

Stoffella Internal Hallux Fixator

Surgical Technique
Implants and Instruments

Überreicht durch:
Presented by:



CE 0123

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LINK[®] **Stoffella Internal Hallux Fixator**
Osteosynthesis Implant
for Treatment of Hallux Valgus Deformity

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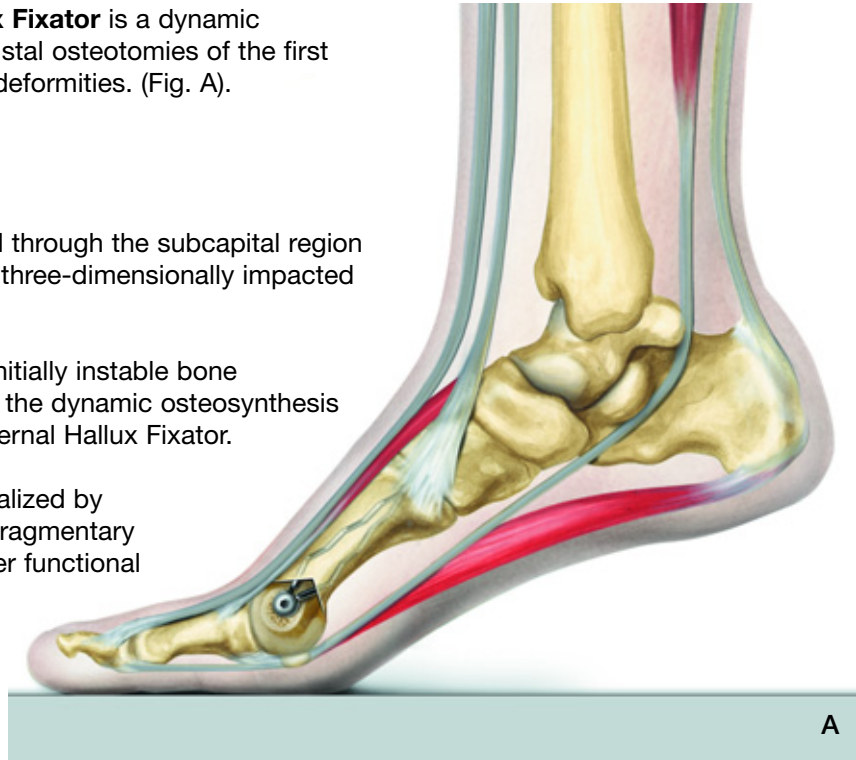
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Surgical Principle and Biomechanics

The LINK® Stoffella 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 Stoffella Internal Hallux Fixator.
- ◆ The occurring torques are neutralized by the inner splint and by the interfragmentary compression which occurs under functional loading.

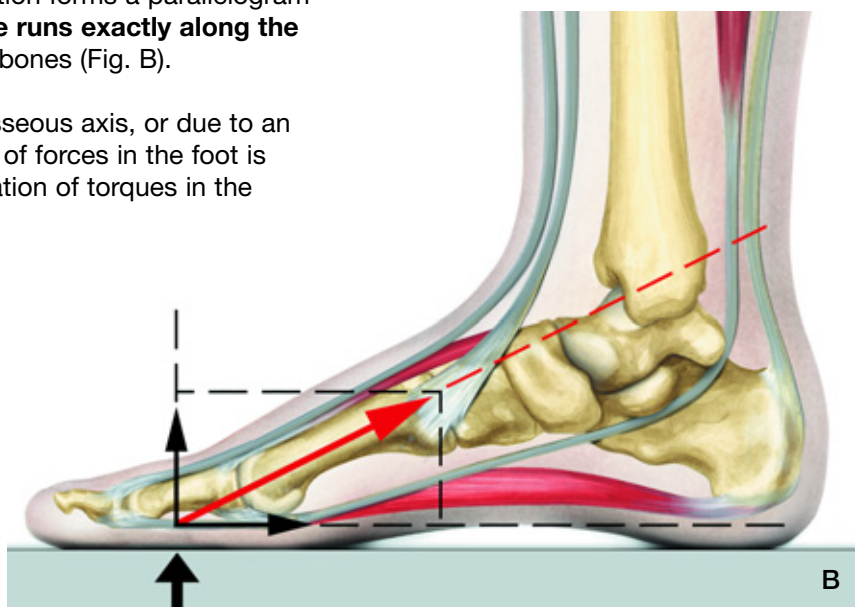


Basic Biomechanical Principles

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.



Surgical Principle and Biomechanics

The Distal Osteotomy of the first Metatarsal according to Stoffella

The 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 Stoffella Internal Hallux Fixator, an inner splint with three support points is created and a stable osteosynthesis is generated through the functional load.

The **Stoffella 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.

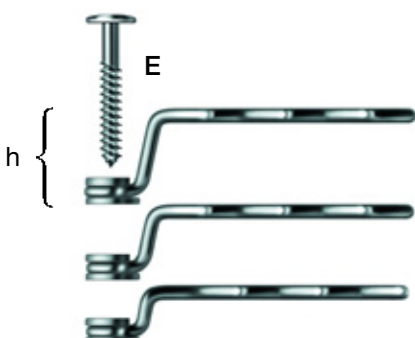
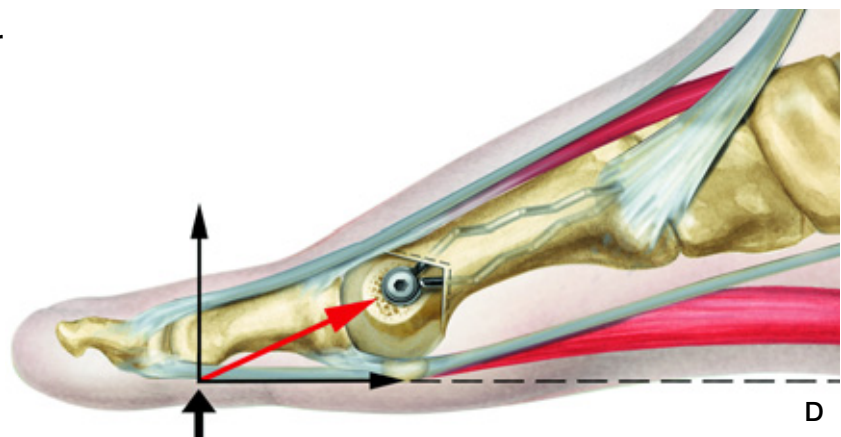
The **static end** is rounded off, recessed, bayonet-shaped and connected to a guiding cylinder through which an aligned small-fragment screw is stuck in order to anchor the distal end with a stable angle to the metatarsal head.



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. C).

When impacting the metatarsal head by means of functional loading, the arms of the implant may glide along the longitudinal axis. – **Gliding effect** (Fig. D)

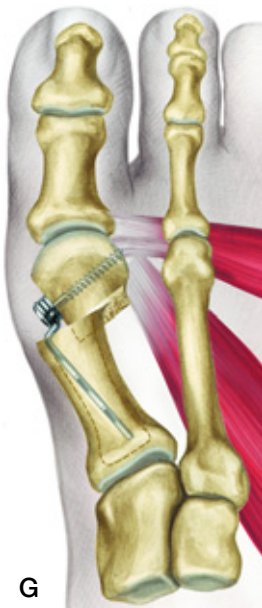
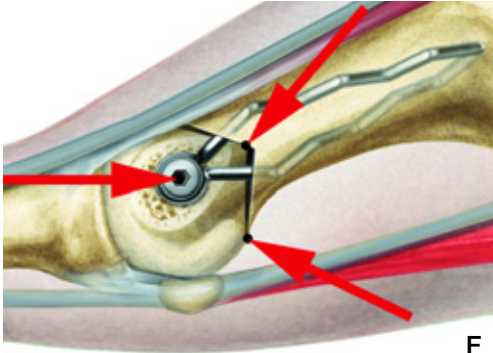
The **Stoffella Internal Hallux Fixator** is available in three different arm lengths (h = 3 mm, 5 mm and 7 mm) in order to achieve the desired lateralization of the metatarsal head (Fig. E).



Surgical Principle and Biomechanics

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 Stoffella Internal Hallux Fixator, a **stable system with three support points** is created from the osseous two-point contact in the angular osteotomy (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.

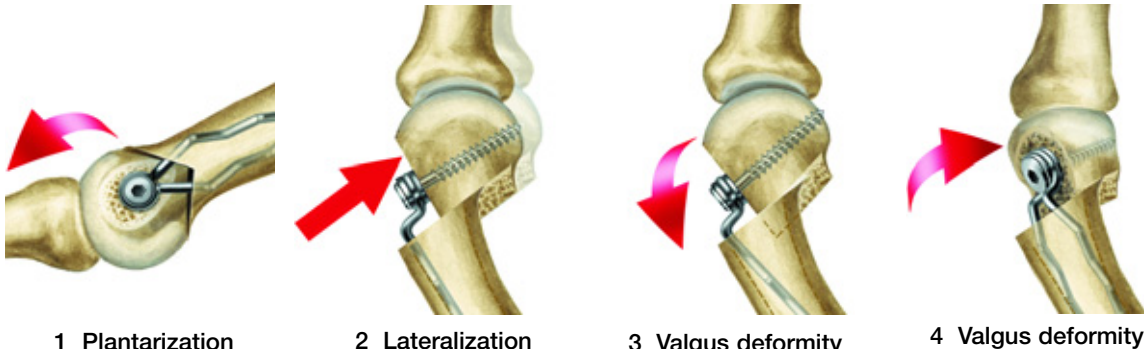
The torque forces in the transversal plane are neutralized via the angular-stable screw fixation of the metatarsal head with the hallux fixator (Fig. G).

Correct 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.

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



1 Plantarization 2 Lateralization 3 Valgus deformity 4 Valgus deformity

Problems and Advantages

Problems with Standard Techniques

Established distal osteotomies of the first metatarsal to correct hallux valgus deformities by applying static osteosynthetic 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.

Indications / Contraindications

Indications / Contraindications

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 metatarsophalange
- Pronounced osteoporosis
- Severe hypermobility in metatarsal joints
- Severe hallux valgus and first metatarsal deformity

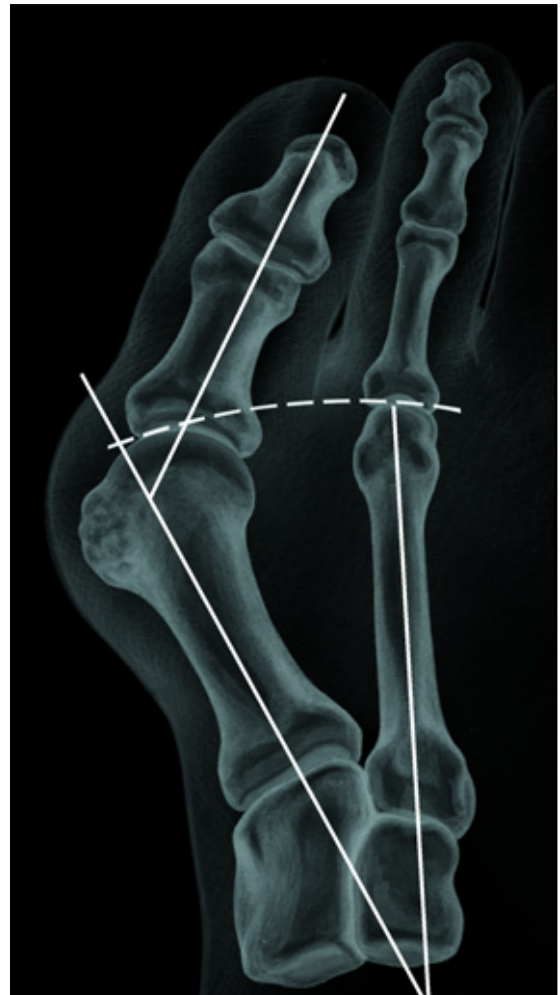
Preoperative Planning

Preoperative Planning

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 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.

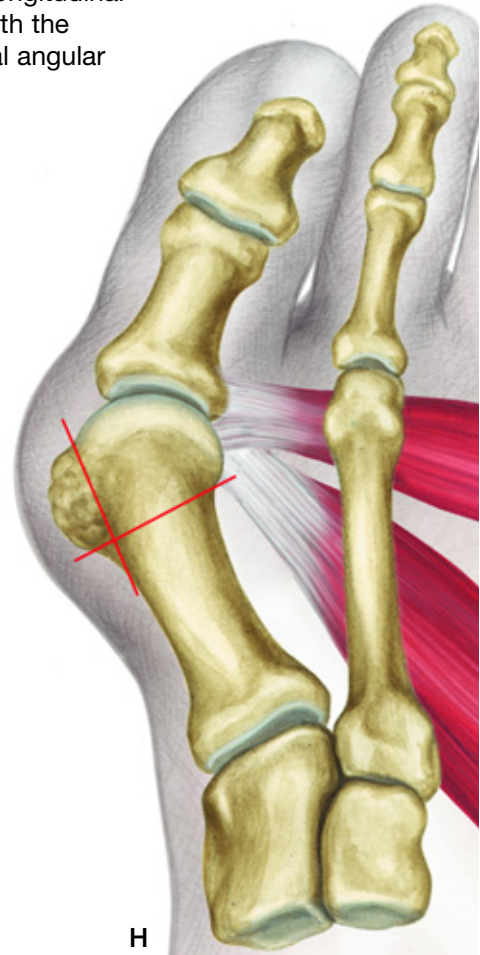
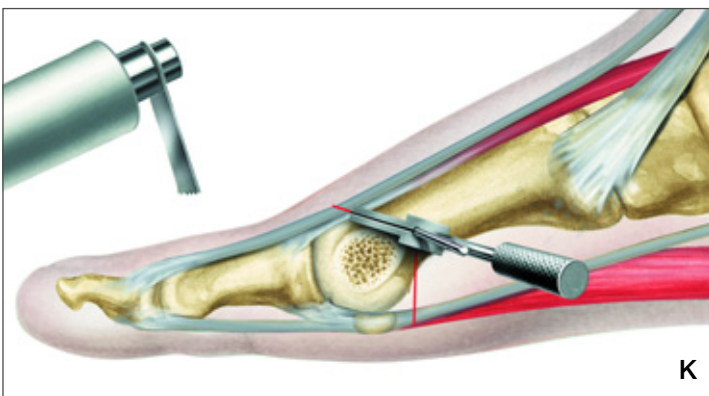
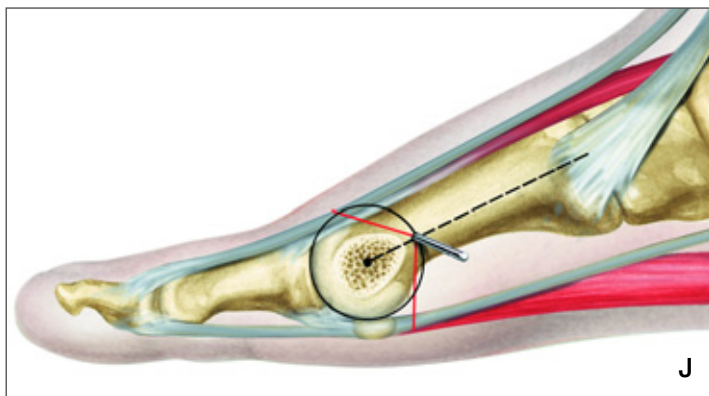
In principle, all three planes of the hallux deformity are to be corrected and tendon equilibrium is to be established.

Surgical Technique

Medial longitudinal cut above the first metatarsophalangeal joint. Longitudinal division of the joint capsule and removal of the pseudoexostosis with the oscillating saw. The osteotomy according to Stoffella is a subcapital angular osteotomy in an extracapsular position (Fig. H).

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 proximally, tangential to the metatarsal head. 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 saw blade (Fig. J+K).



Correction Possibilities based on the Type of Incision

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

Surgical Technique

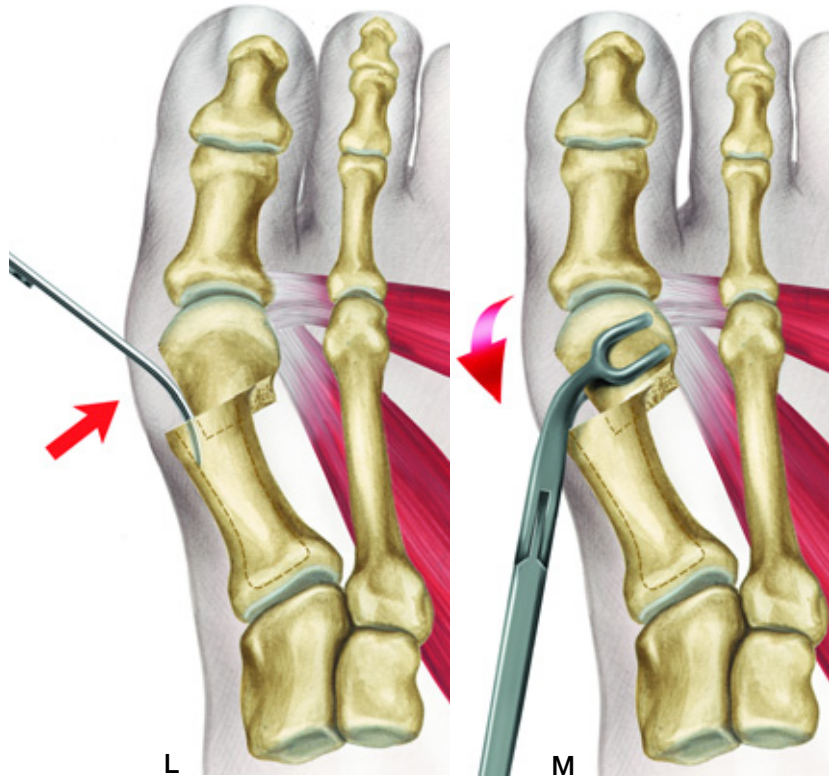
Correction Possibilities through Repositioning

An unstable correction is performed initially.

- 4. 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. L).

The head can be tipped and turned from the level of the osteotomy by means of the **repositioning tongs** (Fig. M).

- 5. **Valgus correction** (Tipping and impaction of head into the medullary canal).
- 6. **Pronation correction** (Turning of the head into supination).



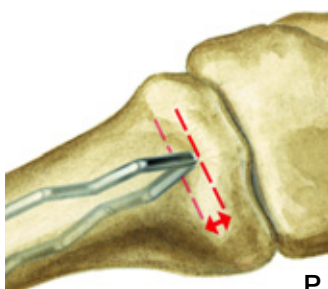
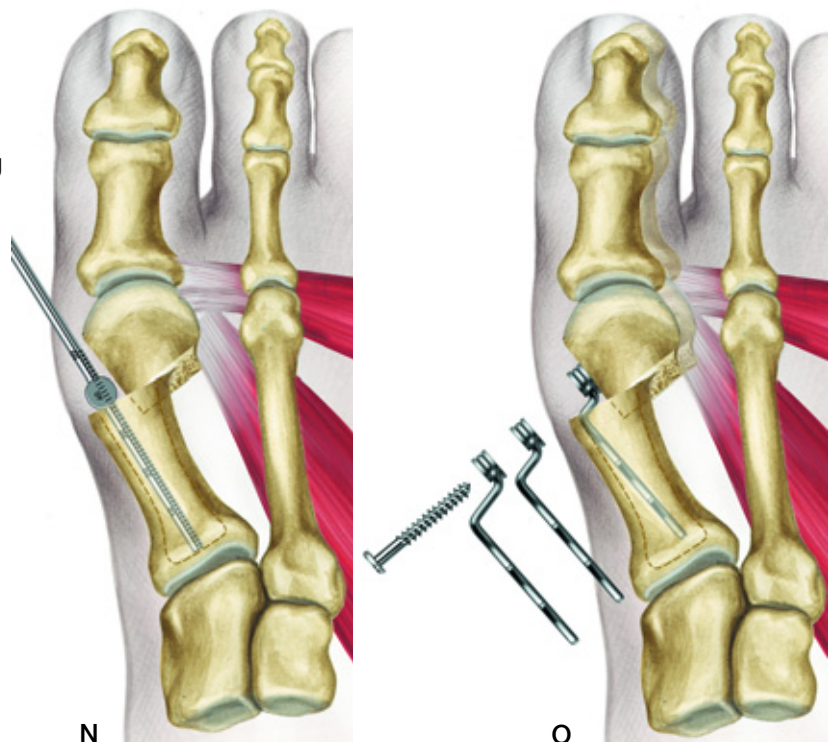
Inspection of medullary canal and implant selection

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

The arms of the clasp are 40 mm long and must have a gliding distance of approx. 3 mm (Fig. P).

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. O).

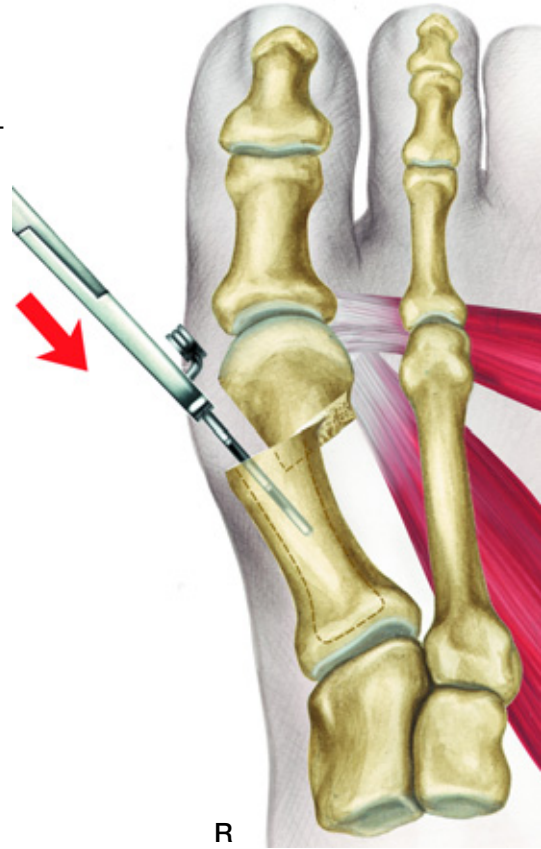


Surgical Technique

Implant Insertion

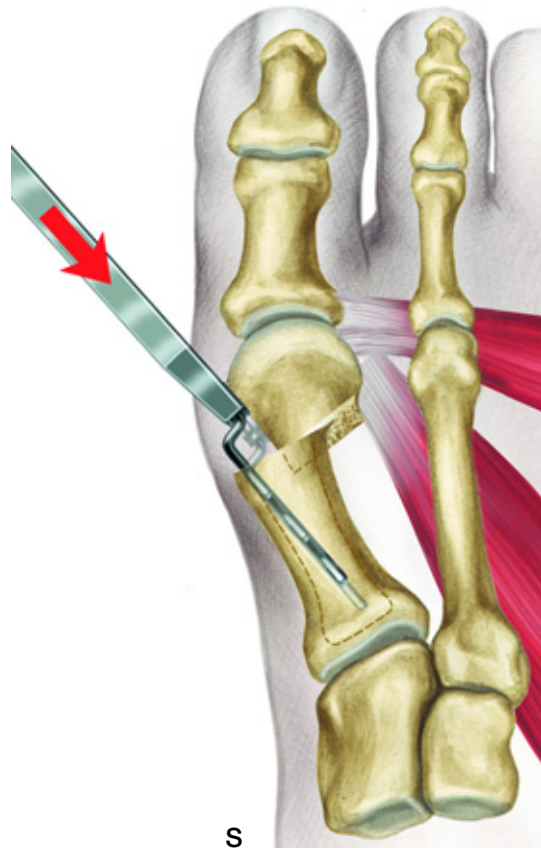
With the aid of the implant clasp, the prestressed arms of the hallux fixator are compressed and inserted into the metatarsal shaft up to the last convolution of the clasp arms in accordance with the intended correction (Fig. R)

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



Implant Impaction

The hallux fixator is driven into its final position in the shaft by means of a bone impaction instrument. A repositioning clasp fixes the metatarsal head to the eyelet of the hallux fixator. The correction of the deformity is reviewed. Should it be required to make changes, the implant can be removed and inserted a new (Fig. S).



Surgical Technique

Proximal Screw Fixation

The canal for the 4-mm cylindrical spongiosa screw is drilled into the metatarsal head through the guide bushing of the hallux fixator. 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. T)

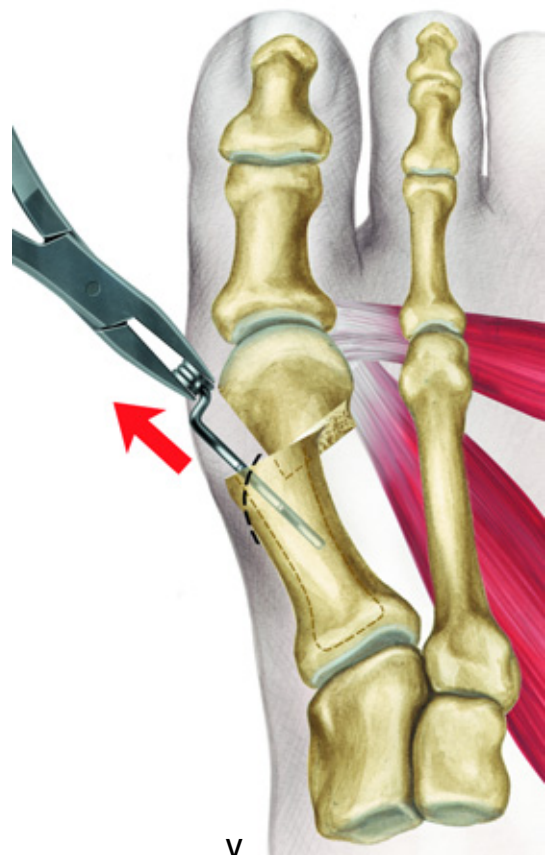
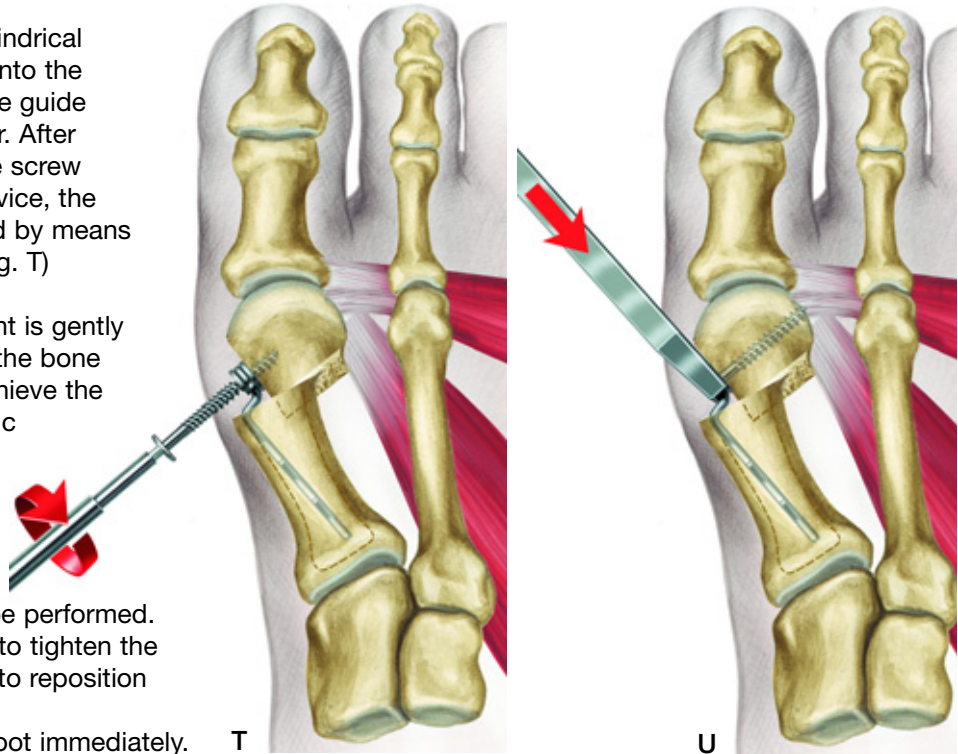
Finally, the impacted implant is gently hammered in by means of the bone impaction instrument to achieve the pre-stressing of the dynamic osteosynthesis (Fig. U)

Should the large toe still be contracted after osteosynthesis, a **lateral soft-tissue release** must be performed. A **medial capsulorrhaphy** to tighten the capsule is always required to reposition the sesamoid bones.

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 six 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 (Fig. V).

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



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Case Study

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

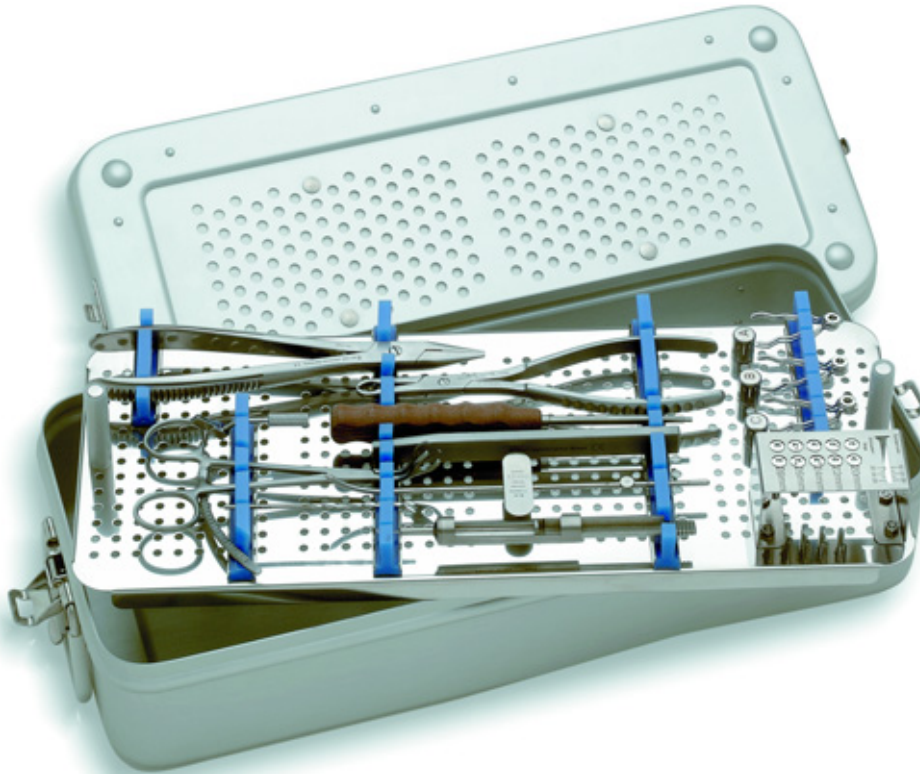


Fig. 2 Osteotomy according to Stoffella, Hallux Fixateur with 7 mm offset



Fig. 3 10 months postoperatively, excellent result

Implants and Instruments



**11-5000/14 Implants and Instruments, complete
LINK® Stoffella Internal Hallux Fixator**
on Storage Tray in Sterilizing Container

consisting of:

05-1000/01 Small Container K 1, empty
incl. Pack of 5 Paper Filters,
460 x 190 x 92 mm 1 ea.

11-5000/13 Storage Tray, empty
perforated stainless steel
405 x 165 mm 1 ea.

Implants

Stoffella Internal Hallux Fixator
Material: Stainless Steel
Bayonet mm ea.

11-5001/53	3	2
11-5001/55	5	2
11-5001/57	7	2

**Cancellous Screws for
Stoffella Internal Hallux Fixator**
Material: Stainless Steel

	Ø mm	System Depth mm	Length mm	ea.
11-5001/18	4	18	20	2
11-5001/20	4	20	22	2
11-5001/22	4	22	24	2
11-5001/24	4	24	26	2
11-5001/26	4	26	28	2

Instruments

11-5002/01 Stoffella Application Forceps
180 mm 1 ea.

11-5002/04 Bone Fragment Clamp
145 mm 1 ea.

10-5373 Hex Screwdriver
Hex 2,5 mm, 180 mm 1 ea.

11-5002/13 Stoffella Driver, modified
160 mm 1 ea.

11-5002/03 Stoffella Lever and Gauge
185 mm 1 ea.

10-5387 Depth Gauge
effective Range 50 mm 1 ea.

10-1680/06 Spiral Drill Bit
Ø 2,5 mm, 90 mm 1 ea.

11-5050 Stoffella Saw Guide 1 ea.

10-1727 Pliers, tapered jaws
200 mm 1 ea.

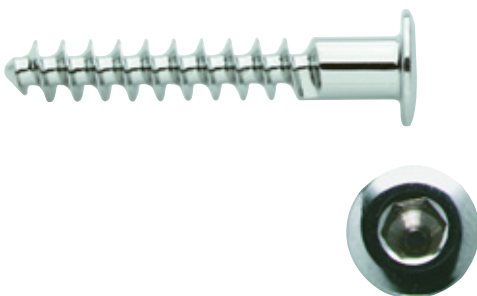
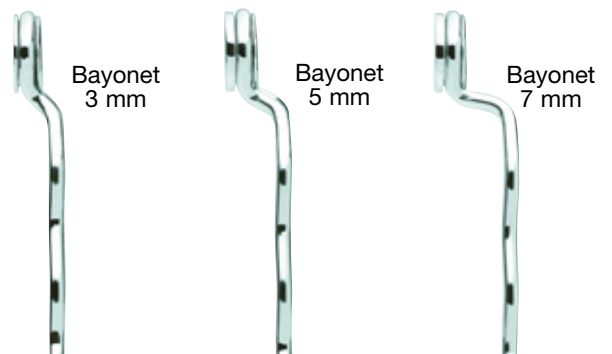
Implants



LINK® Stoffella Internal Hallux Fixator

Material: Stainless Steel

Item No.	Bayonet mm
11-5001/53	3
11-5001/55	5
11-5001/57	7



Cancellous Screws for Stoffella Internal Hallux Fixator

Material: Stainless Steel

Thread Diameter: 4 mm

Core Diameter: 1,8 mm

Item No.	System Depth mm	Length mm
11-5001/18	18	20
11-5001/20	20	22
11-5001/22	22	24
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■ Important Information

More detailed information about our implants can be supplied upon request.

Materials used for our orthopaedic implants:

- CoCrMo alloy, ISO 5832-4/ASTM F75 or ISO 5832-12
- TiAl6V4 alloy, ISO 5832-3/ASTM F136 or ASTM F1108
- Unalloyed titanium, ISO 5832-2/ASTM F67
- Stainless steel, ISO 5832-1/ASTM F138 / ASTM F139
- CoCrNiMoFe, ISO 5832-7/ASTM F1058
- UHMWPE, ISO 5834-2/ASTM F648
- Calcium phosphate coating, ASTM F1609
- Hydroxyapatite coating, ASTM F1185
- Al₂O₃ (aluminium oxide ceramic) BIOLOX®forte*, ISO 6474 / ASTM F603
- Ceramic BIOLOX®delta*, DC 25

* BIOLOX®forte and BIOLOX®delta are products of CeramTec AG, Plochingen, Germany

Please note the following regarding the use of our implants:

1. Choosing the correct implant is extremely important.

The size and shape of human bones restrict the size and shape of the implant. This also restricts the implant's ability to withstand stress. Implants are not designed to withstand unlimited body loads. The physical demand on implants should not surpass normal functional stresses.

2. It is also very important to treat implants correctly.

Altering the shape of a finished implant reduces its lifespan. The following must be actively avoided: bending the implant sharply, bending it back, or making grooves or scratches in it. Our implants may not be combined with implants from other manufacturers.

3. Implants must not be re-used.

Even if a used implant looks undamaged externally, it must be assumed that the material has become fatigued internally.

4. Patient rehabilitation is also very important.

The patient must learn about the limitations of the implant. An implant cannot compare with healthy bone in the ability to withstand stress!

5. Unless otherwise stated, implants are shipped in sterile packaging.

The following are important for storage of packaged implants:

- Avoid extreme or sudden changes in temperature.
- We recommend a storage temperature of 18 – 22 °C with 50 – 65 % humidity.
- Avoid direct sunlight.≠
- Protect implants from damp and from mechanical damage.
- Implants may be stored for up to 5 years in their original packaging. The 'Use by' date is on the product label.
- Do not use an implant if its packaging has been damaged.

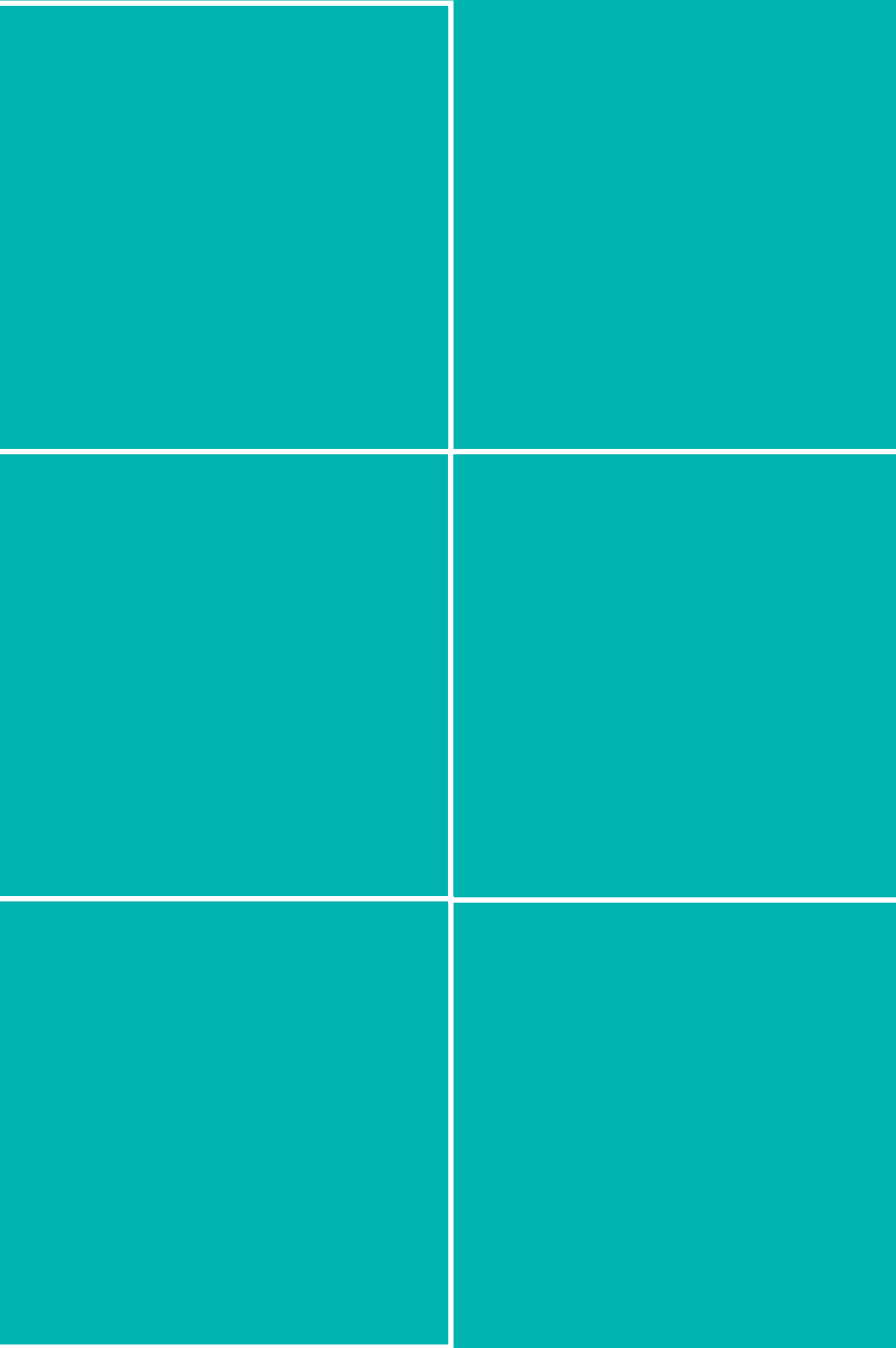
6. The documentation trail is important.

Please use the documentation sticker included in the packaging for this purpose.

WALDEMAR LINK GmbH & Co. KG, Hamburg

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All instruments, unless otherwise noted, are made of Stainless Steel.



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