGLE
TGXS00	ToeGrip® Classic EXTRA-SMALL 0°		0°
TGXS10	ToeGrip® Classic EXTRA-SMALL 10°	XS	10°
TGXS20	ToeGrip® Classic EXTRA-SMALL 20°		20°
TGSS00	ToeGrip® Classic SMALL 0°		0°
TGSS10	ToeGrip® Classic SMALL 10°	SS	10°
TGSS20	ToeGrip® Classic SMALL 20°		20°
TGMM00	ToeGrip® Classic MEDIUM 0°		0°
TGMM10	ToeGrip® Classic MEDIUM 10°	MM	10°
TGMM20	ToeGrip® Classic MEDIUM 20°		20°
TGLL00	ToeGrip® Classic LARGE 0°		0°
TGLL10	ToeGrip® Classic LARGE 10°	LL	10°
TGLL20	ToeGrip® Classic LARGE 20°		20°
TGXL00	ToeGrip® Classic EXTRA-LARGE 0°	<i>on request</i>	0°
TGXL10	ToeGrip® Classic EXTRA-LARGE 10°	<i>on request</i> XL	10°
TGXL20	ToeGrip® Classic EXTRA-LARGE 20°	<i>on request</i>	20°

12 Sizes Core Portfolio XS, SS, MM and LL in 0°,10° and 20°



Instruments

ToeGrip® Classic

	REFERENCE	DESIGNATION
	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
	TG0241-Starter	P2 COMPACTOR - STARTER - AO COUPLING
	TG0241-XS	P2 COMPACTOR - XS - AO COUPLING
	TG0241-SS	P2 COMPACTOR - S - AO COUPLING
	TG0241-MM	P2 COMPACTOR - M - AO COUPLING
	TG0241-LL	P2 COMPACTOR - L - AO COUPLING
	TG0010	CALCAR REAMER
	HV9010	AO HANDLE
	TG0203	REDUCER
	TG0009	HOLDER SIZE XS
	TG0006	HOLDER SIZE S
	TG0007	HOLDER SIZE M
	TG0008	HOLDER SIZE L
	TG1013	ToeGrip® Classic INSTRUMENT TRAY

Instruments

ToeGrip® Classic



REFERENCE	DESIGNATION
TG0001	RASP Size S
TG0002	RASP Size M
TG0003	RASP Size L
TG0004	RASP Size XS



TG0012	HOLDER size XL
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TG0204	TOE HORN
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TG0113	P1 COMPACTOR - STARTER - WIRE COUPLING
TG0114	P1 COMPACTOR - XS - WIRE COUPLING
TG0115	P1 COMPACTOR - S - WIRE COUPLING
TG0116	P1 COMPACTOR - M- WIRE COUPLING
TG0117	P1 COMPACTOR - L - WIRE COUPLING



TG0119	P2 COMPACTOR - XS - WIRE COUPLING
TG0120	P2 COMPACTOR - S - WIRE COUPLING
TG0121	P2 COMPACTOR - M- WIRE COUPLING
TG0122	P2 COMPACTOR - L - WIRE COUPLING
TG0123	P2 COMPACTOR - XL - WIRE COUPLING
TG0124	P2 COMPACTOR - STARTER - WIRE COUPLING



TG0005	ToeGrip® Classic - REAMER
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ToeGrip® Classic instruments kit

Legal and regulatory disclaimers

This material is intended for health care professionals. Distribution to any other recipient is prohibited. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert. Check for country product clearances and reference product-specific instructions for use (SUP_7.015). This document is intended for professionals authorized to perform lower limb surgery. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

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® Classic is manufactured using PEEK material as per ASTM F2026.

MEDICAL DEVICES:

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