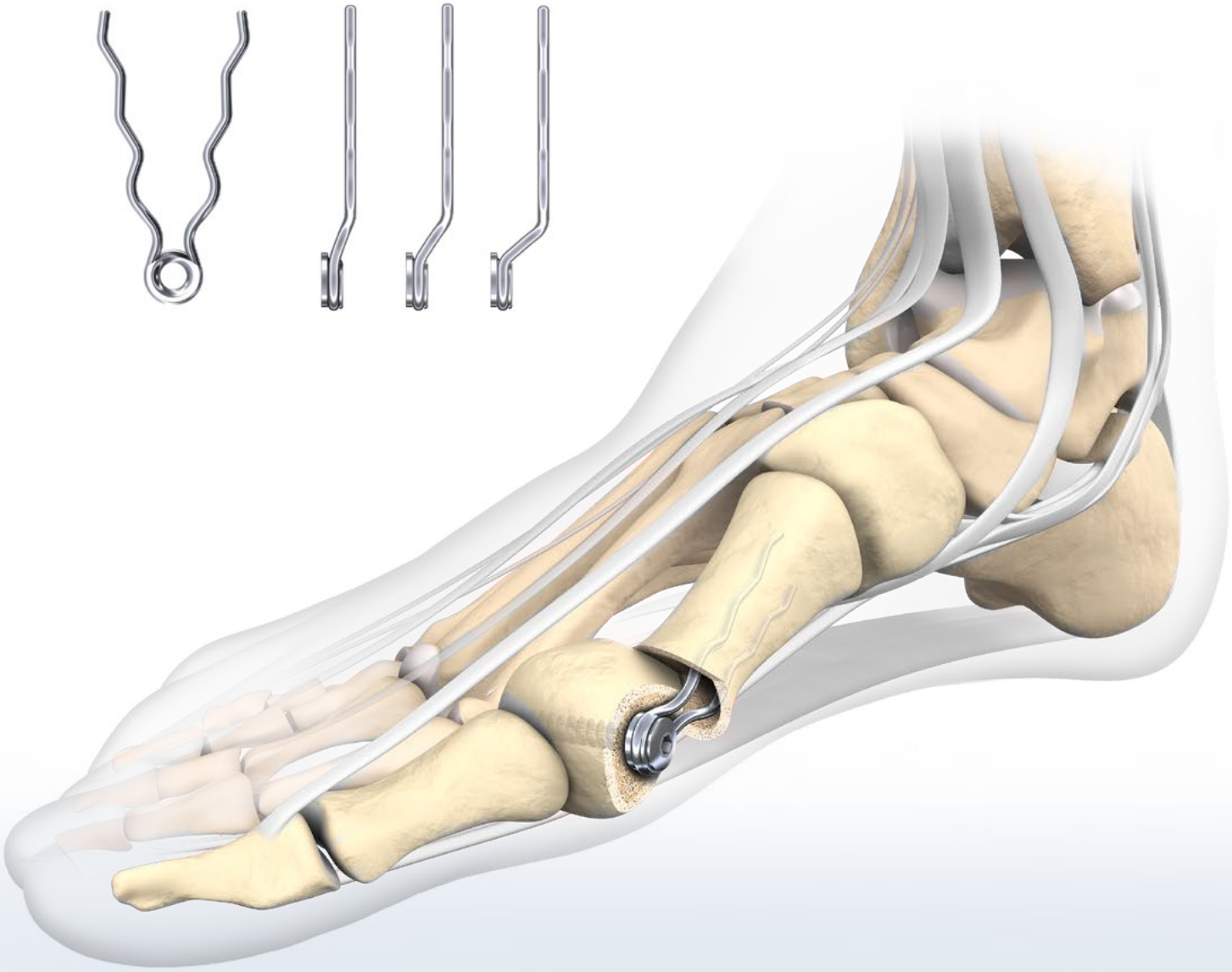


Link Internal Hallux Fixator

Surgical Technique Implants and Instruments

Surgical Technique

Legend

CE / CE 0482

Explanation of Pictograms	
	Manufacturer
REF	Article number
MAT	Material (number)
CE	Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

St **Stainless Steel**

Please note the following regarding the use of our implants:

1. **Choosing the right implant is very important.**
   The size and shape of the human bone determines the size and shape of the implant and also limits the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. **Correct handling of the implant is very important.**
   Under no circumstances should the shape of a finished implant be altered, as this shortens its life span. Our implants must not be combined with implants from other manufacturers. The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. **Implants must not be reused.**
   Implants are supplied sterile and are intended for single use only. Used implants must not be used again.

4. **After-treatment is also very important.**
   The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. **Unless otherwise indicated, implants are supplied in sterile packaging.**
   Note the following conditions for storage of packaged implants:
   - Avoid extreme or sudden changes in temperature.
   - Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the “Use by” date indicated on the packaging.
   - They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
   - Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The “Use by” date is indicated on the product label.
   - Do not use an implant if the packaging is damaged.

6. **Traceability is important.**
   Please use the documentation stickers provided to ensure traceability.

7. **Further information** on the material composition is available on request from the manufacturer.

Follow the instructions for use!

Waldemar Link GmbH & Co. KG, Hamburg

Osteosynthesis Implant for Treatment of Hallux Valgus Deformity

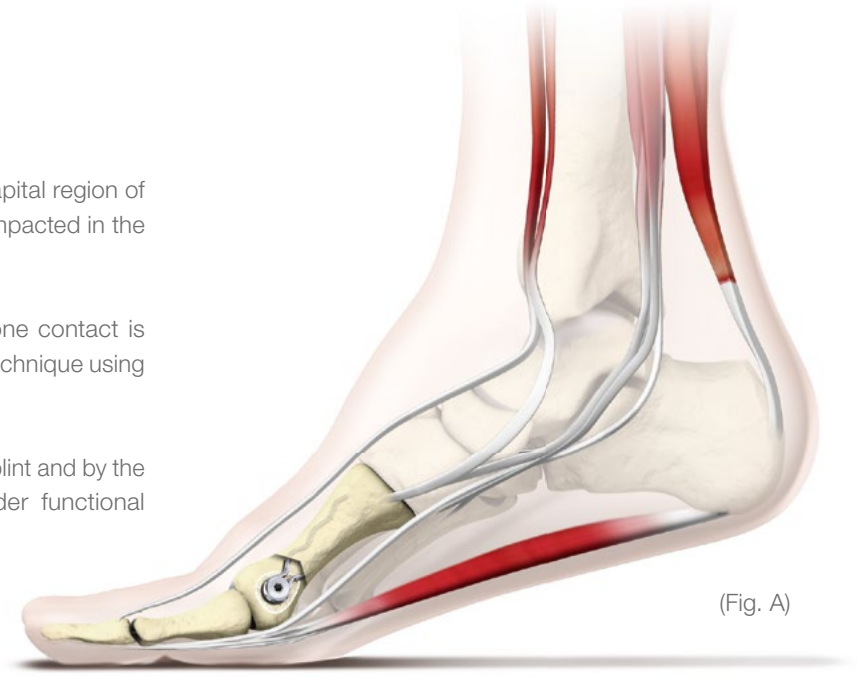
The **LINK Internal Hallux Fixator** is a dynamic osteosynthesis implant applied in distal osteotomies of the first metatarsal to correct hallux valgus deformities. (Fig. A)

The Surgical Principle

Angular osteotomy is performed through the subcapital region of the metatarsal head which is three-dimensionally impacted in the desired position.

A stable osteosynthesis of the initially instable bone contact is achieved by applying the dynamic osteosynthesis technique using the **LINK Internal Hallux Fixator.**

The occurring torques are neutralized by the inner splint and by the interfragmentary compression which occurs under functional loading.



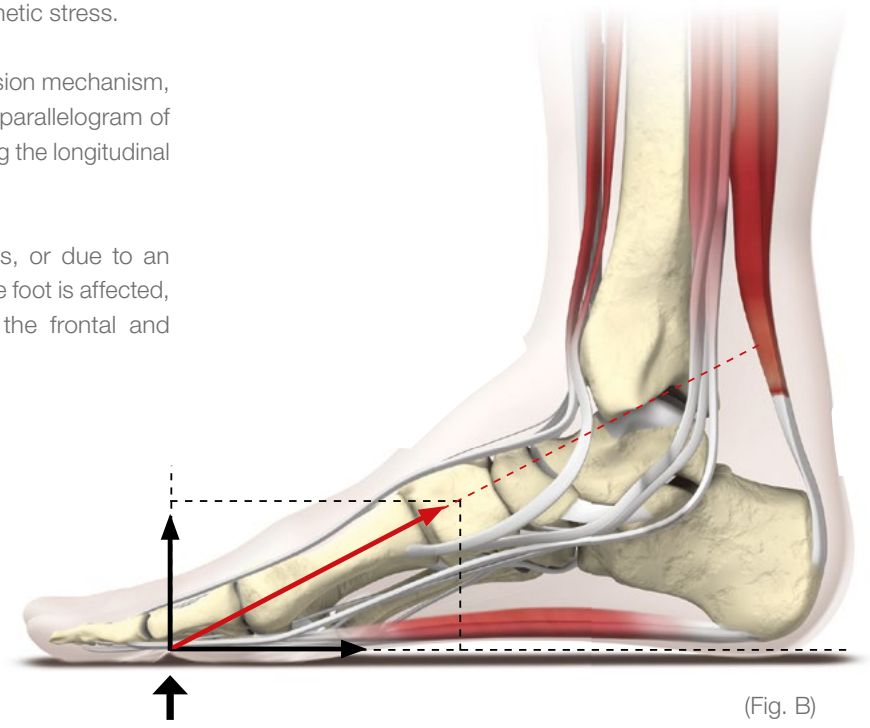
(Fig. A)

Basic Biomechanical Principles

In functioning tension mechanisms, the metatarsal bones are loaded solely in compression under static and kinetic stress.

Together with the tension force of the plantar tension mechanism, the dorsally positioned ground reaction forms a parallelogram of forces whereby the tension force runs exactly along the longitudinal axis of the metatarsal bones. (Fig. B)

In the event of a deformity of the osseous axis, or due to an unbalanced tendon, the equilibrium of forces in the foot is affected, thus leading to the application of torques in the frontal and transversal planes.

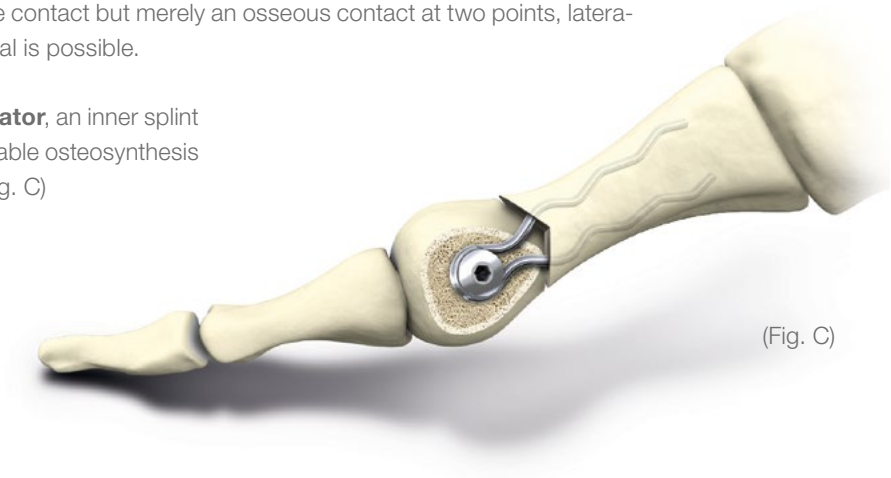


(Fig. B)

The distal osteotomy of the first metatarsal according to Stoffella

Osteotomy according to Stoffella is a subcapital angular osteotomy of the first metatarsal in a plane with arms opened in a distal direction at an angle of 90°-120°. During angular osteotomy, the metatarsal head is impacted without any additional incisions by moving, tipping and turning it into the desired position. Since the fragments do not require a surface contact but merely an osseous contact at two points, lateralization up to the width of the medullary canal is possible.

By implanting the **LINK Internal Hallux Fixator**, an inner splint with three support points is created and a stable osteosynthesis is generated through the functional load. (Fig. C)



(Fig. C)

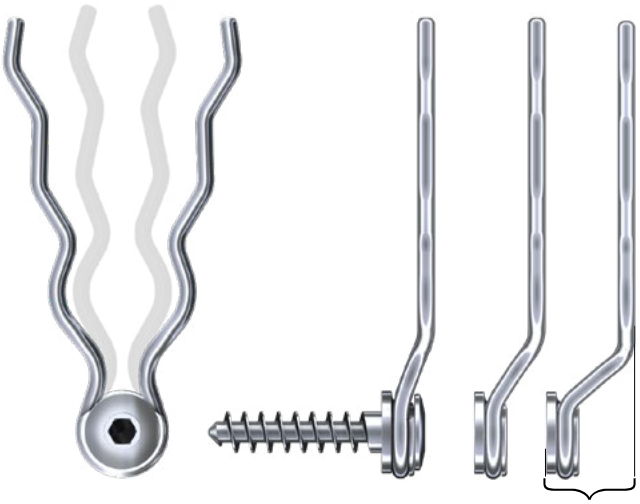
The **LINK Internal Hallux Fixator** is an inner load carrier which was developed to fix the metatarsal head to the metatarsal shaft after correcting its position. The dynamic osteosynthesis implant consists of a 1.7 mm long steel wire formed in the shape of a clasp, with a static and a dynamic end.

The dynamic end consists of two convoluted splayed out pre-stressed arms, which are firmly anchored in the medullary canal of the metatarsal shaft to prevent them from rotating and tilting. (Fig. D1)

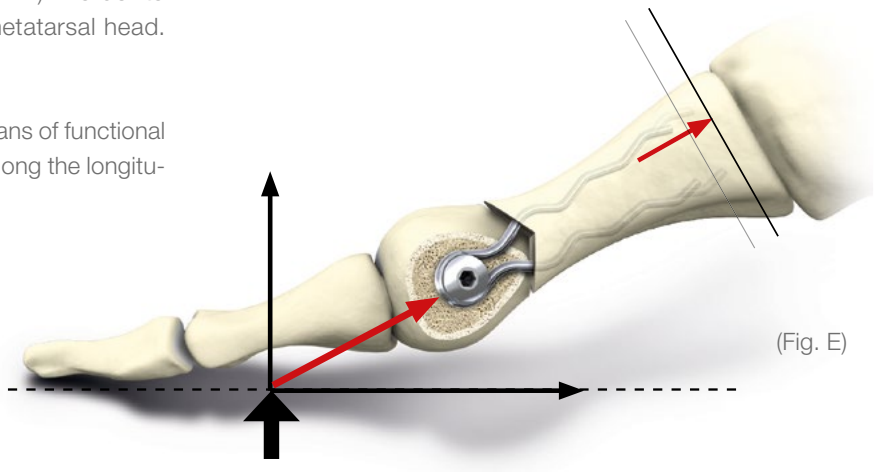
The static end is rounded off, recessed, bayonet-shaped and connected to a guiding cylinder through which an aligned small-fragment screw is stuck in order to anchor the distal end with a stable angle to the metatarsal head. (Fig. D2)

The **LINK Internal Hallux Fixator** is available in three different offsets (h = 3 mm, 5 mm and 7 mm) in order to achieve the desired lateralization of the metatarsal head. (Fig. D3)

When impacting the metatarsal head by means of functional loading, the arms of the implant may glide along the longitutinal axis – gliding effect. (Fig.E)



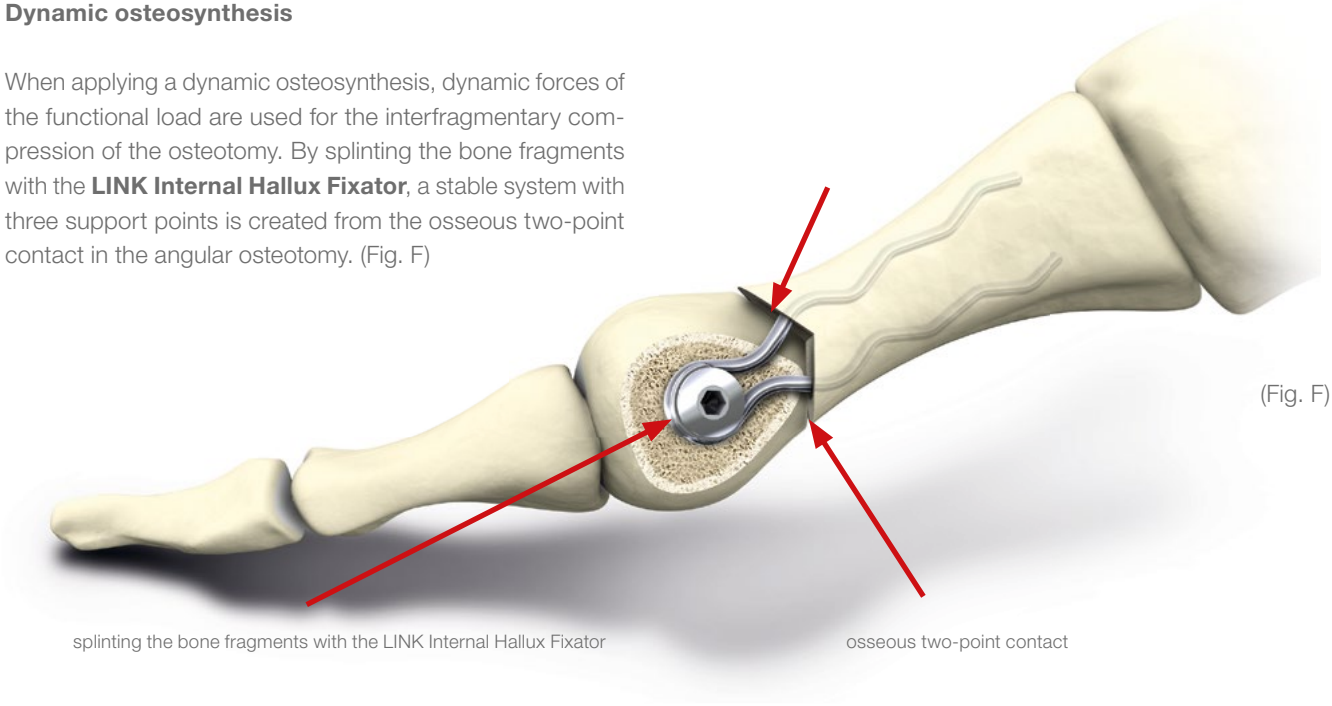
(Fig. D1) (Fig. D2) (Fig. D3) (h)



(Fig. E)

Dynamic osteosynthesis

When applying a dynamic osteosynthesis, dynamic forces of the functional load are used for the interfragmentary compression of the osteotomy. By splinting the bone fragments with the **LINK Internal Hallux Fixator**, a stable system with three support points is created from the osseous two-point contact in the angular osteotomy. (Fig. F)

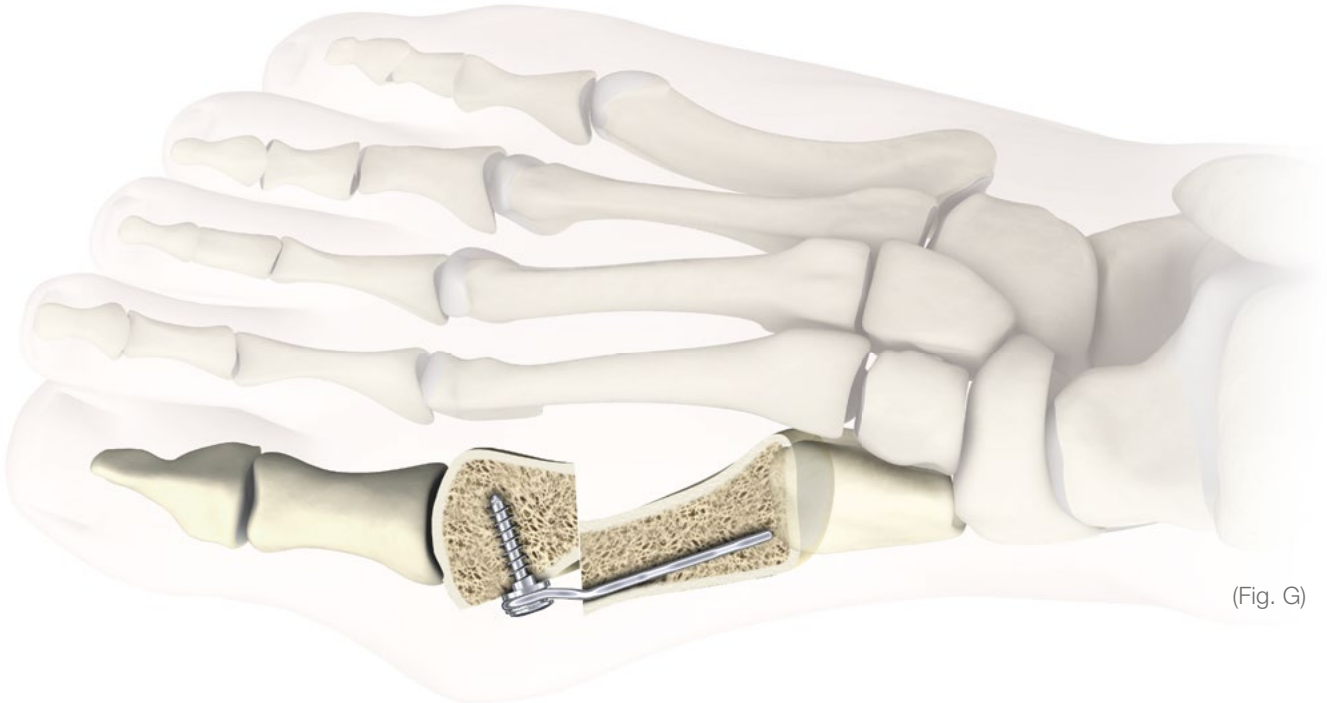


(Fig. F)

The combination of interfragmentary compression and inner splint leads to a dynamic osteosynthesis. The elimination of interfering bending moments and shear forces is effected by the interfragmentary friction in the angular osteotomy and the neutralization effect of the inner load carrier.

The torque forces in the frontal plane are neutralized by the central screw fixation of the metatarsal head with the hallux fixator in the angular osteotomy.

The torque forces in the transversal plane are neutralized via the angular-stable screw fixation of the metatarsal head with the hallux fixator. (Fig. G)

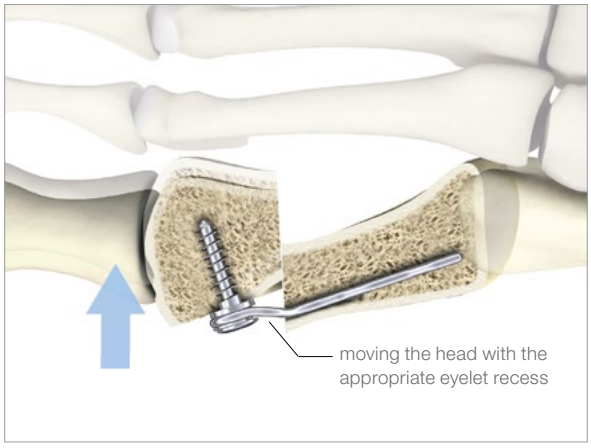


(Fig. G)

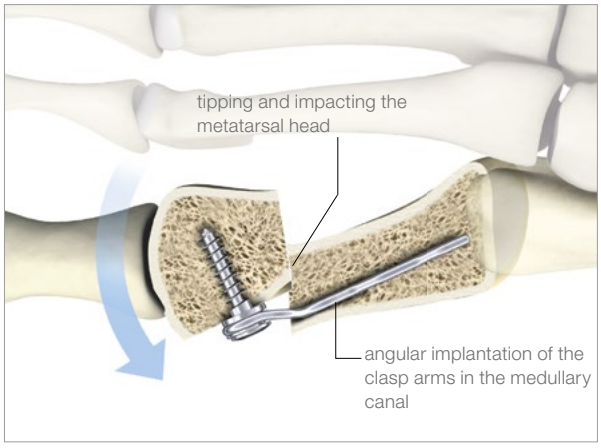
Correction possibilities

The osteotomy according to Stoffella is a subcapital angular osteotomy of the first metatarsal which always has the same angle and does not provide for bone wedge removal. All planes of the hallux deformities can be corrected by means of the support point technique of the dynamic osteosynthesis:

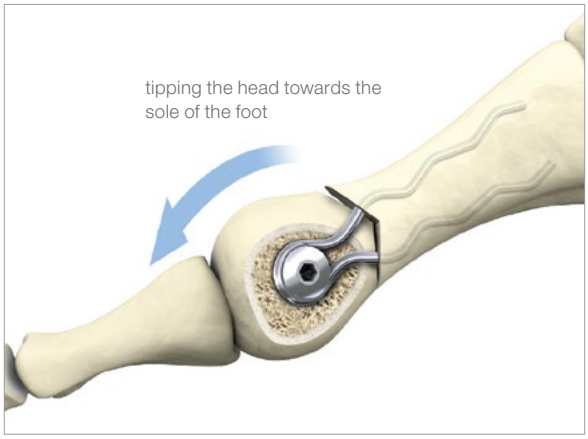
1. Lateralization can be achieved with the appropriate eyelet recess by moving the head.
2. Valgus deformities can be corrected by means of angu-larimplantation of the clasp arms in the medullary canal after tipping and impacting the head.
3. Plantarization can be achieved by a downward ostetomic cut or by tipping the head towards the sole of the foot.
4. Pronation deformities can be corrected by turning the head in the angular osteotomy and by the rotating clasp arms.



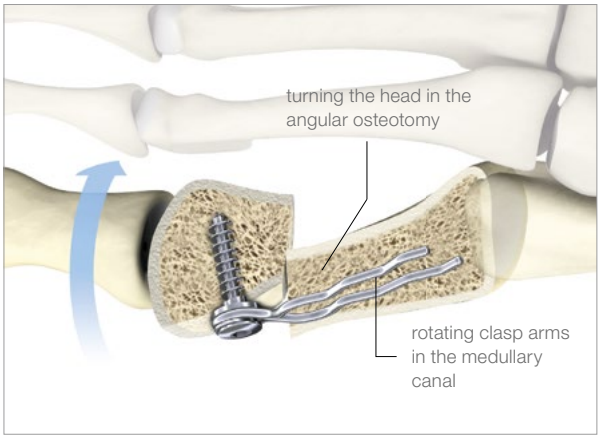
1. Lateralization



2. Valgus deformity



3. Plantarization



4. Pronation deformity

Problems with standard technique

Established distal osteotomies of the first metatarsal to correct hallux valgus deformities by applying static osteosynthesic techniques such as screw fixation or drill wire fixation require a large surface area for bone contact and generally only permit immediate mobilization without functional loading.

- Due to the decreasing osseous area, lateralization of the metatarsal head to correct the intermetatarsal angle is only possible up to half of the shaft width.
- A primarily stable osteosynthesis is only possible in the case of low-grade hallux deformities.
- In the case of medium-grade hallux deformities, a secondary stabilization with surgical shoes and a fixed bandage is required to ensure osteosynthesis.
- A three-dimensional correction of the first metatarsal can only be achieved by means of complex techniques.
- A secondary stabilization delays mobilization and prolongs the rehabilitation time.

Advantages of the osteotomy according to Stoffella

The osteotomy according to Stoffella applying the dynamic osteosynthesis can be accomplished easily and has been successfully applied since 1993.

- High-grade hallux deformities can be easily corrected.
- The osteosynthesis is also stable under load in the case of a correction up to the width of the medullary canal.
- The punctual contact with the bone permits a three-dimensional correction of the position without additional incisions.
- Mobilization is carried out wearing normal shoes with free mobility and without any fixed bandages.
- Functional loading as part of the osteosynthesis technique leads to a significantly shorter rehabilitation period due to the early and pain-free mobilization.

Ideal indications

The ideal indication for Stoffella surgery is from moderate to severe hallux valgus deformity. Hallux valgus angle can be corrected up to 45° and intermetatarsal deformities up to 20°. In incongruent or fixed foot joints an additional soft tissue approach is performed.

Additional indications

- In case of transfermetatarsalgia due to an elevation of the first metatarsal head, middle phalange heads II-III can be released by means of a plantar osteotomy.
- In case of stiff big toe (hallux rigidus), foot joint can be released with plantar or reducing osteosynthesis.

Contraindications

- Advanced arthrosis in the first metatarsophalangeal
- Pronounced osteoporosis
- Severe hypermobility in metatarsal joints
- Severe hallux valgus and first metarsal deformity

Radiological Parameters

Anterior-posterior (a-p) and lateral X-rays are taken of the patient in standing position. The following parameters must be taken into account during preoperative planning

1. Possible arthrosis of the first MTP joint.
2. The hallux valgus angle between the basic phalanx and the first metatarsal and the inclination of the distal joint surface angle.
3. The intermetatarsal angle between the first and second metatarsal and the decentralization of the sesamoid bones.
4. The length of the first metatarsal in the metatarsal index
5. The position of the tarsometatarsal joint and other foot deformities.

Clinical Parameters

The following clinical findings must be taken into consideration during preoperative planning:

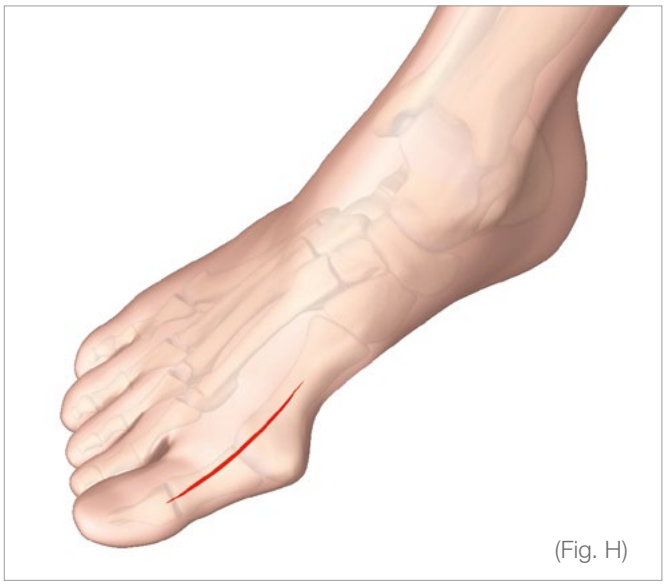
1. The mobility of the large toe and the contraction of the valgus deformity.
2. The hypermobility of the first metatarsal relative to the other metatarsals.
3. The pronation deformity of the large toe.
4. Callosities on the large toe and on the pressure area of the metatarsals.
5. Other toe deformities.

This information determines the operative procedure and the extent of the intended axial correction.

In principle, all three planes of the hallux deformity are to be corrected and tendon equilibrium is to be established.

Incision and removing of pseudoexostosis

Medial longitudinal cut above the first metatarsophalangeal joint and longitudinal division of the joint capsule. (Fig. H)



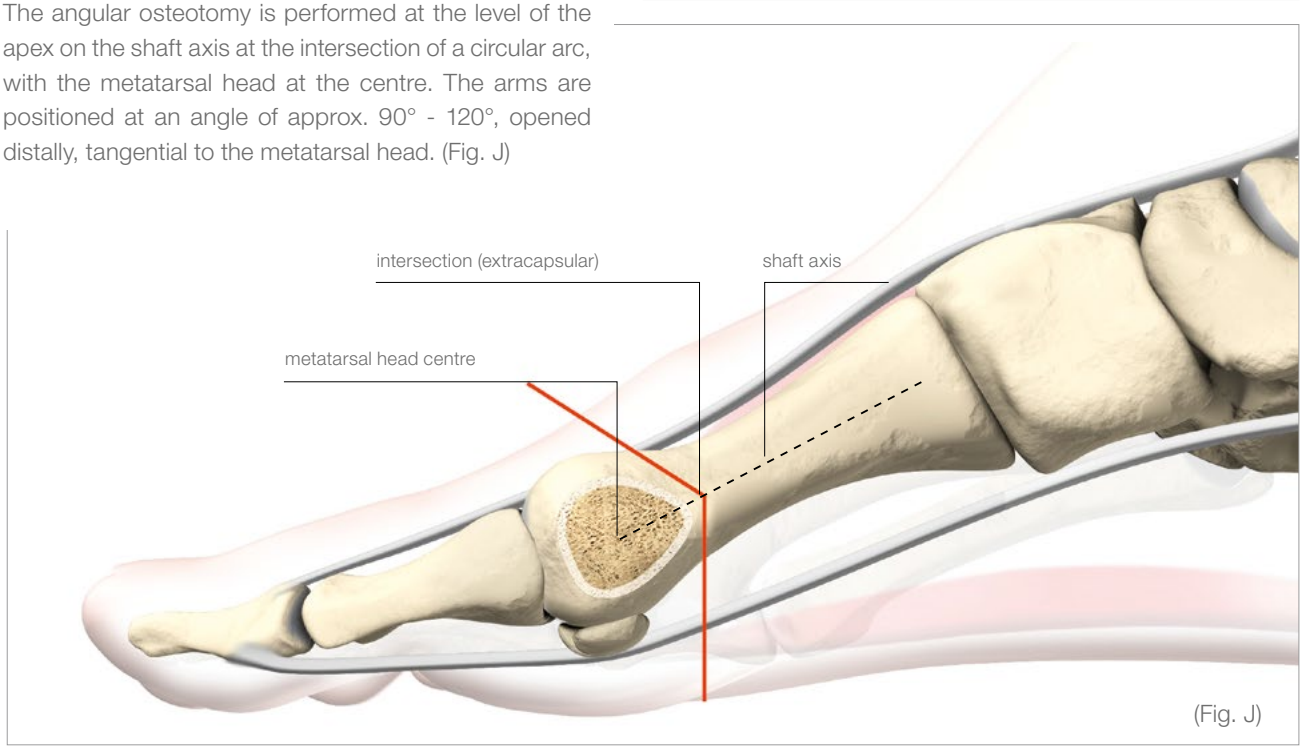
(Fig. H)

Removal of the pseudoexostosis with the oscillating saw. The osteotomy according to Stoffella is a subcapital angular osteotomy in an extracapsular position. (Fig. I)

(Fig. I)

Determination of type of incision

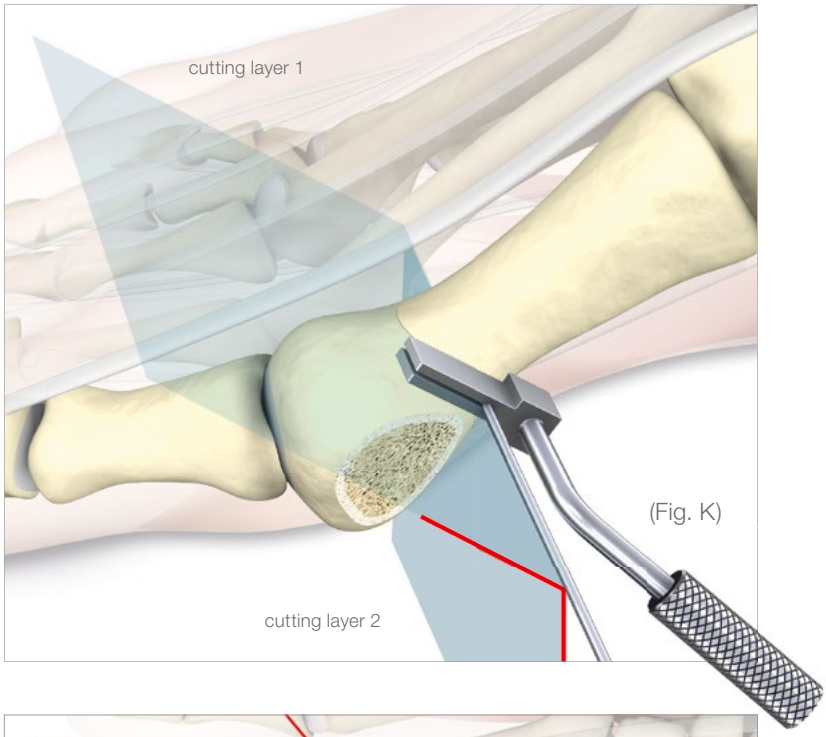
The angular osteotomy is performed at the level of the apex on the shaft axis at the intersection of a circular arc, with the metatarsal head at the centre. The arms are positioned at an angle of approx. 90° - 120°, opened distally, tangential to the metatarsal head. (Fig. J)



(Fig. J)

Osteotomy

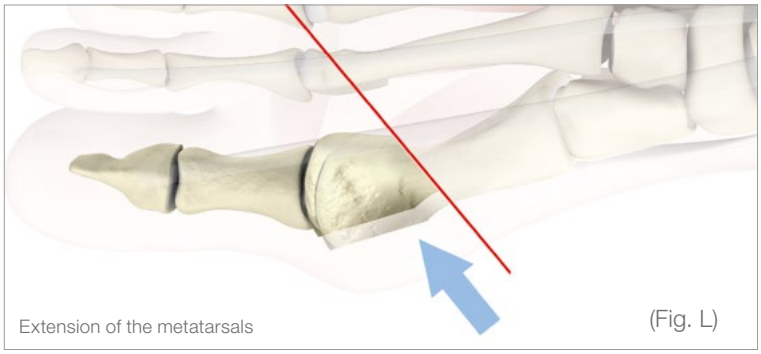
The apex of the osteotomy is fixed with a 1 mm drill wire using a special saw guide.
The bone incisions are performed by means of an oscillating saw with a small sawblade (Fig. K)



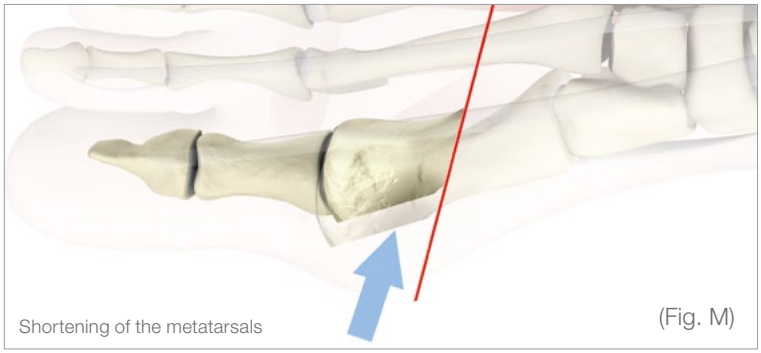
(Fig. K)

Correction possibilities based on the type of incision:

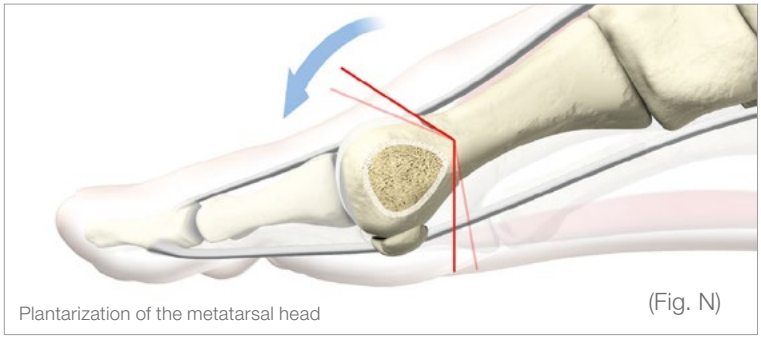
1. Exension of the metatarsals (incision is directed upwards from proximal medial to lateral distal). (Fig. L)
2. Shortening of the metatarsals (incision is directed downwards from distal medial to proximal lateral). (Fig. M)
3. Plantarization of the metatarsal head (incision is directed from medical dorsal to lateral plantar). (Fig. N)



Extension of the metatarsals (Fig. L)



Shortening of the metatarsals (Fig. M)



Plantarization of the metatarsal head (Fig. N)

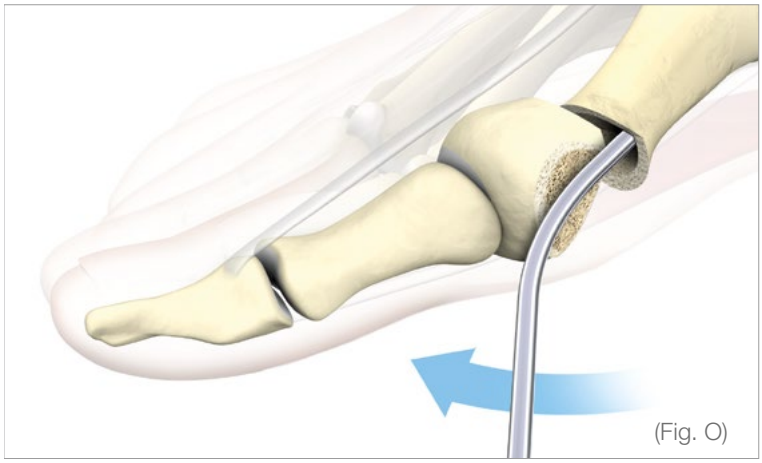
Correction possibilities through repositioning

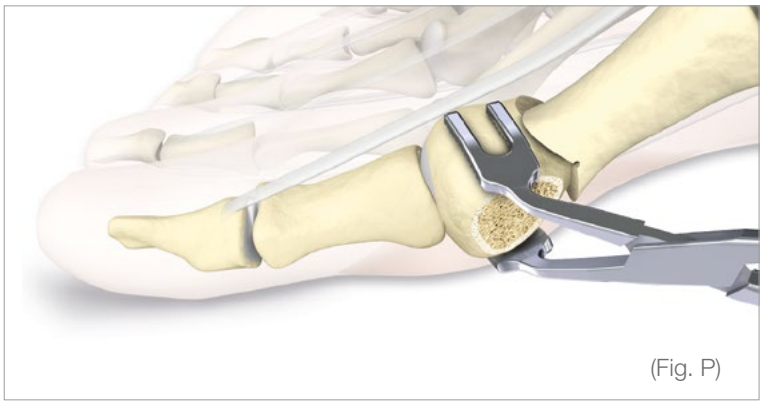
An unstable correction is performed initially

1. The lateralization of the head is performed using the curved part of the lever and flush pin gauge at the level of the osteotomy. (Fig. O)

The head can be tipped and turned from the level of the osteotomy by means of the repositioning tongs. (Fig. P und figures page 7)

2. Valgus correction (Tipping and impaction of head into the medullary canal).
3. Pronation correction (Turning of the head into supination).


(Fig. O)


(Fig. P)

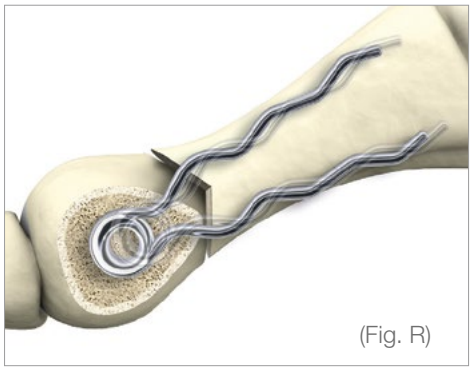
Inspection of medullary canal and implant selection

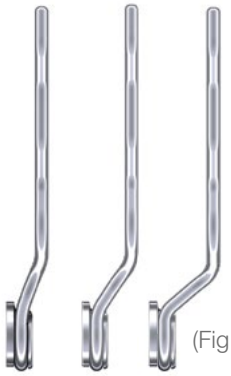
The medullary canal is inspected by means of the depth gauge. (Fig. Q)

The arms of the clasp are 40 mm long and must have a gliding distance of approx. 3 mm. (Fig. R) If the medullary canal does not correspond to this length, the clasp arms must be shortened.

In accordance with preoperative planning procedures, a hallux fixator with applicable lateralization must be selected. (Fig. S)


(Fig. Q)

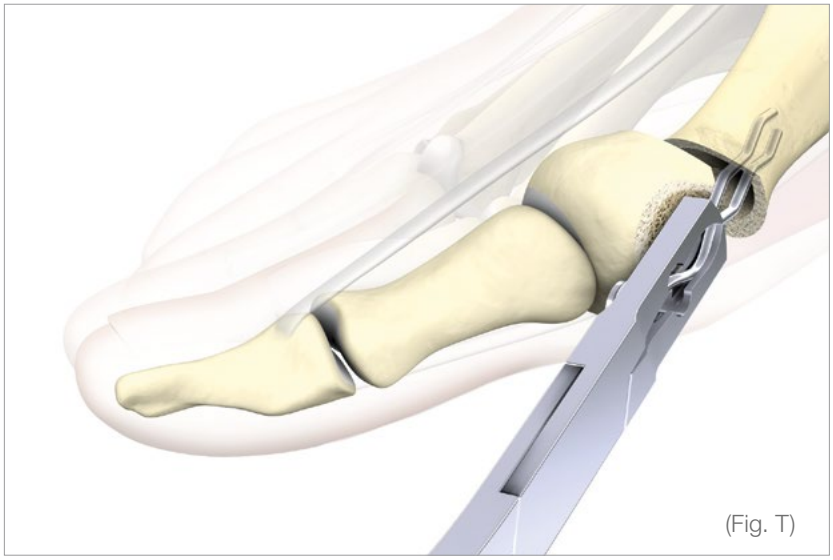

(Fig. R)


(Fig. S)

Implant insertion

With the aid of the implant clasp, the prestressed arms of the hallux fixator are compressed and inserted into the metatarsal shaft up to the last convolution of the clasp arms in accordance with the intended correction. (Fig. T)

- for valgus correction, the arms are inserted transversally;
- for pronation correction the arms are inserted rotated.

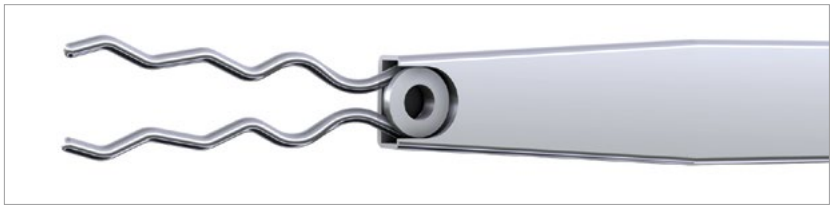


(Fig. T)

Implant impaction

The hallux fixator is driven into its final position in the shaft by means of a bone impaction instrument. (Fig. U)

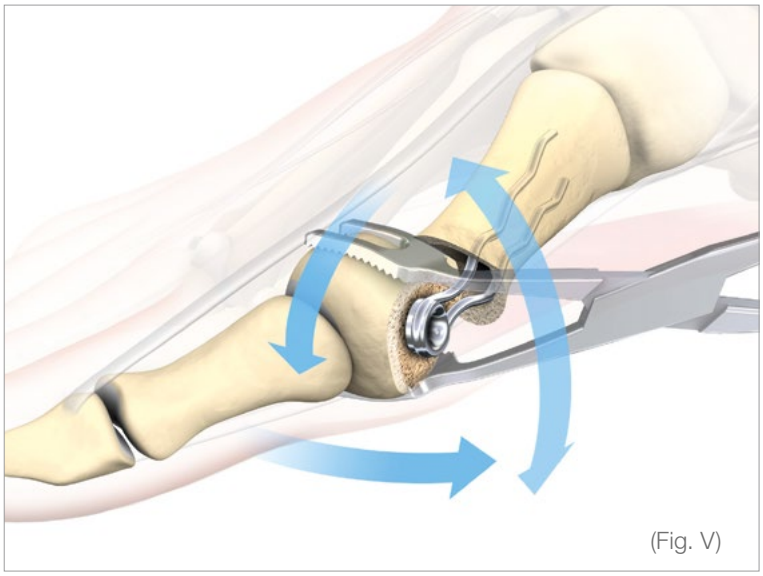
(Fig. U)



Positioning of the metatarsal head

A repositioning clasp fixes the metatarsal head to the eyelet of the hallux fixator. The correction of the deformity is reviewed (Fig. V)

Should it be required to make changes, the implant can be removed and inserted new.

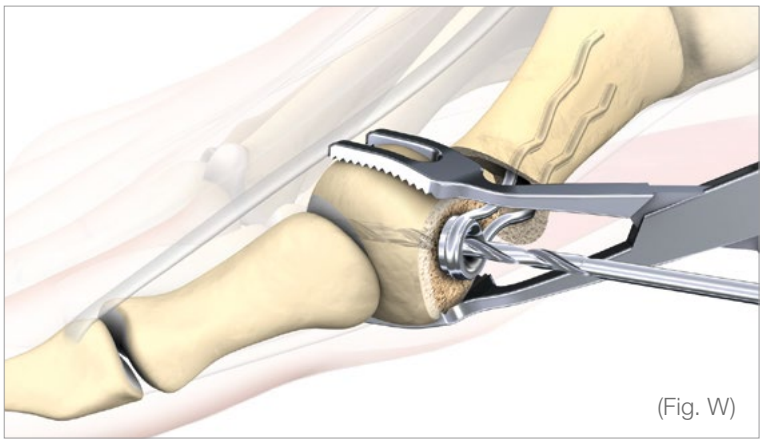


(Fig. V)

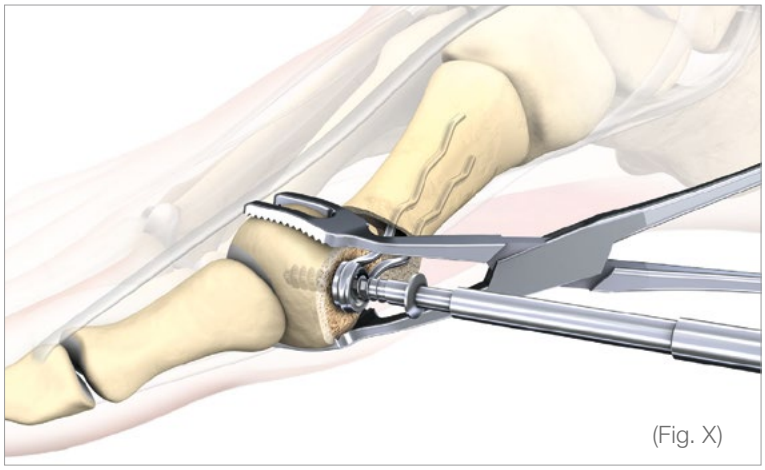
Proximal screw fixation

The canal for the 4mm cylindrical spongiosa screw is drilled with a 2.5mm drill into the metatarsal head through the guide bushing of the hallux fixator. (Fig. W)

After measuring the length of the screw with a screw measuring device, the respective screw is inserted by means of a hex tip screwdriver. (Fig. X)



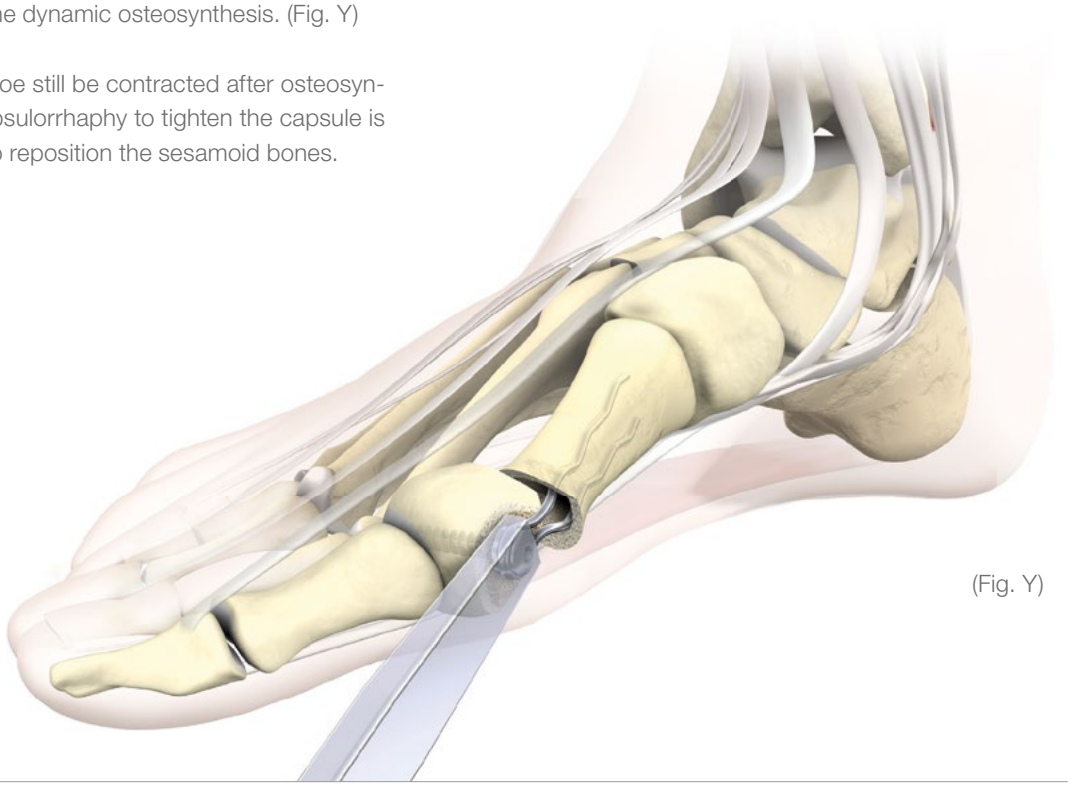
(Fig. W)



(Fig. X)

Finally, the impacted implant is gently hammered in by means of the bone impaction instrument to achieve the pre-stressing of the dynamic osteosynthesis. (Fig. Y)

Should the large toe still be contracted after osteosynthesis, medial capsulorrhaphy to tighten the capsule is always required to reposition the sesamoid bones.



(Fig. Y)

Weight can be put on the foot immediately. The foot should be placed in a plantigrade position and rolled off via the large toe. After soft-tissue surgery, an ace bandage is applied until it is time to remove the stitches. A hallux valgus day bandage is subsequently applied.

Foot mobilization is conducted in standard sandals with flexible soles and Velcro fastener. After the removal of the stitches and after the resolution of swelling, a comfortable shoe may be worn. X-ray control will be conducted postoperatively and before the removal of the implant. The removal of the implant is generally performed about 6 - 12 weeks after the implant was inserted under local anaesthesia by means of a stab incision via the screw. The screw is unscrewed and the implant is extracted from the medullary canal using flat pliers.

Finally, the medial edge of the shaft can be abraded using a luer.

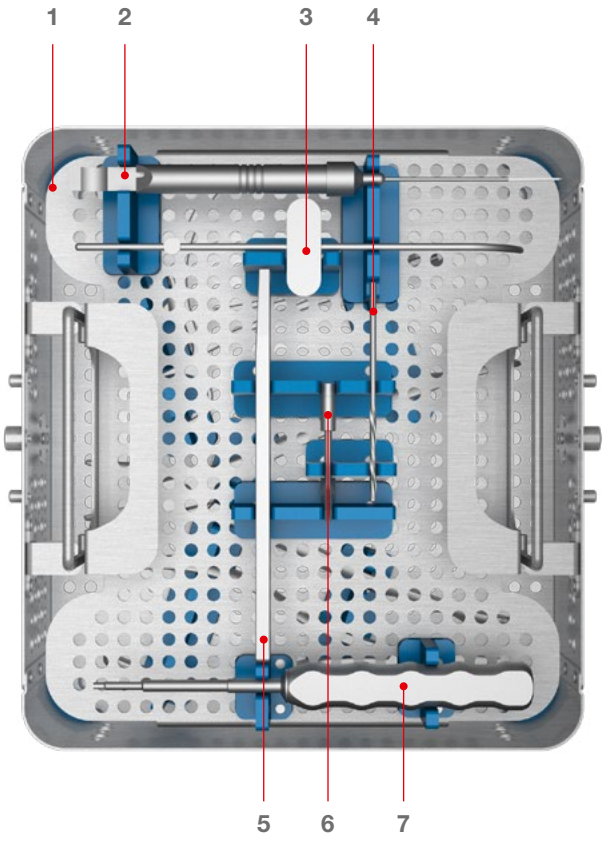
78-year-old patient with a hallux valgus deformity.

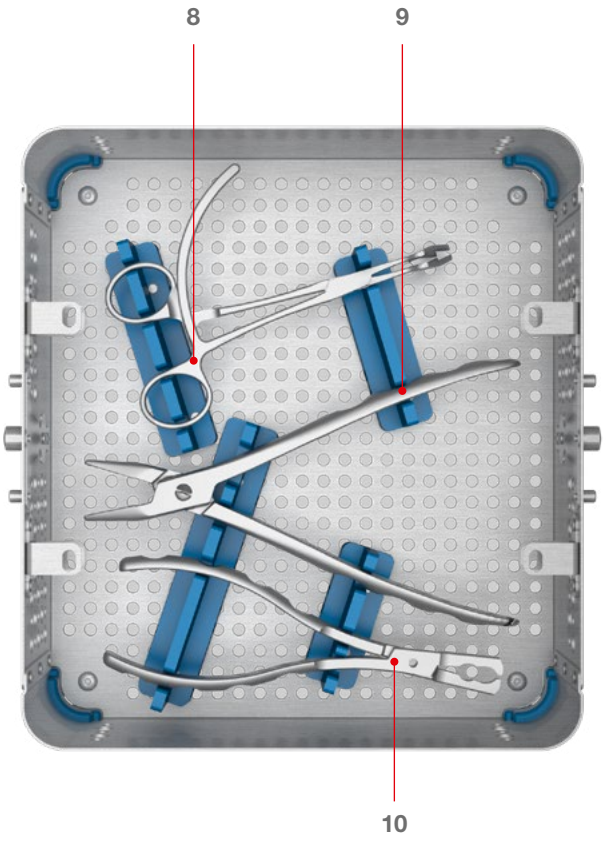
Painful inflammation of bursae (bursitis) on the ball of the foot and severe problems with conventional footwear. The hallux valgus angle of 45° was corrected to 12° and the hallux intermetatarsal angle of 18° was corrected to 6°. In addition, the Hohmann procedure was performed on the second toe due to a hammer toe deformity.

Fig. 1 High-grade hallux valgus deformity

Fig. 2 Osteotomy according to Stoffella, LINK Internal Hallux Fixator with 7 mm offset

Fig. 3 10 months postoperatively, excellent result





11-5002/14

Instruments, complete LINK Internal Hallux Fixator

Nr.	Product	Size	Pc.	REF
1	**Instrument tray, only**	253 × 228 × 76 mm	1	**11-5002/60**
2	**Depth Gauge**	effective range 50 mm	1	**15-8389/01**
3	**Lever and Gauge**	185 mm	1	**11-5002/03**
4	**Spiral Drill Bit**	90 mm, Ø 2,5 mm	1	**10-1680/06**
5	**Driver, modified**	160 mm	1	**11-5002/13**
6	**Saw Guide**	40° angled	1	**11-5050**
7	**Hex Screwdriver**	180 mm, SW 2,5 mm	1	**10-5373**
8	**Bone Fragment Clamp**	145 mm	1	**11-5002/04**
9	**Flat Pliers with tapered jaws**	200 mm	1	**10-1727**
10	**Application Forceps**	180 mm	1	**11-5002/01**

Bayonet 3 mm | Bayonet 5 mm | Bayonet 7 mm

LINK Hallux-Fixateur Interne

Bayonet	MAT	REF
3 mm	St	99-0068/53
5 mm	St	99-0068/55
7 mm	St	99-0068/57

Cancellous Screws for LINK Internal Hallux Fixator

System depth	Ø	MAT	REF
18 mm	4 mm	St	99-0068/18
20 mm	4 mm	St	99-0068/20
22 mm	4 mm	St	99-0068/22
24 mm	4 mm	St	99-0068/24
26 mm	4 mm	St	99-0068/26

Additional Instruments (not included in Instrument Set)

Product	Description	REF
Wire Cutter	with carbide inserts, 180 mm	10-5132
Lambotte Osteotome	2 mm wide, 125 mm	10-5122/02

Literature

Stoffella R.
Die Halluxspange – Fixationsmethode distaler metaphysärer Osteotomien bei der Rekonstruktion des Hallux valgus.
Vortrag am 1. Österreichisch - Deutschen Fußchirurgenkongress, Going/Tirol, 1995

Stoffella R.
Neue Osteotomietechnik zur subkapitalen Metatarsalosteotomie beim Hallux valgus.
Operative Orthopädie und Traumatologie, 1998:10:309-16 (Heft 4), Urban & Vogel, München

Stoffella R.
A new distal osteotomy of the first metatarsal for moderate and severe hallux valgus with a new internal fixation technique- results of the procedure.
Vortrag am EFORT Congress, Brüssel 1999

Stoffella R.
Die dynamische Osteosynthese mit der Link DC-Halluxspange bei der Korrektur der Hallux valgus Fehlstellung.
Videovortrag auf der 63 Jahrestagung der Deutschen Gesellschaft für Unfallchirurgie, Berlin 1999
Videofilm: (Auf Anfrage erhältlich)

LINK NEWS 7 – Orthopädie aktuell
Behandlung der Hallux valgus Deformität mit einem dynamischen Osteosynthese-Implantat
Waldemar Link GmbH & Co. KG, Hamburg 1999

Stoffella R.
Ergebnisse der subkapitalen Metatarsale I Osteotomie nach Stoffella zur Behandlung des Hallux valgus.
Orthopädische Praxis 2000:1:55-58, Medizinisch Literarischer Verlag

Stoffella R.
Stabilisierung des biomechanisch insuffizienten MP-I-Gelenks mit einer 3-D-Korrekturosteotomie.
Vortrag am 25. Jubiläumskongress der Schweizerischen Gesellschaft für Chirurgie des Fußes, Davos 2000

Stoffella R.
Die dynamische Kompressionsspange für die Osteotomie einer distalen MT I Osteotomie zur Korrektur der Halluxfehlstellung.
Vortrag am Deutschen Orthopädenkongress, Wiesbaden 2000

Klein C., Dorn U. (Salzburg)
Die Inzidenz von avaskulären Köpfchennekrosen und Pseudarthrosen nach subcapitaler Osteotomie I des MTK nach Stoffella.
Vortrag am 7. Jahreskongress der D.A.F., Aachen & 49. Jahrestagung der Süddt. Orthop., Baden-Baden 2001

Vollmert O., Süssenbach F. (Ratingen)
Alternative zur subkapitalen Verschiebeosteotomie nach Kramer: Die dynamische Kompressionsspange nach Stoffella.
Vortrag am 7. Jahrestag der D.A.F., Aachen 2001

Klein C., Kiss H., Zembsch A., Dorn U. (Salzburg)
Die subcapitale Osteotomie des Metatarsus I nach Stoffella. Eine Analyse von 30 nach Originaltechnik operierten Fällen.
Vortrag auf der 26. Jahrestagung der Österreichischen Gesellschaft für Orthopädie, Salzburg 2001

Stoffella R.
Die Grundlagen der dynamischen Osteosynthesetechnik bei der Stoffella-Osteotomie zur Korrektur des Hallux valgus.
Poster auf der 26. Jahrestagung der Österreichischen Gesellschaft für Orthopädie, Salzburg 2001

Stoffella R., O35
Frühergebnisse der MT-I-Osteomie nach Stoffella mit der modifizierten winkelstabilen dynamischen Kompressionsspange dem Hallux-Fixateur interne.
Orthopädische Praxis 38. Jahrg. Heft 10, 2002

Stoffella R.
Die Operation nach Stoffella,
Fuss & Sprunggelenk 1 Heft 2, 2003

Bögling U.,Röttger K. und Scholz J.
Pedobarografische Untersuchung der Vorfußlastaufnahme nach retrokapitaler Verschiebeosteotomie mit DC-Halluxspange nach Stoffella,
Orthopädische Praxis 39. Jahrgang Heft 6, 2003

Dieterich K. und Eichhorn J.
Zehn Jahre Erfahrung mit der ambulanten Operation des Hallux valgus nach Stoffella
Chirurgenmagazin 2/2009: 40-44

Dieterich K. und Eichhorn J.
Ambulante Hallux valgus Operation nach Stoffella
Chirurgische Praxis 61, 563-568 (2003)

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